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18 *C. R. Bard, Inc. and*  
19 *Bard Peripheral Vascular, Inc.*

20 **IN THE UNITED STATES DISTRICT COURT**

21 **FOR THE DISTRICT OF ARIZONA**

22 IN RE: Bard IVC Filters Products Liability  
23 Litigation,

24 This Document Relates to:

25 Lisa Hyde, et al. v. C. R. Bard, Inc., et al.  
26 CV-16-00893-PHX-DGC

No. 2:15-MD-02641-DGC

**JOINT REPORT ON  
DETERMINING FILTER TYPE**

(Assigned to the Honorable David G.  
Campbell)

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1 Pursuant to the Court’s Order dated July 26, 2018 (Doc. 12007 at 2 n.1), the Parties  
2 submit the following joint report regarding whether there is a means for determining  
3 Plaintiff Lisa Hyde’s filter type prior to trial, or whether this will be an issue for the jury.  
4 The Parties, having conferred, set forth their respective positions as follows:

5 **Defendants’ Position**

6 Defendants have reviewed the case materials and, after conferring with Plaintiffs,  
7 conclude that there is no definitive means for determining whether Ms. Hyde was  
8 implanted with a G2<sup>®</sup>X or an Eclipse<sup>®</sup> Filter. It is Bard’s position that this evidence  
9 should be presented to the jury as a question of fact for the jury to resolve.

10 **I. Factual Background.**

11 Plaintiffs identified this case as involving a G2<sup>®</sup> Filter in their Complaint (Doc. 1,  
12 2:16-cv-00893-DGC), Plaintiff Profile Form, and Plaintiff Fact Sheet. Defendants’  
13 Exhibit 1, Plaintiffs’ Profile Form at § 3.A. (“Bard G2”); Defendants’ Exhibit 2,  
14 Plaintiffs’ Fact Sheet (“PFS”) at § II.1 (“G2<sup>®</sup>”). At the time of the bellwether selection in  
15 April 2017, Bard identified this case as involving a G2X when Ms. Hyde was proposed as  
16 a bellwether plaintiff. *See* Doc. 5652 at 6 (“Ms. Hyde had a G2X implanted on  
17 2/25/2011.”). At the same time, Plaintiffs identified this case as involving a G2, not a  
18 G2X or an Eclipse. *See* Doc. 5706 at 17 (Sealed Lodged) (“Name: Hyde; Device: G2”;  
19 “Lisa Hyde – G2”; “She . . . had a Bard G2 filter implanted.”); *id.* at 1 n.1 (“Lisa Hyde,  
20 case no. 16-CV-00893 (G2 filter)”); *id.* at 25 (same); *see also* Doc. 5707 at 10 (Sealed  
21 Lodged) (“Hyde – G2 fracture and migration; complex percutaneous retrieval.”).

22 As noted in previous filings (Docs. 7359, 11921), it became apparent to counsel for  
23 Bard during discovery after the bellwether selection process that there is a question of fact  
24 whether Ms. Hyde’s filter is a G2X or an Eclipse Filter. Bard provided notice of this  
25 discovery to Plaintiffs nearly a year ago in its supplemental discovery responses (Doc.  
26 11921-1), and summary judgment briefing in August 2017 (Doc 7359 at 2 n.2). Bard has  
27 subsequently determined that billing and shipping records do not conclusively answer this  
28 question, and Ms. Hyde’s filter type should be a question for the jury.

1 **II. Plaintiffs' Medical Records Are Not Conclusive.**

2 On February 25, 2011, Plaintiff Lisa Hyde was implanted with a Bard Filter  
3 through a jugular approach by Dr. David Henry at Wheaton Franciscan Healthcare –  
4 Franklin (“Wheaton”). Defendants' Exhibit 3, Selected Plaintiff Medical Records at  
5 HYDEL\_WFHF\_RAD00002-03. There is no product sticker and no lot number identified  
6 in the medical records to confirm the filter type. Dr. Henry's implant record identifies the  
7 filter simply as a “Bard G2 retrievable.” *Id.* Other records from the date of implant refer to  
8 the filter as a “G2 jugular/subclavian IVC filter.” Defendants' Exhibit 3 at  
9 HYDEL\_WFHF\_MDR00109. Because imaging shows that the filter had a snarable tip,  
10 the filter is either a G2X or Eclipse, not a G2 which lacks a snarable tip. The Eclipse is an  
11 electropolished version of the G2X Filter.

12 On August 26, 2014, Dr. William Kuo retrieved Ms. Hyde's filter. Dr. Kuo refers  
13 to Ms. Hyde's filter as both a G2X and Eclipse Filter in his medical records. Defendants'  
14 Exhibit 3 at HYDEL\_SHC\_MDR00019 (“The images show an infrarenal Bard Eclipse  
15 IVC filter”), HYDEL\_SHC\_MDR\_00039 (same); HYDEL\_SHC\_MDR\_00055-56 (“Spot  
16 radiograph of the IVC demonstrates a Bard G2X filter”; “Successful retrieval of a  
17 fractured Bard G2X IVC Filter.”). Thus, Plaintiffs' medical records are inconclusive on  
18 the issue.

19 **III. Plaintiff's Physician Deposition Testimony Is Not Conclusive.**

20 Dr. Henry's deposition testimony is not clear on the filter model that he implanted  
21 in Ms. Hyde. When asked whether she received “a G2X IVC filter,” Dr. Henry testified “I  
22 believe it may have been, but I'm not sure.” Defendants' Exhibit 4, April 6, 2017,  
23 Dr. Henry Dep. Tr. at 11:22-24. He had no independent recollection of the encounter,  
24 which was the only encounter Dr. Henry had with Ms. Hyde. *Id.* at 12:5-12.

25 Dr. Kuo's testimony is equally inconclusive. Dr. Kuo testified that it is hard to  
26 distinguish between a G2X or Eclipse from imaging because “[t]hey look the same on the  
27 x-ray.” Defendants' Exhibit 5, March 23, 2017, Dr. Kuo Dep. Tr. at 25:23 to 26:5; 24:25  
28 to 25:1 (“The shape of the device of an Eclipse and a G2X are identical.”); 23:16-22 (“It's

1 the same filter. One of them is just another name for when they added an electro-polish on  
2 the device. But it's pretty much the same filter."); 67:18 to 68:5 ("without having a  
3 written record, it would be hard to see that on the x-ray.").

4 Even after he removed the filter and actually saw the device, Dr. Kuo was still  
5 unable to definitively distinguish whether it was a G2X or an Eclipse filter. *Id.* at 24:10-  
6 15. This is because "when we remove these devices, we can't tell because we don't have  
7 an electron microscope[] in the room [to determine] whether there's an electro-polish on  
8 it." *Id.* at 24:16-25. Ms. Hyde's filter was discarded after it was retrieved, so there is no  
9 way to confirm whether it was electropolished. Thus, Plaintiffs' physician testimony is  
10 equally inconclusive on the issue.

#### 11 **IV. Bard's Sales Representative Deposition Testimony Is Not Conclusive.**

12 On February 16, 2011, Mary Starr, the Interventional Radiology Coordinator for  
13 Wheaton, e-mailed Matt Fermanich, Bard's sales representative for Wheaton at the time:  
14 "I need to order some filters is it the Eclipses [sic] or the G2?" Defendants' Exhibit 6,  
15 BPVEFILTER-48-00004804-07. Later that day, Mr. Fermanich responded, "Mary you  
16 want the Eclipse," and he provided product codes. *Id.* at BPVEFILTER-48-00004804. On  
17 February 17, 2011, Ms. Starr with Wheaton replied: "Thanks Matt. We still have a G2 in  
18 stock. Are those still being used?" *Id.* It does not appear after a review of the discovery in  
19 the parties' possession that Mr. Fermanich responded to this last e-mail. But Tim Hug,  
20 Bard's regional sales manager at the time, testified based on this same e-mail that he  
21 "would assume that Matt would probably tell her that the G2 -- to go ahead and utilize the  
22 G2 and that when she does her reorders to order the Eclipse. Right? I mean, that's -- that's  
23 the direction that we have, and that's the communication that we have, and I would  
24 assume that -- that Matt could carry that out, but I can't say that with certainty obviously."  
25 Defendants' Exhibit 7, August 23, 2017, Tim Hug Dep. Tr. at 199:9 to 200:3.

26 Mr. Fermanich testified that it appeared based on this e-mail that Wheaton was still  
27 "using the G2" at the time. Defendants' Exhibit 8, March 27, 2017, Fermanich Dep. Tr. at  
28 202:10-22 ("Looks like it, yes."). Referring to the same e-mail, when asked whether "at



1 least at this time, it's fair to say that [Wheaton] is using the G2," Mr. Hug testified that it  
2 "would be fair that it sounds like they have some in stock, yes." Defendants' Exhibit 7 at  
3 199:9-14. This e-mail was dated eight days before Ms. Hyde was implanted on  
4 February 25, 2011. Mr. Fermanich does not know if he ever had a discussion with  
5 Wheaton before February 17, 2011, that Bard was discontinuing the G2s and that the  
6 hospital should switch to the Eclipse. Defendants' Exhibit 8 at 202:23 to 204:5. Thus, this  
7 e-mail and related deposition testimony is also inconclusive on the issue.

8 **V. Bard's Sales and Billing Records Are Circumstantial Evidence That Ms. Hyde**  
9 **Received an Eclipse Filter.**

10 Bard's records of IVC filter sales to Wheaton, Ms. Hyde's implanting facility, from  
11 the pertinent time period indicate that there is circumstantial evidence the filter she  
12 received on February 25, 2011, was an Eclipse. Bard acknowledges that it appears that, as  
13 of at least February 17, 2011, Wheaton "still ha[d] a G2 filter in stock," according to  
14 Ms. Starr. Defendants' Exhibit 6 at BPVEFILTER-48-00004804. Importantly, Ms. Starr  
15 did not say that Wheaton had multiple G2 filters in stock. Instead, she said "a" filter,  
16 implying a single filter. *Id.* This appears consistent with the sales history for this facility.

17 Bard sold only two G2X Filters (and no other G2 filters) to Wheaton in the two  
18 years preceding the date Ms. Hyde was implanted with her filter on February 25, 2011.  
19 Defendants' Exhibit 9, BPV-17-01-00262748 (sales records from January 2010 through  
20 February 2011); Defendants' Exhibit 10, BPV-17-01-00262749 to 756 (invoices);  
21 Defendants' Exhibit 11, BPVEFILTER-28-00402336 (sales records showing zero filter  
22 sales in 2009). Both of these G2X Filters were sold in early January 2010, more than a  
23 year before Ms. Hyde received her filter. Defendants' Exhibit 10 at BPV-17-01-  
24 00262749. Critically, only one of those G2X Filters was a Jugular/Subclavian Delivery  
25 Kit, the type of delivery approach Ms. Hyde underwent. *Id.* It is unknowable whether this  
26 single G2X Filter Jugular was available for Ms. Hyde's implant on February 25, 2011.

27 After January 2010, however, Bard sold eight Eclipse Filters to Wheaton.  
28 Defendants' Exhibit 9. One of those Eclipse Filters was a Jugular/Subclavian Delivery

1 Kit. Defendants' Exhibit 10 at BPV-17-01-00262754. This Eclipse Filter Jugular was  
2 ordered on February 22, 2011, invoiced and shipped on February 23, 2011, and delivered  
3 to Wheaton on February 25, 2011 – the day Ms. Hyde received her filter. *Id.* Wheaton  
4 ordered an additional Eclipse Filter Jugular merely four days later on March 1, 2011.  
5 Defendants' Exhibit 10 at BPV-17-01-00262756.

6 Although Mr. Fermanich, Bard's sales representative responsible for Wheaton at  
7 the time, testified that his contact with Ms. Starr on February 17, 2011, "may have been  
8 the first opportunity I had to get to her" concerning orders for Eclipse filters, the sales  
9 records above clearly demonstrate that Wheaton had purchased Eclipse filters as early as  
10 November 2010. Defendants' Exhibit 8 at 203:19 to 204:5. Importantly, neither  
11 Mr. Fermanich nor Mr. Hug affirmatively testified as to what filter type Ms. Hyde  
12 received. Moreover, Mr. Fermanich never testified that the hospital was using G2X filters  
13 *at the time of Plaintiff's implantation procedure*, as Plaintiffs contend. Instead, when  
14 asked "here now we're at February 17, 2011 . . . And you have . . . a relatively good  
15 customer [Wheaton] who's still using the G2," Mr. Fermanich testified: "Looks like it,  
16 yes." *Id.* at 202:10-22; *see also* Defendants' Exhibit 7 at 199:9-14 (When asked "at least  
17 at this time, it's fair to say that [Wheaton] is using the G2," based on the e-mail dated  
18 February 17, 2011, Mr. Hug testified it "would be fair that it sounds like they have some  
19 in stock, yes."). Mr. Fermanich also never testified that Wheaton had yet to switch over to  
20 the Eclipse Filter by the time of Ms. Hyde's implant, even after being specifically asked:  
21 "[s]o obviously they didn't get it switched out in time for Lisa Hyde?" Defendants'  
22 Exhibit 8 at 205:5-20. The record evidence refutes this assertion.

23 Bard submits that it is a question of fact whether Ms. Hyde received the Eclipse  
24 Filter Jugular delivered to Wheaton the day of her implant over the G2X Filter Jugular  
25 that Wheaton purchased more than a year before her date of implant that was potentially  
26 available as late as February 17, 2011. It is Bard's position that this evidence should be  
27 presented to the jury as a question of fact for the jury to resolve.  
28

1 **VI. Bard Should Not Be Estopped From Challenging Ms. Hyde's Filter Type.**

2 Bard should not be estopped from having the jury resolve this admitted question of  
3 fact because Bard's representation during the bellwether selection was based on  
4 inadvertence and mistake, and none of the facts and circumstances that Plaintiffs assert  
5 warrant estoppel.

6 Judicial estoppel is an equitable doctrine, applied at the court's discretion, which  
7 precludes a party from gaining an advantage by asserting one position, and then  
8 subsequently seeking an advantage by taking a clearly inconsistent position. *See*  
9 *Hamilton v. State Farm Fire & Cas. Co.*, 279 F.3d 778, 782 (9th Cir. 2001). The Ninth  
10 Circuit invokes judicial estoppel after analyzing four factors: (1) whether the party's later  
11 position is "clearly inconsistent" with its earlier position, (2) whether the party  
12 successfully advanced the earlier position such that judicial acceptance of an inconsistent  
13 position would create the perception that the court was misled, (3) whether the party  
14 seeking to assert the inconsistent position would derive an unfair advantage if not  
15 estopped, and (4) whether the party to be estopped acted inadvertently or with any degree  
16 of intent. *See Samson v. NAMA Holdings, LLC*, 637 F.3d 915, 935 (9th Cir. 2011) (citing  
17 *New Hampshire v. Maine*, 532 U.S. 742, 749-750 (2001), and *EaglePicher Inc., v.*  
18 *Federal Ins. Co.*, CV-4-870 PHX MHM, 2007 WL 2265659, at \*3 (D. Ariz. Aug. 6,  
19 2007)). In particular, the Ninth Circuit will only apply judicial estoppel where  
20 incompatible positions are based "on knowing misrepresentation or even fraud on the  
21 court" and not "inadvertence or mistake." *Id.* (citations omitted).

22 This Court has consistently applied the *New Hampshire* factors, as well as the  
23 Ninth Circuit principle that judicial estoppel is not applicable in cases of inadvertence or  
24 mistake, to find judicial estoppel unwarranted. *See, e.g., Carbajal v. Dorn*, No. CV 09-  
25 0283-PHX-DGC, 2010 WL 892201, at \*2 (D. Ariz. Mar. 9, 2010) (refusing to apply  
26 judicial estoppel because "[t]he Court cannot, as a matter of undisputed fact, conclude that  
27 any change in position on the part of [the plaintiff] was based on 'chicanery' rather than  
28 inadvertence or mistake."); *Arizona v. Tohono O'odham Nation*, 944 F. Supp. 2d 748, 757

1 (D. Ariz. 2013), *aff'd* 818 F.3d 549 (9th Cir. 2016) (applying *New Hampshire* factors to  
2 determine that judicial estoppel was not warranted).<sup>1</sup>

3 **First**, Bard's representation to the Court in its bellwether submission that  
4 "Ms. Hyde had a G2X implanted on 2/25/2011," (Doc. 5652 at 6), was based on  
5 "inadvertence and mistake," and was in no way a "knowing misrepresentation." *Samson*,  
6 637 F.3d at 935; *Carbajal*, 2010 WL 892201, at \*2. At the time of the bellwether selection  
7 in April 2017, it appeared based on statements in the medical records, and from a review  
8 of the imaging, that Ms. Hyde received a G2X Filter. Bard was understandably mistaken  
9 as evidenced by the inconclusive records and testimony above. Indeed, based on the same  
10 statements in the medical records, Plaintiffs themselves represented in their pleadings and  
11 discovery that Ms. Hyde received a G2 Filter. *See* Compl. ¶ 10 (Doc. 1, 2:16-cv-00893-  
12 DGC); <sup>2</sup> Defendants' Exhibit 1, Plaintiffs' Profile Form at § 3.A. ("Bard G2");  
13 Defendants' Exhibit 2, Plaintiffs' Fact Sheet ("PFS") at § II.1 ("G2®").

14 <sup>1</sup> *See also In re Smith*, 526 B.R. 343, 348 (D. Ariz. 2015) (same); *Am. Realty Capital*  
15 *Properties Inc. v. Holland*, No. CV-14-00673-PHX-DGC, 2014 WL 5023004, at \*4 (D.  
16 Ariz. Oct. 8, 2014) (same); *Zrihan v. Wells Fargo Bank, N.A.*, No. CV-12-02073-PHX-  
17 DGC, 2014 WL 348197, at \*5 (D. Ariz. Jan. 31, 2014) (same); *Advnt Biotechnologies,*  
*LLC v. Schroeder*, No. CV-06-2787-PHX-DGC, 2007 WL 1875667, at \*3 (D. Ariz. June  
28, 2007) (same); *Tavilla v. Cephalon, Inc.*, 870 F. Supp. 2d 759 (D. Ariz. 2012) (same).

18 <sup>2</sup> Bard's original, internal complaint file produced with its Defendants' Profile Form was  
19 prepared based on the only information available to Bard at the time: Plaintiffs' civil  
20 Complaint that represented that Ms. Hyde received a G2 Filter. Defendants' Exhibit 12,  
21 DPS\_HydeL\_CV-16-00893\_000008-21 ("Unknown G2"). Bard re-opened the complaint  
22 file once it received medical records for review. This supplemental complaint file  
23 produced with Defendants' Fact Sheet – which Plaintiffs reference in support of estoppel  
24 – was prepared again based on the only information available to Bard at the time:  
25 Plaintiffs' Complaint and the implant records from Dr. Henry identifying the filter as a  
26 "Bard G2 retrievable." Defendants' Exhibit 13, DFS\_HydeL\_CV-16-00893\_000003-28.  
27 This is why the supplemental complaint file referenced the product as a G2 Filter and  
28 provided the Catalog No: RF320J. Bard later re-opened the complaint file again in May  
2017, after the bellwether submission, once it received the additional medical records and  
imaging collected during discovery. This supplemental complaint file was based on a  
review of these additional records, and was produced to Plaintiffs with Bard's  
Supplemental Defendants' Fact Sheet in August 2017. Defendants' Exhibit 14,  
DFS\_HydeL\_CV-16-00893\_000078-113. The supplemental complaint file stated "Based  
on the image it cannot be determined if the filter was a G2 Express, G2X or a Bard  
Eclipse Filter." *Id.* at DFS\_HydeL\_CV-16-00893\_000080. Bard also prepared a  
supplemental MedWatch Submission to FDA stating "Based on the images provided, the  
identity of the filter cannot be determined." *Id.* at DFS\_HydeL\_CV-16-00893\_000112.  
Bard did not affirmatively identify Ms. Hyde's filter anywhere else in its original or  
supplemental Defendants' Fact Sheets or the documents produced therewith.

1 More importantly, Plaintiffs *repeatedly* represented to the Court in their own  
2 bellwether submission, and response to Bard’s submission, that Ms. Hyde “had a Bard G2  
3 filter implanted,” not a G2X or an Eclipse, based on the exact same facts and  
4 circumstances that Plaintiffs claim warrant estoppel. Doc. 5706 at 17 (Sealed Lodged)  
5 (“Name: Hyde; Device: G2”; “Lisa Hyde – G2”); *id.* at 1 n.1 (“Lisa Hyde, case no. 16-  
6 CV-00893 (G2 filter)”); *id.* at 25 (same); *see also* Doc. 5707 at 10 (Sealed Lodged)  
7 (“Hyde – G2 fracture and migration; complex percutaneous retrieval.”). This is clear  
8 evidence that both parties made inadvertent mistakes in their representations to the Court  
9 concerning Ms. Hyde’s filter type during bellwether selection. Neither party knowingly  
10 misrepresented her filter type to the Court. *Samson*, 637 F.3d at 935; *Carbajal*, 2010 WL  
11 892201, at \*2. The parties were simply and understandably mistaken.

12 When Bard subsequently discovered there was a question of fact as to whether  
13 Ms. Hyde received an Eclipse or a G2X, Bard immediately notified Plaintiffs in its  
14 supplemental discovery responses (Doc. 11921-1), and in its summary judgment briefing  
15 (Doc 7359 at 2 n.2). This occurred nearly a year ago in August 2017. Plaintiffs responded  
16 to Bard’s assertions in their opposition motion. Doc. 7952 at 1 n.1. Plaintiffs do not claim  
17 that they had inadequate notice of Bard’s position.

18 ***Second***, Bard did not seek to mislead Plaintiffs or the Court during bellwether  
19 selection with its inadvertent and mistaken representation to gain an “unfair advantage.”  
20 *Samson*, 637 F.3d at 935. Indeed, Bard’s focus in its bellwether submission was on  
21 choosing representative cases based principally on filter complications, not filter type.  
22 Bard’s representations in its submission make this clear:

23 Ms. Hyde had a G2X implanted on 2/25/2011. **Ms. Hyde’s**  
24 **case is representative as it involves a filter fracture (25%**  
25 **of the pool) and also involves multiple complications in a**  
26 **single case including tilt, perforation, a filter strut to the**  
27 **heart, and a complex filter retrieval.**

28 Doc. 5652 at 6 (emphasis added). Bard’s representations concerning the other proposed  
bellwethers are also illustrative. *See, e.g., id.* at 7 (“Mr. King had a G2 placed. . . . The  
case is representative of cases in which the allegation is that the filter tilted, perforated,

1 and cannot be retrieved.”); *see also id.* at 7-8.<sup>3</sup>

2 **Third**, Bard can see no “unfair advantage” that may be derived in this case if the  
3 jury is permitted to resolve this pure question of fact. *Samson*, 637 F.3d at 935; *Carbajal*,  
4 2010 WL 892201, at \*2. As Bard stated in its bellwether submission, “the G2 group of  
5 filters and Eclipse filters are virtually identical in configuration, the difference being that  
6 the Eclipse was electropolished.” Doc. 5652 at 5. Bard maintains that the Eclipse is an  
7 improvement upon Bard’s G2-line of filters. Plaintiffs throughout this litigation have  
8 consistently asserted to the contrary that the Eclipse is no different than a G2X. *See, e.g.*,  
9 Doc. 10707 at 2-3 (“The fundamental flaw in Bard’s argument is its suggestion that the  
10 Eclipse is a different device than the G2; it is not. . . . Plaintiff’s experts confirm the same  
11 thing.”). Plaintiffs should not now be heard that they will be prejudiced by the  
12 presentation of evidence involving the Eclipse to the jury. This Court has already admitted  
13 evidence of the Recovery<sup>®</sup> Filter’s complications, testing, and design in the *Jones*  
14 (Eclipse) bellwether trial, over Bard’s objection. Doc. 10819. Therefore, Bard will gain no  
15 “unfair advantage” from the jury’s resolution of Ms. Hyde’s filter type, and Bard should  
16 not be estopped because of its inadvertent representation in its bellwether submission.

17 **Finally**, Plaintiffs’ other claim that Bard should be estopped because counsel for  
18 Bard “affirmatively stated” during its questioning of Dr. Henry that “we [Defendants] can  
19 establish it was a G2X,” is disingenuous and without merit. Defendants’ Exhibit 4 at 92:6  
20 to 93:7. First, an attorney’s statement at deposition is not evidence. Second, counsel for  
21 Bard was not making an affirmative statement to anyone, and certainly did not make a  
22 representation to gain an advantage. Third, this line is taken out of context, as counsel for  
23 Bard was clearly indicating that there was no need to further question Dr. Henry about the  
24 filter type, *see id.*, because he had no independent recollection of the encounter, and was  
25 otherwise “not sure” whether Ms. Hyde received a G2 or a G2X. *Id.* at 11:22-24; 12:5-12.

26 \_\_\_\_\_  
27 <sup>3</sup> This is further evidenced by Bard’s opposition to Plaintiffs’ proposed selections which  
28 Bard believed to be “disproportionately weighted toward the most serious types of  
injuries, including open surgeries, fractures of a strut to the heart, and fractures in  
general.” Doc. 5652 at 10; *see also id.* at 10-15.



1 **VII. Conclusion.**

2 For these reasons, it is Bard's position that this evidence should be presented to the  
3 jury to resolve the pure question of fact concerning Ms. Hyde's filter type.

4 **Plaintiffs' Position**

5 This case was submitted by both parties as a G2X case for consideration in the first  
6 round of the MDL bellwether process. In fact, both Plaintiffs and Defendants agreed the  
7 Hyde case should be included in the first bellwether pool of six cases set for trial.  
8 Discovery in the Hyde case was based upon the Bard G2X Filter being the subject device.  
9 As such, Plaintiffs are prepared to try a G2X case, not an Eclipse case.

10 Plaintiffs would not have stipulated with Defendants to include this case in the first  
11 bellwether pool for trial had both sides not agreed at the time that it was a G2X case.  
12 Trying three Eclipse cases in the first six MDL bellwethers would be deleterious to the  
13 purpose of the bellwether process.<sup>4</sup>

14 It is Plaintiffs' position that Defendants should be estopped from now claiming the  
15 product in question is an Eclipse, or anything other than a G2X, considering the following  
16 facts and circumstances:<sup>5</sup>

17 1. The Hyde case is a defense pick. Defendants stated the following in their bellwether  
18 submission:

19 Ms. Hyde had a G2X implanted on 2/25/2011. Ms. Hyde's  
20 case is representative as it involves a filter fracture (25% of  
21 the pool) and also involves multiple complications in a single  
22 case including tilt, perforation, a filter strut to the heart, and a  
complex filter retrieval. Ms. Hyde claims that her filter  
fracture caused her to experience back and abdominal pain. As  
such, the case gives the parties the opportunity to test their

23 <sup>4</sup> Again, Plaintiffs would have objected, as the Defendants have objected to trying even  
24 one Recovery case in the first six despite the fact that it is relevant in all subsequent cases  
25 and was on the market two times longer than the Eclipse. Moreover, the values in  
settlement and potential jury verdicts, the parties agree, could make up 50% or more of  
the global settlement number of the entire litigation.

26 <sup>5</sup> Considering the fact that the Eclipse filter was superseded by the next generation of Bard  
27 filters, the Meridian, within approximately a year and a half of clearance of the Eclipse,  
Defendants can agree another product would have been more appropriate and  
28 representative of the filed cases. *See* Eclipse and Meridian Clearance Letters, attached as  
Plaintiffs' Exhibit 1.



1 arguments as to these numerous complications, including any  
2 interrelationship between the complication modes.

3 \* \* \*

4 Bard recommends that the Hyde case be second in order for  
5 trial. That case involves a G2X with fracture, with a strut  
6 embolizing to the heart. It also involves complications of tilt,  
7 perforation, and a complex percutaneous retrieval of the filter  
8 and strut by a medical doctor at Stanford University.<sup>6</sup>

9 2. The Defendants' Fact Sheet contains numerous references to Mrs. Hyde's filter being  
10 a G2:

- 11 a. Complaint Detail Record Report: "**Product Name: G2 Filter**; Product  
12 Catalog No: RF320J." See DFS\_HydeL\_CV-16-00893-000004.
- 13 b. Investigation Level II conducted for "(Parent) Product Catalog No.: RF320J;  
14 (Parent) **Product Name: G2 Filter.**" See DFS\_HydeL\_CV-16-00893-  
15 000010-11.
- 16 c. Complaint Trend Analysis was conducted for "**Product Name: G2 Filter.**"  
17 See DFS\_HydeL\_CV-16-00893-000015-18.
- 18 d. MedWatch Submission was for "1. Brand Name: **G2 Filter System –  
19 Jugular.**" See DFS\_HydeL\_CV-16-00893-000023.<sup>7</sup>

20 3. The interventional radiologist David A. Henry, M.D. who implanted the Bard filter  
21 noted in his record:

22 Venipuncture was performed and progressive venous dilation  
23 of the tract was performed followed by placement of a Bard  
24 G2 retrievable sheath device in the right iliac vein.<sup>8</sup>

25 4. Defense counsel affirmatively stated during the deposition of David A. Henry, M.D.  
26 that she need not continue questioning Dr. Henry about the identity of the product  
27 because "we [Defendants] can establish it was a G2X.":

28 Q. Now, to clarify, Mrs. Hyde was implanted by you with a  
G2X filter; correct?

A. I believe so. I may not have even mentioned the brand in

<sup>6</sup> See Defendants' Submission Regarding Selection of Cases for Bellwether Group dated April 24, 2017, p. 6 and p. 9 (Doc. 5652), attached as Plaintiffs' Exhibit 2.

<sup>7</sup> See Defendants' Fact Sheet documents, attached as Plaintiffs' Exhibit 3.

<sup>8</sup> See WFH-Franklin Interventional Radiology report, signed by Debra Wiedmeyer, M.D. on behalf of David A. Henry, M.D. dated February 23, 2011, HYDE\_WFHF\_MDR00172-73, attached as Plaintiffs' Exhibit 4.

1 my report.

2 ...  
3 MR. LEIB: I'm not going to be having him answer any  
4 questions, it's privileged. He'd be having to use his expert  
5 opinion as to whether --

6 MS. DALY: That's fair enough.

7 MR. LEIB: Yeah.

8 MS. DALY: **That's fair enough. We can establish it was a  
9 G2X. I don't need to trouble him with that.**<sup>9</sup>

10 5. Bard's sales representative, Matt Fermanich, who was designated by Defendants for a  
11 deposition in the Hyde case, testified:

12 a. The hospital was using G2X Filters at time of Plaintiff's implantation  
13 procedure.<sup>10</sup>

14 b. He does not know if he ever had a discussion with hospital personnel before  
15 Feb. 17, 2011 that Bard planned to discontinue the G2 product line and  
16 about the hospital eventually switching to Eclipse.<sup>11</sup> His testimony was  
17 based upon an e-mail to him from Mary Christine Starr of WFHC-Franklin,  
dated February 17, 2011, where she advised Matt Fermanich that as of  
February 17, 2011 the hospital still had G2 Filters in stock.

18 c. The G2 was still being sold and distributed in the sales region as late as  
19 March 8, 2011. After both the Eclipse *and* Meridian filters had launched.<sup>12</sup>

20 d. Bard was still in the process of transitioning customers from the G2 and to  
21 Meridian as late as December 13, 2011, again implying use of the G2 filters  
22 long after both the Eclipse *and* Meridian filters had launched.<sup>13</sup>

23 6. Bard regional sales manager Tim Hug testified, based on the same e-mail mentioned  
24 above from Mary Christine Starr dated February 17, 2011, that the G2 filter was  
25 stocked and available at the hospital where Plaintiff was implanted. The hospital, per  
26 directions given by sales representatives, was told to utilize the G2 filters in stock

27 <sup>9</sup> See Deposition of David Henry, M.D. dated April 6, 2017 at 92:6 – 93:7, attached as  
28 Plaintiffs' Exhibit 5.

<sup>10</sup> See Deposition of Matthew P. Fermanich dated March 27, 2017 at 202:17-22, attached  
as Plaintiffs' Exhibit 6.

<sup>11</sup> See Deposition of Matthew P. Fermanich dated March 27, 2017 at 201:16 – 204:5,  
attached as Plaintiffs' Exhibit 7.

<sup>12</sup> See Deposition of Matthew P. Fermanich dated March 27, 2017 at 215:20-218:5 and  
Exhibit 25 to the Deposition of Matthew P. Fermanich, attached as Plaintiffs' Exhibit 8.

<sup>13</sup> See Deposition of Matthew P. Fermanich dated March 27, 2017 at 218:6-221:9 and  
Exhibit 26 to the Deposition of Matthew P. Fermanich, attached as Plaintiffs' Exhibit 9.

1 before ordering Eclipse.<sup>14</sup>

2 7. After completion of Mrs. Hyde's filter retrieval procedure on August 25, 2014 at  
3 Stanford Hospital, William T. Kuo, M.D., transcribed the following in his records as  
4 his "impressions":

5 a. "1. Successful retrieval of a fractured G2X IVC filter."

6 b. "Spot radiograph of the IVC demonstrates a Bard G2X filter."

7 8. At his deposition on March 23, 2017, William T. Kuo, M.D. testified that his  
8 experience with the device allowed him to identify it as a G2X filter.<sup>15</sup>

9 9. Mrs. Hyde testified that Dr. Kuo told her the filter was a G2/G2X before her explant  
10 surgery on August 25, 2014.<sup>16</sup>

11 10. The shipping records Defendants cite are inconclusive. The records indicate that an  
12 Eclipse Jugular was shipped via 2-day shipping on February 23, 2011. There is no  
13 reference on the record or within e-mails to indicate the reason the filter was sent.  
14 Mrs. Hyde's filter was implanted 2 days later, with the procedure starting sometime  
15 shortly after 11:00 a.m. and ending around 2:00 p.m.<sup>17</sup>

16 It very unlikely the Eclipse Juglar would have been delivered, checked into the  
17 hospital's inventory, routed to the correct department, delivered to the doctors, and  
18 prepared for implant in time to be placed in Mrs. Hyde. Even if the Eclipse Jugular did  
19 arrive in time, as noted above, Wheaton Hospital had been told by Bard's sales  
20 representatives to use all stock G2/G2X filters and it is known that Wheaton Hospital had  
21 G2X filters in stock on February 17, 2011. As the shipping records point out, Eclipse  
22

23 <sup>14</sup> See Deposition of Tim Hug dated August 23, 2017 at 197:15 – 200:3, attached as  
Plaintiffs' Exhibit 10.

24 <sup>15</sup> See Stanford Hospital records, complex IVC filter retrieval dated August 26, 2015,  
25 HYDEL\_SHC\_MDR00054-56, attached as Plaintiffs' Exhibit 11. Deposition of William  
T. Kuo, M.D. dated March 23, 2017 at 23:12 – 26:5 and 28:17 – 24, attached as Plaintiffs'  
26 Exhibit 12.

27 <sup>16</sup> See Deposition of Lisa Hyde dated January 25, 2017 at 39:10-40:1, attached as  
Plaintiffs' Exhibit 13.

28 <sup>17</sup> See Wheaton Franciscan Hospital Records, HYDEL\_WFHF\_MDR00137-139, attached  
as Plaintiffs' Exhibit 14.

1 Femoral filters had been ordered by the hospital as early as November 2010, 4 months  
2 before Mrs. Hyde's implant procedure. The fact that Wheaton ordered Eclipse filters on  
3 February 22, 2011 does not infer the hospital used its entire stock of G2 filters; as noted  
4 above, it is clear, Mr. Fermanich was pushing Wheaton to order Eclipse filters to  
5 eventually make the switch from G2/G2X.

6 Importantly, inconclusive shipping records should not be given more weight than  
7 Plaintiff's implanting physician's, Dr. Henry, own notes in official hospital records which  
8 he verified at his deposition. If the filter was an Eclipse, the medical records transcribed  
9 by Dr. Henry would have indicated it. Dr. Henry had the experience and knowledge to tell  
10 the difference and to accurately reflect the correct device in his records.

11 Therefore, Plaintiffs request the Court estop Defendants from now claiming the  
12 product in question is an Eclipse and make a determination as to the identity of the Bard  
13 product implanted in Mrs. Hyde.

14 RESPECTFULLY SUBMITTED this 10<sup>th</sup> day of August, 2018.

15 GALLAGHER & KENNEDY, P.A.

NELSON MULLINS RILEY &  
SCARBOROUGH, LLP

17 By: /s/ Mark O'Connor (with permission)

By: /s/ Richard B. North, Jr.

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richard.north@nelsonmullins.com  
matthew.lerner@nelsonmullins.com

23 *Co-Lead/Liaison Counsel for*  
24 *Plaintiffs*

25 //

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*Attorneys for C. R. Bard, Inc. and Bard  
Peripheral Vascular, Inc.*

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 10<sup>th</sup> day of August 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/Richard B. North, Jr.  
Richard B. North, Jr.

# Defendants' Exhibit 6



Message

---

**From:** Starr, Mary Christine [Mary.Starr@wfhc.org]  
**Sent:** 2/17/2011 3:30:18 PM  
**To:** Fermanich, Matt [/O=BARD/OU=MHL-E2K3 AG/cn=Recipients/cn=MFermanich]  
**Subject:** RE: Technician Registration

Thanks Matt. We still have a G2 in stock. Are those still being used? If I can't get in this workshop I can do the next no biggy. I know that the cath lab cant send anyone this round either.

**Mary Starr R.T. (R), V.I.**

Interventional Radiology Coordinator

WFHC-Franklin

414-325-4980

[Mary.C.Starr@wfhc.org](mailto:Mary.C.Starr@wfhc.org)

---

**From:** Fermanich, Matt [mailto:Matt.Fermanich@crbard.com]  
**Sent:** Wednesday, February 16, 2011 7:17 PM  
**To:** Starr, Mary Christine  
**Subject:** RE: Technician Registration

Mary you want the Eclipse...here are the product codes

1. Jugular – EC500J
2. Femoral – EC500F
3. Retrieval Cone – FBRC

I submitted your registration. I soon as I hear back I will let you know. If this class is full we'll get you in the next one if the dates work on your end.

Thanks Mary and let me know if you need anything else



-Matt ☺

**From:** Starr, Mary Christine [mailto:Mary.Starr@wfhc.org]  
**Sent:** Wednesday, February 16, 2011 3:41 PM  
**To:** Fermanich, Matt  
**Subject:** RE: Technician Registration

Matt I filled out the first half of the form the second half you fill out? Also I need to order some filters is it the Eclipses or the G2?

**Mary Starr R.T. (R), V.I.**

Interventional Radiology Coordinator

WFHC-Franklin

414-325-4980

[Mary.C.Starr@wfhc.org](mailto:Mary.C.Starr@wfhc.org)

---

**From:** Fermanich, Matt [mailto:Matt.Fermanich@crbard.com]  
**Sent:** Wednesday, February 16, 2011 3:57 PM  
**To:** Starr, Mary Christine  
**Subject:** Technician Registration

Mary...here is the form I need completed ASAP to forward along for approval.

Please let me know if you have any questions at all.

Thanks and I will talk to you soon

-Matt

Matt Fermanich

Territory Manager - Milwaukee

Bard PV

Phone: 414.736.3191

Fax: 262.354.0007

Email: Matt.Fermanich@crbard.com

---

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# Defendants' Exhibit 7

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UNITED STATES DISTRICT COURT  
DISTRICT OF ARIZONA

In Re Bard IVC Filters Products  
Liability Litigation No.  
MD-15-02641-PHX-DGC

~~~~~

Do Not Disclose  
Subject to Further Confidentiality Review

VIDEOTAPED DEPOSITION OF

TIM HUG

AUGUST 23, 2017

10:00 a.m.

2575 East Camelback Road, 11th Floor

Phoenix, Arizona

SOMMER E. GREENE, CSR, RPR, CR No. 50622

1 can't call medical affairs to get the answer. It's a  
2 physician/medical affairs connection there.

3 Q. Do you recall -- in this particular instance,  
4 do you remember if Mr. Fermanich got back to this  
5 physician?

6 A. I would be angry if Matt did not. I don't  
7 know, though.

8 Q. And what would you have expected him -- or if  
9 you recall, tell me what he provided to the physician.

10 A. I don't know, but I would expect Matt to say,  
11 At the end of the day, we don't know the answer to that,  
12 but I would encourage you to reach out on this phone  
13 number, and perhaps they can do some additional research  
14 to find the answer to that.

15 Q. Okay. This is one I want to show you.

16 (Exhibit 1115 was marked for  
17 identification.)

18 Q. BY MR. LOPEZ: This is Exhibit 1115. All  
19 right. Okay. Just go to the second page real quick.

20 A. Okay.

21 Q. This is an e-mail between Mary Starr and Matt  
22 Fermanich, and you know who Mary Starr is?

23 A. Yeah. I'm not sure what her role was at this  
24 time, but I do know Mary Starr.

25 Q. Okay. Actually it looks like she says --



1 A. Oh, there it is.

2 Q. -- interventional radiology coordinator?

3 A. Yeah. So I knew her when she worked in the  
4 cath lab at saint Francis, another Wheaton facility. So  
5 that's how I knew her.

6 Q. She writes just on the second page at the top,  
7 "Matt, I filled out the first half of the form. The  
8 second half you fill out" --

9 A. Yes.

10 Q. -- "question" -- I don't know if I read that  
11 right.

12 A. Right.

13 Q. "Also I need to order some filters. Is it the  
14 Eclipse or the G2," she's asking, and let's keep in mind  
15 the date here.

16 A. Okay.

17 Q. This is February 16, 2011.

18 A. Okay.

19 Q. And she needs more filters, or the group does,  
20 and then Matt responds. You can go to the first page.

21 A. Yep.

22 Q. "Mary, you want the Eclipse. Here are the  
23 product codes." Okay. And then he provides them.

24 A. Yes.

25 Q. And this was in -- this comported to the

1 instructions or the -- you know, the company directive  
2 that he's aware of.

3 A. Uh-huh.

4 Q. That's a yes?

5 A. It is correct, yes. Sorry.

6 Q. Sorry, it's annoying, but you've got to give  
7 audible responses.

8 A. Yes.

9 Q. And Mary responds and says, "Thanks, Matt. We  
10 still have a G2 in stock. Are those still being used?"  
11 And at least at this time, it's fair to say that this  
12 hospital is using the G2. Right?

13 A. I think that would be fair that it sounds like  
14 they have some in stock, yes.

15 Q. And do you know what Matt replied?

16 A. I don't. I can't recall that.

17 Q. Okay. Yeah, I don't have it --

18 A. I could make an assumption on that, but, yes.

19 Q. What would you expect Matt to have responded?

20 MR. LERNER: Objection to form.

21 THE WITNESS: I would assume that Matt would  
22 probably tell her that the G2 -- to go ahead and utilize  
23 the G2 and that when she does her reorders to order the  
24 Eclipse. Right?

25 I mean, that's -- that's the direction that

1 we have, and that's the communication that we have, and I  
2 would assume that -- that Matt could carry that out, but  
3 I can't say that with certainty obviously.

4 Q. BY MR. LOPEZ: Okay. You can put that one  
5 aside.

6 A. Okay.

7 Q. All right. This is Exhibit 1116.

8 (Exhibit 1116 was marked for  
9 identification.)

10 Q. BY MR. LOPEZ: And let's try to go through this  
11 one a little more quickly than it might look like we're  
12 going to.

13 A. Okay.

14 Q. I know it's a big one, but go to page 18,  
15 please.

16 A. Okay.

17 Q. And you'll see it's a chart at the top. It  
18 says, "What is G2 trend relative to RNF?" And do you  
19 understand the RNF to be the Recovery filter?

20 A. Yes.

21 Q. Okay. Do you see in the left column, second  
22 row, limb detachments, arm/leg hook?

23 A. Yes.

24 Q. And the far right column says, "G2 has less arm  
25 and hook complaints than RNF. G2 has more leg complaints

# Defendants' Exhibit 9



# Defendants' Exhibit 10



**INVOICE**

**SEND INQUIRIES ONLY TO:**

Bard Peripheral Vascular Inc  
 1415 W 3RD ST STE 109  
 TEMPE, AZ 85281

**SHIP TO:**

WHEATON FRANCISCAN HLTHCARE  
 10101 S 27TH ST  
 FRANKLIN, WI 53132

|             |          |                    |  |
|-------------|----------|--------------------|--|
| INVOICE NO. |          | PURCHASE ORDER NO. |  |
| 08550029    |          | K1710424           |  |
| SHIP TO     | SOLD TO  | ACCOUNT            |  |
| 12001637    | 12001637 | 72014              |  |
| SALES REP.  | A/R REP. | DATE               |  |
| 34342       | 11       | 01/07/10           |  |

**BILL TO:**

WHEATON FRANCISCAN HLTHCARE  
 ATTN ACCTS PAYBALE  
 PO BOX 14487  
 MILWAUKEE, WI 53214

**REMIT TO:** C.R. BARD, INC.  
 P.O. BOX 75767  
 CHARLOTTE, NC 28275

**FOR CUSTOMER SERVICE INQUIRIES CALL:**

800-321-4254

**TERMS:** NET 30 - A/R

| DATE SHIPPED                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | BILL OF LADING NUMBER | SHIP VIA       | SALES ORDER NO.                                                                      | CTNS.           | WEIGHT               | FRT. CHARGES    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------|--------------------------------------------------------------------------------------|-----------------|----------------------|-----------------|
| 01/07/10                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 424697536105          | BESTWAY        | S3664562                                                                             | 1               | 0                    | FREIGHT         |
| QTY. SHIP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | U/M                   | CATALOG NUMBER | DESCRIPTION                                                                          | UNIT SALE PRICE | AMOUNT               |                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                       |                | SHIPPING PLEASE USE THE CUSTOMERS ACCT FEDEX/476590167 TO SHIP THEIR ITEMS 2ND DAY!! |                 |                      |                 |
| 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | EA                    | RF400F         | G2 EXPRESS FEM DELIVERY KIT 1/EACH                                                   | 1,250.00        | 1,250.00             |                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                       | RF400F         |                                                                                      |                 |                      |                 |
| 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | EA                    | RF400J         | G2 EXPRESS JUG/SUB DEL KIT 1/EACH                                                    | 1,250.00        | 1,250.00             |                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                       | RF400J         |                                                                                      |                 |                      |                 |
| The above charges may not reflect the true net cost for the above products as other discounts, rebates or reductions in price (collectively 'discounts') may be provided to customer for such products. When the value of any such further discounts become known, Bard will provide customer with further documentation relative to the same. Customer is reminded of its obligation under 42 U.S.C. sec. 1320a-7b(b)(3)(A) and the 'safe harbor' regulations regarding discounts or other reductions in price set forth at 42 C.F.R. sec. 1001.952(h), to fully and accurately report any discounts earned to any federal or state health care programs, including Medicare and Medicaid. |                       |                |                                                                                      |                 |                      |                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                       |                |                                                                                      |                 | <b>INVOICE TOTAL</b> | <b>2,500.00</b> |





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Bard Peripheral Vascular Inc  
 1415 W 3RD ST STE 109  
 TEMPE, AZ 85281

**SHIP TO:**

WHEATON FRANCISCAN HLTHCARE  
 10101 S 27TH ST  
 FRANKLIN, WI 53132

|             |          |                    |  |
|-------------|----------|--------------------|--|
| INVOICE NO. |          | PURCHASE ORDER NO. |  |
| 08813587    |          | K1892443           |  |
| SHIP TO     | SOLD TO  | ACCOUNT            |  |
| 12001637    | 12001637 | 72014              |  |
| SALES REP.  | A/R REP. | DATE               |  |
| 34342       | 11       | 11/29/10           |  |

**BILL TO:**

WHEATON FRANCISCAN HLTHCARE  
 ATTN ACCTS PAYBALE  
 PO BOX 14487  
 MILWAUKEE, WI 53214

**REMIT TO:** C.R. BARD, INC.  
 P.O. BOX 75767  
 CHARLOTTE, NC 28275

**FOR CUSTOMER SERVICE INQUIRIES CALL:**

800-321-4254

**TERMS:** NET 30 - A/R

| DATE SHIPPED                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | BILL OF LADING NUMBER | SHIP VIA       | SALES ORDER NO.                  | CTNS.           | WEIGHT          | FRT. CHARGES |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------|----------------------------------|-----------------|-----------------|--------------|
| 11/29/10                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 462534285793          | FX1PPD         | S3915492                         | 1               | 4               | FREIGHT      |
| QTY. SHIP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | U/M                   | CATALOG NUMBER | DESCRIPTION                      | UNIT SALE PRICE | AMOUNT          |              |
| 2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | EA                    | EC500F         | ECLIPSE FEMORAL FILTER<br>1/EACH | 1,300.00        | 2,600.00        |              |
| SHIPPING PLEASE USE THE CUSTOMERS ACCT FEDEX/476590167 TO SHIP THEIR ITEMS<br>2ND DAY!!<br>(ACTIVE 08-24-09)<br>If shipping charges do not apply to this order please ship v<br>The above charges may not reflect the true net cost for the above products as other<br>discounts, rebates or reductions in price (collectively 'discounts') may be provided to<br>customer for such products. When the value of any such further discounts become known,<br>Bard will provide customer with further documentation relative to the same. Customer is<br>reminded of its obligation under 42 U.S.C. sec. 1320a-7b(b)(3)(A) and the 'safe harbor'<br>regulations regarding discounts or other reductions in price set forth at 42 C.F.R. sec.<br>1001.952(h) to fully and accurately report any discounts earned to any federal or state<br>health care programs, including Medicare and Medicaid. |                       |                |                                  |                 |                 |              |
| <b>INVOICE TOTAL</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                       |                |                                  |                 | <b>2,600.00</b> |              |

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 TEMPE, AZ 85281

**SHIP TO:**

WHEATON FRANCISCAN HLTHCARE  
 10101 S 27TH ST  
 FRANKLIN, WI 53132

|             |          |                    |  |
|-------------|----------|--------------------|--|
| INVOICE NO. |          | PURCHASE ORDER NO. |  |
| 08814398    |          | K1892801           |  |
| SHIP TO     | SOLD TO  | ACCOUNT            |  |
| 12001637    | 12001637 | 72014              |  |
| SALES REP.  | A/R REP. | DATE               |  |
| 34342       | 11       | 11/30/10           |  |

**BILL TO:**

WHEATON FRANCISCAN HLTHCARE  
 ATTN ACCTS PAYBALE  
 PO BOX 14487  
 MILWAUKEE, WI 53214

**REMIT TO:** C.R. BARD, INC.  
 P.O. BOX 75767  
 CHARLOTTE, NC 28275

**FOR CUSTOMER SERVICE INQUIRIES CALL:**

800-321-4254

**TERMS:** NET 30 - A/R

| DATE SHIPPED                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | BILL OF LADING NUMBER | SHIP VIA       | SALES ORDER NO.                  | CTNS.           | WEIGHT          | FRT. CHARGES |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------|----------------------------------|-----------------|-----------------|--------------|
| 11/30/10                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 462534290830          | FX1PPD         | S3916218                         | 1               | 4               | FREIGHT      |
| QTY. SHIP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | U/M                   | CATALOG NUMBER | DESCRIPTION                      | UNIT SALE PRICE | AMOUNT          |              |
| 2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | EA                    | EC500F         | ECLIPSE FEMORAL FILTER<br>1/EACH | 1,300.00        | 2,600.00        |              |
| <p>SHIPPING PLEASE USE THE CUSTOMERS ACCT FEDEX/476590167 TO SHIP THEIR ITEMS<br/>                 2ND DAY!!<br/>                 (ACTIVE 08-24-09)</p> <p>The above charges may not reflect the true net cost for the above products as other discounts, rebates or reductions in price (collectively 'discounts') may be provided to customer for such products. When the value of any such further discounts become known, Bard will provide customer with further documentation relative to the same. Customer is reminded of its obligation under 42 U.S.C. sec. 1320a-7b(b)(3)(A) and the 'safe harbor' regulations regarding discounts or other reductions in price set for at 42 C.F.R. sec. 1001.952(h) to fully and accurately report any discounts earned to any federal or state health care programs, including Medicare and Medicaid.</p> |                       |                |                                  |                 |                 |              |
| <b>DUPLICATE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                       |                |                                  |                 |                 |              |
| <b>INVOICE TOTAL</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                       |                |                                  |                 | <b>2,600.00</b> |              |



**INVOICE**

**SEND INQUIRIES ONLY TO:**

Bard Peripheral Vascular Inc  
1415 W 3RD ST STE 109  
TEMPE, AZ 85281

**SHIP TO:**

WHEATON FRANCISCAN HLTHCARE  
10101 S 27TH ST  
FRANKLIN, WI 53132

|             |          |                    |  |
|-------------|----------|--------------------|--|
| INVOICE NO. |          | PURCHASE ORDER NO. |  |
| 08827802    |          | K1900907           |  |
| SHIP TO     | SOLD TO  | ACCOUNT            |  |
| 12001637    | 12001637 | 72014              |  |
| SALES REP.  | A/R REP. | DATE               |  |
| 34342       | 11       | 12/15/10           |  |

**BILL TO:**

WHEATON FRANCISCAN HLTHCARE  
ATTN ACCTS PAYBALE  
PO BOX 14487  
MILWAUKEE, WI 53214

**REMIT TO:** C.R. BARD, INC.  
P.O. BOX 75767  
CHARLOTTE, NC 28275

**FOR CUSTOMER SERVICE INQUIRIES CALL:**

800-321-4254

**TERMS:** NET 30 - A/R

| DATE SHIPPED | BILL OF LADING NUMBER | SHIP VIA | SALES ORDER NO. | CTNS. | WEIGHT | FRT. CHARGES |
|--------------|-----------------------|----------|-----------------|-------|--------|--------------|
| 12/15/10     | 462534386314          | FX1PPD   | S3929077        | 1     | 3      | FREIGHT      |

| QTY. SHIP | U/M | CATALOG NUMBER | DESCRIPTION                      | UNIT SALE PRICE | AMOUNT   |
|-----------|-----|----------------|----------------------------------|-----------------|----------|
| 1         | EA  | EC500F         | ECLIPSE FEMORAL FILTER<br>1/EACH | 1,300.00        | 1,300.00 |

SHIPPING PLEASE USE THE CUSTOMERS ACCT FEDEX/476590167 TO SHIP THEIR ITEMS 2ND DAY!! (ACTIVE 08-24-09)

The above charges may not reflect the true net cost for the above products as other discounts, rebates or reductions in price (collectively 'discounts') may be provided to customer for such products. When the value of any such further discounts become known, Bard will provide customer with further documentation relative to the same. Customer is reminded of its obligation under 42 U.S.C. sec. 1320a-7b(b)(3)(A) and the 'safe harbor' regulations regarding discounts or other reductions in price set for at 42 C.F.R. sec. 1001.952(h) to fully and accurately report any discounts earned to any federal or state health care programs, including Medicare and Medicaid.

DUPLICATE

|               |          |
|---------------|----------|
| INVOICE TOTAL | 1,300.00 |
|---------------|----------|



**INVOICE**

**SEND INQUIRIES ONLY TO:**

Bard Peripheral Vascular Inc  
 1415 W 3RD ST STE 109  
 TEMPE, AZ 85281

**SHIP TO:**

WHEATON FRANCISCAN HLTHCARE  
 10101 S 27TH ST  
 FRANKLIN, WI 53132

|             |          |                    |  |
|-------------|----------|--------------------|--|
| INVOICE NO. |          | PURCHASE ORDER NO. |  |
| 08847565    |          | K1913720           |  |
| SHIP TO     | SOLD TO  | ACCOUNT            |  |
| 12001637    | 12001637 | 72014              |  |
| SALES REP.  | A/R REP. | DATE               |  |
| 34342       | 11       | 01/12/11           |  |

**BILL TO:**

WHEATON FRANCISCAN HLTHCARE  
 ATTN ACCTS PAYBALE  
 PO BOX 14487  
 MILWAUKEE, WI 53214

**REMIT TO: C.R. BARD, INC.**  
**P.O. BOX 75767**  
**CHARLOTTE, NC 28275**

**FOR CUSTOMER SERVICE INQUIRIES CALL:**

**800-321-4254**

**TERMS: NET 30 - A/R**

| DATE SHIPPED                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | BILL OF LADING NUMBER | SHIP VIA       | SALES ORDER NO.                  | CTNS.           | WEIGHT               | FRT. CHARGES    |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------|----------------------------------|-----------------|----------------------|-----------------|
| 01/12/11                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 462534532099          | FX1PPD         | S3947923                         | 1               | 3                    | FREIGHT         |
| QTY. SHIP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | U/M                   | CATALOG NUMBER | DESCRIPTION                      | UNIT SALE PRICE | AMOUNT               |                 |
| 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | EA                    | EC500F         | ECLIPSE FEMORAL FILTER<br>1/EACH | 1,250.00        | 1,250.00             |                 |
| SHIPPING PLEASE USE THE CUSTOMERS ACCT FEDEX/476590167 TO SHIP THEIR ITEMS<br>2ND DAY!!<br>(ACTIVE 08-24-09)<br><br>The above charges may not reflect the true net cost for the above products as other discounts, rebates or reductions in price (collectively 'discounts') may be provided to customer for such products. When the value of any such further discounts become known, Bard will provide customer with further documentation relative to the same. Customer is reminded of its obligation under 42 U.S.C. sec. 1320a-7b(b)(3)(A) and the 'safe harbor' regulations regarding discounts or other reductions in price set for at 42 C.F.R. sec. 1001.952(h) to fully and accurately report any discounts earned to any federal or state health care programs, including Medicare and Medicaid. |                       |                |                                  |                 |                      |                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                       |                |                                  |                 | <b>INVOICE TOTAL</b> | <b>1,250.00</b> |

DUPLICATE





**INVOICE**

**SEND INQUIRIES ONLY TO:**

Bard Peripheral Vascular Inc  
 1415 W 3RD ST STE 109  
 TEMPE, AZ 85281

**SHIP TO:**

WHEATON FRANCISCAN HLTHCARE  
 10101 S 27TH ST  
 FRANKLIN, WI 53132

|                    |                 |                           |  |
|--------------------|-----------------|---------------------------|--|
| <b>INVOICE NO.</b> |                 | <b>PURCHASE ORDER NO.</b> |  |
| 08886693           |                 | K1938221                  |  |
| <b>SHIP TO</b>     | <b>SOLD TO</b>  | <b>ACCOUNT</b>            |  |
| 12001637           | 12001637        | 72014                     |  |
| <b>SALES REP.</b>  | <b>A/R REP.</b> | <b>DATE</b>               |  |
| 34342              | 11              | 02/23/11                  |  |

**BILL TO:**

WHEATON FRANCISCAN HLTHCARE  
 ATTN ACCTS PAYBALE  
 PO BOX 14487  
 MILWAUKEE, WI 53214

**REMIT TO:** C.R. BARD, INC.  
 P.O. BOX 75767  
 CHARLOTTE, NC 28275

**FOR CUSTOMER SERVICE INQUIRIES CALL:**

800-321-4254

**TERMS:** NET 30 - A/R

| DATE SHIPPED                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | BILL OF LADING NUMBER | SHIP VIA       | SALES ORDER NO.                                                                                                     | CTNS.           | WEIGHT          | FRT. CHARGES |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------|---------------------------------------------------------------------------------------------------------------------|-----------------|-----------------|--------------|
| 02/23/11                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 462534801000          | FX1PPD         | S3985358                                                                                                            | 1               | 4               | FREIGHT      |
| QTY. SHIP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | U/M                   | CATALOG NUMBER | DESCRIPTION                                                                                                         | UNIT SALE PRICE | AMOUNT          |              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                       |                | SHIPPING PLEASE USE THE CUSTOMERS ACCT FEDEX/476590167 TO SHIP THEIR ITEMS<br>2ND DAY!!<br>(ACTIVE 08-24-09)<br>HSS |                 |                 |              |
| 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | EA                    | EC500J         | ECLIPSE JUGULAR FILTER<br>1/EACH                                                                                    | 1,250.00        | 1,250.00        |              |
| 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | EA                    | EC500F         | ECLIPSE FEMORAL FILTER<br>1/EACH                                                                                    | 1,250.00        | 1,250.00        |              |
| The above charges may not reflect the true net cost for the above products as other discounts, rebates or reductions in price (collectively 'discounts') may be provided to customer for such products. When the value of any such further discounts become known, Bard will provide customer with further documentation relative to the same. Customer is reminded of its obligation under 42 U.S.C. sec. 1320a-7(b)(3)(A) and the 'safe harbor' regulations regarding discounts or other reductions in price set forth at 42 C.F.R. sec. 1001.952(h), to fully and accurately report any discounts earned to any federal or state health care programs, including Medicare and Medicaid. |                       |                |                                                                                                                     |                 |                 |              |
| <b>INVOICE TOTAL</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                       |                |                                                                                                                     |                 | <b>2,500.00</b> |              |



**INVOICE**

**SEND INQUIRIES ONLY TO:**

Bard Peripheral Vascular Inc  
 1415 W 3RD ST STE 109  
 TEMPE, AZ 85281

**SHIP TO:**

WHEATON FRANCISCAN HLTHCARE  
 10101 S 27TH ST  
 FRANKLIN, WI 53132

| INVOICE NO. |          | PURCHASE ORDER NO. |  |
|-------------|----------|--------------------|--|
| 08905942    |          | K1950259           |  |
| SHIP TO     | SOLD TO  | ACCOUNT            |  |
| 12001637    | 12001637 | 72014              |  |
| SALES REP.  | A/R REP. | DATE               |  |
| 34342       | 11       | 03/16/11           |  |

**BILL TO:**

WHEATON FRANCISCAN HLTHCARE  
 ATTN ACCTS PAYBALE  
 PO BOX 14487  
 MILWAUKEE, WI 53214

**REMIT TO:** C.R. BARD, INC.  
 P.O. BOX 75767  
 CHARLOTTE, NC 28275

**FOR CUSTOMER SERVICE INQUIRIES CALL:**

800-321-4254

**TERMS:** NET 30 - A/R

| DATE SHIPPED                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | BILL OF LADING NUMBER | SHIP VIA       | SALES ORDER NO.                  | CTNS.           | WEIGHT          | FRT. CHARGES |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------|----------------------------------|-----------------|-----------------|--------------|
| 03/16/11                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 462534918692          | FX1PPD         | S4004339                         | 1               | 3               | FREIGHT      |
| QTY. SHIP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | U/M                   | CATALOG NUMBER | DESCRIPTION                      | UNIT SALE PRICE | AMOUNT          |              |
| 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | EA                    | EC500F         | ECLIPSE FEMORAL FILTER<br>1/EACH | 1,250.00        | 1,250.00        |              |
| SHIPPING PLEASE USE THE CUSTOMERS ACCT FEDEX/476590167 TO SHIP THEIR ITEMS<br>2ND DAY!!<br>(ACTIVE 08-24-09)<br>HSS<br>The above charges may not reflect the true net cost for the above products as other discounts, rebates or reductions in price (collectively 'discounts') may be provided to customer for such products. When the value of any such further discounts become known, Bard will provide customer with further documentation relative to the same. Customer is reminded of its obligation under 42 U.S.C. sec. 1320a-7b(b)(3)(A) and the 'safe harbor' regulations regarding discounts or other reductions in price set forth at 42 C.F.R. sec. 1001.952(h) to fully and accurately report any discounts earned to any federal or state health care programs, including Medicare and Medicaid. |                       |                |                                  |                 |                 |              |
| <b>DUPLICATE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                       |                |                                  |                 |                 |              |
| <b>INVOICE TOTAL</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                       |                |                                  |                 | <b>1,250.00</b> |              |



**INVOICE**

**SEND INQUIRIES ONLY TO:**

Bard Peripheral Vascular Inc  
 1415 W 3RD ST STE 109  
 TEMPE, AZ 85281

**SHIP TO:**

WHEATON FRANCISCAN HLTHCARE  
 10101 S 27TH ST  
 FRANKLIN, WI 53132

|             |          |                    |  |
|-------------|----------|--------------------|--|
| INVOICE NO. |          | PURCHASE ORDER NO. |  |
| 08892156    |          | K1941801           |  |
| SHIP TO     | SOLD TO  | ACCOUNT            |  |
| 12001637    | 12001637 | 72014              |  |
| SALES REP.  | A/R REP. | DATE               |  |
| 34342       | 11       | 03/01/11           |  |

**BILL TO:**

WHEATON FRANCISCAN HLTHCARE  
 ATTN ACCTS PAYBALE  
 PO BOX 14487  
 MILWAUKEE, WI 53214

**REMIT TO:** C.R. BARD, INC.  
 P.O. BOX 75767  
 CHARLOTTE, NC 28275

**FOR CUSTOMER SERVICE INQUIRIES CALL:**

800-321-4254

**TERMS:** NET 30 - A/R

| DATE SHIPPED                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | BILL OF LADING NUMBER | SHIP VIA       | SALES ORDER NO.                  | CTNS.           | WEIGHT          | FRT. CHARGES |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------|----------------------------------|-----------------|-----------------|--------------|
| 03/01/11                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 462534835122          | FX1PPD         | S3990839                         | 1               | 3               | FREIGHT      |
| QTY. SHIP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | U/M                   | CATALOG NUMBER | DESCRIPTION                      | UNIT SALE PRICE | AMOUNT          |              |
| 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | EA                    | EC500J         | ECLIPSE JUGULAR FILTER<br>1/EACH | 1,250.00        | 1,250.00        |              |
| SHIPPING PLEASE USE THE CUSTOMERS ACCT FEDEX/476590167 TO SHIP THEIR ITEMS<br>2ND DAY!!<br>(ACTIVE 08-24-09)<br><br>The above charges may not reflect the true net cost for the above products as other discounts, rebates or reductions in price (collectively 'discounts') may be provided to customer for such products. When the value of any such further discounts become known, Bard will provide customer with further documentation relative to the same. Customer is reminded of its obligation under 42 U.S.C. sec. 1320a-7b(b)(3)(A) and the 'safe harbor' regulations regarding discounts or other reductions in price set for at 42 C.F.R. sec. 1001.952(h) to fully and accurately report any discounts earned to any federal or state health care programs, including Medicare and Medicaid. |                       |                |                                  |                 |                 |              |
| <b>DUPLICATE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                       |                |                                  |                 |                 |              |
| <b>INVOICE TOTAL</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                       |                |                                  |                 | <b>1,250.00</b> |              |

# Defendants' Exhibit 11



This is a snapshot of a document produced at BPVEFILTER-28-00402336

|       | A                                                | B                    | C    | D     | E     | F | G                                                                                                                                                                                                                                                                                                  | H | I | J | K | L | M  | N  | O  | P      |
|-------|--------------------------------------------------|----------------------|------|-------|-------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|---|---|---|---|----|----|----|--------|
| 1     | <b>SHAD - August 2009</b>                        |                      |      |       |       |   |                                                                                                                                                                                                                                                                                                    |   |   |   |   |   |    |    |    |        |
| 2     | COMM                                             | (All)                |      | REG   | (All) |   | <div style="border: 1px solid black; padding: 5px;">                     This report displays monthly sales by year. The Reg, Dist, Terr, and Customer Name fields may be added/removed to the report by dragging. Filter the report using the drop-down fields at the top.                 </div> |   |   |   |   |   |    |    |    |        |
| 3     | BSGP                                             | (All)                |      | TERR  | (All) |   |                                                                                                                                                                                                                                                                                                    |   |   |   |   |   |    |    |    |        |
| 4     | CAT                                              | (All)                |      | DIST  | (All) |   |                                                                                                                                                                                                                                                                                                    |   |   |   |   |   |    |    |    |        |
| 5     | CHANNEL                                          | (All)                |      |       |       |   |                                                                                                                                                                                                                                                                                                    |   |   |   |   |   |    |    |    |        |
| 6     |                                                  |                      |      |       |       |   |                                                                                                                                                                                                                                                                                                    |   |   |   |   |   |    |    |    |        |
| 7     | UNITS                                            |                      |      | MONTH |       |   |                                                                                                                                                                                                                                                                                                    |   |   |   |   |   |    |    |    |        |
| 8     | CUSTOMER                                         | GROUP                | YEAR | 1     | 2     | 3 | 4                                                                                                                                                                                                                                                                                                  | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | Annual |
| 82878 | WHEATON FRANCISCAN HLTHCARE FRANKLIN, WI12001637 | G2 X JUGULAR         | 2009 |       |       |   |                                                                                                                                                                                                                                                                                                    |   |   |   |   |   |    |    |    |        |
| 82879 |                                                  |                      | 2010 | 1     |       |   |                                                                                                                                                                                                                                                                                                    |   |   |   |   |   |    |    |    | 1      |
| 82880 |                                                  | G2 X JUGULAR Total   |      | 1     |       |   |                                                                                                                                                                                                                                                                                                    |   |   |   |   |   |    |    |    | 1      |
| 82881 |                                                  | G2 X FEM             | 2009 |       |       |   |                                                                                                                                                                                                                                                                                                    |   |   |   |   |   |    |    |    |        |
| 82882 |                                                  |                      | 2010 | 1     |       |   |                                                                                                                                                                                                                                                                                                    |   |   |   |   |   |    |    |    | 1      |
| 82883 |                                                  | G2 X FEM Total       |      | 1     |       |   |                                                                                                                                                                                                                                                                                                    |   |   |   |   |   |    |    |    | 1      |
| 82884 |                                                  | ECLISPE FILTER       | 2009 |       |       |   |                                                                                                                                                                                                                                                                                                    |   |   |   |   |   |    |    |    |        |
| 82885 |                                                  |                      | 2010 |       |       |   |                                                                                                                                                                                                                                                                                                    |   |   |   |   |   | 4  | 1  |    | 5      |
| 82886 |                                                  | ECLISPE FILTER Total |      |       |       |   |                                                                                                                                                                                                                                                                                                    |   |   |   |   |   | 4  | 1  |    | 5      |

# PLAINTIFFS' EXHIBIT 1



TD-01619, Rev. 0 - Page 1 of 7

**TD-01619, Rev. 0**

TO: DHF 8113  
FROM: Joni Creal  
DATE: 9/27/2010  
SUBJECT: Eclipse Filter Post-Market - Regulatory

---

Regulatory Filing – Special 510(k) – K093659

US Submission: November 25, 2009  
AI Request: December 15, 2009 (Radial Force, Migration Resistance, Tensile)  
Clearance: January 14, 2010



DEC. 15. 2009 12:28PM

TD-01619, Rev. 0 - Page 2 of 7

NO. 4402 P. 1/3



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

DEC 15 2009

Bard Peripheral Vascular, Inc.  
c/o Ms. Joni Creal  
Regulatory Affairs Associate  
1625 West Third Street  
Tempe, AZ 85280-1749

Re: K093659  
ECLIPSE Filter System – Femoral and Jugular/Subclavian Delivery Kits  
Dated: November 23, 2009  
Received: November 25, 2009

Dear Ms. Creal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following deficiency to be addressed.

You have completed corrosion resistance testing, cyclic fatigue testing, and arm fatigue testing to validate the electropolishing of your filter. However, it does not appear that radial force testing, migration/clot trapping testing, or filter tensile strength testing has been completed on the modified filter. These tests are considered important as electropolishing the legs and arms will affect their strength. Please either complete the tests noted above or provide a justification for why each of these tests is not necessary.

The deficiency identified above represents the issue that we believe needs to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiency, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

1625 West 3<sup>rd</sup> Street • P. O. Box 1740 • Tempe, AZ 85280-1740  
Tel: 1-800-321-4254 • 1-480-894-9515 • Fax: 1-480-966-7062 • www.bardpv.com



DEC. 15. 2009 12:28PM

NO. 4402 P. 2/3

Page 2 – Ms. Joni Creal

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k) (21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements" at [www.fda.gov/cdrb/ode/guidance/1655.html](http://www.fda.gov/cdrb/ode/guidance/1655.html).

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-0609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002



TD-01619, Rev. 0 - Page 4 of 7

DEC. 15. 2009 12:28PM

NO. 4402 P. 3/3

Page 3 -- Ms. Joni Creal

If you have any questions concerning the contents of the letter, please contact Nelson Anderson at (301) 796-6367. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "KC", written over a horizontal line.

Kenneth J. Cavanaugh Jr., Ph.D.  
Chief, Peripheral Vascular  
Devices Branch  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health





TD-01619, Rev. 0 - Page 5 of 7



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

JAN 14 2010

Bard Peripheral Vascular, Inc.  
c/o Ms. Joni Creal  
Regulatory Affairs Associate  
1625 West Third Street  
Tempe, AZ 85280-1749

Re: K093659

Trade/Device Name: ECLIPSE Filter System, Femoral and Jugular/Subclavian Delivery Kits  
Regulation Number: 21 CFR 870.3375  
Regulation Name: Cardiovascular intravascular filter  
Regulatory Class: Class II (two)  
Product Code: DTK  
Dated: December 17, 2009  
Received: December 18, 2009

Dear Ms. Creal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

1625 West 3<sup>rd</sup> Street • P. O. Box 1740 • Tempe, AZ 85280-1740  
Tel: 1-800-321-4254 • 1-480-894-9515 • Fax: 1-480-966-7062 • www.bardpv.com




Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure





Page 1 of 1

ECLIPSE™ Filter System  
Special 510(k) Premarket Notification

Page 6 of 163

**Indications for Use**

510(k) Number (if known): K093659

Device Name: ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery Kits

**Indications for Use:**

The ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery Kits are indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- ECLIPSE™ Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Kohn  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K093659

TRADE SECRET/CONFIDENTIAL INFORMATION  
Notify CR Bard Before Releasing this Document.





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room --WO66-G609  
Silver Spring, MD 20993-0002

Bard Peripheral Vascular, Inc.  
c/o Ms. Joni Creal  
Regulatory Affairs Associate  
1625 West Third Street  
Tempe, AZ 85281

AUG 24 2011

Re: K102511

Trade Name: MERIDIAN Filter System -- Jugular/Subclavian Delivery Kit  
Regulation Number: 21 CFR 870.3375  
Regulation Name: Cardiovascular intravascular filter  
Regulatory Class: Class II  
Product Code: DTK  
Dated: June 27, 2011  
Received: June 28, 2011

Dear Ms. Creal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

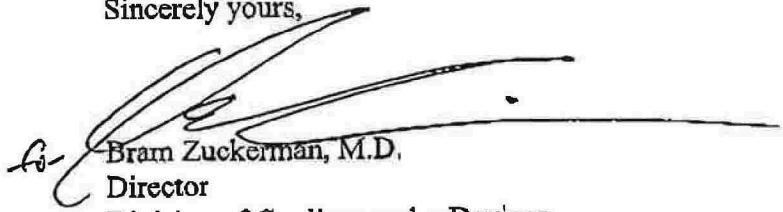
Page 2 – Ms. Joni Creal

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



### Indications for Use

510(k) Number (if known):

Device Name: MERIDIAN™ Filter System –Jugular/Subclavian Delivery Kits

**Indications for Use:**

The MERIDIAN™ Filter System –Jugular/Subclavian Delivery Kits are indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

MERIDIAN™ Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K10254

Bard Peripheral Vascular, Inc.

# PLAINTIFFS' EXHIBIT 2

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*Attorneys for Defendants C. R. Bard, Inc.  
and Bard Peripheral Vascular, Inc.*

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability  
Litigation,

No. 2:15-MD-02641-DGC

**DEFENDANTS' SUBMISSION  
REGARDING SELECTION OF CASES  
FOR BELLWETHER GROUP 1**

In accordance with Case Management Order No. 11 [Doc. 1662], Para. V.A.2., and No. 20 [Doc. 4335], Defendants (hereinafter "Bard") hereby file their Submission Regarding Selection of Cases for Bellwether Group 1, providing their memorandum in support of their selections, proposed Order of Trials, and memorandum in opposition to certain of Plaintiffs' selections, and show the Court as follows:

The overarching goal of the bellwether trial process in MDLs is to allow the parties to test their claims and defenses and ultimately to evaluate the strengths and weaknesses of their cases, thereby assisting in facilitating global settlement. Manual for Complex

1 Litigation (Fourth) § 20.132. However, the likelihood of bellwether trials yielding  
2 information useful in furthering these goals depends upon a critical factor; the extent to  
3 which bellwether trials fairly represent the cases making up the greater MDL as a whole:

4  
5 If individual trials, sometimes referred to as bellwether trials or test cases,  
6 are to produce reliable information about other mass tort cases, the specific  
7 plaintiffs and their claims should be representative of the range of case.  
8 Some judges permit the plaintiffs and defendants to choose which cases to  
9 try initially, but this technique may skew the information that is produced.  
10 To obtain the most representative cases from the available pool, a judge  
11 should direct the parties to select test cases randomly or limit the selection  
12 to cases that the parties agree are typical of the mix of cases.

13 Manual for Complex Litigation (Fourth) § 22.315.<sup>1</sup>

14 When bellwether cases are not fairly representative of the MDL as a whole, their  
15 trials lose the ability to inform the parties' respective assessments of their cases' strengths  
16 and weaknesses and can actually decrease the likelihood of eventual global settlement,  
17 ultimately resulting in a waste of substantial amounts of money and judicial resources.  
18 *See*, Eldon E. Fallon, et al., *The Problem of Multidistrict Litigation: Bellwether Trials in*  
19 *Multidistrict Litigation*, 82 Tul. L. Rev. 2323, 2343-44 (2008). Defendants have concern  
20 that such could be the case here, should Plaintiffs' strategy of selecting cases intended to

21  
22 <sup>1</sup> Only when a "representative...range of cases" is selected may "individual  
23 trials...produce reliable information about other mass tort cases." MCL § 22.315; *In re*  
24 *Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, MDL No.  
25 2100, 2010 U.S. Dist. LEXIS 108107, at \*4, \*6-7 (S.D. Ill. Oct. 8, 2010) (finding that it is  
26 critical to a successful bellwether plan that an honest representative sampling of cases be  
27 achieved because "[l]ittle credibility will be attached to this process, and it will be a waste  
28 of everyone's time and resources, if cases are selected which do not accurately reflect the  
run-of-the-mill case."). *See also In re Hydroxycut Mktg. & Sales Practices Litig.*, No. 09-  
md-2087 BTM (KSC), 2012 U.S. Dist. LEXIS 1118980, at \*56 (S.D. Cal. Aug. 21, 2012)  
("The bellwether cases should be representative cases that will best produce information  
regarding value ascertainment for settlement purposes or to answer causation or liability  
issues common to the universe of plaintiffs."); *In re Chevron U.S.A., Inc.*, 109 F.3d 1016,  
1019 (5th Cir. 1997) (finding that "representativeness" is a "core element" that must be  
present for a bellwether trial to achieve its purpose of value ascertainment for settlement  
purposes or to answer troubling causation or liability issues common to the universe of  
claimants).

1 reap the largest judgments possible be permitted to predominate this bellwether selection  
2 process.

3 From the beginning of the bellwether selection process in this case, Bard's  
4 approach has been premised on the widely accepted belief that the process loses its utility  
5 if the cases in each respective stage of the process are not representative of the overall  
6 makeup of the MDL. Moreover, the Court instructed the parties to identify bellwether  
7 cases "in a manner consistent with the goal of identifying representative cases." *See* Case  
8 Management Order No. 18 [Doc. 3684]. As a result, Bard has expended considerable  
9 resources to determine which cases are representative of the pool in this MDL, the trial of  
10 which will most likely further the fundamental goals of this process.

11  
12  
13 In making selections for Discovery Group 1 (from which Bellwether Group 1 cases  
14 will be selected), Bard analyzed the MDL pool and sought to select representative cases  
15 for that group. Bard then used the time period afforded it by Case Management Order No.  
16 20 [Doc. 4335] to further investigate the cases in Discovery Group 1. The six (6) cases  
17 Bard has selected make up a truly representative group of cases that meet the goals of the  
18 Court, and all parties, in this case. Bard and Plaintiffs have both selected one case in  
19 common -- the *Debra Mulkey* case. Defendants agree that the *Mulkey* case meets the  
20 goals of this litigation, but believe that the remaining five (5) cases selected by Plaintiffs  
21 do not, either individually or as a group.

22  
23  
24 To demonstrate which cases are, or are not, representative in this litigation, Bard  
25 relies on the data drawn from the 1330 Plaintiff Profile Sheets submitted in the litigation  
26  
27  
28



1 through March 29, 2017<sup>2</sup>. Bard has used that data as a guide to select representative  
 2 cases, and has compared that data to the characteristics of the remaining five bellwether  
 3 cases selected by the Plaintiffs. In this submission, Bard will summarize that data.  
 4 Additionally, Bard will provide the Court with overviews on each of its selected cases,  
 5 including *Mulkey*, demonstrating both the representative nature of each case individually,  
 6 and the cases as a group. Bard then provides overviews regarding each of the five cases  
 7 identified by the Plaintiffs and explains why each lacks representativeness.  
 8

### 9 **I. The MDL Pool Data<sup>3</sup>**

10 The Plaintiff Profile Forms provide a wealth of detailed information regarding each  
 11 case. On the Forms, the Plaintiffs specify the model filter they had implanted. They  
 12 specify each complication (fracture, migration, tilt, perforation, etc.) they are alleging.  
 13 Importantly, the Plaintiffs are specifically asked whether they have undergone any surgery  
 14 in an effort to remove the filter. In that regard, they are asked to specify whether the  
 15

16 \_\_\_\_\_  
 17 <sup>2</sup> In their Submission Re Discovery Group 1 [Doc. 4341], the Defendants provided the  
 18 Court with the same data for 936 cases with served Plaintiff Profile Forms at that time.  
 19 The data provided in this submission includes 1330 Plaintiff Profile Forms and data from  
 20 any supplements provided by the plaintiffs in those cases over time.

21 <sup>3</sup> Bard has carefully reviewed the information provided in, and in some cases attached to,  
 22 the 1330 Plaintiff Profile Forms submitted in this MDL through March 29, 2017, and  
 23 believes that its quoted data is accurate. Nevertheless, Bard anticipates that Plaintiffs will  
 24 argue that the data Bard has cited is somehow not accurate, or is incomplete. However,  
 25 Bard notes that the data relevant to the parties' and the Court's analysis, for bellwether  
 26 selections, can only be obtained through review of the information discovered to date  
 27 through the Plaintiff Profile Forms submitted in this MDL. Case Management Order No.  
 28 5 [Doc. 365] required that these forms be "substantially complete in all respects", noted  
 that "a completed PPF shall be considered interrogatory answers under Fed. R. Civ. P. 33  
 . . . and will be governed by the standards applicable to written discovery under Federal  
 Rules 26 and 37." Further, Fed. R. Civ. P. 26(e)(i)(A) requires timely supplementation of  
 disclosures to provide new, responsive information. To the extent that any data cited by  
 Bard here is inaccurate, that inaccuracy is a failing on Plaintiffs' part and should be  
 construed against them.

1 surgery was an open abdominal or open chest procedure. Plaintiffs are also required to  
 2 disclose whether they have any retained struts from a fractured filter, and if so, where in  
 3 the body those struts are located.

4  
 5 When tabulated, those profile forms reveal a number of pertinent data points  
 6 regarding the MDL inventory. For example, the data demonstrates that cases involving  
 7 the G2 and Eclipse filters exceed the number of cases involving other filters by a  
 8 substantial margin:

|            | <b>Total</b> | <b>Percent</b> |
|------------|--------------|----------------|
| SNF        | 17           | 1.28%          |
| Recovery   | 136          | 10.23%         |
| G2         | 435          | 32.71%         |
| G2X        | 55           | 4.14%          |
| G2 Express | 64           | 4.81%          |
| Eclipse    | 286          | 21.50%         |
| Meridian   | 177          | 13.31%         |
| Denali     | 150          | 11.28%         |
| Unknown    | 10           | 0.75%          |
|            | <b>1330</b>  | <b>100.00%</b> |

10  
 11  
 12  
 13  
 14  
 15  
 16  
 17 Of significance, the G2 group of filters and Eclipse filters are virtually identical in  
 18 configuration, the difference being that the Eclipse was electropolished.

19  
 20 The data also demonstrates that fracture and migration – the two complications  
 21 emphasized by the plaintiffs – are alleged by only a minority of the plaintiffs:

| <b>Complication</b>                                  | <b>Number of Cases</b> | <b>Percentage</b> |
|------------------------------------------------------|------------------------|-------------------|
| Fracture                                             | 336                    | 25.26%            |
| Migration                                            | 76                     | 5.71%             |
| Other (tilt,<br>perforation, non<br>retrieval, etc.) | 808                    | 60.75%            |
| No Injury                                            | 110                    | 8.27%             |
| <b>Total</b>                                         | <b>1330</b>            | <b>99.99%</b>     |

1  
2 The data also compellingly demonstrates that only a very small number of  
3 plaintiffs have undergone an open surgical procedure:

| Procedure            | Number of Cases | Percentage |
|----------------------|-----------------|------------|
| Open Chest           | 28              | 2.11%      |
| Other Open Procedure | 51              | 3.83%      |
| No Open Surgery      | 1,251           | 94.06%     |
| Total                | 1330            | 100%       |

4  
5  
6  
7  
8  
9 **II. Bard's Case Selections**

10 Bard's case selections *Hyde, Jones, King, Kruse, Mulkey, and Nelson* are  
11 representative cases, individually and as a group. Those cases include representative  
12 filters (three G2 and three Eclipse filters, which together represent 63% of the pool),  
13 representative plaintiffs (plaintiffs with typical medical histories, indications for use,  
14 social and employment histories), and representative filter complications (plaintiffs with  
15 tilt, perforation, fracture, unsuccessful filter retrieval, retained filter struts, and  
16 combinations of such complications). Both parties have selected either G2 group or  
17 Eclipse filter cases for Bellwether Group 1, with the exception of Plaintiffs' selection of  
18 the *Tinlin* Recovery filter case.<sup>4</sup> Bard explains in its opposition to the *Tinlin* case why a  
19 Recovery filter case should not be included in Bellwether Group 1.

20 **Lisa Hyde (G2X)**

21 Ms. Hyde had a G2X implanted on 2/25/2011. Ms. Hyde's case is representative as it  
22 involves a filter fracture (25% of the pool) and also involves multiple complications in a  
23 single case including tilt, perforation, a filter strut to the heart, and a complex filter  
24 retrieval. Ms. Hyde claims that her filter fracture caused her to experience back and  
25 abdominal pain. As such, the case gives the parties the opportunity to test their arguments  
26 as to these numerous complications, including any interrelationship between the  
27 complication modes. This case was one of the cases initially selected by Plaintiffs for  
28 Discovery Group 1. The transferor court is USDC Wisconsin, Eastern District.

<sup>4</sup> Bard notes that neither Plaintiffs nor Bard have selected a Meridian or Denali case for Bellwether Group 1, which together make up 24% of the MDL pool. See Table, Section I, p. 5 above.

1  
2 **Doris Jones (Eclipse)**

3 Ms. Jones had a G2 placed on 8/24/2010, following two episodes of DVT and bleeding  
4 from a peptic ulcer. She experienced a fracture. Her filter was percutaneously retrieved;  
5 one filter strut remains in her right middle lobe pulmonary artery. Plaintiff Jones is  
6 representative of the 94% of the pool who did not require subsequent surgery. Plaintiff  
7 Jones is further representative of the MDL plaintiffs alleging fracture, which make up  
8 approximately 25% of the MDL pool. The transferor court was the USDC Georgia,  
9 Southern District.

10  
11 **Michael King (G2)**

12 Mr. King had a G2 placed on 8/6/2003 following a plane crash which resulted in  
13 pulmonary embolus, multiple fractures, and other injuries. He underwent a percutaneous  
14 retrieval of the filter on 2/15/2016, which was unsuccessful. The filter remains *in situ*.  
15 The case is representative of cases in which the allegation is that the filter tilted,  
16 perforated, and cannot be retrieved. The transferor court was the USDC Illinois, Central  
17 District. The *King* case presents a unique situation in this selection process, which Bard  
18 discusses further in **Section V** below.

19  
20 **Carol Kruse ( G2)**

21 Ms. Kruse, who suffered from degenerative joint disease and a history of right knee  
22 replacement surgery, developed a DVT, was placed on anticoagulants, and had a G2 filter  
23 implanted on 7/08/2009. She underwent a percutaneous retrieval of the filter on  
24 4/07/2011, which was unsuccessful. The filter remains *in situ*. Plaintiff alleges migration,  
25 tilt and pain associated with the filter. This case is representative of numerous cases in the  
26 MDL pool with tilt, perforation, and/or an unsuccessful retrieval attempt. The transferor  
27 court was the USDC Nebraska.

28 **Debra Mulkey (Eclipse)**

Ms. Mulkey had an Eclipse filter placed on 4/11/2012 prior to bariatric surgery, gall  
bladder surgery, and a liver biopsy. She underwent a percutaneous filter retrieval  
procedure on 10/4/12, at which time the filter was noted to have perforated and tilted with  
the tip of the filter abutting the medial wall of the IVC. Despite multiple retrieval  
attempts, the retrieval procedure was unsuccessful. This case is representative as it  
involves multiple complications including tilt and non retrieval. The transferor court is the  
USDC West Virginia, Southern District.

1  
2 **Randy Nelson (Eclipse)**

3 Mr. Nelson had an Eclipse filter placed on 6/20/2013, several days after sustaining a  
4 subdural hematoma in a moped accident. The hematoma prevented him from taking  
5 anticoagulants to treat a DVT that developed in his right leg days after the accident. His  
6 filter was successfully retrieved, percutaneously, on 10/24/13. At that time, it was  
7 observed that the filter was tilted and there was one fractured strut embedded in the IVC  
8 wall. The fractured limb could not be dislodged from the IVC wall and was left *in situ*.  
9 This case is representative of 25% of MDL pool cases which involve fracture, and it  
10 includes the further complications of tilt and a retained filter strut. The transferor court  
11 was the USDC South Dakota.

12 Bard respectfully suggests that its proposed selections of *Hyde, Jones, King, Kruse,*  
13 *Mulkey* and *Nelson* will result in a group of cases most representative of the cases pending  
14 in this MDL as a whole.

15 **III. Bard's Proposed Order of Trials for its Bellwether Group 1 Selections**

16 Bard proposes that the cases it has argued for selection into Bellwether Group 1  
17 should be ordered for trial as follows, and for the reasons set forth below: *Mulkey, Hyde,*  
18 *Jones, Kruse, Nelson, King.*

19 *Mulkey* was the only case selected by both Plaintiffs and Bard for inclusion in the  
20 Bellwether Group 1 cases. For that reason alone, selecting *Mulkey* as the first case tried  
21 has merit. *Mulkey* is an Eclipse case. The G2 group of filters plus Eclipse filters make up  
22 63% of the MDL pool. See Table, Section I, p. 5 above. The filter was placed for  
23 prophylactic use, in advance of bariatric surgery. The filter tilted and perforated. Despite  
24 retrieval attempts, the filter remains *in situ*. The case therefore provides an opportunity  
25 for the parties to present several different complications to the jury for a filter type that is  
26 well represented in the MDL Pool. The transferor court is the USDC, West Virginia.  
27  
28

1 West Virginia products liability and other law that may be applicable to this case is  
2 similar to the law of a majority of the states represented in the MDL pool.

3  
4 Bard recommends that the *Hyde* case be second in order for trial. That case  
5 involves a G2X with fracture, with a strut embolizing to the heart. It also involves  
6 complications of tilt, perforation, and a complex percutaneous retrieval of the filter and  
7 strut by a medical doctor at Stanford University. The transferor court is the USDC  
8 Wisconsin. Wisconsin has not specifically adopted learned intermediary or Comment k,  
9 providing the parties the opportunity to try a case applying a minority view of the law.  
10 *Hyde* was initially one of Plaintiffs' selections into Discovery Group 1.

11  
12 Bard then recommends that *Jones* and *Kruse* be tried as Cases No. 3 and 4. *Jones*  
13 is another Eclipse case in which the filter was placed due to a history of DVT and while  
14 the plaintiff was suffering from bleeding from an ulcer. In *Jones*, the filter has been  
15 percutaneously retrieved, but a fracture occurred, and the strut is retained in her  
16 pulmonary artery, giving the parties the opportunity to try a case where a fragment of the  
17 filter remains *in situ*. *Kruse* is a G2 case placed in a patient with history of DVT and  
18 before knee replacement surgery, who had an unsuccessful attempt at retrieval, and her  
19 entire filter remains *in situ*.

20  
21  
22 Bard recommends as Case No. 5, *Nelson*, another Eclipse case placed  
23 prophylactically following trauma including a head injury and development of DVT.  
24 Plaintiff's filter was percutaneously retrieved, but fractured, and a fractured strut remains  
25 in his IVC wall.  
26  
27  
28

1 Finally, Bard recommends as Case No. 6 the *King* case. As explained in Section  
 2 V. of this Submission, *King* presents an unusual situation which Bard argues can only be  
 3 remedied by the parties agreeing to a Bellwether Group 1 limited to five cases. Bard has  
 4 ordered *King* last for the reasons stated in Section V.  
 5

6 Bard respectfully shows the Court that its proposed Order of Trials will allow trial  
 7 of the most common filter types, and all of the common complications types represented  
 8 in the MDL pool as a whole.  
 9

#### 10 **IV. Bard's Opposition to Plaintiffs Case Selections**

11 With the exception of *Mulkey*, Plaintiffs' selections – *Booker*, *Dewitt*, *Mixson*,  
 12 *Peterson* and *Tinlin* -- are disproportionately weighted toward the most serious types of  
 13 injuries, including open surgeries, fractures of a strut to the heart, and fractures in general.  
 14 The selections also include plaintiffs who have personal histories, unrelated to the IVC  
 15 filter, making them uniquely sympathetic to a jury. Further, one case, *Tinlin*, involves the  
 16 Recovery filter, which is at issue in only 10% of the MDL cases. These cases, if accepted,  
 17 will result in Bellwether Group 1 failing to serve as a group of cases capable of informing  
 18 the parties' respective assessments of cases strengths and weaknesses which may apply to  
 19 large groups of other cases pending in the MDL.

#### 20 **Sherr Una Booker (G2)**

21 Ms. Booker had a G2 filter implanted 6/21/2007, prior to surgery for a cervical mass, due  
 22 to a history of DVT and PE. In 2013, a fractured strut was seen on imaging. Ms. Booker  
 23 alleges she was not informed of that finding. In 2016, three fractured struts were identified  
 24 (one in the heart). Her filter and two of the struts were percutaneously retrieved. During  
 25 efforts to retrieve the strut in her heart, her tricuspid valve was damaged and her doctors  
 26 opted to perform open heart surgery to repair that valve and to retrieve the strut in the  
 27 heart. While Bard cannot confirm if there are any other cases in the MDL pool involving  
 28 percutaneous retrieval attempts leading to damage requiring open heart surgical repair, if  
 such a case exists it is certainly a small subset of the open heart surgery cases in the MDL  
 pool, which comprise only 2% of the total pool. Therefore selecting *Booker* into  
 Bellwether Group 1, even without including any of the other open surgery cases selected  
 by Plaintiffs, would place a highly non representative case in the group. The MDL pool



1 data shows that open surgeries of any kind make up only 6% of the pool. Including  
2 *Booker* with the *Dewitt*, *Peterson* and *Tinlin* cases selected by Plaintiffs brings to 75% the  
3 percentage of open surgery cases Plaintiffs seek to include in Bellwether Group 1, and  
4 brings to 33% (*Booker/Tinlin*) the percentage of cases involving open chest surgery when  
5 those types of surgery make up but 2% of the MDL pool, making the group Plaintiffs have  
6 selected highly non representative as a whole. The transferor court was the USDC  
7 Georgia, Northern District.

### 6 **Brent Dewitt (G2)**

7 Plaintiff had a G2 implanted on 9/5/2009, following a vehicular accident in which he  
8 suffered multiple long bone and other fractures. At some point in time, his filter was  
9 observed to have tilted, perforated and fractured. Mr. Dewitt's case should not be  
10 included in Bellwether Group 1 because, according to his Second Amended Plaintiff Fact  
11 Sheet "he is currently coordinating removal of the filter through an open procedure, which  
12 will require a prolonged recovery time . . ." See Exhibit A, pp. 12-13. His intent to consult  
13 with a surgeon for open filter removal surgery was confirmed in Mr. Dewitt's deposition.  
14 See Exhibit B, Dewitt Deposition, pages 212:18 – 213:4. Given Mr. Dewitt's expected  
15 surgery, presumably an open abdominal surgery, Bard is currently unable to assess his  
16 case fully. It is unknown what the timing of his open procedure will be or what period of  
17 time will be necessary for his recovery from that surgery. Accordingly, the selection of  
18 *Dewitt* in the initial bellwether pool is premature. Additionally, *Dewitt* should not be  
19 selected because his alleged injuries are not representative of the majority of plaintiffs in  
20 the case pool, given that he experienced multiple fractures, with one strut to the heart.  
21 Including *Dewitt* in Bellwether Group 1, even without including any other open surgery  
22 case selected by Plaintiffs, would place a highly non representative case in the group. The  
23 MDL pool data shows that open surgeries of any kind make up only 6% of the pool.  
24 Including *Dewitt*, along with the *Booker*, *Tinlin*, and *Peterson* cases selected by Plaintiffs,  
25 brings to 75% the percentage of open surgery cases Plaintiffs seek to include in  
26 Bellwether Group 1, making the entire group highly non representative. The transferor  
27 court was the USDC New York, Southern District.

### 21 **Joseph Mixson (G2)**

22 Mr. Mixson is an Iraq War hero who received a Bard filter when, at age 21 and while on  
23 active duty, his military vehicle was struck with an "IED" (improvised explosive device).  
24 The door adjacent to Mr. Mixson was blown off, and he was thrown out. He suffered  
25 multiple injuries including open head wounds, fractures to limbs and substantial injuries  
26 to his legs. He was also wounded by small arms fire. He was airlifted to a base near  
27 Baghdad, and received emergency care before being flown to Germany. Both of his legs  
28 had to be amputated. Mr. Mixson was then flown to Brooke Army Medical Center in  
Texas where he received a Bard filter after having flat-lined multiple times and  
experienced bilateral pulmonary embolism. Mr. Mixson's service to this country has left  
him wheelchair bound and a double, above-the-knee amputee. Mr. Mixson's presentation,



1 treatment with a filter, and his subsequent medical course are inextricably bound to, and  
 2 intertwined with, his war veteran status. These facts inject significant sympathy for the  
 3 plaintiff into the case, unrelated to any filter issue, which may prejudice Bard and impact  
 4 the outcome of the case. Given those circumstances, any verdict for the plaintiffs would  
 5 not be predictive of other plaintiffs' cases. Mr. Mixson's case is not representative of the  
 cases in the MDL and therefore is not a suitable bellwether case. The transferor court was  
 the USDC Florida, Northern District.

### 6 **Debra Mulkey (Eclipse)**

7 Ms. Mulkey is addressed in **Section II** above. Bard agrees her case is representative.  
 8

### 9 **Justin Peterson (Eclipse)**

10 Mr. Peterson's filter was implanted with an Eclipse filter on 6/26/2010 following a leg  
 11 fracture, and due to his history of bilateral PE and right leg DVT one year beforehand. He  
 12 had a history of May-Thurner syndrome (compression of the iliac vein) and polycythemia  
 13 (increased viscosity of the blood), both of which increase the risk for developing DVT. He  
 14 experienced perforations leading to open abdominal surgery. In addition, while the parties  
 15 disagree as to whether the post surgery events relate to the IVC filter, Mr. Peterson  
 16 experienced unusual medical complications following his surgery, including a hematoma  
 17 and hernia, making his case non-representative on that basis as well. This case is not  
 18 representative of the overall MDL pool in that only 6% of cases involve open surgery.  
 19 Including *Peterson* in Bellwether Group 1, even without including any other open surgery  
 20 case, would place a highly non-representative case in the group. Including *Peterson* with  
 21 Plaintiffs' selections of *Booker*, *Dewitt* and *Tinlin* brings to 75% the percentage of cases  
 22 Plaintiffs seeks to include in Bellwether Group 1 that include open surgeries, making the  
 23 entire group highly non representative. The transferor court was the USDC Oregon.

### 24 **Debra Tinlin (Recovery)**

25 Ms. Tinlin had a Recovery filter implanted on 5/07/2005 which fractured, with struts  
 26 migrating to the heart, resulting in a pericardial effusion, cardiac tamponade, and open-  
 27 heart surgery. Ms. Tinlin's medical history includes Multiple Sclerosis, Graves disease,  
 28 Type I diabetes, prothrombin genetic mutation with related deep vein thrombosis and  
 pulmonary embolism, osteoarthritis, short-term memory loss, and other conditions. Ms.  
 Tinlin testified in her February 2017 deposition that she was diagnosed with MS in 2005,  
 at which time she became permanently disabled and wheelchair bound. During her  
 deposition, Ms. Tinlin both appeared to be, and testified that she was, uncomfortable and  
 in pain while sitting for the deposition. Exhibit C, Tinlin deposition at 144:6 – 145:3. Mr.  
 Tinlin's deposition, which took place immediately after Ms. Tinlin's, could not be  
 completed, as Ms. Tinlin was in significant discomfort and needed to be taken home. Ms.  
 Tinlin, who lives in Wisconsin, testified that her physicians recommend she not fly on an  
 airplane, or travel by car for any long distance.

1 Ms. Tinlin's case is not representative, as the filter type, a Recovery filter, makes up only  
2 10% of the MDL pool of cases. Second, her complications of fractures with struts to the  
3 heart and open heart surgery, are very rare complications within the MDL pool (2% of  
4 cases involve an open chest surgery), making her case an outlier with respect to the  
5 complications involved as well. Including *Tinlin* in Bellwether Group 1, even without  
6 including any other open surgery case in that group, would over represent the cases in the  
7 MDL pool with these complications. The MDL pool data shows that open surgeries of  
8 any kind make up only 6% of the pool. Including *Tinlin* with the *Booker*, *Dewitt*, and  
9 *Peterson* cases selected by Plaintiffs brings to 75% the percentage of open surgery cases  
10 Plaintiffs seek to include in Bellwether Group 1, and brings to 33% (*Booker/Tinlin*) the  
11 percentage of cases involving open chest surgery, making the group Plaintiffs have  
12 selected highly non representative as a whole. Third, Ms. Tinlin is likely to have some  
13 limitations in her ability to participate at trial of the case. Finally, Ms. Tinlin's many  
14 medical ailments, which predate the placement of her filter, inject significant sympathy  
15 for the plaintiff into the case, unrelated to any filter issue, which may prejudice Bard and  
16 impact the outcome of the case, thereby not meeting the goals of bellwether cases. The  
17 transferor court was the USDC Wisconsin, Eastern District.

#### 12 V. The Michael King Case Presents a Unique Issue

13 Complicating matters in this selection process is the inclusion in Discovery Group  
14 1 of the *King* case. Bard originally selected the *King* case for Discovery Group 1.  
15 Plaintiffs previously argued against the designation of *King* because its addition "over  
16 represented non retrieval cases," and Plaintiffs have indicated they will object to his  
17 inclusion in Bellwether Group 1 as well. However, the real reason that King may lack  
18 representativeness is the curious manipulation by plaintiffs' counsel of a "treating doctor"  
19 in this case. What became apparent to Defendants during the Discovery Group 1  
20 discovery phase – but was known to Plaintiffs counsel in that case before *King* was ever  
21 selected into Discovery Group 1 – is that Plaintiffs' counsel provided King with a "no  
22 interest" loan to travel far from his home and his initial filter treater, Dr. Andrew Chiou,  
23 to visit a testifying medical expert who had been retained by the plaintiff's attorney.  
24 After that retention, the expert attempted, but was unsuccessful in, retrieval of the filter in  
25 Mr. King. That retrieval attempt occurred on February 15, 2016. Strangely, the imaging  
26 and full procedure report from the attempted retrieval performed by Plaintiffs' counsel's  
27 retained expert has disappeared.  
28

1           Bard previously demonstrated that *King* was representative of the pool in filter  
2 type and the complications experienced and the case was included in Discovery Group 1  
3 for those reasons. Admittedly, the fact that there may have been odd involvement by an  
4 expert witness in *King* now makes the case non-representative in that regard (at least  
5 Bard is unaware at this time of other cases in the pool involving a similar situation).  
6 However, any "lack of representativeness" in this case is a self-inflicted wound by  
7 Plaintiffs. The issue in the case was known to them before the case was ever placed into  
8 Discovery Group 1. The elimination of *King* from Discovery Group 1 due to this issue  
9 would give Plaintiffs an unfair advantage in the group that remains from which  
10 Bellwether Group 1 can be selected. If the Court is inclined to eliminate *King* because of  
11 the unusual circumstances, Bard respectfully requests that the Court strike one case (other  
12 than the parties' agreed upon case of *Mulkey*) from Plaintiffs other five selected cases, to  
13 even the playing field. In that scenario, the Bellwether Group I should be reduced to five  
14 cases.

## 15           **VI. Conclusion**

16           Plaintiffs' selections are not representative, and are clearly aimed toward choosing  
17 the most sympathetic cases and cases more likely to produce larger verdicts. However,  
18 that is not the purpose of the bellwether process. Other MDL courts have emphatically  
19 rejected that strategy.

20           The judge handling the General Motors Ignition Switch litigation perhaps put it  
21 best. In that case, certain plaintiffs' counsel sought to replace the existing leadership after  
22 the first bellwether trial went badly. They complained that "it is axiomatic that plaintiffs'  
23 counsel always want to try their best case first in an MDL litigation." *See* Plaintiffs'  
24 Motion to Remove the Co-Leads and Reconsider the Bellwether Trial Schedule at 1, 10;  
25 *In re General Motors LLC Ignition Switch Litig.*, No. 14-MC-2543 (S.D.N.Y. Feb 1,  
26 2016) (Dkt. No. 2179). The MDL court, however, rejected that argument:  
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[I]f by "best," the Cooper Plaintiffs mean "most likely to result in a large plaintiff's verdict," that proposition is by no means "axiomatic." After all, because the primary purpose of bellwether trials is to provide data points for settlement discussions with respect to the universe of cases, **the goal is to select the "best" representatives of the universe of cases, not outliers likely to result in victory for one side or the other.** To that end, the Order setting up the bellwether selection process dictated that the bellwether selections be "representative" claims.

*In re: General Motors LLC Ignition Switch Litig.*, No. 14-MC-2543 (JMF), 2016 WL 1441804, at \*9 (S.D.N.Y. Apr. 12, 2016).

Here, the plaintiffs' selections are "outliers" clearly chosen to generate disproportionately high verdicts. Three of their six cases have had open surgery (with a fourth presently scheduling an open procedure), when only 6% of the entire MDL inventory involves plaintiffs who have endured invasive surgery. Three of their six cases involve a filter strut in the heart. One of their selections is an Iraq war veteran who lost his legs in combat, and another selection suffers from extremely debilitating MS, both guaranteed to present unique sympathy factors.

The trial of those cases will not be enlightening. They will not be representative. The results will not "provide data points for settlement discussions with respect to the universe of cases." To make this process meaningful, the defendants therefore respectfully ask that the Court accept their recommendations for Bellwether Group I, and reject the "outliers" proposed by the plaintiffs.

Nelson Mullins Riley & Scarborough

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DATED this 24th day of April, 2017.

By: s/Matthew B. Lerner  
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Attorneys for C. R. Bard, Inc. and Bard  
Peripheral Vascular, Inc.

# **EXHIBIT A**



**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF ARIZONA**

*MDL No. 2641*

*In Re Bard IVC Filter Products Liability Litigation*

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**SECOND AMENDED PLAINTIFF FACT SHEET**

Each plaintiff who allegedly suffered injury as a result of a Bard Inferior Vena Cava Filter must complete the following Plaintiff Fact Sheet (“Plaintiff Fact Sheet”). In completing this Fact Sheet, you are **under oath and must answer every question**. You must provide information that is true and correct to the best of your knowledge. If you cannot recall all of the details as requested, please provide as much information as you can and then state that your answer is incomplete and explain why, as appropriate. If you select an “I Don’t Know” answer, please state all that you do know about that subject. If any information you need to complete any part of the Fact Sheet is in the possession of your attorney, please consult with your attorney so that you can fully and accurately respond to the questions set out below. If you are completing the Fact Sheet for someone who cannot complete the Fact Sheet for himself/herself, please answer as completely as you can.

The Fact Sheet shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order. A completed Fact Sheet shall be considered interrogatory answers pursuant to Fed. R. Civ. P. 33 and responses to requests for production pursuant to Fed. R. Civ. P. 34 and will be governed by the standards applicable to written discovery under Fed. R. Civ. P. 26 through 37. Therefore, you must supplement your responses if you learn that they are incomplete or incorrect in any material respect. The questions and requests for production of documents contained in this Fact Sheet are non-objectionable and shall be answered without objection. This Fact Sheet shall not preclude Bard Defendants from seeking additional documents and information on a reasonable, case-by-case basis, pursuant to the Federal Rules of Civil Procedure and as permitted by the applicable Case Management Order.

In filling out this form, “healthcare provider” shall mean any medical provider, doctor, physician, surgeon, pharmacist, hospital, clinic, medical center, physician's office, infirmary, medical/diagnostic laboratory, or any other facility that provides medical care or advice, along with any pharmacy, x-ray department, radiology department, laboratory, physical therapist/physical therapy department, rehabilitation specialist, chiropractor, or other persons or entities involved in your diagnosis, care and/or treatment.

In filling out this form, the terms “You” or “Your” refer to the person who received a Bard Inferior Vena Cava Filter manufactured and/or distributed by C. R. Bard, Inc. or Bard Peripheral Vascular, Inc. (“Bard Defendants”) and who is identified in Question 1(a) below.

To the extent that the form does not provide enough space to complete your responses or answers, please attach additional sheets as necessary. Information provided by Plaintiff will only

be used for the purposes related to this litigation and may be disclosed only as permitted under the protective order in this litigation.

**I. BACKGROUND INFORMATION**

1. Please state:
  - (a) Full name of the person who received the Bard inferior vena cava filter, including maiden name: Brent Dewitt
  - (b) List all names by which you have ever been known, if different from that listed in 1(a): N/A
  - (c) Full name of the person completing this form, if different from the person listed in 1(a) above, and the relationship of the person completing this form to the person listed in 1(a) above: N/A
  - (d) The name and address of your primary attorney:
 

Lopez McHugh LLP  
100 Bayview Circle, Suite 5600  
Newport Beach, CA 92660
  - (e) When did you first retain an attorney to represent you in your lawsuit against Bard? In or around December 2010

2. Your Social Security Number: 077-60-9197

3. Your Date of Birth: October 5, 1971

4. Your current residential address: 617 Lybolt Road, Bullville, NY 10915

5. If you have lived at this address for less than 10 years, provide each of your prior residential addresses from 2000 to the present:

| Prior Residential Address           | Dates You Lived At This Address        |
|-------------------------------------|----------------------------------------|
| 89 M&M Road<br>Middletown, NY 10940 | In or around October 1995 to July 2008 |

6. Have you ever been married? Yes  X  No

If yes, provide the names and addresses of each spouse and the inclusive dates of your marriage to each person:

Providencia Dewitt, 617 Lybolt Road, Bullville, NY 10915, April 2016 to present; and  
Leigh Dewitt, New York, June 1995 to August 2008.

7. Do you have children? Yes \_\_\_\_\_ No  X

If Yes, please provide the following information with respect to each child:

| Full Name of Child | Date of Birth | Home Address | Whether Biological/Adopted |
|--------------------|---------------|--------------|----------------------------|
| N/A                | N/A           | N/A          | N/A                        |

8. Identify the name and age of any person who currently resides with you and their relationship to you:

Providencia Dewitt, 46, wife

9. Identify the name and age of any person who has resided with you at any point over the past ten (10) years:

Providencia Dewitt, 46

10. Identify all secondary and post-secondary schools you attended, starting with high school, and please provide the following information with respect to each:

| Name of School                    | Address                                           | Dates of Attendance          | Degree Awarded         | Major or Primary Field of Study |
|-----------------------------------|---------------------------------------------------|------------------------------|------------------------|---------------------------------|
| Middletown High School            | 24 Gardner Ext Ave.<br>Middletown, NY<br>10940    | In or around<br>1985 to 1989 | High School<br>Diploma | N/A                             |
| The Art Institute of Philadelphia | 1622 Chestnut Street<br>Philadelphia, PA<br>19103 | In or around<br>1989 to 1991 | N/A                    | Visual<br>Communications        |

11. Please provide the following information for your employment history over the past 10 years up until the present:

| Employer Name        | Address                              | Job Title/Description of Duties | Dates of Employment             | Salary/Rate of Pay   |
|----------------------|--------------------------------------|---------------------------------|---------------------------------|----------------------|
| Blue Dog Contracting | PO Box 457<br>Bullville, NY<br>10915 | Owner                           | In or around<br>2005 to present | \$24,000 per<br>year |

12. Have you ever served in any branch of the military? Yes \_\_\_\_\_ No  X

If Yes, please provide the following information:

(a) Branch and dates of service, rank upon discharge, and type of discharge received:

\_\_\_\_\_

(b) Were you discharged from the military at any time for any reason relating to your medical, physical, or psychiatric condition? Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes, state what that condition was: \_\_\_\_\_

- 13. Within the last ten years, have you been convicted of, or plead guilty to, a felony and/or crime of fraud or dishonesty? Yes \_\_\_\_\_ No  X

If Yes, please set forth where and when and identify the felony and/or crime:

\_\_\_\_\_

- 14. Before contacting any attorney regarding this lawsuit or claim, had you ever seen any television or print advertisements regarding possible claims against inferior Vena Cava Filter manufacturers? Yes \_\_\_\_\_ No  X

If Yes, set forth the approximate date and nature of any such advertisement, whether the advertisement included the name of a law firm, whether the advertisement specifically mentioned C. R. Bard, Inc., Bard Peripheral Vascular, Inc., or "Bard", and other details that you recall. \_\_\_\_\_

**II. CLAIM INFORMATION**

- 1. Have you ever received a Bard Inferior Vena Cava Filter? Yes  X  No \_\_\_\_\_

If Yes, please check the box(es) for each type of Bard Inferior Vena Cava Filter you have received:

- Recovery®
- G2®
- G2®X
- G2®Express
- Eclipse®
- Meridian®
- Denali®
- Simon Nitinol
- Other (please identify): \_\_\_\_\_

- 2. For each Bard Inferior Vena Cava Filter identified above, please provide the following information:

(a) The date each Bard Inferior Vena Cava Filter was implanted in you:

On or about September 5, 2009

- (b) The product code and lot number of each Bard Inferior Vena Cava Filter implanted in you:

RF-310F, Lot No. GFTD2015

- (c) Current location of the Bard Inferior Vena Cava Filter, including any portion thereof, if known:

The filter body remains implanted, last seen in the inferior vena cava. The two fractured struts that have been removed both reside at Steelgate Inc., 2307 58<sup>th</sup> Avenue East, Bradenton, FL 34203.

- 3. Describe your understanding of the medical condition for which you received the Bard Inferior Vena Cava Filter(s):

Plaintiff's car was hit by a drunk driver and he suffered open left femur and right tibia/fibular fractures, with hip dislocation, and splenic laceration. He would be at increased DVT risk while bedridden.

- 4. Give the name and address of the doctor who implanted the Bard Inferior Vena Cava Filter(s): Romeo Mateo, M.D., 19 Bradhurst Avenue Suite 700, Hawthorne, NY 10532

- 5. Give the name and address of the hospital or other healthcare facility where the Bard Inferior Vena Cava Filter was implanted: Westchester Medical Center, 100 Woods Road, Valhalla, NY 10595

- 6. Have you ever been implanted with any other vena cava filters or related product(s) besides the Bard Inferior Vena Cava Filter(s) for the treatment of the same or similar condition(s) identified in your response to question 3 above? Yes  No

If Yes:

- (a) Please identify any such device(s) or product(s). \_\_\_\_\_

- (b) When was this device or product implanted in you? \_\_\_\_\_

- (c) Did the implantation take place before, at the same time, or after the procedure during which you were implanted with a Bard Inferior Vena Cava Filter?

- (d) Who was the physician who implanted this other device or product?

- (e) At what hospital or facility was this other device or product implanted in you?

\_\_\_\_\_  
(f) Why was this other device or product implanted in you?  
\_\_\_\_\_

7. Other than the Bard Inferior Vena Cava Filter device that is the subject of your lawsuit or identified in response to question 6 above, are you aware of any other Vena Cava Filter(s) implanted inside your body at any time? Yes \_\_\_\_\_ No X

If yes, please provide the following information:

(a) Product name: \_\_\_\_\_

(b) Date of procedure placing it and name and address of doctor who placed it:  
\_\_\_\_\_

(c) Condition sought to be treated through placement of the device:  
\_\_\_\_\_

(d) Any complications you encountered with the medical product or procedure:  
\_\_\_\_\_

(e) Does that product remain implanted inside of you today? Yes \_\_\_\_\_ No \_\_\_\_\_

8. Prior to implantation with a Bard Inferior Vena Cava Filter, did you receive any written and/or verbal information or instructions regarding the Bard Inferior Vena Cava Filter, including any risks or complications that might be associated with the use of the same?

Yes \_\_\_\_\_ No X Don't Know \_\_\_\_\_

If Yes:

(a) Provide the date you received the written and/or verbal information or instructions:  
\_\_\_\_\_

(b) Identify by name and address the person(s) who provided the information and instructions:  
\_\_\_\_\_

(c) What information or instructions did you receive?  
\_\_\_\_\_

(d) If you have copies of the written information or instructions you received, please attach copies to your response.  
\_\_\_\_\_



(e) Were you told of any potential complications from the implantation of the Bard Inferior Vena Cava Filter(s)? Yes \_\_\_\_\_ No \_\_\_\_\_ Don't Know \_\_\_\_\_

(f) If yes to (e), by whom?

\_\_\_\_\_  
(g) If yes to (e), what potential complications were described to you?

9. Do you believe that the Bard Inferior Vena Cava Filter(s) remains implanted in you?

Yes  No \_\_\_\_\_ Don't Know \_\_\_\_\_

If Yes:

(a) Has any doctor recommended removal of the Bard Inferior Vena Cava Filter(s)?

Yes  No \_\_\_\_\_

If Yes:

(i) Identify by name and address every doctor who recommended removal of the Bard Inferior Vena Cava Filter(s): Romeo Mateo, M.D., 19 Bradhurst Avenue Suite 700, Hawthorne, NY 10532; Frank Lynch, M.D., 500 University Drive, Hershey, PA 17033; and David Han, M.D., 500 University Drive, Hershey, PA 17033

(ii) For each doctor identified in response to question 8(a)(i) above, state your understanding of why the doctor recommended removal. When retrieval was first attempted, the filter was only intended as a temporary device and was no longer needed. When it was discovered that the retained filter had fractured and one of the struts had migrated to his heart, it was recommended that he undergo a second procedure in an attempt to retrieve the fractured filter and strut from the heart. When it was discovered that the retained strut had moved from the heart to the lung, it was recommended that he undergo a third procedure to retrieve the fractured strut from the lung. Plaintiff's physicians have now recommended that he undergo an open abdominal procedure to remove the severely tilted, perforating filter.

(iii) For each doctor identified in response to question 8(a)(i) above, state when the doctor recommended removal. In or around December 2009,  
February 2016, January 2017

10. Has the Bard Inferior Vena Cava Filter(s) implanted in you been removed, in whole or in part?

Yes X No \_\_\_\_\_ Don't Know \_\_\_\_\_

If Yes:

(a) Where, when, and by whom was the Bard Inferior Vena Cava Filter(s), or any portion of it, removed? Penn State Milton S. Hershey Medical Center, Frank Lynch, M.D., on or about June 17, 2016; and Penn State Milton S. Hershey Medical Center, Frank Lynch, M.D., on or about February 21, 2017

(b) What portion of the Bard Inferior Vena Cava Filter(s) was removed on the date indicated in response to question 9(a) above? Two fragments of the filter were removed.

© Please check all that apply regarding the removal procedure(s):

- Removed percutaneously
- Removed via an open abdominal procedure
- Removed via an open chest procedure
- Other, Describe: \_\_\_\_\_
- Unknown

(d) Does any portion of the Bard Inferior Vena Cava Filter(s) remain implanted in you? Yes X No \_\_\_\_\_ Don't Know \_\_\_\_\_  
If Yes, explain what portion of the Bard Inferior Vena Cava Filter(s) you believe is still implanted in you: The filter body remains implanted, last seen in the inferior vena cava.

© Explain why you consented to have the Bard Inferior Vena Cava Filter(s), or any portion thereof, removed?  
The filter was only intended as a temporary device and was no longer needed, so retrieval was attempted as planned, at which time it was discovered that the filter had tilted and at least three legs were perforating outside the vena cava. When it

was discovered that the device had fractured and a piece had migrated to the right ventricle of his heart, Plaintiff consented to a second procedure, in an attempt to retrieve the embedded filter and the intracardiac strut. When it was discovered that the retained strut migrated from his heart to the lung, Plaintiff consented to a third procedure to retrieve the strut. Plaintiff's physicians have now recommended open abdominal surgery to retrieve the severely tilted, perforating filter.

- (f) Does any medical provider, physician, entity, or anyone else acting on your behalf have possession of any portion of the Bard Inferior Vena Cava Filter that was previously implanted in you and subsequently removed?

Yes  X  No \_\_\_\_\_ Don't Know \_\_\_\_\_

If Yes, please state the name and address of the person or entity having possession of same. Steelgate Inc., 2307 58<sup>th</sup> Avenue East, Bradenton, FL 34203.

- 11. Has any doctor or healthcare provider unsuccessfully attempted to remove the Bard Inferior Vena Cava Filter(s) implanted in you?

Yes  X  No \_\_\_\_\_ Don't Know \_\_\_\_\_

If Yes:

- (a) How many attempts have been made to remove the Bard Inferior Vena Cava Filter(s) implanted in you? Two attempts, both of which were unsuccessful
- (b) Provide the name and address of the doctor who removed (or attempted to remove) the filter strut(s) and the hospital or medical facility at which it was removed (or attempted to be removed).

Filter Attempted Removal #1

Doctor: Romeo Mateo, M.D.

Hospital/Medical Facility: Westchester Medical Center

Date: On or about December 15, 2009

Filter Attempted Removal #2

Doctor: Frank Lynch, M.D.

Hospital/Medical Facility: Penn State Milton S. Hershey Medical Center

Date: On or about June 17, 2016

- © Please check all that apply regarding attempted removal procedure #1:

Attempted but unsuccessful percutaneous removal procedure

- Attempted but unsuccessful open abdominal procedure
- Attempted but unsuccessful open chest procedure
- Other, Describe: \_\_\_\_\_
- Unknown

(d) Please check all that apply regarding attempted removal procedure #2:

- Attempted but unsuccessful percutaneous removal procedure
- Attempted but unsuccessful open abdominal procedure
- Attempted but unsuccessful open chest procedure
- Other, Describe: \_\_\_\_\_
- Unknown

12. Do you claim that your Bard Inferior Vena Cava Filter(s) fractured?

Yes X No \_\_\_\_\_

If Yes:

- (i) Please state the number of fractured struts retained in your body?  
None.
- (ii) Please identify the location(s) within your body of each retained filter strut.  
N/A
- (iii) Please provide the date or approximate date when you were first informed of each fractured strut.  
On or about March 9, 2016
- (iv) Has any health care provider recommended to you that a retained filter strut(s) should be removed?  
Yes X No \_\_\_\_\_

If Yes, provide the name and address of any such healthcare provider, as well as the approximate date on which the communication occurred.

Romeo Mateo, M.D., 19 Bradhurst Avenue Suite 700, Hawthorne, NY 10532, in or around March 2016; and Frank Lynch, M.D., 500 University Drive, Hershey, PA 17033, in or around January 2017

- (v) Has any health care provider recommended to you that a retained filter strut should not be removed?

Yes \_\_\_\_\_ No X

If Yes, provide the name and address of any such healthcare provider, as well as the approximate date on which the communication occurred.

- (vi) Have any fractured struts been removed, or attempted to have been removed, from your body?

Yes X No \_\_\_\_\_

If Yes:

- (1) If any fractured filter strut has been removed (or a doctor has attempted to remove any strut), please check all that apply regarding the removal/attempted removal procedure(s):

- Removed percutaneously
- Removed via an open abdominal procedure
- Removed via an open chest procedure
- Attempted but unsuccessful percutaneous removal procedure
- Attempted but unsuccessful open abdominal procedure
- Attempted but unsuccessful open chest procedure
- Other, Describe: \_\_\_\_\_
- Unknown

- (2) Provide the name and address of the doctor who removed (or attempted to remove) the filter strut(s) and the hospital or medical facility at which it was removed (or attempted to be removed).

Filter Strut Removal/Attempted Removal #1

Doctor: Frank Lynch, M.D.

Hospital/Medical Facility: Penn State Milton S. Hershey Medical Center

Date: On or about June 17, 2016

Filter Strut Removal/Attempted Removal #2

Doctor: Frank Lynch, M.D.

Hospital/Medical Facility: Penn State Milton S. Hershey Medical Center

Date: On or about February 21, 2017

- 13. Do you claim that you suffered bodily injuries as a result of the implantation of the Bard Inferior Vena Cava Filter(s)? Yes  No

If Yes:

- (a) Describe the bodily injuries, including any emotional or psychological injuries that you claim resulted from the implantation, attempted removal and/or removal of the Bard Inferior Vena Cava Filter(s)?

Plaintiff refers Defendants to his medical records for complete details of the injuries he has suffered stemming from Defendants' IVC filter. Plaintiff's symptoms and injuries include, but are not limited to, emotional and physical pain and suffering. Specifically, Plaintiff returned for planned removal of the filter on December 15, 2009, at which time a venogram demonstrated the filter to have tilted, with three of the filter legs perforating outside the vena cava. The filter could not be removed and the procedure was aborted. In March 2016, Plaintiff developed an increase in blood pressure and it was discovered on March 9, 2016 that the device had fractured and one strut had migrated to his right ventricle, while another strut still resided in the IVC but had incorporated into the IVC wall. Retrieval of the filter and strut was attempted again on June 17, 2016, but detailed angiography of the filter apex showed significant perforation of the filter cap, arms, and legs; the surgeon felt that retrieval carried a high risk of caval injury and elected not to proceed. He did attempt to remove the strut in the right ventricle, but it was fully embedded and could not be captured. The fractured strut retained in the IVC was removed at this time. On December 27, 2016, the fractured strut could not be located in the right ventricle on an imaging scan. An x-ray on December 28, 2016 discovered that it had migrated to the right upper lobe of the lung. The fractured strut was successfully removed from his lung on February 21, 2017. Plaintiff continues to have severe anxiety and insomnia while the filter remains implanted and is currently coordinating removal of the filter



through an open abdominal procedure, which will require a prolonged recovery time and cause disfigurement in the form of an extensive abdominal scar. He must also continue to take blood pressure medication, having been diagnosed with hypertension at the time the filter strut was discovered in the heart.

- (b) When was the first time you experienced symptoms of any of the bodily injuries you claim in your lawsuit to have resulted from the Bard Inferior Vena Cava Filter(s)?

In or around December 2009

- © When did you first attribute these bodily injuries to the Bard Inferior Vena Cava Filter(s)? On or about December 15, 2009

- (d) To the best of your knowledge and recollection, please state the approximate date when you first saw a health care provider for any of the bodily injuries, or symptoms related thereto, you claim to have experienced related to the Bard Inferior Vena Cava Filter(s)?

On or about December 15, 2009

- © To the best of your knowledge and recollection, has any health care provider ever told you orally or in writing that any symptoms related to bodily injury are related to the Bard Inferior Vena Cava Filter(s)?

Yes  No

If Yes, please state the name and address of any such health care provider, as well as providing the approximate date the statement was made, and provide the details of the communication: \_\_\_\_\_

- (f) Are you currently experiencing symptoms related to your claimed bodily injuries?

Yes  No

If Yes, please describe your symptoms in detail:

Plaintiff's blood pressure has increased since the fractured strut moved into his right ventricle and he must now take blood pressure medication for the rest of his life. He also has severe anxiety since learning that the device has fractured and the fractured filter and strut could not be retrieved as planned. His anxiety only worsened upon learning that the fractured strut had migrated from his heart to his lung and would require additional intervention. Plaintiff continues to suffer from severe anxiety in anticipation of the open abdominal surgery to remove the filter.

(g) Are you currently seeing, or have you ever seen, a doctor or healthcare provider for any of the bodily injuries or symptoms listed above?

Yes  No

If Yes, please list all doctors you have seen for treatment of any of the bodily injuries you have listed above.

| Provider Name and Address                                                                    | Condition Treated                                                                                     | Approximate Dates of Treatment                      |
|----------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| Romeo Mateo, M.D.<br>19 Bradhurst Avenue, Suite 700<br>Hawthorne, NY 10532                   | Attempted retrieval of filter, with discovery of tilt and perforation                                 | In or around December 2009 to present               |
| David Spielvogel, M.D.<br>Westchester Medical Center<br>100 Woods Road<br>Valhalla, NY 10595 | Evaluation of the fractured strut in the right ventricle                                              | In or around March 2016                             |
| Frank Lynch M.D.<br>500 University Drive<br>Hershey, PA 17033                                | Attempted retrieval of filter and intracardiac strut, with retrieval of floating fragment             | In or around June 2016 and December 2016 to present |
| David Han, M.D.<br>500 University Drive<br>Hershey, PA 17033                                 | Evaluation of filter, with plans to attempt removal of the filter through an open abdominal procedure | In or around February 2017 to present               |

h) Were you hospitalized at any time for the bodily injuries you listed above?

Yes  No

If Yes, please provide the following:

| Provider Name and Address                                                                   | Condition Treated                                                                      | Approximate Dates of Treatment |
|---------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|--------------------------------|
| Westchester Medical Center<br>100 Woods Road<br>Valhalla, NY 10595                          | Failed retrieval of filter, with discovery of tilt and perforation                     | On or about December 15, 2009  |
| Penn State Milton S.<br>Hershey Medical Center<br>500 University Drive<br>Hershey, PA 17033 | Failed retrieval of filter and intracardiac strut, with retrieval of floating fragment | On or about June 17, 2016      |
| Penn State Milton S.<br>Hershey Medical Center<br>500 University Drive<br>Hershey, PA 17033 | Retrieval of fractured strut from lung                                                 | On or about February 21, 2017  |

14. Are you making a claim for lost wages or lost earning capacity?

Yes  No

(a) If yes, state the annual gross income derived from your employment for each year, beginning five (5) years prior to the implantation of the Bard Inferior Vena Cava Filter(s) until the present: \_\_\_\_\_

(b) If yes, for what period of time are you claiming lost wages? \_\_\_\_\_

© If you are claiming lost earning capacity, do you claim that you have a claim for future lost wages?

Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, for what period of time do you claim you have lost future wages?

15. Are you making a claim for lost out-of-pocket expenses? Yes \_\_\_\_\_ No X \_\_\_\_\_

If yes, please identify and itemize all out-of-pocket expenses you have incurred.

16. Has anyone filed a loss of consortium claim in connection with your lawsuit regarding the Bard Inferior Vena Cava Filter(s)?

Yes \_\_\_\_\_ No X \_\_\_\_\_

If yes, identify by name and address the person who filed the loss of consortium claim (“Consortium Plaintiff”) and state the relationship of that person to you and state the specific nature of the Consortium Plaintiff’s claim. N/A

17. Please indicate whether the Consortium Plaintiff alleges any of the damages set forth below:

| Claims                                    | Yes/No |
|-------------------------------------------|--------|
| Loss of services of spouse                | N/A    |
| Impaired sexual relations                 | N/A    |
| Lost wages/lost earning capacity          | N/A    |
| Lost out-of-pocket expenses               | N/A    |
| Physical injuries                         | N/A    |
| Psychological injuries/emotional injuries | N/A    |
| Other                                     |        |

18. Please list the name and address of any healthcare providers the Consortium Plaintiff has sought treatment for any physical, emotional, or psychological injuries or symptoms alleged to be related to his/her claim. N/A

19. Have you or anyone acting on your behalf had any communication, oral or written, with any of the Bard Defendants and/or their representatives?

Yes \_\_\_\_\_ No X Don't Know \_\_\_\_\_

If yes, set forth: (a) the date of any communication, (b) the method of communication, (c) the name of the person with whom you communicated, and (d) the substance of the communications. \_\_\_\_\_

**III. MEDICAL BACKGROUND**

1. Provide your current: Age 44 Height 5'8" Weight 185 lbs.
2. Provide your: Age 37 Weight 165 lbs. (approximate, if unknown) at the time the Bard Inferior Vena Cava Filter was implanted in you.
3. In chronological order, list any and all surgeries, procedures and/or hospitalizations you had in the ten (10) year period BEFORE implantation of the Bard Inferior Vena Cava Filter(s). Identify by name and address the doctor(s), hospital(s) or other healthcare provider(s) involved with each surgery or procedure; and provide the approximate date(s) for each:

| Approximate Date                              | Description of Surgery or Hospitalization                                                                                | Doctor or Healthcare Provider Involved (including address)         |
|-----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| On or about September 5 to September 22, 2009 | Open left femur and right tibia/fibular fractures, hip dislocation, and splenic laceration, with placement of IVC filter | Westchester Medical Center<br>100 Woods Road<br>Valhalla, NY 10595 |

*[Attach additional sheets as necessary to provide the same information for any and all surgeries and hospitalizations leading up to the implantation of the Bard Inferior Vena Cava Filter.]*

4. In chronological order, list any and all surgeries, procedures and/or hospitalizations you had AFTER implantation of the Bard Inferior Vena Cava Filter(s). Identify by name and address the doctor(s), hospital(s) or other healthcare provider(s) involved with each surgery or procedure; and provide the approximate date(s) for each:

| Approximate Date              | Description of Surgery or Hospitalization                                                                    | Doctor or Healthcare Provider Involved (including address)                                                    |
|-------------------------------|--------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|
| On or about December 15, 2009 | Attempted retrieval of filter, with discovery of tilt and perforation                                        | Romeo Mateo, M.D.<br>19 Bradhurst Avenue, Suite 700<br>Hawthorne, NY 10532                                    |
| On or about June 17, 2016     | Attempted retrieval of filter and intracardiac strut, with retrieval of fractured strut embedded in IVC wall | Frank Lynch, M.D.<br>Penn State Milton S. Hershey Medical Center<br>500 University Drive<br>Hershey, PA 17033 |

|                               |                                        |                                                                                                               |
|-------------------------------|----------------------------------------|---------------------------------------------------------------------------------------------------------------|
| On or about February 21, 2017 | Retrieval of fractured strut from lung | Frank Lynch, M.D.<br>Penn State Milton S. Hershey Medical Center<br>500 University Drive<br>Hershey, PA 17033 |
|-------------------------------|----------------------------------------|---------------------------------------------------------------------------------------------------------------|

*[Attach additional sheets as necessary to provide the same information for any and all surgeries and hospitalizations after the implantation of the Bard Inferior Vena Cava Filter.]*

5. To the extent not already provided in the charts above, provide the name, address, and telephone number of every doctor, hospital or other health care provider from which you have received medical advice and/or treatment from ten (10) years before the date the filter was implanted to the present:

| Name and Specialty                    | Address                                   | Approximate Date/Years of Visits |
|---------------------------------------|-------------------------------------------|----------------------------------|
| Craig Amnott, M.D.<br>Family Medicine | 1200 NY-208<br>Monroe, NY 10950           | In or around 2014 to present     |
| Jacek Kura, MSPT<br>Physical Therapy  | 80 Sullivan Street<br>Wurtsboro, NY 12790 | In or around 2009 to present     |

6. *Before the implantation of the Bard Inferior Vena Cava Filter(s), did you regularly exercise or participate in activities that required lifting or strenuous physical activity? (Please include all physical activities associated with daily living, physical fitness, household tasks, and employment-related activities.)*

Yes  No

If yes, please describe each activity in detail.

Mixed martial arts, power lifting, weight training, body building, karate

7. *Since the implantation of the Bard Inferior Vena Cava Filter(s), have you regularly exercised or participated in activities that required lifting or strenuous physical activity? (Please describe all range of physical activities associated with daily living, physical fitness, household tasks, and employment-related activities.)*

Yes  No

If yes, please describe each activity in detail.

Work as a contractor and yard work

8. During the past ten (10) years, what have been your primary hobbies or recreational activities? Mixed martial arts, power lifting, body building, karate

(a) Do you claim that you are unable to participate in any of the hobbies or recreational activities listed in response to question 8 above as a result of you having been implanted with a Bard Inferior Vena Cava Filter(s)?

Yes  X  No \_\_\_\_\_

(b) If yes, what hobbies or recreational activities do you claim that you are unable to participate in as a result of having been implanted with a Bard Inferior Vena Cava Filter(s)? The filter's malfunction has drastically altered Plaintiff's lifestyle, as he has been forced to live a restrained lifestyle and refrain from power lifting, body building, karate, and mixed martial arts.

(c) For what period of time do you claim that you were or have been unable to participate in any hobbies or recreational activities as a result of having been implanted with a Bard Inferior Vena Cava Filter(s)?

In or around September 2009 to present

9. To the best of your knowledge, have you ever been told by a doctor or another health care provider that you have suffered, may have suffered, or presently do suffer from any of the following:

No Lupus

No Crohn's Disease

No Factor V Leiden

No Protein Deficiency

No Spinal Fusion or Other Back Procedures

No Anti-thrombin Deficiency

No Prothrombin Mutation

No Deep Vein Thrombosis

No Pulmonary Embolism

No Auto Immune Disorder

No Varicose Veins

No Heart Procedures

No Blood Disorder

Please Describe: \_\_\_\_\_

No Bariatric Surgery



No Anticoagulation Medication (e.g., Coumadin, Warfarin, etc.)

No Ulcerative Colitis/Inflammatory Bowel Disease (IBD)

No Cancer

Please Describe: \_\_\_\_\_

\*\*\*\*\*

THE FOLLOWING QUESTIONS ARE CONFIDENTIAL AND SUBJECT TO THE PROTECTIVE ORDER APPLICABLE TO THIS CASE.

(A) Have you been diagnosed with and/or treated for any drug, alcohol, chemical and/or other addiction or dependency during the five (5) years prior to the filing of this lawsuit through the present? Yes \_\_\_\_\_ No X

If yes, specify type and time period of dependency, type of treatment received, name of treatment provider, and current status of condition:

\_\_\_\_\_

(B) Have you experienced, been diagnosed with or received psychiatric or psychological treatment of any type, including therapy, for any mental health conditions including depression, anxiety, or other emotional or psychiatric disorders during the five (5) years prior to the filing of this lawsuit through the present? Yes X No \_\_\_\_\_

If yes, specify condition, date of onset, medication/treatment, treating physician and current status of condition:

Anxiety and insomnia following accidents; in or around 2009; prescribed

Ambien; Mark Guido, Ph.D. and Quazi Al-Tariq, M.D.; and ongoing

\*\*\*\*\*

10. Do you now or have you ever smoked tobacco products? Yes \_\_\_\_\_ No X

If yes:

How long have/did you smoke? \_\_\_\_\_

11. List each prescription medication you have taken for more than three (3) months at a time during the timeframe beginning five (5) years prior to implantation of the Bard Inferior Vena Cava Filter and continuing to the present, giving the name and address of the

pharmacy where you received/filled the medication, the reason you took the medication, and the approximate dates of use.

| Medication and Dosage                      | Prescribing Physician | Pharmacy Name and Address                                 | Reason for Taking Medication | Approximate Date(s) of Use                 |
|--------------------------------------------|-----------------------|-----------------------------------------------------------|------------------------------|--------------------------------------------|
| Ambien<br>10mg once daily                  | Craig Amnott,<br>M.D. | Rite Aid Pharmacy<br>1 Fitzgerald Drive<br>Middletown, NY | Anxiety and<br>insomnia      | In or around<br>January 2016 to<br>present |
| Amlodipine<br>(Norvasc)<br>10mg once daily | Craig Amnott,<br>M.D. | Rite Aid Pharmacy<br>1 Fitzgerald Drive<br>Middletown, NY | Blood pressure               | In or around<br>March 2016 to<br>present   |

**IV. INSURANCE INFORMATION**

1. Provide the following information for any past or present medical insurance coverage from the timeframe beginning five (5) years prior to implantation of the Bard Inferior Vena Cava Filter and continuing to the present:

| Insurance Company Name and Address                                                | Policy Number | Name of Policy Holder/Insured (if different than yourself) | Approximate Dates of Coverage                |
|-----------------------------------------------------------------------------------|---------------|------------------------------------------------------------|----------------------------------------------|
| Health Republic<br>Insurance of New York<br>30 Broad Street<br>New York, NY 10004 | Y60531901     | N/A                                                        | In or around 2013 to<br>2015                 |
| State Farm Insurance                                                              | 528345990     | N/A                                                        | In or around<br>September 2009 to<br>present |

2. To the best of your knowledge, have you ever been approved to receive or are you currently receiving Medicare/Medicaid benefits due to age, disability, condition, or any other reason or basis?

Yes \_\_\_\_\_ No  X

If yes, please specify the date on which you first became eligible: \_\_\_\_\_

*[Please note: if you are not currently a Medicare-eligible beneficiary, but become eligible for Medicare during the pendency of this lawsuit, you must supplement your response at that time. This information is necessary for all parties to comply with Medicare regulations. See 42 U.S.C. 1395y(b)(8), also known as Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 and 42 U.S.C. 1395y(b)(2) also known as the Medicare Secondary Payer Act.]*

**V. PRIOR CLAIM INFORMATION**

1. Have you filed a lawsuit or made a claim in the last ten (10) years, other than in the present suit relating to any bodily injury?

Yes \_\_\_\_\_ No  X

If yes, please specify the following:

(a) Court in which the lawsuit/claim was filed or initiated: \_\_\_\_\_

(b) Case/Claim Number: \_\_\_\_\_

(c) Nature of Claim/Injury: \_\_\_\_\_

2. Have you ever applied for Workers' Compensation (WC), Social Security disability (SSI or SSD) benefits, or other State or Federal disability benefits?

Yes \_\_\_\_\_ No  X

If yes, please specify the following:

(a) Date (or year) of application: \_\_\_\_\_

(b) Type of benefits sought: \_\_\_\_\_

(c) Agency/Insurer from which you sought the benefits: \_\_\_\_\_

(d) Nature of the claimed injury/disability: \_\_\_\_\_

(e) Whether the claim was accepted or denied: \_\_\_\_\_

**VI. FACT WITNESSES**

1. Identify by name, address, and relationship to you, all persons (other than your healthcare providers) who possess information concerning your injuries and/or current medical condition:

| Name               | Address                                | Relationship to You | Information You Believe Person Possesses |
|--------------------|----------------------------------------|---------------------|------------------------------------------|
| Providencia Dewitt | 617 Lybolt Road<br>Bullville, NY 10915 | Wife                | Injuries caused by filter                |

**VII. IDENTIFICATION OF DOCUMENTS AND OTHER ELECTRONICALLY STORED INFORMATION**

For the period beginning three (3) years prior to the implantation of the Bard Inferior Vena Cava Filter until the present, please identify all research, including on-line research, that you conducted regarding the medical complaints or condition for which you received the Bard Inferior Vena Cava Filter (pulmonary thromboembolism, anticoagulant therapy, etc.) Identify the date, time, and source, including any websites visited. (Research conducted subsequent to

and for the purpose of understanding the legal and strategic advice of your counsel is not considered responsive to this request.)

In or around December 2009, Plaintiff conducted online research on Google and YouTube about the Bard IVC filter and the various malfunctions that have occurred in other patients. Upon learning that the filter fractured and a strut had migrated to his heart in March 2016, Plaintiff conducted various online research about IVC filter retrieval methods and his doctor, Dr. Frank Lynch, who performed the filter retrieval, attempted retrieval of the strut from the heart, and the successful retrieval of the strut from his lung.

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### VIII. DOCUMENT REQUESTS

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1. RELEASES.

**NOTE:** Please sign and attach to this Fact Sheet the authorizations for the release of records appended hereto.

2. DOCUMENTS. State whether you have any of the following documents in your possession, custody, and/or control. If you do, please provide a true and correct copy of any such documents with this completed Fact Sheet. Please ensure that the production of documentation includes specific reference to the questions to which the document is provided in response.

(a) If you were appointed by a Court to represent the plaintiff in this lawsuit, produce any documents demonstrating such appointment.

(i) Not applicable  X

(ii) The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_

(b) If you represent the Estate of a deceased person in this lawsuit, produce a copy of the decedent's death certificate and autopsy report (if applicable).

(i) Not applicable  X

(ii) The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_

(c) Produce each and every medical record of each and every medical facility, pharmacy, or practitioner of the healing arts identified by you in response to the questions in Sections II and III above regarding your medical care and history for the time period beginning ten (10) years prior to the implantation of the Bard Inferior Vena Cava Filter and continuing to the present.

(i) Not applicable \_\_\_\_\_

(ii) The documents are attached  X  [OR] I have no documents \_\_\_\_\_

- (d) Produce any communication (sent or received) in your possession, which shall include materials accessible to you from any computer on which you have sent or received such communications, concerning the Bard Inferior Vena Cava Filter(s) or subject of this litigation, including, but not limited to all letters, emails, blogs, Facebook posts, Tweets, newsletters, etc. sent or received by you. (Research conducted subsequent to and to understand the legal and strategic advice of your counsel is not considered responsive to this request.)
- (i) Not applicable  X
- (ii) The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_
- (e) Produce all documents, including journal entries, lists, memoranda, notes, diaries, photographs, video, DVDs or other media, discussing or referencing the Bard Inferior Vena Cava Filter(s), the injuries and/or damages you claim resulted from the Bard Inferior Vena Cava Filter(s), and/or evidencing your physical condition from three (3) years prior to the implantation of the Bard Inferior Vena Cava Filter(s) to present. (Research conducted subsequent to and to understand the legal and strategic advice of your counsel is not considered responsive to this request.)
- (i) Not applicable  X
- (ii) The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_
- (f) Produce any Bard Inferior Vena Cava Filter product packaging, labeling, advertising, or any other product-related items in your possession, custody or control.
- (i) Not applicable  X
- (ii) The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_
- (g) Produce all documents concerning any communication between you, your attorney(s), your agent(s), your expert(s), or your representative(s) and the Food and Drug Administration (FDA), or between you and any employee or agent of the Bard Defendants, regarding Bard Inferior Vena Cava Filters.
- (i) Not applicable  X
- (ii) The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_
- (h) Produce all documents that you, your attorney(s), your agent(s), your expert(s), or your representative(s) provided to the Food and Drug Administration (FDA)

and/or the Department of Health and Human Services regarding Bard Inferior Vena Cava Filters.

(i) Not applicable  X

(ii) The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_

(i) Produce all documents concerning any communication between you, your attorney(s), your agent(s), your expert(s), or your representative(s) with anyone at any television station, radio station, newspaper, periodical, magazine, weblog, internet website, or any other media outlet regarding Bard Inferior Vena Cava Filters.

(i) Not applicable  X

(ii) The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_

(j) Produce all documents that you, your attorney(s), your agent(s), your expert(s), or your representative(s) provided to anyone at any television station, radio station, newspaper, periodical, magazine, weblog, internet website, or any other media outlet regarding Bard Inferior Vena Cava Filters.

(i) Not applicable  X

(ii) The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_

(k) Produce all documents in your possession, custody, or control evidencing or relating to any correspondence or communication between C. R. Bard, Inc. or Bard Peripheral Vascular, Inc. (or any related companies or divisions) and any of your doctors, healthcare providers, and/or you relating to Bard Inferior Vena Cava Filters, except as to those communications which are protected by the attorney-client privilege or attorney work product doctrine.

(i) Not applicable  X

(ii) The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_

(l) Produce all documents in your possession, custody, or control reflecting, describing, or in any way relating to any instructions or warnings you received prior to implantation of any Inferior Vena Cava Filter(s) concerning the risks and/or benefits associated with Inferior Vena Cava Filter(s), including but not limited to the Bard Inferior Vena Cava Filter implanted in you.

(i) Not applicable  X

- (ii) The documents are attached\_\_\_\_\_ [OR] I have no documents\_\_\_\_\_
- (m) Produce any and all documents reflecting the model number and lot number of the Bard Inferior Vena Cava Filter(s) you received.
  - (i) Not applicable\_\_\_\_\_
  - (ii) The documents are attached X [OR] I have no documents\_\_\_\_\_
- (n) If you underwent surgery or any other procedure to remove, in whole or in part, the Bard Inferior Vena Cava Filter(s), produce any and all documents, other than documents that may have been generated by expert witnesses retained by your counsel for litigation purposes, that relate to any evaluation of the Bard Inferior Vena Cava Filter(s) removed from you.
  - (i) Not applicable\_\_\_\_\_
  - (ii) The documents are attached X [OR] I have no documents\_\_\_\_\_
- (o) If you claim lost wages or lost earning capacity, produce copies of your Federal and State tax returns for the five (5) years prior to implantation of the Bard Inferior Vena Cava Filter(s) to the present redacting irrelevant information.
  - (i) Not applicable X
  - (ii) The documents are attached\_\_\_\_\_ [OR] I have no documents\_\_\_\_\_
- (p) Produce all documents in your possession, custody, or control concerning payment by Medicare on behalf of the injured party and relating to the injuries claimed in this lawsuit. This includes, but is not limited to Interim Conditional Payment summaries and/or estimates prepared by Medicare or its representatives regarding payments made on your behalf for medical expenses relating to the subject of this litigation.
  - (i) Not applicable X
  - (ii) The documents are attached\_\_\_\_\_ [OR] I have no documents\_\_\_\_\_

*[Please note: if you are not currently a Medicare-eligible beneficiary, but become eligible for Medicare during the pendency of this lawsuit, you must supplement your response at that time. This information is necessary for all parties to comply with Medicare regulations. See 42 U.S.C. 1395y(b)(8), also known as Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 and 42 U.S.C. 1395y(b)(2) also known as the Medicare Secondary Payer Act.]*

- (q) Produce all screenshots of all webpages of each type of social media used by you (including, but not limited to, Facebook, Twitter, Instagram, Vine, Snapchat,



YouTube, LinkedIn) showing any and all “posts” and/or “messages” from the date of implantation to the present.

- (i) Not applicable  X
- (ii) The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_
- (r) Produce the Bard Inferior Vena Cava Filter(s) or any and all components thereof previously implanted in you.

**VERIFICATION**

I, Brent J. Whit, declare under penalty of perjury, subject to all applicable laws and in the presence of the below named witness, that I have carefully reviewed the final copy of this Amended Plaintiff Fact Sheet dated March 1, 2017 and verified that all of the information provided is true and correct to the best of my knowledge, information and belief.

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Name of Witness

\_\_\_\_\_  
Address of Witness

  
\_\_\_\_\_  
Signature of Plaintiff

# EXHIBIT B



Deposition of:  
**Brent Dewitt**

*February 15, 2017*

In the Matter of:

**In Re: Bard IVC Filters Products  
Liability**

Veritext Legal Solutions  
1075 Peachtree St. NE , Suite 3625  
Atlanta, GA, 30309  
800.808.4958 | [calendar-atl@veritext.com](mailto:calendar-atl@veritext.com) | 770.343.9696

Brent Dewitt  
In Re: Bard IVC Filters Products Liability

February 15, 2017

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1 strut?

2 A. Yes.

3 Q. When is that retrieval scheduled to  
4 proceed?

5 A. Tuesday.

6 Q. February 21st, 2017?

7 A. Yes.

8 Q. Who's doing the procedure?

9 A. Dr. Lynch.

10 Q. What did Dr. Lynch tell you about the  
11 likelihood of being able to retrieve the filter  
12 strut from your lung?

13 A. It's a 50 percent -- 50 to 60 percent  
14 chance it will be successful.

15 Q. Is the procedure going to be  
16 percutaneous or is it an open surgery?

17 A. Percutaneous.

18 Q. Are you also scheduled to have an open  
19 abdominal procedure to retrieve the filter in your  
20 IVC?

21 A. I'm going to have a consult, the same  
22 time I meet with Dr. Lynch, with another physician  
23 that he's referring, who's more specialized in doing  
24 open abdominal retrievals.

25 Q. What's the name of the doctor that

Brent Dewitt  
In Re: Bard IVC Filters Products Liability

February 15, 2017

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1 you're going to have a consult with in order to  
2 determine whether or not to have an open abdominal  
3 procedure to remove the IVC filter?

4 A. David Hahn.

5 Q. Have you spoken to Dr. Han before?

6 A. No.

7 Q. You seem like you paused for a second,  
8 or maybe that's just me.

9 A. I've spoken with --

10 MR. MANKOFF: Object to form.

11 Go ahead.

12 THE WITNESS: I've spoken with his  
13 staff in reference to scheduling.

14 BY MR. BUSMAN:

15 Q. Okay. You've never had any  
16 conversations with Dr. Han; right?

17 A. No.

18 Q. The only conversations you've had with  
19 anybody in Dr. Han's office have been with his staff  
20 in order to try to schedule appointment with him;  
21 right?

22 A. Yes.

23 Q. Is Dr. Han located in Hershey,  
24 Pennsylvania?

25 A. Yes.

# EXHIBIT C





Deposition of:  
**Debra Tinlin**

*February 8, 2017*

In the Matter of:

**In Re: Bard IVC Filters Products  
Liability**

Veritext Legal Solutions  
1075 Peachtree St. NE , Suite 3625  
Atlanta, GA, 30309  
800.808.4958 | [calendar-atl@veritext.com](mailto:calendar-atl@veritext.com) | 770.343.9696

Debra Tinlin  
In Re: Bard IVC Filters Products Liability

February 8, 2017

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1 THE VIDEOGRAPHER: We are back on the  
2 record. The time now is 2:57 p.m. and this is  
3 the beginning of Media Unit 4 of the video  
4 deposition of Debra Ann Tinlin.

5 BY MS. KOWALZYK:

6 Q Ms. Tinlin, I know that we've been going for a  
7 long time today, for, I don't know, maybe five  
8 hours total depo time. And I can see that  
9 you're a little uncomfortable. Are you okay  
10 with keeping going or would you, I guess, how  
11 are you feeling?

12 A I would like to get it finished.

13 Q Are you uncomfortable?

14 A I'm uncomfortable just sitting here. It's  
15 painful, yes.

16 Q Okay. And if you were at home it would be less  
17 painful because you would be able to be laying  
18 down or in your recliner?

19 A Yes. Yeah, move around more, yes.

20 Q Okay. Well, I will try to finish up as quickly  
21 as I can, but I'm trying to avoid us all having  
22 to do this again, so -- but if you want to  
23 stop --

24 A No.

25 Q -- at any point --

Debra Tinlin  
In Re: Bard IVC Filters Products Liability

February 8, 2017

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- 1 A Let's go.
- 2 Q -- let me know.
- 3 A Okay. Thank you.
- 4 Q Uh-huh. What was the most recent doctor visit  
5 that you had?
- 6 A The 19th I had the endoscopy.
- 7 Q Okay.
- 8 A Before that the 13th I saw Dr. Gautam, the  
9 hematologist, in his office so he could bridge  
10 me off of my Coumadin for the procedure.
- 11 Q So Dr. Gautam is the hematologist who now  
12 handles your Coumadin?
- 13 A Well, he -- he only handles it if I need to  
14 bridge. Dr. Leah Nitke takes care of it on a  
15 daily basis.
- 16 Q Got it.
- 17 A But if I need to go off for a procedure then  
18 he'll handle the bridging.
- 19 Q What appointments do you have currently to see  
20 doctors?
- 21 A I see Dr. Newell, the endocrinologist this  
22 month. I'm going to see a neurologist this  
23 month. In March I'm going to see an  
24 orthopedic, Dr. Schnaubelt.
- 25 Q Who's the neurologist that you see this month?

**PLAINTIFFS’  
EXHIBIT 6**

1 Q. How big is Wheaton?

2 A. In terms of what?

3 Q. In terms of numbers.

4 MR. BROWN: Object to the form.

5 THE WITNESS: I have no idea off the top  
6 of my head.

7 BY MR. O'CONNOR:

8 Q. Did they bring you good numbers?

9 A. I don't know what the answer to that is.

10 Q. Well, we know that back in April 2010,  
11 Bard wanted G2s -- Eclipse switched out for the G2,  
12 and here now we're at February 17, 2011.

13 A. Okay.

14 Q. Not quite a year, but several months  
15 after this e-mail came from Bret Baird; right?

16 A. Sure.

17 Q. And you have, I'm going to hazard a  
18 guess, a relatively good customer who's still using  
19 the G2.

20 A. Okay.

21 Q. Right?

22 A. Looks like it, yes.

23 Q. And you took this opportunity to tell  
24 Mary Starr, the interventional radiology  
25 coordinator at Wheaton, that she needs to be

**PLAINTIFFS’  
EXHIBIT 7**

1 you ever make that phone call?

2 MR. BROWN: Object to the form.

3 THE WITNESS: No. At the same time I  
4 didn't make the phone call, you know, asking why we  
5 were doing it or what that was for. So no.

6 BY MR. O'CONNOR:

7 Q. And that's my point. You didn't make the  
8 call. If Bard told you to do something, you're  
9 going to do it if you could do it?

10 A. Sure.

11 Q. You didn't ask any questions, you just do  
12 it if you could?

13 A. If I was able to, sure.

14 (Exhibit 21 marked for identification.)

15 BY MR. O'CONNOR:

16 Q. Wheaton Franciscan was a big client,  
17 weren't they?

18 A. I don't know how to say how big they are.  
19 I don't know exactly how you're describing big.

20 Q. Were they an important client?

21 A. All my customers are important, so --

22 Q. Wheaton somebody you wanted to keep  
23 happy?

24 A. All my customers were people that I  
25 wanted to keep happy.



1 Q. How big is Wheaton?

2 A. In terms of what?

3 Q. In terms of numbers.

4 MR. BROWN: Object to the form.

5 THE WITNESS: I have no idea off the top  
6 of my head.

7 BY MR. O'CONNOR:

8 Q. Did they bring you good numbers?

9 A. I don't know what the answer to that is.

10 Q. Well, we know that back in April 2010,  
11 Bard wanted G2s -- Eclipse switched out for the G2,  
12 and here now we're at February 17, 2011.

13 A. Okay.

14 Q. Not quite a year, but several months  
15 after this e-mail came from Bret Baird; right?

16 A. Sure.

17 Q. And you have, I'm going to hazard a  
18 guess, a relatively good customer who's still using  
19 the G2.

20 A. Okay.

21 Q. Right?

22 A. Looks like it, yes.

23 Q. And you took this opportunity to tell  
24 Mary Starr, the interventional radiology  
25 coordinator at Wheaton, that she needs to be

1 switching out and using the Eclipse; right?

2 A. I don't know that I -- I was asked -- was  
3 I asked that question, to switch out?

4 Q. "Mary, you want the Eclipse, here are the  
5 product codes." See where I read that?

6 A. Sure. That doesn't sound like me --

7 Q. Those are your words. Pardon me?

8 A. That doesn't sound like me mandating her  
9 to switch anything. Am I responding to a question?

10 Q. Well, look at it.

11 A. Yeah, she asked me if I should order the  
12 Eclipses or the G2s.

13 Q. And what did you tell her?

14 A. You want to order the Eclipse 'cause the  
15 G2s are being discontinued, right? So the  
16 product's not going to be available anymore. So we  
17 would want to get them over to the next iteration.  
18 There's not going to be any product left.

19 Q. When had you ever told her, or anybody at  
20 Wheaton before February 17, 2011, that Bard was  
21 switching out -- switching the Eclipse for the G2?

22 A. I don't know. I mean, I would -- I don't  
23 know when I would have tried, if I ever was able to  
24 get to her before this. This may have been the  
25 first opportunity I had to get to her. I don't

1 know.

2 Q. So the first opportunity you may have had  
3 was not quite a year but several months after Bret  
4 Baird sent that e-mail out?

5 A. Could have been.

6 Q. And still by this time you never asked  
7 Bard hey, Bret, why are we switching these out?  
8 Never made that phone call?

9 A. I didn't, no.

10 Q. Okay.

11 MR. BROWN: Object to the form.

12 BY MR. O'CONNOR:

13 Q. But by this time, you knew that this  
14 hospital should be using the Eclipse?

15 A. Yeah, I mean at -- obviously that was our  
16 new filter line. The G2s were going away, they  
17 weren't going to have anymore. They didn't have  
18 the option; they weren't going to be able to order  
19 anymore G2s.

20 Q. And if the reason Bard was so intent on  
21 switching out was because of known problems with  
22 the G2, you just don't know?

23 MR. BROWN: Object to the form.

24 BY MR. O'CONNOR:

25 Q. You never asked?

**PLAINTIFFS’  
EXHIBIT 8**

1 Q. Why was it done? Why was there a new  
2 iteration?

3 A. I don't know necessarily why there was a  
4 new iteration.

5 Q. The Eclipse didn't last very long, did  
6 it?

7 A. I don't recall exactly how long it was on  
8 the market for.

9 Q. Well, we saw somewhere it was supposed to  
10 begin in April, 2010; right?

11 A. That -- it was supposed to begin?

12 Q. That G2 was stopped, according to Bret  
13 Baird, and the Eclipse was supposed to be switched  
14 out.

15 A. Okay.

16 MR. BROWN: Object to the form.

17 BY MR. O'CONNOR:

18 Q. Right?

19 A. Okay.

20 (Exhibit 25 marked for identification.)

21 BY MR. O'CONNOR:

22 Q. 25. It's not even a year, it's March 8,  
23 2011, since the Bret Baird e-mail about the Eclipse  
24 and the G2. And here you're talking about the  
25 Meridian. What was up with that?

1 MR. BROWN: Object to the form.

2 BY MR. O'CONNOR:

3 Q. Why is the Eclipse coming down so fast?

4 MR. BROWN: Object to the form.

5 THE WITNESS: I have no idea.

6 BY MR. O'CONNOR:

7 Q. Did you ever ask?

8 A. No.

9 Q. I mean, you just barely got to these  
10 people in 2011 about the switch-out, and now  
11 they're changing it on you again.

12 MR. BROWN: Object to the form.

13 BY MR. O'CONNOR:

14 Q. Right?

15 A. Looks that way, yeah.

16 Q. Now they're talking about the Meridian;  
17 right?

18 A. Looks like that's -- yes.

19 Q. But the problem is, in this e-mail,  
20 March 8, 2011, that the Meridian's not even ready  
21 to be sold, it's backordered. Am I reading that  
22 right?

23 A. Possibly. It says --

24 Q. Well, you tell me. What's Bret telling  
25 you folks?

1           A.     So it's -- how I'm reading that,  
2     there's -- looks like he says a delay. I don't  
3     know what that means.

4           Q.     Well, and they're bringing back the G2  
5     for a reunion tour; right?

6           A.     I don't know if that was the case.

7           Q.     Well, tell me what that means. They're  
8     not talking about the Eclipse staying out there,  
9     they're talking about the G2. As a matter of fact,  
10    let's read what it says, the first sentence. Would  
11    you read that?

12          A.     It says, "In the next day or so we will  
13    be going on backorder for the femoral G2 filter as  
14    a result of the Meridian delay."

15          Q.     Continue.

16          A.     "As you are aware, we had been working on  
17    finishing the remaining G2 product in preparation  
18    for discontinuation. But with the Meridian delay,  
19    we have turned production back on temporarily."

20          Q.     What did -- I'm sorry, go ahead.

21          A.     Did you want me to finish that, or no?

22          Q.     Sure.

23          A.     "We should be out of the backorder by  
24    next week."

25          Q.     What did the Meridian have that the



1 Eclipse didn't?

2 A. Oh, I think this is when they had hooks  
3 or anchors on the shoulders. But I can't remember  
4 if that's the Meridian or the Denali, which one is  
5 which. It's been a while.

6 (Exhibit 26 marked for identification.)

7 BY MR. O'CONNOR:

8 Q. It's getting a little confusing now,  
9 isn't it? Because this e-mail on Exhibit 26 is  
10 dated December 13, 2011; right?

11 A. Uh-huh.

12 Q. Yes?

13 A. Yes. Sorry.

14 Q. And we've gone from G2 being discontinued  
15 in April of 2010 to the Eclipse, to the Meridian in  
16 early 2011, and now here we are at the end of 2011  
17 and they're still talking about the G2 filter being  
18 discontinued. Do you see that?

19 A. I do.

20 Q. How did you keep up?

21 A. How did I keep up with what?

22 Q. Well, this changing and what you were  
23 supposed to do. I mean, one minute the G2 is being  
24 discontinued, the next minute it's gotta make a  
25 comeback because they don't have the Meridian

**To:** Aghakhan, Ninef[Ninef.Aghakhan@crbard.com]; Calcagno, Geno[Geno.Calcagno@crbard.com]; Fermanich, Matt[Matt.Fermanich@crbard.com]; Lay, Jason[Jason.Lay@crbard.com]; Scherer, Cindy[Cindy.Scherer@crbard.com]; Torres, Erin[Erin.Torres@crbard.com]; Trottier, Aimee[Aimee.Trottier@crbard.com]  
**From:** Hug, Tim  
**Sent:** Tue 3/8/2011 6:44:48 PM  
**Importance:** Normal  
**Subject:** FW: G2 Fem Filter Backorder  
**Received:** Tue 3/8/2011 6:44:00 PM

FYI

**Tim Hug**  
Great Lakes District Manager

Direct: 631 334 0526  
Fax: 262 542 2810  
[tim.hug@crbard.com](mailto:tim.hug@crbard.com)  
[www.bardpv.com](http://www.bardpv.com)

**BAIRD** | PERIPHERAL  
VASCULAR

---

**From:** Baird, Bret  
**Sent:** Tuesday, March 08, 2011 10:01 AM  
**To:** TPE-PV DM's-DG  
**Cc:** Righi, Robert; Pellicio, Jeffrey; Randall, Mike; Warren, Kathleen; Casanova, Mike  
**Subject:** G2 Fem Filter Backorder

Dear DM's,

In the next day or so we will be going on backorder for the Femoral G2 Filter as a result of the Meridian delay. As you are aware, we had been working to finish the remaining G2 product in preparation for discontinuation, but with the Meridian delay we have turned production back on temporarily. We should be out of backorder by next week.

At this time we do not foresee a backorder for the G2 Jug system, since we have enough product to cover us.

Thanks for your patience.

**Bret Baird**  
Marketing Manager, IVC Filters

Direct: 480 379 2875  
Fax: 480 303 2783  
Main: 480 894 9515  
[bret.baird@crbard.com](mailto:bret.baird@crbard.com)  
[www.bardpv.com](http://www.bardpv.com)

**BAIRD** | PERIPHERAL  
VASCULAR



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CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

BPVEFILTER-01-01941407



**PLAINTIFFS’  
EXHIBIT 9**

1 Eclipse didn't?

2 A. Oh, I think this is when they had hooks  
3 or anchors on the shoulders. But I can't remember  
4 if that's the Meridian or the Denali, which one is  
5 which. It's been a while.

6 (Exhibit 26 marked for identification.)

7 BY MR. O'CONNOR:

8 Q. It's getting a little confusing now,  
9 isn't it? Because this e-mail on Exhibit 26 is  
10 dated December 13, 2011; right?

11 A. Uh-huh.

12 Q. Yes?

13 A. Yes. Sorry.

14 Q. And we've gone from G2 being discontinued  
15 in April of 2010 to the Eclipse, to the Meridian in  
16 early 2011, and now here we are at the end of 2011  
17 and they're still talking about the G2 filter being  
18 discontinued. Do you see that?

19 A. I do.

20 Q. How did you keep up?

21 A. How did I keep up with what?

22 Q. Well, this changing and what you were  
23 supposed to do. I mean, one minute the G2 is being  
24 discontinued, the next minute it's gotta make a  
25 comeback because they don't have the Meridian

1 ready. How were you able to work your job and get  
2 the filters out there and promote and educate these  
3 doctors?

4 A. I don't recall exactly, to answer your  
5 question, how I kept up. I don't necessarily know  
6 what you're asking.

7 Q. Was it a time you're trying to just  
8 forget and put behind you?

9 A. No. It's over six years ago, or six  
10 years ago. I just don't remember my day-to-day  
11 activities six years ago extremely well.

12 Q. Well, do you know who Kim Romney is?

13 A. I know the name. I don't know her  
14 personally, no.

15 Q. She says, "Sales of the G2 filter is now  
16 obsolete. Our inventory is exhausted and customer  
17 service can no longer take orders." You see where  
18 I read?

19 A. I do.

20 Q. Then she goes on to say that, "I know you  
21 are all in transition right now with the  
22 realignment, but please help us see this through by  
23 checking in with your G2 accounts to confirm that  
24 they successfully switched to the Meridian." Did I  
25 read that correctly?

1 A. You did.

2 Q. And then she goes on to say, "If you're  
3 not sure which accounts to switch, or sure which  
4 accounts these are, please check with your DMs, who  
5 have a current list of G2 accounts in your  
6 territories." Did I read that correctly?

7 A. You did.

8 Q. And your DM was Tim Hug?

9 A. It looks like it at the time, yes.

10 Q. And did you call him and say what are my  
11 territories?

12 A. I don't know if I called him. I mean, it  
13 looks like I e-mailed him here about UW, but I  
14 don't know that I called him about this.

15 Q. If Tim was a poor communicator, it looks  
16 like that was happening throughout the company,  
17 because you see it and I see it, how many times was  
18 the G2 discontinued just in our discussion today?  
19 Couple times.

20 MR. BROWN: Object to the statement.

21 THE WITNESS: Yeah, I don't recall.

22 BY MR. O'CONNOR:

23 Q. Sounds like there were problems with  
24 communication, doesn't it?

25 MR. BROWN: Object to the form.

1 THE WITNESS: Well, you have to remember,  
2 I think that there's -- one of the issues going on  
3 here is that there's customers that like the G2,  
4 probably, that continued to use and use and use and  
5 use and use, and some saw no reason to try out a  
6 new product because they were -- you know, the  
7 performance of the G2 worked for them, so they  
8 didn't want to switch out to it. I'm sure that's  
9 part of it.

10 BY MR. O'CONNOR:

11 Q. Well, see, here's why I don't see it that  
12 way. Because we just went through an e-mail that  
13 said they were bringing the G2 back.

14 A. Okay.

15 Q. You remember that?

16 A. Sure.

17 Q. Let's look at your problem. And your  
18 problem looks like it's up on top here.

19 A. Okay.

20 Q. You say, "It's gonna hurt us with UW  
21 Hospital's OR order."

22 MR. BROWN: Object to the form.

23 BY MR. O'CONNOR:

24 Q. Oh -- no, I'm sorry, you're right. I'll  
25 sustain that. "Is this going to hurt us with the



**To:** Fermanich, Matt[Matt.Fermanich@crbard.com]  
**From:** Hug, Tim  
**Sent:** Tue 12/13/2011 6:42:48 PM  
**Importance:** Normal  
**Subject:** Re: G2 Filter Discontinued  
**Received:** Tue 12/13/2011 6:42:48 PM  
[image001.gif](#)

No...they ordered eclipse

Tim Hug

"Fermanich, Matt" <Matt.Fermanich@crbard.com> wrote:

Is this gonna hurt us with UW Hospital's OR order?

---

**From:** Romney, Kim  
**Sent:** Tuesday, December 13, 2011 11:26 AM  
**To:** TPE-PV Sales-DG; TPE-Marketing-DG  
**Cc:** Everett, Annette; Seisinger, Raye; Warren, Kathleen  
**Subject:** G2 Filter Discontinued

Sales Team,

The **G2 Filter (RF310F and RF320J)** is now **obsolete**. Our inventory is exhausted and customer service can no longer take orders. I know you all are in transition right now with the realignment but please help us see this through by **checking in with your G2 accounts to confirm that they've successfully switched to the Meridian Filter (MD800F and MD800J)**. If you are not sure which accounts these are, please check with your DM's who have a current list of G2 accounts in your territories.

Thanks,



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**PLAINTIFFS’  
EXHIBIT 10**

1 can't call medical affairs to get the answer. It's a  
2 physician/medical affairs connection there.

3 Q. Do you recall -- in this particular instance,  
4 do you remember if Mr. Fermanich got back to this  
5 physician?

6 A. I would be angry if Matt did not. I don't  
7 know, though.

8 Q. And what would you have expected him -- or if  
9 you recall, tell me what he provided to the physician.

10 A. I don't know, but I would expect Matt to say,  
11 At the end of the day, we don't know the answer to that,  
12 but I would encourage you to reach out on this phone  
13 number, and perhaps they can do some additional research  
14 to find the answer to that.

15 Q. Okay. This is one I want to show you.

16 (Exhibit 1115 was marked for  
17 identification.)

18 Q. BY MR. LOPEZ: This is Exhibit 1115. All  
19 right. Okay. Just go to the second page real quick.

20 A. Okay.

21 Q. This is an e-mail between Mary Starr and Matt  
22 Fermanich, and you know who Mary Starr is?

23 A. Yeah. I'm not sure what her role was at this  
24 time, but I do know Mary Starr.

25 Q. Okay. Actually it looks like she says --

1 A. Oh, there it is.

2 Q. -- interventional radiology coordinator?

3 A. Yeah. So I knew her when she worked in the  
4 cath lab at saint Francis, another Wheaton facility. So  
5 that's how I knew her.

6 Q. She writes just on the second page at the top,  
7 "Matt, I filled out the first half of the form. The  
8 second half you fill out" --

9 A. Yes.

10 Q. -- "question" -- I don't know if I read that  
11 right.

12 A. Right.

13 Q. "Also I need to order some filters. Is it the  
14 Eclipse or the G2," she's asking, and let's keep in mind  
15 the date here.

16 A. Okay.

17 Q. This is February 16, 2011.

18 A. Okay.

19 Q. And she needs more filters, or the group does,  
20 and then Matt responds. You can go to the first page.

21 A. Yep.

22 Q. "Mary, you want the Eclipse. Here are the  
23 product codes." Okay. And then he provides them.

24 A. Yes.

25 Q. And this was in -- this comported to the

1 instructions or the -- you know, the company directive  
2 that he's aware of.

3 A. Uh-huh.

4 Q. That's a yes?

5 A. It is correct, yes. Sorry.

6 Q. Sorry, it's annoying, but you've got to give  
7 audible responses.

8 A. Yes.

9 Q. And Mary responds and says, "Thanks, Matt. We  
10 still have a G2 in stock. Are those still being used?"  
11 And at least at this time, it's fair to say that this  
12 hospital is using the G2. Right?

13 A. I think that would be fair that it sounds like  
14 they have some in stock, yes.

15 Q. And do you know what Matt replied?

16 A. I don't. I can't recall that.

17 Q. Okay. Yeah, I don't have it --

18 A. I could make an assumption on that, but, yes.

19 Q. What would you expect Matt to have responded?

20 MR. LERNER: Objection to form.

21 THE WITNESS: I would assume that Matt would  
22 probably tell her that the G2 -- to go ahead and utilize  
23 the G2 and that when she does her reorders to order the  
24 Eclipse. Right?

25 I mean, that's -- that's the direction that

1 we have, and that's the communication that we have, and I  
2 would assume that -- that Matt could carry that out, but  
3 I can't say that with certainty obviously.

4 Q. BY MR. LOPEZ: Okay. You can put that one  
5 aside.

6 A. Okay.

7 Q. All right. This is Exhibit 1116.

8 (Exhibit 1116 was marked for  
9 identification.)

10 Q. BY MR. LOPEZ: And let's try to go through this  
11 one a little more quickly than it might look like we're  
12 going to.

13 A. Okay.

14 Q. I know it's a big one, but go to page 18,  
15 please.

16 A. Okay.

17 Q. And you'll see it's a chart at the top. It  
18 says, "What is G2 trend relative to RNF?" And do you  
19 understand the RNF to be the Recovery filter?

20 A. Yes.

21 Q. Okay. Do you see in the left column, second  
22 row, limb detachments, arm/leg hook?

23 A. Yes.

24 Q. And the far right column says, "G2 has less arm  
25 and hook complaints than RNF. G2 has more leg complaints