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11  
12 **IN THE UNITED STATES DISTRICT COURT**  
13 **FOR THE DISTRICT OF ARIZONA**  
14

15 IN RE: Bard Implanted Port Catheter  
16 Products Liability Litigation

MDL No. 3081

17 **JOINT MEMORANDUM RE**  
18 **ISSUES TO BE ADDRESSED AT**  
19 **THE MAY 10, 2024 CASE**  
20 **MANAGEMENT CONFERENCE**

(Applies to All Actions)

21  
22 Pursuant to Case Management Order No. 18 (“CMO 18”), the Parties submit  
23 this Joint Memorandum in advance of the sixth Case Management Conference  
24 (“CMC”) scheduled for May 10, 2024. *See* Doc. 525, at 6.

25 **I. Case Statistics & Overview**

26 There are 223cases pending in the MDL. 11 cases have been dismissed from  
27 the MDL. There are 38 cases pending in the Superior Court of New Jersey.  
28 Defendants have moved, or will move, to dismiss on *forum non conveniens* grounds

1 all cases in the Superior Court of New Jersey that were filed by non-resident  
2 plaintiffs where there is complete diversity (29 of 38 cases). The New Jersey state  
3 court liaison has advised Defendants that he intends to refile an application for  
4 multicounty litigation (“MCL”) designation. The parties are not aware of any cases  
5 pending in Arizona state court.

6 **II. Common-Issue Discovery**

7 **A. The Parties’ Conferrals Pursuant to CMO 18**

8 The Court ordered that the parties “meet and confer regarding successor  
9 liability custodians and non-custodial sources by April 26, 2024.” Doc. 525, at 4.  
10 The parties hereby set forth the outcome of those conferrals, and there are no  
11 disputes for the Court to resolve at this time.

12 **1. Non-Custodial Sources**

13 The parties conferred about Non-Custodial Sources and agreed to the  
14 following substantial completion deadlines:

- 15 • WorkDay: produced April 23, 2024
- 16 • Master Control & Master Control Archive: June 17, 2024
- 17 • EasyTrack & TrackWise: June 17, 2024
- 18 • SharePoint/Shared Drives: July 1, 2024
- 19 • VeevaVault Clinical: July 1, 2024
- 20 • Second Priority Sources:<sup>1</sup> August 30, 2024

21 Defendants have advised Plaintiffs that they will promptly schedule a  
22 conferral in the event that any unforeseen technical or logistical issues impact these  
23 deadlines. Defendants have also advised Plaintiffs that because of technical issues  
24 they cannot yet commit to a deadline by which they will produce documents from  
25 DocuShare, but will update Plaintiffs as soon as information becomes available.  
26 Defendants have further noted that, to the extent additional shared drives or

27 \_\_\_\_\_  
28 <sup>1</sup> Those sources include Veeva Vault Promomats, iCertis, Global Sales Data Warehouse, J.D. Edwards (JDE), and MFG Pro.

1 SharePoint sites are identified by Custodians, Defendants will strive to produce  
2 those drives or sites after July 1<sup>st</sup> but in advance of the individual’s deposition.

3 Plaintiffs have cautioned Defendants that, should materials relevant to a  
4 deposition not be produced on schedule or in reasonable time to be reviewed and  
5 used in that deposition, Plaintiffs intend to reopen the deposition.

## 6 **2. Successor Liability Custodians**

7 Plaintiffs requested the identification of four proposed custodians in advance  
8 of the parties’ conferral scheduled for April 17<sup>th</sup>, which Defendants provided.  
9 Defendants requested that the parties discuss again whether an agreement can be  
10 reached to avoid the need for discovery on successor liability issues. The parties  
11 intend to continue their conferrals to determine whether the scope of successor  
12 liability issues and discovery can be narrowed as general liability discovery  
13 progresses. The parties anticipate that they will have ample time to conduct  
14 successor liability discovery should the negotiations fail.

## 15 **B. Production of Documents**

### 16 **1. Plaintiffs’ Position**

17 In March, following collaboration with the Plaintiffs, Defendants agreed to  
18 employ a search methodology utilizing a technology assisted review (“TAR”)  
19 protocol. The Parties agreed to work together – and to share metrics and data about  
20 the performance of the protocol – to collaboratively narrow the volume of  
21 documents necessary to make Defendants’ production of information responsive to  
22 Plaintiffs’ discovery requests. Although Defendants from the inception of the TAR  
23 plan promised to share metrics and data, they were unable to do so until the day  
24 before a draft of this memorandum was due, on April 30.

25 As Plaintiffs have just recently received the preliminary metrics and data  
26 necessary to assist Defendants with narrowing production, (and the parties agree  
27 that narrowing is warranted,) the issue is not yet ripe for the Court. Assuming that  
28 Defendants will continue to share metrics, collaborate with a high degree of

1 transparency, timely respond to iterative metrics requests, and make time for  
 2 conferrals, Plaintiffs agree with Defendants proposal of another case management  
 3 conference around May 24, 2024.

## 4 **2. Defendants' Position**

### 5 **a. Update on Defendants' Productions**

6 Defendants continue to work diligently to identify, collect, and produce  
 7 documents responsive to Plaintiffs' Requests for Production ("RFP"). This chart  
 8 summarizes Defendants' productions to date:

9	<b>PRODUCTION</b>	<b>DATE</b>	<b>DESCRIPTION</b>	<b>DOCS</b>	<b>PAGES</b>
10	BARD_IPC_MDL_001	12/26/2023	Cruz Production	6,290	91,035
11	BARD_IPC_MDL_002a	1/5/2024	Prior Patent Litig. Production (I of IV)	211,955	993,418
12	BARD_IPC_MDL_003	1/5/2024	Prior Port Litig. Deposition Transcripts	48	1,794
13	BARD_IPC_MDL_003	1/5/2024	Prior Port Litig. Deposition Transcripts	48	1,794
14	BARD_IPC_MDL_003	1/5/2024	Prior Port Litig. Deposition Transcripts	48	1,794
15	BARD_IPC_MDL_002b	1/11/2024	Prior Patent Litig. Production (II of IV)	200,966	1,396,347
16	BARD_IPC_MDL_002b	1/11/2024	Prior Patent Litig. Production (II of IV)	200,966	1,396,347
17	BARD_IPC_MDL_004	1/12/2024	CV of Information Infrastructure Rule 30(b)(6) Deponent & Related standard operating procedures ("SOPs")	18	241
18	BARD_IPC_MDL_004	1/12/2024	CV of Information Infrastructure Rule 30(b)(6) Deponent & Related standard operating procedures ("SOPs")	18	241
19	BARD_IPC_MDL_004	1/12/2024	CV of Information Infrastructure Rule 30(b)(6) Deponent & Related standard operating procedures ("SOPs")	18	241
20	BARD_IPC_MDL_004	1/12/2024	CV of Information Infrastructure Rule 30(b)(6) Deponent & Related standard operating procedures ("SOPs")	18	241
21	BARD_IPC_MDL_005	1/17/2024	SOPs and corporate org document related to Information Infrastructure Deposition	4	50
22	BARD_IPC_MDL_005	1/17/2024	SOPs and corporate org document related to Information Infrastructure Deposition	4	50
23	BARD_IPC_MDL_005	1/17/2024	SOPs and corporate org document related to Information Infrastructure Deposition	4	50
24	BARD_IPC_MDL_006	1/19/2024	Information Infrastructure Document	1	9
25	BARD_IPC_MDL_006	1/19/2024	Information Infrastructure Document	1	9
26	BARD_IPC_MDL_002c	1/19/2024	Prior Patent Litig. Production (III of IV)	97,634	449,900
27	BARD_IPC_MDL_002c	1/19/2024	Prior Patent Litig. Production (III of IV)	97,634	449,900
28	BARD_IPC_MDL_002c	1/19/2024	Prior Patent Litig. Production (III of IV)	97,634	449,900

	<b>PRODUCTION</b>	<b>DATE</b>	<b>DESCRIPTION</b>	<b>DOCS</b>	<b>PAGES</b>
1					
2	BARD_IPC_MDL_002d	1/24/2024	Prior Patent Litig. Production (IV of IV)	137,420	814,251
3					
4	BARD_IPC_MDL_007	1/26/2024	510(k) submissions related to the Product Codes	19	4,599
5					
6	BARD_IPC_MDL_008	2/2/2024	510(k) submissions and related docs for the Product Codes	498	15,508
7					
8	BARD_IPC_MDL_009	2/9/2024	Corrective and Preventative Actions (CAPAs), Remedial Action Plans (RAPs), Situational Analyses (SAs), Health Hazard Evaluations (HHEs) / Health Risk Assessments (HRAs), and Failure Investigation reporting documentation associated with the Product Codes	293	8,583
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18	BARD_IPC_MDL_010	2/16/2024	Marketing team documents, SOPs, supplement of three 510(k)s	2,168	20,057
19					
20					
21	BARD_IPC_MDL_011	2/23/2024	Marketing team documents	4,316	24,239
22	BARD_IPC_MDL_012	2/29/2024	Design History Files, Instructions for Use, Patient Guides, and CAPAs	6,650	120,589
23					
24					
25	BARD_IPC_MDL_013	3/8/2024	Marketing shared drives, R&D shared drives, and Notes to File regarding various 510(k)'s	16,588	150,676
26					
27					
28					

<b>PRODUCTION</b>	<b>DATE</b>	<b>DESCRIPTION</b>	<b>DOCS</b>	<b>PAGES</b>
BARD_IPC_MDL_014	3/15/2024	Documents from Design History Files and SOPs collected from Master Control	394	3,471
BARD_IPC_MDL_015	3/15/2024	Marketing shared drives and R&D shared drives	16,030	114,792
BARD_IPC_MDL_016	3/22/2024	Marketing shared drives and R&D shared drives	11,907	238,458
BARD_IPC_MDL_017	3/30/2024	R&D, Regulatory, Clinical Affairs, and Marketing departmental shared drives	14,220	111,010
BARD_IPC_MDL_018	4/5/2024	Marketing, R&D, Regulatory, & Medical Affairs departmental shared drives	12,613	69,351
BARD_IPC_MDL_019	4/12/2024	Marketing & R&D departmental shared drives	14,982	60,484
BARD_IPC_MDL_020	4/20/2024	Documents from Master Control Archive	19,918	105,149
BARD_IPC_MDL_021	4/23/2024	R&D, Marketing, Regulatory, & Clinical Affairs departmental shared areas, and an export from WorkDay	6,927	64,542
BARD_IPC_MDL_022	4/26/2024	Custodial Files & Volume 1 of Defendants' Privilege Log	42,300	168,088
BARD_IPC_MDL_023	5/3/2024	Regulatory departmental shared drive documents	3,328	25,384

1	PRODUCTION	DATE	DESCRIPTION	DOCS	PAGES
2	BARD_IPC_MDL_024	5/3/2024	Documents from Master	26,254	125,322
3			Control Archive		
4	<b>Total</b>			853,741	5,052,025

### 6 **b. Defendants' Proportionality Concerns**

7 Following the last CMC, a significant discovery issue has arisen through no  
8 fault of the parties. Specifically, it has become clear that proceeding with the  
9 processing and review of Custodial ESI data as the parties originally contemplated  
10 would be prohibitively expensive—exceeding \$16 million in review costs for 60  
11 Custodians. The parties are conferring about alternative approaches, but Defendants  
12 request that the Court establish an expedited schedule for the parties to address this  
13 issue.

14 After the last conference, Defendants agreed to utilize Technology Assisted  
15 Review (“TAR”) to prioritize documents from Custodial Files and certain Non-  
16 Custodial Sources for review. “To focus the TAR population and mitigate expense  
17 of hosting irrelevant documents, Defendants [agreed to] run Plaintiffs’ proposed 728  
18 search terms over Custodial File collections and collections of certain unstructured  
19 Non-Custodial Sources.” Joint Mem. at 3, Doc. 552. When Defendants agreed to  
20 that compromise,<sup>2</sup> neither party had data regarding the volume of documents that  
21 would be pulled into the TAR universe from the first set of Custodial Files. In other  
22 words, neither party knew whether Plaintiffs’ search terms would in fact achieve the  
23 goals of focusing the TAR universe and mitigating expense.

24 Defendants now have that data from the initial 30 Custodial File collections,  
25 which indicates that the search terms do not accomplish those intended goals given  
26 the substantial volume of documents populating the TAR universe. Defendants thus

27 \_\_\_\_\_  
28 <sup>2</sup> Defendants raised overbreadth concerns regarding Plaintiffs’ search terms with the Court  
previously. *See* Joint Mem., at 22-23, Feb. 27, 2024, Doc. 451.

1 raised their concerns with Plaintiffs, and the parties are actively conferring  
2 regarding modifications to Plaintiffs' search terms. While Defendants have not yet  
3 exhausted their conferrals with Plaintiffs on this issue, Defendants respectfully  
4 request that the Court schedule a CMC on or before May 24, 2024 for the parties to  
5 advise the Court if agreement has been reached, and if not, for resolution of this  
6 matter to ensure that ESI discovery proceeds in an efficient and cost-effective  
7 manner.

8 **i. The Parties' Conferrals to Date**

9 On April 15, 2024, during a scheduled conferral regarding ESI discovery,  
10 Defendants raised their concerns about the overwhelming volume of non-responsive  
11 documents identified in initial collections of 30 Custodial Files that hit on Plaintiffs'  
12 search terms and the corresponding expense associated with review of such volume.  
13 Defendants explained that this was just a fraction of the data for the first 30  
14 Custodians, and that their discovery vendor, Epiq, was in the process of loading  
15 more documents in addition to certain Custodial sources that were still in the process  
16 of being collected. Plaintiffs acknowledged Defendants' concerns, and agreed to  
17 confer once Defendants provided Plaintiffs with the appropriate data and proposed  
18 alternatives. Defendants advised Plaintiffs that they would provide Plaintiffs with  
19 the metrics and proposal as soon as they received the supporting data from Epiq.

20 In order to provide Plaintiffs with the most fulsome metrics and analysis of  
21 the search terms, Defendants asked Epiq to include the additional Custodial  
22 collections they were in the middle of processing. Given the volume of these  
23 collections (totaling over 11 million documents), running the necessary analytics to  
24 identify the actual universe of documents that would be subject to review required  
25 machine time that could not be accelerated. In addition, unforeseen technical  
26 issues—many of which were caused by the sheer volume of data—delayed Epiq's  
27 ability to promptly provide Defendants with the necessary information  
28 notwithstanding the urgency. Epiq therefore was not able to provide Defendants

1 (and hence, Plaintiffs) the data needed until April 30th. That afternoon, Defendants  
2 provided Plaintiffs with the data, an analysis of that data, and an alternative proposal  
3 on how to proceed. Defendants advised Plaintiffs that:

- 4 • 6,125,815 documents have been identified for TAR review *to date* for the  
5 first 30 Custodians;<sup>3</sup>
- 6 • A statistically significant 95/5 random sample of 400 documents in the TAR  
7 workflow revealed a 9.50% responsiveness rate. Stated otherwise, more than  
8 90% of the collected documents would have no bearing on Plaintiffs' claims;
- 9 • Epiq estimates that review-related expense (first-level review, privilege  
10 review and logging, and redactions being performed by over 200 contract  
11 review attorneys) will exceed \$8 million for the first 30 Custodians—a figure  
12 that is expected to double for the second 30 Custodians;<sup>4</sup>
- 13 • Epiq's experts analyzed over 267,000 Custodial documents coded by  
14 reviewers in the TAR workflow and, based on this analysis, have proposed  
15 modifications to Plaintiffs' search terms that are focused on removing the  
16 significant volume of irrelevant documents currently being pulled in by  
17 Plaintiffs' terms; and
- 18 • Applying Defendants' initial proposal reduces the volume from 6.1 million  
19 documents to 1,375,848 documents, but only reduces the cost from \$8  
20 million to approximately \$4 million for the first 30 Custodians.<sup>5</sup>

21  
22  
23 <sup>3</sup> This is the volume after suppression of document level duplicates that are being suppressed for  
24 review purposes but will be included in production if responsive. This number will increase once  
remaining collections for the first 30 Custodians are processed and added.

25 <sup>4</sup> The estimate does not include outside counsel fees associated with document review. Nor does  
26 this include the expense associated with review of Non-Custodial Sources, which is another  
significant cost component for Defendants.

27 <sup>5</sup> The reduction in review related expense is not as significant as the reduction in document volume  
28 because a greater number of documents in the universe returned by Defendants' proposal will need  
to be reviewed in the TAR workflow since it contains more responsive documents.

- 1 • The reduced cost based on Epiq’s proposed search terms remains  
2 disproportionate to the needs of this litigation and, as a result, Defendants are  
3 continuing to explore alternative forms of relief to reduce volume and  
4 expense, including proposals to reduce the number of Custodians and apply  
5 more discrete temporal limitations.

6 **ii. Defendants’ Request for Another CMC**

7 Defendants recognize that the parties need adequate time to meaningfully  
8 meet and confer to develop appropriate proposals to address these proportionality  
9 issues. Defendants also recognize that the time passed between Defendants’  
10 flagging of this development on April 15<sup>th</sup> and Epiq’s delivery of the data on April  
11 30<sup>th</sup> prevented the parties from working through any proposals prior to the  
12 submission of this Joint Memorandum. Defendants nonetheless submit that  
13 resolution of these issues must be accomplished as expeditiously as possible in order  
14 to reduce the financial and substantive burden on Defendants, to enable Defendants  
15 to meet the current substantial completion deadlines, and to allow ESI discovery to  
16 proceed in an efficient and timely manner. Accordingly, Defendants respectfully  
17 request the Court schedule a CMC on or before May 24<sup>th</sup>, and further order the  
18 parties to provide their joint or competing proposals to the Court in advance thereof.

19 **C. Disputes Regarding the Scope of Discovery**

20 The parties are productively negotiating disputes about whether certain  
21 categories of documents fall within the scope of discovery and appear to be nearing  
22 resolution. These disputes concern 1) the relevance of subject matter contained in  
23 documents from Plaintiffs’ proposed training set in the TAR universe and 2) the  
24 discoverability of certain devices and projects from Plaintiffs’ Request for  
25 Production (“RFP”) regarding Design and Manufacture No. 11.

26 On March 18<sup>th</sup>, Plaintiffs provided 2,075 documents to Defendants to  
27 consider for inclusion in the TAR training set. On April 8<sup>th</sup>, Defendants identified  
28 309 documents they believed were not responsive or otherwise inappropriate for

1 training the system. Following several conferrals, the parties resolved their  
2 disagreements over the substantial majority of those documents.

3       On April 8<sup>th</sup>, Plaintiffs served their Second Set of RFPs regarding Design and  
4 Manufacture on each Defendant. RFP No. 11 seeks the production of “all  
5 Information, communications, testing, studies (internal and external), regulatory  
6 and/or third-party communications relating to, referring to, or embodying” 44  
7 different catheters, ports, or projects. The parties promptly met and conferred over  
8 the scope of RFP No. 11 and resolved their disagreements over the majority of these  
9 projects and devices, as well as the scope of the RFP itself. Defendants’ Responses  
10 and Objections to Plaintiffs’ Second Set of RFPs are due May 8<sup>th</sup>.

11       The following non-exhaustive list identifies the general categories of documents  
12 that are the subject of the parties’ ongoing conferrals: (1) peripherally inserted  
13 central catheters (“PICCs”); (2) central venous catheters (“CVCs”); (3) ethanol  
14 locks; (4) 3CG/ECG catheter positioning technology; (5) BAS’s acquisition of Spire  
15 Corp.’s hemodialysis catheter technology; and (6) certain OUS materials. In  
16 response to Defendants’ relevance and proportionality objections, Plaintiffs have  
17 proposed limiting discovery into the non-IPC devices and technologies to  
18 documents that implicate the alleged failure modes at issue in this MDL. Defendants  
19 intend to confer with Plaintiffs over the proper definition of the alleged failure  
20 modes as well as any other necessary limitations on this discovery, and reserve all  
21 rights with respect to their objections. With respect to OUS materials, the parties are  
22 similarly working on the contours of the limited scope of that discovery.<sup>6</sup>

### 23 **III. Plaintiff Profile Forms**

#### 24 **A. Defendants’ Position**

25       CMO 10 set a deadline of May 1, 2024, for service of all cases in the Initial  
26 Plaintiff pool. *See* Doc. 115, at 1. CMOs 15 and 18 set a deadline of May 1, 2024,

27

28 <sup>6</sup> The parties agree that they will brief any disputes over these categories of discovery in advance  
of the next CMC, should any remain.

1 for the completion production of deficient PPFs identified at the fourth CMC. *See*  
2 Doc. 454, at 6-7; Doc. 525, at 4-5.

3       The parties have collectively made substantial progress to resolve the  
4 deficiencies in the PPFs. Defendants have provided Plaintiffs' Leadership with  
5 weekly charts on the status of PPFs and the parties have met regularly to discuss the  
6 PPFs and missing information. However, despite expending substantial time and  
7 money and following up beyond what is required by CMO 8, Defendants still have  
8 not received complete profile forms from all of the plaintiffs in the Initial Plaintiff  
9 Pool (as defined by CMO 10 (Doc. 115)). Defendants simply seek the information  
10 that all parties have agreed that Defendants need to evaluate the cases at this stage  
11 of the litigation. Defendants have conferred with Plaintiffs' Leadership on all of  
12 these issues. Defendants hereby address the profile forms by categories of missing  
13 information:

14                   **1. No Profile Form Served**

15       Despite the Court's orders in CMO 8, 10, 15 and 18, as of May 1, 2024,  
16 Defendants have not received PPFs from 5 plaintiffs. In addition, none of those  
17 plaintiffs created an account in MDL Centrality or made any contact with  
18 Defendants regarding the need for an extension. Pursuant to CMO 8, Defendants  
19 sent letters to each plaintiff's counsel (and copied Plaintiffs' Leadership) requesting  
20 that they serve a PPF within 21 days. None of the 5 plaintiffs responded to the letter  
21 or made any contact with Defendants. As a result, Defendants request that (even if  
22 they ultimately serve a PPF) these plaintiffs be excluded from the Initial Plaintiff  
23 Pool. Defendants respectfully submit that this is a fair sanction for failure to comply  
24 with four orders of this Court.

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Plaintiff and Member Case Number	Date of Delinquent PPF Notice
Wright, Diana 2:24-cv-00438	4/2/2024
Bennett, Patricia 2:24-cv-00660	4/26/2024
Garza, Amber 2:24-cv-00700	4/30/2024
Graham, Janice 2:24-cv-00696	4/30/2024
Palazzo, Susan (deceased) 2:24-cv-00701	4/30/2024

In addition, because more than 21 days have expired since a deficiency notice was sent to Plaintiff Diana Wright. On May 7, 2024, Counsel for Plaintiff Diana Wright sent an email stating that she is dismissing her complaint. The remaining four plaintiffs still have time within the 21 days to cure the deficiency prescribed by CMO 8, and Defendants will address those plaintiffs in the next joint submission if no PPF is served.<sup>7</sup>

## 2. Certain or all Medical Records Not Produced

All parties agree that the medical records required to be produced by CMO 8 are vital to the review and evaluation of the cases, as well as to the determination whether a particular case should be included in the PFS/DFS Group 1 that is to be selected by July 1<sup>st</sup>. *See* Doc. 115, at 2. However, Defendants recognize that there can be delays in obtaining records. In the cases in the chart below, plaintiffs did not produce all or some of the medical records required with the PPF and have not

<sup>7</sup> Defendants note that as of the filing of this Joint Memorandum, 11 Plaintiffs have failed to provide complete product identification (product code and lot number) as required in CMO 8, and an additional eight Plaintiffs have not provided a Lot Number for the device or devices alleged to be at issue.

1 responded to Defendants' requests that they produce them. Defendants  
 2 acknowledge that in some instances the plaintiffs have produced multiple medical  
 3 records, and Defendants have reviewed those records to determine whether they  
 4 include the records required by the PPF.

Plaintiff and Member Case Number	Date of Deficiency Notice
Hawkins, Vera 2:23-cv-02020-DGC	1/4/2024
Eckert, Rebecca 2:24-cv-00139-DGC	3/26/2024* *LTR asking for supplementation based on review of medical records
Shelby, Burgandy 2:24-cv-00359	4/1/2024
Whitby, Latwon 2:24-cv-00482-DGC	4/12/2024
Gay, Paisami 2:23-cv-1755-DGC	1/4/2024
Kessler, Paul 2:23-cv-1696-DGC	1/4/2024
Catanzaro, August 2:24-cv-00292-DGC	3/29/2024

23  
 24 For each of these plaintiffs, Defendants request that the Court enter an order  
 25 compelling each plaintiff in this category do one of the following on or before May  
 26 24, 2024:

- 27 a. Produce the missing records;
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- b. Produce a certification from the medical provider where the treatment occurred stating that no records exist; or
- c. Produce a declaration from plaintiff’s counsel of record stating that the records were requested before the PPF served and the date the request was made and stating that the records have not been received

**Inconsistencies in Information, Unclear Claims or Incomplete Medical Records Produced**

In reviewing the PPFs and medical records produced, Defendants have identified some inconsistencies between the information in the PPF and the medical records and, in other instances, incomplete information, all of which is important to Defendants’ evaluation of the cases, and all of which is known to the plaintiff. For example, some plaintiffs have produced medical records identifying a second port that was implanted but did not respond in the PPF indicating whether they are making a claim for that second port. Defendants have raised these inconsistencies, and many plaintiffs have responded and resolved the issues. However, the plaintiffs in the chart below (or attached) have not responded to Defendants’ inquiries.

Plaintiff and Member Case Number	Date of Deficiency Notice
Kessler, Paul 2:23-cv-1696-DGC	1/4/2024
Catanzaro, August 2:24-cv-00292-DGC	3/29/2024
Dragon, Melissa 2:24-cv-00480	4/9/2024
Gay, Paisami 2:23-cv-1755-DGC	1/4/2024

Plaintiff and Member Case Number	Date of Deficiency Notice
Amos, Larissa 2:24-cv-00290-DGC	3/22/2024
Nicosia, Danielle 2:23-cv-2122-DGC	1/23/2024
Prescott, Jennifer 2:23-cv-2729-DGC	2/21/2024

While Defendants acknowledge that the parties did not contemplate these inconsistencies occurring and CMO 8 does not specifically address this issue, so that Defendants have complete and accurate information to evaluate the cases, they request that the Court enter an order compelling that the plaintiffs in the chart respond to Defendants' inquiries on or before May 24, 2024.

#### **PPFs in the 15 day Cure Period**

Many cases were filed in the last few days before the April 1, 2024, deadline so as to be included in the Initial Plaintiff Pool. As a result, Defendants received many PPFs in the few days leading to and including the May 1<sup>st</sup> deadline established by CMO 10. So as not to delay the process, Defendants worked diligently to review the PPFs and correspond with the plaintiffs. Defendants served all of the deficiency notices by May 6, 2024. Unfortunately, there are currently 31 cases (17% of the Initial Plaintiff Pool) that have deficient PPFs (many with very little information provided) that are still in the 15-day cure period allowed by CMO 8.

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<b>Plaintiff and Member Case Number</b>	<b>Date of Deficiency Notice</b>
Edgell, Joshua 2:24-cv-00531-DGC	4/23/2024
McLaurin, Erin 2:24-cv-00487-DGC	4/23/2024
DeStefano, Christine (deceased) 2:24-cv-00588-DGC	4/23/2024
Galvan, Marisella 2:24-cv-00578-DGC	4/23/2024
Holzman, Karen 2:24-cv-00590	4/24/2024
Jackson, Jeffrey 2:24-cv-00599	4/24/2024
Latham, Lindy 2:24-cv-00586	4/24/2024
Stack, Gary 2:24-cv-00619-DGC	4/26/2024
Toranzo, Giny 2:24-cv-00577-DGC	4/26/2024
Traylor, Donna 2:24-cv-00621-DGC	4/26/2024
Wilson, Piper 2:24-cv-00425	4/26/2024

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<b>Plaintiff and Member Case Number</b>	<b>Date of Deficiency Notice</b>
Chapman, Tina 2:24-cv-00651	4/29/2024
Peterson, George 2:24-cv-00678	4/29/2024
Young, Gloria 2:24-cv-00679	4/29/2024
Mobley, Cynthia 2:24-cv-00677	4/29/2024
Farmer-Garmon 2:24-cv-00620	5/1/2024
Cunningham, Jeanette 2:24-cv-00664-DGC	5/1/2024
Taylor, Sabrina 2:24-cv-00704	5/1/2024
Woods, Marilyn 2:24-cv-00615	5/1/2024
Terry, Misty 2:24-cv-00686	5/1/2024
Morgan, Annalisa 2:24-cv-00627	N/A
Gallaher, Kathy 2:24-cv-00723	5/2/2024

Plaintiff and Member Case Number	Date of Deficiency Notice
Fogle, A (minor) 2:24-cv-00720	5/2/2024
Holdridge, Donna 2:24-cv-00719	5/2/2024
Myers, Rebecca 2:24-cv-00718	5/2/2024
Miller, Linda 2:24-cv-00724	5/2/2024
Verdugo, Shirley 2:24-cv-00721	5/2/2024
Johnson, Linda 2:24-cv-00687	5/2/2024
Holcomb, Angela (deceased) 2:24-cv-00707	5/3/2024
Perry, Anetria 2:24-cv-00722	5/3/2024
Hall, Vicky 2:24-cv-00716	5/3/2023
LaPlante, Angel 2:24-cv-00418	5/6/2023

Plaintiffs' Leadership is aware of each of the cases and has indicated that they are contacting the attorneys involved. Because the July 1<sup>st</sup> deadline to select the PFS/DFS Group 1 is fast approaching, Defendants request that the Court order

1 the plaintiffs who are still within the 15 day cure period to serve full and complete  
2 PPFs and, if applicable, include any missing medical records (or certification of no  
3 records or declaration that they have been requested and not receive) and resolve  
4 any uncertainties or inconsistencies, on or before May 24, 2024.

5 **d. Port Body Claims**

6 Amended CMO 8 (Doc. 477) requires that plaintiffs who served their PPFs  
7 after March 15<sup>th</sup> use the new PPF that included information about claims involving  
8 the port body. It also required plaintiffs who had served their PPF before March 15  
9 to amend it by May 1, 2024, if they are asserting a claim relating to the port body  
10 (and many did). Defendants have noticed two issues that leave uncertainty as to  
11 whether port body claims are being asserted: (1) some plaintiffs who used the post-  
12 March 15 version of the PPF left the page blank regarding port bodies (although it  
13 contains a box to check to say no claim is being asserted), and (2) in discussions,  
14 Plaintiffs' Leadership has emphasized that each plaintiff has a duty to supplement  
15 under Rule 26 – implying that a plaintiff could assert a port body claim after the  
16 Plaintiff Initial Pool is selected. The purpose of the PPF process is for all parties to  
17 know what claims are being asserted by each plaintiff. Defendants believe that if  
18 plaintiffs have collected the information required by the PPF they should know if  
19 they are asserting a port body claim, and Defendants should not be faced with  
20 additional claims being added after the Initial Plaintiff Pool is selected. Defendants  
21 request that the Court enter an order setting a deadline of May 24, 2024, for any  
22 plaintiff who filed a SFC on or before April 1, 2024, to amend their PPF and assert  
23 a port body claim and ruling that the port body claim will be excluded for any  
24 plaintiff who fails to meet that deadline.

25 **B. Plaintiffs' Position**

26 Plaintiffs agree that the parties have made substantial progress resolving  
27 Defendants' claims of deficiencies in the PPFs and records served by plaintiffs in  
28 this MDL. Plaintiffs also agree that the parties have spent significant time and

1 resources over the intervening weeks to investigate and address a wide variety of  
2 issues which Defendants have raised and characterized as “deficiencies” within the  
3 purview of CMO No. 8. The Plaintiffs’ efforts in this respect have involved  
4 substantial interaction and cooperation between the PLC and individual plaintiffs’  
5 counsel, including (1) numerous individual conferences with plaintiffs’ counsel, (2)  
6 review and analysis of PPF submissions and accompanying medical records  
7 submitted through the MDL Centrality platform, and (3) town hall-style meetings  
8 with plaintiffs’ counsel regarding use of the MDL Centrality platform; best practices  
9 for retrieval, review and compilation of supporting medical records; and guidelines  
10 for compliance with CMO No. 8, disclosure supplantation, etc. As a result of these  
11 efforts, coupled with the cooperation with counsel for the Defendants, a great many  
12 of the existing deficiencies have been cured, and PPF deficiencies that are identified  
13 have been addressed and, in many cases, cured more quickly and efficiently.

14 The parties’ efforts have also been helpful in identifying areas of agreement  
15 and dispute, respectively, regarding the PPF disclosures more generally. These  
16 categories of deficiencies and alleged deficiencies are addressed in turn below.

#### 17 **Cases in Which a PPF has not been Served**

18 According to Defendants, there are five cases filed on or before April 1, 2024  
19 in which a PPF has yet to be served. Discussions with counsel for the plaintiffs at  
20 issue in these cases indicate that at least some of these issues arise from difficulties  
21 contacting plaintiffs that have arisen relatively recently and that the efforts to re-  
22 establish communication and serve the completed PPFs are ongoing. In one or more  
23 of the subject cases, counsel intends to effect voluntarily dismissal pursuant to Fed.  
24 R. Civ. P. to avoid the time and expense of motion practice.

25 Although CMO No. 10 does not explicitly call for the exclusion from  
26 PFS/DFS Group 1 those cases where a PPF has not been served by May 1, 2024,  
27 Plaintiffs recognize the underlying purposes of CMO No. 8 as it relates to bellwether  
28 selection in this MDL. In light of the upcoming selection exchange date set forth in

1 CMO No. 10 (Dkt. No. 115 at p. 2), Plaintiffs will not oppose the exclusion of the  
 2 five cases referenced herein from the selection process for PFS/DFS Group 1.

3 **Cases in which Defendants Claim That no Records have been Produced**

4 Although Defendants appear to claim that there is a large category of cases  
 5 in which the medical records required by CMO No. 8 are “not produced,” the cases  
 6 in this category are more typically marked by having produced medical records  
 7 which raise one or more issues which Defendants seek to address through the  
 8 deficiency process outlined in CMO No. 8. Each case in this category is unique  
 9 with respect to the records produced and the issue(s) raised by Defendants, but the  
 10 current status of the PPF disclosure process for the cases identified by Defendants  
 11 is reflected below:

Plaintiff and Member Case Number	Date of Deficiency Notice	Curative Records Submissions
Hawkins, Vera 2:23-cv-02020-DGC	1/4/2024	1/9/2024 1/17/2024 2/19/2024 5/6/2024
Eckert, Rebecca 2:24-cv-00139-DGC	3/26/2024* *LTR asking for supplementation based on review of medical records	
Shelby, Burgandy 2:24-cv-00359	4/1/2024	4/12/2024 4/15/2024
Whitby, Latwon 2:24-cv-00482-DGC	4/12/2024	Records produced 4/5/2024

Plaintiff and Member Case Number	Date of Deficiency Notice	Curative Records Submissions
Gay, Paisami 2:23-cv-1755-DGC	1/4/2024	1/17/2024 2/9/2024 2/19/2024 3/25/2024
Kessler, Paul 2:23-cv-1696-DGC	1/4/2024	1/9/2024 1/18/2024 3/26/2024
Catanzaro, August 2:24-cv-00292-DGC	3/29/2024	Records produced 3/13/2024

In many cases, plaintiffs in the above-referenced actions have produced more records than those which are required by CMO 8 in order to address the issues raised by Defendants. Plaintiffs take no position as to whether the records produced in the curative submissions are required by CMO 8 or whether they are produced in response to a valid deficiency. Rather, the initial PPF disclosures are diverse in the issues they raise for Defendants, and the curative submissions are equally diverse.

As to the remedies that Defendants request, Plaintiffs believe that the language of CMO No. 8 and the PPF are clear, as are the remedies outlined therein. However, Plaintiffs acknowledge that the approaching deadline for selection of cases for PFS/DFS Group 1 underlines the importance of compliance with CMO No. 8 by all parties. To that end, Plaintiffs will not oppose an added process which would assure that the purposes of the bellwether selection process are being served by the parties' disclosures and help define the contours of CMO 8 compliance. It is Plaintiffs' position that any action required by the plaintiffs identified by Defendants on the proposed May 24 deadline should be limited to:

- a. Producing missing records required by CMO No. 8;

1 b. Stating that the plaintiff takes the position that their PPF disclosures are  
2 currently compliant with CMO No. 8; or

3 c. Providing an affirmative communication to Defense counsel stating that  
4 any required records have been requested but have not been received.  
5

6 **Cases Where Defendants Claim Inconsistencies in Information,**  
7 **Unclear Claims or Incomplete Medical Records Produced**

8 As a threshold matter, Plaintiffs dispute the claim that CMO 8 generally  
9 requires Plaintiffs to provide information outside of that required by CMO 8.  
10 However, the limited number of cases referenced by Defendants on this issue and  
11 the importance of defining the universe of claims in the bellwether pool do counsel  
12 toward resolution of valid inquiries arising from ambiguities in plaintiffs'  
13 disclosures, where they exist. Plaintiffs will not oppose an added requirement of  
14 the identified plaintiffs to provide a response to Defendants' inquiries.  
15

16 **Port Body Claims**

17 Contrary to Defendants' suggestions, a "port body claim" is not a monolithic  
18 case theory that is readily discernible to every plaintiff, possibly with the exception  
19 of port erosion through the tissue of the implantation site. Rather, as is set forth in  
20 the Amended Master Complaint, the alleged defects in the port body may manifest  
21 in very different clinical complications which may or may not be recorded in a  
22 medical record. For example, it is not within the normal course of diagnosis and  
23 treatment for a treating physician to make a determination whether an infectious  
24 biofilm initially formed in a port reservoir or a catheter. Further, corporate  
25 discovery is still in its early stages. The role(s) of the particular defects of the port  
26 bodies in precipitating the injuries set forth in the Master Complaint cannot be  
27 determined without additional discovery, and plaintiffs would be prejudiced if  
28

1 multiple theories for defect and causation are foreclosed prior to the close of  
2 discovery.

3  
4 Dated: May 7, 2024

Respectfully submitted,

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