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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard Implanted Port Catheter Products Liability Litigation	MDL No. 3081 **JOINT MEMORANDUM RE ISSUES TO BE ADDRESSED AT MARCH 1, 2024 CASE MANAGEMENT CONFERENCE** (Applies to All Actions)

Pursuant to Case Management Order No. 13 ("CMO 13"), the parties submit the following Joint Memorandum in advance of the Case Management Conference ("CMC") scheduled for March 1, 2024. *See* Doc. 298 at 2.

I. Case Statistics & Overview

a. MDL Filings

There are presently 113 cases pending in the MDL. Forty-five plaintiffs have directly filed in the MDL pursuant to CMO No. 7. Two plaintiffs filed in the District of Arizona prior to the entry of CMO No. 7, whose cases were included in the MDL by this Court. The Judicial Panel on Multidistrict Litigation ("JPML" or the "Panel") has transferred sixty-six cases to the MDL, including three cases most recently on

February 5, 2024 pursuant to its Order denying Defendants' Motion to Vacate Conditional Transfer Orders 10 and 11. *See* Doc. 366.

i. Plaintiffs' Position

According to MDL Centrality, which collects information from Plaintiff Profile Forms, the cases pending in this MDL are fairly diverse in terms of the Bard IPCs at issue, covering at least 15 of the 25 Bard IPCs identified in the Master Complaint. That number could be higher, as some Plaintiffs await medical records to confirm the Bard IPC used in their cases. The cases also appear diverse as to injury: 44 plaintiffs suffered catheter-related infection, 19 thrombosis, 9 fracture without migration, 27 fracture with migration, and the rest have "other" injuries.

Moreover, Plaintiffs' counsel continue to evaluate potential cases, and they expect more cases to be filed in the near future.

ii. Defendants' Position

Since its formation, Defendants and the Court have accepted Plaintiffs' representations that this MDL would quickly grow to thousands of cases, as well as implicate the more than 200 product codes identified in Exhibit A to the Master Complaint (the "Product Codes").[1] As of February 27, 2024, however, there are less than 120 cases in this MDL. In the six months since the MDL was formed, less than 70 new cases have been filed. Since the last CMC on January 8, 2024, only about a dozen new cases have been filed. With respect to the Product Codes at issue, only about fifty of the 218 identified in the Master Complaint have been implicated. More than one-third of all cases involve one of the five most common Product Codes. In

[1] In their Motion to Transfer Actions pursuant to 28 U.S.C. § 1407 filed with the JPML, Plaintiffs advised the Panel that this MDL "could feasibly culminate in the filing of related actions in the tens of thousands." Mot. to Transfer Actions, at 2 (J.P.M.L. May 24, 2023). At the initial CMC more than five months ago, Plaintiffs reiterated their contention that "the MDL will ultimately grow past 10,000 cases." Sept. 18, 2023 CMC, Tr. 6:2-23-24. Plaintiffs further contended, by way of a "conservative estimate," that the proposed leadership group had "approximately 2000 unfiled cases" at that time. *Id.* 53:2-6. At the most recent CMC, Plaintiffs attested that the number of cases will grow to "[m]inimally 2,000 and probably most likely above 5,000." Jan. 8, 2024 CMC, Tr. 4:19-20.

other words, more than seventy-five percent of the devices identified in the Master Complaint have no corresponding filings to date.

This MDL has reached a critical juncture and these statistical realities should inform the scope of discovery and proceedings moving forward.

b. Reconsideration of MDL Scope

i. Defendants' Position

1. Scope of Discovery

Defendants have responded to Plaintiffs' extraordinarily broad discovery requests, are engaged in the collection and production of millions of pages of documents, and are continuing to confer with Plaintiffs on what discovery is relevant to the parties' claims and defenses and is proportional to the needs of this MDL. The already-high costs and burdens of discovery on Defendants are increasing, and they will grow considerably more as discovery continues and the parties begin depositions. To date, Defendants have allowed Plaintiffs' representations regarding the anticipated size of this MDL to inform their view of what discovery is proportional under Rule 26. Defendants can no longer afford to do so. Given the low number of cases and the fact that the filed actions implicate only a fraction of the 200-plus Product Codes identified in the Master Complaint, the parties should significantly scale back the scope of discovery.

Defendants expressed a willingness to provide certain materials and Custodial productions—beyond the substantial discovery they have already provided—based on Plaintiffs' representations that this MDL would grow quickly to thousands of cases. Defendants have already reproduced millions of pages of documents that were produced in the port patent litigation and *Cruz* matter. The patent litigation reproduction includes documents from over thirty-five Custodial and Non-Custodial Sources that were identified using incredibly broad search terms such as "port," "ports," and "powerport." The custodians produced in the patent

litigation are some of the same individuals identified by Defendants. Plaintiffs already have in their possession extensive documents spanning back to the 1990s and covering a wide array of subjects, including documents relating to design, quality, manufacturing, and marketing and sales.

Given the volume of documents produced by Defendants to date; the extensive efforts undertaken to respond, identify, and cull additional potentially relevant documents; the low number of pending cases; and the prevalent deficiencies in the cases Plaintiffs have filed, Defendants believe reconsideration of the scope of their offered discovery is warranted. Accordingly, Defendants respectfully request this Court order that:

(1) Discovery on general liability be limited to twenty-five of the forty-one Custodians that Defendants proposed to Plaintiffs on January 29, 2024,[2] and the reasonably tailored search terms Defendants provided to Plaintiffs on February 9, 2024.[3] *See In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices and Antitrust Litig.*, No. 17-MD-2785, 2018 WL 1440923, at *2 (D. Kan. Mar. 15, 2018) ("[T]he party who will be responding to discovery requests is entitled to select the custodians it deems most likely to possess responsive information and to search the files of those individuals. . . . [U]nless the party's choice is manifestly unreasonable or the requesting party demonstrates that the resulting production is deficient, the court should not dictate the designation of ESI custodians." (citations and quotation marks omitted)); CMO No. 12, Doc. 117, at 9 (stating that the Producing Party "shall provide the Requesting Party with the searches it proposes running

[2] Should Plaintiffs identify individuals of interest beyond the forty-one proposed Custodians, Defendants are willing to meet and confer with Plaintiffs to determine which twenty-five Custodians Defendants will collect custodial files for review and production.

[3] Defendants have reserved the right to modify any search terms that return a disproportionate volume of hits and/or high volume of false hits. Defendants intend to provide Plaintiffs with a separate set of proposed Custodians and search terms related to Plaintiffs' First Set of Requests for Production regarding Corporate Liability, which were served several weeks after Plaintiffs' initial six sets of requests for production regarding general liability issues.

across its relevant sources" and that the Requesting Party may only seek to "supplement[]" the proposal "with additional narrowly tailored and proportional keyword or Boolean searches to identify responsive Documents or ESI"); and

(2) Plaintiffs be required to seek leave of Court before serving additional Requests for Production ("RFP") in light of the substantial amount of discovery that has been produced and will be produced, and given the low number of cases and concentration of devices in just a few Product Codes. *See In re Dealer Mgt. Sys. Antitrust Litig.*, No. 18-CV-864, 2018 WL 11260473, at *3 (N.D. Ill. Aug. 14, 2018) ("[P]roportionality focuses on the marginal utility of the discovery sought and in every case—even an MDL—the parties' appetite for further discovery eventually is curbed by the law of diminishing marginal returns." (citations and quotation marks omitted)).

Setting these limitations on discovery is well within this Court's discretion to avoid an undue burden on Defendants. *See Hamer v. LivaNova Deutschland GmbH*, 994 F.3d 173, 178 (3d Cir. 2021) ("[I]n the MDL context, . . . district courts must be granted significant latitude to manage their dockets and to mitigate potential burdens on the defendants and court."); *In re Zetia (Ezetimibe) Antitrust Litig.*, 342 F.R.D. 388, 397 (E.D. Va. 2022) (explaining that the discretionary authority of a court overseeing an MDL is "at its peak'" when it comes to "limit[ing] and manag[ing] discovery").

Plaintiffs' arguments against Defendants' proposed reconsideration on the scope of discovery are without merit. As for Plaintiffs' claimed "surprise," Defendants first note that CMO No. 13 requires the parties to raise any concerns or disagreements regarding "the scope of general liability discovery" in this Joint Memorandum so that those issues can be "addressed and resolved at the next case management conference." CMO No. 13, at 1, Doc. 298. Next, contrary to Plaintiff's repeated contentions, Defendants have raised their concerns regarding the disparity

between the number of filed cases and prior predictions as it relates to the scope of discovery during multiple conferrals.[4] Plaintiffs' contention that this request is "unripe" does not account for the facts that (1) global issues related to the scope of discovery such as the number of custodians and search terms need to be resolved now so that Defendants can move forward with the collection and production of Custodial Files, and so the parties can meet any substantial completion deadline entered by the Court and complete fact discovery by January 2025; and (2) in the more than six months since this MDL was formed, there has only been, on average, approximately *ten cases* filed per month.

As for the burden of requiring a significant number of Custodians, every additional Custodial File imposes costs on Defendants to collect, review, and produce, and has diminishing returns in terms of the production of non-unique documents not captured by other Custodians and Non-Custodial Sources. It is well within this Court's discretion to impose a limitation on the number of Custodians. If Plaintiffs believe that Defendants' document production is deficient, Plaintiffs may seek leave to compel the designation of particular Custodians that would provide unique relevant information that has not already been obtained. *See Fort Worth Employees' Retirement Fund v. J.P. Morgan Chase & Co.*, 297 F.R.D. 99, 107 (S.D.N.Y. 2013). As for Plaintiffs' cited case examples, the number of

[4] In a drafted summary of the conferral held on February 2nd, Plaintiffs noted that, "[i]n thinking about discovery responses, Defendants expressed a concern over the small number of cases filed to date. They said it affects their proportionality considerations." Email from R. Phillips, Esq. to Makenzie Windfelder, Esq., Feb. 2, 2024, at 2:45 p.m. EST. Defendants' response to Plaintiffs' deficiency letter dated February 5, 2024 acknowledged that the low number of cases were concentrated in a small percentage of Product Codes. Defendants again raised the lack of case filings during the parties' February 16th conferral, and noted that Defendants' proposed forty-one custodians was based on Plaintiffs' predictions regarding case counts. Plaintiffs responded during that conferral that they believed more custodians than the number proposed by Defendants was appropriate. In Plaintiffs' summary of the parties' February 22nd conferrals that day, Plaintiffs acknowledged that Defendants again raised proportionality concerns related to the low number of case filings, and that Defendants intended to push back on the number of custodians. As they have in the past, the parties simultaneously exchanged drafts of the Joint Memorandum in advance of the deadline to submit to allow the parties to crystallize their positions and allow for meaningful conferrals. In short, Plaintiffs' "surprise" is not supported by the record.

custodians in any given litigation depends on its unique facts. The driving considerations here—the low number of cases pending in this MDL, the reproduction of the *Cruz* production and port patent production from over thirty-five Custodians and Non-Custodial Sources, and the substantial discovery that Defendants have agreed to produce from Non-Custodial Sources—merit the imposition of a reasonable cap on the number of Custodians.

Plaintiffs' arguments against Defendants' proposal on requiring leave to serve additional RFPs should likewise be rejected. Defendants are not seeking "ERISA discovery limitations," but just ask that this Court exercise its considerable discretion in managing an MDL to limit the burden on Defendants where, as here, they have responded to essentially open-ended RFPs on a broad array of topics.

Based on the posture of this MDL,[5] Defendants respectfully submit that this Court should adopt Defendants' proposals.

2. Bellwether Selection

The case statistics to date do not support Plaintiffs' contentions that this MDL will grow to the thousands of cases that Plaintiffs predicted at the outset of the litigation. That said, the disparity between the number of filed cases and Plaintiffs' stated estimates raises legitimate concerns regarding the makeup of the Initial Plaintiff Pool. The Initial Plaintiff Pool for the bellwether process closes in about one month, at which time the parties will begin to work up representative cases for trial. Even if Plaintiffs' most conservative estimate is accepted as true (2,000 cases), the parties will be selecting bellwether plaintiffs from cases that equate to less than ten percent of the final numbers.

Given this disparity between the filed cases to date and Plaintiff's estimates, Defendants respectfully submit that "the Court must be careful to avoid distortion

[5] A fulsome report on the status of common-issue discovery can be found *infra* in Section II. Therein, Defendants address Plaintiffs' contentions regarding Defendants' list of individuals with relevant information in response to Interrogatory No. 2; the parties' conferrals over custodians and search terms; and Defendants' productions to date.

of the bellwether process—whether intentional or not." *In re Marriott Intl., Inc., Customer Data Sec. Breach Litig.*, No. 19-MD-2879, 2021 WL 3883265, at *3 (D. Md. Aug. 31, 2021). Therefore, if there is a significant influx of new cases after the Initial Plaintiff Pool deadline of April 1, 2024, Defendants propose that this Court consider amending CMO No. 10 to ensure that the bellwether cases are truly representative of the overall litigation. *See* Doc. 118, Nov. 16, 2023 CMC Tr. 33:10-21 (expressing concern regarding attempts to "manipulate the bellwether pool" and reiterating that the goal of the process is to "find representative cases"); Duke Mass Tort Conference (Second), Best Practice 1E(iv), at 26 ("The transferee judge should adopt rules that will minimize the risk that parties will attempt to 'game' the bellwether trial-selection process to result in test trials of cases that are not representative of the entire case pool.").

ii. Plaintiffs' Position

1. Scope of Discovery

Defendants surprised Plaintiffs by using this joint memorandum to challenge the scope of discovery. The parties have never met and conferred on the issue. Defendants argue that the 100+ cases currently filed are insignificant, that Plaintiffs' representations about the number of cases cannot be trusted, that Defendants have expended much effort and produced millions of pages of information, and that, accordingly, discovery should be drastically curtailed. Each of those premises is suspect, as discussed below. Moreover, Defendants cite no real evidence of burden and never met and conferred with Plaintiffs regarding any supposed burden. Defendants seek to limit the number of custodians to 25, to block any new written discovery, and to be relieved of their commitments under the ESI Protocol.

In sum, Defendants' proposals to limit discovery are unripe and, even if they were not, the proposals are as needlessly extreme as their previous proposal to this Court that it should apply ERISA discovery limitations and require Plaintiffs to seek leave before serving written discovery. Discovery should proceed normally.

First, this MDL is young, and the individual case numbers are expected to grow. Plaintiffs have predicted growth based on scientific literature and have even shared the numbers represented by their own dockets of cases. The fact that more cases have not yet been filed is unsurprising given that 1) there has been no statute-triggering event, like a recall, that would force early filing; 2) Defendants will certainly object if Plaintiffs file cases without vetting, which takes significant time and effort; and 3) the deadline to file for the bellwether pool is in the future.

Even at the MDL's current size, the discovery that Plaintiffs have requested is and will be reasonable – "will be" because Defendants do not yet know Plaintiffs' position regarding the appropriate number of custodians, as Defendants took 90 days to respond to a basic interrogatory seeking the identity of individuals with relevant information. A good example proving that Defendants' requested limitation is abnormal is the Tepezza MDL: ~75 cases filed, 1 product, 1 defendant, 65 custodians ordered. *In Re Tepezza Marketing, Sales Practices, and Products Liability Litigation*, MDL 3079, No. 1:23-cv-03568, Dkt. 78 (N.D. Ill. December, 4). At the high end, Plaintiffs have seen a product case where 850 custodial and non-custodial sources were collected, and a more consistent range appears to be 55-80. *In re Ethicon Physiomesh Flexible Composite Hernia Mesh Prod. Liab. Litig.*, No. CV 1:17-MD-02782-RWS, 2022 WL 17687425, at *3 (N.D. Ga. Nov. 14, 2022) ("Over the course of this MDL, Defendants produced 4,008,567 documents from 846 different custodians or non-custodial sources."); *e.g.*, *In re Biomet M2a Magnum Hip Implant Prod. Liab. Litig.*, No. 3:12-MD-2391, 2018 WL 7683307, at *3 (N.D. Ind. Sept. 6, 2018); *In re Abilify (Aripiprazole) Prod. Liab. Litig.*, No. 3:16-MD-2734, 2017 WL 4399198, at *7 (N.D. Fla. Sept. 29, 2017); *In re Seroquel Prod. Liab. Litig.*, No. MDL 1769, 2007 WL 219989, at *2 (M.D. Fla. Jan. 26, 2007). Defendants themselves offered 40+ custodians to begin with. Similarly, although the specifics of the MDL obviously matter, this Court has written in the past that a limit of 300 hours of depositions, amounting to about 42 seven-hour

depositions, might be reasonable. Hon. Campbell, David G., *Advice to a New MDL Judge on Discovery Management*, UMKC Law Review, June 2021, at 3. From that, one would infer a *minimum* of 42 custodians. As of the date Plaintiff is writing, Defendants have pointed to no better authority.

In support of Defendants' position regarding custodians and search terms, Defendants (incompletely) cite only *In re EpiPen* for the proposition that "the party who will be responding to discovery requests is entitled to select the custodians . . . ." In fact, the more-complete *In re EpiPen* quote states: "[**A]bsent agreement among the parties,** the party who will be responding to discovery requests is entitled to select the custodians . . . ."

There is an agreement in this case, the ESI Protocol, and it says that "[t]he Parties *shall* confer regarding the identification and collection of sources of relevant documents and ESI, including the sources and scope of information, Documents, ESI, and other material to be produced by . . . Defendants' Custodians . . . ." CMO 12, ESI Protocol at 5 (emphasis added). Because Defendants only seven days ago provided Plaintiffs with a list of individuals with relevant information, the parties have not yet had that opportunity to confer. Even absent agreement, Plaintiffs would be entitled to supplement Defendants' custodian proposal by a showing of good cause, and good faith negotiations should be able to eliminate that needless work for all parties and for the Court.

With respect to search terms, Defendants agreed to an "iterative and collaborative" process, where the parties would meet and confer to arrive at reasonable and proportionate additional keywords (individual words) or Boolean (individual words + limiting modifier) search terms. The way to arrive at those additional search terms is by collecting data using a hit report, which Defendants are *obligated* by the ESI Protocol to run if they consider a proposed term overbroad. *Id.* at 10. Nevertheless, Defendants refuse to run a hit report, even though they admit there is no burden and, to quote them, "it does not hurt." *Id.* at 9-10 (emphasis

added). The parties have had one meet and confer, continue to try to work through this hit-report issue, and they should be nowhere near actual impasse. In support of the agreed-upon iterative process, Defendants should not be allowed to ignore the ESI Protocol and force their own search terms.

As to Defendants' millions of pages of production, the vast majority of what has been produced is a re-production. Defendants re-produced around 650,000 documents from the AngioDynamics patent litigation. Defendants re-produced around 6,300 documents from the earlier *Cruz* port case. Defendants re-produced 48 documents, consisting of four prior deposition transcripts and exhibits. Defendants also produced overlays to correct mistakes in those productions.

As of February 23, Defendants had produced fewer than 5,000 documents that are new production: 4,300 marketing documents, around 400 regulatory documents, and around 20 documents produced in advance of the ESI Infrastructure deposition.

As to what remains to be collected, *neither party yet knows.* Plaintiffs have asked for minimal, reasonable additions to non-custodial sources, and Defendants have yet to object. Plaintiffs also thought that the parties were on track to reasonably negotiate the number of custodians, until being surprised by this joint memo. Once agreed custodial sources are collected, the parties will need to negotiate and apply search terms to narrow the production. The number of documents to be collected, reviewed, and produced *cannot* be known before that. At this point in time, a burden argument is not only premature, it is not logical.

With respect to written discovery limitations, Defendants essentially re-raise their argument that extreme, ERISA discovery limitations should apply, forcing Plaintiffs to seek leave before serving new written discovery of any kind. Plaintiffs have served two interrogatories, 68 requests for production on general liability, and 21 requests for production on successor liability. That is simply not unreasonable in a case of this magnitude, and Defendants already know Plaintiffs' intent to front-

load discovery so that the parties can reasonably negotiate substantial completion. Any issue with written discovery is purely hypothetical.

Indeed, Defendants' request to severely restrict discovery amounts to an impermissible discovery motion or impermissible, preemptive motion for protection. Dkt. 42; *e.g. Price v. Sims*, No. 221CV01438CDSDJA, 2023 WL 6539784, at *2 (D. Nev. Sept. 22, 2023) ("Plaintiff is seeking a preemptive protective order in case Defendant propounds a request that Plaintiff finds burdensome. Because Plaintiff has not made a particularized showing, the Court denies his motion for protective order."); *Cline v. Parker Indus., Inc*., No. 2:21-CV-00635, 2022 WL 1606519, at *2-3 (D. Utah May 20, 2022); *In re Broiler Chicken Antitrust Litig*., No. 16 C 8637, 2018 WL 3586183, at *10 (N.D. Ill. July 26, 2018); *Am. Charities for Reasonable Fundraising Regul., Inc. v. O'Bannon*, No. 2:08-CV-00875, 2013 WL 6008302, at *2 (D. Utah Nov. 13, 2013). Defendants have also violated their meet and confer obligations under Federal Rule 26(c), Local Rule 7.2, and the ESI Protocol, and the Court should deal with that accordingly. Defendants' request for relief should be denied.

To the extent the Court is interested, a more detailed account of the parties' interactions is included in the below section entitled Status of Common-Issue Discovery.

2. Bellwether Selection

The Court entered CMO No. 10 on November 22, 2023, setting forth the process for selecting and conducting discovery in bellwether cases to be set for trial in this MDL (Dkt. No. 115). Currently, there are approximately 115 cases pending in this MDL which implicate 15 of the 25 products identified in the Master Complaint. As some Plaintiffs continue to gather medical records to obtain specific model numbers and lot numbers at issue in a subset of cases, the number of the Defendants' products at issue in pending cases may increase in the foreseeable future. Additionally, the injuries alleged by Plaintiffs with pending cases include

all of the principal injury modes referenced in the Master Complaint. Although Plaintiffs continue to expect the number of pending cases to grow, the Initial Plaintiff Pool will be large and sufficiently diverse to allow the parties to select bellwether cases which are representative of the products at issue and the typical injuries for plaintiffs with pending cases as well as future-filed cases.

It is the Plaintiffs' position that the process set forth in CMO No. 10, coupled with the expected addition of case filings prior to April 1, 2024, will result in an Initial Plaintiff Pool that will permit representative selections that fulfill the purposes of the Bellwether Selection protocol ordered by the Court.

c. State Court Actions

There are presently nineteen cases pending in the Superior Court of New Jersey: five in-state plaintiffs and fourteen out-of-state plaintiffs. On September 28, 2023, the New Jersey State Court Liaison filed a Request for Multicounty Litigation Designation of cases alleging substantially the same claims as those made in this MDL ("MCL Application"). On January 29, 2024, the New Jersey Supreme Court denied the MCL Application based "on the limited number of cases at present." Notice to the Bar, *Denial of Appl. for Multicounty Litig. Designation of N.J. State Court Cases Involving Bard Implanted Port Catheter Prods.* (Jan. 29, 2024). At present, the parties are not aware of any related cases pending in Arizona state court.

The parties' positions regarding the status of the state court actions are set forth below.

i. Defendants' Position

New Jersey State Court Liaison Counsel has filed at least four cases in New Jersey state court by nonresidents since the denial of the MCL Application. Defendants will oppose any renewed MCL Application in the event one is filed. The filing of complaints by out-of-state plaintiffs in New Jersey state court as opposed to the MDL risks skewing the MDL bellwether pool to exclude weak cases from the MDL. Indeed, fourteen of the nineteen cases (74%) pending in New Jersey involve

claims that are facially time-barred by the applicable statute of limitations based on the explant dates.[6] In light of the denial of the MCL Application, Defendants requested that the New Jersey State Court Liaison and Plaintiffs' Leadership's consent to dismissal of the nonresident plaintiffs' cases in favor of direct-filing in the MDL to avoid pre-answer motion practice on forum non conveniens, statute of limitations, and other grounds. To date, Defendants have not received a response or Plaintiffs' rationale as to why the Superior Court of New Jersey is a convenient and appropriate forum for these particular nonresident plaintiffs' cases when numerous other plaintiffs from those states have availed themselves of direct-filing into the MDL.

ii. Plaintiffs' Position

The MDL Plaintiffs take no position on any individual plaintiff's choice of forum, whether it be the MDL or the Superior Court of New Jersey. The history of Multi-County Litigation in New Jersey is replete with examples of MCL applications that have been denied and later granted upon reapplication. *See, e.g In Re: Physiomesh Litigation* (MCL No. 627), *In Re Proceed Mesh Litigation* (MCL No. 630),*In Re Prolene Hernia System Mesh Litigation* (MCL No 633)(Plaintiffs initially applied for MCL designation for several models of hernia mesh manufactured by a single manufacturer. The New Jersey Supreme Court denied the initial application, later to grant separate MCL designations for each of the discrete models of mesh products). It is the understanding of the MDL Plaintiffs that a substantial number of cases are expected to be filed in the Superior Court of New

[6] Courts have held in nearly identical litigation against AngioDynamics, Inc., another manufacturer of IPC devices, that claims accrue on the date of explant. *See, e.g., Reed v. AngioDynamics, Inc.*, 2:23-CV-04066-MDH, 2023 WL 8478023, at *3 (W.D. Mo. Dec. 7, 2023) (holding that "Plaintiff's cause of action began to accrue, at the latest, on January 7, 2013, when she underwent surgery to remove the port" where the complaint alleged that "Plaintiff was on notice that the SmartPort was infected, had to be surgically removed, and had caused her alleged damage").

Jersey in the foreseeable future, and a renewed application for MCL designation may be appropriate at a later time.

II. Status of Common-Issue Discovery

The parties' positions regarding the status of common-issue discovery are set forth below.

a. Defendants' Position

i. Defendants' Responses and Productions to Date

Defendants continue to work diligently to respond to Plaintiffs' expansive discovery demands. Defendants BAS and BPV served their respective Responses and Objections to Plaintiffs' First Set of Interrogatories and initial six sets of Requests for Production (RFP) on January 11, 2024.[7] Defendants Bard and BD served their Responses and Objections on January 17, 2024. Plaintiffs' requested Information Infrastructure Rule 30(b)(6) deposition took place on January 18, 2024. Defendants served their respective Responses and Objections to Plaintiffs' First Set of Requests for Production regarding Corporate Liability on January 29, 2024.

The same day, Defendants provided Plaintiffs with a proposed list of forty-one potential Custodians, and, on February 9, 2024, provided Plaintiffs with a proposed list of Non-Custodial Sources as well as a list of search terms that Defendants propose running over their Custodial Files and certain Non-Custodial Sources in order to identify potentially responsive documents for review and production. These search terms included over 280 "anchor" terms to be separately run in conjunction with more than 150 "limiting" terms. By way of example, the anchor terms include "_port_"; "bardport"; "powerport"; "groshong" & "port"; "catheter*" & "port"; each 510(k) number implicated by the Product Codes; and every Product Code listed in the Master Complaint. The limiting terms include

[7] The sets of RFPs are titled: (1) "Marketing"; (2) "Post-Market Surveillance and Regulatory Compliance": (3) "Warnings and Regulatory Compliance"); (4) "Clinical Studies, Literature, and Key Opinion Leaders"; (5) "Corporate Organization, Budgeting, and Litigation" and (6) "Design and Manufacture."

"antithrombo*"; "antimicrobial"; "biocompatib"; "encapsulat*"; "barium" or "BaSO4"; Radiopa*"; "POM"; "Delrin"; "palpation bump*"; "FDA"; "postmarket"; "IFU"; "marketing plan"; "fracture*"; "embolism"; "thromb*"; "blood clot*"; "infection"; "sepsis"; and "erosion."

In addition, Defendants started producing documents in December and continue to make regular rolling productions each week. As reflected in the below table, Defendants have made thirteen document productions consisting of over 660,000 documents and over 3.8 million pages:[8]

PRODUCTION	DATE	DESCRIPTION	DOCS	PAGES
BARD_IPC_MDL_001	12/26/2023	*Cruz* Production	6,290	91,035
BARD_IPC_MDL_002a	1/5/2024	Prior Patent Litig. Production (I of IV)	211,955	993,418
BARD_IPC_MDL_003	1/5/2024	Prior Port Litig. Deposition Transcripts	48	1,794
BARD_IPC_MDL_002b	1/11/2024	Prior Patent Litig. Production (II of IV)	200,966	1,396,347
BARD_IPC_MDL_004	1/12/2024	CV of Information Infrastructure Rule 30(b)(6) Deponent & Related standard operating procedures ("SOPs")	18	241
BARD_IPC_MDL_005	1/17/2024	SOPs and corporate org document related to Information Infrastructure Deposition	4	50
BARD_IPC_MDL_006	1/19/2024	Information Infrastructure Document	1	9
BARD_IPC_MDL_002c	1/19/2024	Prior Patent Litig. Production (III of IV)	97,634	449,900
BARD_IPC_MDL_002d	1/24/2024	Prior Patent Litig. Production (IV of IV)	137,420	814,251
BARD_IPC_MDL_007	1/26/2024	510(k) submissions related to the Product Codes	19	4,599
BARD_IPC_MDL_008	2/2/2024	510(k) submissions and related docs for the Product Codes	498	15,508
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	293	8,583

[8] Page count exceeds this number as documents produced in native format, e.g. Excels, PowerPoints, are counted as a single page.

		documentation associated with the Product Codes		
BARD_IPC_MDL_010	2/16/2024	Marketing team documents, SOPs, supplement of three 510(k)s	2,168	20,057
BARD_IPC_MDL_011	2/23/2024	Marketing team documents	4,316	24,239
Total			661,630	3,820,043

With respect to the patent productions in particular, those productions, which include documents dating back decades, include a number of documents Plaintiffs requested in this MDL. For instance, the patent productions contain R&D documents, correspondences with the FDA related to IPCs, Change Requests, and Instructions for Use; quality documents pertaining to Corrective Action and Preventive Actions ("CAPA") and Device Failure Modes and Effects Analyses ("dFMEA"); as well as sales reports, marketing materials, and market research. More generally, the productions include organizational charts, policies and protocols, and training materials. Defendants promptly reproduced the patent production, as well as the *Cruz* product liability production, so that Plaintiffs would have a critical mass of documents early on in the MDL for negotiation of further discovery and for Plaintiffs' own substantive uses.

In addition to supplementing the categories of documents identified in the above chart, forthcoming productions will include the following from the more than a dozen agreed-upon Non-Custodial Sources:

- Additional organizational charts reflecting individuals who may have had responsibility for implanted port catheter devices;
- Additional SOPs relating to: Product design/development; Manufacturing; Quality and safety; CAPAs; Labeling; and Marketing;
- Instructions for Use associated with the Product Codes;
- Patient Guides associated with the Product Codes;
- Final versions of Design History Files (DHFs) for the Product Codes;

- BPV Quality Management Board Review (QMBR) reports relating to implanted port catheter devices;
- Sales data regarding the volume of units of the Product Codes sold in the U.S.;
- Consultant agreements with HCPs relating to the Product Codes or implanted port catheter devices generally;
- Additional final, approved sales training and marketing materials for the Product Codes or implanted port catheter devices generally;
- Documents from various departmental shared areas; and
- Excel exports of adverse event reports for the Product Codes from Defendants' complaint database pursuant to application of agreed-upon FDA Annex A codes.

ii. The Parties' Conferrals

Defendants objected in their Responses to Plaintiffs' First Set of Interrogatories and RFPs to the substantial overbreadth of a number of demands and invited Plaintiffs to provide narrower requests and/or to explain what Plaintiffs seek during a subsequent meet-and-confer. For example, Defendants interposed valid objections to Plaintiffs' Interrogatories,[9] such as their contention that Interrogatory No. 2's "request for the identification of individuals with 'any responsibility' is inherently subjective and could encompass a voluminous number of employees over a long period of time, many of whom would otherwise have no knowledge that lead to the discovery of relevant information." Defendants further stated that they were "prepared to meet and confer to determine if Plaintiffs can particularize this Interrogatory and provide a more narrowly tailored interrogatory that reasonably

[9] Interrogatory No. 1 requests Defendants "Identify all of the implantable port devices manufactured, sold, marketed/promoted, and/or distributed by You," along with "the dates that the device was manufactured, sold, marketed/promoted, and/or distributed by You." Interrogatory No. 2 requests that, "[f]or *each* of the devices identified in response to Interrogatory No. 1, identify the individuals who had *any responsibility* with respect to each device and/or Components."

identifies a basis for the requested information as it relates to the allegations in the Master Complaint in order to enable Defendant[s] to conduct a reasonably diligent search." Nearly three weeks later, on January 29, 2024, Plaintiffs first provided Defendants with a discovery deficiency letter requesting that (1) Defendants supplement their responses to Interrogatory Nos. 1 and 2; (2) Defendants supplement their responses to the RFPs to comply with Rule 34(b)(2)(C); and (3) the parties meet and confer regarding Defendants' objections to Plaintiffs' temporal scope of 1980 to present and their requests for production of foreign documents and communications. Plaintiffs' letter also raised other items, including the form of the privilege log, the substantial completion deadline, search methodologies and information sources, the deposition protocol, a potential Rule 30(b)(6) deposition pertaining to the devices at issue, and production of exemplar devices. Since the receipt of this letter, the parties have been engaged in telephonic conferrals, email exchanges, and supplemental productions of information on a near-daily basis. Plaintiffs' contention about Defendants' delay and failure to confer on the issues raised herein are belied by the record.

The parties first met and conferred regarding Plaintiffs' deficiency letter on February 2, 2024, and Defendants responded by way of a letter dated February 5, 2024. Defendants reiterated their overbreadth objections to Plaintiffs' Interrogatories, but agreed to provide Plaintiffs with a non-exhaustive list of employees with roles involving port catheter devices. Defendants also provided Plaintiffs with a list of all U.S. Product Codes associated with Defendants' IPC devices. Defendants responded to Plaintiffs' remaining items with additional information, clarification, or invitation to meet and confer.

On February 6, 2024, in furtherance of the parties' conferral, Plaintiffs requested several additional data points regarding each of Defendants' IPC devices as a potential compromise to their request for 30(b)(6) deposition on the composition and history of every IPC device, but reserving the right for a 30(b)(6)

or fact deposition if questions remained after receiving the completed chart. On February 13, 2024, Defendants responded that they would agree to compile the information requested in the chart, as modified for clarity, and anticipated being able to return the completed chart the week of February 19, 2024. Once Defendants started pulling the requested information it became evident that, due to the number of Product Codes and timeframe implicated, certain categories would take longer to compile as the information does not exist in a summarized form in the ordinary course of business, requiring Defendants to pull the information from numerous places. During a February 16, 2024 conferral, Defendants advised Plaintiffs that they anticipated being able to produce roughly half of the requested information in the original timeframe, and the balance would be produced at a later date once complete. Consistent with their representations, on February 23, 2024, Defendants provided Plaintiffs with the chart reflecting the information located to date.

On February 19, 2024, Plaintiffs provided Defendants with their own proposed list of search terms along with a request that Defendants engage in an "initial Search Term Report (STR) evaluation" asking Defendants to run each term individually in order to determine the prevalence of the individual terms in the data set. The parties met and conferred about Plaintiffs' search term request, among other issues, on February 22nd.

Defendants believe they have resolved Plaintiffs' concerns related to Interrogatory No. 1 by way of producing a list of all U.S. based Product Codes as well as the chart with extensive supplemental information that goes beyond the scope of the Interrogatory. Defendants believe that they resolved Plaintiffs' concerns issues related to Interrogatory No. 2 related to the identification of employees with responsibilities for IPCs by way of providing their initial list of forty-one potential Custodians, a supplemental list identifying two hundred employees believed to have had roles involving implanted port catheter devices at points in time, as well as the reproduction of millions of pages of documents

inclusive of organizational charts produced in the port patent litigation and *Cruz* that Plaintiffs can search for persons of interest.

iii. Scope of Discovery & Disputes

Pursuant to CMO No. 13, Defendants hereby set forth the parties' disagreements regarding the scope of discovery. *See* CMO No. 13, Doc. 298 at 1-2. As set forth above, Defendants respectfully submit that the scope of discovery as defined by the number of Custodians and search terms and RFPs should be significantly curtailed based on the low number of cases filed to date, and the extensive discovery Defendants have already produced. There are only three unresolved discovery disputes between the parties that require Court intervention at this time: (1) Plaintiffs' demand that Defendants run an initial investigative report using Plaintiff's proposed terms without limiters; (2) the number and selection of Custodians; and (3) the discoverability of foreign Regulatory documents and materials. Although Defendants agree with Plaintiffs that the parties have been working cooperatively through discovery issues and have resolved many to date, Defendants respectfully submit that the parties are at an impasse—or would soon be at an impasse—as to these three issues that impact the overall scope of discovery moving forward, and thus, warrant the Court's resolution.

1. Search Terms

The Parties' search term dispute arises from Plaintiffs' insistence that Defendants run a hit report based on individual terms that Plaintiffs proposed. This "pre-discovery"—sought for the sole purpose of generating data to evaluate the prevalence of those terms in the data set—is inconsistent with CMO No. 12 and well-settled ESI discovery principles.

CMO No. 12 prescribes that

> In the event a Producing Party determines it will apply keyword and/or Boolean searches to its sources, it shall provide the Requesting Party with the searches it

> proposes running across its relevant sources. The Parties will meet and confer in good faith in an iterative and collaborative process to determine if the Producing Party's searches should be supplemented with additional narrowly tailored and proportional keyword or Boolean searches to identify responsive Documents or ESI. In the event a Producing Party objects to inclusion of a requested term as overly broad, disproportionate, or returning a large volume of false hits, the Producing Party shall share a hit report with the Requesting Party that identifies the number of Documents the contested term will add to the review universe. The Parties shall confer in good faith as to reasonable and proportionate refinements to the contested term.

CMO No. 12, Doc. 117, at 9. CMO No. 12 thus contemplates and requires Defendants, as the Producing Party, to provide Plaintiffs with their proposed search terms. Any subsequent conferral over those search terms is limited to Plaintiffs' proposal to "supplement[]" Defendants' terms with "additional narrowly tailored and proportional keyword or Boolean searches to identify responsive Documents or ESI." Contrary to Plaintiffs' position, Defendants are not obligated to share hit reports for *every* individual term proposed by Plaintiffs without limiters. Rather, Defendants shall "share a hit report" for only those terms that Defendants believe are "overly broad, disproportionate, or return[] a large volume of false hits."

Beyond being inconsistent with CMO No. 12's procedure, Plaintiffs' demand that Defendants run a report on their terms without limiters will not provide the parties with any meaningful data and will slow down the negotiations over the truly contested terms. Plaintiffs' requested hit report is not permissible discovery; it is not intended to identify responsive documents related to the litigation. Rather, Plaintiffs seek to assess prevalence of terms in a manner that is divorced from the claims and defenses given their overbreadth and application to Custodians whose responsibilities include devices other than IPCs. These terms include: "angry,"

"bacteria," "benefits," "blood," "blood clot*," "break*," "complication," "defect*," "embolism," "faulty," "foul," "weak*," "benefit*," "mad," "mesh," "protein," "risk," "safe," "strong," "VAD," "INF," "FDA," "upset," "not happy," among others.

Plaintiffs' request for an initial hit report thus falls into the category of discovery on discovery. It is well-settled that "discovery concerning the . . . collection efforts of another party can contribute to unnecessary expense and delay" and is generally disallowed. *Doe v. Heritage Acad., Inc.*, No. 16-cv-03001-PHX-SPL, 2017 WL 6001481, at *13 (D. Ariz. June 9, 2017); *LKQ Corp. v. Kia Motors Am., Inc.*, 345 F.R.D. 152 (N.D. Ill. 2023) (explaining that "[d]iscovery on discovery concerns the process by which a party engaged in its discovery obligations" and that "the Federal Rules of Civil Procedure do not explicitly permit this type of discovery"); 19 Sedona Conf. J. at 123, cmt. b ("[T]here should be no discovery on discovery, absent an agreement between the parties, or specific, tangible, evidence-based indicia . . . of a material failure by the responding party to meet its obligations."). That delay and expense here is exacerbated by the breadth of Plaintiff's terms—which has been Defendants' position since the outset of the relevant conferrals.

As for Plaintiffs' revised proposal that Defendants cull Plaintiffs' list for objectionable keywords and run a hit report of those terms, that proposal remains inconsistent with the ESI Protocol because it flips the parties' burdens. It is Plaintiffs' burden to identify narrowly tailored terms that they wish to include. If Defendants object to those terms, only then is Defendants obligated to share a hit report. There is no requirement for Defendants to run a hit report on standalone keywords that are not narrowly tailored to this litigation, such as "FDA," "benefit," and "safe." Accordingly, this Court should reject Plaintiffs' request in favor of CMO No. 12's procedure for search term disputes.

2. Limitations on Custodians

As set forth above, Defendants respectfully submit that this Court should limit the number of Custodians to a subset of those provided to Plaintiffs on January 29th, subject only to the Parties' agreement to substitute certain Custodians selected by Plaintiffs. Defendants' proposed cap on the number of Custodians is supported by proportionality concerns given the low number of cases to date and volume of ESI already produced from the patent and *Cruz* litigations and in this MDL. *See In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices and Antitrust Litig.*, 2018 WL 1440923, at *2 ("[U]nless the party's choice is manifestly unreasonable or the requesting party demonstrates that the resulting production is deficient, the court should not dictate the designation of ESI custodians.").

As of the date of this Joint Memorandum, Plaintiffs have failed to provide Defendants with any substantive feedback regarding the list of forty-one potential Custodians that were provided over a month ago, or identify their own proposed Custodians. Defendants vehemently disagree with any assertion that Defendants have caused delay or obstructed Plaintiffs' endeavor to do so. Plaintiffs have had the *Cruz* product liability discovery since December 26, 2023, and the first million pages of the prior patent litigation discovery since January 5, 2024. Given the significant overbreadth of Plaintiffs' Interrogatory calling for the identification of every "individual[] who had *any* responsibility with respect to each device and/or Components," Defendants reasonably relied on Rule 33(d) and the initial list of Custodians as a starting point prior to conferrals, before supplementing that list to bring the total number of employees to over 200 following the parties' conferrals.

Contrary to Plaintiffs' contentions, Defendants have not "[a]bandon[ed]" the ESI Protocol. Defendants instead ask this Court to impose a cap on the number of custodians that comports with Rule 26(b). Defendants have no objection to the parties negotiating the identity of those custodians, and note that they may come from Defendants' initial list of proposed custodians, the supplemental list of

employees of knowledge, or persons identified by Plaintiffs from their review of the discovery produced to date. As discussed *supra*, if Plaintiffs believe that Defendants' document production is deficient, Plaintiffs may seek leave to compel the designation of particular ESI custodians that would provide unique relevant information that has not already been obtained. *See Fort Worth Employees' Retirement Fund*, 297 F.R.D. at 107.

3. Foreign Discovery

Plaintiffs submit that information regarding foreign regulatory agencies that is in Defendants' possession, custody, and control in the United States should be produced. Defendants submit that, because Plaintiffs are U.S. residents and allege use of U.S. products, the potential marginal relevance of the foreign regulatory materials sought does not justify the burden on Defendants to search for and produce those documents—irrespective of whether those documents are located in the United States.[10]

Defendants' position is consistent with this Court's decision in *In re Bard IVC Filters Products Liab. Litig.*, 317 F.R.D. 562, 563 (D. Ariz. 2016) wherein the Court denied Plaintiffs' request for ESI generated by foreign subsidiaries or divisions of C. R. Bard, Inc. that sold IVC filters abroad. The Court concluded that the relevance of communications with foreign regulators was "uncertain for at least two reasons": "First, there are no Plaintiffs in this MDL from foreign countries. All plaintiffs received their Bard filters and allegedly were injured in the United States. Second, Plaintiffs seek communications with foreign regulators for a narrow purpose—to determine if any of those communications have been inconsistent with Defendants' communications with American regulators." *Id.* at 566.

The same considerations that prompted the Court to hold that the communications at issue were "only potentially relevant—more hope than

[10] Defendants have agreed to produce adverse event reporting information from their TrackWise application without geographic limitation.

likelihood"—continue to apply here given the absence of foreign plaintiffs and devices. *Id.* On proportionality, discovery into foreign regulatory matters is not proportional to the needs of this MDL given the low number of cases, the substantial discovery underway with respect to Defendants' communications and submissions to the FDA, and the *de minimis* importance of foreign discovery in resolving the issues in this litigation. With respect to the burden and expense, Defendants will have to search for and identify submissions to and communications with foreign regulators over decades for a substantial number of devices for which no Plaintiff in this MDL had alleged complications. If this Court were to be inclined to permit foreign discovery, it should be narrowly curtailed to discrete issues and devices, and the Court should consider cost-shifting.

b. Plaintiffs' Position

The parties have made good progress on common-issue discovery, but some progress has been slower and met more resistance than is warranted. Perhaps the best example of delay is Defendants' response to Plaintiffs' interrogatory seeking the identity of individuals with relevant information – Defendants served only objections. Defendants only truly remedied the obvious and time-sensitive deficiency seven days ago – after 90 days to respond – and only after much unnecessary conferring.

To elaborate, on November 22, 2023, Plaintiffs served an interrogatory seeking the identities of individuals with relevant information. Given the holidays, Defendants requested and Plaintiffs obliged an extension to respond to the interrogatory. On January 11, 2024, after being given seven weeks to respond, Defendants served *only objections* to the interrogatory.

On January 29, after receiving all of Defendants' responses to pending discovery requests on January 17, Plaintiffs served a comprehensive discovery deficiency letter addressing global deficiencies, including Defendants' interrogatory non-answer. In the letter, Plaintiffs threatened to call the Court about the unanswered interrogatory and

expressed that, without a response, they could not meaningfully participate in the selection of custodians or the negotiation of substantial completion deadline.

Late that night, Defendants sent Plaintiffs a list of approximately 40 pre-determined custodians from whom Defendants stated their intention to collect documents. Plaintiffs explained that, pursuant to the ESI Protocol, they are entitled to participate in the selection of custodians and that, because Defendants have the ability to interview their clients, the best source of information regarding individuals with relevant information, Defendants were handicapping Plaintiffs' ability to meaningfully participate in the negotiation of custodians.

Only on the evening of February 20, after the parties expended much time and effort on the issue, did Defendants provide Plaintiffs with a more complete list of individuals with relevant information, which Plaintiffs are now in the process of analyzing to determine an appropriate list of custodians. Although rushed, in the hopes of furthering the conversation at the case management conference, Plaintiffs plan to identify their list of proposed custodians on or before February 29.

Defendants took a similar approach to Plaintiffs' only other interrogatory, which requested that Defendants identify each of their IPC products. Plaintiffs sought the information because new Plaintiffs continue to surface who have new products and because Plaintiffs continue to find new product codes in documents produced by Defendants. Plaintiffs need the information to comprehensively conduct general fact discovery, and it should not be burdensome for Defendants to respond. Nevertheless, after a generous extension, Defendants served only objections and produced nothing until Plaintiffs threatened to involve the Court or take a 30(b)(6) deposition. Defendants are now working with Plaintiffs on a chart that will help the parties identify all IPC products and their respective materials so that the parties may identify which products are similar, if not identical, allowing them to most comprehensively conduct general fact discovery but as narrowly as can reasonably be achieved.

i. Issues Raised by Defendants

Until seeing Defendants' draft of this joint memorandum, Plaintiffs had thought that the parties were working mostly in cooperation, if slower and with more resistance than necessary. That apparently not being the case, each of the relevant discovery issues is discussed in more detail below.

As a threshold issue, there has been *no* meet and confer to fully discuss or attempt to narrow the issue of whether discovery should be limited based on the number of cases filed. Defendants can hardly even be said to have fairly raised the issue with Plaintiffs. At best, Defendants have done the following: a) made a last-minute, quick phone call specifically for the purpose of avoiding surprise to Plaintiffs in the joint memo, during which counsel told Plaintiffs (and for the first time) only that they would seek to limit the number of custodians; b) once questioned in passing, during a meet and confer regarding other topics, why more cases had not yet been filed (Plaintiffs offered what they until now believed had been a satisfactory explanation); and c) mentioned as part of that same conversation that they might in the future seek to somehow, non-specifically, limit discovery to the products associated with filed cases (again, Plaintiffs offered what they until now believed was a satisfactory reason that such a limitation would be problematic). Notably, in a February 5 letter from Defendants to Plaintiffs regarding the discovery issues raised by Plaintiffs that *were* discussed during their meet and confer, Defendants said nothing relating to how the number of filed cases might cause them to seek discovery relief from the Court or what relief they needed. A truncated history of each specific issue raised by Defendants and Plaintiffs' position follows.

1. Limitation of Custodians

By way of background, Defendants themselves initially proposed that Plaintiffs should receive 40+ custodians. Defendants inexplicably, for the first time, sprung a contrary proposal in a quick phone call on February 22, 2024 made for the sole purpose of avoiding surprise. The call lasted less than three minutes, and

Defendants did not state how restrictively they would propose reducing the number of custodians.

Prior to that last-minute phone call, the parties had only discussed casually, during one meet and confer, that the Defendants wondered why more cases were not on file and that, at some point, they might raise then-nebulous proportionality concerns. From the conversation, Plaintiffs thought they had allayed Defendants' concerns, at least for the time. Defendants certainly never articulated any specific burden or need for specific relief or limitations on discovery. With respect to custodians in particular, the parties had until February 23 been amicably discussing changing and adding to the custodians that Defendants initially proposed.

Defendants' new proposal regarding custodians is antithetical to the ESI Protocol, which requires the parties to negotiate custodians. "The Parties shall confer regarding the identification and collection of sources of relevant documents and ESI, including the sources and scope of information, Documents, ESI, and other material to be produced by . . . Defendants' Custodians . . . ." CMO 12, ESI Protocol at 5. Abandoning that agreement, and despite the fact that custodial negotiations seemed to be going fine, Defendants now take the position that the number of custodians should be limited to 25 and only to the individuals who Defendants choose.

Defendants' abandonment of the negotiation agreed to in the ESI Protocol is particularly confusing given that negotiations had not even come close to impasse, and Plaintiffs have repeatedly expressed to Defendants their intention to be reasonable in the discovery process. As part of that intention, in an effort to reduce the burden on all parties and to avoid the necessity of multiple collections of responsive information as much as is possible – and especially in light of the parties' tight discovery schedule – Plaintiffs have put a lot of effort into attempting to choose the right custodians and to narrow them as much as is possible. Defendants have multiple times been made aware of that goal.

Toward the goal of efficient document collection, on November 22, 2023, Plaintiffs served an interrogatory seeking the identity of individuals with relevant information. On January 11, 2024, after an extension for the holiday, Defendants responded with only objections (not a single individual), and Plaintiffs threatened to call the Court. Late in the night on that same day, Defendants sent Plaintiffs a list of 41 individuals in an email titled "Proposed Custodians," which stated in the body "[p]lease find attached Defendants' proposed Custodians . . . We look forward to meeting and conferring with you regarding Plaintiffs' reasonable and proportionate proposed *additions* to this list." (emphasis added).

Given Defendants position that 40+ custodians were appropriate, and given that the agreed ESI Protocol, requires that "[t]he Parties shall confer regarding the identification and collection of . . . Defendants' Custodians," Plaintiffs insisted that Defendants respond to Plaintiffs' November 22 interrogatory and provide a reasonably comprehensive list of individuals with relevant information, as Plaintiffs could not without that information be expected to meaningfully participate in a negotiation of the most-appropriate custodians. Indeed, the very point is recognized in a case relied upon by Defendants: "[T]he party responding to discovery requests is typically in the best position to know and identify those individuals within its organization likely to have information relevant to the case." *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, No. 17-MD-2785-DDC-TJJ, 2018 WL 1440923, at *2 (D. Kan. Mar. 15, 2018). Plaintiffs communicated as much to Defendants early and multiple times, including in written correspondence.

Defendants expressed concern about compiling a more reasonably comprehensive list of individuals with relevant information lest Plaintiffs attempt to make every individual into a custodian. So Plaintiffs committed in writing not to make every individual identified into a custodian and only to use the interrogatory response for the purpose of identifying the most appropriate custodians. Plaintiffs

expressed sincere anticipation that Defendants and Plaintiffs would be able to agree on the number of custodians and on the specific individuals.

Plaintiffs finally received a response to their interrogatory only seven days ago – 90 days after the interrogatory was first served. Two days after receiving that critical information, when Defendants first let Plaintiffs know they would challenge the number of custodians on the basis of proportionality, Plaintiffs were in the process of analyzing that list of 200 individuals, comparing it to Defendants' proposed 40 custodians, comparing it to Plaintiffs' internal list of relevant individuals (compiled by reviewing documents), and trying to determine who Plaintiffs believe to be the most relevant individuals; from there, Plaintiffs intend to determine what a reasonable and appropriate list of custodians, including a number, and presumably including some custodians named by Defendants. Defendants were aware of Plaintiffs process, were until February 22 apparently on board with that process. At the time of filing this joint memo, Defendants still have no idea what Plaintiffs' custodian proposal would be, and nevertheless they have determined to involve the Court.

Defendants are violating the ESI Protocol by ignoring their commitment to meet and confer in good faith regarding disputed discovery issues and "prior to scheduling a call with the Court to address [the issues], [and to] identif[y] the scope of the issues as narrowly and accurately as possible." CMO 12, ESI Protocol at 9-10. Defendants committed to identify and narrow the scope of any issues prior to seeking relief from the Court. That simply has not been done.

Defendants are also violating the meet and confer certification requirements of Federal Rule of Civil Procedure 26(c) and Local Rule 7.2(j). Local Rule 7.2 even states that "[a]ny discovery motion brought before the Court without prior personal consultation with the other party and a sincere effort to resolve the matter, may result in sanctions." Here, Defendants simply cannot satisfy the sincere effort and

personal consultation requirements, and the Court should deal with Defendants accordingly.

As to Plaintiffs' position on appropriate custodians, given that Defendants' only seven days ago reasonably responded to Plaintiffs' interrogatory requesting the identity of individuals with relevant information, Plaintiffs are in the process of determining which custodians would be reasonable and hope to have a completed list prepared to share with Defendants by February 29. Until the parties have met and conferred about that list, the issue simply cannot be ripe. Moreover, to move forward now with Defendants' proposed 25 custodians will simply ensure more fighting about the custodians later. This Court should order the parties to continue negotiations.

2. Limitation on Written Discovery

Defendants first raised their proposal that Plaintiffs be required to seek leave of Court before serving additional discovery on February 23, 2024, when Plaintiffs received Defendants' draft of this joint memo. The parties have never discussed such a limitation on written discovery. Moreover, Defendants have yet to put their foot down on any written discovery issue that the parties are negotiating, save foreign regulatory materials and hit reports. Because the parties have yet to negotiate either custodians or search terms, Defendants literally do not know what the burden of production might be.

Moreover, exactly what written discovery limitations Defendants seek remains unclear: Does it apply to requests for production, interrogatories, requests for admission, depositions on written questions? Plaintiffs have served only *two* interrogatories (to both of which Defendants only objected and Plaintiffs had to threaten to call the Court to get any response). Regarding requests for production, Plaintiffs have been very open about, and they thought helpful in, endeavoring to front-load their requests for production in an attempt to aid the parties in negotiating a reasonable substantial completion deadline. In other words, Defendants already

know that Plaintiffs are not currently anticipating substantial new asks for production in the future, save important, relevant information that the parties may discover moving forward. Indeed, the "six sets" of requests for production that Defendants lament amount to 68 individual requests for production regarding general liability, split into six subject areas in an effort to make deficiency discussions run more smoothly. Plaintiff served one additional set of 21 requests for production regarding successor liability. Defendants point to literally no authority that such a number is unreasonable, particularly when successor liability is at issue.

Defendants make their undefined ask in part based on the "substantial amount of discovery that has been produced and will be produced." First, as has been discussed, Defendants do not yet know what "will be produced" or, therefore, what the burden will be. There is literally no basis for that argument. Second, the vast majority of what Defendants have already produced up through February 22 is a mere *re-production* from their patent lawsuit against AngioDynamics; that production comprises nearly 650,000 documents. *Cruz* constitutes over 6,000 documents. Little new has been produced.

As discussed above, in failing to meet and confer with Plaintiffs about limitations on written discovery, Defendants are violating Federal Rule 26(c)'s requirement to meet and confer in good faith regarding discovery disputes before raising them with the Court, as well as Local Rule 7.2(j)'s and the ESI Protocol's similar requirements.

Finally, the case relied upon by Defendants better proves Plaintiffs' point and shows a way forward. In *In re Dealer Mgmt. Sys. Antitrust Litig.*, the parties disputed whether 1.6 million documents should be produced *without* negotiating any limitation on search terms; faced with proportionality concerns, the Court instructed the parties to negotiate. No. 18-CV-864, 2018 WL 11260473, at *1 (N.D. Ill. Aug. 14, 2018). Similarly, with respect to written discovery Plaintiffs proposed

that the only reasonable path forward is that the parties negotiate any written discovery issues as they arise.

3. Search Terms & Hit Reports

As with the above issues, this issue raised by Defendants is not ripe. To begin, Defendants agreed in the ESI Protocol that the determination of appropriate search terms would be an "**iterative** and collaborative" process. CMO 12, ESI Protocol at 9. "The Parties will meet and confer in good faith to determine if the Producing Party's searches should be supplemented with additional narrowly tailored and proportionate keyword *or* Boolean searches to identify responsive documents or ESI." *Id.* at 9-10 (emphasis added).

The ESI Protocol also contemplates that so-called "hit reports" will be used as part of the iterative process to ensure that additional search terms are in fact "narrowly tailored and proportionate." A hit report is a report that Defendants run on their custodians which tells the parties how many documents a custodian has that are responsive to each of the test search terms. A hit report *does not* dictate what a party will produce. A hit report is merely a tool to provide the parties with data to help them determine whether the additional search terms will be appropriately tailored and proportionate. Regarding hit reports, the ESI Protocol provides: "In the event a Producing Party objects to inclusion of a requested term as overly broad, disproportionate, or returning a large volume of false hits, the Producing party *shall* share a hit report with the Requesting Party that identifies the number of documents the contested term will add to the review universe." *Id.* at 10 (emphasis added).

Thus, Pursuant to the ESI Protocol, after receiving Defendants' proposed, all-Boolean search terms (e.g. "port" and "defect"), Plaintiffs engaged in the iterative process, proposed keywords (e.g. individual words), and requested that Defendants run a hit report. While Defendants admit that some of Plaintiffs' keywords may already be narrowly tailored and appropriate, Defendants argued that other of Plaintiffs' test terms were overbroad and insisted that Plaintiffs' narrow

them with Boolean connectors. But the ESI Protocol does not require that; it requires that, when Defendants believe a term is overbroad, that they *shall* run a hit report. *Id.* at 10. Nevertheless, Defendants refuse to run a hit report.

Defendants flatly admitted in meet and confer that running the hit report with all of Plaintiffs test keywords (rather than a limited amount) placed literally no burden on Defendants. To quote Defendants when Plaintiffs asked how running the proposed hit report hurt them: "It does not hurt." Defendants were able to articulate only that running the hit report might (inexplicably) cause negotiations to be slowed in the future. Plaintiffs believe the opposite is true; the hit report will provide valuable information on how to limit their search terms and help the parties move forward more quickly. By contrast, requiring the parties to negotiate which test keywords are overbroad and how they should be limited runs contrary to the ESI Protocol's iterative process, contrary to Defendants' obligation to run a hit report when they believe a term is overbroad, and would *definitely* cause both parties to spend unnecessary additional time and effort.

On February 25, in an attempt to compromise, Plaintiffs requested that Defendants identify the keywords that Defendants found objectionable. Defendants refused. On February 26, Plaintiffs reached out to Defendants in another attempt to find a path forward. Defendants yet again rejected it.

Thus, while there does exist an impasse between Defendants and Plaintiffs regarding the use of a hit report, the parties have not reached impasse on which additional search terms should ultimately be added because Plaintiffs have not yet been allowed to test any terms, pursuant to the ESI Protocol, and to negotiate them. As Plaintiffs have expressed many times to Defendants, they expect the parties should be able to reach agreement on which additional keywords and Boolean terms should be added. The hit report will assist in the process by ensuring that Plaintiffs do not add Boolean terms to their detriment and/or refuse to add Boolean terms to

Defendants' detriment. Defendants should be ordered to run a hit report and to continue the negotiations.

4. Collection of Documents in Defendants' Possession Regarding Foreign Regulatory Information

Plaintiffs seek discovery regarding foreign regulatory agencies only insofar as those documents are in Defendants' possession, custody, and control in the United States. It is Plaintiffs' position, not Defendants' position, that is consistent with this Court's decision in *IVC.* Indeed, Plaintiffs' attempted compromise on this issue was guided by the Court's ruling in *IVC* that Plaintiffs were entitled to "communications with foreign regulators that originate in the United States," just not "communications that originate abroad." *In re Bard IVC Filters Prods. Liab. Litig.*, 317 F.R.D. 562, 566 (D. Ariz. 2016). Defendants do not explain why they are unwilling to produce that which they produced in *IVC*.

For starters, the Court's holding in *IVC* that the relevancy of communications with foreign regulators was "uncertain" was limited to those "communications that originate abroad and may not be captured in the current searches." *Id.* at 566. The Court did not hold, as Defendants intimate, that "communications with foreign regulators [that] originate in the United States" were irrelevant. *See id.* Moreover, Defendants' relevance argument focuses on Plaintiffs' residence and use of U.S. products, but glosses over the fact that Defendants market identical products abroad (just under different model numbers). Plaintiffs do not insist on a deep dive of foreign documents held in foreign countries, but there is no reason that Defendants should withhold documents about identical products sold in foreign countries where those documents are held by domestic Defendants.

What is more, Plaintiffs seek discovery on—and Defendants have already produced documents about—certain foreign products that may be safer alternative designs. Defendants should not be able to withhold relevant information about those alternatives simply because they are foreign.

Defendants further claim an undue burden, but their burden argument is abstract and unsubstantiated. While Plaintiffs agree that Defendants need not undertake the burden of "searching ESI from 18 foreign entities," there is no basis for Defendants to withhold documents about foreign regulatory affairs that are already "captured by the ESI searches currently underway." *Id.* If anything, the burden would lie in selectively withholding foreign regulatory documents that originate in the United States but are otherwise responsive to Defendants' searches.

III. Substantial Completion Deadline

The parties' positions regarding the substantial completion deadline are set forth below.

a. Defendants' Position

Defendants propose a substantial completion deadline of December 13, 2024. Defendants have been working hard to identify, collect, and produce documents in a forensically sound manner to preserve metadata. However, some items cannot be finalized yet, including those, like Custodial Files, that will be subject to the application of search terms. Further, Defendants' discovery is not without logistical and technical challenges. By way of one example, certain documents used by some functions reside in Docushare, a third party cloud based system. Defendants have reached out to the vendor several times but have yet to receive a substantive response. Even if Defendants were to collect the documents themselves, it is a laborious, manual process that requires downloading of each document individually. While Defendants believe they will be able to get the vendor to collect the documents, this is just an example of challenges that arise.

Additionally, Defendants utilize Master Control, which is a document management system licensed from an eponymous vendor. In addition to Master Control's search functionality being limited, in order to produce the requisite metadata that corresponds to the documents as contemplated by the ESI Order, Defendants must engage the vendor to export the documents. This is a time intensive

process. Defendants must identify each individual document based on its control number, provide that information to Master Control, and then separately engage Master Control to pull those documents pursuant to a statement of work. As discussed with Plaintiffs during the parties' February 16, 2024 meet and confer, Defendants have undertaken efforts to collect specific categories of requested documents. Given Master Control's limited search functionality, Defendants are also working with the business as well as reviewing filename listings to identify potentially responsive documents for collection. The control numbers for these documents will be provided to Master Control to collect the documents. As discovery progresses it is possible additional collections may be necessary and Defendants have raised with Plaintiffs the possibility that these subsequent collections would be executed by the business, rather than Master Control, which would allow for more timely collection and production but will diverge from the ESI Order requirements with respect to metadata production.

Even with the more proportionate scope of discovery sought herein, Defendants will need time to collect, review and produce responsive documents from the dozens of Custodial and Non-Custodial Sources.[11]

Plaintiffs' cited cases are inapposite as the substantial completion date came years into the litigation—presumably to provide Defendants with adequate time to collect, review, and produce discovery. *See, e.g.*, *In re Int. Rate Swaps Antitrust Litig.*, No. 16 MC 2704, ECF Nos. 56, 102 (S.D.N.Y.) (opening discovery in August 2017 and extending substantial completion deadline to at least October 5, 2018). Here, in this MDL where there was little-to-no discovery exchanged beforehand, it is simply impracticable for Defendants to substantially complete their document production within seven months of service of RFPs.

[11] For the sake of clarity, Defendants are not requesting an extension of the deadline for common-issue fact discovery. Defendants respectfully submit that an extension is not necessary at this time and that good cause does not presently exist for modification of the Court's schedule.

Defendants have been, and will continue, to make orderly and proportional productions of their ESI discovery, such that they should not be dumping the bulk of their remaining documents on Plaintiffs at or near the substantial completion deadline. Defendants will work with Plaintiffs on the timing of depositions before and after the substantial completion deadline.

b. Plaintiffs' Position

From the inception of the parties' discussions about what a reasonable substantial completion deadline should be, the parties have been far, far apart. Plaintiffs originally suggested June 7, 2024 as a substantial completion deadline, roughly splitting the proposed discovery period with Defendants, and Defendants originally suggested December 22, 2024, right before the close of general fact discovery.

Defendants insisted that they could not negotiate an earlier substantial completion deadline without understanding what information they will need to collect. In order to accommodate Defendants and to attempt to resolve the gap between the parties, Plaintiffs have allowed Defendants more time.

At least as early as January 29, Plaintiffs put Defendants on notice in writing that they were impeding Plaintiffs' own ability to negotiate a reasonable substantial completion deadline by not providing them with a response to a November 22 interrogatory seeking a list of individuals with relevant information to inform their analysis of necessary custodians. Just seven days ago, Plaintiffs finally received a list of approximately 200 individuals which they need to analyze. Although rushed, Plaintiffs intend to provide Defendants with what they believe is a reasonable custodian list on or before February 29.

Even though non-custodial sources have been negotiated and even though the parties were making progress on custodians, Defendants have apparently learned nothing in the intervening months to bring the parties closer together on what the substantial completion deadline should be, as they continue to advocate for December 2024, roughly

a month prior to the ultimate discovery deadline. That substantial completion deadline is wholly unworkable.

The point of a substantial completion deadline is 1) to keep the parties on schedule and 2) to allow the Plaintiffs time to *review and use* the production as they move forward with general fact discovery and depositions. If the parties agree, the substantial completion deadline can also allow Defendants a reprieve from depositions while they collect and produce.

Given the point of the substantial completion deadline, it is axiomatic that the deadline must come well before the end of general fact discovery, and many cases support the same. *See, e.g., In re Int. Rate Swaps Antitrust Litig.*, No. 16 MC 2704 (PAE), 2019 WL 1147149, at *30 (S.D.N.Y. Mar. 13, 2019) (setting substantial completion deadline on June 29, 2018 and discovery deadline more than nine months later, on April 10, 2019); *In re Int. Rate Swaps Antitrust Litig.*, No. 16-MC-2704 (PAE), 2018 WL 2332069, at *4 (S.D.N.Y. May 23, 2018) (setting substantial completion on May 21, 2018 and discovery deadline approximately seven months later, on December 21, 2018); *In re Abilify (Aripiprazole) Prod. Liab. Litig.*, No. 3:16-MD-2734, 2017 WL 4399198, at *8 (N.D. Fla. Sept. 29, 2017) (setting most depositions after the date of substantial completion).

Given what Plaintiffs know about what discovery will need to be collected and what work has already been done, given that Defendants have given the parties no real opportunity to discuss the issues because of their long lag in appropriately responding to discovery, and given Plaintiffs' robust experience with ESI productions and expectation to be reasonable, Plaintiffs believe that Defendants can finish production in four months.

As such, Plaintiffs propose a substantial completion deadline of June 7, 2024. Since discovery opened on November 20, 2023 and closes on January 31, 2024, that substantial completion deadline roughly splits the discovery period between the parties.

IV. Profile Forms

a. Defendants' Position

Pursuant to CMO 8 (Doc. 113), and as of February 25, 2024, 101 Plaintiff Profile Forms ("PPF's) were due to be served. In fourteen cases (over twelve percent of the cases filed and over fourteen percent of the PPFs due), no PPF was received in the time required and Defendants had to send letters requesting a PPF.[12] Five Plaintiffs have either dismissed or indicating that they are dismissing their cases in response to inquiry about missing or incomplete PPFs.[13]

Defendants are concerned with the plaintiffs' diligence in completing the PPFs.[14] As of February 25, 2024, Defendants have received ninety-seven PPFs. Of that number, sixty-one (approximately sixty-three percent) were incomplete in some fashion. In some, the form itself was not complete. In others, all or some of the required medical records were missing. Some PPFs suffered from both deficiencies. As a result, Defendants have spent a tremendous amount of time and expense reviewing the PPFs and medical records and following up with Plaintiffs to request clarification where necessary.[15] Even in those circumstances, Defendants did not automatically send a deficiency notice. Instead, if the PPF form itself was not complete, but the information could be located in a medical record that had been produced, Defendants have treated the PPF as complete. In addition, Defendants have followed up with Plaintiffs, including Plaintiffs' Leadership, to request missing information that appeared to be available to them based on the other records

[12] CMO 8 requires that a plaintiff serve a PPF within 21 days after notice from Defendants that the PPF was not timely served.

[13] Of the fourteen cases referenced above in which Defendants had to request a PPF, after Defendants requested the PPF, eight served a PPF, two requested an extension to serve a PPF (and the extension has not yet expired), and three are still within the twenty-one day response period. Plaintiff Tonya Harvey never served a profile form and the twenty-one day response period ended on February 21, 2024.

[14] During the negotiation of the PPF, Plaintiffs' Leadership agreed that the information requested in the PPFs is necessary to evaluate the cases at this stage of the litigation.

[15] For example, Defendants discovered that one plaintiff who had ostensibly verified the PPF had died months before the date of her signature. Defendants asked that plaintiff's lawyer to substitute the proper party and serve a properly verified PPF.

produced. Defendants also specifically reached out to one member of Plaintiffs' Leadership Committee to address concerns about the number of deficiencies in the PPFs served and held a meet and confer conference. After that conference, that lawyer indicated that some of the records were indeed available and uploaded them, and in other cases agreed to supplement, but no supplements have been served.

If any plaintiff's counsel informed Defendants that the records have been requested but were not yet available, Defendants did not treat that as a deficiency, instead anticipating that the plaintiffs will supplement the PPF.

Unfortunately, despite all those efforts, Defendants had to serve sixty-one deficiency letters. Even after those letters were served and some plaintiffs supplemented, thirty-four PPFs (thirty-five percent of the PPFs served) remain incomplete.[16] At this high deficiency rate, the burden and expense for Defendants to continue to review PPFs and records, seek clarification when necessary, and then send deficiency notices will increase exponentially, particularly if Plaintiffs' past predictions about the eventual size of this MDL come to fruition.

i. Request for Order Requiring Supplementation

The significant number of incomplete PPFs negatively impacts Defendants' ability to evaluate the cases for bellwether discovery selection. CMO No. 10 (Doc. 115) sets a May 1, 2024, deadline for the submission of completed PPFs for cases in the Initial Plaintiff Pool. Defendants are waiting on supplementation of PPFs in twenty-four cases. A chart showing the missing information is attached as Exhibit A. So that Defendants have the information necessary to evaluate those cases, Defendants request that the Court enter an Order requiring that all plaintiffs who have indicated that they are supplementing their PPF submit complete PPFs and all accompanying records (or supplement the PPF to indicate that the records do not exist) by May 1, 2024.

[16] The thirty-five percent that remain incomplete does not include 8 deficient profile forms that are still in the 15-day cure period.

ii. Request to Compel Full and Complete PPFs

There are ten cases in which the plaintiffs either did not response to the letter requesting supplementation, or did not produce the all the required information and did not say that further supplementation is forthcoming. Pursuant to CMO No. 8, Defendants request to move to compel full and complete PPF's (including all medical records requested) by May 1, 2024, for the Plaintiffs and deficiencies identified in the chart attached as Exhibit B.

iii. Request to Dismiss Cases in which no PPF was Served

CMO No. 8 allows Defendants to move to dismiss cases in which a PPF is not served, after notice from Defendants. Consistent with that provision, Defendants request to move to dismiss any cases in which no PPF has been served and more than 21 days has passed since the serve of a letter requesting the PPF. At the time of this filing, there is one case, and Defendants are still waiting to hear from three plaintiffs who are still within the response period.

iv. Defendants' Request to File Motions to Dismiss

During the profile form exchange, Defendants learned that there are some complaints filed in the name of individuals for personal injuries, when the plaintiff was already deceased at the time of filing. Defendants could not tell from the information provided in the PPF that the plaintiffs were deceased at the time of original filing, and as a result, mistakenly filed suggestions of death. After those filings and based on information obtained, Defendants determined that the plaintiffs were deceased at the time of filing the complaints. As a result, Defendants request permission to file motions to dismiss those complaints.

b. Plaintiffs' Position

Defendants have served notices of alleged deficiency in a number of cases. Plaintiffs' Co-Lead Counsel has been in communication with various firms that received such notices, and it appears from those discussions that individual case counsel and counsel for the Defendants have been engaging in good faith on the

alleged deficiencies with the intent to resolve them in compliance with the Court's Orders. Although the discussions and communications typically occur between counsel for the Defendants and counsel for the individual plaintiff whose case is the subject of the alleged deficiencies, Plaintiffs' Co-Lead Counsel remains willing to assist in the efforts to resolve existing deficiencies and facilitate ongoing production of PPFs which comply with the requirements of CMO 8.

Plaintiffs have recently begun to receive production of Defense Profile Forms in individual cases. Counsel for plaintiffs are in the process of reviewing those disclosures and will follow the protocols set forth in CMO 8 with regard to any deficiencies which are identified.

In short, the processes Ordered by the Court in CMO No. 8 are being undertaken by the Parties in good faith and appear to be effective with respect to prompt identification and purposeful resolution of alleged deficiencies. Any persistent or irremediable deficiencies in individual cases will be addressed by the protocols agreed to by the parties. If any systemic PPF deficiencies should arise that apply to the MDL more broadly, those should be addressed in the first instance with a request to meet and confer with Plaintiffs' Co-Lead Counsel prior to a request for omnibus relief from the Court. Defendants' have not made any such request to date, but Plaintiffs' Co-Lead Counsel remain willing to engage and attempt to resolve such issues should they arise.

Regarding complaints which were allegedly filed in the name of an individual who was deceased at the time of filing, motion practice in individual cases is premature. Because the outcome of any such motion would require individualized legal and factual analyses (*e.g.* whether and how the nullity doctrine applies pursuant to the applicable state law and the facts of the case), permitting motions to dismiss these cases on this basis would entail unnecessary consumption of resources of the Court and the parties. Again, such an issue is more reasonably addressed though a meet and confer process. It is conceivable that counsel who

unknowingly filed the above-described cases would voluntarily dismiss them rather than engage in motion practice on the issue. Defendants do not indicate whether they have undertaken such discussions. Were Defendants to engage in the meet and confer process with plaintiffs' counsel in the cases described herein, Plaintiffs' Co-Lead Counsel would be willing to assist in the resolution of any issues in order to avoid unnecessary motion practice and keep the MDL focused on its core objectives.

V. Fact Sheets

a. Defendants' Position

The parties have reached an agreement with respect to the Plaintiff Fact Sheet. Regarding the Defendants Fact Sheet, counsel for the parties have met and conferred extensively and reached agreement on many areas of preliminary disagreement. Although some areas of disagreement still exist, the parties will continue to meet and confer over the course of the next few days in an attempt to reach full agreement regarding the substance of the Defendants Fact Sheet. To the extent we are unable to reach full agreement, the parties will submit a brief supplemental joint memorandum identifying any areas of disagreement and attaching proposed versions of the Defendants Fact Sheets by noon on Thursday.

b. Plaintiffs' Position

The parties have exchanged drafts of the Plaintiff Fact Sheet and the Defense Fact Sheet, respectively. The parties intend to meet and confer promptly to reach agreement on the form and content of each of those forms. The parties were able to reach substantial agreement in the same respects with regard to the Plaintiff Profile Form, and those negotiations are expected to yield helpful results in discussions regarding Fast Sheets.

VI. Update regarding Port-Reservoir Allegations

On December 12, 2023, Defendants moved to vacate two Conditional Transfer Orders ("CTO") comprised of three cases that contained port-reservoir defects. *See In re: Bard Implanted Port Catheter Prods. Liab. Litig.*, MDL No. 3081, Doc. No. 127

(J.P.M.L. Dec. 12, 2023). On February 5, 2024, the JPML denied the Motion to Vacate and transferred the three actions. *See* Doc. 366.

a. Defendants' Position

In light of the JPML's ruling, Defendants consent to the filing of Plaintiffs' original Proposed Master Complaint that contained the port reservoir defects (Doc. 93-1). Defendants do not oppose Plaintiffs' request to amend the Plaintiff Profile Form (PPF) so long as the amended form applies prospectively. Defendants agree with Plaintiffs' proposal that the amended PPF become effective for all PPFs due on or after March 15, 2024. The parties do not need to amend the form for Plaintiffs to who have already submitted PPFs as the current version has allowed for plaintiffs to identify any failure mode related to the port reservoir in the "Other" category, as several plaintiffs have done so. *See* Doc. 113-1, at 3; *see, e.g.*, *Swindle v. Becton, Dickinson and Co.*, (identifying "Catheter-related infection" and "Other: Port erosion" in completed PPF). To the extent that any Plaintiff seeks to amend his or her PPF, Defendants respectfully request that they be ordered to do so by April 1, 2024 so as to ensure that the parties' tracking of cases remains accurate once the bellwether selection process commences on that date.

b. Plaintiffs' Position

On February 5, 2024, the JPML denied Defendants' motion to vacate the conditional transfer order involving three cases alleging port-reservoir defects, including polyoxymethylene ("POM") and palpation-bump allegations. *See* Doc. 366 at 1-2. Centralization was warranted despite "[t]he addition of these alternative theories of causation" because those Plaintiffs "allege claims against the same defendants, regarding the same products, and alleging similar injuries as the MDL plaintiffs." *Id.* As this Court noted in Case Management Order 13, the JPML's "ruling will determine whether the Master Complaint should be amended to include port-reservoir defects." Doc. 298 at 1.

Plaintiffs' position is that the Master Complaint should be amended to include port-reservoir allegations. This coheres with the Court's initial instruction that POM and palpation-bump "allegations can be added later if the Panel expands this MDL to include them." Doc. 111 at 4-5. Because port-reservoir allegations are the only difference between the original Master Complaint, Doc. 93-1, and the current Master Complaint, Doc. 119, the Court could adopt the original Master Complaint. This could be accomplished through an amendment to Case Management Order No. 7, Doc. 145, or a new order, *cf.* Doc. 121 (approving revised Short-Form Complaint). Defendants would file their Master Answer 14 days after the Court approves the Master Complaint. *Cf.* Doc. 145 at 1.

Plaintiffs do not believe the Short-Form Complaint requires amendment. Although Defendants opposed port-body allegations in the Master Complaint, *see* Doc. 111 at 2 (citing Docs. 99, 102 at 3-12), Defendants did not propose any related changes to the Short-Form Complaint, *see* Doc. 93-2. The current Short-Form Complaint allows Plaintiffs to check the box for "[i]nfection" or "[t]hrombosis," as well as use the fill-in-the-blank field to allege, for example, "erosion." *See* Doc. 121-1 at 4; *see also* Doc. 366 at 1 (observing that port-body allegations resulted in "similar injuries as the MDL plaintiffs," including "thrombosis and infection," as well as "ulceration and tissue necrosis"). Because Plaintiffs' port-body injuries are "indivisible" from their catheter-related injuries, Doc. 366 at 2, there is no need to amend the Short-Form Complaint.

Unlike the Short-Form Complaint, Defendants did propose questions in the Plaintiff Profile Form regarding "port-body/reservoir-related claims." Doc. 102-3 at 4. The parties stipulated to those questions, "subject [only] to Defendants' objection that [port-body] claims should be stricken from the Master Complaint." *Id.*; *see* Doc. 102 at 34-37. The Court likewise suggested this "section on port reservoir-related claims" could be included if the port-body allegations were "added later." *Cf.* Doc. 111 at 5-6. Accordingly, if the Court approves the inclusion of port-body allegations in the Master Complaint, Case Management Order No. 8 should be amended, *see* Doc. 113, and the

Plaintiff Profile Form should be updated to include the section on "port-body/reservoir-related claims" set forth in the parties' original proposal, *see* Doc. 102-3 at 4. While Plaintiffs agree with Defendants that the PPF need not apply retroactively (i.e., not every Plaintiff needs to re-execute the PPF), all Plaintiffs should be permitted to amend to add in the port-reservoir section should they so choose. Additionally, Plaintiffs propose that the amended PPF become effective for all PPFs due on or after March 15, 2024.

VII. Deposition Protocol

The Parties have agreed to a deposition protocol and will submit it before the CMC.

VIII. Privilege Log Protocol

Plaintiffs requested that Defendants engage in discussions regarding an agreed protocol for dealing with privileged documents. Defendants agreed, and the parties are currently cooperatively working toward completing the same.

IX. Preservation Order

a. Defendants' Position

As the Court will recall, multiple extensions of time to submit a proposed Preservation Order have been granted to the parties. These extensions were required to allow the parties to more fully explore with their experts the potential impact of Plaintiffs' proposed procedure for preserving explanted devices and any adherent tissue on the integrity of those devices. That was the only issue that necessitated the multiple extensions granted by the court. Initially, Plaintiffs had proposed to instruct hospitals to ship any explanted devices and adherent tissue in 10% formalin solution. However, this initial proposed protocol did not limit the timeframe in which the devices could remain in formalin, which raised concerns about potential degradation of the devices over time.

After consultation with materials experts and based on ASTM Standard F0561-19, Defendants proposed that the devices and tissue should be kept immersed in the

formalin solution for approximately twenty-four hours in order to prevent degradation of the explanted devices. Defendants provided additional scientific support identified by their experts in support of that protocol. In response, Plaintiffs in an email dated December 18, 2023 agreed that Defendants' scientific support "counsel toward avoiding long term formalin exposure for these devices." Defendants subsequently confirmed to Plaintiffs that this protocol was also acceptable to Defendants.

Then, on February 19, 2024, eight weeks after Plaintiffs had advised that immersion of explanted devices in formalin for twenty-four hours was acceptable, Plaintiffs advised for the first time that they wanted to propose a *separate* additional protocol that once again called for the indefinite storage of some explanted devices in formalin. After Defendants objected again to any protocol that called for the indefinite storage of explanted devices in formalin and questioned Plaintiffs' purported scientific support for this additional protocol, Plaintiffs relented and, on February 23, 2024 withdrew their proposal for a separate additional protocol. Plaintiffs also advised that they had "forthcoming edits to the Proposed Order . . . that should be uncontroversial."

Three days later, on Monday, February 26, 2024, Plaintiffs provided their proposed edits to the Order. After months of negotiations and multiple court extensions that were requested and granted for unrelated reasons, Plaintiffs proposed to require Defendants to provide them notice within ten (10) business days of the Order or the filing of a new case of any instance where they received an explanted device from a hospital in connection with adverse event complaint handling pursuant to FDA regulations. Plaintiffs also proposed to require Defendants to change aspects of their internal procedures for such handling of devices. At no time during the months of negotiations and the exchange of multiple redlined drafts of the Preservation Order did Plaintiffs propose these revisions or raise these issues. On Tuesday morning, February 27, 2024, Defendants counsel raised these objections with Plaintiffs' counsel in a meet and confer session explaining that Plaintiffs would be notified as to whether Defendants were in possession of any explanted devices when responding to the Defendants'

Profile Form and the Defendants' Fact Sheet, and that there was no basis to Order that this information be provided sooner or to require Defendants to deviate from their internal procedures for the handling of explanted devices that it may receive in the normal course of business. Defendants then sent Plaintiffs a revised proposed Preservation Order reflecting the provisions it would agree to and the provisions to which it objected.

To the extent that the parties are unable to reach agreement on the Proposed Preservation Order by February 29, 2024, Defendants request that the Court enter their version of the order, which is attached as Exhibit C. (For the Court's convenience, Plaintiffs' proposed revisions to which Defendants object are redlined in the version attached as Exhibit D).

b. Plaintiffs' Position

The parties have continued to engage in discussions regarding the Preservation Order with the guidance of their respective consultants. The parties have sought multiple extensions to the deadline to submit a proposed order out of mutual caution and concern for the preservation of physical evidence which is relevant to the claims in this MDL. After extensive negotiations guided by the respective consultants for Plaintiffs and Defendants, the parties have reached agreement as to the retrieval and storage protocols to be submitted for approval by the Court. Although the long-term specimen storage protocol required extended analysis due to the different types of physical evidence that may require preservation in cases involving different injury modes, the parties are satisfied that the agreed-upon protocol which does not subject the explanted specimens to long-term formalin exposure is adequate to preserve the evidence which will be relevant in these cases.

X. Proposed Case Management Order Re: Joint Collection of Medical Records for Plaintiffs Included in the PFS/DFS Group of the Bellwether Process

The parties reached agreement on a proposed case management order regarding the collection of medical records and will submit that proposed order to the Court.

Dated: February 27, 2024

Respectfully submitted,

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Exhibit A

Plaintiff and Member Case No.	Date of Deficiency Notice	Date of Amended PPF	Missing information remaining
Axley, Karen 2:23-cv-02520-DGC	January 19, 2024	February 21, 2024[1]	**Incomplete PPF:** • information regarding the subsequent device that was implanted on December 9, 2022
Bigsbee, Beverly 2:23-cv-2021-DGC	January 4, 2024	January 18, 2024	**Missing medical records:** • no removal operative report • no medical records confirming product identification (although product identification provided via handwritten note)
Bradford, Tashera 2:23-cv-2123-DGC	January 19, 2024	January 29, 2024	**No product identification:** • no product code for device one or device two • no lot number for device one or device two **Incomplete PPF:** • Device One: no lot number, no product code, no removing physician, no date of removal, no removal records, no information regarding subsequent device • Device Two: no lot number, no product code, unknown implant date, no implanting physician, no implant records, no removal information, no removing physician, no date of removal

[1] This Amended Fact Sheet was submitted late.

			Missing medical records: • no product identification for device one or device two • no implant operative report for device one or device two • no removal operative report for device one or device two **Verification:** • improper verification of Amended PPF • no verification for Device 2 PPF
Canales, Sylvia 2:23-cv-1764-DGC	January 19, 2024	January 31, 2024	**No product identification:** • no product code • no lot number **Missing medical records:** • no implant operative report • no removal operative report
Criner, Stacey 2:23-cv-1707-DGC	N/A	N/A	**Invalid product identification:** • invalid lot number provided
Cunningham, Jean 2:23-cv-1625-DGC	February 15, 2024	February 23, 2024	**Insufficient product identification:** • no lot number for Device One
Curry, Tammy 2:23-cv-1756-DGC	January 23, 2024	February 7, 2024	**No product identification:** • no lot number • no product code
Doner, Teddy 2:23-cv-1757-DGC	N/A	N/A	**Invalid Product Identification:** • invalid lot number provided for Device Two
Ellis, Mary 2:23-cv-1705-DGC	January 23, 2024	February 7, 2024	**Missing medical records:** • no implant operative report
Franks, Carrie 2:23-cv-2163-DGC	January 19, 2024	January 26, 2024	**Incomplete PPF:** • information regarding the subsequent device

			Verification: • No verification for substantive information in amended PPF
Green Rebecca 2:23-cv-1704-DGC	January 4, 2024	January 18, 2024	**Missing medical records:** • no implant operative report
Hawkins, Vera 2:23-cv-02020-DGC	January 4, 2024	January 19, 2024	**Missing medical records:** • no implant operative report • no removal operative report
James, Peter 2:23-cv-02669-DGC	January 4, 2024	January 8, 2024	**No product identification:** • no lot number • no product code
Kessler, Paul 2:23-cv-1696-DGC	January 4, 2024	January 18, 2024	**Insufficient product identification:** • no lot number **Incomplete PPF:** • no implant date **Missing medical records:** • no implant operative report • no removal operative report
Prentice, Lori 2:23-cv-0627-DGC	January 23, 2024	February 7, 2024	**Incomplete PPF:** • information regarding the subsequent device **Verification:** • no verification for substantive information in amended PPF
McKinley, Donald 2:23-cv-1702-DGC	January 4, 2024	January 9, 2024 (First Amended); January 17, 2024 (Second Amended)	**Missing medical records:** • no removal operative report

Gay, Paisami 2:23-cv-1755-DGC	January 4, 2024	February 9, 2024	**Missing medical records:** • no removal operative report
Reed, Auntron 2:23-cv-02695-DGC	N/A	N/A	**No product identification:** • no lot number • no product code
Russow, Hiliary 2:23-cv-1701-DGC	January 4, 2024	January 18, 2024	**Missing medical records:** • no implant operative report • no removal operative report
Sanders, Michelle 2:23-cv-1698-DGC	January 19, 2024	February 6, 2024	**Verification**: • improper verification to Amended PPF that provided substantive information
Smith, Tracie Lewis 2:23-cv-1709-DGC	January 23, 2024	February 7, 2024	**Insufficient product identification:** • no lot number
Sorensen, Lloyd 2:23-cv-2557-DGC	January 30, 2024	February 14, 2024	**No product identification:** • no lot number • no product code **Verification:** • amended PPF with new substantive information was not verified
Sours, Jay 2:23-cv-1706-DGC	N/A	N/A	**Invalid product identification:** • invalid lot number provided
Stone, Cindy 2:23-cv-02696-DGC	February 7, 2024	February 21, 2024	**Insufficient product identification:** • no lot number **Missing medical records:** • no removal operative report

Exhibit B

Plaintiff and Member Case No.	Date of Deficiency Notice	Date of Amended PPF	Missing Information Remaining
Nicosia, Danielle 2:23-cv-2122-DGC	January 23, 2024	NONE	**No product identification:** • no lot number • no product code **Incomplete PPF:** • it is unclear whether subsequent product is at issue in this lawsuit and plaintiff did not respond to deficiency letter asking for clarification
Songy, Brandie 2:23-cv-1699-DGC	January 19, 2024	NONE	**Incomplete PPF**: • did not provide Plaintiff's former name or occupation
Zumalt, Tyler 2:23-cv-1697-DGC	January 19, 2024	NONE	**Incomplete PPF Device 2:** • no type of infection identified • no date of complication diagnosis identified • no medical provider who identified and/or treated the complication identified **Missing medical records Device 2:** • no records reflecting diagnosis of alleged complication **Verification** • no verification for Device 2 PPF
Beltz, Dana 2:23-cv-1640-DGC	January 23, 2024	February 7, 2024	**Verification:** • no verification for substantive information in amended PPF
Cabello, Christopher or Elizabeth (deceased) 2:23-cv-01729-DGC	January 4, 2024	January 18, 2024	**Missing medical records:** • no implant operative report **PPF claims and Complaint claims are not consistent:** • it is unclear (and inconsistent) whether this is a wrongful death claim, or a survivor

			claim with loss of consortium. • The original Complaint is plead as a wrongful death claim. The SFC is improperly filed in the decedent's name and is plead as a survival claim, but no loss of consortium is alleged. The initial PPF indicates that it is a survival claim and alleges pain and anxiety, but no loss of consortium. The amended PPF alleges loss of consortium.
Divelbliss, Kimberly 2:23-cv-1627-DGC	February 1, 2024	February 9, 2024	**Medical records and claims in Amended PPF do not match:** • Based on our review of the medical records, Plaintiff had multiple ports implanted, and because the medical records produced and the claims in the PPF and Amended PPF do not match, Defendants cannot tell which port(s) are at issue or whether the medical records produced relate to the port at issue. • In the Amended PPF, for example, Plaintiff alleges that she "seeks damages only for the failure of a device installed on 7/13/17 at Las Palmas Medical Center," but she produced medical records dated 07/13/17 showing that a port was implanted by a different doctor at a different facility. Plaintiff did not provide any implant records for any port implanted on that day at Las Palmas Medical Center.

Elwell, Shannon 2:23-cv-1662-DGC	January 4, 2024	January 18, 2024	**Missing medical records:** • incomplete implant operative report • incomplete diagnostic records
Hawkins, Tiffany 2:23-cv-1735-DGC	January 23, 2024	February 7, 2024	**Unable to determine what product is at issue in the lawsuit:** • SFC and PPF identify different lot numbers and implant dates. Medical records show yet a third possible implant date and no lot number. **Verification**: • no verification for substantive information in amended PPF
Hickman, LaDawn 2:23-cv-02721-DGC	February 19, 2024	February 21, 2024	**Missing medical records:** • no removal operative report **Incomplete PPF:** • PPF is unclear with respect to whether catheter fragments were removed on 1/4/22, or the device as a whole was removed on 1/4/22
Willis, Ann 2:23-cv-02604-DGC	January 30, 2024	February 14, 2024	**Verification:** • No verification for substantive information in amended PPF

Exhibit C

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: BARD IMPLANTED PORT CATHETER PRODUCTS LIABILITY LITIGATION	Case No. 2:23-md-3081-PHX-DGC **CASE MANAGEMENT ORDER NO. ___** **(PRESERVATION ORDER)**

I. SCOPE OF ORDER

Discovery in this proceeding may involve the collection, division, storage, preservation, and production of biomaterials evidence for which special handling, division, storage, and preservation would be warranted. Accordingly, the Parties herein hereby stipulate to and petition the Court to enter this evidence preservation protocol order ("Preservation Order").

This stipulation is entered on behalf of all plaintiffs in MDL 3081 and Defendants Becton, Dickinson & Company, C.R. Bard, Inc., Bard Access Systems, Inc., and Bard Peripheral Vascular, Inc. (hereinafter each a "Party" or collectively, the "Parties"), by and through their respective counsel, to provide a protocol for the collection, preservation, storage, and division of the Materials (as defined in section A, below).

By stipulating to this Preservation Order, the Parties have agreed to be bound by its terms and to request its entry by the presiding judge. Upon entry of this Order, the Order will apply to all current and future actions in MDL 3081.

It is hereby ORDERED as follows:

II. PRESERVATION PROTOCOL

A. DEFINITIONS

"Litigation" or "MDL" is defined as In Re: Bard Implanted Port Catheter Products Liability Litigation, MDL 3081 (D.Az.), including all current and future member cases transferred to, removed to, or filed in this District.

"Medical Facility" is defined to include healthcare facilities where a plaintiff underwent or will undergo a revision, excision, explant, or any other surgery in which a device at issue in this Litigation or portions of a such a device may be removed, as well as medical facilities responsible for the preservation and/or maintenance of excised or explanted Materials from such procedures.

"Materials" is defined as explanted devices or explanted portions of devices at issue in this Lawsuit, as well as any and all gross and microscopic material purported to contain a device at issue in this Lawsuit, or any portion of such devices, and/or any other of tissue excised or explanted from plaintiff found upon, or in proximity to, the location of a device or portions of a device at issue in this Lawsuit, including but not limited to any pathology evidence, histology slides, paraffin blocks containing tissue, pieces of a device, and/or gross material.

"The Storage Facility" or "Steelgate" is defined as the Plaintiffs' central storage vendor for Materials to be preserved in this MDL.

B. INTENT

It is the intention of the Parties that all Materials that have been previously analyzed or tested, as well as Materials which have not previously been analyzed or tested, be preserved in a manner that permits the Parties equal access to and analysis of the Materials. With one exception, the Parties will not interfere with or circumvent the analysis and preservation of Materials by the Medical Facilities to which any of plaintiffs' treating physicians have sent or will send the Materials in the usual course of business. The exception is where, in the usual course of business, the Medical Facility would destroy the Materials.

C. PROTOCOL FOR HANDLING OF CURRENTLY AVAILABLE MATERIALS EXISTING IN POSSESSION OF PLAINTIFFS, PLAINTIFFS' REPRESENTATIVES, PLAINTIFFS' COUNSEL, OR OTHER STORAGE VENDORS

1. Notice of Available Materials

In all cases pending in MDL 3081 as of the date of this Order, plaintiff's counsel in each individual case shall notify counsel for Defendants within ten (10) business days of this Order, via email at Brandee.Kowalzyk@nelsonmullins.com of the known existence of Materials in the possession of a plaintiff, plaintiffs' representatives, plaintiffs' counsel, or a Storage Vendor. Such notification shall identify who is in possession of such Materials, and the Materials they possess. In all cases filed after the date of this Order, said notice shall be provided by plaintiff's counsel that is aware of the existence of Materials to counsel for Defendants within ten (10) business days of the case being directly filed in or transferred to MDL 3081, or as soon thereafter as practicable. A plaintiff's

obligation to provide the information described in this paragraph shall be satisfied by serving a completed Plaintiff Profile Form (PPF) on Defendants wherein responses regarding Materials are provided in Section 5 of the PPF. A plaintiff's notification to opposing counsel via service of the PPF that Materials have been previously sent to Steelgate using a Chain of Custody form substantially similar to the form attached hereto will be deemed compliant with the terms of this Order, and no additional preservation notice will be required.

To the extent that any photographs, video or other documentary evidence of such Materials are in the possession of plaintiff, plaintiff's representatives, plaintiff's counsel, or Other Storage Vendors, a copy of said evidence will be provided to counsel for Defendants as attachments to the Plaintiff Profile Form.

2. Disposition of Materials in Plaintiffs' Possession

Plaintiffs' counsel will document the Materials in their possession on a Chain of Custody form containing the information provided on Exhibit A hereto, or by way of such Chain of Custody forms as were used to document the chain of custody prior to entry of this Order.

The Parties agree that with respect to any Materials that is in the possession of a plaintiff, plaintiffs' representatives, plaintiff's counsel, or a Storage Vendor other than Steelgate, counsel for plaintiff shall send a letter with copy to Defendants' counsel to such person or entity in possession of any Materials advising them of the need to collect,

preserve and ship the Materials to The Storage Facility (Steelgate), and will coordinate with such person or entity to achieve preservation of the Materials.

Chain of Custody forms shall be completed by each person or entity, that takes possession of and/or transmits the Materials or any portion thereof.

The Parties agree that Plaintiffs will be responsible for the costs of this process, and for the costs of storage at The Storage Facility (Steelgate) thereafter. The Parties agree that, as this litigation proceeds, Plaintiffs may request, and meet and confer with Defendants regarding, contribution from Defendants to the costs of storage of some, or all, of the preserved Materials. If the Parties are unable to agree on the issue, the Parties will promptly advise the Court and seek guidance.

Materials shall be properly stored and maintained, undivided, at The Storage Facility until such time as the Parties agree upon, and the Court approves, protocols for examination of such Materials.

D. PROTOCOL FOR HANDLING OF CURRENTLY AVAILABLE MATERIALS EXISTING AT A MEDICAL FACILITY

1. Instructions to the Facility

In all cases pending in MDL 3081, as of the date of this Order, counsel for each plaintiff that has actual knowledge of the existence of Materials at a Medical Facility shall send a letter with a copy by email to Defendants' counsel and Plaintiffs' Co-Lead Counsel, to the Medical Facility where the counsel for plaintiff has actual knowledge that the Medical Facility is in possession of Materials, in the form attached as Exhibit A, within five (5) days of the date of this Order. In all cases directly filed in, or transferred to, MDL

3081, said letter shall be sent, with a copy to Defendants' counsel via email at Brandee.Kowalzyk@nelsonmullins.com and Plaintiffs' Co-Lead Counsel via, within five (5) days of the date on which counsel for a plaintiff obtains actual knowledge of the existence of currently available Materials at a Medical Facility. It is the intention of the Parties that this letter shall advise the Medical Facility of the need to collect, preserve, and ship certain of the Materials as potential evidence in the Litigation, and of the need to follow the protocols set forth in Exhibit A in collecting, preserving, and shipping those materials, until further notice. Should the Materials be in the possession of a person or entity that is not a Medical Facility, as defined in this Order, counsel for plaintiff shall also send a letter (similar to Exhibit A), copied to Defendants' counsel, to such person or entity advising them of the need to collect, and preserve the Materials, and coordinate with such person or entity to achieve preservation of the Materials.

Materials shall be properly stored and maintained, undivided, at The Storage Facility until such time as the Parties agree upon, and the Court approves, protocols for examination of such Materials.

Exhibit A also includes a Chain of Custody Form that the Parties shall request that the Medical Facilities execute for any Materials that any party removes from any Medical Facility. This Chain of Custody form does not in any way affect the validity of any Chain of Custody Form utilized to obtain Materials prior to the date of entry of this Order. After the Materials leave the possession of any Medical Facility, the Chain of Custody Form

will be requested to be completed by each individual or entity obtaining and/or releasing custody of any Materials thereafter.

2. Retrieval, Storage, and Evaluation of Materials

The terms and procedures outlined in Section E below shall apply, and the Parties may only alter the terms of this Stipulation by written agreement as required to carry out its purpose.

E. PROTOCOL FOR PRESERVATION OF MATERIALS FROM FUTURE SURGERY

1. Notice Of Surgery

Within five (5) business days of receipt of information that a plaintiff in the Litigation intends to undergo or has scheduled a revision, excision, explant, or any other surgery that may involve removal of the device or portions of the device, or as soon as practicable thereafter, plaintiffs' counsel in such case shall notify counsel for Defendants of the intent for revision, excision, or explant surgery as well as the date and location of such surgery (if scheduled). The notice shall be provided via email to: via email at Brandee.Kowalzyk@nelsonmullins.com.

2. Instructions to the Facility

Concurrently with provision of the above-referenced notice, counsel for plaintiff(s) in the individual case shall send instructions with a copy to Defendants' counsel to the Medical Facility where the surgery is to occur in the form attached as Exhibit B. It is the intention of the Parties that Exhibit B shall advise the Medical Facility of the need to

collect, preserve, and ship certain of the Materials as potential evidence in the Litigation, and of the need to follow the protocols set forth in Exhibit B in collecting, preserving, and shipping the Materials.

Exhibit B also includes Chain of Custody forms that the plaintiff shall request that the Medical Facility execute attendant to any collection and/or shipment of Materials. This Chain of Custody form does not in any way affect the validity of any Chain of Custody form utilized to obtain Materials prior to the date of entry of this Order. Subsequently, the Chain of Custody forms will be completed by each individual or entity having custody of the Materials from the time those Materials leave the possession of each Medical Facility.

Concurrently with provision of the above-referenced notice, plaintiffs shall provide to the Medical Facility a HIPAA-compliant authorization allowing the Medical Facility to accommodate the requests in Exhibit B.

3. Retrieval, Storage, and Evaluation of Materials

The Parties will use reasonable efforts to cooperate in the evaluation of the explanted Materials and may alter the terms of this Stipulation only by written agreement as required to carry out its purpose.

For all Materials not yet explanted as of the date of this Order, the Parties will use Steelgate, Inc. ("The Storage Facility") to receive and store the Materials for the purposes set forth in this Order. The Storage Facility shall receive the protocols agreed upon by the Parties for the preservation, storage, and shipping of the Materials, contained in Exhibits A and B to this Order, and shall be instructed to strictly adhere to those protocols. Neither

party shall have the right to remove the Materials from The Storage Facility unilaterally. Plaintiffs will be responsible for the costs associated with the shipping and storage of all Materials. The Parties agree that, as this litigation proceeds, Plaintiffs may request, and meet and confer with Defendants regarding, contribution from Defendants for the costs of storage of some, or all, of the preserved Materials. If the Parties are unable to agree on the issue, the Parties will promptly advise the Court and seek guidance.

At any time after a case is filed in MDL 3081, either Party may request the opportunity to perform a non-destructive gross evaluation of the Materials at The Storage Facility relating to that case, or may request such evaluation at another location if agreed upon by the Parties, by providing advanced written notice of ten (10) days to the opposing Party and allowing the opposing Party the opportunity, at their own costs, to have a pathologist, or other types of experts, present and/or to have the gross evaluation videotaped. Any gross examination conducted pursuant to this section may include microscopic evaluation and or photography. The Parties will work together to find a mutually convenient date and time for any such non-destructive gross evaluation. Neither Party will perform any inspection, review, analysis, division or testing on the Materials or alter the Materials in any manner prior to reaching a mutually agreeable protocol.

If in any case filed in MDL 3081, either Party wishes to perform additional testing on the Materials in that case, following the gross examination, the Parties agree that the procedures for additional testing must be agreed to by the Parties and that any division of the Materials must be accomplished via the least destructive means. If either party objects

to the procedures or the division of the Materials the Parties shall be required to meet and confer in an effort to resolve the dispute. If the dispute cannot be resolved, the Parties will promptly advise the Court and seek guidance. Prior to any division of Materials the opposing party will have the opportunity to have their experts or consultants evaluate the gross pathology and be present for any division. The Parties will work together to find a mutually convenient date and time for any such division.

Chain of Custody forms shall be completed by any entity, including any storage facility, taking possession of and/or transmitting the Materials or any portion thereof.

F. MEDICAL FACILITIES THAT DO NOT RELEASE MATERIALS

If any Medical Facility will not release explanted devices, or portions of same, photographs or videos of such Materials, the Parties will meet and confer on an appropriate method for seeking to obtain same. If any Medical Facility will not release pathology-related Materials to The Storage Facility, then plaintiffs, on behalf of both Parties, may request recuts and/or slides from the Facility in possession of the Materials. Plaintiffs shall pay all costs for such requests. If Defendants also request such materials, Defendants will pay one half of the cost of this process.

Prior to requesting any recuts or slides, plaintiff's counsel shall notify Defendants via email at via email at Brandee.Kowalzyk@nelsonmullins.com that Plaintiff intends to make such a request. Within 14 days of receiving such notice, Defendants shall notify plaintiff's counsel whether they want any slides to be ordered and the type of stain to be

utilized, if any. In the event that plaintiff does not seek to obtain recuts or slides, plaintiff's counsel shall notify Defendants of that information via email at Brandee.Kowalzyk@nelsonmullins.com within 30 days of learning that a Medical Facility is in possession of Material(s) but will not release it, or within 60 days of the entry of this Order, whichever period is longer. Defendants are then authorized to seek such slides directly from the Medical Facility, and plaintiff agrees to provide in a timely manner any necessary authorizations to facilitate this request. Prior to any such request, Defendants will notify plaintiff that Defendants intend to request such slides. Plaintiff's counsel will then have 14 days to object to such request or advise Defendants whether plaintiff requires any slides from the Medical Facility. To the extent the Parties are unable to agree, they will seek the Court's intervention.

No Party shall be allowed to conduct any destructive testing of any Materials, whether with respect to devices, portions of devices, or pathology-related slides and related materials, with the exception of staining of recut slides.

G. ISSUES DIVIDING THE SAMPLES

If in the course of the litigation, both Parties request the division of any preserved Materials, the Parties agree to meet and confer on a protocol by which such Materials may be divided, such that they can be used in the same manner by each side. Neither Party will perform any review, analysis, division or testing on the Materials, or alter the Materials in any way, prior to reaching such a mutually agreeable protocol. In the event no agreement can be reached, the Parties will seek the Court's guidance.

H. VIEWING OTHER PARTY MATERIALS

Regardless of how Materials described in this Order are obtained, each Party shall have the right to examine those Materials, including any photographs or videos obtained of such Materials at an appropriate time in discovery, and in a manner that provides both Plaintiffs' and Defendants' experts sufficient time to evaluate those Materials.

I. MATERIALS PREVIOUSLY DIVIDED, ANALYZED AND/OR TESTED

If any of the Materials for any plaintiff in the Litigation have been divided, analyzed and/or tested by any Party prior to the effective date of this Order, or prior to a case having been directly filed in or transferred to MDL 3081, Plaintiff's counsel having knowledge of division, analysis or testing shall advise Defendants' counsel at within five (5) days of receipt of such information via email to Brandee.Kowalzyk@nelsonmullins.com. The Parties agree to meet and confer and attempt to arrive at a mutually agreeable disposition as to such Materials. With the exception of testing or analyses that have already begun that may be compromised by delay or stoppage, neither Party will perform any further review analysis, division, or testing on the Materials or alter the Materials in any way prior to reaching agreement.

J. NO WAIVER

Nothing herein shall be construed to preclude the Parties from presenting modifications to the methods for preservation of any Materials, based upon new information.

The court DIRECTS the Clerk to file a copy of this order in 2:23-md-3081, and it shall apply to each member related case previously transferred to, removed to, or filed in this district, as well as cases filed after the entry of this CMO. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Plaintiffs Leadership Committee to counsel appearing in each new action by operation of the MDL Centrality platform. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Plaintiffs Leadership Committee to counsel appearing in each new action by operation of the MDL Centrality platform. It shall be the responsibility of the Parties to review and abide by all pretrial orders previously entered by the Court. The orders may be accessed through the CM/ECF system or the court's website at www.wvsd.uscourts.gov.

Dated this _____ day of _____, 2023.

_____
David G. Campbell
United States District Judge

EXHIBIT A

IMPORTANT – REQUEST FOR PRESERVATION OF PATHOLOGY MATERIALS

[Date]

Attn: Departments of Surgery and Pathology
[Address of Explant Facility]

Re: [MDL 3081 case caption; name and birth date of Plaintiff and date of known Explant Surgery, Case Caption]

Dear Departments of Surgery and Pathology:

I represent your patient [Mr./Ms. Plaintiff's Full Name/date of birth] in a product liability lawsuit. To be clear, there is no lawsuit pending or anticipated against your facility or the treating physician. Rather, the lawsuit is a product liability lawsuit against Becton, Dickinson & Company, C.R. Bard, Inc., Bard Access Systems, Inc., and Bard Peripheral Vascular, Inc., relating to port catheter devices designed, manufactured, and sold by those companies. The law firm of Nelson Mullins, copied below, represents those companies in the lawsuit.

It is our understanding that [Mr./Ms. Plaintiff's Full Name] underwent a procedure on [date], performed by Dr. [Explant Surgeon], that may have involved the explanation of a port catheter device. I write to request the preservation of pathology material, as well as the explanted port catheter device, any and all pieces of that device, and any tissue removed with it, from [Mr./Ms. Plaintiff's last name] during such procedure**.**

Please be advised that any pathology, tissues, as well as the explanted port catheter device, and any and all pieces of the device obtained during that procedure, are critical pieces of evidence in this case. If your facility is in possession of the device, which includes both the port and catheter, or any portions of that device, please ensure that the entire device is preserved for inspection and analysis by representatives of the Parties to this lawsuit. Please do not discard or destroy the device or any of its parts, and please ensure that no one else discards, destroys, or takes any action of any sort that would destroy, damage, or compromise the integrity or current condition of the device. The Parties may be prejudiced if any evidence has been altered, damaged, or destroyed.

Please call or email me at [INSERT] at your earliest convenience to confirm the whereabouts of the evidence referenced above and that steps have been taken to preserve it. Please also contact me if you have any questions relating to the Instructions for Preservation of the materials listed below. If you are not the appropriate recipient of this request, please notify us and forward a copy of this letter to the appropriate person or entity responsible for ensuring compliance with the terms of this preservation request, at your earliest convenience. Thank you very much for your assistance.

The parties request that you preserve the materials identified in this letter, but that you prepare and ship ONLY the explanted device or portions of the explanted device, along with any tissue explanted with it, in the manner described below.

Instructions for Immediate Preservation of the Specimen(s):

1. Please preserve **all** explanted materials.
2. If possible, photograph the device and any retained tissue.
3. All components of the explanted device should be placed in a container of dilute neutral buffered formalin (10% formalin is standard.). Tissue samples may be placed in the same container along with the components of the explanted device for this formalin exposure.
4. Keep the device and tissue in the formalin solution for approximately 24 hours.
5. After 24 hours, remove the device from the formalin and rinse the device thoroughly under cold running tap water for 10 to 20 seconds. Any tissue specimens not attached to the device should stay in the formalin solution.
6. Allow the device components to air dry.
7. The removed device, or parts thereof, should be prepared and shipped as follows:
   a) Place all of the components of the removed device into a "Bio Bottle" container (or a similar system or container) and follow the instructions provided with that container system in the standard course. Any separate tissue specimens explanted with the device, but separate from it, should remain in formalin and be placed in a separate Bio Bottle or similar container.
   b) Standard delivery FedEx or UPS shipping is sufficient. Ship the Bio Bottle containers to:

      Steelgate, Inc.
      Re: [Plaintiff's Name c/o Plaintiff's Law Firm]
      2307 58th Avenue East
      Bradenton, Fl. 34203

8. The attached Chain of Custody Form provided by Steelgate, Inc. should be completed and executed attendant to transmission of any Materials contemplated herein.

To the extent that your diagnosis and/or treatment of the patient necessitates that you prepare and analyze histology samples from the pathology explanted, please keep intact as much of the pathology as possible, pursuant to the above protocol, and preserve any blocks or slides prepared in the normal course of business. Please also provide at least thirty (30) days' notice to the Parties before destroying or discarding any explanted devices or portions thereof, or any pathology blocks or slides prepared in the normal course of business.

In order to facilitate this request, enclosed please find a **HIPAA-Compliant Authorization** for the release of the specimens to be removed during this surgery, signed by [Mr./Ms. Plaintiff's last name], as well as a **Chain of Custody Form**.

Very truly yours,

_____

[Counsel for Plaintiff]
Counsel for Plaintiff

Enclosures:

1. HIPAA Authorization
2. Chain of Custody Form

cc: Brandee Kowalzyk
Nelson Mullins
Atlanta Station, Suite 1700
201 17th Street NW
Atlanta, GA 30363
404-322-6000

INSERT STEELGATE CHAIN OF CUSTODY PDF and HIPAA

EXHIBIT B

IMPORTANT – REQUEST FOR PRESERVATION OF PATHOLOGY MATERIALS

[Date]

Attn: Department of Surgery and Pathology
[Address of Explant Facility]

Re: [MDL 3081 case caption; name and birth date of Plaintiff and Date of Anticipated Explant Surgery, Case Caption]

Dear Departments of Surgery and Pathology:

I represent your patient [Mr./Ms. Plaintiff's Full Name/date of birth] in a product liability lawsuit. To be clear, there is no lawsuit pending or anticipated against your facility or the treating physician. Rather, the lawsuit is a product liability lawsuit against Becton, Dickinson & Company, C.R. Bard, Inc., Bard Access Systems, Inc., and Bard Peripheral Vascular, Inc., relating to port catheter devices designed, manufactured, and sold by those companies. The law firm of Nelson Mullins, copied below, represents those companies in the lawsuit.

It is our understanding that [Mr./Ms. Plainitff's Full Name] is scheduled to undergo a procedure on [date] to be performed by Dr. [Explant Surgeon] that may involve the explantation of a port catheter device. I write to request the preservation of pathology material, and any and all pieces of the port catheter device, removed from [Mr./Ms. Plaintiff's last name]'s during such procedure.

Please be advised that any pathology, tissues, as well as the explanted port catheter device, and any and all pieces of the device obtained during that procedure, are critical pieces of evidence in this case. If your facility is in possession of the device, which includes both the port and catheter, or any portions of that device, please ensure that the entire device is preserved for inspection and analysis by representatives of the Parties to this lawsuit. Please do not discard or destroy the device or any of its parts, and please ensure that no one else discards, destroys, or takes any action of any sort that would destroy, damage, or compromise the integrity or current condition of the device. The Parties may be prejudiced if any evidence has been altered, damaged, or destroyed.

Please call or email me at [INSERT] at your earliest convenience to confirm the whereabouts of the evidence referenced above and that steps have been taken to preserve it. Please also contact me if you have any questions relating to the Instructions for Preservation of the materials listed below. If you are not the appropriate recipient of this request, please notify us and forward a copy of this letter to the appropriate person or entity responsible for ensuring compliance with the terms of this preservation request, at your earliest convenience. Thank you very much for your assistance.

The parties request that you preserve the materials identified in this letter, but that you prepare and ship ONLY the explanted device or portions of the explanted device, along with any tissue explanted with it, in the manner described below.

Instructions for Immediate Preservation of the Specimen(s):

1. Please preserve **all** explanted materials.

2. If possible, photograph the device and any retained tissue.

3. All components of the explanted device should be placed in a container of dilute neutral buffered formalin (10% formalin is standard.) Tissue samples may be placed in the same container along with the components of the explanted device for this formalin exposure.

4. Keep the device and tissue in the formalin solution for approximately 24 hours.

5. After 24 hours, remove the device from the formalin and rinse the device thoroughly under cold running tap water for 10 to 20 seconds. Any tissue specimens not attached to the device should stay in the formalin solution.

6. Allow the device components to air dry.

7. The removed devices and soft tissue samples should be prepared and shipped as follows:

   a) Place all of the components of the removed device into a "Bio Bottle" container (or a similar system or container) and follow the instructions provided with that container system in the standard course. Any separate tissue specimens should remain in formalin and be placed in a separate Bio Bottle or similar container.

   b) Standard delivery FedEx or UPS shipping is sufficient. Ship the Bio Bottle container to:

      Steelgate, Inc.
      Re: [Plaintiff's Name c/o Plaintiff's Law Firm]
      2307 58th Avenue East
      Bradenton, Fl. 34203

8. The attached Chain of Custody Form provided by Steelgate, Inc. should be completed and executed attendant to transmission of any Materials contemplated herein.

To the extent that your diagnosis and/or treatment of the patient necessitates that you prepare and analyze histology samples from the pathology explanted, please keep intact as much of the pathology as possible, pursuant to the above protocol, and preserve any blocks or slides prepared in the normal course of business. Please also provide at least thirty (30) days' notice to

the Parties before destroying or discarding any explanted device, or portion thereof, or any pathology blocks or slides prepared in the normal course of business.

In order to facilitate this request, enclosed please find a **HIPAA-Compliant Authorization** for the release of the specimens to be removed during this surgery, signed by [Mr./Ms. Plaintiff's last name], as well as a **Chain of Custody Form**.

Very truly yours,

_____

[Counsel for Plaintiff]
Counsel for Plaintiff

Enclosures:

1. HIPAA Authorization
2. Chain of Custody Form

cc: Brandee Kowalzyk
Nelson Mullins
Atlanta Station, Suite 1700
201 17th Street NW
Atlanta, GA 30363
404-322-6000

INSERT STEELGATE CHAIN OF CUSTODY PDF and HIPAA

Exhibit D

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: BARD IMPLANTED PORT CATHETER PRODUCTS LIABILITY LITIGATION	Case No. 2:23-md-3081-PHX-DGC **CASE MANAGEMENT ORDER NO. ___** **(PRESERVATION ORDER)**

I. SCOPE OF ORDER

Discovery in this proceeding may involve the collection, division, storage, preservation, and production of biomaterials evidence for which special handling, division, storage, and preservation would be warranted. Accordingly, the Parties herein hereby stipulate to and petition the Court to enter this evidence preservation protocol order ("Preservation Order").

This stipulation is entered on behalf of all plaintiffs in MDL 3081 and Defendants Becton, Dickinson & Company, C.R. Bard, Inc., Bard Access Systems, Inc., and Bard Peripheral Vascular, Inc. (hereinafter each a "Party" or collectively, the "Parties"), by and through their respective counsel, to provide a protocol for the collection, preservation, storage, and division of the Materials (as defined in section A, below).

By stipulating to this Preservation Order, the Parties have agreed to be bound by its terms and to request its entry by the presiding judge. Upon entry of this Order, the Order will apply to all current and future actions in MDL 3081.

It is hereby ORDERED as follows:

II. PRESERVATION PROTOCOL

A. DEFINITIONS

"Litigation" or "MDL" is defined as In Re: Bard Implanted Port Catheter Products Liability Litigation, MDL 3081 (D.Az.), including all current and future member cases transferred to, removed to, or filed in this District.

"Medical Facility" is defined to include healthcare facilities where a plaintiff underwent or will undergo a revision, excision, explant, or any other surgery in which a device at issue in this Litigation or portions of a such a device may be removed, as well as medical facilities responsible for the preservation and/or maintenance of excised or explanted Materials from such procedures.

"Materials" is defined as explanted devices or explanted portions of devices at issue in this Lawsuit, as well as any and all gross and microscopic material purported to contain a device at issue in this Lawsuit, or any portion of such devices, and/or any other of tissue excised or explanted from plaintiff found upon, or in proximity to, the location of a device or portions of a device at issue in this Lawsuit, including but not limited to any pathology evidence, histology slides, paraffin blocks containing tissue, pieces of a device, and/or gross material.

"The Storage Facility" or "Steelgate" is defined as the Plaintiffs' central storage vendor for Materials to be preserved in this MDL.

B. INTENT

It is the intention of the Parties that all Materials that have been previously analyzed or tested, as well as Materials which have not previously been analyzed or tested, be preserved in a manner that permits the Parties equal access to and analysis of the Materials. With one exception, the Parties will not interfere with or circumvent the analysis and preservation of Materials by the Medical Facilities to which any of plaintiffs' treating physicians have sent or will send the Materials in the usual course of business. The exception is where, in the usual course of business, the Medical Facility would destroy the Materials.

C. PROTOCOL FOR HANDLING OF CURRENTLY AVAILABLE MATERIALS EXISTING IN POSSESSION OF ~~PLAINTIFFS~~ANY PARTY, ~~PLAINTIFFS' A~~ PARTY'S REPRESENTATIVES, ~~PLAINTIFFS' A~~ PARTY's COUNSEL, OR OTHER STORAGE VENDORS

1. Notice of Available Materials

In all cases pending in MDL 3081 as of the date of this Order, ~~plaintiff's~~ counsel for any party that is possession of an individual's Materials ~~in each individual case make prompt and reasonable inquiry into~~ shall notify opposing counsel ~~for Defendants~~ within ~~five~~ ten (10~~5~~) ~~10~~ business days of this Order, via email ~~sent to: [~~INSERT]~~~~ of the known existence of Materials in the possession of a ~~plaintiff~~party, ~~plaintiffs' a~~ party's representatives, ~~plaintiffs' a~~ party's counsel.~~,~~ or ~~Other~~ a Storage Vendor~~s, If Materials exist and are in the possession of a plaintiff, plaintiffs' representatives, or plaintiffs' counsel as of the date of this Order, plaintiff's counseland shall notify counsel for Defendants within ten (10) business days of this Order or as soon thereafter as practicable,~~

~~via email sent to: [INSERT].~~ Such notification shall~~,~~ identify~~ing~~ who is in possession of such Materials, and the Materials they possess. In all cases filed after the date of this Order, said notice shall be provided by ~~plaintiff's~~ a party's counsel that is aware of the existence of Materials to opposing counsel ~~for Defendants~~ within ten (10) business~~five (5)~~ days of the case being directly filed in or transferred to MDL 3081, or as soon thereafter as practicable. A plaintiff's obligation to provide the information described in this paragraph shall be satisfied by serving a completed Plaintiff Profile Form (PPF) on Defendants wherein responses regarding Materials are provided in Section 5 of the PPF. A plaintiff's notification to opposing counsel via service of the PPF that Materials have been previously sent to Steelgate using a Chain of Custody form substantially similar to the form attached hereto will be deemed compliant with the terms of this Order, and no additional preservation notice will be required.

To the extent that any photographs, video or other documentary evidence of such Materials are in the possession of ~~plaintiff~~a party, ~~plaintiff's~~ a party's representatives, ~~plaintiff's~~ a party's counsel, or Other Storage Vendors, a copy of said evidence will be provided to opposing counsel as an attachment to the Profile Form served on the opposing party.. ~~for Defendants as attachments to the Plaintiff Profile Form. within five (5) days of the date of this Order for all cases pending in MDL 3081 as of the date of this Order, or within five (5) days of the date that a case is directly filed or transferred to MDL 3081, for those cases not pending in MDL 3081 as of the date of this Order.~~

2. Disposition of Materials in a Party's ~~Plaintiffs'~~ Possession

~~Plaintiffs'~~ The disclosing counsel will document the Materials in their possession on a Chain of Custody form containing the information provided on Exhibit A hereto, or by way of such Chain of Custody forms as were used to document the chain of custody prior to entry of this Order.

The Parties agree that with respect to any Materials that is in the possession of a ~~plaintiff~~party, ~~plaintiffs'~~ a party's representatives, ~~plaintiff's~~ a party's counsel, ~~or~~ Other a Storage Vendor other than Steelgates, counsel for ~~plaintiff~~ the party in possession shall send a letter with copy to ~~Defendants'~~ opposing counsel to such person or entity in possession of any Materials advising them of the need to collect, preserve and ship the Materials to The Storage Facility (Steelgate), and will coordinate with such person or entity to achieve preservation of the Materials.

Chain of Custody forms shall be completed by each person or entity, that takes possession of and/or transmits the Materials or any portion thereof.

The Parties agree that ~~Plaintiffs~~ the~~each~~ Party in possession of the materials will be responsible for the costs of the retrieval and preservation~~is~~ processes, and for the costs of storage at The Storage Facility (Steelgate) thereafter. The Parties agree that, as this litigation proceeds, ~~Plaintiffs may request~~any Party may request to~~, and~~ meet and confer with ~~Defendants~~ the opposing party regarding~~,~~ contribution ~~from Defendants to~~or sharing of the costs of storage of some, or all, of the preserved Materials. If the Parties are unable to agree on the issue, the Parties will promptly advise the Court and seek guidance.

Materials shall be properly stored and maintained, undivided, at The Storage Facility until such time as the Parties agree upon, and the Court approves, protocols for examination of such Materials.

D. PROTOCOL FOR HANDLING OF CURRENTLY AVAILABLE MATERIALS EXISTING AT A MEDICAL FACILITY

1. Instructions to the Facility

In all cases pending in MDL 3081, as of the date of this Order, counsel for each plaintiff that has actual knowledge of the existence of Materials at a Medical Facility shall send a letter with a copy by email to Defendants' counsel and Plaintiffs' Co-Lead Counsel, to the Medical Facility where the Party has actual knowledge that the Medical Facility is in possession of Materials, in the form attached as Exhibit A, within five (5) days of the date of this Order. In all cases directly filed in, or transferred to, MDL 3081, said letter shall be sent, with a copy to Defendants' counsel via email at Brandee.Kowalzyk@nelsonmullins.com and Plaintiffs' Co-Lead Counsel via ~~.~~, within five (5) days of the date on which counsel for the discovering Party ~~a plaintiff is~~obtains~~has~~ actual knowledge ~~made aware~~ of the existence of currently available Materials at a Medical Facility. It is the intention of the Parties that this letter shall advise the Medical Facility of the need to collect, ~~and~~ preserve, and ship certain of the Materials as potential evidence in the Litigation, and of the need to follow the protocols set forth in Exhibit A in collecting, preserving, and shipping those materials, until further notice. Should the Materials be in the possession of a person or entity that is not a Medical Facility, as defined in this Order, counsel for plaintiff shall also send a letter (similar to Exhibit A), copied to

Defendants' counsel, to such person or entity advising them of the need to collect, and preserve the Materials, and coordinate with such person or entity to achieve preservation of the Materials.

Materials shall be properly stored and maintained, undivided, at The Storage Facility until such time as the Parties agree upon, and the Court approves, protocols for examination of such Materials.

Exhibit A also includes a Chain of Custody Form that the Parties shall request that the Medical Facilities execute for any Materials that any party removes from any Medical Facility. This Chain of Custody form does not in any way affect the validity of any Chain of Custody Form utilized to obtain Materials prior to the date of entry of this Order. After the Materials leave the possession of any Medical Facility, the Chain of Custody Form will be requested to be completed by each individual or entity obtaining and/or releasing custody of any Materials thereafter.

2. Retrieval, Storage, and Evaluation of Materials

The terms and procedures outlined in Section E below shall apply, and the Parties may only alter the terms of this Stipulation by written agreement as required to carry out its purpose.

E. PROTOCOL FOR PRESERVATION OF MATERIALS FROM FUTURE SURGERY

1. Notice Of Surgery

Within five (5) business days of receipt of information that a plaintiff in the Litigation intends to undergo or has scheduled a revision, excision, explant, or any other surgery that may involve removal of the device or portions of the device, or as soon as practicable thereafter, plaintiffs' counsel in such case shall notify counsel for Defendants of the intent for revision, excision, or explant surgery as well as the date and location of such surgery (if scheduled). The notice shall be provided via email to: via email at Brandee.Kowalzyk@nelsonmullins.com.

2. Instructions to the Facility

Concurrently with provision of the above-referenced notice, counsel for plaintiff(s) in the individual case shall send instructions with a copy to Defendants' counsel to the Medical Facility where the surgery is to occur in the form attached as Exhibit B. It is the intention of the Parties that Exhibit B shall advise the Medical Facility of the need to collect, preserve, and ship certain of the Materials as potential evidence in the Litigation, and of the need to follow the protocols set forth in Exhibit B in collecting, preserving, and shipping the Materials.

Exhibit B also includes Chain of Custody forms that the plaintiff shall request that the Medical Facility execute attendant to any collection and/or shipment of Materials. This Chain of Custody form does not in any way affect the validity of any Chain of Custody form utilized to obtain Materials prior to the date of entry of this Order. Subsequently, the Chain of Custody forms will be completed by each individual or entity having custody of the Materials from the time those Materials leave the possession of each Medical Facility.

Concurrently with provision of the above-referenced notice, plaintiffs shall provide to the Medical Facility a HIPAA-compliant authorization allowing the Medical Facility to accommodate the requests in Exhibit B.

3. Retrieval, Storage, and Evaluation of Materials

The Parties will use reasonable efforts to cooperate in the evaluation of the explanted Materials and may alter the terms of this Stipulation only by written agreement as required to carry out its purpose.

For all Materials not yet explanted as of the date of this Order, the Parties will use Steelgate, Inc. ("The Storage Facility") to receive and store the Materials for the purposes set forth in this Order. The Storage Facility shall receive the protocols agreed upon by the Parties for the preservation, storage, and shipping of the Materials, contained in Exhibits A and B to this Order, and shall be instructed to strictly adhere to those protocols. Neither party shall have the right to remove the Materials from The Storage Facility unilaterally. Plaintiffs will be responsible for the costs associated with the shipping and storage of all Materials. The Parties agree that, as this litigation proceeds, Plaintiffs may request, and meet and confer with Defendants regarding, contribution from Defendants for the costs of storage of some, or all, of the preserved Materials. If the Parties are unable to agree on the issue, the Parties will promptly advise the Court and seek guidance.

At any time after a case is filed in MDL 3081, either Party may request the opportunity to perform a non-destructive gross evaluation of the Materials at The Storage Facility relating to that case, or may request such evaluation at another location if agreed

upon by the Parties, by providing advanced written notice of ten (10) days to the opposing Party and allowing the opposing Party the opportunity, at their own costs, to have a pathologist, or other types of experts, present and/or to have the gross evaluation videotaped. Any gross examination conducted pursuant to this section may include microscopic evaluation and or photography. The Parties will work together to find a mutually convenient date and time for any such non-destructive gross evaluation. Neither Party will perform any inspection, review, analysis, division or testing on the Materials or alter the Materials in any manner prior to reaching a mutually agreeable protocol.

If in any case filed in MDL 3081, either Party wishes to perform additional testing on the Materials in that case, following the gross examination, the Parties agree that the procedures for additional testing must be agreed to by the Parties and that any division of the Materials must be accomplished via the least destructive means. If either party objects to the procedures or the division of the Materials the Parties shall be required to meet and confer in an effort to resolve the dispute. If the dispute cannot be resolved, the Parties will promptly advise the Court and seek guidance. Prior to any division of Materials the opposing party will have the opportunity to have their experts or consultants evaluate the gross pathology and be present for any division. The Parties will work together to find a mutually convenient date and time for any such division.

Chain of Custody forms shall be completed by any entity, including any storage facility, taking possession of and/or transmitting the Materials or any portion thereof.

F. MEDICAL FACILITIES THAT DO NOT RELEASE MATERIALS

If any Medical Facility will not release explanted devices, or portions of same, photographs or videos of such Materials, the Parties will meet and confer on an appropriate method for seeking to obtain same. If any Medical Facility will not release pathology-related Materials to The Storage Facility, then plaintiffs, on behalf of both Parties, may request recuts and/or slides from the Facility in possession of the Materials. Plaintiffs shall pay all costs for such requests. If Defendants also request such materials, Defendants will pay one half of the cost of this process.

Prior to requesting any recuts or slides, plaintiff's counsel shall notify Defendants via email at via email at Brandee.Kowalzyk@nelsonmullins.com that Plaintiff intends to make such a request. Within 14 days of receiving such notice, Defendants shall notify plaintiff's counsel whether they want any slides to be ordered and the type of stain to be utilized, if any. In the event that plaintiff does not seek to obtain recuts or slides, plaintiff's counsel shall notify Defendants of that information via email at Brandee.Kowalzyk@nelsonmullins.com within 30 days of learning that a Medical Facility is in possession of Material(s) but will not release it, or within 60 days of the entry of this Order, whichever period is longer. Defendants are then authorized to seek such slides directly from the Medical Facility, and plaintiff agrees to provide in a timely manner any necessary authorizations to facilitate this request. Prior to any such request, Defendants will notify plaintiff that Defendants intend to request such slides. Plaintiff's counsel will then have 14 days to object to such request or advise Defendants whether plaintiff requires

any slides from the Medical Facility. To the extent the Parties are unable to agree, they will seek the Court's intervention.

No Party shall be allowed to conduct any destructive testing of any Materials, whether with respect to devices, portions of devices, or pathology-related slides and related materials, with the exception of staining of recut slides.

G. ISSUES DIVIDING THE SAMPLES

If in the course of the litigation, both Parties request the division of any preserved Materials, the Parties agree to meet and confer on a protocol by which such Materials may be divided, such that they can be used in the same manner by each side. Neither Party will perform any review, analysis, division or testing on the Materials, or alter the Materials in any way, prior to reaching such a mutually agreeable protocol. In the event no agreement can be reached, the Parties will seek the Court's guidance.

H. VIEWING OTHER PARTY MATERIALS

Regardless of how Materials described in this Order are obtained, each Party shall have the right to examine those Materials, including any photographs or videos obtained of such Materials at an appropriate time in discovery, and in a manner that provides both Plaintiffs' and Defendants' experts sufficient time to evaluate those Materials.

I. MATERIALS PREVIOUSLY DIVIDED, ANALYZED AND/OR TESTED

If any of the Materials for any plaintiff in the Litigation have been divided, analyzed and/or tested by any Party prior to the effective date of this Order, or prior to a case having

been directly filed in or transferred to MDL 3081, ~~[make this reciprocal] Plaintiff's~~counsel having knowledge of division, analysis or testing ~~counsel~~ shall advise ~~Defendants'~~ opposing counsel ~~[in our PPF or DPF?]~~ within five (5) days of receipt of such information. Such notifications shall be directed, as applicable, to plaintiff's counsel via email, with a copy to Plaintiffs' Co-Lead Counsel and to counsel for the Defendants– via email to [INSERT]., ~~and the~~The Parties agree to meet and confer and attempt to arrive at a mutually agreeable disposition as to such Materials. With the exception of testing or analyses that have already begun that may be compromised by delay or stoppage, neither Party will perform any further review analysis, division, or testing on the Materials or alter the Materials in any way prior to reaching agreement.

J. NO WAIVER

Nothing herein shall be construed to preclude the Parties from presenting modifications to the methods for preservation of any Materials, based upon new information.

The court DIRECTS the Clerk to file a copy of this order in 2:23-md-3081, and it shall apply to each member related case previously transferred to, removed to, or filed in this district, as well as cases filed after the entry of this CMO. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Plaintiffs Leadership Committee to counsel appearing in each new action by operation of the MDL Centrality platform. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Plaintiffs Leadership Committee to

counsel appearing in each new action by operation of the MDL Centrality platform. It shall be the responsibility of the Parties to review and abide by all pretrial orders previously entered by the Court. The orders may be accessed through the CM/ECF system or the court's website at www.wvsd.uscourts.gov.

Dated this _____ day of _____, 2023.

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David G. Campbell
United States District Judge