Case 2:23-md-03081-DGC Document 529 Filed 04/04/24 Page 1 of 10 NIGH GOLDENBERG RASO & VAUGHN 2 3 4 5 6 IN THE UNITED STATES DISTRICT COURT 7 FOR THE DISTRICT OF ARIZONA 8 9 10 MDL No. 3081 **IN RE: Bard Implanted Port Catheter** Products Liability Litigation 11 **CASE MANAGEMENT ORDER NO. 20** 12 (Preservation Order) 13 (Applies to All Actions) 14 15 I. **SCOPE OF ORDER** 16 Discovery in this proceeding may involve the collection, division, storage, 17 preservation, and production of biomaterials evidence for which special handling, 18 division, storage, and preservation would be warranted. Accordingly, the Parties herein 19 hereby stipulate to and petition the Court to enter this evidence preservation protocol order 20 ("Preservation Order"). 21 This stipulation is entered on behalf of all Plaintiffs in MDL 3081 and Defendants 22 Becton, Dickinson & Company, C.R. Bard, Inc., Bard Access Systems, Inc., and Bard 23 Peripheral Vascular, Inc. (hereinafter each a "Party" or collectively, the "Parties"), by and 24 through their respective counsel, to provide a protocol for the collection, preservation, 25 storage, and division of the Materials (as defined in Section A, below). 26 By stipulating to this Preservation Order, the Parties have agreed to be bound by its 27 terms and to request its entry by the presiding judge. Upon entry of this Order, the Order

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will apply to all current and future actions in MDL 3081.

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# IT IS HEREBY ORDERED:

# 2 II. PRESERVATION PROTOCOL

# A. DEFINITIONS

"Litigation" or "MDL" is defined as In Re: Bard Implanted Port Catheter Products
Liability Litigation, MDL 3081 (D. Ariz.), 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 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.

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

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B. INTENT

21 It is the intention of the Parties that all Materials that have been previously 22 analyzed or tested, as well as Materials which have not previously been analyzed or tested, 23 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 24 analysis and preservation of Materials by the Medical Facilities to which any of plaintiffs' 25 treating physicians have sent or will send the Materials in the usual course of business. 26 The exception is where, in the usual course of business, the Medical Facility would destroy 27 the Materials. 28

## 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

4 In all cases pending in MDL 3081 as of the date of this Order, plaintiff's counsel 5 in each individual case shall notify counsel for Defendants within ten (10) business days 6 of this Order, via email at Brandee.Kowalzyk@nelsonmullins.com of the known existence 7 of Materials in the possession of a plaintiff, plaintiffs' representatives, plaintiffs' counsel, 8 or other entity. Such notification shall identify who is in possession of such Materials, and 9 the Materials they possess. In all cases filed after the date of this Order, said notice shall 10 be provided by plaintiff's counsel that is aware of the existence of Materials to counsel for 11 Defendants within ten (10) business days of the case being directly filed in or transferred 12 to MDL 3081, or as soon thereafter as practicable. A plaintiff's obligation to provide the 13 information described in this paragraph shall be satisfied by serving a completed Plaintiff 14 Profile Form (PPF) on Defendants wherein responses regarding Materials are provided in 15 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 16 substantially similar to the form attached hereto as Exhibit A, will be deemed compliant 17 with the terms of this Order, and no additional preservation notice will be required. 18

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

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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, attached hereto, or by way of such chain of custody forms that were used to document the chain of custody prior to entry of this Order.

The Parties agree that with respect to any Materials that are in the possession of a
 plaintiff, plaintiffs' representatives, plaintiffs' counsel, or any entity other than Steelgate,

counsel for plaintiff shall send a letter with copy to Defendants' counsel to such person or 1 entity in possession of any Materials, advising them of the need to collect, preserve and 2 ship the Materials to Steelgate, and will coordinate with such person or entity to achieve 3 preservation of the Materials. 4

Chain of Custody forms, following the format of Exhibit A hereto, 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 8 for the costs of storage at Steelgate thereafter. The Parties agree that, as this litigation 9 proceeds, Plaintiffs may request, and meet and confer with Defendants regarding, 10 contribution from Defendants to the costs of storage of some, or all, of the preserved 11 Materials. If the Parties are unable to agree on the issue, the Parties will promptly advise 12 the Court and seek guidance.

13 Materials shall be properly stored and maintained, undivided, at Steelgate until such 14 time as the Parties agree upon, and the Court approves, additional protocols for 15 examination of such Materials, as described in Section F below.

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#### PROTOCOL FOR HANDLING OF CURRENTLY **AVAILABLE** MATERIALS EXISTING AT A MEDICAL FACILITY

D.

1. Instructions to the Facility

19 In all cases pending in MDL 3081, as of the date of this Order, counsel for each 20 plaintiff that has actual knowledge of the existence of Materials at a Medical Facility shall 21 send a letter, with a copy by email to Defendants' counsel and Plaintiffs' Co-Lead 22 Counsel, to the Medical Facility where the counsel for plaintiff has actual knowledge that 23 the Medical Facility is in possession of Materials, in the form attached as Exhibit B, within 24 five (5) days of the date of this Order. In all cases directly filed in, or transferred to, MDL 25 3081, said letter shall be sent, with a copy to Defendants' counsel via email at Brandee.Kowalzyk@nelsonmullins.com and to Plaintiffs' Co-Lead Counsel, within five 26 (5) days of the date on which counsel for a plaintiff obtains actual knowledge of the 27 existence of currently available Materials at a Medical Facility. It is the intention of the 28

Parties that this letter shall advise the Medical Facility of the need to collect, preserve, and 1 ship certain of the Materials as potential evidence in the Litigation, and of the need to 2 follow the protocols set forth in Exhibit B in collecting, preserving, and shipping those 3 materials, until further notice. Should the Materials be in the possession of a person or 4 entity that is not a Medical Facility, as defined in this Order, counsel for plaintiff shall also 5 send a letter (similar to Exhibit B), copied to Defendants' counsel and to Plaintiffs' Co-6 Lead Counsel, to such person or entity advising them of the need to collect, and preserve 7 the Materials, and coordinate with such person or entity to achieve preservation of the 8 Materials. 9

Plaintiff shall include with its letter Exhibit B to any Medical Facility, or other 10 person or entity having possession of Materials, a Chain of Custody Form (Exhibit A) that 11 the Parties shall request that the Medical Facilities, or the person or entity having 12 possession of Materials, execute when sending Materials to Steelgate. This Chain of 13 Custody Form (Exhibit A) does not in any way affect the validity of any previous chain 14 of custody document utilized to obtain Materials prior to the date of entry of this Order. 15 After the Materials leave the possession of any Medical Facility, the Chain of Custody 16 Form (Exhibit A) will be requested to be completed by each individual or entity obtaining 17 and/or releasing custody of any Materials thereafter.

- Plaintiffs shall also include with the letter to the Medical Facility (Exhibit B) a
  HIPAA-compliant authorization (Exhibit D), allowing the Medical Facility to
  accommodate the requests in Exhibit B.
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- 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
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2. Instructions to the Facility

Concurrently with provision of the above-referenced notice, counsel for plaintiff(s)
in the individual case shall send a letter, with a copy to Defendants' counsel, to the Medical
Facility where the surgery is to occur, in the form attached as Exhibit C. It is the intention
of the Parties that Exhibit C 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 C in collecting, preserving, and
shipping the Materials.

Plaintiffs shall include with the letter to the Medical Facility (Exhibit C) the Chain of Custody Form (Exhibit A) requesting that the Medical Facility also execute that form, attendant to any collection and/or shipment of Materials. This Chain of Custody Form (Exhibit A) 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 Form (Exhibit A) 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.

Plaintiffs shall also include with the letter to the Medical Facility (Exhibit C) a
 HIPAA-compliant authorization (Exhibit D), allowing the Medical Facility to
 accommodate the requests in Exhibit C.

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.

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3. Instructions to Steelgate

For all Materials not yet explanted as of the date of this Order, the Parties will use Steelgate to receive and store the Materials for the purposes set forth in this Order. Steelgate shall receive the protocols agreed upon by the Parties for the preservation, storage, and shipping of the Materials, contained in Exhibits B and C to this Order, and shall be instructed to strictly adhere to those protocols. Neither party shall have the right
to remove the Materials from Steelgate 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.

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# F. EVALUATION OF MATERIALS

Materials shall be properly stored and maintained, undivided, at Steelgate. At any 9 time after a case is filed in MDL 3081, either Party may request the opportunity to perform 10 a non-destructive gross evaluation of the Materials at Steelgate relating to that case, or 11 may request such evaluation at another location if agreed upon by the Parties, by providing 12 advance written notice of ten (10) days to the opposing Party and allowing the opposing 13 Party the opportunity, at their own costs, to have a pathologist, or other types of experts, 14 present and/or to have the gross evaluation video taped. Any gross examination conducted 15 pursuant to this section may include microscopic evaluation and/or photography. The 16 Parties will work together to find a mutually convenient date and time for any such non-17 destructive gross evaluation. Neither Party will perform any inspection, review, analysis, 18 division or testing on the Materials, or alter the Materials in any manner, prior to reaching 19 a mutually agreeable protocol.

20 If in any case filed in MDL 3081, either Party wishes to perform additional testing 21 on the Materials in that case, following the gross examination, the Parties agree that the 22 procedures for additional testing must be agreed to by the Parties and that any division of 23 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 24 confer in an effort to resolve the dispute. If the dispute cannot be resolved, the Parties will 25 promptly advise the Court and seek guidance. Prior to any division of Materials, the 26 opposing party will have the opportunity to have their experts or consultants evaluate the 27

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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.

The Chain of Custody Form (Exhibit A) shall be completed by any entity, including any storage facility, taking possession of and/or transmitting the Materials or any portion thereof.

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## G. 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 pathologyrelated Materials to Steelgate, then plaintiffs, on behalf of both Parties, may request recuts
and/or slides from the Medical 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 14 via email at Brandee.Kowalzyk@nelsonmullins.com that Plaintiff intends to make such a 15 request. Within 14 days of receiving such notice, Defendants shall notify plaintiff's 16 counsel whether they want any slides to be ordered and the type of stain to be utilized, if 17 any. In the event that plaintiff does not seek to obtain recuts or slides, plaintiff's counsel 18 shall of notify Defendants that information via email at 19 Brandee.Kowalzyk@nelsonmullins.com within 30 days of learning that a Medical Facility 20 is in possession of Materials, but will not release it, or within 60 days of the entry of this 21 Order, whichever period is longer. Defendants are then authorized to seek such slides 22 directly from the Medical Facility, and plaintiff agrees to provide in a timely manner any 23 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 24 then have 14 days to object to such request or advise Defendants whether plaintiff requires 25 any slides from the Medical Facility. To the extent the Parties are unable to agree, they 26 will seek the Court's guidance. 27

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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.

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# H. ISSUES RELATING TO 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.

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# 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.

15 J. MATERIALS PREVIOUSLY DIVIDED, ANALYZED AND/OR
 16 TESTED

17 If any of the Materials for any plaintiff in the Litigation have been divided, analyzed 18 and/or tested by any Party prior to the effective date of this Order, or prior to a case having 19 been directly filed in or transferred to MDL 3081, Plaintiff's counsel having knowledge 20 of such division, analysis or testing shall advise Defendants' counsel, within five (5) days 21 of receipt of such information, via email to Brandee.Kowalzyk@nelsonmullins.com. The 22 Parties agree to meet and confer and attempt to arrive at a mutually agreeable disposition 23 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 24 review analysis, division, or testing on the Materials or alter the Materials in any way prior 25 to reaching agreement. 26

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# K. NO WAIVER

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Nothing herein shall be construed to preclude the Parties from meeting and
conferring on modifications to the protocols for preservation of any Materials, set forth in
Exhibits B and C hereto, based upon new information, mutually agreeing upon and
presenting such modifications to the Court for approval, or in the event no agreement can
be reached relative to such modifications, seeking the Court's guidance.

This order shall apply to each member related case previously transferred to, 7 removed to, or filed in this district, as well as cases filed after the entry of this CMO. In 8 cases subsequently filed in this district, a copy of the most recent Preservation Order 9 entered in this Litigation will be provided by the Plaintiffs Leadership Committee to 10 counsel appearing in each new action by operation of the MDL Centrality platform. In 11 cases subsequently removed or transferred to this court, a copy of the most recent 12 Preservation Order entered in this Litigation will be provided by the Plaintiffs Leadership 13 Committee to counsel appearing in each new action by operation of the MDL Centrality 14 platform. It shall be the responsibility of the Parties to review and abide by all pretrial 15 orders previously entered by the Court. The orders may be accessed through the CM/ECF 16 system or the Court's website at www.azd.uscourts.gov. 17

Dated this 4th day of April, 2024.

Daniel G. Complett

David G. Campbell Senior United States District Judge