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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
CASE MANAGEMENT ORDER NO. 20
(Preservation Order)
(Applies to All Actions)

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.

1 **IT IS HEREBY ORDERED:**

2 **II. PRESERVATION PROTOCOL**

3 A. DEFINITIONS

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

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

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

19 “Steelgate” is defined as the Plaintiffs’ central storage vendor for Materials to be
20 preserved in this MDL.

21 B. INTENT

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

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

5 1. Notice of Available Materials

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

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

25 2. Disposition of Materials in Plaintiffs' Possession

26 Plaintiffs' counsel will document the Materials in their possession on a Chain of
27 Custody form containing the information provided on Exhibit A, attached hereto, or by
28 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,

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

5 Chain of Custody forms, following the format of Exhibit A hereto, shall be
6 completed by each person or entity, that takes possession of and/or transmits the Materials
7 or any portion thereof.

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

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

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

19 1. Instructions to the Facility

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

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

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

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

22 E. PROTOCOL FOR PRESERVATION OF MATERIALS FROM FUTURE 23 SURGERY

24 1. Notice Of Surgery

25 Within five (5) business days of receipt of information that a plaintiff in the
26 Litigation intends to undergo or has scheduled a revision, excision, explant, or any other
27 surgery that may involve removal of the device or portions of the device, or as soon as
28 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

1 such surgery (if scheduled). The notice shall be provided via email to
2 Brandee.Kowalzyk@nelsonmullins.com.

3 2. Instructions to the Facility

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

11 Plaintiffs shall include with the letter to the Medical Facility (Exhibit C) the Chain
12 of Custody Form (Exhibit A) requesting that the Medical Facility also execute that form,
13 attendant to any collection and/or shipment of Materials. This Chain of Custody Form
14 (Exhibit A) does not in any way affect the validity of any chain of custody form utilized
15 to obtain Materials prior to the date of entry of this Order. Subsequently, the Chain of
16 Custody Form (Exhibit A) will be completed by each individual or entity having custody
17 of the Materials from the time those Materials leave the possession of each Medical
18 Facility.

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

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

25 3. Instructions to Steelgate

26 For all Materials not yet explanted as of the date of this Order, the Parties will use
27 Steelgate to receive and store the Materials for the purposes set forth in this Order.
28 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

1 shall be instructed to strictly adhere to those protocols. Neither party shall have the right
2 to remove the Materials from Steelgate unilaterally. Plaintiffs will be responsible for the
3 costs associated with the shipping and storage of all Materials. The Parties agree that, as
4 this litigation proceeds, Plaintiffs may request, and meet and confer with Defendants
5 regarding, contribution from Defendants for the costs of storage of some, or all, of the
6 preserved Materials. If the Parties are unable to agree on the issue, the Parties will
7 promptly advise the Court and seek guidance.

8 F. EVALUATION OF MATERIALS

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

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

1 gross pathology and be present for any division. The Parties will work together to find a
2 mutually convenient date and time for any such division.

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

6 G. MEDICAL FACILITIES THAT DO NOT RELEASE MATERIALS

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

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

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

4 H. ISSUES RELATING TO DIVIDING THE SAMPLES

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

11 I. VIEWING OTHER PARTY MATERIALS

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

16 J. MATERIALS PREVIOUSLY DIVIDED, ANALYZED AND/OR 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,
24 that may be compromised by delay or stoppage, neither Party will perform any further
25 review analysis, division, or testing on the Materials or alter the Materials in any way prior
26 to reaching agreement.

27 ///

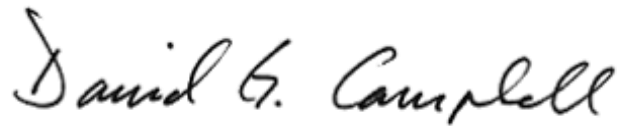
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1 K. NO WAIVER

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

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

18 Dated this 4th day of April, 2024.

19 

20 _____
21 David G. Campbell
22 Senior United States District Judge
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EXHIBIT A

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

Patient Name: _____ Date: _____
Law Firm: _____ Surgery Date: _____

ENTRY NO. 1: Pick Up Location / Releasing Party Information

Facility Name: _____
Address: _____
Address: _____
Contact Name: _____ Department: _____
Contact Phone #: _____ Contact Email: _____

Specimen Description (include manner of preservation, size of specimen, slide number, any other identifying mark(s).

(1) _____ (2) _____
(3) _____ (4) _____

Person RELEASING Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness: _____ (sign/print)

Date: _____ Time: _____

FOR STEELGATE USE ONLY

ENTRY NO. 1: Recipient Location/Receipt information

Facility Name: Steelgate Inc., 2307 58th Avenue East, Bradenton, FL 34203

Specimen Description (include manner of preservation, size of specimen, slide number, any other identifying mark(s).

(1) _____ (2) _____
(3) _____ (4) _____

Note any changes of condition:

Condition of specimen: ambient (___), frozen (___), unfrozen (___), refrigerated (___)

Condition of Container: undamaged (___), damaged (___), describe: _____

Person RECEIVING Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness: _____ (sign/print)

EXHIBIT A

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

Patient Name: _____ Date: _____
Law Firm: _____ Surgery Date: _____
Date: _____ Time: _____

Exhibit C

ENTRY NO. 2: Pick Up Location / Releasing Party Information

Facility Name: Steelgate Inc., 2307 58th Avenue East, Bradenton, FL 34203

Specimen Description (include manner of preservation, size of specimen, slide number, any other identifying mark(s).

(1) _____ (2) _____

(3) _____ (4) _____

Person RELEASING Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness: _____ (sign/print)

Date: _____ Time: _____

ENTRY NO. 2: Recipient Location/Receipt information

Facility Name:

Address: _____

Address: _____

Contact Name: _____ Department _____

Contact Phone #: _____ Contact Email: _____

Specimen Description (include manner of preservation, size of specimen, slide number, any other identifying mark(s).

(1) _____ (2) _____

(3) _____ (4) _____

Note any changes of condition:

Condition of specimen: ambient (___), frozen (___), unfrozen (___), refrigerated (___)

Condition of Container: undamaged (___), damaged (___), describe: _____

Person **RECEIVING** Shipment: _____ (sign/print)

Date: _____ Time: _____

EXHIBIT A

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

Patient Name: _____ Date: _____
 Law Firm: _____ Surgery Date: _____
 Witness: _____ (sign/print)

Date: _____ Time: _____

ENTRY NO. 3: Pick Up Location / Releasing Party Information

Facility Name: _____

Specimen Description (include manner of preservation, size of specimen, slide number, any other identifying mark(s).

(1) _____ (2) _____

(3) _____ (4) _____

Person RELEASING Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness: _____ (sign/print)

Date: _____ Time: _____

ENTRY NO.3: Recipient Location/Receipt information

Facility Name: _____

Address: _____

Address: _____

Contact Name: _____ Department _____

Contact Phone #: _____ Contact Email: _____

Specimen Description (include manner of preservation, size of specimen, slide number, any other identifying mark(s).

(1) _____ (2) _____

(3) _____ (4) _____

Note any changes of condition:

Condition of specimen: ambient (___), frozen (___), unfrozen (___), refrigerated (___)

Condition of Container: undamaged (___), damaged (___), describe: _____

Person **RECEIVING** Shipment: _____ (sign/print)

EXHIBIT A

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

Patient Name: _____ Date: _____

Law Firm: _____ Surgery Date: _____

Date: _____ Time: _____

Witness: _____ (sign/print)

Date: _____ Time: _____

EXHIBIT B

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. Chain of Custody Form (Exhibit C)
2. HIPAA Authorization (Exhibit D)

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

EXHIBIT C

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. Plaintiff'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. Chain of Custody Form (Exhibit C)
2. HIPAA Authorization (Exhibit D)

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

EXHIBIT D

AUTHORIZATION FOR USE OR DISCLOSURE OF PROTECTED HEALTH INFORMATION

Patient Name: _____ Social Security Number: _____

Date of Birth: _____ Address: _____

Authorized Medical Provider(s) to Use or Disclose Information (including its agents, employees and associates):

I hereby authorize the use and disclosure of my protected health information related to my care, treatment and/or services otherwise known as "Protected Health Information" (PHI), as permitted by the Federal Health Privacy Law (HIPAA), as detailed below:

Information to be used or disclosed:

Dates of Services(s): _____ to _____

Specific Description/Type of PHI: All PHI in medical record; all admission form, office notes, reports, opinions, x-rays, MRI, CT or other scans, tests, operative report(s); admission forms, dictation reports, physician orders, intake/outtake/clinical tests/ medication sheets; operative information, Cath, lab reports, special test/therapy, rhythm strips, nursing information, transfer forms, ER information, itemized bill including, but not limited to HCFA or UB-92, and all records to be provided to you by other medical providers/facilities.

- All Medical Records Itemized Billing Radiology/Imaging
- Abstract of Medical Records ER Records Operative Reports
- Admissions/Face Sheet Fetal Monitoring Strips Pathology Reports
- Ambulance Records Gastrointestinal (GD) Lab Reports Pharmacy Records
- Attending Physician's Statement History & Physical Reports Photographs
- Autopsy Reports Implant/Explant Logs Physical Therapy Records
- Anesthesia Records Intra-Operative Nursing Notes Pre-Op Standing Orders
- Chart Stickers Laboratory Reports Product ID/Implant Label
- Consultation Reports Nurse's Notes Psychiatric Records
- Discharge Summary Nurse's Medication Records Radiology/Diagnostic Reports
- Doctor's Records Office Notes Recovery Room Records

Other Pathology materials including but not limited to tissues, the explanted port catheter device, and any and all pieces of the device.

Information May Be Disclosed/Released to: Steelgate, Inc., 2307 58th Ave East, Bradenton, FL 34203
and/or _____

Reason(s) for Use or Disclosure: (At the request of the Patient) To allow my attorney representing me from Dickerson Oxtan, LLC, to adequately and properly investigate and handle my potential claim.

We are requesting an accurate and complete copy of the above referenced patient's medical records from

_____ to _____.

I understand that:

1. I may refuse to sign this authorization and that it is strictly voluntary.
2. My treatment, payment, enrollment or eligibility for benefits may not be conditioned on signing this authorization. 45 CFR 164.508(C)(2)(ii).
3. I may revoke this authorization at any time in writing, but if I do, it will not have any effect on any actions taken prior to receiving the revocation. Further details may be found in the Notice of Privacy Practices.
4. If the requester or receiver is not a health plan or health care provider, the released information may no longer be protected by federal privacy regulations and may be re-disclosed.

5. I understand that I may see and obtain a copy of the information described on this form, for a reasonable copy fee, if I ask for it.
6. This authorization will expire two years (24 months) after the date on which it was signed.
7. I understand that the information in my health record may include information relating to sexually transmitted disease, acquired immunodeficiency syndrome (AIDS) or human immunodeficiency virus (HIV). It may also include information about behavioral or mental health services, treatment for alcohol and drug abuse, genetic testing and communicable and non-communicable diseases. I acknowledge the same and hereby consent to the release of such information.
8. I understand that once the above information is disclosed, it may be re-disclosed by the recipient and the information may not be protected by federal privacy laws or regulations.

I have read the above and authorize the disclosure of the protected health information as stated.

Signature	Date
Print Name	Relationship to Patient (if signed by guardian/representative)