

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD,
INC., POLYPROPYLENE HERNIA
MESH PRODUCTS LIABILITY
LITIGATION

Case No. 2:18-md-2846

CHIEF JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
ALL ACTIONS.

CASE MANAGEMENT ORDER NO. 13

Stipulated Pathology Preservation Protocol

Plaintiffs' Lead Counsel and Defendants C. R. Bard, Inc. and Davol Inc. (collectively "Bard") (with Plaintiffs, the "Parties"), hereby stipulate and agree that the following protocol will govern as to the pathology specimen, including mesh explants, histology slides, paraffin blocks containing tissue, loose mesh, mesh and tissue, dry mesh, and gross material, of any given Plaintiff in this coordinated proceeding (hereinafter referred to as the "Pathology Specimen").

1. 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. This Protocol shall not have retroactive effect, and shall not apply to any steps taken or handling prior to entry of this Protocol and the Parties reserve the right to file a spoliation motion at the proper time based on any conduct before the entry of this Order.

2. The Parties will use Steelgate, Inc. ("Steelgate") to receive, photograph, document, and store the Pathology Specimen according to the process outlined in Instructions to Steelgate, Inc. Chain of Custody Forms shall be completed by each entity, including Steelgate, that takes

possession of any portion of the Pathology Specimen.¹ The Parties agree to equally split the costs of this process and jointly enter into a contract with Steelgate regarding any fees.

3. Protocol for Handling of Currently Available Pathology Specimens Existing at a Facility-

(a) If, prior to the entry of this Order, or otherwise becoming subject to this Order, counsel for a Plaintiff in an individual case had previously sent correspondence to a Facility requesting the preservation of a Pathology Specimen, counsel for Plaintiff shall send copies of said correspondence along with any response from the Facility to: FederalBardService@ReedSmith.com within 30 days of the entry of, or becoming subject to, this Order, or as soon as practicable thereafter. If the Facility has indicated that it did not retain any portion of a Pathology Specimen or otherwise does not have possession of any Pathology Specimen, counsel for the Plaintiff does not need to take any further action. If, in response to Plaintiff's request to preserve the Pathology Specimen, the Facility has indicated it will preserve the Pathology Specimen for a period of 10 years or longer, Plaintiff has the option of 1) sending to Steelgate as outlined in paragraph 3(b) below or 2) allowing the Facility to remain in possession of the specimen until the Facility indicates it will no longer preserve the Pathology Specimen. If retrieval becomes necessary for any reason, the Parties will follow the steps outlined in paragraph 3(b) of this Protocol.

(b) If no prior preservation request as outlined in paragraph 3(a) has been sent, within 10 business days of Plaintiff's counsel learning that that a Pathology Specimen regarding a particular plaintiff exists at a Facility, or as soon as practicable thereafter, Plaintiff's counsel in the individual case shall send a letter, with a copy to Bard's counsel at FederalBardService@ReedSmith.com, to the Facility where the revision, excision, or explant surgery occurred in the form attached as

¹ Mail couriers are not required to fill out the Chain of Custody Forms.

Attachment A, along with a HIPAA-compliant authorization. It is the intention of the Parties that this letter shall advise the Facility of the need to collect, preserve, and/or ship the Pathology Specimen as potential evidence in the Litigation in accordance with the Facility's usual practices. The Chain of Custody Form attached as **Attachment C** will be requested to be completed by each individual or entity obtaining and/or releasing custody of any Pathology Specimen. This Chain of Custody Form does not in any way affect the validity of any Chain of Custody Form utilized to obtain a Pathology Specimen prior to the date of entry of this Order or becoming subject to this Order. After a letter in the form set forth in **Attachment A** has been sent to a Facility, each party will be responsible for payment of one-half of any costs associated with the preservation and shipment of the Pathology Specimen. If the Facility indicates it will preserve the Pathology Specimen for a period of 10 years or longer, Plaintiff has the option of 1) sending to Steelgate as outlined in this paragraph or 2) allowing the Facility to remain in possession of the specimen until the Facility indicates it will no longer preserve the Pathology Specimen, at such time, the Parties will follow the procedures outlined in this paragraph.

(c) If a Facility will not release original slides and/or paraffin tissue blocks, the Parties shall not order recuts until the case is selected for discovery work-up. A subsequent case management order will address the ordering of recuts once a case is selected for discovery work-up.

4. **Protocol for Preservation of Pathology Specimens From Future Surgery-** Within five business days of a scheduled hernia mesh revision, excision, or explant surgery known to Plaintiff's counsel, or as soon as practicable thereafter, counsel for the Plaintiff shall send instructions with a copy to Bard's counsel at FederalBardService@ReedSmith.com to the Facility where the revision, excision, or explant surgery is scheduled in the form attached as **Attachment**

B, along with a HIPAA-compliant authorization. It is the intention of the Parties that **Attachment B** shall advise the Facility of the need to collect, preserve, and/or ship the Pathology Specimen as potential evidence in the Litigation. The Chain of Custody Form attached as **Attachment C** will be requested to be completed by each individual or entity obtaining and/or releasing custody of any Pathology Specimen. This Chain of Custody form does not in any way affect the validity of any Chain of Custody form utilized to obtain Pathology Specimens prior to the date of entry of this Order or becoming subject to this Order. After **Attachment B** has been sent to a Facility, each party will be responsible for payment of one-half of any costs associated with the collection, preservation, and shipment of the Pathology Specimen.

5. Protocol for Handling of Currently Available Pathology Specimens Existing in Possession of Plaintiffs' Counsel or Plaintiffs' Representatives as of the Date of this Order-

If Plaintiffs or Plaintiffs' Representatives (*e.g.*, Steelgate, Inc. or similar entity) are already in possession of any Pathology Specimen, within 45 days of this Order being entered or otherwise becoming subject to this Order, or as soon as practicable thereafter, Plaintiffs' counsel shall notify counsel for Bard of the existence of the Pathology Specimen and the name of the facility from which the Pathology Specimen was collected. To the extent such information is known to Plaintiffs, Plaintiffs will provide the date of the surgery during which the Pathology Specimen was removed. The notice shall be provided via email to: FederalBardService@ReedSmith.com. Plaintiffs' counsel will document the Pathology Specimens in their possession on a Chain of Custody Form containing the information provided on the Attachments to this Order, or by way of such Chain of Custody Forms as were used to document the chain of custody prior to entry of this Order or otherwise becoming subject to this Order. If a third-party laboratory/repository similar to Steelgate is preserving the Pathology Specimen at the time of entry of this Order, or becoming subject to this Order, that entity may continue to preserve the Pathology Specimen until

the case is selected for discovery work-up and Bard will not be required to split the fees of such storage. Bard reserves its right to challenge the method of such facility's preservation. If Plaintiffs' counsel or Plaintiffs' expert is in possession of the Pathology Specimen, within 45 days of the entry of this Order or otherwise becoming subject to this Order, or as soon as practical thereafter, Plaintiffs' counsel will arrange for the shipment of the Pathology Specimen in accordance with the instruction on **Attachment A**. In order to avoid the premature disclosure of experts, Plaintiffs' counsel will provide a completed copy of the Chain of Custody Form to counsel for Bard at the time of Plaintiffs' expert disclosures.

6. A separate case management order will be entered later that discusses review of any Pathology Specimen by a party or their expert. Until a case is selected for discovery work-up, no cutting and/or testing, including destructive testing, may occur by either party.

7. Nothing herein shall be construed to preclude a Party from challenging the method of preservation of the Pathology Specimen.

8. The Parties agree that Steelgate will maintain custody and the preservation of any portion of the Pathology Specimen that it is in possession of until such time as the parties to this agreement by written amendment hereto, nevertheless, authorize the Pathology Specimen to be delivered to the Court, opposing counsel, or otherwise destroy the specimen.

IT IS SO ORDERED.

12-19-2018
DATE



EDMUND A. SARGUS, JR.
CHIEF UNITED STATES DISTRICT JUDGE

12/19/2018
DATE



KIMBERLY A. JOLSON
UNITED STATES MAGISTRATE JUDGE

ATTACHMENT A

NOTICE TO PRESERVE PATHOLOGY MATERIALS

Date

FACILITY
ATTN:Pathology Department
Address

Re: [Case Caption]
Patient: _____
Date of Surgery: _____

Dear Department of Pathology:

I represent the Plaintiff, _____, and Michael Brown, Esq. and Eric Alexander, Esq. of Reed Smith, copied below, represent the Defendants, Davol Inc. and C.R. Bard, Inc. (collectively "Bard"), in the above-referenced lawsuit. There is no litigation pending against your facility or the treating physician in this matter. The pathology and any explanted mesh material is important evidence in pending litigation against Bard and preservation of these items is critical. I write to request the following:

- **Please verify if any pathology and explant material is available, including histology slides, from [FIRST, MIDDLE, LAST NAME]'s [date] surgery performed by Dr. [Explant Surgeon], if so, please continue to preserve using your standard method of preserving pathology and/or explant materials.** It is of utmost importance that you **DO NOT DISCARD OR DESTROY THESE MATERIALS.**
- If your standard method of preserving pathology, histology slides, and/or explant materials contemplates that you preserve these materials for a period that spans at least 10 years from the date of this letter, then you need do nothing further than continue to preserve these materials, unless instructions are provided, which will be sent separately.
- If any specimen, histology slide, or explant material is available and, pursuant to your protocols, is due to be destroyed within less than 10 years from the date of this letter, the parties further request that you immediately contact our pathology specimen storage facility representative to arrange for the shipment and storage of these preserved materials once your normal pathology procedures have been completed. Standard delivery FedEx or UPS shipping is sufficient, however, please comply with your usual practice for the shipment of these materials to:

Kate Grayson
Steelgate, Inc.,
2307 58th Avenue East
Bradenton, Florida 34203
kate@steelgateinc.com
(941) 758-1122 or (866) 647-8335

To facilitate this request, enclosed please find a HIPAA-compliant authorization signed by the above-referenced Plaintiff for the release of the pathology and explant specimens to Steelgate as instructed above.

Instructions for Reimbursement for Costs Incurred: For reimbursement of costs incurred in the collection, preservation, and shipping of the specimens, please submit an itemized invoice to:

[Plaintiff's Counsel information]

Should you have any questions or concerns regarding this matter, please contact us by email directed to representatives of both parties: [counsel for Plaintiff] and Eric Alexander, Esq., ealexander@reedsmith.com (counsel for Bard) as well as Kate Grayson, kate@steelgateinc.com.

If you are not the appropriate recipient of this request, please notify and forward a copy of this letter to the appropriate person or entity responsible for ensuring compliance with the terms of this request at your earliest convenience. Thank you very much for your assistance

ENCLOSURE: as stated

Cc: Michael Brown, Esq. and Eric Alexander, Esq. (FederalBardService@ReedSmith.com)
Kate Grayson (kate@steelgateinc.com)

ATTACHMENT B

NOTICE TO PRESERVE PATHOLOGY MATERIALS

Date

FACILITY

ATTN: Department of Surgery and Pathology

Address

Re: [Case Caption]

Patient:

Date of Surgery: _____ [Date of Anticipated Explant]

Dear Department of Surgery and Pathology:

I represent the Plaintiff, _____, and Michael Brown, Esq. and Eric Alexander, Esq. of Reed Smith, copied below, represent the Defendants, Davol Inc. and C.R. Bard, Inc. (collectively "Bard"), in the above-referenced lawsuit. We have been informed that [PLAINTIFF FIRST, MIDDLE, LAST NAME]'s surgery is scheduled for [date], to be performed by Dr. [Explant Surgeon]. There is no litigation pending against your facility or the treating physician in this matter. The pathology and any remaining explanted mesh material is important evidence in pending litigation against Bard and preservation of these items is critical. I write to request the following:

- **Please follow the pathology procedures your facility uses in the ordinary course of business.** Once you have completed your normal pathology procedures, we request that any pathology, paraffin blocks, and/or pathology slides, as well as any tissues and/or the explanted mesh obtained during [PLAINTIFF FIRST, MIDDLE, LAST NAME]'s upcoming surgery, should be preserved by using your standard operating procedures for preserving pathology and explant materials. The only exception is if your policies or procedures contemplate discarding any of the materials, in which we would request that you not discard any materials. Remaining gross specimens containing mesh and/or tissue should be placed in a container of dilute formalin (10% is standard). All pathology described above should be handled in accordance with the following procedures:
 - If your standard method of preserving pathology, histology slides, and/or explant materials contemplates that you preserve these materials for a period that spans at least 10 years from the date of this letter, then you need do nothing further than continue to preserve these materials and **DO NOT DISCARD THEM**, unless instructions are provided, which will be sent separately.
 - If any specimen, histology slide, or explant material is available and, pursuant to your protocols, is due to be destroyed within less than 10 years from the date of this letter, the parties further request that you immediately contact our pathology specimen storage facility representative to arrange for the shipment and storage of these materials. Contact information is as follows:

Kate Grayson
Steelgate, Inc.,
2307 58th Avenue East
Bradenton, Florida 34203
kate@steelgateinc.com
(941) 758-1122 or (866) 647-8335

To facilitate this request, enclosed please find a HIPAA-compliant authorization signed by the above-referenced Plaintiff for the release of the pathology and explant specimens to Steelgate as instructed above.

Instructions for Reimbursement for Costs Incurred: For reimbursement of costs incurred in the collection, preservation, and shipping of the specimens, please submit an itemized invoice to:

[Plaintiff's Counsel's Information]

Should you have any questions or concerns regarding this matter, please contact us by email directed to representatives of both parties: [counsel for Plaintiff] and Eric Alexander, Esq., ealexander@reedsmith.com (counsel for Bard) as well as Kate Grayson, kate@steelgateinc.com.

If you are not the appropriate recipient of this request, please notify and forward a copy of this letter to the appropriate person or entity responsible for ensuring compliance with the terms of this request at your earliest convenience. Thank you very much for your assistance

ENCLOSURE: as stated

Cc: Michael Brown, Esq. and Eric Alexander, Esq. (FederalBardService@ReedSmith.com)
Kate Grayson (kate@steelgateinc.com)

ATTACHMENT C
CHAIN OF CUSTODY FORM

[Case caption]

ENTRY NO. []

Applicable Surgery Date for Specimen: _____

	Submitter	Receiver
Name (Print):		
Company/ Organization:		
Address:		
Date:		
Time:		

ITEM DESCRIPTION – Completed by Submitter

Gross Description of Item:

Photographed While in Your Possession? Yes: _____ No: _____

Type of Specimen (paraffin block, slides, loose and dry, loose and in liquid, etc.):

Size and Weight of Specimen (if in container – do not remove, just record data of container):

Other Identifying Marks or Comments (e.g. slide or block numbers)

Signature of Submitter: _____

ITEM DESCRIPTION – Completed by Receiver

Gross Description of Item:

Photographed While in Your Possession? Yes: _____ No: _____

Type of Specimen (paraffin block, slides, loose and dry, loose and in liquid, etc.):

Size and Weight of Specimen (if in container -- do not remove, just record data of container):

Other Identifying Marks or Comments (e.g. slide or block numbers)

Signature of Receiver: _____

INSTRUCTIONS TO STEELGATE, INC.

Steelgate, Inc. (“Steelgate”) will be instructed to adhere to the following processes for the receipt, documentation, photography, and storage of the Pathology Specimens. Plaintiffs will provide a HIPAA compliant authorization to Steelgate.

Receipt of Materials

Upon receipt of Pathology Specimen(s), Steelgate will notify the Parties via email as follows: FederalBardService@ReedSmith.com for Defendants and [counsel for Plaintiff] for Plaintiffs.

Documentation

Please document receipt of the Pathology Specimen(s) on the applicable Chain of Custody forms.

Photographs

Please photograph the Pathology Specimen(s) as follows:

- I. THE PHOTOGRAPHS SHOULD DEPICT THE ENTIRE SPECIMEN (OR SPECIMENS, IF EXCISED IN MORE THAN ONE PART) WITH SCALE AND IDENTIFIERS.
- II. CONFIRM THAT EACH PHOTOGRAPH IS SUFFICIENTLY IN FOCUS TO ALLOW RECOGNITION OF SPECIMEN DETAIL.
- III. TAKE AT LEAST TWO (2) OVERVIEW PHOTOGRAPHS OF THE SPECIMEN(S) FROM OVERHEAD.
- IV. TAKE AT LEAST ONE (1) PHOTOGRAPH FROM EACH OF FOUR EQUALLY SPACED DIRECTIONS TAKEN AT AN OBLIQUE ANGLE.
- V. TURN THE SPECIMEN OVER AND REPEAT STEPS 3 AND 4, ABOVE.
- VI. THERE SHOULD BE AT LEAST 12 PHOTOGRAPHS TOTAL.

Weighing

Please weigh the Pathology Specimen(s) and document the weight in writing and correspond to the appropriate photographs. If the Pathology Specimen is in a container—do not remove, just record data of container.

Minimize Time in Air

The time that the Pathology Specimen(s) is left in air should be minimized so as to avoid drying of any residues on the surface of the sample. As soon as photo-documentation is completed, the specimens should be placed in an appropriate container for storage.

Storage of Materials

The Pathology Specimen(s) should be stored under appropriate conditions. At this time no division of the Pathology Specimen(s) should take place. Separate instructions will be provided for division and shipping of the Pathology Specimen(s) at a later time.