IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: C.R. BARD, INC., PELVIC REPAIR
SYSTEM PRODUCTS LIABILITY LITIGATION

MDL No. 2187

THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER # 121
(Stipulated Evidence Preservation Protocol for Potential Trial Selection Cases)

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 (the "Parties") hereby stipulate to and petition the court to enter this stipulated evidence preservation protocol order ("Order") in this matter. **Upon entry of this Order, the Order will apply to all current and future actions selected for trial preparation in MDL 2187 pursuant to order of the Court, including the 200 individual cases selected for trial pursuant to Pretrial Orders # 102 and 118 as well as any similar future Pretrial Orders designating individual actions for trial preparation. This protocol is not intended to apply generally to all cases in this MDL proceeding.**

II. The Order

By stipulating to this Evidence Protocol Order, the parties have agreed to be bound by its terms and to request its entry by the presiding district or magistrate judge. It is hereby **ORDERED** as follows:

This stipulation is entered between Plaintiffs whose cases have been or may be selected for potential trial work-up in the Litigation (as defined in Section A, below) and Defendant C. R. Bard, Inc. ("Bard") (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 in the Litigation (as defined in section A, below).

A. DEFINITIONS

"Facility" is defined to include healthcare facilities where a plaintiff underwent or will undergo a mesh revision, excision, or explant surgery, as well as facilities responsible for the preservation and/or maintenance of excised or explanted materials from such surgeries.

"Litigation" is defined as *In re: C.R. Bard, Inc., Pelvic Repair System Products Liability Litigation*, MDL No. 2187 (S.D. W.Va.), and this Order is intended to apply to those member cases in this Litigation that have been selected for trial preparation in MDL 2187 pursuant to order of the Court, including the 200 individual cases selected for trial pursuant to Pretrial Orders # 102 and 118 as well as any similar future Pretrial Orders designating individual actions for trial preparation. This protocol is not intended to apply generally to all cases in this MDL proceeding.

"Material" or "Materials" is defined as any and all gross and microscopic material purported to contain mesh or any other of these Plaintiffs' pelvic floor tissue excised or explanted from any of these Plaintiffs, including but not limited to any pathology evidence, mesh explants, histology slides, paraffin blocks containing tissue, loose mesh, mesh and tissue, dry mesh, and gross material.

B. INTENT

It is the intention of the Parties that all Material that has not previously been analyzed or tested, be preserved in a manner that permits the Parties equal access to and analysis of the Material, and that neither Party will perform any analysis or testing on Materials or alter the Materials in any way prior to reaching a mutual agreement in writing regarding the equal

division of the Materials. In the event that no such agreement can be reached, the parties will seek the Court's guidance. The Parties will not interfere with or circumvent the analysis and preservation of Materials by the Facilities to which any of Plaintiffs' treating physicians have sent or will send the Materials in the usual course of business.

C. **PROTOCOL FOR PRESERVATION OF MATERIALS FROM FUTURE SURGERY**

1. **Notice Of Surgery**

Within five (5) business days of receipt of information that a Plaintiff selected for potential trial work-up in the Litigation intends to undergo or has scheduled a mesh revision, excision, or explant surgery, or as soon as practicable thereafter, Plaintiffs' counsel in such case shall notify counsel for Bard 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: Bard.MDL@gtlaw.com

2. **Instructions To The Facility**

Concurrently with provision of the above-referenced notice, counsel for Plaintiffs in the individual case shall send a letter with a copy to Bard's counsel to the Facility where the revision, excision, or explant surgery is to occur in the form attached as **Attachment A**. It is the intention of the Parties that this letter shall advise the Facility of the need to collect, preserve, and document the Material as potential evidence in the Litigation. **Attachment A** also includes Chain of Custody forms that the Parties shall request that the Facility execute for any Material any party removes from any 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. Subsequently, the Chain of Custody form will be completed by each individual or entity having custody of the Material from the time it leaves the possession of each Facility.

After a letter in the form set forth in **Attachment A** has been sent to a Facility, it shall be incumbent on Plaintiffs to arrange for payment of any costs associated with the preservation and shipment of Materials. All costs associated with the preservation and shipment of the Material under this protocol shall be borne by the specific Plaintiff.

Concurrently with provision of the above-referenced notice, Plaintiffs shall provide to the Facility a HIPAA-compliant authorization.

3. **Third Party Laboratory**

For all Materials not yet explanted as of the date of this Order, the Parties will agree on a third party laboratory to receive, photograph, document, and divide the Materials according to the process outlined in **Attachment C**. In the event no agreement can be reached, the parties will seek the Court's guidance. The Parties agree to equally split the costs of this process.

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

1. **Notice Of Available Materials**. Within five (5) business days of receipt of knowledge that Materials regarding a particular plaintiff exist at a Facility, or as soon as practicable thereafter, Plaintiffs' counsel in the individual case shall notify counsel for Bard of the date and location of each such surgery resulting in Materials. The notice shall be provided via email to: Bard.MDL@gtlaw.com

2. **Instructions To The Facility**

Concurrently with provision of the above-referenced notice, counsel for such Plaintiff shall send a letter with a copy to Bard's counsel to the Facility where the revision, excision, or explant surgery occurred in the form attached as **Attachment B**. It is the intention of the Parties that this letter shall advise the Facility of the need to collect, preserve, and document the Material as potential evidence in the Litigation. **Attachment B** also includes a Chain of Custody form

that the Parties shall request that the Facility execute for any Material that any party removes from any 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 Material leaves the possession of any Facility, the Chain of Custody form will be requested to be completed by each individual or entity obtaining and/or releasing custody of any Material thereafter.

After a letter in the form set forth in **Attachment B** has been sent to a Facility, it shall be incumbent on the specific Plaintiff to arrange for payment of any costs associated with the requested shipment of Material. All costs associated with the preservation and shipment of the Material under this protocol shall be borne by the specific Plaintiff.

Plaintiffs shall provide to the Facility a HIPAA-compliant authorization.

3. **Third Party Laboratory**

For all Materials not yet requested by any Party as of the date of this Order, the Parties will agree on a third party laboratory to receive, photograph, document, and divide the Materials according to the process outlined in **Attachment C**. The Parties agree to equally split the costs of this process. In the event no agreement can be reached, the parties will seek the Court's guidance.

E. PROTOCOL FOR HANDLING OF CURRENTLY AVAILABLE MATERIALS EXISTING IN POSSESSION OF PLAINTIFFS' COUNSEL OR FACILITIES AS OF THE DATE OF THIS ORDER

1. **Notice Of Available Materials**. If Plaintiffs or facilities that have received Materials (e.g., Steelgate, Inc. or similar entity) are already in possession of any Materials as of the date of this Order, within five (5) days of this Order being entered or as soon as practicable thereafter, Plaintiffs' counsel shall notify counsel for Bard of the existence of the

Materials and the present location of the Materials. To the extent documentation, photographs, videos, or any other documentary or related evidence exists regarding these Materials, Plaintiffs will provide all such evidence to counsel for Bard within five (5) days of this Order being entered or as soon as practicable thereafter. To the extent such information is known to Plaintiffs, Plaintiffs will provide the date of the surgery during which the Materials were removed. The notice shall be provided via email to: Bard.MDL@gtlaw.com

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 the Attachments 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. Plaintiffs' counsel will provide a completed copy of the Chain of Custody form to counsel for Bard. Plaintiffs' counsel will ship all Materials in their possession to Steelgate, Inc., 2307 58th Avenue, East Bradenton, Florida 34203. All costs associated with the preservation and shipment of the Material under this protocol shall be borne by the specific Plaintiff.

The Parties agree that for the Materials already in the possession of Plaintiffs' counsel or other facilities, Steelgate, Inc. shall receive, photograph, document, and divide the Materials according to the process outlined in **Attachment C**. The Parties agree to equally split the costs of this process. To the extent any Party uses Steelgate, Inc. for any other purpose, including but not limited to storage, that Party will bear its own costs.

F. ISSUES DIVIDING THE SAMPLES

If in the course of dividing the Materials, that have not been previously divided prior to the entry of this Order, to preserve at least one-half for use by each Party, it becomes impossible to provide the Parties with Materials that can be used in the same manner by each side, the

Parties agree to immediately meet and confer and attempt to arrive at a mutually agreeable protocol as to such Materials. Neither Party will perform any review, analysis, division or testing on the Materials or alter the Materials in any way prior to reaching a mutually agreeable protocol. In the event no agreement can be reached, the parties will seek the Court's guidance.

G. MATERIALS PREVIOUSLY DIVIDED, ANALYZED AND/OR TESTED

If, at the time this Order is submitted to the Court by the Parties, the Materials for any Plaintiff in the Litigation have already been divided, analyzed and/or tested by any Party, the Parties agree to immediately 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.

H. NO WAIVER

Nothing herein shall be construed to preclude a Party from challenging the method of preservation of any Materials.

The court DIRECTS the Clerk to file a copy of this order in 2:10-md-2187 and **in each Wave 1 and Wave 2 case selected for potential trial work-up as outlined hereinabove** and in each member related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2:14-cv-15075. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order

will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. 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 of the court's website at www.wvsd.uscourts.gov.

ENTER: April 22, 2014

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

ATTACHMENT A

VERY IMPORTANT – REQUEST FOR PRESERVATION OF PATHOLOGY MATERIALS

[Date]

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

Re: [Date of Anticipated Explant Surgery, Case Caption]

Dear Departments of Surgery and Pathology:

I represent the Plaintiff, Ms. [Plaintiff's last name], and Lori Cohen, Esq. and Sara Deskins Tucker, Esq. of Greenberg Traurig copied below represent the Defendant, C.R. Bard, Inc. (Bard), in the above-referenced lawsuit. There is no litigation pending against your facility or the treating physician in this matter. I write to request the preservation of pathology material from Ms. [Plaintiff's last name]'s surgery, scheduled for [date] to be performed by Dr. [Explant Surgeon].

It is important that any pathology, including tissues and/or mesh, obtained during this upcoming surgery be preserved for future analysis by their respective experts. The parties request that you preserve the specimen(s) obtained as follows:

Instructions for Immediate Preservation of the Specimen(s):

1. Please preserve **all** explanted materials.
2. HISTOLOGY:
    a. Please process the pathology specimens according to your usual practice for the creation of histology slides. (For example, preserve in formalin, place into a paraffin block, and cut slides).
3. EXPLANTS:
    a. With regard to explanted mesh, please place it in an appropriate leak-proof container(s) filled with normal saline and refrigerate promptly. PLEASE DO NOT PLACE THESE MATERIALS IN FORMALIN OR ANY OTHER FIXATIVE.

Instructions for Shipping

Please complete the enclosed Chain of Custody form describing the specimens. Please forward it along with all of the specimens (including histology and the explants in saline filled containers) packaged in dry ice to[1]:

[INDEPENDENT THIRD PARTY LABORATORY
TO BE AGREED UPON BY THE PARTIES]

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:

[insert Plaintiff's contact info]

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 Sara Deskins Tucker, Esq., tuckers@gtlaw.com (counsel for Bard).

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.

Very truly yours,

_____
[Counsel for Plaintiff]
Counsel for Plaintiff

Encls. as stated

cc: Lori G. Cohen, Esq. *(Counsel for Defendant, C.R. Bard, Inc.)*
Sara Deskins Tucker, Esq. *(Counsel for Defendant, C.R. Bard, Inc.)*

[1] Plaintiffs do not agree that saline or dry ice is necessary for the preservation and shipment of these Materials. In the interest of compromise, Plaintiffs have agreed to request the preservation and shipment of the Materials in saline and dry ice. Plaintiffs do not waive any argument they have regarding the appropriate method for preservation or shipment of the Materials and expressly state that the preservation of the Materials in saline and the shipment of the Materials with dry ice is unnecessary.

ATTACHMENT B

VERY IMPORTANT – REQUEST FOR PATHOLOGY MATERIALS

[Date]

Attn: Department of Pathology
[Address of Facility]

Re: [Date of Surgery, Case Caption]

Dear Department of Pathology:

I represent the Plaintiff, Ms. [Plaintiff's last name], and Lori Cohen, Esq. of Greenberg Traurig copied below represents the Defendant, C.R. Bard, Inc. (Bard), in the above-referenced lawsuit. There is no litigation pending against your facility or the treating physician in this matter. I write to request the preservation of available pathology material from Ms. [Plaintiff's last name]'s [date] surgery performed by Dr. [Explant Surgeon].

It is important that any pathology, including tissues and/or mesh, obtained during this surgery be preserved for future analysis. The parties request that you preserve the specimen(s) obtained as follows:

Instructions for Immediate Preservation of the Specimen(s):

1. Please preserve **all** explanted materials.
2. HISTOLOGY:
    a. Please process the pathology specimens according to your usual practice for the creation of histology slides. (For example, preserve in formalin, place into a paraffin block, and cut slides).
3. EXPLANTS:
    a. With regard to explanted mesh, please place it in an appropriate leak-proof container(s) filled with normal saline and refrigerate promptly. PLEASE DO NOT PLACE THESE MATERIALS IN FORMALIN OR ANY OTHER FIXATIVE.[2]

4. If the explanted materials have already been preserved in a different manner, please keep the materials in the manner they are currently preserved and ship as described below.

[2] Plaintiffs do not agree that saline or refrigeration is necessary for the preservation of these Materials. In the interest of compromise, Plaintiffs have agreed to request the preservation of the Materials in refrigerated saline. Plaintiffs do not waive any argument they have regarding the appropriate method for preservation of the Materials and expressly state that the preservation of the Materials in refrigerated saline is unnecessary and preservation in formalin or other fixative is appropriate.

Instructions for Shipping

Please complete the enclosed Chain of Custody form describing the specimens. Please forward it along with all of the specimens (including histology and the explants) packaged in dry-ice to[3]:

[INDEPENDENT THIRD PARTY LABORATORY
TO BE AGREED UPON BY THE PARTIES]

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:

[insert Plaintiff's contact info]

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 Ms. [Plaintiff's last name]. Also enclosed is a Chain of Custody form; the Parties request that this form accompany the specimens when they leave your facility.

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 Sara Deskins Tucker, Esq., tuckers@gtlaw.com (counsel for Bard).

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.

Very truly yours,

_____
[Counsel for Plaintiff]
Counsel for Plaintiff

Encls. as stated

cc: Lori G. Cohen, Esq. *(Counsel for Defendant, C.R. Bard, Inc.)*

[3] Plaintiffs do not agree that saline or dry ice is necessary for the preservation and shipment of these Materials. In the interest of compromise, Plaintiffs have agreed to request the preservation and shipment of the Materials in saline and dry ice. Plaintiffs do not waive any argument they have regarding the appropriate method for preservation or shipment of the Materials and expressly state that the preservation of the Materials in saline and the shipment of the Materials with dry ice is unnecessary.

Sara Deskins Tucker, Esq. *(Counsel for Defendant, C.R. Bard, Inc.)*

CHAIN OF CUSTODY FORM

[Case caption]

ENTRY NO. [ ]

Received by:

Name:_____

Company/Organization:_____

Address:_____

Telephone Number:_____

Date:_____

Time:_____

Signature of Recipient:_____

ITEM DESCRIPTION

Gross Description of Item *(including date of surgery when material removed and slide numbers if applicable)*	**Photographed While in Your Possession** *(Yes/No)*	**Manner of Preservation** *(paraffin block, histology slides, loose and dry, loose and in liquid, etc.)*	**Size of Specimen** *(millimeters and weight)*	**Other identifying marks or comments**

Note any change of condition:

_____

_____

Released by:

Name:_____

Company/Organization:_____

Address:_____

Telephone Number:_____

Date:_____

Time:_____

Signature of Recipient:_____

ATTACHMENT C

These instructions will be provided to the independent third party laboratory as agreed upon by the Parties and a telephone call with a representative from the laboratory will be set up with representatives from both parties to discuss logistics.

The laboratory will be instructed to adhere to the following processes for the receipt, documentation, photography, division, and shipping of the Materials. Plaintiffs will provide a HIPAA compliant authorization allowing the independent third party laboratory to release Bard's portion of the Materials to Bard's counsel as instructed below.

Receipt of Materials

Upon receipt of Materials, the laboratory will notify the Parties via email sent to: [plaintiff's email] and Bard.MDL@gtlaw.com

The Parties will be given the opportunity to have a representative present for the division and inspection of the Materials before any division of the Materials is performed.

Documentation

Please document receipt of the Materials on the applicable Chain of Custody forms.

Photographs

Please document the method of division and photograph the specimen(s) **prior to and after** its equal division, as follows:

1. The photographs should depict the entire specimen (or specimens, if excised in more than one part), fresh, without fixative, with scale and identifiers.
2. Confirm that each photograph is sufficiently in focus to allow recognition of specimen detail.
3. Take at least two (2) overview photographs of the specimen(s) from overhead.
4. Take at least one (1) photograph from each of four equally spaced directions taken at an oblique angle.
5. Turn the specimen over and repeat steps 3 and 4, above.
6. There should be at least 12 photographs total.

Weighing

Please weigh the specimen(s) prior to and after division and document the weight in writing and correspond to the appropriate photographs.

Minimize Time in Air

The time that the 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 division and photo-documentation is completed, the specimens should be placed in saline and stored in the refrigerator.

Division of Materials

EXPLANTS

The explant specimen(s) should be divided such that the amount of foreign material (i.e., mesh), if any, is approximately equal in the two samples.

1. To the extent possible, minimize handling the specimens and gently use forceps or tweezers to minimize the damage to the underlying mesh.
2. Cut the specimen(s) through the longest axis of the mesh into two pieces (may or may not be the longest axis of the entire tissue);
3. If there is mucosa, the cut needs to be through the point where the mesh is closest to the surface of the mucosal defect/ulceration if present;
4. If there is a nodule, the cut should be through the middle of the nodule; and
5. Any foreign material and surrounding tissue in the specimen(s) should not be separated prior to dividing the specimen(s) in half.
6. Weight the pieces.
7. Place the two pieces adjacent to each other and take at least two (2) overview photographs of the pieces from overhead, with scale and identifiers.
8. Place each half of the specimen in an appropriate sized container filled with normal saline and refrigerate promptly.[4]

If in the course of dividing the specimen(s), it becomes impossible to provide two equal halves of the specimen(s), please immediately notify the representatives of the parties before conducting any division. The parties will confer about access to the specimen(s) and provide further instructions about division of the specimens.

HISTOLOGY

The histology Materials should be divided evenly between the Parties.

[4] Plaintiffs do not agree that saline or refrigeration is necessary for the preservation of these Materials. In the interest of compromise, Plaintiffs have agreed to request the preservation of the Materials in refrigerated saline. Plaintiffs do not waive any argument they have regarding the appropriate method for preservation of the Materials and expressly state that the preservation of the Materials in refrigerated saline is unnecessary and preservation in formalin or other fixative is appropriate.

Shipping of Materials to Parties

Please forward one half of the explanted material and four histology slides (if available) packaged in dry-ice to each party as follows:

Plaintiff's half of the Materials:
[insert Plaintiff's or facility contact info]

Bard's half of the Materials:
Attn: Sara Tucker, Esq.
Greenberg Traurig LLP
3333 Piedmont Road NE, Suite 2500
Atlanta, Georgia 30305
(678) 553-7377
tuckers@gtlaw.com