

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: ETHICON PHYSIOMESH	:	MDL DOCKET NO. 2782
FLEXIBLE COMPOSITE	:	ALL CASES
HERNIA MESH PRODUCTS	:	
LIABILITY LITIGATION	:	
	:	
	:	CIVIL ACTION NO.
	:	1:17-MD-02782-RWS
	:	
	:	
	:	

PRACTICE AND PROCEDURE ORDER NO. 11

**PATHOLOGY PROTOCOL FOR PRESERVATION AND TESTING OF
EXPLANTS AND TISSUE SAMPLES TAKEN FROM PLAINTIFFS**

1. This protocol governs the preservation, collection, storage, and division of gross and microscopic material purported to contain mesh or any other of Plaintiffs' tissue excised or surgically explanted from Plaintiffs at or near the site of mesh implantation, including but not limited to slides, tissue/paraffin blocks, and gross specimens (collectively, the "Materials").
2. This protocol applies to all cases in this MDL.

3. With one exception, nothing in this protocol directs healthcare facilities to deviate from normal procedures and policies regarding patient care, pathology processing and analysis, and specimen retention. The exception is where, in the normal course of business, any healthcare facility would destroy explanted mesh or Materials.

A. Preservation and Collection

1. Each Plaintiff will notify the health care facility that takes possession of the explanted Materials at the time of the mesh removal that the Materials should be preserved and that the Materials should be sent to Steelgate, Inc. (“Steelgate”).
 - a. Where Plaintiffs’ Counsel learns of a Plaintiff’s potential revision/explant surgery AFTER the date the surgery occurred, Plaintiffs’ Counsel must provide the agreed upon Past Surgery preservation notice to the facility (attached as Exhibit A). Defendants’ Lead Counsel must be copied on this correspondence.
 - b. Where Plaintiffs’ Counsel learns of a Plaintiff’s potential revision/explant surgery BEFORE the scheduled date of surgery, Plaintiffs’ counsel must timely provide the agreed upon Future Surgery preservation notice to the facility (attached as Exhibit B).

Defendants' Lead Counsel must be copied on this correspondence.

2. Once a preservation notice has been sent, Steelgate will arrange shipment of the Materials to its facility in Florida. Steelgate will then act as a third-party repository of any such Materials.
3. The parties will not interfere with the analysis and preservation of the Materials by the explanting facilities to which any of the Plaintiffs' treating physicians have sent or will send the Materials in the normal course of business.
4. Steelgate will timely notify Plaintiffs and Defendants if and when the Materials are requested from any facility and of obtaining the Materials. The written notification of receipt will include the facility from which the Materials were received and an itemized inventory of the Materials obtained (including collection date, type of specimen, and source site). Plaintiffs, Defendants, and Steelgate shall document the chain of custody for all the Materials using the form attached as Exhibit C.
5. To the extent that the Materials have already been requested and/or are in possession of Plaintiffs or any of Plaintiffs' representative(s), within forty-five (45) days of the entry of this Order, Plaintiffs will

provide Defendants with a list of cases where such Materials have already been collected, surgery date for each specimen, the type of materials collected, the name of the facility from which the materials were collected, and information regarding whether the Materials have been altered in any fashion. Plaintiffs will then, within sixty (60) days of the entry of this Order, transfer such Materials for storage at Steelgate. To the extent that the Materials are already in the Possession of Steelgate, Plaintiffs shall be able to rely upon a report from Steelgate.

6. This Order specifically authorizes any facility in possession of any Materials for any Plaintiff to provide the Materials to Steelgate when requested, assuming Healthcare Insurance Portability and Accountability Act requirements are otherwise satisfied.

B. Storage

1. The Materials shall be preserved in a manner that permits the parties equal access and analysis.
2. The parties agree to split the expense of the monthly storage fees incurred by storage of Materials at Steelgate for cases pending in this MDL. Should the Gross Specimen be divided in a particular case,

each party shall bear its own costs of continued storage of its share of the Materials at Steelgate, if any.

C. Evaluation of “Materials” and Division of “Gross Specimens”

1. For the purposes of this section, the phrase “Gross Specimens” is defined as preserved, explanted meshes and/or tissues that have not been processed into tissue/paraffin blocks or histology slides.
2. At any time, either party may arrange to perform a non-destructive gross examination of the Material at Steelgate, at a date and time mutually convenient for both parties, by providing advanced written notice of ten (10) days to the opposing party and allowing the opposing party the opportunity, at their own costs, to have a representative present.
3. Gross examination shall include visual observations, photography and/or video recording, digital palpation, and physical measurements. No tissue will be dissected or separated from the mesh prior to an agreed upon division of the Gross Specimen, unless both parties’

representatives present at the examination agree to the manner and extent of limited dissection or separation.

4. If either party wishes to perform examination or testing of the Gross Specimens other than described in paragraphs C.2. and C.3. above, the Parties agree that the Gross Specimens will be handled as outlined in this paragraph and the subparagraphs that follow. Prior to any additional examination or testing, the non-requesting party will have the opportunity to have their representative evaluate the Gross Specimens and be present for the division of the Gross Specimens. The parties will work together to find a mutually convenient date and time for any such division. The parties shall be entitled to photographs and/or video recording of the division of materials.

- a) Each party is entitled to a representative and approximately equal sample of any Gross Specimens in the exact form as received from the explanting healthcare facility.

- b) Division of Gross Specimens will be carried out by the requesting party's representative with the coordination and input of the non-requesting party's representative to protect the

non-requesting party's interest in receiving a representative one-half of the Gross Specimens.

c) The non-requesting party's representative will have the right to inspect the Gross Specimens and obtain photographs and optical micrographs of the specimen prior to any alteration by or on behalf of the requesting party's representative, and will have the right to observe, and provide input into, division of the specimen into two comparable and approximately equal samples of mesh and tissue.

d) If the parties cannot agree regarding the manner of division of the Gross Specimens or any portion thereof, the parties will meet and confer in good faith before any division takes place. No division, analysis, or testing of the Gross Specimens will take place before the parties reach mutual agreement on division. In the event no agreement can be reached, the parties will seek the Court's guidance.

e) Following division of any Gross Specimens into halves that are agreed upon by the parties' representatives present at

the division of the Gross Specimens, the parties are free to conduct any testing or analysis on their halves, including destructive testing.

D. Other Pathology

1. Each Party is entitled to examination of any paraffin blocks and/or histology slides using routine pathology methods. This includes the creation of additional histology slides from tissue/paraffin blocks (i.e., “recut slides”) for use by the parties, if necessary. Each party is entitled to equal access to existing slides and is entitled to an equal number of recut slides from existing tissue/paraffin blocks.
2. Each party shall have a right to view the slides of the other. Plaintiffs shall provide their slides to Defendant following completion of review by Plaintiff’s expert, no later than two weeks prior to the deadline for Defendant’s expert reports. Defendant shall provide its slides to Plaintiffs no later than two weeks prior to the depositions of the Defendant’s experts.
3. Upon receipt, Steelgate will maintain any tissue/paraffin blocks or histology slides obtained from pathology (“the Slides”) in an

appropriate manner that effectively preserves them for examination and testing by the parties.


- a. To the extent pathology slides are held by Steelgate, they will be equally apportioned between the parties upon request. If this is not possible, the parties will meet and confer. In the event no agreement can be reached, the parties will seek the Court's guidance.
 - b. To the extent Steelgate receives and stores paraffin/tissue blocks, the parties will meet and confer regarding the creation of histology slides from those blocks using standard operating procedures.
4. If a hospital or other medical facility will not release original slides and/or paraffin/tissue blocks to Steelgate, the Plaintiff may request recut slides from the facility as set forth below. Plaintiffs shall advise Defendants by email of the existence of slides or paraffin/tissue blocks within 48 hours of learning of the existence of such slides or paraffin/tissue blocks. Plaintiffs on behalf of both parties may request such recut and/or original slides from the Facility in possession of the Material. Prior to any such request, Plaintiffs shall notify Defendants that Plaintiffs intend to request such slides. Upon receipt of such

notice, within 10 days, the Defendants shall advise Plaintiffs as to whether they want any slides stained and the type of stain to be utilized.

5. In the event that slides and/or paraffin blocks exist where a plaintiff does not seek to obtain recut slides or original slides, Defendant is authorized to seek such slides 60 days prior to Defendant's expert deadline in the case. Prior to any such request, Defendant will notify Plaintiffs that Defendant intends to request such slides. Plaintiff will then have the opportunity to advise Defendants, within 5 days, whether they require any slides from the facility.

The Court **DIRECTS** the Clerk to file a copy of this Order in 1:17-MD-02782-RWS and it shall apply to each member related care previously transferred to, removed to, or filed in this Court. In cases subsequently filed in this Court, 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 assessed through the CM/ECF system and the Court's website at <http://www.gand.uscourts.gov/17md2782>.

SO ORDERED, this 29th day of May, 2018.



RICHARD W. STORY
United States District Judge

EXHIBIT "A"

NOTICE TO PRESERVE EVIDENCE
URGENT ACTION REQUIRED

[Date]

Attn: Department of Pathology
[Address of Facility]

Re: [Date of Surgery, Case Caption]

Dear Department of Pathology:

I represent the Plaintiff, [PLAINTIFF FIRST, MIDDLE, LAST NAME], and _____, copied below, represents the Defendant, Ethicon, Inc. (Ethicon), 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 Ethicon and preservation of these items is critical. I write to request the following:

- **Please verify if any pathology and explant material is available** 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.**
- If a specimen or explant material is available, the parties further request that you contact our explant pathology 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 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, FIRM NAME, ADDRESS, PHONE/EMAIL]

Should you have any questions or concerns regarding this matter, please contact either Ms. Grayson or the undersigned.

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,

[Signature Block: Counsel for Plaintiff]

Encls. as stated

cc: [Defense counsel (email)]
Kate Grayson (kate@steelgateinc.com)

EXHIBIT “B”

NOTICE TO PRESERVE EVIDENCE
URGENT ACTION REQUIRED

[Date]

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

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

Dear Department of Surgery and Pathology:

I represent the Plaintiff, [PLAINTIFF FIRST, MIDDLE, LAST NAME], and _____, copied below, represents the Defendant, Ethicon, Inc. (Ethicon), in the above-referenced lawsuit. 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 Ethicon 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. 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 then be shipped to our storage facility, at our expense, as discussed below.
 - [PLAINTIFF FIRST, MIDDLE, LAST NAME]’s surgery is scheduled for [date], to be performed by Dr. [Explant Surgeon].
- Please contact our explant pathology 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 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, FIRM NAME, ADDRESS, PHONE/EMAIL]

Should you have any questions or concerns regarding this matter, please contact either Ms. Grayson or the undersigned.

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,
[Signature Block: Counsel for
Plaintiff]

Encls. as stated

cc: [Defense counsel (email)]
Kate Grayson (kate@steelgateinc.com)

EXHIBIT "C"

Attached as a pdf.

EXHIBIT "C"

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: _____

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

(1) _____ (2) _____

(3) _____ (4) _____

Person RELEASING Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness: _____ (sign/print)

Date: _____ Time: _____

ENTRY NO. 1: Recipient Location/Receipt information:

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

Item Description (include manner of preservation, size of specimen, slide number and 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)

Date: _____ Time: _____

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

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

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

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

Item Description (include manner of preservation, size of specimen, slide number and 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: _____

(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)

Date: _____ Time: _____

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

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

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

Facility Name: _____

Item Description (include manner of preservation, size of specimen, slide number and 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: _____

Item Description (include manner of preservation, size of specimen, slide number and 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)

Date: _____ Time: _____