FILED

FEB 11 2020

JOHN C. PORTO, J.S.C.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: ATLANTIC COUNTY
MASTER CASE NO. ATL-L-173-20

MCL CASE NO. 633

Civil Action

IN RE PROLENE HERNIA SYSTEM MESH LITIGATION

**CASE MANAGEMENT ORDER NO. 3**

**[PATHOLOGY PROTOCOL FOR PRESERVATION, DIVISION, AND TESTING OF EXPLANTED MESH AND TISSUE SAMPLES TAKEN FROM PLAINTIFFS]**

This matter having been opened to The Court by the parties; and the parties having indicated they have no objection to the form and entry of the within Order; and the Plaintiffs' Executive Committee and the attorneys for the Defendants Johnson & Johnson and Ethicon, Inc. (collectively "Defendants") (with Plaintiffs, the "Parties"), having stipulated and agreed that the within protocol will govern the preservation, collection, storage, division, and testing of explanted 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 histology slides, tissue/paraffin blocks, and/or gross specimens (hereinafter referred to as "Materials"); and good cause appearing;

**IT IS** on this 11th day of February, ~~2019,~~ 2020

**ORDERED**:

1. Discovery in this proceeding may involve the collection, preservation, storage, division, production, and testing of the Materials, evidence for which special handling, division, storage, and preservation would be warranted.

2. This protocol applies to all cases in this MCL.

3. 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 an appropriate motion at the proper time based on any conduct before the entry of this Order.

4. 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.

5. For the purposes of this Order, the phrase "Gross Specimen" is defined as preserved, explanted mesh and/or tissues that have not been processed into tissue/paraffin blocks or histology slides.

6. The Materials shall be preserved in a manner that permits the parties equal access and analysis. Except as expressly provided in this Order, the Parties will use Steelgate, Inc. ("Steelgate") to receive, photograph, document, and store the Materials 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 Materials.[1] The Parties agree to split the costs of this process equally and will enter into contracts with Steelgate regarding any fees. 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, or a similar entity, if any.

a) All Gross Specimens are to be obtained from the explanting facility and stored at Steelgate. To the extent a Gross Specimen is held by any Plaintiffs' representative, those specimens will be handled and stored as described paragraph 9 of this Protocol.

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

b) Materials other than Gross Specimens are to be obtained and stored at Steelgate, unless an explanting facility has confirmed in writing that it will preserve the Materials for a period of 10 years or longer from the date of the preservation notice, whereupon Plaintiff has the option of 1) sending the Materials to Steelgate or 2) allowing the Facility to remain in possession of the Materials (other than a Gross Specimen) until the case is added to the discovery pool, until six months prior to the expiration of the retention period confirmed by the Facility, or until the Facility otherwise indicates it will no longer preserve the Materials, whichever occurs first.

7. **Protocol for Handling of Currently Available Materials Existing at a Facility**

a) Within 30 days of becoming subject to this Order, either at entry or subsequently, where a Plaintiff or counsel for a Plaintiff has previously sent correspondence to a Facility requesting the preservation of Materials, counsel for Plaintiff shall send copies of said correspondence and any responses from the Facility to Defendants, at njphspathology@butlersnow.com. In the event a Plaintiff or counsel for a Plaintiff is unable to comply with this provision of the Order within 30 days, the Parties shall meet and confer. Defendants shall not unreasonably withhold an extension of time to comply with this provision of the Order.

i. If the Facility says it did not retain any portion of Materials from a procedure, counsel for the Plaintiff shall notify Defendants by E-mail at njphspathology@butlersnow.com that the Materials no longer exist. After notifying Defendants that the Materials no longer exist, no further action is required of the Plaintiff with respect to the Materials from that procedure.

ii. If the Facility responds that it possesses any Gross Specimens, such Gross Specimens shall be sent to Steelgate for storage consistent with this Protocol.

iii. If the Facility has said it possesses only Materials other than Gross Specimens, and it has confirmed in writing that it will preserve the Materials for a period of 10 years or longer from the date of the preservation notice, Plaintiff has the option of 1) sending the Materials to Steelgate consistent with this Protocol or 2) allowing the Facility to remain in possession of the Materials (other than Gross Specimens) until the case is added to the discovery pool, until six months prior to the expiration of the 10-year retention period, or until the Facility otherwise indicates it will no longer preserve the Materials, whichever occurs first. If retrieval becomes necessary for any reason, the Parties will follow the steps outlined in this Protocol regarding shipment to Steelgate.

b) If, prior to becoming subject to this Order, either at entry or subsequently, no preservation request has been sent, within 7 business days of Plaintiff's counsel learning that a Plaintiff has undergone a surgery that was potentially a mesh revision, excision, or explant surgery, Plaintiff's counsel shall send a letter, with a copy to Defendants, at njphspathology@butlersnow.com, to the Facility where the revision, excision, or explant surgery occurred in the form attached as **Attachment A,** along with a HIPAA-compliant authorization. In the event a Plaintiff or counsel for a Plaintiff is unable to comply with this provision of the Order within 7 days, the Parties shall meet and confer. Defendants shall not unreasonably withhold an extension of time to comply with this provision of the Order. This letter is intended to advise the Facility of the need to collect, preserve, and/or ship the Materials as potential evidence in the litigation, in accordance with the Facility's usual practices. The letter instructs that the Chain of Custody Form attached as **Attachment C** be completed by each individual or entity obtaining and/or releasing custody of any Materials. 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 or becoming subject to this Order. Each party will be responsible

for payment of one-half of any costs associated with the preservation and shipment of the Materials to Steelgate. If the Facility says that it possesses any Gross Specimens, such Gross Specimens shall be sent to Steelgate for storage. If the Facility has indicated that it possesses only Materials other than Gross Specimens and has confirmed in writing that it will preserve the Materials for a period of 10 years or longer, Plaintiff has the option of 1) sending the Materials to Steelgate consistent with this Protocol or 2) allowing the Facility to remain in possession of the Materials (other than Gross Specimen) until the case is added to the discovery pool or the Facility indicates it will no longer preserve the Materials.

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, until six months prior to the expiration the Facility's retention period, or until the Facility otherwise indicates it will no longer preserve the Materials, whichever occurs first. Paragraph 16 of this Order addresses the process for ordering recuts.

8. **Protocol for Preservation of Materials From Future Surgery**

Within 5 days of counsel for the Plaintiff learning of a scheduled hernia mesh revision, excision, or explant surgery, counsel for the Plaintiff shall send a letter containing instructions, with a copy to Defendants' counsel at njphspathology@butlersnow.com, to the Facility where the revision, excision, or explant surgery is scheduled to occur. The letter shall be in the form attached as **Attachment B,** and will include a HIPAA-compliant authorization. This letter is intended to advise the Facility of the need to collect, preserve, and/or ship the Materials as potential evidence in the Litigation. The letter instructs that the Chain of Custody Form attached as **Attachment C** be completed by each individual or entity obtaining and/or releasing custody of any Materials. 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 or

becoming subject to this Order. Each party will be responsible for payment of one-half of any costs associated with the collection, preservation, and shipment of the Materials. If the Facility says that it possesses any Gross Specimens, such Gross Specimens shall be sent to Steelgate for storage. If the Facility says it possesses only Materials other that Gross Specimens, and confirms in writing that it will preserve the Materials for a period of 10 years or longer, Plaintiff has the option of 1) sending the Materials to Steelgate consistent with this Protocol or 2) allowing the Facility to remain in possession of the Materials (other than Gross Specimens) until the case is added to the discovery pool or the Facility indicates it will no longer preserve the Materials.

9. **Protocol for Handling of Materials in the Possession of Plaintiffs' Counsel or Plaintiffs' Representatives as of the Date of this Order**

a) If Plaintiffs or Plaintiffs' representatives (*e.g.,* counsel, experts, consultants, third party repositories, etc.) are already in possession of any Materials, within 30 days of this Order being entered or otherwise becoming subject to this Order, counsel shall notify counsel for Defendants of the existence of any Materials in the possession of Plaintiffs or any of Plaintiffs' representatives. To the extent such information is known to Plaintiffs, Plaintiffs must also provide Defendants with the name of the facility from which the Materials were collected, the date of the surgery during which the Materials were removed, the type of Materials (e.g., tissue blocks, slides, or gross specimens), and whether the Materials have been altered in any way. The notice shall be provided to Defendants by E-mail njphspathology@butlersnow.com. To the extent that the Materials are already in the possession of Steelgate, the Parties shall be able to rely upon a report from Steelgate. In the event a Plaintiff or counsel for a Plaintiff is unable to comply with this provision of the Order within 30 days, the Parties shall meet and confer. Defendants shall not unreasonably withhold an extension of time to comply with this provision of the Order.

b) Plaintiffs' counsel will document the Materials in the possession of Plaintiffs or any of Plaintiffs' representatives 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.

c) If a third-party laboratory/repository similar to Steelgate is preserving the Materials at the time of entry of this Order, or becoming subject to this Order, that entity may continue to preserve the Materials until the case is selected for discovery work-up. Defendants will not be required to split the fees of such storage at the alternative location and also reserve their right to challenge the method of such facility's preservation.

d) If Plaintiffs, Plaintiffs' counsel or Plaintiffs' representatives (other than a third-party repository discussed above) is in possession of the Materials, within 60 days of the entry of this Order or otherwise becoming subject to this Order, 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 Ethicon at the time of Plaintiffs' expert disclosures. In the event a Plaintiff or counsel for a Plaintiff is unable to comply with this provision of the Order within 60 days, the Parties shall meet and confer. Defendants shall not unreasonably withhold an extension of time to comply with this provision of the Order.

10. Until a case is selected for discovery work-up, no cutting and/or testing, including destructive testing, may occur by either party.

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

12. **Evaluation of "Materials" and Division of "Gross Specimens"**

Once a case is selected for discovery work-up, either party may arrange to perform a non-destructive gross examination of the Materials, at a date, time, and location mutually convenient for both parties, by providing advanced written notice of 14 days to the opposing party and allowing the opposing party the opportunity, at their own costs, to have a representative present.

13. 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.

14. If either party wishes to perform examination or testing of the Gross Specimens other than described in paragraph 13 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, time, and location 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.

15. **Other Pathology**

Once a case is selected for discovery work-up, 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.

16. If any Facility will not release original slides and/or paraffin/tissue blocks to Steelgate, and the circumstances outlined in Paragraph 7(c) of this Protocol exist, the Plaintiff may request recut slides from the facility as set forth below. Plaintiffs, on behalf of both parties, may request such recut and/or original slides from the Facility in possession of the Materials. Prior to any such request, Plaintiffs shall notify Defendants that Plaintiffs intend to request such

slides. Within 10 days of receiving such notice, the Defendants shall tell Plaintiffs whether they want any slides to be ordered and the type of stain to be utilized. In the event that slides and/or paraffin blocks exist where a plaintiff does not seek to obtain recut slides or original slides, Defendants are authorized to seek such slides directly from the facility 60 days prior to Defendants' expert deadline in the case. Prior to any such request, Defendants will notify Plaintiffs that Defendants intend to request such slides. Plaintiffs will then have 14 days to advise Defendants whether they require any slides from the facility.

17. Each party shall have a right to view the slides of the other. Plaintiffs shall provide their slides to Defendants following completion of review by Plaintiffs' expert, no later than two weeks prior to the deadline for Defendants' expert reports. Defendants shall provide its slides to Plaintiffs no later than two weeks prior to the depositions of the Plaintiffs' experts, unless this would result in the transfer of slides occurring prior to Defendants' expert deadline. If so, Defendants shall provide its slides to Plaintiffs no later than two weeks following Defendants' expert deadline.

18. Upon receipt, Steelgate will maintain any tissue/paraffin blocks or histology slides obtained from pathology in an appropriate manner that effectively preserves them for examination and testing by the Parties.

19. 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.

20. 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.

JOHN C. PORTO, J.S.C.

**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 _____, copied below, represent the Defendants, Johnson & Johnson and Ethicon, Inc. (collectively "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 (including slides, tissue/paraffin blocks, and/or gross specimens),** 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 you possess any Gross Specimens OR if your standard method of preserving pathology, paraffin/tissue blocks, histology slides, and/or explant materials contemplates that you preserve these materials for a period that is less than 10 years from the date of this letter, the parties 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

- If you DO NOT POSSESS ANY GROSS SPECIMENS **AND** your standard method of preserving histology slides and/or blocks of tissue contemplates that you preserve these materials for a period that is at least10 years from the date of this letter, then you need to do nothing further other than 1) continue to preserve these materials unless you receive separate instructions, and 2) provide written confirmation of your retention policy.

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: njphspathology@butlersnow.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 _____copied below, represent the Defendants, Johnson & Johnson and Ethicon, Inc. (collectively "Ethicon"), 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 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 (including gross specimens, paraffin/tissue blocks, and/or pathology slides) 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. 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 any Gross Specimens are retrieved from this procedure OR if your standard method of preserving pathology, paraffin/tissue blocks, histology slides, and/or explant materials contemplates that you preserve these materials for a period that is less than 10 years from the date of this letter, the parties 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

- If you do not possess any Gross Specimens **AND** your standard method of preserving histology slides and/or blocks of tissue contemplates that you preserve these materials for a period that is at least 10 years from the date of this letter, then you need to do nothing further other than 1) continue to preserve these materials unless you receive separate instructions, and 2) provide written confirmation of your retention policy.

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: njphspathology@butlersnow.com
Kate Grayson (kate@steelgateinc.com)

# ATTACHMENT C

## CHAIN OF CUSTODY FORM

**[Case caption]**

**Patient Name:**

**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; gross specimen -- 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; gross specimen -- 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 Materials. Plaintiffs will provide a HIPAA compliant authorization to Steelgate.

## Receipt of Materials

Upon receipt of Materials, Steelgate will notify the Parties via email as follows: njphspathology@butlersnow.com for Defendants and case counsel for Plaintiffs.

## Documentation

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

## Photographs

Please photograph the Materials. Gross Specimens should remain in their original containers and may be photographed only in the original container.

## Weighing

Please weigh the Gross Specimen containers and document the weight in writing and correspond to the appropriate photographs.

## Storage of Materials

The Materials should be stored under appropriate conditions. The parties will coordinate inspection and division of any Materials.

If any Gross Specimen arrives in a container that is cracked, open, and/or leaking fluid, Steelgate will notify the Plaintiffs and Defendants. The Plaintiffs and Defendants will then discuss whether any additional steps should be taken, and such steps will be taken only after mutual agreement.

## Communications

With respect to any written communications from Steelgate involving Materials, counsel from both parties are to be copied on all such communications. Following the division of any Gross Specimen, Steelgate is no longer required to copy both parties on communications regarding their share of the divided Gross Specimen (i.e., Steelgate may communicate directly with the party whose share is the subject of the communication).