

SUPERIOR COURT OF NEW JERSEY
IN RE: PELVIC MESH/GYNECARE
LITIGATION

LAW DIVISION: BERGEN COUNTY

CASE NO. 291
MASTER DOCKET NO.: BER-L-11575-14

FILED

MAR 29 2022

RACHELLE L. HARZ
J.S.C.

CIVIL ACTION

CASE
MANAGEMENT ORDER #81
(Pathology Protocol)

All prior orders remain in full force and effect except as modified by this Order.

THIS MATTER having been reassigned to the Bergen County Vicinage, from Atlantic County, pursuant to the Supreme Court's Order of October 31, 2014; the Court having conducted a Case Management Conference; counsel appearing; for good cause shown and for the reasons set forth on the record;

IT IS on this 29th day of March, 2022, **ORDERED** as follows:

Plaintiffs' Liaison Counsel and Defendants Johnson & Johnson and Ethicon, Inc. (collectively "Defendants") hereby stipulate and agree that the following 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").

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 consistent with this Order. Following final resolution of the individual case after completed settlement and dismissal with prejudice, or after appellate rights have expired, the parties are no longer required to preserve such evidence. 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. (**Attachment E**). 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. In the event that a health care facility refuses to release Materials or imposes additional requirements prior to releasing materials, the

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

parties will attempt to comply with any additional requirements and, if needed, will meet and confer in order to ensure that the Materials are preserved and that the Parties receive equal access for any analysis.

a) All Gross Specimens are to be obtained from the explanting facility (hereinafter referred to as "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 in Paragraph 9 of this Protocol.

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, except as stated above with regard to a Facility that refuses to release the Materials.

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, and/or has already engaged Steelgate or another similar facility to obtain the Materials, counsel for Plaintiff shall confirm with Defense counsel in writing the status of the Materials, and may send copies of correspondence, including Steelgate correspondence and/or any responses from the Facility to Defendants, at njpelvicpreservation@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 njpelvicpreservation@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, or otherwise be addressed, 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, except as stated above with regard to a Facility that refuses to release the Materials 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, or earlier if the process is initiated prior pursuant to Paragraph 10, 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 njpelvicpreservation@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 and preserve in accordance with the Facility's usual practices, 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 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, or earlier if the process is initiated prior pursuant to Paragraph 10.

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 of the Facility's retention period, or until the Facility otherwise indicates it will no

longer preserve the Materials, or earlier if the process is initiated prior pursuant to Paragraph 10, 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 pelvic mesh revision, excision, or explant surgery, counsel for the Plaintiff shall send a letter containing instructions, with a copy to Defendants' counsel at njpelvicpreservation@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 except as stated above with regard to a Facility that refuses to release the Materials. If the Facility says it possesses only Materials other than 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, or earlier if the process is initiated prior pursuant to Paragraph 10.

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 known to Plaintiff or Plaintiff's counsel. The notice shall be provided to Defendants by E-mail (njpelvicpreservation@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, or otherwise pursuant to

Paragraph 10. Defendants reserve their right to raise concerns as to the method and costs associated with such Facility's preservation, and will initiate a meet and confer with plaintiff's counsel as soon as reasonably possible when such concerns arise, and the parties will endeavor to resolve any issues before seeking any relief from the Court.

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 Materials 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 Defendants 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, is required, however if a party determines it is necessary to initiate this process earlier as part of its litigation strategy it may do so, on notice to the other party.

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

12. **Evaluation of "Materials"**

Once a case is selected for discovery work-up, or earlier if the process is initiated prior pursuant to Paragraph 10, either party may arrange to perform a non-destructive gross examination of the Materials, where good cause exists, 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, and physical measurements. No digital palpation will occur and 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 and document same in writing.

14. **Division of "Gross Specimens"** If either party wishes to perform examination or testing of the Gross Specimens other than described in paragraph 13 above, the Parties agree to coordinate with Steelgate to use a third-party laboratory to divide any Gross Specimens in accordance with **Attachment D**, the Pathology Splitting Protocol. To the extent permitted by the third-party laboratory, each party is permitted to have a representative present to observe the division and any additional inspection of the Materials, as long as this will not unreasonably delay the process.

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) If in the course of dividing the Gross Specimens, it becomes impossible to provide two equal halves of the specimens, the third-party laboratory shall immediately notify the Parties before conducting any division. The parties will confer about access to the specimen(s) and provide further instructions about division of the Gross Specimen(s). In the event no agreement can be reached, the Parties will seek the Court's guidance.

c) 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) In the event that the third-party laboratory is not available to divide the Gross Specimens, the division under this Paragraph may take place by a representative of one of the Parties as outlined in this subparagraph. The parties shall meet and confer about which Party will have a representative divide the specimen. Division under this subparagraph shall, to the extent possible, comply with Attachment 4. Each Party will have the opportunity to have their representative inspect and evaluate the Gross Specimens prior to any alteration and be present for the division of the Gross Specimens. Division of Gross Specimens will be carried out with the coordination and input of the non-dividing party's representative to protect the non-dividing party's interest in receiving a representative one-half of the Gross Specimens. Each Party shall be entitled to photographs and/or video recording of the division of materials.

e) 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.

15. Other Pathology

Once a case is selected for discovery work-up, or if the process is initiated prior pursuant to Paragraph 10, 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.

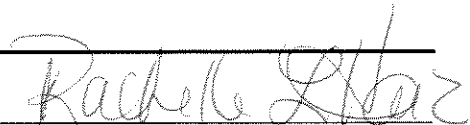
16. If any Facility will not release original slides and/or paraffin/tissue blocks to Steelgate, and the circumstances outlined in Paragraph 7(c) of this Protocol exist, the Plaintiff may request recut slides from the facility as set forth below. Plaintiffs, on behalf of both parties, may request such 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, but in all cases a sufficient time in advance of the Plaintiffs' expert deposition for the Plaintiffs' expert to review and prepare for his or her deposition, along with the defense expert's report.

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, which shall occur consistent with this protocol to the extent possible.


RACHELLE L. HARZ, 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 in a manner that will preserve the utility of the 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 least 10 years from the date of this letter, then you are requested 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: njpelvicpreservation@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, which are assumed to provide for the preservation of the pathology material and the utility thereof, 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 case 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 are requested 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: njpelvicpreservation@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. accession number, 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: _____

ATTACHMENT D

PATHOLOGY SPLITTING PROTOCOL PLAINTIFFS AND DEFENDANTS

These instructions will be provided to the independent third party laboratory as agreed upon by the Parties. If necessary, 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 Defendant's portion of the Materials to Defendants' counsel as instructed below.

Receipt of Materials

Upon receipt of Materials, the laboratory will notify the Parties via email as follows:

For the Plaintiff sent to: [INSERT CONTACT INFORMATION FOR PLAINTIFF'S COUNSEL]

For the Defendants send to: njpelvicpreservation@butlersnow.com

The Parties may have a representative present to observe the division and inspection of

the Materials.

Documentation

Please document receipt of the Materials on the applicable Chain of Custody forms. The Lab checklist must be completed and provided with the divided specimens.

Photographs

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

1. Photograph the as-received specimen jar and all labels on the jar. Confirm that labels are sufficiently in focus to be legible.
2. The photographs should depict the entire specimen (or specimens, if excised in more than one part) with scale and identifiers.
3. All photographs of the specimen(s) should fill as much of the camera field of view as possible.
4. Confirm that each photograph is sufficiently in focus to allow recognition of specimen detail.
5. Take at least two (2) overview photographs of each side of the specimen(s) from overhead.
6. Take at least one (1) photograph from each of four equally spaced directions taken at an oblique angle.
7. Turn the specimen over and repeat steps 5 and 6, above.
8. There should be at least 15 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

Only one specimen container should be opened at any one time. Care must be taken that specimens are not combined with those from other containers, even if from the same patient. 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 an appropriate container for shipment to the parties' respective counsel as set forth below. Plaintiff's half of the materials shall always be stored and shipped in formalin, unless Plaintiff advises Steelgate and Suncoast otherwise. Defendant's half of the materials shall always be stored and shipped in the manner in which it was received (e.g., in formalin if specimens were received in formalin, or dry if specimens were received dry).

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) perpendicularly 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 – placing specimens such that the cut edges are immediately adjacent to one another -- and take at least two (2) overview photographs of the pieces from overhead, with scale and identifiers. Turn the specimens over and repeat overview photographs of this side.
8. Place each half of the specimen in an appropriately sized container. Plaintiff's half of the materials shall always be stored and shipped in formalin, unless Plaintiff advises Steelgate and Suncoast otherwise. Defendants' half of the materials shall always be stored and shipped in the manner in which it was received (e.g., in formalin if specimens were received in formalin, or dry if specimens were received dry.)

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

Any microscope slides available from the Plaintiff's explant procedure(s) should be divided evenly between the Parties and handled as discussed in the Pathology Protocol agreed upon by the parties.

Shipping of Materials to Parties

Please forward one half of the explanted material and an equal number of histology slides (if available) to each party as follows:

Plaintiff's half of the Materials:
[Address]

Defendants' half of the Materials:
[Address]

ATTACHMENT E

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: njpelvicpreservation@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 or Materials arrives in a container that is cracked, open, and/or leaking fluid, and/or the Gross Specimen or Materials appears to be potentially compromised in any way, Steelgate will immediately notify the Plaintiffs and Defendants. The Plaintiffs and Defendants will then discuss whether any additional steps should be taken, in particular to preserve the utility of the Gross Specimen or Material, and such steps will be taken only after mutual agreement.

Communications

With respect to any written communications from Steelgate involving Materials, prior to division of a Gross Specimen, 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, and the identity of the expert or consultant to whom the Materials are to be sent (i.e., Steelgate may communicate directly with the party whose share is the subject of the communication).