

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**IN RE: COVIDIEN HERNIA MESH
PRODUCTS LIABILITY LITIGATION
NO. II,**

This Document Relates To:

All Cases

MDL No. 1:22-md-03029-PBS

CASE MANAGEMENT ORDER NO. 14

Stipulated Pathology Examination and Division Protocol for Bellwether Pool Cases

Plaintiffs' Lead Counsel and Defendants Covidien LP and Sofradim Production SAS (with Plaintiffs, the "Parties"), hereby stipulate and agree that the following protocol will govern as to the examination and division of the Pathology Materials, which is defined below, of each Bellwether Plaintiff in this MDL.

I. Scope of Order

This Protocol applies to all Plaintiffs, Defendants and their counsel in all actions selected as Bellwether Discovery Pool Cases pursuant to CMO No. 4.

II. Definitions

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

B. "Material" or "Materials" or "Pathology Materials" is defined as any and all gross and microscopic material purported to contain mesh or any other tissue excised or explanted from Plaintiff, 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 specimens.

III. Intent

It is the intention of the Parties that all Material that has not previously been analyzed, tested, or made available to both parties, be preserved in a manner that permits the Parties equal access to and analysis of the Material. With one exception, 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. The exception is where, in the usual course of business, the Facility would destroy the Materials.

IV. Transfer of Materials to Steelgate, Inc.

Unless already transferred to Steelgate, Inc., the Parties agree that for all Materials in the cases that are subject to this Order and are in the possession of Plaintiffs' counsel or other facilities, those Materials will be shipped to Steelgate, Inc. Upon its receipt of the Materials, Steelgate, Inc. shall transmit the Materials to a vendor to be mutually agreed upon by the Parties (the "Pathology Vendor"), which in turn shall receive, photograph, document, and divide the Materials according to the process outlined in Section VI below. Chain of Custody forms shall be completed by each entity, including Steelgate, Inc. and the Pathology Vendor, that takes possession of, and/or transmits, the Materials or any portion thereof. The Parties agree to equally split the costs of this process.

V. Facilities That Do Not Release Certain Materials

If any Facility will not release original slides and/or paraffin/tissue blocks to Steelgate, Inc., then Plaintiffs, on behalf of both parties, may request recut slides from the Facility in possession of the Materials. Prior to any such request, Plaintiff's counsel shall notify Defendants via email at jessica.wilson@us.dlapiper.com that Plaintiff intends to request such slides. Within

14 days of receiving such notice, Defendants shall notify Plaintiff's counsel whether they want any slides to be ordered and the type of stain to be utilized, if any.

In the event that Plaintiff does not seek to obtain recut slides, Plaintiff's counsel shall notify Defendants of that information via email at jessica.wilson@us.dlapiper.com within 30 days of learning that a Facility is in possession of Material(s) but will not release it, or within 60 days of the entry of this Order, whichever period is longer. Defendants are then authorized to seek such slides directly from the Facility and Plaintiff agrees to provide in a timely manner any necessary authorizations to facilitate this request. Prior to any such request, Defendants will notify Plaintiff that Defendants intend to request such slides. Plaintiff's counsel will then have 14 days to advise Defendants whether Plaintiff requires any slides from the Facility. To the extent the Parties are unable to agree, they will seek the Court's intervention.

No Party shall be allowed to conduct any destructive testing of any histology slides, with the exception of staining of the slides.

Each Party shall have the right to view the slides of the other Party. Plaintiffs shall provide their slides to Defendants following completion of review by Plaintiffs' expert, but no later than two weeks prior to the deadline for Defendants' expert reports. Defendants shall provide their slides to Plaintiffs no later than two weeks prior to the deadline for Plaintiffs' expert reports. If Defendants are unable to provide the slides within two weeks of Plaintiffs' expert reports, the Parties shall meet and confer in good faith to ensure that Plaintiffs' experts have adequate time to review Defendants' slides.

VI. Division of Gross Pathology Specimen and Explanted Material

With the exception of histology slides and paraffin/tissue blocks, Section VI applies to all Materials in cases that are subject to this Order.

Before any division of Material, each party is entitled to inspect the Material. No party will alter or do any destructive testing of the Material before division.

If the Parties decide the Material should be divided, the division of Material will be carried out by Plaintiff's Pathology Vendor(s) with the coordination and input of Defendants' representative(s) to protect Defendants' interest in receiving a representative one-half of the Material.

No tissue will be separated from mesh prior to dividing the Material.

These instructions will be provided to the Pathology Vendor along with the Covidien Hernia Mesh Specimen Documentation and Division Checklist, attached as Exhibit A, which shall be completed by the Pathology Vendor. Before any action is taken, a telephone call with a representative from the Pathology Vendor's laboratory shall be set up with representatives for each Party to discuss logistics.

The Pathology Vendor will be instructed to adhere to the following processes for the receipt, documentation, photography, division, and shipping of the explanted Materials. Plaintiff's counsel will provide a HIPAA-compliant authorization allowing the Pathology Vendor to release Defendants' portion of the Materials to Defendants' counsel as instructed below.

A. Receipt of Materials

Upon receipt of Materials, the Pathology Vendor will notify the Parties via email sent to: Plaintiff's counsel of record, with a copy to the PSC's designee at kstokes@fleming-law.com, and Defendants' counsel of record, with a copy to jessica.wilson@us.dlapiper.com.

The Parties may have a representative physically present, or appearing via video conference call, for the division and inspection of the Materials.

B. Documentation

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

C. Photographs

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

1. The photographs should depict the entire Material (or Materials, if excised in more than one part) with scale and identifiers.
2. Confirm that each photograph is sufficiently in focus to allow recognition of Material detail.
3. Take at least two overview photographs of the Material(s) from overhead.
4. Take at least one photograph from each of four equally spaced directions taken at an oblique angle.
5. Turn the Material(s) over and repeat steps 3 and 4, above.
6. After division, place the two pieces of Material adjacent to each other and take at least two overview photographs of the pieces from overhead, with scale and identifiers.
7. Turn the two pieces of Material over and take at least two additional overview photographs of the pieces from overhead, with scale and identifiers.
8. There should be at least 16 photographs total.

D. Weighing

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

E. Division of Explanted Materials

The explanted Materials(s) should be divided such that the amount of foreign material (*i.e.*, mesh), if any, and associated tissue, is approximately equal in the two samples. Before the explanted Materials are divided, the Pathology Vendor will notify the Parties via email sent to: Plaintiff's counsel of record, with a copy to the PSC at kstokes@fleming-law.com, and Defendants' counsel of record, with a copy to jessica.wilson@us.dlapiper.com. The Plaintiffs' Pathology Vendor will set up a telephone call with each Party's representative to discuss how the Materials(s) should be divided into two parts (for example along the longest axis, shortest axis, or along a certain piece of tissue).

To the extent possible, minimize handling the Material(s) and gently use forceps or tweezers to minimize the damage to the underlying mesh.

Cut the Materials(s) as the Parties' representatives have agreed during the call discussed above.

Place each half of the Material in an appropriately sized container. The Material(s) shall be placed back into the medium in which the Material(s) arrived. For example, if the Material(s) was received in formalin, the Material(s) will be placed back into formalin after division. If the Material(s) was received dry, the Material(s) will be placed back dry into a container after division.

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

F. Minimize Time in Air

The time that the Materials are left in air should be minimized. As soon as division and photo-documentation are complete, the Material(s) should be placed in an appropriate container for shipment to the Parties' respective counsel as set forth below.

G. Shipping of Materials to Parties

Please forward one half of the explanted Material(s) to each Party as follows:

Plaintiff's half of the Materials:
The address provided by
Plaintiff's counsel of record.

Defendants' half of the Materials:
The address provided by Defendants'
counsel of record.

H. Review, Analysis, Division or Testing of the Materials

As long as the following above procedures are met, the Parties are free to review, analyze, divide, test, or alter the Materials as they see fit.

VII. Original Paraffin/Tissue Blocks and Histology Slides

If a Facility releases to Steelgate, Inc. an original paraffin/tissue block or original histology slides, then the following procedures will apply.

A. Original Paraffin/Tissue Blocks

Any division of original paraffin/tissue block(s) will be carried out by the Pathology Vendor. Before any action is taken, a telephone call with a representative from the Pathology Vendor's laboratory shall be set up with representatives for each Party to discuss logistics. Upon receipt of the paraffin/tissue block(s), the Pathology Vendor will notify the Parties via email sent to: Plaintiff's counsel of record, with a copy to the PSC's designee at kstokes@fleming-law.com, and Defendants' counsel of record, with a copy to jessica.wilson@us.dlapiper.com. The Parties may have a representative physically present, or appearing via video conference call, for the division and inspection of the paraffin/tissue block(s).

Plaintiff's counsel will provide a HIPAA-compliant authorization allowing the Pathology Vendor to release Defendants' portion of the paraffin/tissue block(s) to Defendants' counsel as instructed below.

Division of the paraffin/tissue block(s) shall be made into two comparable and approximately equal samples of mesh and tissue. The Pathology vendor shall photograph the paraffin/tissue block(s) prior to, and after, its equal division with scale and identifiers, ensuring that each photograph is sufficiently in focus.

If the Parties cannot agree regarding the manner of division of the paraffin/tissue block(s) or any portion thereof, then the Parties will meet and confer in good faith before any division takes place.

If the amount of the paraffin/tissue block(s) is such that division in a manner permitting analysis of the mesh and surrounding tissue by both Parties is uncertain, then the Parties will meet and confer in good faith. No Party will perform any examination, analysis, or testing of the paraffin/tissue block(s) or alter the paraffin/tissue block(s) in any way prior to reaching mutual agreement. In the event that no agreement can be reached, the Parties will seek the Court's guidance.

The Pathology Vendor shall forward each Party's half of the paraffin/tissue block(s) to each Party as follows:

Plaintiff's half:

The address provided by
Plaintiff's counsel of record.

Defendants' half:

The address provided by
Defendants' counsel of record.

Once the paraffin/tissue block(s) is divided, the Parties may each create their own slides and stain them as each Party deems appropriate.

Each Party shall have the right to view the slides of the other Party. Plaintiffs shall provide their slides to Defendants following completion of review by Plaintiffs' expert, but no later than two weeks prior to the deadline for Defendants' expert reports. Defendants shall provide their slides to Plaintiffs no later than two weeks prior to the deadline for Plaintiffs' expert reports. If Defendants are unable to provide the slides within two weeks of Plaintiffs' expert reports, the Parties shall meet and confer in good faith to ensure that Plaintiffs' experts have adequate time to review Defendants' slides.

B. Histology

If a Facility releases histology slides to Steelgate, Inc., the histology Materials should be divided evenly between the Parties, with each Party getting every other adjacent slide.

No Party shall be allowed to conduct any destructive testing of any histology slides, with the exception of staining of the slides.

Each Party shall have the right to view the slides of the other Party. Plaintiffs shall provide their slides to Defendants following completion of review by Plaintiffs' expert, but no later than two weeks prior to the deadline for Defendants' expert reports. Defendants shall provide their slides to Plaintiffs no later than two weeks prior to the deadline for Plaintiffs' expert reports. If Defendants are unable to provide the slides within two weeks of Plaintiffs' expert reports, the Parties shall meet and confer in good faith to ensure that Plaintiffs' experts have adequate time to review Defendants' slides.

VIII. Issues Dividing The Materials

If in the course of dividing the Materials pursuant to this Order, 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.

IX. 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 Bellwether Discovery Pool Plaintiff has already been divided, analyzed and/or tested by any Party, the Parties agree to meet and confer and attempt to arrive at a mutually agreeable disposition as to such Materials. With the exception of testing or analyses that has 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.

X. No Waiver

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

XI. Cost Sharing

Plaintiffs are responsible for storage fees incurred at Steelgate prior to the entry of this Order or any individual plaintiff being selected as a Bellwether plaintiff, whichever is later. Following the division of any pathology, each party shall bear its own costs of continued storage of its share of the Materials at Steelgate, if any.

The Parties agree that the costs will be split as follows:

1. Acquisition of Materials—If Steelgate acquires the Materials, the parties agree to split the cost. Defendants will not reimburse Plaintiffs for Materials acquired in any method other than using Steelgate.

2. Division of Materials—The Parties agree to split the cost of dividing the Materials by the Pathology Vendor as contemplated in this Protocol.

3. Storage of Materials—Prior to division of the Materials, the Parties agree to split the costs of storage of the Materials. Once the Materials have been divided in accordance with this Protocol, the Parties agree that each side will incur the cost of storing its half of the Materials at Steelgate. The Parties agree that Plaintiffs may make appropriate alternative storage arrangements for any remaining Materials once division is complete and will be responsible for maintaining appropriate chain of custody forms for the Materials until final disposition of the individual case.

XII. Return of Materials

The Parties agree that after final disposition of the case, including any applicable appeals, Plaintiffs may request the return of any Materials provided to Defendants or Defendants' experts. This request must be made within 120 days of final disposition of the case. If Defendants do not receive a request for the return of the Materials within 120 days of final disposition, the Parties agree that the Materials may be destroyed in accordance with accepted methods for the destruction and disposal of biohazardous materials. Notwithstanding the foregoing, Defendants shall not destroy any Materials without first giving Plaintiffs' counsel of record 10 days written notice of their intent to destroy such Materials. The Party requesting destruction of the Materials will bear the cost of same.

IT IS SO ORDERED.

9/24/2024

DATE

/s/M. Page Kelley

U.S. Magistrate Judge

EXHIBIT A

COVIDIEN HERNIA MESH SPECIMEN DOCUMENTATION AND DIVISION

Patient Name: _____

Surgery Date: _____

Case Information: _____

COC Received and Completed: _____
Initial / Date**ENTIRE - SPECIMEN PHOTOGRAPHS:**

1. Container inside of biohazard bag: _____

2. Container Photos (Photo of each label on specimen container): _____ (002) with ruler _____

3. Condition of specimen when delivered to Suncoast: Dry ☐ Wet ☐ Soaked in Fixative ☐

4. Does there appear to be sufficient amount of specimen to divide?

If NO, do not remove specimen from container, check below and contact SteelgateToo small ☐ SLIDE ☐ BLOCK ☐ STONE ☐ Specimen NOT divided: _____**If YES**, CONTINUE: Remove Specimen from Container (Only one container should be opened at any one time; do not combine specimens from different containers):**5. RECORD START TIME:** _____

Please initial next to each task upon completion (photos should be taken at close-up so that specimens fill as much of the camera field of view as possible).

6. PHOTOS

Side 1 - Overhead Photos (2 minimum): (1A) _____ (1B) with ruler _____

Side 1 - North Angle: (2A) _____

Side 1 - South Angle: (3A) _____

Side 1 - East Angle: (4A) _____

Side 1 - West Angle: (5A) _____

Side 2 - Overhead Photos (2 minimum): (6A) _____ (6B) with ruler _____

Side 2 - North Angle: (7A) _____

Side 2 - South Angle: (8A) _____

Side 2 - East Angle: (9A) _____

Side 2 - West Angle: (10A) _____

Scale is tarred with weight boat: _____

7. Entire Specimen **START weight:** _____

Record weight and initial

COVIDIEN HERNIA MESH SPECIMEN DOCUMENTATION AND DIVISION

Patient Name: _____

Surgery Date: _____

Case Information: _____

SPECIMEN DIVISION:

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

8. DIVIDED - SPECIMEN PHOTOGRAPHS:

Place both samples next to each other such that the cut edges are immediately adjacent to one another; photos should be taken close-up so that specimens fill as much of the camera field of view as possible:

Overhead SAMPLE A&B photo 1: (11A) _____ with ruler: (11B) _____

Overhead SAMPLE A&B (turn over the samples and place samples such that the cut edges are immediately adjacent to one another) Photo 1: (12A) _____ with ruler: (12B) _____

Scale is tarred with weight boat: _____

9. FINAL WEIGHT

Sample A weight: _____

Record weight and initial

Sample B weight: _____

Record weight and initial

10. SPECIMEN STORAGE:

Place SAMPLE A into pathology jar marked A with patient name. _____

Place SAMPLE B into pathology jar marked B with patient name. _____

- *For samples received DRY, Leave the samples dry.*
- *For samples received soaked in fixative, from the original pathology jar, equally split the fixative between jars A&B so that there is approximately an equal amount of fixative in each. If there is an insufficient amount of original formalin to equally cover each split specimen, please add more formalin so that there is a 1 to 10 ratio (1:10) of specimen to formalin.*

CIRCLE YES OR NOWAS New Formalin added to jar A **YES NO**, WAS New Formalin added to jar B **YES NO****11. RECORD END TIME:** _____**12. FINAL PHOTOS after split**

Take photo of SAMPLE A pathology jar: (13) _____

Take photo of SAMPLE B pathology jar: (14) _____

Take photo of original pathology jar with lid next to jar with no sample: (15) _____

Process completed by: _____

Name / initial

COVIDIEN HERNIA MESH SPECIMEN DOCUMENTATION AND DIVISION

Patient Name:

Surgery Date:

Case Information:

Date / Time