

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE**

**In Re: Atrium Medical Corp. C-Qur Mesh Products
Liability Litigation (MDL No. 2753)**

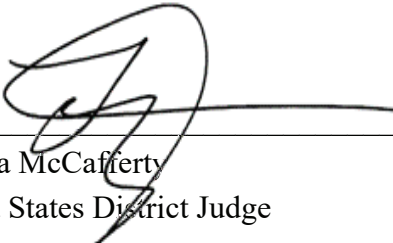
**MDL Docket No. 16-md-2753-LM
ALL CASES**

SECOND AMENDED CASE MANAGEMENT ORDER 3C

**(AGREED ORDER AND STIPULATION REGARDING PROTOCOL FOR
COLLECTION, PRESERVATION, AND DIVISION OF PATHOLOGY MATERIAL)**

Counsel for Plaintiffs and Counsel for Defendants have met and conferred regarding amendments to the Collection, Preservation, and Division of Pathology Material Pretrial Order No. 3C. Following that meet and confer, the parties have stipulated to and petitioned the Court to enter the following Stipulation in this matter, attached as **Exhibit A**. Upon entry of this Order, the Court approves the protocol and same will apply to all actions that are or become a part of MDL 2753, until further order of the Court.

IT IS SO ORDERED.



Landya McCafferty
United States District Judge

October 16, 2019

cc: All Counsel of Record

EXHIBIT A
**STIPULATION REGARDING COLLECTION, DIVISION AND PRESERVATION OF
PATHOLOGY MATERIAL**

This stipulation is entered between Plaintiffs and the Defendants (collectively, the “Parties”), by and through their respective counsel, to provide a protocol for the collection, preservation, and division of all gross and microscopic material purported to contain mesh or any other of Plaintiffs’ tissue excised or explanted from Plaintiffs, including but not limited to slides, special stains, blocks, and gross material (the “Material”).

It is the intention of the Parties that all Material be preserved in a manner that permits the Parties equal access to and analysis of the Material. The Parties will not interfere with or circumvent the analysis and preservation of pathology by the Facilities¹ to which any of Plaintiffs’ treating physicians have sent or will send the Material for analysis required for the diagnosis and treatment of any disease or medical issue involving Plaintiff. It is the intent of this agreement that neither party shall be in unilateral control or custody of pathological materials collected in this MDL after such time as they are submitted to Steelgate, Inc., or another agreed upon storage facility by the parties (“Storage Facility”).

**PROTOCOL FOR PRESERVATION OF MATERIALS FROM FUTURE SURGERY;
CURRENTLY AVAILABLE MATERIALS EXISTING AT A FACILITY; OR
CURRENTLY IN PLAINTIFFS' COUNSEL'S POSSESSION**

Notice of Explant

1. Within 48 hours of receipt of information that a plaintiff has scheduled a mesh revision, excision, or explant surgery, or as soon as practicable thereafter, plaintiffs’ individual counsel shall notify counsel for Atrium of the date and location of such surgery.

2. Such notice shall be provided by email to: katherine.armstrong@dechert.com and katherine.ungerdavis@dechert.com.

Joint Request for Collection and Preservation of the Material

1. In those case where an explant procedure has already occurred and the Material is already in the possession of a hospital or other medical facility, the provisions of this section shall apply. Plaintiffs in those cases shall undertake these procedures prior to the due date for the PPF if the existence of Material is known or within 10 days of learning of the existence of such material, inclusive of the 48-hour notice provision above.

2. In cases where Plaintiffs’ Counsel has physical possession of Materials, the provision of this section shall apply and Plaintiffs in those cases shall undertake these procedures prior to the due date for the PPF.

¹ For purposes of this stipulation the term Facility shall mean the location where any of Plaintiffs’ treating physicians have sent or will send the Material in the usual course of business.

3. Concurrently with provision of the above-referenced notice, counsel for that plaintiff shall send a letter to the Facility (copying Defendants) where the revision, excision, or explant surgery is to occur, or has previously occurred, in the form attached as Exhibit B. It is the intention of the parties that this letter shall advise the Facility of the need to collect and preserve the Material as evidence in the MDL 2753 Litigation, and that the Parties are jointly providing specific instructions for preservation, collection, and shipment of the Material.

4. After a letter in the form set forth in Exhibit B has been sent to the Facility, it shall be incumbent on the individual plaintiffs on behalf of both parties to provide the Facility with instructions for the preservation and shipment of the Material, and to arrange for payment of any costs associated with the requested preservation and shipment.

5. When requesting Material from a Facility, plaintiffs' individual counsel shall use the instructions contained in Exhibit B, which provides for the collection, transmission and storage of the Material at the Storage Facility.

6. Plaintiffs shall provide to the Facility a HIPAA-compliant authorization and any other document requiring Plaintiff's signature necessary to effectuate the collection and transmission of the Material to the Storage Facility.

7. The parties will use reasonable efforts to cooperate in the evaluation of the explanted Material and may alter the terms of this Stipulation only by written agreement as required to carry out its purpose.

8. Neither party shall have the right to remove the Material from the Storage Facility unilaterally.

9. At any time, either party may arrange to perform a non-destructive gross evaluation of the Material at the storage facility 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 pathologist present and/ or to have the gross evaluation videotaped. At either party's election, the photography necessary to adequately depict the specimen(s) before and after division shall include microscopic examination and photography. The parties will work together to find a mutually convenient date and time for any such non-destructive gross evaluation.

10. If either party wishes to perform additional testing on the Material, the Parties agree that the Material will be divided as outlined below. Prior to any division, the opposing party will have the opportunity to have their expert evaluate the gross pathology and be present for any division. The parties will work together to find a mutually convenient date and time for any such division.

11. In dividing the Material, the Parties must utilize the least destructive means. If either party objects to the division of the Material, the Parties shall be required to meet and confer in an effort to resolve the dispute. If the cannot be resolved, the Parties will promptly advise the Court and seek guidance.

12. The Parties shall request that the Facilities execute an original chain of custody in the form attached as Exhibit C for any Material the Storage Facility removes from any Facility. Subsequently, each individual or entity having custody of the Material from the time it leaves the possession of the Facilities and enters the possession of the Storage Facility will complete the chain of custody form.

13. All costs incurred by the Storage Facility to maintain and store the Material under this protocol shall be shared equally by the Parties. The costs of collecting and preserving the Material shall be born solely by Plaintiffs until such time as the material is in the possession, custody, or control of the Storage Facility.

14. If no gross pathological material exists and a hospital or other medical facility has preserved only slides or paraffin blocks, the parties shall be entitled to equal access to the existing slides and shall be entitled to an equal number of recut slides. Plaintiffs shall advise Defendants by email of the existence of slides or paraffin blocks within 48 hours of learning of the existence of such slides or paraffin blocks. Plaintiffs on behalf of both parties may request such 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. Each party shall have a right to view the slides of the other, produced under this paragraph, no later than two weeks prior to the depositions of the other parties' experts.

Instructions for Division of Material

1. One expert or consultant on behalf of the Plaintiffs and on behalf of the Defendants shall have the right to participate in the division of each specimen or the parties may agree to split the cost of a neutral pathologist. However, division must utilize the principle that each specimen or specimens shall be divided in equal or nearly equal portions for their respective analysis as follows:

The specimen(s) should be divided such that the amount of foreign material, if any, is approximately equal in the two samples. The division of the specimen(s) into two equal (or nearly equal) portions for analysis by the Parties shall be as follows:

- (a) cut the specimen(s) (or each piece of the specimen) through the longest axis of the mesh part into two pieces (may or may not be the longest axis of entire tissue);
- (b) if there is mucosa, the cut needs to be through the point where the mesh is closest to the surface or mucosal defect/ulceration if present;
- (c) if there is a nodule, the cut should be through the middle of the nodule; and
- (d) any foreign material and surrounding tissue in the specimen(s) should not be separated prior to dividing the specimen(s) in half.

2. If in the course of dividing the specimen(s), it becomes impossible to provide two equal (or nearly equal) halves of the specimen(s), representatives of the parties will meet and confer on the best manner to go forward utilizing the principles of this agreement.

3. Additionally, the parties shall photograph as necessary to adequately depict the specimen(s) before and after division as follows:

(a) depicting entire specimen (or specimens, if excised in more than one part) prior to splitting, fresh, without fixative, with scale and identifiers; and

(b) depicting entire specimen (or specimens, if excised in more than one part) after splitting, fresh, without fixative, with scale and identifiers.

Nothing in this Stipulation shall be construed to preclude a Party from challenging the method of preservation of the Material and/or from moving for spoliation sanction APPROVED:

<p><u>/s/Jonathan D. Orent</u></p> <p>LEAD COUNSEL FOR PLAINTIFFS</p>	<p><u>/s/Katherine Armstrong</u></p> <p><u>/s/Katherine Unger Davis</u></p> <p>ATTORNEYS FOR THE ATRIUM DEFENDANTS</p>
---	--

EXHIBIT B

VERY IMPORTANT – REQUEST FOR PRESERVATION OF PATHOLOGY

[Date]

Attn: Departments of Surgery and Pathology

[Address of Explant Facility]

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

Dear Departments of Surgery and Pathology:

I represent the Plaintiff, Mr./Mrs./Ms. [Plaintiff's last name], and Katherine Armstrong and Katherine Unger Davis who are copied below represent the Defendant, Atrium Medical Corporation (Atrium), in the above-captioned lawsuit. There is no litigation pending against your facility or the treating physician in this matter. I write to request the preservation and shipment of pathology material from Mr./Mrs./Ms. [Plaintiff's last name]'s [upcoming/prior] surgery, [scheduled for/ that occurred] on [Date] with Dr. [Explant Surgeon].

It is important to both parties to this lawsuit that any pathology obtained during this [upcoming/prior] surgery be preserved for future analysis by their respective experts.

Instructions for Immediate Preservation of the Specimen(s):

Explanted Mesh and Tissue

First, it is very important that we obtain any and all of the hernia mesh device and/or pieces of the device that are removed. Mr./Mrs./Ms. [Plaintiff's last name] requests you utilize the following procedure to preserve his/ her explanted device immediately following completion of his/her surgery **and any medical or diagnostic testing accompanying her procedure, including pathological testing ordered by the treating Doctors at your facility.** This request is not intended to interfere with and should follow the completion of any pathological or histological testing of the explanted material that you may order as part of ordinary treatment of Mr./Mrs./Ms. [Plaintiff's last name]. We have also asked the explanting surgeon to preserve any explanted mesh and/or tissue. Mr./Mrs./Ms. [Plaintiff's last name] requests that the removed hernia mesh device and/or any and all pieces or parts thereof, be sent to the address identified below using the following protocol:

1. All components of the mesh device should be placed in a container of dilute formalin, 10% formalin is standard.
2. Tissue samples may be placed in the same container along with the components of the explanted mesh.
3. It is advisable that soft tissue samples immediately adjacent to the mesh and/or affixed to the mesh be preserved and collected at the time of the revision surgery. These tissue

- samples should be obtained from areas immediately around the mesh.
4. The explanted device and tissue samples can be kept at room temperature or refrigerated. The samples do not need to be frozen.
 5. The removed devices and soft tissue samples should be prepared and mailed as follows:
 - a. Place all of the components of the removed mesh along with soft tissue samples into a "Bio Bottle" container (or a similar system or container) and follow the instructions provided with that container system in the standard course.
 - b. Standard delivery FedEx or UPS shipping is sufficient. Ship the Bio Bottle container to:
Steelgate, Inc.
Re: [Plaintiff's Name c/o Plaintiff's Law Firm]
2307 58th Avenue East
Bradenton, Fl. 34203

VERY IMPORTANT

Please be advised that the hernia mesh device explant, including all parts and soft tissue, may be material evidence relevant to the claims Mr./Mrs./Ms. [Plaintiff's last name] is asserting against the manufacturer of the device or to the defenses of the manufacturer of the device.

Again, this request does NOT implicate any pending litigation against Mr./Mrs./Ms. [Plaintiff's last name] physicians or any medical providers or entities regarding his/her care and treatment with respect to the subject device, but rather is a direct request for the preservation of the explanted medical device and other important evidence.

Please forward a copy of this letter to the appropriate person or entity who/which will ensure said preservation and maintenance.

In order to facilitate this request, enclosed please find a HIPAA-compliant authorization for the release of the specimen(s) to be removed during this surgery, signed by Mr./Mrs./Ms. [Plaintiff's last name]. Also enclosed is a chain of custody form; the parties request that this form accompany the specimen(s) when it leaves your facility.

If you are not the appropriate recipient of this request, please forward a copy of this letter to the appropriate person or entity responsible for ensuring compliance with the terms of this preservation request. Thank you very much for your assistance.

Very truly yours,

/s/

Counsel for Plaintiff

ENCLOSURE

cc: Katherine Armstrong, Esq. and Katherine Unger Davis, Esq.. (Counsel for Defendant, Atrium)

EXHIBIT C

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

Plaintiff(s) v. Atrium Medical Corp.

ENTRY NO. 1

Received by (Name, Company/Organization, Address, and Telephone Number):

Date:

Time:

Signature of Recipient _____

Item Description (include manner of preservation, size of specimen, slide numbers and any other identifying marks):

(1) _____

(2) _____

(3) _____

Note any change of condition:

Name of Releasing Party

Date:

Time:

Signature of Releasing Party _____

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

Plaintiff(s) v. Atrium Medical Corp.

ENTRY NO. 2

Received by (Name, Company/Organization, Address, and Telephone Number):

Date:

Time:

Signature of Recipient _____

Item Description (include manner of preservation, size of specimen, slide numbers and any other identifying marks):

(1) _____

(2) _____

(3) _____

Note any change of condition:

Name of Releasing Party

Date:

Time:

Signature of Releasing Party _____

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

Plaintiff(s) v. Atrium Medical Corp.

ENTRY NO. 3

Received by (Name, Company/Organization, Address, and Telephone Number):

Date:

Time:

Signature of Recipient _____

Item Description (include manner of preservation, size of specimen, slide numbers and any other identifying marks):

(1) _____

(2) _____

(3) _____

Note any change of condition:

Name of Releasing Party

Date:

Time:

Signature of Releasing Party _____

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

Plaintiff(s) v. Atrium Medical Corp.

ENTRY NO. 4

Received by (Name, Company/Organization, Address, and Telephone Number):

Date:

Time:

Signature of Recipient _____

Item Description (include manner of preservation, size of specimen, slide numbers and any other identifying marks):

(1) _____

(2) _____

(3) _____

Note any change of condition:

Name of Releasing Party

Date:

Time:

Signature of Releasing Party _____

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

Plaintiff(s) v. Atrium Medical Corp.

ENTRY NO. 5

Received by (Name, Company/Organization, Address, and Telephone Number):

Date:

Time:

Signature of Recipient _____

Item Description (include manner of preservation, size of specimen, slide numbers and any other identifying marks):

(1) _____

(2) _____

(3) _____

Note any change of condition:

Name of Releasing Party

Date:

Time:

Signature of Releasing Party _____

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

Plaintiff(s) v. Atrium Medical Corp.

ENTRY NO. 6

Received by (Name, Company/Organization, Address, and Telephone Number):

Date:

Time:

Signature of Recipient _____

Item Description (include manner of preservation, size of specimen, slide numbers and any other identifying marks):

(1) _____

(2) _____

(3) _____

Note any change of condition:

Name of Releasing Party

Date:

Time:

Signature of Releasing Party _____

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

Plaintiff(s) v. Atrium Medical Corp.

ENTRY NO. 7

Received by (Name, Company/Organization, Address, and Telephone Number):

Date:

Time:

Signature of Recipient _____

Item Description (include manner of preservation, size of specimen, slide numbers and any other identifying marks):

(1) _____

(2) _____

(3) _____

Note any change of condition:

Name of Releasing Party

Date:

Time:

Signature of Releasing Party _____