

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

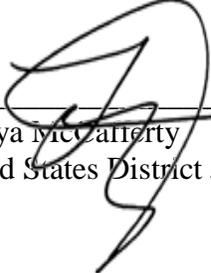
**In Re: Atrium Medical Corp. C-Qur Mesh
Products Liability Litigation (MDL No. 2753)**

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

PRETRIAL ORDER NO. 3C
REGARDING PROTOCOL FOR COLLECTION, PRESERVATION,
AND DIVISION OF PATHOLOGY MATERIAL

Discovery in this proceeding may involve the collection, division, storage, preservation, and production of biomaterials evidence for which special handling, division, storage, and preservation would be warranted. Accordingly, Counsel for Plaintiffs and Counsel for Defendants (“Atrium”) have met and conferred regarding the collection, preservation, and division of pathology material. 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 protocols and same will apply to all actions that are or become a part of MDL 2753, until further order of the court. .

SO ORDERED.



Landya McCafferty
United States District Judge

March 13, 2017

cc: All Counsel of Record

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

This stipulation is entered between Plaintiffs and the Atrium Defendants¹ (“Atrium”) (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 Facilities² to which any of Plaintiffs’ treating physicians have sent or will send the Material in the usual course of business.

PROTOCOL FOR PRESERVATION OF MATERIALS FROM FUTURE SURGERY

Notice of Explant

1. Within 24 hours of receipt of information that a plaintiff has scheduled a mesh revision, excision, or explant surgery, or as soon as practicable thereafter, Plaintiffs’ Liaison Counsel shall notify counsel for the Atrium Defendants of the date and location of such surgery.

2. Such notice shall be provided by email to: hugh.turner@akerman.com and enjolique.aytch@akerman.com.

Joint Request for Collection, Preservation, and Division of the Material

1. Concurrently with provision of the above-referenced notice, Liaison Counsel for Plaintiffs shall send a letter to the Facility where the revision, excision, or explant surgery is to occur in the form attached as Attachment A. It is the intention of the parties that this letter shall advise the Facility of the need to collect, preserve, and divide the Material as critical evidence in the MDL 2753 Litigation, and that each of the Parties will separately provide specific instructions for preservation and shipment of its respective half of the Material.

2. After a letter in the form set forth in Attachment A has been sent to the Facility, it shall be incumbent on each Party to provide the Facility with instructions for the preservation and shipment of its half of the Material, and to arrange for payment of any costs associated with the requested preservation and shipment. In no event shall Plaintiffs be responsible for the manner, method, or timing of the preservation of the Material for Atrium. Plaintiff assumes no additional responsibilities for the preservation of the Atrium Material beyond providing instruction as set forth in Attachment A.

¹ Atrium Medical Corporation, Getinge AB, Maquet Cardiovascular US Sales, LLC, Maquet Cardiovascular, LLC, and Getinge USA, Inc.

² For purposes of this stipulation, the term Facility shall mean the location where a plaintiff underwent or will undergo a mesh revision, excision, or explant surgery, and a location where any of Plaintiffs’ treating physicians have sent or will send the Material in the usual course of business.

3. When requesting Material from a Facility for any purpose, Plaintiffs' Liaison Counsel shall use the instructions contained in Attachment A.

4. Plaintiffs shall provide to the Facility a HIPAA-compliant authorization and any other form requiring Plaintiff's signature for the collection and division of the Material.

PROTOCOL FOR HANDLING OF CURRENTLY AVAILABLE MATERIALS EXISTING AT A FACILITY

Notice Of Available Materials

1. Within five (5) business days of receipt of knowledge that Materials regarding a particular plaintiff exist at a Facility, or as soon as practicable thereafter, Plaintiffs' counsel in the individual case shall notify counsel for the Atrium Defendants of the date and location of each such surgery resulting in Materials.

2. Such notice shall be provided by email to: hugh.turner@akerman.com and enjolique.aytch@akerman.com.

Joint Request for Collection, Preservation, and Division of the Material

Concurrently with provision of the above-referenced notice, counsel for such Plaintiff shall send a letter with a copy to counsel for the Atrium Defendants to the Facility where the revision, excision, or explant surgery occurred in the form attached as Attachment B. It is the intention of the Parties that this letter shall advise the Facility of the need to collect, preserve, and document the Material as critical evidence in the MDL 2753 Litigation, and that each of the Parties will separately provide specific instructions for preservation and shipment of its respective half of the Material.

PROTOCOL FOR HANDLING OF CURRENTLY AVAILABLE MATERIALS EXISTING AT A FACILITY IN POSSESSION OF PLAINTIFFS' COUNSEL

Notice Of Available Materials

1. If Plaintiffs are already in possession of any Materials as of the date of this Order, within five (5) days of this Order being entered or as soon as practicable thereafter, Plaintiffs' counsel shall notify counsel for the Atrium Defendants of the existence of the Materials and the present location of the Materials. To the extent documentation, photographs, videos, or any other documentary or related evidence exists regarding these Materials, Plaintiffs will provide all such evidence to counsel for the Atrium Defendants within five (5) days of this Order being entered or as soon as practicable thereafter. To the extent such information is known to Plaintiffs, Plaintiffs will provide the date of the surgery during which the Materials were removed.

2. Such notice shall be provided by email to: hugh.turner@akerman.com and enjolique.aytch@akerman.com.

Disposition of Materials in Plaintiffs' Possession

Plaintiffs' counsel will document the Materials in their possession on a Chain of Custody form containing the information provided on the Attachments hereto, or by way of such Chain of Custody forms as were used to document the chain of custody prior to entry of this Order. Plaintiffs' counsel will provide a completed copy of the Chain of Custody form to counsel for the Atrium Defendants. Plaintiffs' counsel will ship all Materials in their possession to the facility of the Atrium Defendants' selection. All costs associated with the preservation and shipment of the Material under this provision shall be borne by the specific Plaintiff.

Indivisible and Small Samples

1. If in the course of dividing the Material to preserve at least one-half for use by the other Party it becomes impossible to provide two equal (or nearly equal) halves of the Material, the Parties agree to meet and confer and attempt to arrive at a mutually agreeable protocol as to the Material. Neither Party will perform any review, analysis, or testing on the Material or alter the Material in any way prior to reaching a mutually agreeable protocol. In the event that no agreement can be reached, the Parties will seek the Court's guidance.

2. In the event that any of the Material is less than 120 mg. in mass of a foreign body and surrounding tissue (herein after "Small Sample"), this shall be considered too small to be divided equally among the Parties. In the event of a Small Sample, the parties agree to meet and confer and attempt to arrive at a mutually agreeable protocol to allow for equal examination of the Small Sample. Neither party shall perform any review, analysis, or testing on the Small Sample or alter the Small Sample 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.

Misc.

1. The Parties shall request that the Facilities execute an original chain of custody in the form attached at Attachment C for any Material any party removes from any Facility. Subsequently, the chain of custody will be completed by each individual or entity having custody of the Material from the time it leaves the possession of the Facilities.

2. All costs associated with the division of the Material under this protocol shall be shared equally by the Parties. All costs associated with the preservation of the Material after its division under this protocol shall be borne by the Party requesting such preservation. And all costs associated with the evaluation of the Material under this protocol shall be borne by the Party performing the evaluation.

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/Robert J Bonignore</u></p> <p>TEMPORARY LEAD COUNSEL FOR PLAINTIFFS</p>	<p><u>/s/Hugh Turner</u></p> <p><u>/s/Enjoliqué Aytch</u></p> <p>ATTORNEYS FOR THE ATRIUM DEFENDANTS</p>
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ATTACHMENT A

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. [Plaintiff's last name], and Hugh Turner and Enjoliqué Aytch, 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, in advance, the preservation of pathology material from Mr. [Plaintiff's last name]'s surgery, scheduled for [Date] to be performed by Dr. [Explant Surgeon].

It is important to both parties to this lawsuit that any pathology obtained during this upcoming surgery be preserved for future analysis by their respective experts. The parties request that you preserve, photograph, and divide the specimen(s) obtained as follows:

Instructions for Immediate Preservation of the Specimen(s):

The parties request immediate preservation of the specimen(s) and will separately provide further instructions for preservation of the specimen(s) immediately upon explant.

Instructions for Division into Equal Specimen(s):

The parties request division of each specimen or specimens 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.

If in the course of dividing the specimen(s), it becomes impossible to provide two equal (or nearly equal) halves of the specimen(s), please immediately notify the representatives of the parties listed below. The parties will confer re: access to the specimen(s) and provide further instructions re: same.

Instructions for Photographing Specimen(s) Before and After Division:

Additionally, the parties request photographs depicting the specimen(s) before and after division as follows:

Please document the method of division and photograph the specimen(s) prior to and after its 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.

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. [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.

Each party will follow-up separately with further instructions on the mode of preservation and shipping of its half of the specimen(s), and to arrange for reimbursement for any costs incurred by you for preservation, division, and shipping. Should you have any questions or concerns regarding this matter, please contact us by email directed to representatives of both parties: [Robert Bonsignore at rbonsignore@classactions.us](mailto:rbonsignore@classactions.us) (counsel for Plaintiff), and Hugh Turner at hugh.turner@akerman.com and Enjoliqué Aytch at enjolique.aytch@akerman.com (counsel for Defendant).

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/ Robert J Bonsignore Counsel
for Plaintiff

ENCLOSURE

cc: Hugh Turner Jr., Esq. and Enjoliqué Aytch, Esq. (Counsel for Defendant Atrium)

ATTACHMENT B

VERY IMPORTANT – REQUEST FOR PRESERVATION OF PATHOLOGY

[Date]

Attn: Department of Pathology

[Address of Explant Facility]

Re: [Date of Surgery, Case Caption]

Dear Department of Pathology:

I represent the Plaintiff, Mr. [Plaintiff's last name], and Hugh Turner and Enjoliqué Aytch, who are copied below, represent the Defendant, Atrium Medical Corporation (Atrium), in the abovecaptioned lawsuit. There is no litigation pending against your facility or the treating physician in this matter. I write to request the preservation of pathology material from Mr. [Plaintiff's last name]'s [date] surgery performed by Dr. [Explant Surgeon].

It is important to both parties to this lawsuit that any pathology, including tissues and/or mesh, obtained during this surgery be preserved for future analysis by their respective experts. The parties request that you preserve, photograph, and divide the specimen(s) obtained as follows:

Instructions for Immediate Preservation of the Specimen(s):

The parties request immediate preservation of the specimen(s) and will separately provide further instructions for preservation of the specimen(s).

Instructions for Division into Equal Specimen(s):

The parties request division of each specimen or specimens 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.

If in the course of dividing the specimen(s), it becomes impossible to provide two equal (or nearly equal) halves of the specimen(s), please immediately notify the representatives of the parties listed below. The parties will confer re: access to the specimen(s) and provide further instructions re: same.

Instructions for Photographing Specimen(s) Before and After Division:

Additionally, the parties request photographs depicting the specimen(s) before and after division as follows:

Please document the method of division and photograph the specimen(s) prior to and after its 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.

In order to facilitate this request, enclosed please find a HIPAA-compliant authorization for the release of the specimen(s) removed during the surgery, signed by Mr. [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.

Each party will follow-up separately with further instructions on the mode of preservation and shipping of its half of the specimen(s), and to arrange for reimbursement for any costs incurred by you for preservation, division, and shipping. Should you have any questions or concerns regarding this matter, please contact us by email directed to representatives of both parties: [Robert Bonsignore at rbonsignore@classactions.us](mailto:rbonsignore@classactions.us) (counsel for Plaintiff), and Hugh Turner at hugh.turner@akerman.com and Enjoliqué Aytch at enjolique.aytch@akerman.com (counsel for Defendant).

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/ Robert J Bonsignore Counsel
for Plaintiff

ENCLOSURE

cc: Hugh Turner Jr., Esq. and Enjoliqué Aytch, Esq. (Counsel for Defendant Atrium)

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

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

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 _____