IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: AMERICAN MEDICAL SYSTEMS, INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION MDL No. 2325

THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER # 171
(Order Amending Pretrial Order #118 Agreed Order and Stipulation Regarding Protocol for Collection, Preservation, and Division of Pathology Material)

Counsel for Plaintiffs and Counsel for Defendant American Medical Systems ("AMS") 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 approve the following Stipulation in this matter, attached as **Exhibit A**, which is an amendment to Pretrial Order No. 118 entered on February 19, 2014. Upon entry of this Order, the Court approves the protocols and same will apply to all filed actions which are part of MDL 2325, until further order of the Court. IT IS SO ORDERED.

The Court DIRECTS the Clerk to file a copy of this order in 2:12-md-2325 and it shall apply to each member AMS-related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2:14-cv-15157. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this Court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the Court. The orders may be accessed through the CM/ECF system or the Court's website at www.wvsd.uscourts.gov.

ENTER: April 23, 2014

Cheryl A. Eifert
United States Magistrate Judge

EXHIBIT A

STIPULATION REGARDING COLLECTION, DIVISION AND PRESERVATION OF PATHOLOGY MATERIAL

This stipulation is entered between Plaintiffs and Defendant American Medical Systems, Inc. ("AMS") (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' pelvic floor tissue excised or explanted from Plaintiffs, including but not limited to slides, special stains, blocks, and gross material (the "Material"). It is intended that this protocol attach to filed cases only, it is not required in any case prior to filing.

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 Facilities to which any of Plaintiffs' treating physicians have sent or will send the Material in the usual course of business.

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' counsel shall notify counsel for AMS of the date and location of such surgery.

2. Such notice shall be provided by email to: AMSService@reedsmith.com.

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

1. Concurrently with provision of the above-referenced notice, 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 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 AMS. Plaintiff assumes no additional responsibilities for the preservation of the AMS Material beyond providing instruction as set forth in Attachment A.

3. When requesting Material from a Facility for any purpose, Plaintiffs 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. Such

form shall specify that the requested Material is to be released to counsel for or other representative of both Parties, using the form at Attachment B or some similar form.

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.

3. 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 sanctions.

4. If a facility is unable to comply with this protocol and either Party has Material preserved in a sealed container, that container cannot be required to be opened and photographed until such time, if ever, that the Material is examined by an expert of either Party, either retained or non-retained.

APPROVED:

/s/Amy Eskin /s/Fidelma Fitzpatrick ATTORNEYS FOR PLAINTIFFS	/s/Barbara Binis /s/Tracy Weiss ATTORNEYS FOR AMERICAN MEDICAL SYSTEMS, INC.

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, Ms. [Plaintiff's last name], and Heather Ritch cc'ed below represents the Defendant, American Medical Systems (AMS), 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 of pathology material from Ms. [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; <u>and</u>

(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 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.

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: [plaintiff's counsel's contact] at [plaintiff's counsel's contact's email address] (counsel for Plaintiff) and Heather Ritch at hritch@reedsmith.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/ [plaintiff's counsel]
[plaintiff's counsel]
Counsel for Plaintiff

ENCLOSURE

cc: Heather A. Ritch, Esq. (Counsel for Defendant, American Medical Systems)

Attachment B

HIPAA COMPLIANT AUTHORIZATION FOR THE RELEASE OF PATHOLOGY MATERIALS PURSUANT TO 45 CFR 164.508

TO: _____
Name of Healthcare Provider/Physician/Facility

_____
Address

_____
City, State and Zip Code

RE: Patient Name:_____

Date of Birth:_____ Social Security Number: _____

Address: _____

_____

I authorize the disclosure of all protected information for the purpose of review and evaluation in connection with a legal claim. I expressly request that the designated records custodian/department of surgery/department of pathology of all covered entities under HIPAA identified above disclose the following: gross and microscopic material or any other of my pelvic floor tissue excised or explanted from me, including but not limited to slides, special stains, blocks, and gross material, from the surgery that took place on/will take place on _____ [date], as requested by representatives of me and defendant American Medical Systems, Inc. This protected health information is disclosed for purposes of my personal injury lawsuit pending in the United States District Court for the Southern District of West Virginia – MDL 2325.

You are authorized to release the above pathology materials to the following representatives of myself and defendants in the above-entitled matter who have agreed to pay reasonable charges made by you to supply copies of such materials:

Representative of Patient/Plaintiff(s):	Representative of Defendant AMS:
_____ Name of Representative	**Jennifer Eppensteiner, Esq.** Name of Representative
_____ Attorney for Plaintiff(s)	**Reed Smith LLP** Attorney for Defendant AMS
_____ Street Address	**Three Logan Place, 1717 Arch Street** Street Address
_____ City, State and Zip Code	**Philadelphia, PA 19103** City, State and Zip Code

I acknowledge that I have the right to revoke this authorization, in writing, by sending written notification to you at the above referenced address. However, I understand that any actions already taken in reliance on this authorization cannot be reversed, and my revocation will not affect those actions. I acknowledge the potential for information disclosed pursuant to this authorization to be subject to re-disclosure by the recipient and no longer be protected under 45 CFR 164.508.

I understand that the covered entity to whom this authorization is directed may not condition treatment, payment, enrollment or eligibility benefits on whether or not I sign the authorization.

Any facsimile, copy or photocopy of the authorization shall authorize you to release the records herein. This authorization shall be in force and effect until two years from date of execution at which time this authorization expires.

_____

Signature of Patient or Personal Representative

_____

Dated

_____

Name of Patient or Personal Representative

_____

Description of Personal Representative's Authority to
Sign for Patient (attach documents which show authority)

_____

Witness Signature

_____

Dated

Attachment C

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

Patient Name: _____ Date: _____
Law Firm: _____ Surgery Date: _____

ENTRY NO. 1: Pick Up Location / Releasing Party Information
Facility Name:
Address: _____

Contact Name: _____ Department_____

Contact Phone #: _____Contact Email: _____

Item Description (include manner of preservation, size of specimen, slide number and any other identifying mark(s).

(1)_____ (2) _____

(3) _____ (4) _____

Person RELEASING Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness:_____ (sign/print)

Date: _____ Time: _____

ENTRY NO. 1: Recipient Location/Receipt information:
Facility Name:
Address: _____

Item Description (include manner of preservation, size of specimen, slide number and any other identifying mark(s).

(1) _____ (2) _____

(3) _____ (4) _____

Note any changes of condition:
Condition of specimen: ambient (__) , frozen (__), unfrozen (__)

Condition of Container: undamaged (__), damaged (__), describe: _____

Person **RECEIVING** Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness: _____ (sign/print)

Date: _____ Time: _____

Attachment C

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

Patient Name: _____ Date: _____
Law Firm: _____ Surgery Date: _____

ENTRY NO. 2: Pick Up Location / Releasing Party Information
Facility Name:
Address: _____

Item Description (include manner of preservation, size of specimen, slide number and any other identifying mark(s).

(1)_____ (2) _____

(3) _____ (4) _____

Person RELEASING Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness:_____ (sign/print)

Date: _____ Time: _____

ENTRY NO. 2: Recipient Location/Receipt information:
Facility Name:
Address: _____

Contact Name: _____ Department_____

Contact Phone #: _____Contact Email: _____

(1) _____ (2) _____

(3) _____ (4) _____

Note any changes of condition:

Condition of specimen: ambient (__) , frozen (__), unfrozen (__)

Condition of Container: undamaged (__), damaged (__), describe: _____

Person **RECEIVING** Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness: _____ (sign/print)

Date: _____ Time: _____

Attachment C

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

Patient Name: _____ Date: _____
Law Firm: _____ Surgery Date: _____

ENTRY NO. 3: Pick Up Location / Releasing Party Information
Facility Name:
Address: _____

Item Description (include manner of preservation, size of specimen, slide number and any other identifying mark(s).

(1)_____ (2) _____

(3) _____ (4) _____

Person RELEASING Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness:_____ (sign/print)

Date: _____ Time: _____

ENTRY NO.3: Recipient Location/Receipt information:
Facility Name:
Address: _____

Contact Name: _____ Department_____

Contact Phone #: _____Contact Email: _____

Item Description (include manner of preservation, size of specimen, slide number and any other identifying mark(s).
(1) _____ (2) _____

(3) _____ (4) _____

Note any changes of condition:
Condition of specimen: ambient (__) , frozen (__), unfrozen (__)

Condition of Container: undamaged (__), damaged (__), describe: _____

Person **RECEIVING** Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness: _____ (sign/print)

Date: _____ Time: _____