

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

IN RE: ETHICON, INC., POWER MORCELLATOR
PRODUCTS LIABILITY LITIGATION

(This Document Relates to All Cases)

MDL No. 2652

D. Kan. No. 15-md-2652-KHV

**ORDER REGARDING
PATHOLOGY EVIDENCE PRESERVATION**

On January 4, 2016, as contemplated by Scheduling Order No. 1 in this MDL proceeding (*see* ECF doc. 80, pp. 1-2), U.S. District Judge Kathryn H. Vratil and U.S. Magistrate Judge James P. O'Hara received a jointly proposed order from the parties' attorneys of record to govern the preservation of pathology evidence. By stipulating to the order, the parties agreed to be bound by its terms and to request entry by the presiding district or magistrate judge. As discussed during a status conference with counsel on January 6, 2016, the court finds good cause to enter the proposed order, with some minor modifications.

This stipulation is entered between the parties, by and through their respective counsel, to provide a protocol for the collection, preservation, storage, and division of the pathology evidence in this Litigation, as defined below. The parties intend that all Material, as defined below, which has not previously been analyzed or tested, 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 Materials by the Facilities, as defined below, to which any of plaintiffs' treating physicians have sent or will send the Materials in the usual course of business.

I. SCOPE

Discovery in this proceeding may involve the collection, division, storage, preservation, and production of biomaterials for which special handling, division, storage, and preservation is warranted. Accordingly, the parties have stipulated to and asked the court to enter this evidence preservation order. Upon entry of this order, it will apply to all current and future actions in MDL 2652.

II. DEFINITIONS

"Facility" is defined to include healthcare facilities where a plaintiff underwent or will undergo morcellation or other surgery resulting in the excision of Materials, as well as other facilities responsible for the preservation and/or maintenance of excised materials from such surgeries.

"Litigation" is defined as *In re: Ethicon, Inc. Power Morcellator Products Liability Litigation*, MDL No. 2652 (D. Kan.), including all current and future member cases transferred to, removed to, or filed in this district.

"Barnett," where specifically identified, is defined as *Robyn Barnett v. Karl Storz Endoscopy-America, Inc., et al.*, D. Kan. Case No. 15-9326-KHV, in which there are currently Ethicon and KARL STORZ entities as defendants.

"Material" or "Materials" is defined as any and all gross and microscopic material purported to contain tissue excised from a plaintiff, including but not limited to any

pathology evidence, histology slides, paraffin blocks containing tissue, and gross material.

III. PROTOCOL FOR PRESERVATION OF MATERIALS FROM FUTURE SURGERY

A. Notice of Surgery

Within 10 business days of receipt of information that a plaintiff in the Litigation intends to undergo or has scheduled a surgery related to the claims in this Litigation, or as soon as practicable thereafter, plaintiffs' counsel in such case must notify counsel for defendants of the intent for surgery as well as the date and location of such surgery (if scheduled).

B. Instructions to the Facility

Concurrently with provision of the above-referenced notice, counsel for plaintiff in the individual case must send instructions with a copy to the Ethicon defendants' counsel, to the Facility where the surgery is to occur in the form attached as Attachment A. With respect to *Barnett*, counsel for KARL STORZ must be copied on the instructions submitted in accordance with Attachment A. The parties intend that Attachment A will advise the Facility of the need to collect, preserve, and ship the Material as potential evidence in the Litigation. Attachment A includes a chain-of-custody form the parties must request the Facility execute for any Material any party removes from any Facility. This form does not in any way affect the validity of any similar form utilized to obtain Materials before the date of entry of this order.

Subsequently, the chain-of-custody form must be completed by each individual or entity having custody of the Material from the time it leaves the possession of each Facility.

After Attachment A has been sent to a Facility for any plaintiff other than in *Barnett*, each party must be responsible for payment of one-half of any costs associated with the collection, preservation, division, and shipment of Materials. With respect to *Barnett*, each party will be responsible for payment of one-third of any such costs. Concurrently with provision of the above-referenced notice, plaintiffs must provide to the Facility a HIPAA-compliant authorization allowing the Facility to accommodate the requests in Attachment A.

C. Third-Party Laboratory

For all Materials not yet excised as of the date this order is filed, the parties must use Steelgate, Inc., to receive, photograph, document, and divide the Materials according to the general process outlined in Attachment C. Chain-of-custody forms must be completed by any entity, including Steelgate, Inc., taking possession of and/or transmitting the Materials or any portion thereof. The parties agree to equally split the costs of this process. Chain-of-custody forms reflecting transmittal to the parties' experts or consultants must not be disclosed to the opposing counsel until expert discovery in the case.

IV. PROTOCOL FOR HANDLING OF CURRENTLY AVAILABLE MATERIALS EXISTING AT A FACILITY

A. Notice of Available Materials

Within 10 business days of receipt of knowledge that Materials regarding a particular plaintiff exist at a Facility, or within 20 days of the date this order is filed, whichever is sooner, or as soon as practicable thereafter, plaintiffs' counsel in the individual case must notify counsel for defendants of the date and location of each such surgery resulting in Materials.

B. Instructions to the Facility

Concurrently with provision of the above-referenced notice, counsel for such plaintiff must send a letter, with a copy to the Ethicon defendants' counsel, to the Facility where the surgery occurred in the form attached as Attachment B. With respect to *Barnett*, counsel for KARL STORZ must be copied on the letter submitted in accordance with Attachment B. The parties intend that this letter will advise the Facility of the need to collect, preserve, and ship the Material as potential evidence in the Litigation in accordance with the Facility's usual practices. Attachment B also includes a chain-of-custody form that the parties must request the Facilities execute for any Material any party removes from any Facility. This chain-of-custody form does not in any way affect the validity of any similar form utilized to obtain Materials prior to the date this order is filed. After the Material leaves the possession of any Facility, the chain-of-custody form must be requested to be completed by each individual or entity obtaining and/or releasing custody of any Material thereafter.

After a letter in the form set forth in Attachment B has been sent to a Facility, each party is responsible for payment of one-half of any costs associated with the preservation and shipment of Materials. With respect to *Barnett*, each party is responsible for payment of one-third of any such costs.

Plaintiffs must provide to the Facility a HIPAA-compliant authorization.

C. Third-Party Laboratory

For all Materials not yet requested by any party as of the date this Order is filed, the Parties will use Steelgate, Inc., to receive, photograph, document, and divide the Materials according to the general process outlined in Attachment C. Chain-of-custody forms must be completed by any entity, including Steelgate, Inc., taking possession of and/or transmitting the Materials or any portion thereof. The parties must equally split the costs of this process. Chain-of-custody forms reflecting transmittal to the parties' experts or consultants must not be disclosed to the opposing counsel until expert discovery in the case.

V. PROTOCOL FOR HANDLING OF CURRENTLY AVAILABLE MATERIALS EXISTING IN POSSESSION OF PLAINTIFFS' OR DEFENDANTS' COUNSEL AS OF THE DATE THIS ORDER IS FILED

A. Notice of Available Materials

If plaintiffs' or defendants' counsel already are in possession of any Materials as of the date this order is filed, within 10 business days of this order being filed or as soon as practicable thereafter, counsel must notify their adversary of the existence of the Materials. To the extent documentation, photographs, videos, or any other documentary

or related evidence regarding these Materials is in a party's possession, the party must provide all such evidence to counsel for the other parties within 30 days of this order being filed or as soon as practicable thereafter; to the extent such evidence is subject to a claim of work-product privilege, it is exempted from this requirement. Plaintiffs must provide the date of the surgery during which such Materials were removed to the extent it is known to plaintiffs.

B. Disposition and Handling of Materials in a Party's Possession

Counsel will document the Materials in their possession on a chain-of-custody form containing the information provided on the attachments to this order, or by way of such forms as were used to document the chain of custody prior to entry of this order. Chain-of-custody forms reflecting transmittal to the parties' experts or consultants must not be disclosed to the opposing counsel until expert discovery in the case.

A protocol for an orderly division and exchange of slides and/or Materials and the designation of a storage facility for such slides and Materials will be established in a subsequent stipulation.

As of the date this order is filed, 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.

VI. MATERIALS PREVIOUSLY DIVIDED, ANALYZED AND/OR TESTED

If, at the time this order is filed, the Materials for any plaintiff in the Litigation have already been divided, analyzed, and/or tested by any party, the parties must meet and confer and attempt to arrive at a mutually agreeable disposition as to such Materials. With the exception of testing or analyses that have already begun that may be compromised by delay or stoppage, neither party may perform any further review, analysis, division, or testing on the Materials or alter the Materials in any way prior to reaching agreement.

VII. NO WAIVER

Nothing in this order precludes a party from challenging the method of preservation of any Materials.

IT IS SO ORDERED.

Dated February 1, 2016, at Kansas City, Kansas.

s/ James P. O'Hara
James P. O'Hara
U.S. Magistrate Judge

ATTACHMENT A

IMPORTANT – REQUEST FOR PRESERVATION OF PATHOLOGY MATERIALS

[Date]

Attn: Department of Surgery and Pathology

[Address of Facility]

Re: [Date of Anticipated Surgery, Case Caption]

Dear Departments of Surgery and Pathology:

I represent the Plaintiff, Ms. [Plaintiff's last name] (your patient), and John D. Winter, Esq. of Patterson Belknap Webb & Tyler copied below represents the Defendant, Ethicon, Inc. ("Ethicon"), and Kathleen H. Warin, Esq. of Wilson, Elser, Moskowitz, Edelman and Dicker copied below represents the Defendant KARL STORZ (as to *Barnett*) in the above-referenced 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. [Surgeon].

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

Instructions for Immediate Preservation of the Specimen(s):

1. **EXCISED TISSUE:**

- a. Please preserve all excised tissue in 10% neutral buffered formalin.

2. **HISTOLOGY:**

- a. Please process the pathology specimens according to your usual practice for the creation of histology slides. (For example, preserve in formalin, place into a paraffin block, and cut slides).
- b. We request the below recuts of pathology slides regarding the [date] surgery:
- 8 H&E stained slides of each surgical specimen; and
 - 8 unstained slides of each surgical specimen.

3. EXCESS TISSUE:

- a. If there is excess tissue remaining after the recuts of pathology slides described above, we request the excess tissue be stored in 10% neutral buffered formalin.

Instructions for Shipping:

Please complete the enclosed Chain of Custody form describing the histology slides and excess tissue. Please forward both histology slides and excess tissue in appropriate containers according to your usual practice for the shipment of such materials to the attention of:

Kate Grayson
Steelgate, Inc.
2307 58th Avenue East
Bradenton, Florida 34203
Email: kate@steelgateinc.com
(941) 758-1122 or (866) 647-8335

Instructions for Reimbursement for Costs Incurred:

For reimbursement of costs incurred in the collection, division, preservation, and shipping of the specimens, the parties have agreed to divide such costs evenly. Please submit an itemized invoice for the costs to:

[insert Plaintiff's contact info]

Should you have any questions or concerns regarding this matter, please contact us by email directed to representatives of all parties: [counsel for Plaintiff] and John D. Winter, Esq., jwinter@pbwt.com (counsel for Ethicon) and Kathleen H. Warin, Esq., kathleen.warin@wilsonelser.com (counsel for KARL STORZ) (as to *Barnett*).

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

Very truly yours,

[Counsel for Plaintiff]

Counsel for Plaintiff

Enclosures:

1. HIPAA Authorizations
2. Chain of Custody Forms

cc: John D. Winter, Esq. (*Counsel for Defendant, Ethicon, Inc.*)
Kathleen H. Warin, Esq. (*Counsel for Defendants KARL STORZ*) (as to *Barnett*)

ATTACHMENT B

IMPORTANT – REQUEST FOR PATHOLOGY MATERIALS

[Date]

Attn: Department of Pathology

[Address of Facility]

Re: [Date of Surgery, Case Caption]

Dear Department of Pathology:

I represent the Plaintiff, Ms. [Plaintiff's last name] (your patient), and John D. Winter, Esq. of Patterson Belknap Webb & Tyler copied below represents the Defendant, Ethicon, Inc. (“Ethicon”), and Kathleen H. Warin, Esq. of Wilson, Elser, Moskowitz, Edelman and Dicker copied below represents the Defendant KARL STORZ (as to *Barnett*) in the above-referenced lawsuit. There is no litigation pending against your facility or the treating physician in this matter. I write to request the preservation of available pathology material from Ms. [Plaintiff's last name]'s [date] surgery performed by Dr. [Surgeon].

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

Instructions for Immediate Preservation of the Specimen(s):

1. EXCISED TISSUE:
 - a. Please preserve all excised tissue in 10% neutral buffered formalin.

2. HISTOLOGY:
 - a. Please process the pathology specimens according to your usual practice for the creation of histology slides. (For example, preserve in formalin, place into a paraffin block, and cut slides).
 - b. We request the below recuts of pathology slides regarding the [date] surgery:
 - 8 H&E stained slides of each surgical specimen; and
 - 8 unstained slides of each surgical specimen.

3. EXCESS TISSUE:
 - a. If there is excess tissue remaining after the recuts of pathology slides described above, we request the excess tissue be stored in 10% neutral buffered formalin.

Instructions for Shipping:

Please complete the enclosed Chain of Custody form describing the histology slides and excess tissue. Please forward both histology slides and excess tissue in appropriate containers according to your usual practice for the shipment of such materials to the attention of:

Kate Grayson
Steelgate, Inc.
2307 58th Avenue East
Bradenton, Florida 34203
Email: kate@steelgateinc.com
(941) 758-1122 or (866) 647-8335

Instructions for Reimbursement for Costs Incurred:

For reimbursement of costs incurred in the collection, preservation, and shipping of the specimens, the parties have agreed to divide such costs evenly, please submit an itemized invoice to:

[insert Plaintiff's contact info]

In order to facilitate this request, enclosed please find a HIPAA-compliant authorization for the release of the specimens 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 specimens when they leave your facility.

Should you have any questions or concerns regarding this matter, please contact us by email directed to representatives of all parties: [counsel for Plaintiff] and John D. Winter, Esq., jwinter@pbwt.com (counsel for Ethicon) and Kathleen H. Warin, Esq., kathleen.warin@wilsonelser.com (counsel for KARL STORZ) (as to *Barnett*)..

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,

[Counsel for Plaintiff]
Counsel for Plaintiff

Encls. as stated

cc: John D. Winter, Esq. (*Counsel for Defendant, Ethicon, Inc.*)
Kathleen H. Warin, Esq. (*Counsel for Defendants KARL STORZ*) (as to *Barnett*)

CHAIN OF CUSTODY FORM

[Case caption]

ENTRY NO. []

Released by:

Name: _____

Company/Organization: _____

Address: _____

Telephone Number: _____

Date: _____

Time: _____

Signature of Recipient: _____

ITEM DESCRIPTION

Gross Description of Item <i>(including date of surgery when material removed and slide numbers if applicable)</i>	Photographed While in Your Possession <i>(Yes/No)</i>	Manner of Preservation <i>(paraffin block, histology slides, loose and dry, loose and in liquid, etc.)</i>	Size of Specimen <i>(millimeters and weight)</i>	Other identifying marks or comments

Note any change of condition:

Received by:

Name: _____

Company/Organization: _____

Address: _____

Telephone Number: _____

Date: _____

Time: _____

Signature of Recipient: _____

ENTRY NO.

Released by:

Name: _____

Company/Organization: _____

Address: _____

Telephone Number: _____

Date: _____

Time: _____

Signature of Recipient: _____

ITEM DESCRIPTION

Gross Description of Item <i>(including date of surgery when material removed and slide numbers if applicable)</i>	Photographed While in Your Possession <i>(Yes/No)</i>	Manner of Preservation <i>(paraffin block, histology slides, loose and dry, loose and in liquid, etc.)</i>	Size of Specimen <i>(millimeters and weight)</i>	Other identifying marks or comments

Note any change of condition:

Received by:

Name: _____

Company/Organization: _____

Address: _____

Telephone Number: _____

Date: _____

Time: _____

Signature of Recipient: _____

ENTRY NO. []

Released by:

Name: _____

Company/Organization: _____

Address: _____

Telephone Number: _____

Date: _____

Time: _____

Signature of Recipient: _____

ITEM DESCRIPTION

Gross Description of Item <i>(including date of surgery when material removed and slide numbers if applicable)</i>	Photographed While in Your Possession <i>(Yes/No)</i>	Manner of Preservation <i>(paraffin block, histology slides, loose and dry, loose and in liquid, etc.)</i>	Size of Specimen <i>(millimeters and weight)</i>	Other identifying marks or comments

Note any change of condition:

Received by:

Name: _____

Company/Organization: _____

Address: _____

Telephone Number: _____

Date: _____

Time: _____

Signature of Recipient: _____

ATTACHMENT C

These instructions will be provided to the independent third party laboratory as agreed upon by the Parties and a telephone call with a representative from the laboratory will be set up with representatives from all 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.

Please be advised that for cases in *In re: Ethicon, Inc. Power Morcellator Products Liability Litigation*, MDL No. 2652 (D. Kan.), in which Ethicon and related entities are defendants, pathology materials will be divided into equal halves. For cases in *In re: Ethicon, Inc. Power Morcellator Products Liability Litigation*, MDL No. 2652 (D. Kan.), in which Ethicon and related entities and Karl Storz Endoscopy-America, Inc. and related entities are defendants including *Barnett v. Karl Storz Endoscopy-America, Inc., et al.*, D. Kan. 15-9326-KHV-JPO, pathology materials will be divided into equal thirds. Plaintiff will notify Steelgate, Inc. which protocol to follow on a case-by-case basis.

Plaintiffs will provide a HIPAA compliant authorization allowing the independent third party laboratory to release -'s portion of the Materials to -'s counsel as instructed below.

Receipt of Materials:

Upon receipt of Materials, the laboratory will notify the Parties via email sent to: [plaintiff's email] and jwinter@pbwt.com and kathleen.warin@wilsonelser.com (as to *Barnett*).

The Parties may have a representative present for the division and inspection of the Materials.

Documentation:

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

Photographs:

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

1. The photographs should depict the entire specimen (or specimens, if excised in more than one part) with scale and identifiers.
2. Confirm that each photograph is sufficiently in focus to allow recognition of specimen detail.
3. Take at least two (2) overview photographs of the specimen(s) from overhead.
4. Take at least one (1) photograph from each of four equally spaced directions taken at an oblique angle.
5. Turn the specimen over and repeat steps 3 and 4, above.
6. There should be at least 12 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.

Division of Materials

The histology Materials should be divided evenly between the Parties.

Minimize Time in Air:

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.

Shipping of Materials to Parties:

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

Plaintiff's half of the Materials:
[insert Plaintiff's or facility contact info]

Ethicon's half of the materials:
[insert Defendant's or facility contact info]

With respect to *Barnett*:

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

Plaintiff's third of the Materials:
[insert Plaintiff's or facility contact info]

Ethicon's third of the materials:
[insert Defendant's or facility contact
info]

KARL STORZ's third of the materials:
[insert Defendant's or facility contact info]