

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF INDIANA  
INDIANAPOLIS DIVISION

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In Re: COOK MEDICAL, INC., IVC FILTERS  
MARKETING, SALES PRACTICES AND  
PRODUCTS LIABILITY LITIGATION

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Case No. 1:14-ml-2570-RLY-TAB  
MDL No. 2570

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This Document Relates to ALL ACTIONS

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**SECOND AMENDED CASE MANAGEMENT ORDER # 1**  
**(PATHOLOGY AND MEDICAL DEVICE PROTOCOL)**

**I. Scope of Order**

Discovery in this proceeding may involve the collection, storage, preservation, and production of autopsy specimens and/or retrieved or explanted medical devices, evidence for which special handling, division, storage, and preservation procedures may be warranted. Accordingly, Plaintiffs and Cook Defendants (collectively the “Parties”), by their respective Lead Counsel, hereby stipulate to and petition the Court to enter this stipulated pathology and medical device protocol order (“Pathology and Medical Device Protocol Order” or “Order”) in this matter. Upon entry of this Order, the Order will apply to all actions that are or become part of MDL 2570, until further order of the Court.

**II. The Order**

By stipulating to this Order, the Parties have agreed to be bound by its terms and to request its entry by the presiding district or magistrate judge. It is hereby **ORDERED** as follows:

**A. Definitions**

“Decedent Plaintiff” is defined as a deceased individual whose estate has brought a lawsuit included in MDL 2570.

“Facility” is defined to include healthcare facilities where a Plaintiff underwent a Günther Tulip™ Inferior Vena Cava Filter or Celect® Inferior Vena Cava Filter (collectively, “Cook Filters”) retrieval or explant procedure, medical examiner facilities where an autopsy was conducted on a Decedent Plaintiff, and facilities responsible for the preservation and/or maintenance of retrieved, explanted, or excised materials from such procedures or autopsies.

“Litigation” is defined as *In re: Cook Medical, Inc., IVC Filters Marketing, Sales Practices and Products Liability Litigation*, MDL No. 2570 (S.D. Ind.), and this Order is intended to apply to all actions that are or become part of MDL 2570.

“Material” or “Materials” is defined as any and all Cook Filters or any portion thereof retrieved, explanted, or excised from a Plaintiff or Decedent Plaintiff, any portion of an inferior vena cava excised from a plaintiff or Decedent Plaintiff, and gross and microscopic specimens, which may contain portions of a Cook Filter, including but not limited to any pathology evidence, histology slides, paraffin blocks, and/or stock jars containing vena cava, tissue, gross material, and/or a Cook Filter.

**B. Intent**

It is the intention of the Parties that all Material that has not previously been analyzed or tested, be preserved in a manner that permits the Parties equal access to and analysis of the Material, and that neither Party will alter the Materials in any way prior to reaching a mutual agreement in writing regarding the equal division of the Materials. Only in the event that no such agreement can be reached will the Parties seek the Court’s guidance. The Parties will not interfere with or circumvent the analysis and preservation of Materials by the Facilities to which a Plaintiff’s treating physician has sent or will send the Materials in the usual course of business, or by the Facilities conducting an autopsy on a Decedent Plaintiff.

**C. Protocol for Preservation of Materials from Future Procedures**

1. Notice of Explant or Retrieval Procedure

Within twenty-four (24) hours of receipt of information that a Plaintiff or individual represented by Plaintiffs' Counsel has scheduled a Cook Filter retrieval or explant procedure, Plaintiffs' Counsel shall notify Cook's Counsel of the date and location of such procedure, as well as the name of the physician performing the procedure. Such Notice shall be provided by email to: CookFilterMDL@FaegreBD.com. Cook's Counsel must acknowledge receipt of such Notice prior to the retrieval or explant procedure proceeding.

2. Instructions to the Facility

Concurrently with provision of the above-referenced notice, Plaintiffs' Counsel shall send a letter, with a copy to Cook's Counsel, to the Facility where the explant surgery is to occur in the form attached hereto as Attachment A. 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 potential evidence in the Litigation. Plaintiffs' Counsel shall also include with the letter a Chain of Custody form, in the form attached hereto as Attachment B, which the Parties shall request that the Facility execute for any Material leaving the possession of the Facility. Additionally, Plaintiffs' Counsel shall provide to the Facility a HIPAA-compliant authorization and any other form requiring a Plaintiff's signature for the collection of the Material.

After a letter in the form set forth in Attachment A has been sent to a Facility, Plaintiffs' Counsel must pay any costs or fees associated with the preservation and shipment of Materials. All costs and fees associated with the preservation and shipment of the Material under this protocol shall be borne by the specific Plaintiff and/or Plaintiff's Counsel.

**D. Protocol for Handling of Materials Currently Available at a Facility**

1. Notice of Available Materials

Within seven (7) days of receipt of knowledge that Material regarding a particular Plaintiff or Decedent Plaintiff exists at a Facility, Plaintiffs' Counsel shall notify Cook's Counsel of the date and location of the procedure or autopsy resulting in Material, as well as the name of the applicable physician or medical examiner. Such notice shall be provided by email to: CookFilterMDL@FaegreBD.com.

2. Instructions to the Facility

Concurrently with provision of the above-referenced notice, Plaintiffs' Counsel shall send a letter, with a copy to Cook's Counsel, to the Facility where the procedure or autopsy occurred in the form attached hereto as Attachment C. 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 potential evidence in the Litigation. Plaintiffs' Counsel shall also include with the letter a Chain of Custody form, in the form attached hereto as Attachment B, which the Parties shall request that the Facility execute for any Material leaving the possession of the Facility. Additionally, Plaintiffs' Counsel shall provide to the Facility a HIPAA-compliant authorization and any other form requiring a Plaintiff's signature for the collection of the Material.

After a letter in the form set forth in Attachment C has been sent to a Facility, Plaintiffs' Counsel must pay any costs or fees associated with the preservation and shipment of Materials. All costs and fees associated with the preservation and shipment of the Material under this protocol shall be borne by the specific Plaintiff and/or Plaintiff's Counsel.

**E. PROTOCOL FOR HANDLING OF CURRENTLY AVAILABLE MATERIALS EXISTING IN POSSESSION OR CONTROL OF PLAINTIFFS**

1. Notice of Available Material

If Plaintiffs are already in possession of any Materials as of the date of this Order, within seven (7) days of this Order being entered, Plaintiffs' Counsel shall notify Cook's Counsel 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' Counsel will provide all such evidence to Cook's Counsel within seven (7) days of this Order being entered. To the extent such information is known to Plaintiffs, Plaintiffs will provide the date and location of the procedure or autopsy during which the Materials were removed, as well as the name of the applicable physician or medical examiner. Such notice shall be provided by email to: CookFilterMDL@FaegreBD.com.

2. Disposition of Materials in Plaintiffs' Possession

Plaintiffs' Counsel will document the Materials in Plaintiffs' possession or control on a Chain of Custody form, in the form attached hereto as Attachment B. Plaintiffs' Counsel will provide a completed copy of the Chain of Custody form to Cook's Counsel upon shipment of all Materials to Cook's designee. All costs and fees associated with the preservation and shipment of the Materials under this protocol shall be borne by the specific Plaintiff and/or Plaintiff's Counsel.

**F. Materials Associated with Potential Claimants**

Plaintiffs' Counsel acknowledges their obligation to preserve all Materials associated with any potential claimants whom they represent. Plaintiffs' Counsel agrees that the protocols outlined above in Sections C-E shall apply to all such potential claimants.

**G. Disposition of Materials**

The Parties agree that all Materials shall be handled according to the process outlined below:

1. All Materials collected from a Facility shall be shipped to a third-party vendor ("Vendor") agreed upon by the Parties.

2. Specimens on slides or on stock jars will be shipped to Cooks' designee for review by a pathologist and then returned to Vendor once the review is complete. The specimens will then be shipped to Plaintiffs' designee for review by a pathologist and then returned to Vendor once the review is complete;

3. To the extent possible, specimens in paraffin wax or involving tissue preserved in formalin will be shipped to Cook's designee, where he or she will split the specimen in half; Plaintiffs' designee may be present when the specimen is split and will receive the remaining half of the specimen;

4. If in the course of dividing the Material it becomes impossible to provide two equal (or nearly equal) halves of the Material, or if the Material is too small to reasonably be divided equally among the Parties, 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 Material or alter the Material 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.

5. A Chain of Custody form, in the form attached hereto as Attachment B, shall be completed by each individual or entity having custody of any Materials from the time it leaves the possession of the Facilities, or the possession or control of Plaintiffs for any Materials that were in possession or control of Plaintiffs at the time this Order was entered.

6. 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 shall be borne by the Party requesting such preservation. All costs associated with the evaluation of the Material under this protocol shall be borne by the Party performing the evaluation. All costs associated with the use of Vendor for the preservation of Materials that have not yet been or cannot be divided shall be shared equally by the Parties.

**H. Materials Previously Divided, Analyzed, or Tested**

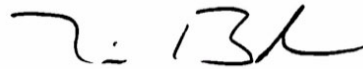
If, at the time this Order is submitted to the Court by the Parties, Material for any Plaintiff in the Litigation has already been divided, analyzed and/or tested, Plaintiffs' Counsel shall notify Cook's Counsel within seven (7) days of this Order being entered. After notice has been given, the Parties agree to immediately meet and confer and attempt to arrive at a mutually agreeable disposition as to such Material. With the exception of testing or analyses that have already begun that may be compromised by delay or stoppage, neither Party will perform any further review analysis, division or testing on the Material or alter the Material in any way prior to reaching agreement.

**I. No Waiver**

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

The Court DIRECTS the Clerk to file a copy of this order in MDL 2570 and it shall apply to all cases that are or become a part of MDL 2570. 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.

**SO ORDERED: 3/29/2017**



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Tim A. Baker  
United States Magistrate Judge  
Southern District of Indiana

Distribution to all registered counsel of record via the Court's ECF system.  
Distribution to all non-registered counsel of record to be made by Plaintiffs' Lead Counsel.



**ATTACHMENT A**

**VERY IMPORTANT – REQUEST FOR PRESERVATION OF PATHOLOGY  
MATERIALS AND/OR MEDICAL DEVICES FROM UPCOMING PROCEDURE**

[Date]

**Attn: Departments of Surgery and Pathology**  
[Address of Retrieval/Explant Facility]

**Re: [Case Caption]**

Dear Departments of Surgery and Pathology:

I represent the Plaintiff, [Plaintiff's name], and the attorneys copied below represent the Cook Defendants 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 materials and/or medical devices ("Materials") from [Plaintiff's name]'s upcoming procedure, scheduled for [date] to be performed by Dr. [Retrieval/Explant Physician].

It is very important that any pathology and/or medical devices obtained during this upcoming procedure be preserved for future analysis by the parties' respective experts. The parties request that you preserve the Material(s) obtained as follows:

**Instructions for Immediate Preservation of the Material(s):**

1. Please preserve **all** retrieved or explanted Materials.
2. Histology:
  - a. Please process any 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).
3. Medical Devices:
  - a. With regard to retrieved or explanted medical devices, sterilization/decontamination may be conducted via use of ethylene oxide, Cidex®, or a minimum of 1-hour soak in 10% neutral buffered formalin followed by a rinse with distilled water. If these methods are not available to you, please contact counsel at the information listed below. Thereafter, please place the medical device in an appropriate leak-proof container. **EXCEPT AS NOTED ABOVE, PLEASE DO NOT PLACE THE MEDICAL DEVICE IN FORMALIN OR ANY OTHER FIXATIVE.**

**Instructions for Shipping:**

Please complete the enclosed Chain of Custody form describing the Material(s). Please forward it along with all of the Material(s) to:

[INSERT DESIGNEE AGREED TO BY THE PARTIES]

### **Instructions for Reimbursement for Costs Incurred**

For reimbursement of costs incurred in the collection, preservation, and shipping of the Material(s), please submit an itemized invoice to:

[Counsel for Plaintiff's contact information]

In order to facilitate this request, enclosed please find a HIPAA-compliant authorization for the release of the Material(s), signed by [Plaintiff's name].

Should you have any questions or concerns regarding this matter, please feel free to contact me.

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]

Enclosures

cc: Andrea R. Pierson, *Counsel for Cook Defendants*  
John T. Schlafer, *Counsel for Cook Defendants*

**ATTACHMENT B**

**CHAIN OF CUSTODY FORM**

**Case/Cause No.:**

**ENTRY NO. 1**

**RELEASING Party Information:**

Person/Facility Name: \_\_\_\_\_

Person/Facility Address: \_\_\_\_\_

**Description of Materials being released:**

**A.** Name of patient/plaintiff from whom IVC filter explanted: \_\_\_\_\_

**B.** General Description of Material (including number of any filter fragments separated from main body of IVC Filter):  
\_\_\_\_\_

Full Name of Person Releasing Material: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_ Time: \_\_\_\_\_

Released to: \_\_\_\_\_

Signature: \_\_\_\_\_

Transferred via FedEx:  Yes  No

FedEx Tracking No.: \_\_\_\_\_

**RECEIVING Party Information:**

Receiving Person/Facility Name: \_\_\_\_\_

Receiving Person/Facility Address: \_\_\_\_\_

**Description of Materials received:**

**A.** Name of patient/plaintiff from whom filter explanted: \_\_\_\_\_

**B.** General Description of Material (including number of any filter fragments separated from main body of IVC Filter):  
\_\_\_\_\_

Full Name of Person Receiving Shipment: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_ Time: \_\_\_\_\_

Material Received from: \_\_\_\_\_

Manner in which received (*FedEx, etc.*): \_\_\_\_\_

FedEx Tracking No.: \_\_\_\_\_

Signature: \_\_\_\_\_

**ENTRY NO. 2**

**RELEASING Party Information:**

Person/Facility Name: \_\_\_\_\_

Person/Facility Address: \_\_\_\_\_

**Description of Materials being released:**

A. Name of patient/plaintiff from whom IVC filter explanted: \_\_\_\_\_

B. General Description of Material (including number of any filter fragments separated from main body of IVC Filter):

\_\_\_\_\_  
\_\_\_\_\_

Full Name of Person Releasing Material: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_ Time: \_\_\_\_\_

Released to: \_\_\_\_\_

Signature: \_\_\_\_\_

Transferred via FedEx:  Yes  No

FedEx Tracking No.: \_\_\_\_\_

**RECEIVING Party Information:**

Receiving Person/Facility Name: \_\_\_\_\_

Receiving Person/Facility Address: \_\_\_\_\_

**Description of Materials received:**

A. Name of patient/plaintiff from whom filter explanted: \_\_\_\_\_

B. General Description of Material (including number of any filter fragments separated from main body of IVC Filter):

\_\_\_\_\_  
\_\_\_\_\_

Full Name of Person Receiving Shipment: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_ Time: \_\_\_\_\_

Material Received from: \_\_\_\_\_

Manner in which received (*FedEx, etc.*): \_\_\_\_\_

FedEx Tracking No.: \_\_\_\_\_

Signature: \_\_\_\_\_

**ATTACHMENT C**

**VERY IMPORTANT – REQUEST FOR PRESERVATION OF PATHOLOGY MATERIALS AND/OR MEDICAL DEVICES FROM PREVIOUS PROCEDURE**

[Date]

**Attn: Departments of Surgery and Pathology [or Medical Examiner’s Office]**  
[Address of Retrieval/Explant/Autopsy Facility]

**Re: [Case Caption]**

Dear Departments of Surgery and Pathology [or Medical Examiner]:

I represent the Plaintiff, [[the estate of] [Decedent] Plaintiff’s name], and the attorneys copied below represent the Cook Defendants in the above-referenced lawsuit. There is no litigation pending against your facility or the treating physician [or medical examiner] in this matter. I write to request the preservation of pathology materials and/or medical devices (“Materials”) from [Plaintiff’s name]’s previous procedure [or autopsy], which was performed by Dr. [Retrieval/Explant Physician or Medical Examiner] on [date].

It is very important that any pathology and/or medical devices that were obtained during the procedure [or autopsy] be preserved for future analysis by the parties’ respective experts. The parties request that you preserve the Material(s) that were obtained as follows:

**Instructions for Immediate Preservation of the Material(s):**

1. Please preserve **all** retrieved or explanted Materials.
2. Histology:
  - a. Please process any 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).
3. Medical Devices:
  - a. With regard to retrieved or explanted medical devices, sterilization/decontamination may be conducted via use of ethylene oxide, Cidex®, or a minimum of 1-hour soak in 10% neutral buffered formalin followed by a rinse with distilled water. If these methods are not available to you, please contact counsel at the information listed below. Thereafter, please place the medical device in an appropriate leak-proof container. **EXCEPT AS NOTED ABOVE, PLEASE DO NOT PLACE THE MEDICAL DEVICE IN FORMALIN OR ANY OTHER FIXATIVE.**
4. If the Materials have already been preserved in a different manner, please keep the Materials in the manner they are currently preserved.

**Instructions for Shipping:**

Please complete the enclosed Chain of Custody form describing the Material(s). Please forward it along with all of the Material(s) to:

[INSERT DESIGNEE AGREED TO BY THE PARTIES]

**Instructions for Reimbursement for Costs Incurred**

For reimbursement of costs incurred in the collection, preservation, and shipping of the Material(s), please submit an itemized invoice to:

[Counsel for Plaintiff's contact information]

In order to facilitate this request, enclosed please find a HIPAA-compliant authorization for the release of the Material(s), signed by [Plaintiff's name].

Should you have any questions or concerns regarding this matter, please feel free to contact me.

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]

Enclosures

cc: Andrea R. Pierson, *Counsel for Cook Defendants*  
John T. Schlafer, *Counsel for Cook Defendants*