

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

<b>IN RE: COOK MEDICAL, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>MDL No. 2440</b>  <b>JOSEPH R. GOODWIN, U.S. DISTRICT JUDGE</b>
<b>THIS DOCUMENT RELATES TO ALL CASES</b>	

**PRETRIAL ORDER # 49**  
**(AGREED ORDER AND STIPULATION REGARDING PATHOLOGY PROTOCOL  
FOR PRESERVATION AND TESTING OF PLAINTIFFS' TISSUE SAMPLES AND  
HANDLING OF PLAINTIFFS' PATHOLOGY SLIDES)**

**I. Scope of Order**

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, the parties herein (the “Parties”) hereby stipulate to and petition the Court to enter this stipulated pathology protocol order (“Pathology Protocol Order” or “Order”) in this matter. Upon entry of this Order, the Order will apply to all current actions selected for trial preparation in MDL 2440 pursuant to order of the Court (including, but not limited to, the current discovery pool cases in MDL 2440), as well as any similar future Pretrial Orders designating discovery pool cases or individual actions for trial preparation. This protocol is not intended to apply generally to all cases in this MDL proceeding.

## **II. The Order**

By stipulating to this Pathology Protocol 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:

This stipulation is entered between Plaintiffs whose cases have been or may be selected as discovery pool cases or for potential trial work-up in the Litigation (as defined in Section A, below) and Defendants Cook Medical Incorporated, Cook Incorporated, and/or Cook Biotech Incorporated (collectively “Cook”) (hereinafter each a “Party” or collectively, the “Parties”), by and through their respective counsel, to provide a protocol for the collection, preservation, storage, and division of the Materials in the Litigation (as defined in section A, below).

### **A. Definitions**

“Facility” is defined to include healthcare facilities where a plaintiff underwent a Cook product revision, excision, or explant surgery, as well as facilities responsible for the preservation and/or maintenance of excised or explanted materials from such surgeries.

“Litigation” is defined as *In re: Cook Medical, Inc., et al., Pelvic Repair System Products Liability Litigation*, MDL No. 2440 (S.D. W.Va.), and this Order is intended to apply to those member cases in this Litigation that have been or may be in the future, selected as discovery pool cases or for trial preparation in MDL 2440 pursuant to order of the Court, as well as any similar future Pretrial Orders designating individual actions for trial preparation. This protocol is not intended to apply generally to all cases in this MDL proceeding.

“Material” or “Materials” is defined as any and all gross and microscopic material purported to contain Cook implant product(s) or any other of these Plaintiffs’ pelvic floor tissue excised or explanted from any of these Plaintiffs, including but not limited to any pathology evidence, histology slides, paraffin blocks containing tissue and gross material.

“Third Party Facility” is identified as Steelgate, Inc., located at 2307 58<sup>th</sup> Avenue, East, Bradenton, FL 34203.

**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. In the event that no such agreement can be reached, the parties will seek the Court’s guidance. The Parties will not interfere with or circumvent the analysis and preservation of Materials by the Facilities to which any of Plaintiffs’ treating physicians have sent or will send the Materials in the usual course of business.

**C. Protocol for Preservation of Materials for All Tissue**

**1. Third Party Facility**

Steelgate will obtain and/or maintain all pathology, whether on slides, preserved in paraffin block, or tissue preserved in formalin, for all Plaintiffs selected for discovery pool cases or potential trial work-up in the MDL 2440 litigation. A request to obtain pathology, whether on slides, preserved in paraffin block, or tissue preserved in formalin, for any discovery pool Plaintiff from any Facility may be made by any Party to Steelgate, with a copy of any such request to be sent to counsel for all other Parties to that individual case by email.

**D. Protocol for Handling of Currently Available Materials Existing at Steelgate**

Within five (5) business days of the Court’s Order establishing this Pathology Protocol, Plaintiffs’ Counsel in the individual discovery pool cases shall notify counsel for Cook of the

Plaintiff's identity and description of Material that is already being maintained at Steelgate. The notice shall be provided via email to: [CookMDL@woodmclaw.com](mailto:CookMDL@woodmclaw.com).

**E. Disposition of Materials**

The Parties agree that for the Materials, Steelgate shall receive, photograph, document, and divide the Materials according to the process outlined below:

1. Specimens on slides will be shipped to Plaintiffs' pathology expert for review, returned to Steelgate, and then shipped to Cook's identified pathology expert for review, and then returned to Steelgate;
2. Specimens in paraffin wax will be shipped to Plaintiffs' pathology expert, where he or she will split the specimen in half; Cook's pathology expert can be present when the specimen is received, and Cook's pathology expert can receive the remaining half of the specimen; and
3. Specimens involving tissue preserved in formalin will be shipped to Plaintiffs' pathology expert, where he or she will split the specimen in half; Cook's pathology expert can be present when the specimen is received, and Cook's pathology expert can receive the remaining half of the specimen.
4. Steelgate shall collect/execute/maintain Chain-Of-Custody forms (Attached hereto as Exhibit A) for all materials sent and/or received to any expert and/or Parties.

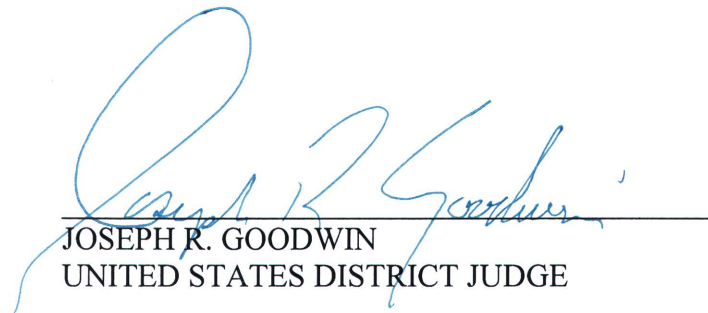
The Parties agree to equally split the costs of this process. To the extent any Party uses Steelgate, Inc. for any other purpose, including but not limited to storage, that Party will bear its own costs.

**F. 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 2440 and it shall apply to each member case selected as a discovery pool case or for potential trial work-up as outlined hereinabove. In cases subsequently filed in this district, following case number 2:14-cv-27435, 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 of the court's website at [www.wvsd.uscourts.gov](http://www.wvsd.uscourts.gov).

ENTER: December 10, 2014



JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE

**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: \_\_\_\_\_  
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: \_\_\_\_\_

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**ENTRY NO. 1: Recipient Location/Receipt information:**

**Facility Name:** Steelgate Inc., 2307 58<sup>th</sup> Avenue East, Bradenton, FL 34203

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 (\_\_\_), refrigerated (\_\_\_)

Condition of Container: undamaged (\_\_\_), damaged (\_\_\_), describe: \_\_\_\_\_

Person **RECEIVING** Shipment: \_\_\_\_\_ (sign/print)

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

Witness: \_\_\_\_\_ (sign/print)

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

# 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:** Steelgate Inc., 2307 58<sup>th</sup> Avenue East, Bradenton, FL 34203

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: \_\_\_\_\_

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## ENTRY NO. 2: Recipient Location/Receipt information:

Facility Name:

Address: \_\_\_\_\_

Address: \_\_\_\_\_

Contact Name: \_\_\_\_\_ Department \_\_\_\_\_

Contact Phone #: \_\_\_\_\_ Contact Email: \_\_\_\_\_

(1) \_\_\_\_\_ (2) \_\_\_\_\_

(3) \_\_\_\_\_ (4) \_\_\_\_\_

## Note any changes of condition:

Condition of specimen: ambient (\_\_\_), frozen (\_\_\_), unfrozen (\_\_\_), refrigerated (\_\_\_)

Condition of Container: undamaged (\_\_\_), damaged (\_\_\_), describe: \_\_\_\_\_

Person **RECEIVING** Shipment: \_\_\_\_\_ (sign/print)

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

Witness: \_\_\_\_\_ (sign/print)

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

# 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: \_\_\_\_\_

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: \_\_\_\_\_

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## **ENTRY NO.3: Recipient Location/Receipt information:**

Facility Name: \_\_\_\_\_

Address: \_\_\_\_\_

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 (\_\_\_), refrigerated (\_\_\_)

Condition of Container: undamaged (\_\_\_), damaged (\_\_\_), describe: \_\_\_\_\_

**Person RECEIVING Shipment:** \_\_\_\_\_ (sign/print)

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

Witness: \_\_\_\_\_ (sign/print)

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