

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

IN RE: COOK MEDICAL, INC., IVC
FILTERS MARKETING, SALES PRACTICES
AND PRODUCT LIABILITY LITIGATION

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

This Document Relates to All Actions

CASE MANAGEMENT ORDER # 14

(SUPPLEMENTAL PRESERVATION, INSPECTION AND TESTING PROTOCOL)

I. Scope of This Order

This Agreed Order supplements the provisions of Case Management Order #1 and any subsequent amended versions thereof (“CMO #1”), and governs any and all inspections and/or testing of explanted filter(s) (or fragment(s) thereof) (collectively referred to herein as the “Filter”), and any biological material and/or tissue that is on, in, or in any way attached to the Filter (“Attached Tissue”). This Order applies to all cases within MDL 2570, and applies to potential claimants in conjunction with section II.F. of CMO #1.

Within this Order, certain procedures are outlined for sterilizing the Filter and addressing Attached Tissue. Any action by a Party to sterilize or remove Attached Tissue beyond the procedures agreed to herein may be considered “Destructive Testing” and requires a separate written agreement first be executed by the Parties. Furthermore, any other action by a Party that may alter the structure, existence, integrity, appearance or nature of the Filter in any way, including its surfaces, which has not been agreed to herein will be considered “Destructive Testing” and requires a separate written agreement by the Parties. Any Party who wants to undertake Destructive Testing must provide 30 days advance notice to all other Parties and provide a written proposal of the nature, extent and

methods of the proposed Destructive Testing such that the other Parties may evaluate and/or object to the proposal. The Destructive Testing will not occur unless the Parties execute a written agreement, or any disagreement between the Parties regarding the testing is resolved by the Court. Inspection or testing of the Filter which will not alter the Filter beyond that allowed by this Order will be considered “Non-Destructive Testing.”

II. Standards for Shipping, Handling, and Inspection Generally

The Parties agree to utilize reasonable efforts to safeguard the Filter and Attached Tissue by utilizing appropriate methods in all aspects of shipping, handling, inspection and testing so as to avoid alteration of the Filter and Attached Tissue in any manner not agreed to herein.

Shipping of the Filter shall be via Federal Express overnight delivery, packaged in a plastic container that is slightly larger than the Filter, packed with cotton. The plastic container shall be wrapped in bubble wrap or placed in a bubble wrap envelope and placed in a box of adequate strength for shipping to avoid any alteration or damage to the device while in transit. The Chain of Custody form (“Attachment B” to CMO #1) shall be used for all transfers and/or changes of possession.

III. Notice of Intended Non-Destructive Testing

Any Party intending to conduct Non-Destructive Testing will provide at least ten (10) days advance written notice to all other Parties. This notice will allow all Parties to coordinate the availability of the Filter for inspection, and provide notice to Parties conducting subsequent inspection that the Filter has been previously inspected by another Party.

IV. Initial Intake by Testing/Inspection Laboratory

Upon receipt at the laboratory for Non-Destructive Testing, the initial intake procedure should include the following steps:

- The package containing the Filter will be inspected before opening it and the shipment and receipt information documented on the Chain of Custody Document.
- Photographs and/or video will be taken of the package, and the manner in which the Filter and any Attached Tissue were packaged inside by the person who sent it.
- After the Filter is removed from its internal packaging, photographs and/or video of the Filter and any Attached Tissue shall be taken from a variety of angles and magnifications *prior to* any manipulation or testing of any kind.
- The Party conducting the inspection or testing must video record the entire event, starting prior to opening the shipping box the Filter arrived in and continuing until the Filter is again sealed in a box for shipment away from the location of the inspection/testing. The Party conducting the testing must also video record the settings selected on the testing machinery/equipment. The cost to rent and/or purchase the equipment necessary to record this video as well as the additional staffing or expert time associated with this process shall be the responsibility of the opposing party.
- At the time the Filter is placed into any machine or device for Scanning Electron Microscopy, Energy Dispersive Spectroscopy, or any non-destructive analysis, the Party shall video the manner in which the Filter is secured for said testing. Upon removal of the Filter from any testing machine or device, the Party shall video the manner in which the Filter is released from its secured position.

V. Possession of Photographs and Video

All photographs and videos taken during Non-Destructive Testing conducted by a Party shall remain in the possession of that Party's counsel unless and until another Party provides notice that it believes the Filter was altered in some way during the purported Non-Destructive Testing. Upon such a challenge by any Party, the opposing Party shall request a status conference with the Magistrate Judge to discuss whether *in camera* review of the photographs and video from the testing is necessary to determine whether the integrity of the filter was compromised in a material way.

VI. Sterilization/Decontamination and Tissue Removal

For sterilization, the Filter shall initially be soaked in 10% neutral buffered formalin for a minimum of one (1) hour followed by a rinse with distilled water. Alternatively, ethylene oxide

and/or Cidex® may be used for sterilization. In addition, prior to Scanning Electron Microscopy (SEM) or Energy Dispersive Spectroscopy (EDS), the Filter will be cleaned with ethanol to remove any surface contamination.

If Attached Tissue is in or on the Filter, and if the Attached Tissue will impede the intended inspection and/or testing, removal of the Attached Tissue will first be attempted by use of careful mechanical means (without contact with the Filter itself). If in a particular case careful mechanical means is insufficient to remove Attached Tissue to the extent required by a Party, that Party shall provide notice to all other Parties of the action it desires to take under the Destructive Testing procedures in Section I. of this Order except that notice shall be five business days prior to any attempt to remove Attached Tissue. As under the Destructive Testing procedures in Section I. of this Order, a written agreement must be executed between the Parties before the Party who provided notice of Destructive Testing may move forward.

If Attached Tissue is successfully removed from the Filter, additional photographs must be taken of the Filter from a variety of angles and magnifications using scales for size reference prior to any further manipulation or testing. Attached Tissue will be retained and stored in an appropriate container.

VII. Return of Filter

Upon completion of the intended Non-Destructive Testing, the Filter will be promptly returned to the agreed third party vendor for storage (Steelgate, Inc., 2307 58th Avenue East, Bradenton, Florida 34203) or the Party's counsel who will in turn forward the Filter to Steelgate for storage in accordance with applicable provisions for proper shipping, unless any alternative written agreement has been executed by the Parties regarding where the Filter should be sent.

A Party shipping a Filter and/or Attached Tissue to Steelgate will copy the opposing Party on the correspondence. Upon entry of this Order, the Parties will direct Steelgate to provide an

inventory of all materials it is storing for the Parties, to provide an updated inventory on a monthly basis and with any invoice it issues. Cook Defendants will pay one-half of the Steelgate storage charges for materials covered by this Order and for which Plaintiff's counsel has provided information sufficient to confirm the filter is a Cook IVC filter.

VIII. Chain of Custody

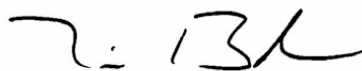
The designated chain of custody form shall accompany the Filter and Attached Material as it is shipped to any new location. However, if the chain of custody for any given shipment would disclose the identity of a consulting expert of one of the Parties, counsel for that Party may first ship the filter back to counsel's office and retain the chain of custody which reveals the identity of the consulting expert. Counsel may then use a new or redacted chain of custody form to send the materials back to Steelgate. Counsel who elects to retain chain of custody forms for this reason shall retain them until the case to which the particular filter pertains is concluded via trial (and any appeal) or executed settlement.

IX. Material In Possession, Custody or Control of Defendants

In the event that a Filter is already in the possession of Defendants, Defense Counsel shall notify the specific Plaintiff's Counsel and Plaintiffs' Liaison Counsel within 14 days of this Order, unless such notification has already occurred prior to entry of this Order. If the Filter is in the possession of the Defendants, Defendants shall produce all photographs, videos or any other documentary or related evidence regarding the Filter, if not already produced, unless subject to being withheld due to privilege, work product doctrine, or other valid objection. Defendants' Counsel shall ship the Filter to the designated storage facility, Steelgate, set forth by this Order.

SO ORDERED.

Date: 5/24/2016



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

AGREED TO BY:

/s/ Ben C. Martin (with consent)

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