

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

IN RE: ETHICON, INC.,  
PELVIC REPAIR SYSTEM  
PRODUCTS LIABILITY LITIGATION

MDL No. 2327

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THIS DOCUMENT RELATES TO ALL CASES

**PRETRIAL ORDER # 45  
(Preservation Order)**

The parties have submitted this agreed preservation order to me and, upon review and consideration thereof, it is **ORDERED** as follows:

**I. GENERAL**

Defendants have informed Plaintiffs and the Court that certain of their affiliated manufacturing facilities are preparing to cease or have ceased operations. The Court is cognizant of Defendants' need to continue its business operations in the regular course and also of Plaintiffs' concerns about preservation of potentially relevant evidence during such business operations. Accordingly, consistent with the goal of "best preserv[ing] relevant matter without imposing undue burdens," Manual for Complex Litigation, Fourth Edition § 11.442, the Court enters the following Order regarding the preservation of potentially relevant documents, data, electronically stored information ("ESI") and tangible things (collectively "Materials") within the possession, custody and/or control of the parties in cases filed in, or consolidated before, this Court.

## **II. SCOPE OF THE ORDER**

The Order addresses the preservation of documents, ESI, data and tangible things as defined herein. The Order does not address, limit or determine the relevancy, discoverability, or admissibility of any Materials regardless of whether such Materials are required to be preserved pursuant to the terms of this Order. The Order also does not address the parties' respective responsibilities for the costs of retrieving or producing Materials that may be subject to discovery. Each party reserves its right to seek reimbursement of the costs associated with preservation of Materials under this Order. Moreover, nothing in the Order limits or specifies the form of production of Materials as provided in the Federal Rules of Civil Procedure or as may be agreed to by the Parties or ordered by the Court. Finally, nothing in this Order is intended to suggest or imply that the Defendants were not previously under preservation obligations as required by applicable law, nor is it intended to act as a waiver for any claim of spoliation and/or other relief in the event materials have been destroyed in violation of applicable law.

## **III. DEFINITIONS**

1. "Defendants" or "Ethicon Defendants" shall mean Defendants Johnson & Johnson, Ethicon, Inc., Ethicon SARL, Ethicon SAS, Ethicon LLC, Johnson and Johnson Medical LTD, and Johnson and Johnson Medical GMBH. After a diligent inquiry, the Ethicon Defendants believe these are the subsidiaries, affiliates or entities that will have possession, custody or control over core items, data or material that may be the subject of this Order. If the parties subsequently determine that other subsidiaries, affiliates or entities should be subject to this Order, the parties shall identify such other subsidiaries, affiliates or entities, and an amended Order shall be requested from the Court.

2. “Relevant Time Frame” means January 1995 to the present.
3. “Computers” refer to microcomputers (also known as personal computers), laptop computers (also known as portable computers or notebook computers), tablet computers, palmtop computers (also known as personal digital assistants or PDAs), mainframe computers (also known as servers) and smartphones.
4. “Backup System(s)” refers to computer systems or devices that periodically store electronic information, including both digital and analog information on disks, tapes or other media to permit recovery of the information in the event of disaster such as equipment failure, or loss of information due to any other reason.
5. “Backup Media” refers to disks, tapes, flash drives (also known as thumb drives), external hard drives, or other media onto which Computers or Backup Systems store such electronic information, including both digital and analog information.
6. “Network Accessible Storage Device(s)” shall mean any hard drive or other data storage device, server or electronic repository mounted or connected through a network directly, or indirectly via an internet, LAN or intranet, whether wired or wireless, such that it is accessible to multiple users and shall include any peer-to-peer networks.
7. “Preservation” and “Preserve” shall be interpreted to accomplish the goal of maintaining the integrity of potentially relevant Documents, ESI and Tangible Things and shall include taking reasonable steps to prevent the partial or full destruction, alteration, shredding or deletion of such materials relevant to plaintiffs’ claims. Provided that reasonable steps have otherwise been taken to preserve potentially relevant Documents, ESI and Tangible Things related to Plaintiffs’ claims, Defendants may continue the practice of rewriting and/or reusing backup tapes and media.

8. “Document, Data and ESI” shall have the meaning set forth in Fed. R. Civ. P. 34(a)(1)(A): “[A]ny designated documents or electronically stored information – including writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations – stored in any medium from which information can be obtained either directly or, if necessary, after translation [of data] by the responding party into a reasonably usable form”. Any medium shall include, but not be limited to, Computers, Backup Systems, Backup Media, and Network Accessible Storage Devices.

9. “Tangible Things” shall mean:

- i. Exemplars of Pelvic Mesh Products, as defined below;
- ii. All equipment used to test or manufacture, Pelvic Mesh Products located in the Ethicon Defendants’ facilities. After a diligent investigation, the Ethicon Defendants believe the following facilities likely contain such equipment: Neuchatel, Switzerland, Norderstedt, Germany, Cornelia, Georgia, San Angelo, Texas and San Lorenzo and Guaynabo, Puerto Rico.

10. “Pelvic Mesh”, or “Pelvic Mesh Products” shall include products produced under the trade names Prolene mesh, Prolene Soft (PS), Prolift, Prolift +M, Proxima, NEO, TVT, TVT-AA, TVT-D, TVT Blue System, ProteGen, TVT-Obturator, TVT-Secur, TVT-Exact, TVT-Abbrevio, TVT-Catheter Guide, TVT-Introducer, Gynecare TVT Family of Products, Gynecare TVT Retropubic System Tension-Free Support for Incontinence, Gynecare Family of Products for Pelvic Floor Repair, in the United States, or any other trade name outside the United States. This shall also include any “kits” which contain any of these products, any components of these kits such as cannulas and trocars and any associated labeling and IFUs.

11. “Draft” (and all of its variants) shall mean a document which has not yet been put into final form by its author or creator but has been circulated internally or externally. “Draft” shall not include incremental changes, such as each time the document is saved or auto-saved.

12. “Identical Copy” (and all of its variants) shall mean:

i. A full and complete copy of the original paper Document that does not differ from the original paper Document because of highlights, underlining, marginalia, total pages, attachments, notes, markings or other alterations. Each such differing copy shall itself be considered an original paper Document and not an Identical Copy. For example where there are two documents with identical content but one has highlighting and the other does not, in such a situation, the two documents shall not be considered identical.

ii. An electronic Document that is a copy of the original electronic Document excluding metadata. An Identical Copy shall include matching Documents that contain the same content excluding metadata. For example, an Identical Copy would include copies of the same Document saved on the local hard drives and network shared drives of multiple individuals.

#### **IV. PRESERVATION OBLIGATIONS**

1. Defendants shall take reasonable steps, including the dissemination of Legal Hold Notices to Preserve all Documents, Data, ESI and Tangible Things, all as defined above, reasonably likely to be relevant to Plaintiffs’ claims in this litigation.

2. To the extent practicable, Documents, Data and ESI shall be Preserved in their native format. Given the number of parties and the wide range of approaches used by the parties to manage Documents (including the management of ESI and the systems used for its recovery in the event of a disaster), it is not practical to define a single detailed process that all parties must follow to preserve Documents. Accordingly, subject to the below guidelines, this Order

does not require any of the parties to utilize a particular method for the preservation of ESI or require any of the parties to modify its computer systems or suspend operating protocols of computer systems and applications so long as the party meets its preservation obligations under law as set forth in this Order.

a. Paper Documents

For Documents that exist solely in paper form, the parties must preserve at least one Identical Copy of such Documents in paper form. This Order does not obligate a party to retain paper Documents if a party in the ordinary course of its business practices scans, microfiches or otherwise images hard copies of documents for purposes of records retention.

b. Electronic Mail

For electronic mail Documents, Defendants shall take reasonable steps to Preserve such Documents, including attachments, in their native format (including associated metadata included in Appendix 2 to PTO # 13) as used in the ordinary course of business, including, by way of example, Preserving .pst files.

c. Other Electronic Documents on Computer Systems Saved on Network Accessible Storage Devices, Local Hard Drives, External Drives or Media

For Documents maintained in electronic form on Network Accessible Storage Devices and not covered above, Defendants shall take reasonable steps to Preserve at least one copy of all such Documents including the metadata included in Appendix 2 to PTO # 13 that is contained within a file when the file is Preserved. For electronic Documents saved to a local hard drive, or to external drives or other media such as CDs or DVDs and thumb drives, Defendants shall take reasonable steps to Preserve such Documents.

d. Equipment

Defendants' obligation to preserve equipment as set forth in Section III.9.ii. shall terminate after six months from the date of entry of this Order. If counsel for Plaintiffs desire to inspect such equipment, they shall arrange with counsel for Defendants to do so within this time period. After the expiration of six months following the entry of this Order, Defendants shall no longer be required to preserve the equipment.

3. The preservation obligations of this Order shall continue until final adjudication of this action, including any appeals.

#### **V. DOCUMENTS, DATA, ESI AND TANGIBLE THINGS NOT REQUIRED TO BE PRESERVED**

The Defendants have no obligation to Preserve the following:

1. "System" data created by the normal operation of computer systems, such as metadata and temporary system files and data fragments contained in slack space or unused portions of a hard drive that could only be read using forensic recovery tools.

2. Identical Copies.

#### **VI. PERMISSIBLE MODIFICATIONS AND ALTERATIONS OF DOCUMENTS**

Defendants shall not be in violation of the Order if they take any of the following actions in the ordinary course of business:

1. Routine maintenance and operation of a party's computer systems so long as the conduct does not result in the destruction or alteration of a Document, ESI or Data required to be Preserved in this Order.

2. Upgrading, loading, reprogramming, customizing or migrating Data, even if such actions modify or alter the way that Data is maintained, stored or viewed, provided that the Data itself is not altered.

3. Material editing, modifying or taking down web pages, internet, extranet or intranet sites, as long as reasonable steps are taken to maintain each page or site prior to its modification.

## **VII. IMPLEMENTATION AND MODIFICATION OF ORDER**

1. The Parties must communicate the existence and substance of this Order to (i) those individuals, entities or employees responsible for carrying out the party's obligations set forth herein and (ii) employees and entities whom the party reasonably believes possesses Documents, Data, ESI or Tangible Things required to be Preserved in this Order. In addition, the Ethicon Defendants shall provide this Preservation Order to all manufacturers of Pelvic Mesh Product who have ceased operations or have notified Defendants of an intention to do so and shall notify them that the Ethicon Defendants have been ordered to instruct them to comply with it.

2. If a party has a reasonable belief that a non-party is in possession of unique Documents, Data, ESI or Tangible Things (i.e. not duplicated within the files or other sources of information in the possession of a party) relevant to the litigation and that the non-party is within the control of the party, the party shall investigate and, if the non-party has possession of such unique Documents, Data, ESI or Tangible Things, shall notify the non-party of the duty to Preserve. If Plaintiffs believe or receive information that a third party is in possession of materials that should be the subject of such a notification, they shall immediately advise Defendants in writing of such belief.

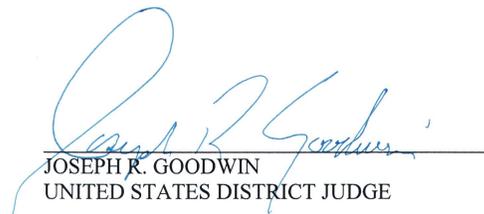
3. The parties are directed to confer to resolve questions as to what Documents, Data, ESI or Tangible Things are to be Preserved under this Order. Counsel for the parties may stipulate and agree in writing that specific items need or need not be Preserved.

4. If the provisions of this Order present particular and/or unique problems for a party, or make it unreasonably burdensome or impossible for a party to comply with, that party and opposing counsel may negotiate and agree to any reasonable exception to or modification of the Order. If such negotiation does not lead to an agreed modification, the party may apply to this Court for an exception to or modification of the Order.

5. If the parties are unable to agree as to what Documents, Data, ESI or Tangible Things: (i) are outside the scope of this Order, (ii) may be destroyed, lost or otherwise altered pursuant to routine policies and programs, or (iii) otherwise need not be Preserved, any party may apply to the Court for clarification or relief from the Order upon reasonable notice.

The court **DIRECTS** the Clerk to file a copy of this order in 2:12-md-2327 and it shall apply to each member 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 2:13-cv-08727. 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.wvsc.uscourts.gov](http://www.wvsc.uscourts.gov).

ENTER: April 25, 2013

  
JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE