

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION**

IN RE: ETHICON PHYSIOMESH FLEXIBLE COMPOSITE HERNIA MESH PRODUCTS LIABILITY LITIGATION	MDL DOCKET NO. 2782 CIVIL ACTION NO. 1:17-md-02782-RWS
THIS DOCUMENT RELATES TO ALL CASES	

CONFIDENTIALITY AND PROTECTIVE ORDER

Before the Court is the parties stipulated confidentiality and protective order (“Protective Order”). After careful consideration, it is hereby ORDERED as follows:

1. Definitions.

“Action” or “Proceeding” means the above-captioned proceeding.

“Competitor” means any manufacturer of, or any entity involved in the sale of hernia mesh or pelvic mesh, and any person who, upon reasonable and good faith inquiry, could be determined to be employed by, to be a consultant doing research for, or otherwise to be retained by any manufacturer of, or any entity involved in the sale of, hernia mesh or pelvic mesh.

“Consultant” means an expert, consultant, or case-specific medical professional whom counsel has retained, or is considering for retention, to assist in preparing for the trial of the Action, whether or not designated as a testifying expert.

“Designating Party” means the Party or non-party that designates Documents, Testimony, or Information as CONFIDENTIAL or HIGHLY CONFIDENTIAL.

“Document” or “Documents” has the meaning set out in Federal Rule of Civil Procedure 34(a) and includes electronically stored information.

“Information” includes the content of Documents or Testimony, as well as any matter derived therefrom or based thereon.

“Party/Parties” means the plaintiffs, defendants, and any other parties to this Action and, as applicable, the parties’ respective corporate parents, subsidiaries, affiliates, successors, attorneys, principals, experts, consultants, representatives, directors, officers, and employees. For purposes of this Protective Order, the terms “Party” and “Parties” shall also include any and all third parties who elect to avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order by signing the Agreement attached hereto as Exhibit A.

“Producing Party” means any Party or non-party who discloses Documents, Testimony, or Information in this Proceeding.

“Qualified Person” means any person or entity authorized to receive or see Confidential or Highly Confidential Material under the terms of this Order, as described in Paragraph 3 below.

“Receiving Party” means any Party to whom Documents, Testimony, or Information are disclosed in this Proceeding.

“Testimony” means all depositions, declarations or affidavits, or other pre-trial statements such as interrogatory answers and responses to requests for admission, whether or not given under oath, used in this Proceeding.

2. Introduction, Scope, and Applicability.

This Protective Order shall govern all hard copy and electronic Documents and Information disclosed in this proceeding that are identified by the Designating Party as CONFIDENTIAL or HIGHLY CONFIDENTIAL under this Order. This

Protective Order is applicable to all Parties (as defined in Paragraph 1), and all other signatories to the Agreement attached hereto as Exhibit A, the terms of which are deemed to be incorporated into this Order. It is expressly ordered that this Protective Order will not be used, in any manner or form, direct or indirect, as evidence in any trial or any hearing, or referred to in any trial or any hearing on the merits of this case, save and except a hearing which involves issues related to the enforcement of any provision of this Protective Order. This provision is an essential part of this Protective Order and is not severable from any remaining paragraph or provision thereof. Nothing herein shall be construed as an admission or concession by a Designating Party that any designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Information constitutes material, relevant, or admissible evidence in this proceeding.

3. Confidential Information.

Any Party may designate as CONFIDENTIAL any Documents or Information the Designating Party believes in good faith constitutes or discloses Information that qualifies for protection under Federal Rules of Civil Procedure 26(c)(1)(G) or other applicable laws or regulations. CONFIDENTIAL Documents or Information include Documents or Information that contain trade secret information as defined by Section 1(4) of the Uniform Trade Secrets Act, or other confidential research, development, proprietary or commercial information, and

materials that are deemed confidential under Federal Drug Administration (“FDA”) regulations and Health Insurance Portability and Accountability Act (“HIPAA”) statutes and/or other similar state or local laws or regulations. Nonetheless, the Parties acknowledge that this Order does not confer blanket protections on all disclosures or responses to discovery and that the protection it affords from public disclosure and use extends only to the information or items that are entitled to confidential treatment under the applicable legal principles. *See Court’s Standing Order Regarding Civil Litigation, Section II.c.*

CONFIDENTIAL Documents or Information may be further designated as HIGHLY CONFIDENTIAL if the Designating Party believes in good faith that, if disclosed, the Documents or Information would cause substantial economic harm to the competitive position of the Designating Party or Producing Party because it is HIGHLY CONFIDENTIAL research and development material on a new product that has not been approved or cleared by the FDA or similar regulatory body or reflects a Party’s price competitiveness in the market or marketing business strategies of a Party concerning a current or new product. The plaintiff(s) will inform the Producing Party and Designating Party of its intent to disclose HIGHLY CONFIDENTIAL information to any individual who is currently, or who at any time during the pendency of this Proceeding becomes, a consultant to a competitor of the Producing Party or Designating Party in the pelvic organ mesh or

hernia mesh business, or is a consultant to any entity actively investigating entering such businesses, and plaintiff(s) will follow the procedures for disclosure of such materials in accordance with the terms set forth in this Protective Order.

“Qualified Persons” means:

- a. For HIGHLY CONFIDENTIAL Documents or Information:
 - i. retained counsel for the Parties in this litigation and their respective staff;
 - ii. actual or potential independent experts or consultants (and their administrative or clerical staff) engaged in connection with this litigation (which shall not include the current employees, officers, members, or agents of parties or affiliates of parties);
 - iii. litigation vendors, court reporters, and other litigation support personnel;
 - iv. this Court and its staff and any other tribunal or dispute resolution officer duly appointed or assigned in connection with this litigation.
- b. For CONFIDENTIAL Documents or Information:
 - i. all the persons identified in subparagraph 3(a);
 - ii. the Party, if a natural person;
 - iii. if the Party is an entity, such officers or employees of the Party who are actively involved in the prosecution or defense of this Action;
 - iv. witnesses, prospective witnesses in this action, or deponents;

- v. any person who was an author, addressee, or intended or authorized recipient of the CONFIDENTIAL information and who agrees to keep the information confidential, provided that such persons may see and use the CONFIDENTIAL information but not retain a copy.
- c. Such other person as this Court may designate after notice and an opportunity to be heard.

Any Party designating any person as a Qualified Person shall have the duty to reasonably ensure that such person observes the terms of this Protective Order and complies with the requirements of Section 16 below with respect to signing the Agreement in Exhibit A. To the extent that this Court permits disclosure of the Producing Party's documents to treating physicians, nothing herein shall be construed to prevent the non-Designating Party from discussing the contents of documents designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL with a treating physician who does not execute Exhibit A to the Protective Order, provided that (i) the non-Designating Party first advises the treating physician that the documents are designated CONFIDENTIAL or HIGHLY CONFIDENTIAL under the Protective Order and therefore not in the public domain; and (ii) the treating physician orally agrees not to disclose the contents of such documents to individuals who are not Qualified Persons.

4. Use of CONFIDENTIAL or HIGHLY CONFIDENTIAL Documents or Information.

All CONFIDENTIAL or HIGHLY CONFIDENTIAL Documents or Information provided by any Party in the course of this litigation shall be used solely for the purpose of litigation preparation, trial(s), and appeal(s) of this Proceeding and for no other purpose, and shall not be disclosed except in accordance with the terms hereof. However, this paragraph does not apply to material initially designated as Confidential that has been de-designated, material that has been filed and not sealed, material that has been used in hearings or trial for which Defendants did not object or timely file a motion to seal, or material that is otherwise in the public domain.

5. Marking of Documents.

Documents provided in this litigation may be designated by the Designating Party as CONFIDENTIAL or HIGHLY CONFIDENTIAL by marking each page of the Documents so designated with a stamp indicating that the Document is CONFIDENTIAL, or HIGHLY CONFIDENTIAL.”¹ The marking shall not cover any information or alter the document in any way other than the mark itself. In lieu of marking the original of a Document, if the original is not provided, the

¹ Highly Confidential Documents may be stamped “HIGHLY CONFIDENTIAL *p*”.

Designating Party may mark the copies that are provided. Originals shall be preserved for inspection.

The parties recognize that material previously produced in another litigation, or in a constituent action in this MDL, may be produced in this Proceeding. Any material previously produced and marked CONFIDENTIAL or HIGHLY CONFIDENTIAL in another litigation or in a constituent action in this MDL will be considered to have the same designations (i.e. CONFIDENTIAL or HIGHLY CONFIDENTIAL) and be subject to this Protective Order.

6. Disclosure at Depositions.

To preserve Confidential designations, a party may designate the transcript of any deposition in this action, or any portion thereof, including exhibits thereto, as CONFIDENTIAL OR HIGHLY CONFIDENTIAL by either advising the Court reporter and the Parties in real time during the deposition or by designating the entire transcript confidential at the commencement of the deposition. The use of a HIGHLY CONFIDENTIAL document during the deposition shall not, in and of itself, render the entire transcript HIGHLY CONFIDENTIAL. However, to the extent that a non-Confidential or CONFIDENTIAL transcript includes HIGHLY CONFIDENTIAL exhibits, the Court Reporter shall note on the cover page that the transcript includes exhibits that are CONFIDENTIAL OR HIGHLY CONFIDENTIAL exhibits.

Any Party also may designate information disclosed at a deposition as CONFIDENTIAL or HIGHLY CONFIDENTIAL by notifying all parties to this action in writing no later than thirty (30) days following receipt of the transcript that the transcript should be treated as CONFIDENTIAL or HIGHLY CONFIDENTIAL thereafter. Each Party shall attach a copy of each such written notice to the face of the transcript and each copy thereof in that Party's possession, custody, or control. All deposition transcripts shall be treated as HIGHLY CONFIDENTIAL for a period of thirty (30) days after initial receipt of the transcript.

Upon receipt of the confidential designation, the Court reporter shall indicate on the cover page of the transcript that the transcript is either Confidential or Highly Confidential pursuant to the Protective Order. Nothing herein shall preclude the Non-Designating Party from providing depositions designated CONFIDENTIAL or HIGHLY CONFIDENTIAL to Qualified Persons in accordance with the terms set forth in Paragraph 3.

7. Disclosure to Qualified Persons.

a. *To Whom.* CONFIDENTIAL or HIGHLY CONFIDENTIAL Documents or Information shall not be disclosed or made available by the Receiving Party to persons other than Qualified Persons except as necessary to comply with applicable law or a valid order of a court of competent jurisdiction;

provided, however, that if another court or an administrative agency subpoenas or otherwise orders production of a Document or Information designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL that a person has obtained under the terms of this Order, the person to whom the subpoena or other process is directed shall promptly, and, if possible within five (5) business days of service, notify counsel for the Designating Party and Producing Party in writing via email of all of the following: (i) the Documents or Information designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL that are requested for production in the subpoena; (ii) the date on which compliance with the subpoena is requested; (iii) the location at which compliance with the subpoena is requested; (iv) the identity of the party serving the subpoena; and (v) the case number, jurisdiction and index, docket, complaint, charge, civil action or other identification number, or other designation identifying the litigation, administrative proceeding, or other proceeding in which the subpoena or other process has been issued. In no event shall a designated Document or Information be produced prior to the expiration of fifteen (15) days following transmission of written notice to counsel for the Designating Party and Producing Party unless required to do so by the subpoena.

b. *Retention of Copies During This Litigation.* Outside counsel for the Receiving Party shall take reasonable and appropriate steps to ensure that CONFIDENTIAL and HIGHLY CONFIDENTIAL documents are maintained in a

secure environment and that reasonable and appropriate measures are taken when transmitting such documents to Qualified Persons. In addition, printouts of HIGHLY CONFIDENTIAL Documents and Information shall be maintained only in the offices of outside counsel for the Receiving Party, and to the extent supplied to experts described in subparagraph 3(a)(ii), in the offices of those experts. Copies of Documents and Information and exhibits containing CONFIDENTIAL Documents and Information may be prepared by independent copy services, printers, or illustrators for the purpose of this Action.

8. Disclosure Requirements for HIGHLY CONFIDENTIAL Information to Competitors.

Prior to disclosure, plaintiff(s) or other disclosing party will inform the Designating Party and Producing Party of its intent to disclose HIGHLY CONFIDENTIAL Documents or Information to anyone who is currently, or who at any time during the pendency of this Action becomes, a consultant to a Competitor in the manner set forth below:

a. Give at least ten (10) days' notice in writing to counsel for the Designating Party and Producing Party of the intent to so disclose such Document or Information, although the plaintiff(s) or other disclosing party is not required to identify the intended recipient of such materials.

b. Within ten (10) days thereafter, counsel for the plaintiff(s)/other disclosing party, Producing Party, and Designating Party shall attempt to resolve

any disputes among them regarding the disclosure of the HIGHLY CONFIDENTIAL material to the intended recipient.

c. If counsel are unable to resolve any dispute regarding such disclosure, within an additional seven (7) days, the Designating Party shall file a motion objecting to the proposed disclosure. In making such motion, it shall be the Designating Party's burden to demonstrate good cause for preventing the disclosure.

d. If the Court permits disclosure of the Document or Information designated as HIGHLY CONFIDENTIAL at issue, the Document or Information remains designated as HIGHLY CONFIDENTIAL and the individual(s) receiving such information shall be bound by the requirements of this Protective Order.

9. Inadvertent Failure to Properly Designate Confidential Material.

Inadvertent production of any Document or Information without designation as CONFIDENTIAL or HIGHLY CONFIDENTIAL will not be deemed to waive a Party's claim to its confidential nature or stop said Party from designating said Document or Information as CONFIDENTIAL or HIGHLY CONFIDENTIAL at a later date. Disclosure of said Document or Information by another Party prior to such later designation shall not be deemed a violation of the provisions of this Order.

10. Consent to Disclosure and Use in Examination.

Nothing in this Order shall prevent disclosure beyond the terms of this Order if each Designating Party consents to such disclosure, if the Confidentiality status is terminated for failure to timely file a Motion to Preserve Confidentiality pursuant to the challenge process set forth in Paragraph 11 below, or if the Court, after notice to all affected Parties and nonparties, orders such disclosure.

11. Challenging the Designation.

a. *CONFIDENTIAL or HIGHLY CONFIDENTIAL Documents or Information.* A Party shall not be obligated to challenge the propriety of a designation of CONFIDENTIAL Documents or Information at the time such designation is made, and a failure to do so shall not preclude a subsequent challenge to the designation. In the event that any Party disagrees at any stage of these proceedings with the designation of any Document or Information (including portions of a document) as CONFIDENTIAL or HIGHLY CONFIDENTIAL, the Parties shall first try to resolve the dispute in good faith on an informal basis, such as by production of redacted copies. If the dispute cannot be resolved, the objecting party may invoke this Protective Order by objecting in writing to the Designating Party and Producing Party and identifying by bates range the specific documents for which the objecting party is challenging the designation. The Designating Party and/or Producing Party shall then have fourteen (14) calendar

days to move the Court for an order preserving the designated status of the disputed information (“Motion to Preserve Confidentiality”), unless additional time is agreed to. The Parties acknowledge that the process of challenging confidentiality designations and making Motions to Preserve Confidentiality is a time consuming and costly process for both the Designating and Non-Designating Parties, and they will act in good faith in making such challenges and motions. For example, the Non-Designating Party will challenge only those documents for which there is legitimate need to remove or modify a confidentiality designation and specifically identify the challenged documents by bates range along with an explanation as to the reason(s) for such challenge. Similarly, the Designating Party shall make a good faith review of the challenged documents and make reasonable efforts to limit the documents for which it makes a Motion to Preserve Confidentiality. In addition, a senior lawyer for the Designating Party will review each document that is the subject of a Motion to Preserve Confidentiality prior to the filing of the motion. The disputed information shall remain CONFIDENTIAL or HIGHLY CONFIDENTIAL unless and until the Court orders otherwise. Failure to timely file a Motion to Preserve Confidentiality shall constitute a termination of the status of such item as CONFIDENTIAL or HIGHLY CONFIDENTIAL Document or Information, unless the Parties otherwise agree or extend the time for filing a motion.

b. *Qualified Persons*. In the event that any Party in good faith disagrees with the designation of a person as a Qualified Person or the disclosure of particular CONFIDENTIAL or HIGHLY CONFIDENTIAL Documents or Information to such person, the Parties shall first try to resolve the dispute in good faith on an informal basis. If the dispute cannot be resolved, the objecting party shall move the Court for an order denying the disputed person: (i) status as a Qualified Person; or (ii) access to particular CONFIDENTIAL or HIGHLY CONFIDENTIAL Documents or Information. The objecting person shall have the burden of demonstrating that disclosure to the disputed person would expose the objecting party to the risk of serious harm.

12.Manner of Use in Proceedings.

Any documents (including briefs), tangible things, or information designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL that are submitted to the Court in support of or in opposition to a motion or introduced at a hearing or during trial may retain their protected confidential status only by order of the Court in accordance with the procedures outlined in section II.c. of the Court's Standing Order Regarding Civil Litigation.

The Non-Designating Party may *provisionally* file documents designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL per the directions in the Court's Standing Order Regarding Civil Litigation and Procedures for Electronic Filing

Under Seal in Civil Cases. Within thirty (30) days of the provisional filing (or such additional time as may be agreed upon by the Parties) the Designating Party shall provide to the Non-Designating Party in writing the identification of (a) those documents for which it agrees to withdraw its confidentiality designation, (b) those documents for which it agrees to substitute a redacted copy and withdraw its confidentiality designation regarding the remaining portion of the document (indicating the specific language it proposes to redact), and (c) those documents for which it maintains its confidentiality designation as to the entire document. The parties shall meet and confer to address any documents in categories (b) and (c) to discuss methods to avoid or limit public disclosure of documents for which no agreement can be reached. As to those documents in categories (b) and (c) the Designating Party shall file a Motion for Leave to File Under Seal (indicating in the motion those documents which the Non-Designating Party does not oppose to filing under seal and those documents for which the Designating Party agrees to withdraw its confidentiality designation) within thirty (30) days of the meet and confer. The documents that are the subject of such Motion for Leave to File Under Seal shall remain CONFIDENTIAL or HIGHLY CONFIDENTIAL unless and until the Court orders otherwise. The Designating Party shall be permitted to appeal any order denying any Motion to File Under Seal.

13.Redaction of Confidential Material.

The Parties recognize that the rules of the United States Food & Drug Administration (FDA), and other governmental agencies, and certain federal statutes require redaction of certain information prior to production by the Producing Party and that the Producing Party will comply with those requirements and redact such information as directed.

14.Return of Documents.

Upon written request received from the Producing Party, any CONFIDENTIAL or HIGHLY CONFIDENTIAL Documents and Information, all reproductions of such Documents and Information, and any notes, summaries, or descriptions of such Documents and Information in the possession of any of the Qualified Persons specified in Paragraph 3 (except subparagraph 3(a)(iii)) shall be returned to the Producing Party or destroyed, except as this Court may otherwise order or to the extent such information has been used as evidence at any trial or hearing. Notwithstanding this obligation to return or destroy Documents and Information upon receipt of written request, counsel may retain attorney work product, including document indices, so long as that work product does not duplicate verbatim substantial portions of the text of any CONFIDENTIAL or HIGHLY CONFIDENTIAL information. Counsel may also retain Confidential

Documents as required to comply with any malpractice Errors & Omissions obligations.

15. Ongoing Obligations.

Insofar as the provisions of this Protective Order, or any other protective orders entered in this Action, restrict the communication and use of the Documents and Information protected by it, such provisions shall continue to be binding after the conclusion of this Action, except that: (a) there shall be no restriction on documents that are used as exhibits in open court unless such exhibits were filed under seal or the Designating Party or Producing Party otherwise takes timely steps to maintain the confidentiality of said exhibits; and (b) a Party may seek the written permission of the producing party or order of the Court to modify this, or any other, protective order.

This Protective Order shall remain in full force and effect and each person subject to this Order shall continue to be subject to the jurisdiction of this Court, for the purposes of this Order, in perpetuity, and the Court shall not be divested of jurisdiction of any person or of the subject matter of this Order by the occurrence of conclusion of this case, or by the filing of a notice of appeal, or other pleading which would have the effect of divesting this Court of jurisdiction of this matter generally.

16. Duty to Ensure Compliance.

Any Party designating any person as a Qualified Person shall have the duty to reasonably ensure that such person observes the terms of this Protective Order. Before being given access to any CONFIDENTIAL OR HIGHLY CONFIDENTIAL material each Qualified Person, other than the Court, the employees and staff of the Court, must execute the Exhibit A to this Protective Order and agree to submit to the jurisdiction of this Court.

Each party's counsel shall maintain a list of Qualified Persons who have signed this Protective Order and shall produce that list to producing party upon a motion for good cause shown as ordered by the Court. Notwithstanding the foregoing, nothing in this Paragraph shall be construed to require any party to disclose the identity of any expert or consultant not required to be disclosed under the Federal Rules of Civil Procedure, or to require disclosure prior to the time that such expert and/or consultant is required to be disclosed under the Federal Rules of Civil Procedure.

To the extent that this Court permits disclosure of the Producing Party's documents to treating physicians, nothing herein shall be construed to prevent the non-Designating Party from discussing the contents of documents designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL with a treating physician who does not execute Exhibit A to the Protective Order, provided that (i) the non-

Designating Party first advises the treating physician that the documents are designated CONFIDENTIAL or HIGHLY CONFIDENTIAL under the Protective Order and therefore not in the public domain; and (ii) the treating physician orally agrees not to disclose the contents of such documents to individuals who are not Qualified Persons.

17.Modification and Exceptions.

The Parties may, by stipulation, provide for exceptions to this Order and any party may seek an order of this Court modifying this Protective Order.


So stipulated this 9th day of November, 2017.

/s/ William Gage
Attorney for Defendants Johnson & Johnson and Ethicon, Inc.

/s/ Henry Garrard
Plaintiffs' Co-Lead Counsel

/s/ Donald Migliori
Plaintiffs' Co-Lead Counsel

It is SO ORDERED this 9th day of November, 2017.



Hon. RICHARD W. STORY
UNITED STATES DISTRICT COURT JUDGE

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION**

EXHIBIT A

IN RE: ETHICON PHYSIOMESH FLEXIBLE COMPOSITE HERNIA MESH PRODUCTS LIABILITY LITIGATION	MDL DOCKET NO. 2782 CIVIL ACTION NO. 1:17-md-02782-RWS
THIS DOCUMENT RELATES TO ALL CASES	

AGREEMENT TO BE BOUND BY THE PROTECTIVE ORDER

I have read and understand the Protective Order entered in the above captioned case, and I agree to be bound by its terms. Specifically, and without limitation upon such terms, I agree not to use or disclose any CONFIDENTIAL or HIGHLY CONFIDENTIAL Documents or Information made available to me other than in accordance with this Protective Order.

I further agree and attest to my understanding that my obligation to honor the confidentiality of such CONFIDENTIAL and HIGHLY CONFIDENTIAL Documents and Information will continue even after this Litigation concludes.

I further agree and attest to my understanding that, if I fail to abide by the terms of the Order, I may be subject to sanctions, including contempt of court, for such failure. I hereby agree to submit to the jurisdiction of this court for enforcement of the undertaking I have made herein.

Dated: _____

Signed Name: _____

Printed Name: _____