IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: COLOPLAST CORP. PELVIC SUPPORT SYSTEMS PRODUCTS LIABILITY LITIGATION

MDL No. 2387

THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER # 43 (Stipulated Protective Order Regarding Nonparty Documents)

A. Scope of Order

By Order dated October 11, 2013, the Court ordered the production of certain documents by nonparties MedStar Funding, LC and Daniel J. Christensen (collectively, "MedStar") pursuant to subpoenas issued by defendant American Medical Systems, Inc. ("AMS") in MDL No. 2325. (Dkt. No. 916) The same Order required MedStar and AMS to submit a Stipulated Protective Order ("SPO") to be applicable in connection with productions pursuant to said subpoenas. Thereafter, MedStar agreed to produce similar documents pursuant to a subpoena issued by Defendant Mentor Worldwide LLC. ("Mentor") in MDL No. 2387. Accordingly, Mentor and MedStar hereby stipulate to and petition the court to enter their Stipulated Protective Order ("Protective Order") in this matter. Upon entry of this PTO # 43, the Protective Order will apply to all productions of documents pursuant to said subpoenas.

B. THE ORDER

It is hereby **ORDERED** as follows:

- 1. For purposes of this Order, the term "document" shall have the full meaning ascribed to it by the Federal Rules of Civil Procedure ("Fed. R. Civ. P").
- 2. MedStar may designate as "CONFIDENTIAL" any material it believes in good faith constitutes or discloses information that qualifies for protection pursuant to Fed. R. Civ. P. 26(c), specifically information that is trade secret or other confidential research, development, or commercial information, and materials that are deemed confidential under Health Insurance Portability and Accountability Act ("HIPAA") statutes and/or regulations.
- 3. MedStar may redact or designate as "HIGHLY CONFIDENTIAL" specific pricing information and formulas, if MedStar believes in good faith that such would, if disclosed, cause substantial economic harm to its competitive position.
- 4. Challenges to Designations or Redacted Information: Mentor may at any time challenge the redaction or the designation of information as CONFIDENTIAL or HIGHLY CONFIDENTIAL by providing written notice of its objection to MedStar, or, in the case of a deposition, either on the record at a deposition or in writing later. If, after a meet-and-confer process, Mentor and MedStar cannot reach agreement, either MedStar or Mentor may, on reasonable notice, apply for an appropriate ruling from the Court. The disputed material shall continue to be treated as designated, or redacted, until the Court orders otherwise. In any such application concerning a ruling on confidentiality or redacted information, the entity claiming the designation of confidentiality or redaction has the burden of establishing that such confidential designation or redaction is proper.

- Mentor shall not distribute, transmit, or otherwise divulge any material marked
 CONFIDENTIAL or HIGHLY CONFIDENTIAL, except in accordance with this Order.
- 6. Use of Confidential Material Limited to Mentor Vaginal Mesh Cases: Mentor, its attorneys, expert witnesses, consultants, or other persons to whom disclosure is made may use any document or other material which is marked CONFIDENTIAL or HIGHLY CONFIDENTIAL, or the contents thereof, only for the purposes of the Vaginal Mesh litigation pending in the United States District Court for the Southern District of West Virginia. Nothing contained in this Order shall prevent the use of any document or the contents thereof, at any deposition taken in this action. If Mentor intends to use material that has been marked as HIGHLY CONFIDENTIAL at the deposition of any of its employees or former employees then Mentor shall notify MedStar ten (10) days in advance of the deposition that it intends to use that category of material. If Mentor and MedStar cannot agree on parameters for usage of the material at the deposition, then Mentor and MedStar will seek the direction of the Court as to the utilization of that category of material in the deposition.
- Access to Confidential Material: If Mentor or its attorneys wish to disclose any document or other material which is marked CONFIDENTIAL or HIGHLY CONFIDENTIAL, or the contents thereof, to any person actively, or retained to, work on this action (e.g., expert witness, paralegal, associate, consultant), or to any representative of any other manufacturer of vaginal mesh involved in the Vaginal Mesh litigation pending in the United States District Court for the

Southern District of West Virginia ("other manufacturer"), including but not limited to other manufacturers attending or cross-noticing any deposition involving such documents or other materials, the person making the disclosure shall do the following:

- (a) Provide a copy of this Order to the person to whom disclosure is made;
- (b) Inform the person to whom disclosure is made that she/he is bound by this Order;
- (c) Require the person to whom disclosure is made to sign an acknowledgment and receipt of this Order;
- (d) Instruct the person to whom disclosure is made to return or, in the alternative and with permission of the producing party, at the conclusion of the case to destroy any document or other material which is marked CONFIDENTIAL or HIGHLY CONFIDENTIAL, including notes or memoranda made from CONFIDENTIAL or HIGHLY CONFIDENTIAL material;
- (e) Maintain a list of persons to whom disclosure was made and the CONFIDENTIAL or HIGHLY CONFIDENTIAL materials which were disclosed to that person;
- (f) At the conclusion of this action, gather the **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** materials, copies thereof, and related notes and memoranda, and return them to MedStar or its attorneys or destroy them, providing a certificate of compliance with the terms of this Protective Order; and

- (g) Only "Designated In-House Counsel" of Mentor may have access to information designated as **HIGHLY CONFIDENTIAL** by MedStar. "Designated In-House Counsel" shall mean: (1) an in-house attorney; and (2) one paralegal and/or clerical employee for each such Designated In-House Counsel to provide administrative support. Each Designated In-House counsel shall complete and sign a copy of the Undertaking in Exhibit A, and each such completed, signed form shall be transmitted by e-mail to counsel for MedStar before disclosure of MedStar's **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** information to the Designated In-House Counsel.
- 8. <u>Use of CONFIDENTIAL Material at Depositions</u>: All transcripts and exhibits shall be treated as if designated CONFIDENTIAL for a period of thirty (30) days after the transcript is available from the court reporter. Counsel for MedStar may designate during the deposition or during the thirty day period after the transcript is available from the court reporter any portion of the transcript as CONFIDENTIAL or HIGHLY CONFIDENTIAL by denominating by page and line, and b designating any exhibits, that are to be considered CONFIDENTIAL or HIGHLY CONFIDENTIAL pursuant to the criteria set forth in this Order. Transcript portions and exhibits designated in accordance with this paragraph shall be disclosed only in accordance with this Order. A party may challenge the CONFIDENTIAL or HIGHLY CONFIDENTIAL designation or portions thereof in accordance with the provisions of Paragraph B.4 above.

- 9. Inadvertent Failure to Properly Designate CONFIDENTIAL Material:
 Inadvertent production of any document or information without a designation of
 CONFIDENTIAL or HIGHLY CONFIDENTIAL will not be deemed to waive
 MedStar's claim to its CONFIDENTIAL nature or stop MedStar from
 designating said document or information as CONFIDENTIAL or HIGHLY
 CONFIDENTIAL at a later date. Disclosure of said document or information by
 Mentor prior to such later designation shall not be deemed a violation of the
 provisions of this Order.
- 10. Inadvertent Disclosure of Privileged Documents, "Clawback" Procedure: Inadvertent production of documents or electronically stored information ("ESI") (collectively "Inadvertently Produced Documents") subject to work-product or attorney-client privilege, or other legal privilege protecting information from discovery, shall not constitute a waiver of the privilege, provided that MedStar shall notify Mentor in writing as set forth herein. In the event that MedStar inadvertently produces documents or ESI subject to a claim of privilege, MedStar shall, within ten (10) days of the discovery of the inadvertent disclosure, notify Mentor in writing of the inadvertent disclosure. MedStar may, in the notice, request a "clawback" of the inadvertently disclosed material. Upon receiving such clawback notice, Mentor shall immediately and diligently act to retrieve the Inadvertently Produced Documents, and all copies, including any loaded to databases, and return them to MedStar or destroy them as agreed between Mentor and MedStar. All notes or other work product of Mentor reflecting the contents of such materials shall be destroyed and not used.

If Mentor elects to file a motion as set forth below, Mentor, subject to the requirements below, may retain possession of the Inadvertently Produced Documents as well as any notes or other work product of MedStar reflecting the contents of such materials pending the resolution by the Court of the motion below, but shall segregate and not use them pending resolution of the motion. If Mentor's motion is denied, Mentor shall promptly comply with the immediately preceding provisions of this paragraph. No use shall be made of such Inadvertently Produced Documents during depositions or at trial, nor shall they be disclosed to anyone who was not given access to them prior to the request to return or destroy them unless otherwise ordered by the Court.

If Mentor receives such Inadvertently Produced Documents, it may, after receipt of MedStar's notice of inadvertent production, move the Court to dispute the claim of privilege.

11. Pursuant to Federal Rule of Evidence ("Fed. R. Evid.") 502, there is no waiver of privilege or work product protection in this matter or any other matter in any other jurisdiction for any document clawed-back under this clause, or for the subject matter of any such document, whether the privileged document was inadvertently provided following review or as part of a "Quick Peek" production. In the event Mentor receives information produced in discovery from MedStar that reasonably appears to be Inadvertently Produced Documents, Mentor shall promptly notify MedStar in writing of the apparent inadvertent production.

C. POST DISCOVERY PHASE

- 1. If Mentor wishes to file, or use as an exhibit or as testimonial evidence at a hearing or trial, any CONFIDENTIAL or HIGHLY CONFIDENTIAL material, Mentor must provide reasonable notice to MedStar of the intended use of such information. Mentor and MedStar shall then attempt to resolve the matter of continued confidentiality by either (a) removing the CONFIDENTIAL or HIGHLY CONFIDENTIAL marking, (b) creating a mutually acceptable redacted version that suffices for purposes of the case, or (c) conferring about methods to avoid or limit public disclosure of such information during testimony. If an amicable resolution proves unsuccessful, Mentor and MedStar may present the issue to the Court for resolution. MedStar will have the burden of persuasion that the document or material should be withheld from the public record in accordance with (a) Local Rule of Civil Procedure 26.4, (b) the Administrative Procedures for Electronic Filing in the Southern District of West Virginia § 12, and (c) controlling precedent. See, e.g., Press-Enterprise Co. v. Superior Court, 478 U.S. 1, 8-9 (1986); Virginia Dept. of State Police v. Washington Post, 386 F.3d 567, 575 (4th Cir. 2004).
- 2. Survival of Protective Order: Throughout and after the conclusion of this litigation, including any appeals, the restrictions on communication and disclosure provided for herein shall continue to be binding upon Mentor and all other persons to whom CONFIDENTIAL or HIGHLY CONFIDENTIAL material has been communicated or disclosed pursuant to the provisions of this Order or any other order of the Court.

- 3. Return or Destruction of CONFIDENTIAL Material Upon Termination of
 Litigation: Within sixty (60) days after the final termination of this action,
 Mentor, upon request of MedStar, shall either return to the MedStar, or destroy,
 all CONFIDENTIAL or HIGHLY CONFIDENTIAL material designated by
 MedStar (including any such material disclosed to third persons), except for any
 attorneys' work-product for Mentor, and shall provide confirmation in writing to
 MedStar's counsel if such materials are destroyed.
- 4. <u>Modification of this Order</u>: Nothing in this Order shall prevent Mentor from seeking amendments broadening or restricting the rights of access to or the use of **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** material or otherwise modifying this Order; and this Order may be amended without leave of the Court by the agreement of the undersigned attorneys for Mentor and MedStar in the form of a Stipulation that shall be filed in this case.

The court **DIRECTS** the Clerk to file a copy of this order in 2:12-md-2387 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-34026. 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.wvsd.uscourts.gov.

ENTER: January 6, 2014

JOSEPH R. GOODWIN UNITED STATES DISTRICT JUDGE

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: COLOPLAST CORP. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION
MDL No. 2387
THIS DOCUMENT RELATES TO ALL CASES
AGREEMENT TO BE BOUND BY PROTECTIVE ORDER
I have read and understand the Protective Order entered in In Re Coloplast Corp. Pelvio
Support Systems Products Liability Litigation, MDL No. 2387 (S.D. W. Va.), 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 Information made available to me other than in accordance with this
Protective Order.
I hereby agree to submit to the jurisdiction of the United States District Court for the
Southern District of West Virginia for enforcement of the undertaking I have made herein.
Dated: Signed name

Printed name _____