

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

CHARLESTON DIVISION

IN RE: AMERICAN MEDICAL SYSTEMS, INC.
PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY
LITIGATION

MDL No. 2325

THIS DOCUMENT RELATES TO ALL CASES

**PRETRIAL ORDER # 169
(Order Amending Stipulated Protective Order (PTO # 13))**

I. Scope of Order

Disclosure and discovery in this proceeding may involve production of confidential, proprietary, and private information for which special protection from public disclosure and from any purpose other than prosecuting this litigation would be warranted. Accordingly, the parties hereby stipulate to and petition the court to enter their Stipulated Protective Order (“Protective Order”) in this matter. Upon entry of this PTO # 13, the Protective Order will apply to all actions that are or become a part of MDL 2325.

II. The Order

A. By stipulating to this Protective Order (the “Order”), the parties have agreed to be bound by its terms and to request its entry by the presiding district or magistrate judge. This Order shall govern all cases directly filed in this district that are included in MDL 2325, as well as all cases transferred to this Court by the Judicial Panel on Multidistrict Litigation (“JPML”) and any tag-along cases transferred to this Court by the JPML. It is hereby **ORDERED** as follows:

B. DISCOVERY PHASE

1. For purposes of this Order, the following definitions shall apply: (a) the term “document” shall have the full meaning ascribed to it by the Federal Rules of Civil Procedure (“Fed. R. Civ. P.”); and (b) the term “producing party” shall be defined as any party or non-party who is required to produce or provide materials or testimony containing confidential information.
2. A producing party may designate as “**CONFIDENTIAL**” any material the producing party 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 Federal Drug Administration (“FDA”) regulations and Health Insurance Portability and Accountability Act (“HIPAA”) statutes and/or regulations.
3. Confidential information may be further designated as “**HIGHLY CONFIDENTIAL**” if a Defendant produces materials that it believes in good faith would, if disclosed, cause substantial economic harm to the competitive position of the entity from which the information was obtained because it is **HIGHLY CONFIDENTIAL** research and development material on a new product that has not been approved or cleared by the FDA or a 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 of its intent to disclose such information to any individual who is currently, or who at any time during the pendency of this litigation becomes, a consultant to a competitor of the producing

party in the pelvic organ mesh business, or is a consultant to an entity actively investigating entering such business, and plaintiff(s) will follow the procedures for disclosure of such materials to such individual as provided in Paragraph II.B.8. of this Protective Order.

4. Challenges to Designations or Redacted Information: Any party 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 the designating party, 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, the parties cannot reach agreement, either the designating party or challenging party 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 party claiming the designation of confidentiality or redaction has the burden of establishing that such confidential designation or redaction is proper.
5. No person or party subject to this Order shall 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 this Action: Except as set forth in II.B.14, below, any document or other material which is marked **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL**, or the contents thereof, may be used by a party, or a party's attorney, expert witness, consultant, or other person to whom disclosure

is made, only for the purpose of this action. Nothing contained in this Order shall prevent the use of any document or the contents thereof, at any deposition taken in this action. If a party intends to use material that has been marked as **HIGHLY CONFIDENTIAL** at the deposition of an employee or former employee of a non-producing party in this litigation, then the party shall notify the producing party ten (10) days in advance of the deposition that it intends to use that category of material. If the parties cannot agree on parameters for usage of the material at the deposition, then the parties will seek the direction of the Court as to the utilization of that category of material in the deposition.

7. Access to Confidential Material: If a party or attorney wishes 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), 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 s/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 the party or attorney who originally disclosed them, or destroy them, providing a certificate of compliance with the terms of this Protective Order; and
- (g) Only “Designated In-House Counsel” of Defendants may have access to information designated as **HIGHLY CONFIDENTIAL** by another producing party. “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 the other parties before disclosure of any such other party’s **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** information to the Designated In-House Counsel.

8. Disclosure Requirements for **HIGHLY CONFIDENTIAL** information to Competitor Related Consultants: Prior to disclosure, plaintiff(s) will inform the producing party of its intent to disclose **HIGHLY CONFIDENTIAL** material to

anyone who is currently, or who at any time during the pendency of this litigation becomes, a consultant to a competitor (as such individuals are defined in Paragraph II.B.3 above) in the manner set forth below:

- (a) Give at least ten (10) days notice in writing to counsel for the party who designated such information as **HIGHLY CONFIDENTIAL** of the intent to so disclose that information, although the disclosing party is not required to identify the intended recipient of such materials.
- (b) Within ten (10) days thereafter, counsel for the parties shall attempt to resolve any disputes between them regarding the production of the **HIGHLY CONFIDENTIAL** material to the intended individuals.
- (c) If the parties are unable to resolve any dispute regarding such production, within an additional seven (7) days, the party who designated the information in question as **HIGHLY CONFIDENTIAL** shall file a motion objecting to the proposed disclosure. In making such motion, it shall be the producing party's burden to demonstrate good cause for preventing the disclosure.
- (d) If the Court permits disclosure of the material designated as **HIGHLY CONFIDENTIAL** at issue, the information remains designated as **HIGHLY CONFIDENTIAL** and the individual receiving such information shall be bound by the requirements of Paragraph II.B.7.

9. Redaction of **CONFIDENTIAL** Material: The parties recognize that certain FDA, other governmental agencies, and certain federal statutes require redaction of certain information prior to production of certain information by Defendants

and that Defendants will comply with those requirements and redact such information as directed. Any party challenging information that has been redacted may do so in accordance with Paragraph II.B.4 of this Protective Order, or otherwise in accordance with the Federal Rules of Civil Procedure.

10. Use of **CONFIDENTIAL** Material at Depositions: 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 any party 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 by designating any exhibits, that are to be considered **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** pursuant to the criteria set forth in this Order. Such designation shall be communicated to all parties. 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 II.B.4 above.
11. 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 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.

12. 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 the producing party shall notify the receiving party in writing as set forth herein. In the event that a party inadvertently produces documents or ESI subject to a claim of privilege, the producing party shall, within ten (10) days of the discovery of the inadvertent disclosure, notify the other party in writing of the inadvertent disclosure. The producing party may, in the notice, request a “clawback” of the inadvertently disclosed material. The party receiving such clawback notice shall immediately and diligently act to retrieve the Inadvertently Produced Documents, and all copies, including any loaded to databases, and return them to the producing party or destroy them as agreed between the parties. All notes or other work product of the receiving party reflecting the contents of such materials shall be destroyed and not used.

If the receiving party elects to file a motion as set forth below, the receiving party, subject to the requirements below, may retain possession of the Inadvertently Produced Documents as well as any notes or other work product of the receiving party 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 the receiving party's motion is denied, the receiving party 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.

The party receiving such Inadvertently Produced Documents may, after receipt of the producing party's notice of inadvertent production, move the Court to dispute the claim of privilege.

13. 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 that any party receives information produced in discovery from any other party that reasonably appears to be Inadvertently Produced Documents, the receiving party shall promptly notify the producing party in writing of the apparent inadvertent production.
14. If AMS is required to produce materials in response to any Civil Investigative Demand, subpoena, or other official process served by any State's Attorney General or other governmental official or entity, such production shall not be deemed: 1) to violate any provision of this Order; 2) to affect the confidentiality of any document designated "Confidential" or "Highly Confidential" in this

MDL; or 3) to effect any waiver, including but not limited to subject matter waiver, of any privilege or protection to which materials produced in this MDL would have been entitled should such production not have occurred.

C. **POST DISCOVERY PHASE**

1. If any party or attorney wishes to file, or use as an exhibit or as testimonial evidence at a hearing or trial, any **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** material, such party must provide reasonable notice to the producing party of the intended use of such information. The parties 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, the parties may present the issue to the Court for resolution. The proponent of continued confidentiality 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 the parties and all other

persons to whom **CONFIDENTIAL** and **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, each party, upon request of the other party, shall either return to the producing party, or destroy, all **CONFIDENTIAL** and **HIGHLY CONFIDENTIAL** material designated by any other party (including any such material disclosed to third persons), except for any attorneys' work-product for the party returning the material, and shall provide confirmation in writing to opposing counsel if such materials are destroyed.
4. Modification of this Order: Nothing in this Order shall prevent any other party from seeking amendments broadening or restricting the rights of access to or the use of **CONFIDENTIAL** and/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 the parties 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-2325, 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 2:14-cv-15046. 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: April 21, 2014



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT
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CHARLESTON DIVISION

IN RE: AMERICAN MEDICAL SYSTEMS, INC.
PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY
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MDL No. 2325

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AGREEMENT TO BE BOUND BY PROTECTIVE ORDER

I have read and understand the Protective Order entered in In Re American Medical Systems, Inc. Pelvic Repair Systems Products Liability Litigation, MDL No. 2325 (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 _____