

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

**CHARLESTON DIVISION**

**IN RE: AVAULTA PELVIC SUPPORT SYSTEMS  
PRODUCTS LIABILITY LITIGATION**

**MDL No. 2187**

**THIS DOCUMENT RELATES TO ALL CASES**

**PRETRIAL ORDER #13**

(Re Stipulated Order Concerning Redaction of Material from Adverse Event Reports,  
Complaints, and Other Documents)

The parties submitted to the court a proposed Stipulated Order concerning the redaction of material from adverse event reports, complaints and other documents. By signing the proposed Stipulated Order, the parties have agreed to be bound by its terms. The Court approves and adopts the terms of the Stipulated Order and the same shall govern all actions that are or become a part of MDL 2187.

It is hereby **ORDERED** as follows:

The parties anticipate producing adverse event reports and complaint files maintained pursuant to 21 U.S.C. § 360i, 21 C.F.R. § 803.18, and 21 C.F.R. § 820.1 - .250 as well as documents relating to those adverse events and complaints files. To the extent that Defendants are able to identify whether these reports and complaint files relate to a particular named Plaintiff at the time they are produced in this litigation, the parties and their attorneys have consented to and agreed that the Defendants shall refrain from redacting the following identifiable information, as defined in 21 C.F.R. § 20.63(f), in the below three circumstances:

- (1) Identifiable information of a Plaintiff in this litigation shall not be redacted, pursuant to 21 C.F.R. § 20.63(f)(1)(iii);

(2) Identifiable information of a Plaintiff in litigation pending in other state or federal courts shall not be redacted, pursuant to 21 C.F.R. § 20.63(f)(1)(iii), if the attorney or law firm representing that Plaintiff is of record in this multi-district proceeding and the other litigation involves a personal injury claim regarding alleged defects with any of the following products or product lines:

- Align®
- Avaulta®
- Avaulta Plus®
- Avaulta Solo®
- Pelvicol®
- Pelvilace®
- PelviSoft®
- Pelvitex®
- Uretex®; and/or
- Ugytex®

(3) Identifiable information of a voluntary reporter shall not be redacted, pursuant to 21 C.F.R. § 20.63(f)(1)(i), where the reporter is an attorney from any of the law firms of record in this multi-district litigation proceeding.

Otherwise, the Defendants shall only redact such information as required to be redacted by 21 C.F.R. § 20.63(f) and other applicable laws, statutes, and regulations, and Plaintiffs shall have the right to object to any redactions made.

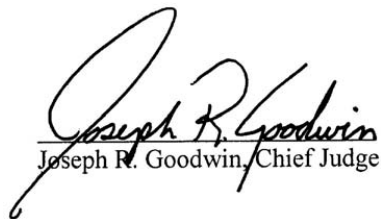
The parties acknowledge that this Stipulated Order is intended to and does satisfy the written consent requirement of the regulations.

Any documents containing any reporter or personal identifying information shall be designated and branded as confidential in accordance with the protective order entered in this case.

**IT IS SO ORDERED.**

The court **DIRECTS** the clerk to file a copy of this order in 2-10-md-2187 and it shall apply to each member Avaulta-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 2-11-cv-00440. 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: July 20, 2011

  
Joseph R. Goodwin, Chief Judge