**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

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THIS DOCUMENT RELATES TO ALL CASES

**PRETRIAL ORDER # 9**

(Plaintiffs' Fact Sheets and Defendants' Fact Sheets)

1. Plaintiffs' Fact Sheets.

a. The parties have agreed upon the use of a form Plaintiff's Fact Sheet ("PFS"), attached to this Order as Exhibit A. The PFS shall apply to each case within MDL 2187, and in all other cases that become part of this MDL by virtue of being filed in, removed to, or transferred to this Court.

b. Each Plaintiff in currently filed cases that were a part of MDL 2187 as of the date of the entry of Pretrial Order #6 (April 25, 2011) shall submit a completed PFS within seventy-five (75) days of the date of this Order. In cases filed and made a part of MDL 2187 after the entry of Pretrial Order #6 (April 25, 2011) but prior to the entry of this Order, each plaintiff shall submit a completed PFS within 135 days of the date of this Order. In cases filed after the date of this Order, each Plaintiff shall submit a completed PFS within sixty (60) days of filing suit.[1]

[1] If a Plaintiff is suing in a representative or derivative capacity, the PFS shall be completed by the person with the legal authority to represent the estate or person under legal disability. Plaintiff spouses with loss of consortium claims shall also sign the PFS, attesting that the

c. A completed PFS shall be considered interrogatory answers under Fed. R. Civ. P. 33, responses to requests for production under Fed. R. Civ. P. 34, and will be governed by the standards applicable to written discovery under Federal Rules 26 through 37. The interrogatories and requests for production in the PFS shall be answered without objection as to the question as posed in the agreed upon PFS, however Plaintiff may assert objections for that individual plaintiff to specific questions where appropriate, and Defendants reserve all rights to challenge such objections. This section does not prohibit a Plaintiff from withholding or redacting information based upon a recognized privilege. If information is withheld or redacted on the basis of privilege, Plaintiff shall provide Defendants with a privilege log simultaneously with submission of the PFS. If a dispute arises concerning the completeness or adequacy of a Plaintiff's response to any request contained in the PFS, this Section shall not prohibit the Plaintiff from asserting that his or her response is adequate, and Defendants reserve all rights and objections.

d. Every Plaintiff is required to provide Defendants with a PFS that is substantially complete in all respects, answering every question in the PFS even if a Plaintiff can only answer the question in good faith by indicating "not applicable" or "I don't know."

e. Authorizations for the release of records. Plaintiffs shall provide agreed upon authorizations for the release of medical, insurance, employment, Medicare/ Medicaid, Social Security. In the event that an institution, agency, or medical provider to whom any authorization is presented refuses to provide records in response to the authorizations Plaintiff provides, the parties' vendor will notify the parties (according to its contract with the parties) and

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responses made to the loss of consortium claim questions in the PFS are true and correct to the best of his knowledge, information and belief, formed after due diligence and reasonable inquiry.

the individual Plaintiff's attorney shall attempt to resolve the issue with the provider, such that the necessary records are promptly provided. The parties' vendor will obtain records and post them to a secure database, accessible to the appropriate individuals for all parties, according to the parties' contract with the vendor and the parties' agreement for a 10 day grace period for Plaintiffs to review documents in advance of such posting.

f. Plaintiffs shall provide dated authorizations, applicable for one year from the date of execution by Plaintiff. Plaintiffs shall have the responsibility of obtaining new releases from any Plaintiff whose authorizations are more than eleven months old and will have the responsibility to promptly obtain new releases for any Plaintiff for whom a provider objects to the age of the authorization within fifteen (15) days of notice of such objection by a provider. In the event that dated authorizations become an impediment to prompt obtaining of records generally, the parties will meet and confer to discuss the provision and protection of undated authorizations. Signed authorizations constitute permission for the parties' vendor to obtain records from records custodians.

g. Any Plaintiff who fails to comply with the PFS obligations under this Order may, for good cause shown, be subject to sanctions, to be determined by the Court, upon motion of the Defendants.

h. If a Plaintiff fails to timely submit a PFS, or if Defendants receive a PFS in the allotted time but the PFS is not substantially complete, Defendants' Lead Counsel shall send a deficiency letter by facsimile and U.S. mail to Plaintiffs' Liaison Counsel and Plaintiffs' individual representative counsel, identifying the purported deficiencies. Plaintiff shall have twenty (20) days from receipt of that letter to serve a PFS that is substantially complete in all respects. This letter shall include sufficient detail for the parties to meet and confer regarding the

alleged deficiencies. Should a Plaintiff fail to cure the deficiencies identified and fail to provide responses that are substantially complete in all respects, Defendant may move under Federal Rule of Civil Procedure 37 for appropriate relief. Any such filing shall be served on Plaintiffs' Liaison Counsel and the Plaintiffs' individual representative counsel, with any response to such filing to be submitted within ten (10) days following the date of service. Any such filing should set forth the efforts the Defendants made to meet and confer regarding the alleged deficiencies in the PFS and failure to cure.

2. Defendant's Fact Sheet.

a. The parties have agreed upon the use of a form Defendant Fact Sheet ("DFS"), attached to this Order as Exhibit B. The DFS shall apply to every case within MDL 2187, and in all other cases that become part of this MDL by virtue of being filed in, removed to, or transferred to this Court.

b. In accordance with the timeframe for service of PFS, Defendants shall submit a substantially completed Defense Fact Sheet specific to each individual Plaintiff within forty five (45) days after service by Plaintiff of each substantially completed Plaintiff Fact Sheet.

c. A completed DFS shall be considered interrogatory answers under Fed. R. Civ. P. 33, responses to requests for production under Fed. R. Civ. P. 34, and will be governed by the standards applicable to written discovery under Federal Rules 26 through 37. The interrogatories and requests for production in the DFS shall be answered without objection as to the question as posed in the agreed upon DFS, however Defendants may assert objections relevant to information specific to an individual plaintiff, where appropriate in that case.

d. A Defendant who fails to comply with the DFS obligations under this Order may be subject, for good cause shown, to sanctions, to be determined by the Court, including those sanctions set forth in Federal Rule of Civil Procedure 37.

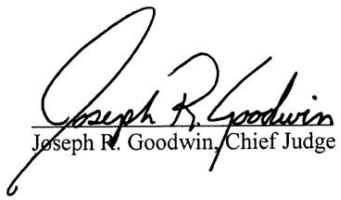
e. If a Defendant fails to timely submit a DFS, or submits within the allotted time a DFS that is not substantially complete, Plaintiffs' Lead Counsel shall send a deficiency letter by facsimile and U.S. mail to Defendants' Liaison Counsel and to Lead Counsel for that Defendant, identifying the purported deficiencies. This letter shall include sufficient detail for the parties to meet and confer regarding the alleged deficiencies. Defendant shall have twenty (20) days from receipt of that letter to serve a DFS that is substantially complete in all respects. Should a Defendant fail to cure the deficiencies identified and fail to provide responses that are substantially complete in all respects within twenty (20) days of service of the deficiency letter, Plaintiff may move for appropriate relief under Federal Rule of Civil Procedure 37. Any such filing shall be served on Defendants' Liaison Counsel and the Lead Counsel for that Defendant, with any response to such filing to be submitted within ten (10) days following the date of service. Any such filing should include the efforts the Plaintiffs made to meet and confer regarding the alleged deficiencies in the DFS and failure to cure.

**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-00383. 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: June 7, 2011



# EXHIBIT “A”

**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**

**Plaintiff: _____**
**Name of Plaintiff**

# PLAINTIFF FACT SHEET

Each plaintiff who allegedly suffered injury as a result of an Avaulta® product must complete this Plaintiff Fact Sheet. In completing this Fact Sheet, you are under oath and must answer every question and provide information that is true and correct to the best of your knowledge. If you cannot recall all of the details requested, please provide as much information as you can and then state that your answer is incomplete and explain why as appropriate. If you select an "I Don't Know" answer, please state all that you do know about that subject. If any information you need to complete any part of the Fact Sheet is in the possession of your attorney, please consult with your attorney so that you can fully and accurately respond to the questions set out below. If you are completing the Fact Sheet for someone who cannot complete the Fact Sheet herself, please answer as completely as you can.

The Fact Sheet shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order. A completed Fact Sheet shall be considered interrogatory answers pursuant to Fed. R. Civ. P. 33 and 34 and will be governed by the standards applicable to written discovery under Fed. R. Civ. P. 26 through 37. You must supplement your responses if you learn that they are incomplete or incorrect in any material respect. The questions and requests for production contained in the Fact Sheet are non-objectionable and shall be answered without objection. This Fact Sheet shall not preclude Defendants from seeking additional documents and information on a reasonable, case-by-case basis pursuant to the Federal Rules of Civil Procedure and as permitted by the applicable Case Management Order.

In filling out this form, please use the following definition: “healthcare provider” means any doctor, physician, surgeon, pharmacist, hospital, clinic, center, physician’s office, infirmary, medical or diagnostic laboratory, or other facility that provides medical care or advice, and any pharmacy, x-ray department, radiology department, laboratory, physical therapist or physical therapy department, rehabilitation specialist, chiropractor, or other persons or entities involved in the diagnosis, care and/or treatment of you.

In filling out this form, the terms "You" or "Your" refer to the person who received an Avaulta® product manufactured by C. R. Bard or Sofradim and who is identified in Question I. 1 (a) below.

To the extent that the form does not provide enough space to complete your responses or answers, please attach additional sheets as necessary.

## I. BACKGROUND INFORMATION

1. Please state:

   a) Full name of the person who received the Avaulta® product(s), including maiden name:

   _____

   b) Full name of the person completing this form, if different from the person listed in 1 (a) above, and the relationship of the person completing this form to the person listed in 1 (a) above: _____

   c) The name and address of your primary attorney:_____

2. Your Social Security Number: _____

3. Your date of birth: _____

4. Your current residence address:_____

   If you have lived at this address for less than 10 years, provide each of your prior residence addresses from 2000 to the present:

| Prior Address | Dates You Lived At This Address |
|---|---|
| | |
| | |
| | |

5. Have you ever been married? **Yes ___ No ___**

   If yes, provide the names and addresses of each spouse and the inclusive dates of your marriage to each person.

   _____

   _____

   _____

6. Do you have children? **Yes ___ No ___**

**If Yes**, please provide the following information with respect to each child:

| Full Name of Child | Date of Birth | Home Address (if different from yours) | Whether Biological/Adopted |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

7. Identify the name and age of any person who currently resides with you and their relationship to you:

_____
_____
_____

8. Identify all secondary and post-secondary schools you attended, starting with high school and please provide the following information with respect to each:

| Name of School | Address | Dates of Attendance | Degree Awarded | Major or Primary Field |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

9. Please provide the following information for your employment history over the past 10 years up until the present:

| Employer Name | Addresses | Job Title/ Description of Duties | Dates of Employment | Salary/Rate of Pay |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

10. Have you ever served in any branch of the military? **Yes ___ No ___**

**If Yes**, please provide the following information:

a. Branch and dates of service, rank upon discharge and the type of discharge you received: _____

_____

b. Were you discharged from the military at any time for any reason relating to your medical, physical, or psychiatric condition? **Yes ___ No ___**

**If Yes**, state what that condition was: _____

_____

11. Within the last ten years, have you been convicted of, or plead guilty to, a felony and/or crime of fraud or dishonesty? **Yes ___ No ___**

**If Yes**, please set forth where, when and the felony and/or crime:

_____

_____

## II. CLAIM INFORMATION

1) Have you ever received an Avaulta® product? **Yes ___ No ___**

**If Yes**, please check the box for each Avaulta® product you have received:

[ ] Avaulta® Anterior BioSynthetic Support System.

[ ] Avaulta® Posterior BioSynthetic Support System

[ ] Avaulta Plus® Anterior BioSynthetic Support System

[ ] Avaulta Plus® Posterior BioSynthetic Support System

[ ] Avaulta Solo® Anterior Synthetic Support System

[ ] Avaulta Solo® Posterior Synthetic Support System

2) For each Avaulta® product identified above, please provide the following information:

a) The date the Avaulta® product(s) was implanted in you: _____

b) The product code and lot number of each Avaulta® product you received: _____

(NOTE: a label clearly identifying the product code and lot number usually accompanies any Avaulta® product and will be affixed to your surgeon's "Op Report" or surgical notes.)

3) Describe your understanding of the medical condition for which you received the Avaulta® product(s): _____

_____

_____

4) Give the name and address of the doctor who implanted the Avaulta® product(s):

_____

5) Give the name and address of the hospital or other healthcare facility where the Avaulta® product(s) was implanted: _____

6) Prior to implantation, did you receive any written and/or verbal information or instructions regarding the Avaulta® product(s), including any risks or complications that might be associated with the use of the product(s)? **Yes ___ No ___ Don't Know _____**

**If Yes:**

a) Provide the date you received the written and/or verbal information or instructions: _____

_____

b) Identify by name and address the person(s) who provided the information or instructions: _____

_____

c) What information or instructions did you receive? _____

_____

_____

d) If you have copies of the written information or instructions you received, please attach copies to your response.

7) If the Avaulta® product(s) remain implanted in you:

a) Has any doctor recommended removal of the Avaulta® product(s)? **Yes ___ No ___**

**If Yes,** Identify by name and address the doctor who recommended removal and state your understanding of why the doctor recommended removal:

_____

8) Was the Avaulta® product(s) that was implanted in you ever removed, in whole or in part? **Yes ___ No ___ Don't Know _____**

**If Yes:**

a) On what date, where and by whom (doctor) was the Avaulta® product(s), or any portion of it, removed? _____

b) Explain why you consented to have the Avaulta® product(s), or any portion of it, removed? _____

c) Does any medical treater, physician, entity, or anybody else on your behalf have possession of any portion of the Avaulta product® that was previously implanted in you and removed? **Yes ___ No ___ Don't Know _____**

**If Yes,** please state name and address of the person or entity having possession of same. _____

9) Do you claim that you suffered bodily injuries as a result or the implantation of Avaulta® product(s)? **Yes ___ No ___**

**If Yes:**

a) Describe the bodily injuries, including any emotional or psychological injuries, that you claim resulted from the implantation of Avaulta® product(s)?

_____
_____
_____
_____

b) When is the first time you experienced symptoms of any of the bodily injuries you claim in your lawsuit to have resulted from the Avaulta® product(s)?

_____
_____
_____
_____

c) When did you first attribute these bodily injuries to the Avaulta® product(s)?

_____
_____
_____
_____

d) To the best of your knowledge and recollection, please state approximately when you first saw a health care provider for each of those bodily injuries you claim to have experienced relating to the Avaulta® product(s):

_____
_____
_____
_____

e) Are you currently experiencing symptoms related to your claimed bodily injuries? **Yes _____ No _____**

**If Yes**, please describe your current symptoms in detail

_____
_____

f) Are you currently seeing, or have you ever seen a doctor or healthcare provider for each of the bodily injuries or symptoms listed above? **Yes ___ No ___**

**If Yes,** please list all doctors you have seen for treatment of any of the bodily injuries you have listed above.

| Provider Name and Address | Condition Treated | Approximate Dates of Treatment |
|---|---|---|
| | | |
| | | |
| | | |

g) Were you hospitalized at any time for the bodily injuries you listed above?
**Yes ___ No ___**

**If Yes**, please provide the following:

| Hospital Name and Address | Condition Treated | Approximate Dates of Treatment |
|---|---|---|
| | | |
| | | |
| | | |

10) Are you making a claim for lost wages or lost earning capacity?

**Yes ___ No ___**

**If Yes**, state the annual gross income you derived from your employment for each year, beginning five years prior to the implantation of the Avaulta® product(s) until the present:

_____

_____

11) Are you making a claim for lost out-of-pocket expenses?

**Yes ___ No ___**

**If Yes**, please identify and itemize all out-of-pocket expenses you have incurred**:**

_____

_____

12) Has anyone filed a loss of consortium claim in connection with your lawsuit regarding the Avaulta® product(s)?

**Yes ___ No ___**

**If Yes,** identify by name and address the person who filed the loss of consortium claim, state the relationship of that person to you, and state the nature of the claim:

_____

_____

_____

13) Please indicate whether the consortium plaintiff is alleging any of the claimed damages set forth below and itemize the alleged damages/expenses:

| **Claims** | **Yes/ No** | **Itemized Damages/Expenses** |
|---|---|---|
| Loss of services of spouse | | **Not applicable** |
| Impaired sexual relations | | **Not applicable** |
| Lost wages/ lost earning capacity | | |
| Lost out-of-pocket expenses | | |
| Physical injuries | | **Not applicable** |
| Psychological Injuries/ Emotional Injuries | | **Not applicable** |
| Other | | **Not applicable** |

14) Please list the name and address of any healthcare providers the consortium plaintiff has seen for treatment for any physical, emotional, or psychological injuries or symptoms alleged to be related to the loss of consortium claim.

_____

_____

_____

_____

_____

15) Have you or anyone acting on your behalf had any communication, oral or written, with any of the defendants or their representatives?

**Yes ___ No ___ Don't Know _____**

**If Yes**, set forth the date of the communication, the method of communication, the name of the person with whom you communicated, and the substance of the communication between you and any defendants or their representatives:

_____

_____

## III. MEDICAL BACKGROUND

1) Provide your current age: _____ Height _____ Weight _____

2) At the time you received the Avaulta® product(s), please state:
Your age _____ Your approximate weight _____

3) State number of vaginal births you have had? _____

4) State the number of cesarean section births you have had? _____

5) In chronological order, list any and all surgeries, procedures, or hospitalizations you had in the 10 year period **BEFORE** implantation of the Avaulta® product(s); identifying by name and address the doctor(s), hospital(s) or other healthcare provider(s) involved with each surgery or procedure; and providing the approximate date(s) for each:

| Approximate. Date | Description of Surgery' Hospitalization | Doctor or Healthcare Provider Involved (including address) |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

**[Attach additional sheets as necessary to provide the same information for any and all surgeries leading up to implantation of the Avaulta® product(s)]**

6) In chronological order, list any and all surgeries, procedures, or hospitalizations you had **AFTER** the implantation of the Avaulta® product(s); identifying by name and address the doctor(s), hospital(s) or other healthcare provider(s) involved with each surgery or procedure; and provide the approximate date(s) for each:

| Approximate Date | Description of Surgery/ Hospitalization | Doctor or Healthcare Provider Involved (including address) |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

7) To the extent not already provided in the charts above, provide the name, address, and telephone number of every doctor, hospital, or other health care provider from which you have received medical advice and/or treatment for the past **10 years**:

| Name and Specialty | Address | Approximate Dates/Years of Visits |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

| Name and Specialty | Address | Approximate Dates/Years of Visits |
|---|---|---|
| | | |
| | | |

8) Before the implantation of the Avaulta® product(s), did you regularly exercise or participate in activities that required lifting or strenuous physical activity? (Please describe all range of physical activities associated with daily living, physical fitness, household tasks, and employment-related activities.)

**Yes ___ No ___**

**If Yes**, please describe each activity in detail.

_____

_____

9) Since the date that the Avaulta® product(s) was implanted, have you regularly exercised, or regularly participated in activities that required lifting, or regularly engaged in strenuous physical activity? (Please describe all range of physical activities associated with daily living, physical fitness, household tasks, and employment-related activities.)

**Yes ___ No ___**

If Yes, please describe each activity in detail.

_____

_____

10) To the best of your knowledge, have you ever been told by a doctor or another health care provider, that you have suffered, may have suffered, or presently do suffer from any of the following:

a) Adhesions **Yes ___ No ___**

b) Bleeding or clotting disorders **Yes ___ No ___**

c) Bowel Obstruction **Yes ___ No ___**

d) Bowel Perforation **Yes ___ No ___**

e) Cancer **Yes ___ No ___**

f) Chronic Constipation **Yes ___ No ___**

g) Collagen Disorder/Deficiency **Yes ___ No ___**

h) Connective Tissue Disorder **Yes ___ No ___**

i) Crohn's Disease, Irritable Bowel Syndrome,
Ulcerative Colotis or Chronic Diarrhea **Yes ___ No ___**

If **Yes**, please explain which condition and treatment prescribed

_____

j) Cystocele **Yes ___ No ___**

k) Diabetes **Yes ___ No ___**

l) Diverticulitis **Yes ___ No ___**

m) Dyspareunia **Yes ___ No ____**

n) Enterocele **Yes ___ No ___**

o) Fistulas **Yes ___ No ___**

p) Hernias **Yes ___ No ___**

q) Hypertension or High Blood Pressure **Yes ___ No ___**

r) Hypotension or Low Blood Pressure **Yes ___ No ___**

s) Immune System Disease or Dysfunction including HIV/AIDS **Yes ___ No ___**

**If Yes**, specify disease/dysfunction: _____

t) Malnutrition **Yes ___ No ___**

u) Muscle or Muscle-Wasting Disorder **Yes ___ No ___**

**If Yes**, specify disorder: _____

v) Neuromuscular Disease or Disorder **Yes ___ No ___**

**If Yes**, specify disease/disorder:_____

w) Obesity **Yes ___ No ___**

x) Pelvic Trauma **Yes ___ No ___**

**If Yes**, describe the nature of the trauma you experienced:

_____

y) Pelvic Tumors or Fibroids **Yes ___ No ___**

z) Peritonitis/Sepsis **Yes ___ No ___**

aa) Rectocele **Yes ___ No ___**

bb) Recurrent or Chronic vaginal or bladder infections **Yes ___ No ___**

Specify location and nature of infection: _____

cc) Recurrent Vaginal Pain **Yes ___ No**

If Yes, describe the nature of the vaginal pain you experienced:

_____

dd) Urinary Incontinence **Yes ___ No ___**

ee) Urinary Retention **Yes ___ No ____**

ff) Uterine Prolapse **Yes ___ No ____**

gg) Vaginal Vault Prolapse **Yes __ No _____**

hh) Wound healing problems **Yes ___ No ___**

ii) Any other disease of the gut, intestines, or bowel **Yes ___ No ___**

If Yes, specify condition:

_____

*** * * * * * * * * * * * * * ***

**THE FOLLOWING QUESTIONS ARE CONFIDENTIAL AND SUBJECT TO THE PROTECTIVE ORDER APPLICABLE TO THIS CASE.**

jj) **Were you diagnosed with and/or treated for Sexually Transmitted Diseases for the five year period prior to the implantation of the Avaulta® product(s) through the present?**

**Yes ___ No ___**

**If Yes, specify the disease, date of onset, medication/treatment, treating physician and current status of condition:**

_____

_____

kk) **Have you been diagnosed with and/or treated for any alcohol or chemical dependency for the one year prior to the implantation of the Avaulta® product(s) through the present? Yes ___ No ___**

**If Yes, specify type and time period of dependency, type of treatment received, name of treatment provider, and current status of condition:**

_____

_____

ll) **Have you experienced, been diagnosed with or been treated for any mental health conditions including depression, anxiety or other emotional or psychiatric disorders in the 5 year period before implantation of the Avaulta® product(s).**

**Yes ___ No ___**

**If Yes, specify condition, date of onset, medication/treatment, treating physician and current status of condition:**

_____

_____

*** * * * * * * * * * * * * * ***

11) Have you experienced menopause? **Yes ___ No ___**

**If Yes**, at what age did it begin? _____

12) Have you undergone vaginal estrogen therapy, hormone therapy, or systemic estrogen replacement therapy (ERT)? **Yes ___ No ___**

**If Yes**, please provide the type of therapy you received, date(s) of the therapy, and the name and address of the healthcare provider providing the therapy.

_____

_____

13) Do you now or have you ever smoked tobacco products? **Yes ___ No ___**

**If Yes**:

a) How long have/did you smoke?

_____

_____

14) Other than the implantation of the Avaulta® product(s) that are the subject of your lawsuit, are you aware of any other Avaulta® product(s) being implanted inside your body? **Yes ___ No ___**

**If Yes**, please provide the following information:

a) Product Name: _____

b) Date of Procedure Placing it and name and address of Doctor who placed it:

_____

c) Condition sought to be treated through placement of the device:

_____

d) Any complications you encountered with the medical product or procedure:

_____

e) Does that product remain implanted inside of you today? **Yes ___ No ___**

15) List each prescription medication you have taken **for more than 3 months at a time, within the last 5 years prior to implant,** giving the name and address of the pharmacy where you received/filled the medication, the reason you took the medication, and the approximate dates of use.

| Medication and Dosage | Pharmacy (Name and Address) | Reason for Taking Medication | Approximate Date(s) of use |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

## IV. INSURANCE INFORMATION

1) Provide the following information for any past or present medical insurance coverage within the last 10 years:

| Insurance Company (Name and Address) | Policy Number | Name of Policy Holder/Insured (if different than you) | Approx. Dates of Coverage |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

2) Have you ever been denied life insurance for reasons relating to your health?

**Yes ___ No ___ Don't Know _____**

**If Yes**, please state when the denial occurred, the name of the life insurance company, and the company's reason for denial: _____

_____

_____

3) To the best of your knowledge, have you been approved to receive or are you receiving Medicare benefits due to age, disability, condition or any other reason or basis?

**Yes ___ No ___**

**If Yes**, please specify the following:

a) The date on which you first became eligible: _____

*[Please note: if you are not currently a Medicare-eligible beneficiary, but become eligible for Medicare during the pendency of this lawsuit, you must supplement your response at that time. This information is necessary for all parties to comply with Medicare regulations. See 42 U.S.C. 1395y(b)(8), also known as Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007 and 42 U.S.C. 1395y(b)(2) also known as the Medicare Secondary Payer Act.]*

## V. PRIOR CLAIM INFORMATION

1) Have you filed a lawsuit or made a claim in the last 10 years, other than in the present suit relating to any bodily injury?

**Yes ___ No ___**

**If Yes**, please specify the following:

a) Court in which suit/claim filed or made:_____

b) Case/Claim Number:_____

c) Nature of Claim/Injury:_____

2) Have you applied for workers' compensation (WC), Social Security disability (SSI or SSD) benefits, or other state or federal disability benefits within the past 10 years?

**Yes ___ No ___**

**If Yes**, please specify the following:

a) Date (or year) of application: _____

b) Type of benefits sought _____

c) Agency/Insurer from which you sought the benefits:_____

d) The nature of the claimed injury/disability: _____

e) Whether the claim was accepted or denied: _____

## VI. FACT WITNESSES

1) Please identify all persons who you believe possess information concerning your injury(ies) and current medical conditions, other than your healthcare providers, and please state their name address and his/her/their relationship to you:

| Name | Address | Relationship to You | Information you Believe Person Possesses |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
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## VII. IDENTIFICATION OF DOCUMENTS AND OTHER ELECTRONICALLY STORED INFORMATION

For the period beginning three years prior to implantation of the Avaulta® product(s), please identify all research, including on-line research, you have conducted prior to implantation of the Avaulta® product(s) regarding the subjects of this litigation, including the implantation of Avaulta® product(s), the injuries and/or damages you claim resulted from the implantation of Avaulta® product(s), or your medical or physical condition. Identify date, time, and source, including any websites visited. Research conducted to understand the legal and strategic advice of your counsel is not considered responsive to this request.

## VIII. DOCUMENT REQUESTS

1) **RELEASES**.

**NOTE: Please sign and attach to this Fact Sheet the authorizations for the release of records appended hereto.**

2) **DOCUMENTS.** State whether you have any of the following documents in your possession, custody, and/or control. If you do, please provide a true and correct copy of any such documents with this completed Fact Sheet.

a) If you were appointed by a court to represent the plaintiff in this lawsuit, produce any documents demonstrating your appointment as such.

i. Not Applicable _____

ii. The documents are attached _____ [OR] I have no documents _____

b) If you represent the estate of a deceased person in this lawsuit, produce a copy of the decedent's death certificate and autopsy report (if applicable).

i. Not Applicable _____

ii. The documents are attached _____ [OR] I have no documents _____

c) Produce any communications (sent or received) in your possession, which shall include materials accessible to you from any computer on which you have sent or received such communications, concerning the Avaulta® product(s) or subject litigation, including but not limited to all letters, e-mails, blogs, Facebook posts, tweets, newsletters, etc. sent or received by you. Research conducted to understand the legal and strategic advice of your counsel is not considered responsive to this request.

i. Not Applicable _____

ii. The documents are attached _____ [OR] I have no documents_____

d) Produce all documents (including journal entries, lists, memoranda, notes, diaries), photographs, video, DVDS or other media, including all copies, discussing or referencing the subjects of this litigation including the Avaulta® product(s), the injuries and/or damages you claim resulted from the Avaulta® product(s), or evidencing your physical condition from three years prior to the implantation of Avaulta® product(s) to present, including but not limited to the injuries for which you claim relief in this lawsuit. Research conducted to understand the legal and strategic advice of your counsel is not considered responsive to this request.

i. Not Applicable _____

ii. The documents are attached _____ [OR] I have no documents _____

e) Produce any Avaulta® product packaging, labeling, advertising, or any other Avaulta® product product-related items in your possession, custody or control.

i. Not Applicable _____

ii. The documents are attached _____ [OR] I have no documents _____

f) Produce all documents concerning any communication between you and the Food and Drug Administration (FDA) or between you and any employee or agent of the Defendants, regarding the Avaulta® product(s) at issue, except as to those communications which are attorney client/work product privileged.

i. Not Applicable _____

ii. The documents are attached _____ [OR] I have no documents _____

g) Produce all documents in your possession, custody or control evidencing or relating to any correspondence or communication between C. R. Bard, Inc., Covidien or Sofradim (or any of its related companies or divisions) and any of your doctors, healthcare providers, and/or you relating to the Avaulta® product(s), except as to those communications which are attorney client/work product privileged.

i. Not Applicable _____

ii. The documents are attached _____ [OR] I have no documents _____

h) Produce any and all documents in your possession, custody or control reflecting, describing, or in any way relating to any instructions or warnings you received prior to implantation of any Avaulta® product(s) concerning the risks and/or benefits of your surgery, including but not limited to any risks and/or benefits associated with the Avaulta® product(s).

i. Not Applicable _____

ii. The documents are attached _____ [OR] I have no documents _____

i) Produce any and all documents reflecting the model number and lot number of the Avaulta® product(s) you received.

i. Not Applicable _____

ii. The documents are attached _____ [OR] I have no documents _____

j) If you underwent surgery to explain in whole or in part the Avaulta® product(s) that you received: produce any and all documents in your possession, custody or control aside from documents that may have been generated by experts retained by your counsel for litigation purposes, relating to any evaluation of the Avaulta® product(s) and any other material that was (were) surgically removed from you.

i. Not Applicable _____

ii. The documents are attached _____ [OR] I have no documents _____

k) If you claim lost wages or lost earning capacity, copies of your federal and state tax returns for the two years prior to implantation of the Avaulta® product(s) to the present.

i. Not Applicable _____

ii. The documents are attached _____ [OR] I have no documents _____

l) All documents in your possession, custody or control concerning payment by Medicare on the injured party's behalf relating to the injuries claimed in this lawsuit, including but not limited to Interim Conditional Payment summaries and/or estimates prepared by Medicare or its representatives regarding payments made on your behalf for medical expenses relating to the subject of this litigation.

i. Not Applicable _____

ii. The documents are attached _____ [OR] I have no documents _____

*[Please note: if you are not currently a Medicare-eligible beneficiary, but become eligible for Medicare during the pendency of this lawsuit, you must supplement your response at that time. This information is necessary for all parties to comply with Medicare regulations. See 42 U.S.C. 1395y(b)(8), also known as Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007 and 42 U.S.C. 1395y(b)(2) also known as the Medicare Secondary Payer Act.]*

## SWORN DECLARATION

I, _____, declare under penalty of perjury that the facts contained in the foregoing Plaintiff Fact Sheet are true and correct to the best of my knowledge, information and belief.

Executed on:

_____
Date

_____
Signature

**APPENDIX "A"**

**(Authorization Forms)**

# EXHIBIT “B”

**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

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THIS DOCUMENT RELATES TO ALL CASES

# DEFENDANTS' FACT SHEET

For each case, the Bard defendants must complete this Fact Sheet. Except as otherwise set forth in any Order, this Fact Sheet must be completed and served on plaintiffs' counsel in each individual case within 45 days after Defendants' receipt of Plaintiffs' Fact sheet in each individual case.

## I. CASE INFORMATION

This defendant fact sheet pertains to the following case:
Case Name:

## II. CONTACTS WITH TREATING AND EVALUATING PHYSICIANS

Plaintiff has identified each physician who treated and/or evaluated plaintiff for pelvic organ prolapse, stress or urinary incontinence, and/or associated conditions that led to the use of defendants' Avaulta ® products. As to each such physician, provide the following information:

### A. CONSULTATION AND OTHER NON-SALES REPRESENTATIVE CONTACTS

As to each identified physician with whom the defendants were affiliated, consulted or otherwise had contact outside the context of sales representative contacts, set forth the following:

1. Identify the physician.

2. Identity and title of each of defendants' employees who had such contact with the physician.

3. Dates of contact/affiliation with physician.

4. Nature of the contact/affiliation with physician.

5. Set forth any monetary and/or non-monetary benefits, including but not limited to money, travel, and device samples, provided to the physician by any agent of any named defendant, including amounts, dates, and purpose.

6. For any device manufactured by any named defendant, set forth any training provided to or by the physician; including but not limited to date, location, physician's role, cost for attending such training, and subject matter.

7. List any written agreements, contracts, letters, memoranda, or other documents setting forth the terms or nature of any contact or affiliation with the physician; this includes but is not limited to any agreements to research or otherwise study any named defendant's products.

8. For each facility where the physicians were associated, set forth the number and type of Avaulta ® products purchased from you.

9. Set forth any contact between the defendants and the physician with regard to the plaintiff, this includes but is not limited to any information or knowledge defendants have with respect to research studies conducted on or that include information related to plaintiff's implant or associated lot number.

10. Set forth all information provided by the physician to the defendants with regard to the safety, use, or efficacy of the defendants' product(s).

B. SALES REPRESENTATIVE CONTACTS

As to each sales representative who had any contact with an identified physician, set forth the following:

1. Identity of physician.

2. Identity and last known address and telephone number of sales representative.

3. The work history, with you, and current relationship, if any, between the specified defendant(s) and the sales representative.

4. Identity of the sales representative's supervisor(s) during his/her employment.

5. Set forth all information provided by the physician to the sales representative, with regard to the plaintiff.

6. Set forth the date and location of each operation or procedure performed on the plaintiff, which was attended at all by the sales representative.

7. State whether the sales representative, while employed by you, has ever been investigated, reprimanded, and/or otherwise penalized by any person, entity, or government agency for his/her sales or marketing practices, and if so set forth the details thereof.

III. INFORMATION REGARDING THE PLAINTIFF

A. Identify all data, information, objects, and reports in defendants' possession or control or which have been reviewed or analyzed by defendants, with regard to the plaintiff's medical condition; this also includes but is not limited to any study or research that includes plaintiff's specific implant or associated lot number. Attorney-work product is specifically excluded from this request.

B. Identify any direct or indirect contact, either written or oral, between the plaintiff and any employee or representative of the defendants, including but not limited to pre-operative inquiries, and post-operative complaints. This request specifically includes, but is not limited to, calls to the M.S.&S. hotline and calls to the Field Assurance Department.

C. Identify all Med Watch Adverse Event Reports and/or any other documents submitted to the FDA or any other government agency with regard to the plaintiff.

D. If you have any evidence or records indicating or demonstrating the possibility that any person, entity, condition, or product, other than the defendants and their product(s), is a cause of the plaintiff's injuries, ("Alternate Cause") set forth:

1. Identify the Alternate Cause with specificity.

2. Set forth the date and mechanism of alternate causation.

IV. MANUFACTURING INFORMATION

A. Identify the lot number(s) for the device(s) implanted into the plaintiff.

B. Identify the lot number(s) for the device(s) used to implant the defendant's device(s) into the plaintiff.

C. Identify the location and date of manufacture for each lot set forth in response to A and B above.

D. Identify the date of shipping and sale, and the person or entity purchasing, each of plaintiff's device(s).

E. Identify all manufacturing facilities and associated lot number(s) of plaintiff's implanted device(s), including but not limited to all trocars and any other surgical devices or means of implantation included or sold with plaintiff's implant(s).

V. DOCUMENTS

Please ensure that the production of documentation includes specific reference to the question to which the documentation is provided in response. Documentation is defined to include all forms of documents, including but not limited to paper, email, video, audio, spreadsheets, or otherwise.

A. Identify and attach complete documentation of all information set forth in I through IV above; except, you may identify but not serve copies of medical records that were provided to defendants by plaintiff's counsel.

B. Aside from any privileged materials, identify and attach all records, documents, and information that refer or relate to the plaintiff in defendants' possession or control, to the extent not identified and attached in response to a prior question.

C. Produce a true and complete copy of the Device History Record for the Plaintiff's lot number(s).

D. Produce a true and complete copy of the complaint file relating to the Plaintiff.

**VERIFICATION**

_____, being first duly sworn upon his oath, deposes and says:

That I am an authorized agent of C. R. Bard, Inc. and that I verify the Defendant's Response to Plaintiff _____ 's Defense Fact Sheet addressed to C.R. Bard, Inc. in *In Re Avaulta Pelvic Support Systems Products Liability Litigation*, MDL No. 2187 (S.D. W. Va.), and that the matters stated therein are not the personal knowledge of deponent; that the facts stated therein have been assembled by authorized employees and counsel of C. R. Bard, Inc. and deponent is informed that the facts stated therein are true. I hereby certify, in my authorized capacity as an agent for C. R. Bard, Inc., that the responses to the aforementioned Defendants' Fact Sheet are true and complete to the best of C. R. Bard, Inc.'s knowledge.

_____
Title:
C. R. Bard, Inc.

SUBSCRIBED and SWORN to before me this ____ day of _____, 20___.

_____
Notary Public

My Commission expires:

_____