

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA**

MDL No. 3081

In Re Bard Implanted Port Catheter Products Liability Litigation



DEFENDANTS' FACT SHEET

For each case, Becton, Dickinson and Company; C.R. Bard, Inc.; Bard Access Systems, Inc.; and Bard Peripheral Vascular, Inc. (collectively, "Defendants") must complete this Defendants' Fact Sheet ("DFS") in accordance with the requirements set forth in Case Management Order No. 10 and 17.

A completed DFS shall be considered interrogatory answers pursuant to Fed. R. Civ. P. 33, responses to request for production under Fed. R. Civ. P. 34, and will be governed by the standards applicable to written discovery under Fed. R. Civ. P. 26, 33, 34, and 37. Therefore, you must supplement your responses if you learn that they are incomplete or incorrect in any respect. The questions and requests for production of documents contained in this DFS are non-objectionable and shall be answered without objection, except that Defendants may assert, where appropriate, objections based on privilege or work product grounds, in which case they will produce a privilege log. This DFS shall not preclude Plaintiffs 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 Orders.

This DFS must be served on Plaintiff's counsel of record, with a copy to the PLC, in accordance with Case Management Order No. 10 and 17.

In completing this DFS, you must answer every question. The requests for information and documents require Defendants to, at a minimum, conduct a reasonable and diligent search. Each document request and interrogatory not only calls for current knowledge but also for all knowledge that is available to Defendants by reasonable inquiry, including inquiry of your officers, directors, employees, contractors, agents, and assigns.

To the extent this form does not provide enough space to complete your responses or answers, please attach additional sheets as necessary. Please identify any documents that you are producing that are responsive to a question with Bates-Stamp identifiers.

"Document(s)" and "documentation" mean and refer to a writing and/or recording as defined by Fed. R. Civ. P. 34, including, without limitation, the following terms in their broadest sense, whether printed or recorded or reproduced by any other mechanical process, or written or produced by hand: agreements, "communications," State and Federal governmental hearings and reports, correspondence, telegrams, memoranda, summaries or records of telephone conversations, summaries or records of personal conversations or interviews, diaries, graphs, reports, notebooks, note charts, plans, drawings, sketches, maps, summaries or records of

meetings or conferences, summaries or reports of investigations or negotiations, opinions or reports of consultants, radiographs, photographs, motion picture films, brochures, pamphlets, advertisements, circulars, press releases, drafts, letters, any marginal comments appearing on any document, and all other writings.

“Communication” and/or “correspondence” shall mean and refer to any oral, written, spoken, or electronic transmission of information including but not limited to meetings, discussions, conversations, telephone calls, memoranda, letters, emails, text messages, postings, instructions, conferences, seminars, or any other exchange of information between any Defendant, including their agents and contractors, and any other person or entity.

“Device(s)” shall mean the Bard Implanted Port Catheter Product(s) that Plaintiff was implanted with and alleges was defective, as identified in Plaintiff’s Fact Sheet.

“Bard IPCs” shall refer to all Bard Implanted Port Catheter Products as listed in Exhibit A of the Master Complaint.

“Healthcare Provider” shall mean any doctor, physician, surgeon, or other healthcare professional who: (1) prescribed or implanted the Device(s); and/or (2) removed or attempted to remove the Device(s) or any of its components. If a plaintiff identifies additional healthcare professionals whose care of that plaintiff related to the IPC or complications allegedly arising from implantation of the IPC was extensive or critical to the assessment of the particular case for possible inclusion in the bellwether pool, Defendants agree to meet and confer with each such plaintiff on a case by case basis regarding whether it is appropriate to include such additional healthcare professional(s) in the definition contained herein.

“Implanting Healthcare Provider” shall mean the doctor, physician, surgeon, or healthcare professional who implanted the Device(s).

“Sales Representative” shall mean Defendants’ sales employees primarily responsible for promotion and sale of IPCs to the Implanting Healthcare Provider and the institution wherein the IPC was implanted, i.e., the Territory Managers. Also included in this definition for purposes of completion of the Defendants Fact Sheet is each such Territory Manager’s direct supervisor, typically a District Manager.

“You,” “your,” or “yours” refer to each of the Defendants identified in the Master Complaint.

“Key Opinion Leader” or “Thought Leader” shall mean and refer to physicians, experts, or other professionals hired by, consulted with, or retained by Defendants to consult, give lectures, respond to media inquiries, conduct clinical trials, write articles or abstracts, sign their names as authors to articles or abstracts written by others, make presentations on Defendants’ behalf at regulatory meetings or hearings, association meetings, hospital department meetings, or other professional meetings including local, regional, and national meetings, and any other meeting organized and planned by or on behalf of Defendants, among other things.

I. CASE INFORMATION

A. This DFS pertains to the following case:

1. Case caption: _____
2. Civil action number: _____
3. Court in which action was originally filed: _____
4. Date this DFS was completed: _____

B. Please provide the following information about the person(s) who provided the information and/or identified documents responsive to the questions posed herein:

1. Name: _____
2. Current position (if no longer employed, last position with Defendant(s)):

3. City of employment (if no longer employed, city of residence):

II. CONTACTS WITH HEALTHCARE PROVIDERS

For each Healthcare Provider who prescribed, implanted, removed, or attempted to remove a Device, provide the following information:

A. CONSULTATION & OTHER NON-SALES REPRESENTATIVE CONTACTS

For each identified Healthcare Provider with whom Defendants were affiliated, consulted, or otherwise had contact outside the context of sales representative contacts, please:

1. Identify all contacts between the Healthcare Provider and Defendants.
2. Identify all past and present consulting arrangements with the Healthcare Provider.
3. Identify any document previously produced that references the Healthcare Provider.
4. Identify and produce all Form 1099s and any other documentation reflecting payments or reimbursements of any nature to the Healthcare Provider.
5. Identify any Dear Doctor letter or similar communication regarding any Bard IPC that concerns any safety-related issue and that could have been sent to the Healthcare Provider, and identify any record reflecting actual

delivery of the communication to the provider or the facility.

6. Identify (to the extent known) any Defendant-sponsored clinical study in which the Healthcare Provider participated.
7. Identify any training provided to or by the Healthcare Provider, including but not limited to date, location, Healthcare Provider's role, cost for attending such training, and subject matter.
8. Set forth any and all contractual relationships between the Healthcare Provider and Defendant(s), including but not limited to:
 1. whether the provider participated in any study or clinical trials as a principal investigator or supervising physician at any study site which was sponsored by Defendant(s) on Defendants' behalf;
 2. whether the provider has spoken on behalf of Defendant(s) or any of its products, including but not limited to Bard IPCs;
 3. whether the provider has served in any capacity on any of Defendant(s)' advisory boards, consulting groups, focus groups, etc.;
 4. whether the provider has ever served as a Key Opinion Leader or Thought Leader for or on behalf of any Defendant;
 5. whether the provider has functioned in any capacity promoting Defendants' products, including but not limited to Bard IPCs; and
 6. whether the provider has ever been employed by or under contract with Defendant(s).
9. For each facility where a Device was implanted in Plaintiff, set forth the number and type of Bard IPCs purchased from you or otherwise provided by you for a 4-year period (spanning from 2 years before the implant of the Device until 2 years afterward). Produce documentation reflecting same if available. If there are no records of such sales to that facility during the time period in question, identify any distributors or Group Purchasing Organizations known to the Defendants that may have supplied Bard IPCs to the facility, or the names of all purchasers of such products from the lot number(s) identified in the Plaintiff Fact Sheet.

B. SALES REPRESENTATIVE & OTHER RELATED CONTACTS

As to each of Defendants' Sales Representatives, who was assigned to the geographic area where the implanting facility is located and during the two-year period up to and including

the date(s) of implant (“Representative”), please:

1. Identify the identity and last known home address and telephone number of the Representative.
2. Set forth the work history with you and current relationship, if any, between Defendant(s) and the Representative.
3. Identify the identity of the Representative’s supervisor(s) during his/her Employment.
4. For each Representative, produce the most current curriculum vitae or resume. If you are not in possession of a curriculum vitae or resume, produce the portion of that person’s personnel file that reflects their educational background and experience over the past 10 years to the present.
5. Set forth all information provided by the Healthcare Provider to the Representative with regard to Plaintiff.
6. Set forth all information provided to the Healthcare Provider by the Representatives to with regard to Plaintiff.
7. State whether the Representative while employed by you, or acting as an agent or independent contractor on your behalf, was ever reprimanded and/or otherwise penalized by Defendant(s) or any other person, entity, or government agency for his/her sales or marketing practices during the period of employment with you, and if so, set forth the details thereof.

III. INFORMATION REGARDING PLAINTIFF: COMMUNICATIONS AND RELATIONSHIPS WITH PLAINTIFF’S HEALTHCARE PROVIDERS

- A. Identify all data, information, objects, and reports in Defendants’ possession, custody, control, or that have been reviewed or analyzed by Defendants regarding Plaintiff’s medical condition. This information includes but is not limited to any study or research that includes Plaintiff’s specific Device or associated lot number.
- B. Identify any direct or indirect contact, either written or oral, between the Plaintiff and any employee or representative of any Defendant, including but not limited to pre-operative inquiries, post-operative complaints, “Dear Healthcare Provider” letters, “Dear Doctor” letters, “Dear Colleague” letters, or other similar types of documents or letters concerning Bard IPCs, recall letters, and telephone or email contacts or meetings. This request specifically includes but is not limited to calls to any hotline operated or affiliated with any Defendant and calls to the Field Assurance Department.
- C. Identify and produce any Physician’s Information Request Letters (“PIR”) or other similar information request that has ever been initiated between the Plaintiff and

any employee or representative of any Defendant relating to a Bard IPCs, and identify the date of the request, the recipient, the name and address of the sender or requestor, the corresponding Bates number of the request, and whether or not a response to the PIR or other similar information request was generated or provided.

- D. Produce all communications between Plaintiff and any Defendant, including their Representative(s) identified in Section II.B, to the extent such communications are not contained in the complaint file, if any, and identify the Bates numbers of such communications.
- E. Identify all Adverse Event Reports, Medical Device Reports, and all versions of any MedWatch forms and/or any other documents submitted to the FDA or any other government agency with regard to the Plaintiff.
- F. If you have any evidence or records indicating or demonstrating the possibility that any person, entity, condition, or product, other than Defendants and their product(s), is a cause of the Plaintiff's injuries ("Alternate Cause"), please:
 - 1. Identify the Alternate Cause with specificity; and
 - 2. Set forth the date and mechanism of alternate causation.
- G. For each Implanting Healthcare Provider, please respond to the following:
 - 1. State whether you have or had access to any database or information that purports to track any Implanting Healthcare Provider's implanting practices with respect to Bard IPCs.
 - 2. If yes, please produce or identify the database or document that contains that information.

IV. MANUFACTURING INFORMATION

- A. Identify the lot number(s) for the Device(s) implanted into the Plaintiff.
- B. Identify the location(s) and date of manufacture for each lot set forth in response to Section IV.A.
- C. State whether Defendants ever recalled the lot set forth in response to Section IV.A.
- D. Identify third parties which provided raw materials and/or components of the Device(s).
- E. Identify the date of shipping and sale, and the person or entity purchasing, the Device(s).
- F. Identify all manufacturing facilities and associated part number(s) of the Device(s).
- G. Provide the chain of custody of the Device(s) from Defendants to the Healthcare Provider.

V. CONTACTS REGARDING PLAINTIFF

- A. Have you been contacted by Plaintiff, his/her physicians, or anyone concerning Plaintiff?
- B. If yes, please:
 - 1. Identify the name of the person(s) who contacted you;
 - 2. Identify the person(s) who were contacted including their name, address, and telephone number; and
 - 3. Produce or identify any and all documents which reflect any communication between any person and you concerning Plaintiff.

VI. DOCUMENTS

Please ensure that the production of documents includes specific reference to the question to which the document is provided in response.

- A. Identify and produce complete documentation of all information set forth in Section I through V above, except you may identify but not produce copies of medical records that were provided to Defendants by Plaintiff's counsel.

[Bard Defendant Name]

[Title]