# SUPERIOR COURT OF NEW JERSEY LAW DIVISION; BERGEN COUNTY

CASE NO. 624
MASTER DOCKET NO. BER-L-\_\_\_CIVIL ACTION

IN RE STRYKER LFIT CoCr V40 FEMORAL HEADS HIP IMPLANT LITIGATION

#### **DEFENDANT'S FACT SHEET**

Defendant Howmedica Osteoncics Corp. ("HOC") hereby submits the following Phase I Defendant's Fact Sheet responses and related Documents for the above-referenced-case.

## **INSTRUCTIONS**

Please provide the following information for the plaintiff referenced above (or plaintiff's decedent) (hereinafter "Plaintiff") who was implanted with an LFIT<sup>TM</sup> Anatomic CoCr V40<sup>TM</sup> Femoral Head that is the subject of Plaintiff's complaint in the above-referenced action. In filing out any section or sub-section of this form, please submit additional sheets as necessary to provide complete information.

In filling out this form, please respond on the basis of information and/or documents that are reasonably available to the Defendant and use the following definitions:

**DEVICE:** The LFIT<sup>TM</sup> Anatomic CoCr V40<sup>TM</sup> Femoral Head implanted in the Plaintiff, also known as the component.

<u>DOCUMENTS</u>: "Documents" as used in this request is coextensive with the meaning of the terms "documents," "electronically stored information" and "tangible things" as used in the Federal Rules of Civil Procedure, and shall have the broadest possible meaning and interpretation ascribed to those terms.

**HEALTH CARE PROVIDERS:** "Health Care Providers" shall refer to all persons identified in the Plaintiff's Fact Sheet ("PFS") who surgically implanted and/or removed the Device and/or associated components identified in the PFS or who assisted in the implantation or revision surgery.

### A. DEVICE INFORMATION

- 1. For each Device identified by Plaintiff in his/her PFS provide the Device History Record, which includes the date of manufacture, the place of manufacture, the date when the manufacturing process began and the date on which the product was released to finished goods.
- 2. For each Device identified by Plaintiff in his/her PFS provide the Sales Invoices, if available.
- 3. Is Defendant in Possession of any photographs (including SEM) of the component(s) removed from Plaintiff?

Yes [ ] No [ ]

 If yes, provide any readily available identifying information including dates of the photographs, where the photographs were taken and who took the photographs.

## B. MARKETING/SALES REPRESENTATIVE INFORMATION

1. Provide the name, employer and business address of the Device sales representative(s) (whether Defendant's employee, agent of Defendant or third party) for the Health Care Provider at the time Plaintiff's Device was implanted.

#### C. ADVERSE EVENT REPORTS

- 1. Produce a copy of the Product Experience Report (PER) Summary that relates to this Plaintiff. (Subject to Plaintiff providing a signed Authorization for the Release of Adverse Event Reports. A copy of the required authorization is attached hereto as Exhibit A).
- 2. Produce a copy of the Medical Device Adverse Event Report (MDR) that relates to this Plaintiff. (Subject to Plaintiff providing a signed Authorization for the Release of Adverse Event Reports A copy of the required authorization is attached hereto as Exhibit A).

## D. HOC CLAIM INFORMATION

1. If Defendant maintains a file on Plaintiff not addressed by PER and is not the subject of a recognized privilege, then produce any discoverable documents in that file, including any documents that were obtained from Plaintiff, the surgeon or the sales representative, or by issuance of an executed authorization received from Plaintiff, including, but not limited to medical records, employment records, insurance information, statements, e-mails, correspondence, notes, and Releases(s).

## **VERIFICATION**

I am Legal Counsel for Stryker Corporation. Within this capacity I serve as a liaison between the Global IT Department and Howmedica Osteonics Corp. ("Defendant"), the defendant in this action, in connection with litigation matters. In this role I am responsible for the collection of certain information and documents on Defendant's behalf in this action. The foregoing answers were prepared with the assistance of a number of individuals, including counsel for Defendant, upon whose advice and information I relied. I declare under penalty of perjury that all of the information as to the foregoing Defendant provided in this Defendant's Fact Sheet is true and correct to the best of my knowledge upon information and belief, and that I am authorized by Defendant to make this verification on its behalf based upon my role in this action as set forth above.

Date:	
	Signature
Name:	<del>_</del>
Employer:	
Title:	