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January 24, 2017

**VIA FEDERAL EXPRESS**

Hon. Glenn A. Grant, J.A.D.
Administrative Director of the Courts
Administrative Office of the Courts
of the State of New Jersey
Richard J. Hughes Justice Complex
25 W. Market Street
Trenton, New Jersey 08625



***Re: Request for Multi-County Designation of HOC LFIT™ Taper Lock Litigation***

Dear Judge Grant:

This letter is submitted on behalf of twenty-five plaintiffs[1] who have cases filed in Bergen County, New Jersey involving the Stryker LFIT™ Anatomic Cobalt Chromium (CoCr) V40™ femoral heads manufactured by defendant Howmedica Osteonics Corp., a New Jersey corporation, d/b/a Stryker Orthopaedics, hereinafter, "Stryker." Plaintiffs seek a Multi-County Litigation designation in accordance with Rule 4:38A. A voluntary recall of this product was recently announced and posted on the FDA's website.[2] On August 26, 2016, Stryker issued a letter to orthopedic surgeons advising them of a "higher than expected" incidence of taper lock failure for certain sizes and lots of its LFIT™ Anatomic CoCr V40™ Femoral Heads. A Type II Medical Device Recall has also been issued in Canada and a Hazard alert has been issued in Australia. This device is compatible with a variety of Stryker femoral stems, and therefore, it has

[1] See attached Exhibit Schedule A

[2] See attached Exhibit B

been estimated that this device was implanted in many individuals in the United States.[3] While some of the cases involving these products have been pending in Bergen County in excess of two years, with an estimate of more than eighty-five such cases having been filed, the pace of filing has increased recently. Some of those cases in suit may have addressed their allegations to the femoral stems that were used in conjunction with the recalled femoral head, but invariably those cases involving the Accolade and other stems, also relate to the intersection between the stem and the femoral head.

Moreover, a Request for a Multidistrict Litigation (MDL) was filed last week before the United States Panel on Multidistrict Litigation indicating that there were a growing number of cases in suit in the federal courts and seeking the creation of an MDL in the District of Massachusetts and a different submission seeks the District of Minnesota. It is anticipated that the Judicial Panel on Multidistrict Litigation will hear those petitions on March 30 of this year in Phoenix, Arizona.

**Background**

The LFIT™ Anatomic CoCr V40™ Femoral Head has been marketed for use with a variety of femoral stems. Use of these stems made of titanium or TMZF titanium alloy when combined with the cobalt-chromium alloy femoral head and taper are presumed in emerging medical literature to be the source of problems and failures.

In August of this year, Stryker Orthopaedics notified surgeons of hazards that have been identified with the company's LFIT™ Anatomic CoCr V40™ Femoral Heads. Health Canada, the FDA analog in Canada, issued a recall notice of certain sizes and lots of these the cobalt chromium femoral heads in Canada on August 26, 2016. Similarly, the Department of Health-Therapeutic Goods Administration in Australia issued a Hazard alert due to the increased risk of adverse events from potential taper lock failures associated with certain sizes and lots of this femoral head. Potential adverse events include loss of mobility, pain, inflammation, adverse local tissue reaction, disassociation of the femoral head, dislocation, joint instability, broken bones around the components, and need for revision surgery.

Similar to the problem associated with the recalled Stryker Rejuvenate and ABG II modular hip systems designated as a Multi-County Litigation in Bergen County in January 2013, the problem here involves fretting and corrosion in the junction where the femoral head connects to the femoral stem. Corrosion at this junction has led to the systematic release of metal particles into surrounding tissue and bone putting patients at risk of metallosis (a build-up of metallic debris), necrosis (the cell death of affected tissues), osteolysis (the death of bone cell due to blood supply issues), and elevated levels of cobalt and chromium in the blood -- any of which can necessitate revision surgery.

[3] Stryker is in the best position to quantify the precise number sold in the United States.

Furthermore, this device has been associated with sudden and catastrophic disassociation of the femoral head from the femoral stem. Excessive corrosion at the head-neck junction causes the femoral head to break off from the neck of the stem, become loose in the body, and depart from the acetabular cup where it is supposed to articulate as part of the joint requiring immediate revision surgery and replacement of the entire femoral stem and femoral head.

**Stryker LFIT CoCr V40 Femoral Head Litigation in New Jersey**

The recall of this component will implicate many hip implants. Both prior to the recall and in response to the growing problems associated with this Stryker femoral head, at least eighty-five cases alleging personal injury as a result of defective hip implants have been filed in New Jersey state courts, and we anticipate that more cases will be filed in New Jersey in the coming weeks to months to years. Many of the filed cases involve patients who have required revision surgery to remove and replace the head or stem, a very painful and invasive surgery. Indeed, my firm has numerous additional cases we are reviewing and contemplating filing and I know of several other firms that plan on filing numerous cases including our co-counsel, on some of the filed cases, the law firms of Searcy Denney and Beasley Allen. The cases filed presently involve New Jersey plaintiffs residing in Bergen, Essex, Camden and Monmouth County as well as plaintiffs from a number of other states.

**WHY COORDINATION IS APPROPRIATE**

As set forth in the guidelines, mass tort designation, now known as multi-county designation, is warranted when a litigation involves a large number of parties; many claims with common, recurrent issues of law and fact that are associated with a single product; there is geographical dispersement of parties; there is a high degree of commonality of injury; there is a value interdependence between different claims; there is a degree of remoteness between court and actual decision makers in the litigation; among other considerations. This litigation meets the above enunciated criteria. There are already at least 85 filed cases. All cases will involve the recurrent legal issues of design defect, failure to warn, breach of warranty and possibly manufacturing defect. Moreover, there are significant overlapping factual liability issues relating to the nature of the metals in the product and how it was cast or forged; the nature of the defect, failure to recall the device, failure to comply with good manufacturing practices, notice of metallurgical concerns in mixing chromium cobalt components with titanium and other metals, the known risks of metallosis and fretting at taper junctions, among other related factual issues. Separate discovery demands have been filed in many of the cases and responses from Defendants are outstanding.

**WHY BERGEN COUNTY IS AN APPROPRIATE MASS TORT VENUE**

Issues of fairness, geographical location of the parties and attorneys, and the existing civil and mass tort caseload in the vicinage will be considered in determine which vicinage a

particular mass tort will be assigned to for centralized management. *See Mass Torts—Guidelines and Criteria for Designation*, at 2 (Oct. 25, 2007).

Presently, the approximate 85 cases already filed are pending before Judge Rachelle Harz in Bergen County. Prior to Judge Brian Martinotti's appointment to the federal bench, Judge Martinotti presided over these cases and issued a January 7, 2016 order requiring counsel to complete a questionnaire identifying general case information, implant surgery information, revision surgery information, and additional medical information with documentation to be attached. Since Judge Harz is now presiding over these cases and is overseeing all Multi-County Litigations in Bergen County, including the Stryker Rejuvenate and ABG II litigation which involves similar issues, it is both logical and fair to the litigants for these cases to remain in Bergen County before Judge Harz. Additionally, recently several cases involving this device were filed in the United States District Court for the District of New Jersey and assigned to Judge Brian Martinotti so it is possible he could be assigned the MDL in which case seamless coordination could occur between the federal MDL and state MCL litigation.

Geographical location is another factor to be considered when selecting the best venue in which to centralize a mass tort. While all of the available venues for multi-county centralization—Atlantic, Bergen, and Middlesex counties—are convenient to regional and international airports (*e.g.*, Philadelphia, Atlantic City, and Newark) and are within a reasonable driving distance from the offices of defendant and their counsel in New Jersey, it is clear that Bergen County is best suited for this consolidation. Bergen County is most convenient for defendant which is headquartered in Northern Bergen County (Mahwah). While plaintiffs' counsel have some concern about the jury pool given the presence of defendant in the county, Stryker headquarters is more than twenty miles from the Hackensack courthouse and is actually much closer to Suffern, New York (four miles), as it is located near the New York border and the New York City metropolitan area. Accordingly, many of Stryker's employees are actually New York residents and are not in the potential venire. Further, Bergen County is not as populated with other pharmaceutical and medical device companies as is Middlesex County, home to Johnson & Johnson and Bristol-Myers Squibb, to name a few.

An important factor in this determination should be the "existing civil and mass tort caseload in the vicinage" being considered. *See id.* Presently, per this Court's website http://www.judiciary.state.nj.us/mass-tort/index.html there are seven (7) multi-county and centralized litigations in the Middlesex County Superior Court (*Asbestos, AlloDerm, Fosamax, Levaquin, Propecia, Reglan, and Risperdal/Seroquel/Zyprexa, Zometa/Aredia*) and four (4) multi-county litigations centralized in Atlantic County Superior Court (*Accutane, Benicar, Bristol-Myers Squibb, Talcum Powder*). Some of these litigations, such as Accutane and Fosamax, involve thousands of plaintiffs. Furthermore, both *Benicar* and *Talcum Powder* were recently assigned to Atlantic County.

While there are also seven multi-county litigations centralized in Bergen County Superior Court (*Stryker Hip/ ABG II, DePuy ASR Hip Implant, Mirena, Pelvic Mesh, Pompton Lakes, Stryker Trident, Yaz/Yasmin/Ocella*), most of these litigations are largely resolved (*Stryker Hip/ ABG II, DePuy ASR Hip Implant, Stryker Trident, Yaz/Yasmin/Ocella*). Further, a global settlement was just announced on December 19, 2016 involving the Stryker Hip/ABG II litigation that will drastically reduce the number of cases in suit in Bergen County. Furthermore, the centralization request is primarily being made for Bergen County due to the Court's present handling of the 85 cases as well as the Court's knowledge and familiarity with the medical issues arising from metallosis in chromium and cobalt hip implants and the overlapping regulatory issues involved in medical devices that obtain 510(k) clearance due to its current management of the Stryker Rejuvenate and ABG II litigation and DePuy ASR hip litigation. Given the similarities in the above-mentioned litigations, Bergen County's multi-county staff is equipped to handle this litigation.

In light all the factors and information discussed above, plaintiffs respectfully request that the Supreme Court designate the LFIT™ Anatomic CoCr V40™ Femoral Head cases for Multi-County or Centralized Management of such matters in the Bergen County Superior Court.

Respectfully submitted,

Ellen Relkin

cc: Taironda E. Phoenix, Esq., Chief, Civil Court Programs
The Honorable Rachelle L. Harz
Kim M. Catullo, Esq., Gibbons, P.C. (Counsel for Defendants)

# EXHIBIT A

# Exhibit A

| | Plaintiff | Docket Number |
|---|---|---|
| 1 | Laraine Huneke | BER-L-008416-13 |
| 2 | George Bonomi | BER-L-004781-14 |
| 3 | Melissa Chirico | BER-L-006532-14 |
| 4 | Martin Parsons | BER-L-009394-14 |
| 5 | Diana Endress | BER-L-001721-15 |
| 6 | Janet Luparello | BER-L-001817-15 |
| 7 | Hogarth Asing | BER-L-008900-15 |
| 8 | Timothy Dennis | BER-L-003341-16 |
| 9 | Maureen Chapman-Fahey | BER-L-003323-16 |
| 10 | Nancy Anderson | BER-L-003322-16 |
| 11 | Steven Jackmuff | BER-L-003318-16 |
| 12 | William Johnson | BER-L-003316-16 |
| 13 | Monica Stuckert | BER-L-006981-16 |
| 14 | Randolph Stach | BER-L-006994-16 |
| 15 | Stephen Gunning | BER-L-006989-16 |
| 16 | Robert Sova | BER-L-007784-16 |
| 17 | Peder Gundersen | BER-L-007781-16 |
| 18 | Howard Ross | BER-L-007785-16 |
| 19 | Richard King | BER-L-008789-16 |
| 20 | Wayne Smith | BER-L-008787-16 |
| 21 | Kevin Kiely | BER-L-000175-17 |
| 22 | John DeVries | BER-L-000451-17 |
| 23 | Linda Martin | BER-L-000447-17 |

# EXHIBIT B

FDA



**Class 2 Device Recall Stryker LFIT Anatomic V40 Femoral Head**

See Related Information[22]

| | |
|---|---|
| **Date Initiated by Firm** | August 29, 2016 |
| **Create Date** | November 09, 2016 |
| **Recall Status[1]** | Open[3], Classified |
| **Recall Number** | Z-0378-2017 |
| **Recall Event ID** | 75246[23] |
| **510(K)Number** | K022077[24] |
| **Product Classification** | Prosthesis, hip, semi-constrained, metal/polymer, cemented[25] - **Product Code** JDI[26] |
| **Product** | LFIT Anatomic V40 Femoral Head, Low Friction Ion Treatment, Sterile, 36 mm, REF 6260-9-236; Modular components designed to be locked onto a femoral hip stem trunnion during surgery for total hip replacement. |
| **Code Information** | Catalog #6260-9-236 - Head Diameter 36 mm, Offset +5, including all lots manufactured from 1/102 - 7/1/10; Catalog #6260-9-240 - Head Diameter 40 mm, Offset +4, including all lots manufactured from 1/1/06 - 3/4/11; Catalog #6260-9-244 - Head Diameter 44 mm, Offset +4, including all lots manufactured from 1/1/06 - 3/4/11; Catalog #6260-9-340 - Head Diameter 40 mm, Offset +8, including all lots manufactured from 1/1/06 - 3/4/11; Catalog #6260-9-440 - Head Diameter 40 mm, Offset +12, including all lots manufactured from 1/1/06 - 3/4/11; Catalog #6260-9-344 - Head Diameter 44 mm, Offset +8, including all lots manufactured from 1/1/07 - 3/4/11 and Catalog #6260-9-444 - Head Diameter 44 mm, Offset +12, including all lots manufactured from 1/1/06 - 3/4/11. |
| **Recalling Firm/ Manufacturer** | Stryker Howmedica Osteonics Corp.<br>325 Corporate Dr<br>Mahwah NJ 07430-2006 |
| **For Additional Information Contact** | Mr. Michael Van Ryn<br>201-831-5000 |
| **Manufacturer Reason for Recall** | Stryker received several complaints describing incidence of harm secondary to taper lock failure for specific lots of numerous catalog numbers of LFIT Anatomic CoCr V40 Femoral Heads. |
| **FDA Determined Cause [2]** | Under Investigation by firm |
| **Action** | Stryker notified their Branches/Agencies of this recall by e-mail on August 29, 2016 and they were asked to quarantine the affected devices. A Recall Notification Letter and Product Accountability Form was also sent on August 29, 2016 via UPS (with return receipt) to their Branches/Agencies/Hospital Risk Management and Surgeons. On October 11, 2016, Stryker sent an updated recall notification via UPS with return receipt to their affected |

| | |
|---|---|
| | customers because additional customers and lot numbers were identified. |
| **Quantity in Commerce** | 42,519 units (total Catalog numbers) |
| **Distribution** | US Nationwide and Internationally |
| **Total Product Life Cycle** | TPLC Device Report[27] |

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.
[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

**510(K) Database** 510(K)s with Product Code = JDI and Original Applicant = HOWMEDICA OSTEONICS CORP.[29]

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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=75246
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K022077
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=JDI

26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=JDI
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=JDI
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=JDI&knumber=&applicant=HOWMEDICA%20OSTEONICS%20CORP%2E

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