

Civil

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VIA FEDERAL EXPRESS

March 3, 2017

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The 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 Litigation Designation for HOC (Stryker) LFIT™ Taper Lock***

Dear Judge Grant:

I submit this letter on behalf of the seven Plaintiffs identified on Exhibit A.1 All of their cases allege defects in the Stryker LFIT™ Anatomic Cobalt Chromium (CoCr) V40™ femoral head manufactured by Defendant Howmedica Osteonics Corporation, d/b/a Stryker Orthopaedics (“Stryker). Along with co-counsel, I further represent approximately fifteen additional plaintiffs whose cases involving the same Stryker device have not yet been filed. I write to advocate for a Multi-County Litigation designation in accordance with Rule 4:38A.

Stryker recently initiated a voluntary recall of this device in the United States, as announced on the FDA’s website. (See Exhibit B). Late last summer, Stryker issued an “Urgent Medical Device Recall Notification” 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. Health Canada, the Canadian public health agency, issued a recall notification to the general public, healthcare professionals and hospitals regarding certain models of the LFIT CoCr V40 femoral heads, initiating a Type II Medical Device Recall in Canada, and Australian health authorities issued a “Hazard Alert” in that country.

This Stryker femoral head was designed to be compatible with many different Stryker femoral stems, and, according to Stryker, more than 42,000 units were in commerce as of the time of

¹ I was an associate in Pope, McGlamry, Kilpatrick, Morrison & Norwood, P.C.’s Atlanta, Georgia office when these seven (7) cases were first filed. I have since relocated to Levy Konigsberg, LLP in New York, and now am associated as local counsel on these cases.

The Hon. Glenn A. Grant, J.A.D.

March 3, 2017

Page 2

the U.S. recall. We currently do not know how many of these devices have been implanted in patients in the United States, but multiple cases involving the device have been pending in Bergen County, dating back approximately two years. Indeed, approximately eighty-five cases are presently on file in Bergen County, with the number of cases being filed increasing in the past few months.

A Request seeking a federal Multi-District Litigation (or MDL) was filed earlier this month before the United States Joint Panel on Multidistrict Litigation (the JPML). That filing demonstrates a growing number of cases involving the same Stryker decide in federal district courts around the United States. It is anticipated that the JPML will hear argument as to consolidation and where to consolidate those cases at the end of March.

Issues with the Stryker LFIT CoCr head

The LFITTM Anatomic CoCr V40TM femoral head (the “LFIT CoCr head”) has been marketed for use with a variety of different femoral stems. It appears that the use of stems comprised of Titanium or TMZF (a titanium alloy) in combination with the LFIT CoCr head and taper is the source of issues with and failures of hip implants.

In August 2016, in conjunction with its U.S. recall efforts, Stryker notified surgeons of hazards that have been identified with the LFIT CoCr head. Internationally, Health Canada issued a recall of certain sizes and lots of the LFIT CoCr head, and the Australian Department of Health-Therapeutic Goods Administration issued a Hazard Alert due to the increased risk of adverse events from potential taper lock failures associated with certain sizes and lots of the LFIT CoCr head.

The problem here, similar to the problem associated with the Stryker Rejuvenate and ABG II modular hip systems designated as Multi-County Litigations in Bergen County in January 2013, involves fretting and corrosion in the junction where the femoral head connects to the femoral stem of the hip-replacement device. Corrosion at this junction has led to the release of metal particles into surrounding tissue and bone, putting patients at risk of metallosis (a build-up of metal debris), necrosis (cell death), osteolysis (destruction of bone), and systemic issues associated with elevated cobalt and chromium levels in the blood. Any one of these issues can necessitate an invasive, painful revision surgery.

Additionally, the Stryker LFIT CoCr head has been associated with sudden, catastrophic disassociation from the femoral stem. Excessive corrosion at the head-neck junction can cause the femoral head to break off from the neck of the stem, depart from the acetabular cup and become loose in the body. Such catastrophic failures necessitate immediate revision surgery to replace the stem, neck and head components.

Stryker LFIT CoCr head litigation in New Jersey

The recall of this component will implicate multiple different hip implants. As noted above, some eighty-five (85) cases have already been filed in New Jersey state courts, with the rate of filings accelerating since Stryker's recall. No doubt many more cases will be filed in the weeks and months ahead. Many of the filed cases involve patients who have already had to undergo revision surgery to remove and replace the Stryker LFIT CoCr head and other components. My firm is presently reviewing approximately fifteen additional cases involving issues with the Stryker LFIT CoCr head.

Coordination is appropriate due to common issues with the same defective device.

Multi-County Litigation designation for mass tort cases is warranted when a large number of parties present claims with common, recurring issues of law and fact associated with the Stryker LFIT CoCr head. Additionally, there is geographical dispersment of parties, a high degree of commonality of injury; and a likely value interdependence among different claims. All of these considerations warrant MCL designation.

At least eighty-five cases have already been filed, and all involve the recurrent legal issues of design defect, failure to warn, breaches of warranties and the possibility of manufacturing defects. There are significant overlapping factual liability issues relating to the selection of the metal alloy utilized in the device, how it was cast or forged, the nature of the defect, any delay in recalling the device, failure to comply with good manufacturing practices, notice of metallurgical concerns in pairing CoCr with titanium alloys, the known risks of metallosis and fretting at taper junctions, and a host of other related factual issues. Separate discovery demands have been served in many of the cases, and an MCL would allow for efficiencies in discovery that would conserve the resources of the parties and the judicial system.

Bergen County is the most appropriate venue.

Per the current Mass Tort Guidelines and Criteria for Designation, questions of fairness, the locations of the parties and counsel, and the existing civil and mass tort caseload are considered in determining where to centralize the management of a mass tort case.

The previously-filed Stryker LFIT CoCr head cases are pending before the Hon. Rachelle Harz in Bergen County. Until the Hon. Brian Martinotti was appointed to the federal bench, he had presided over these cases. Indeed, on January 7, 2016, Judge Martinotti issued an order requiring counsel to complete a questionnaire identifying general case information, implant surgery information, revision surgery information and additional medical records information. Judge Harz is now presiding over these cases, as well as overseeing all MCLs in Bergen County, including the Stryker Rejuvenate and ABG II matters, which involve similar issues. Accordingly, the most logical and fair procedure for the litigants would be for these cases to remain in Bergen County before Judge

The Hon. Glenn A. Grant, J.A.D.

March 3, 2017

Page 4

Harz. Moreover, several cases involving the Stryker LFIT CoCr head have recently been filed in the United States District Court for the District of New Jersey, and assigned to Judge Martinotti. It is possible that Judge Martinotti could be assigned as the MDL Court overseeing all federal cases involving the Stryker LFIT CoCr head, facilitation coordination between the federal MDL and state MCL litigation.

Geographical location is another factor considered in selecting the venue in which to centralize a mass tort case. Bergen County is the best venue for the consolidation of the Stryker LFIT CoCr head cases. First, Stryker is headquartered in Mahweh, in northern Bergen County. This factor alone makes it more convenient than the other New Jersey counties available for MCL centralization.

The existing civil and mass tort caseload in the venue is also an important factor in selecting an MCL venue. According to the New Jersey Courts' website, seven (7) MCLs are pending in the Middlesex County Superior Court, four (4) MCLs are centralized in the Atlantic County Superior Court, including two recent assignments, and seven (7) MCLs are pending in the Bergen County Superior Court. It should be noted, however, that the Stryker Hip/ABG II litigation announced a global settlement in December 2016, and the resolution of that matter will reduce the Bergen County MCL caseload significantly.

Looking beyond the numbers, however, the Bergen County Superior Court has gained substantial expertise in addressing hip-replacement medical device cases in handling the prior Stryker hip cases. That court is familiar with the medical issues arising from metallosis issues from implanted CoCr hip devices and has an intimate knowledge of the regulatory processes involved in marketing and recalling such devices. Indeed, although my co-counsel's law firm is headquartered in the State of Georgia, we have selected Bergen County, given its prior success in overseeing MCLs involving other metal hip devices, as the best location for the seven (7) cases involving defective Stryker LFIT CoCr heads that we previously filed.

In light of all the factors discussed above, I respectfully join in the request that the New Jersey Supreme Court designate the Stryker LFIT CoCr head cases for MCL management in the Bergen County Superior Court.

Very truly yours,

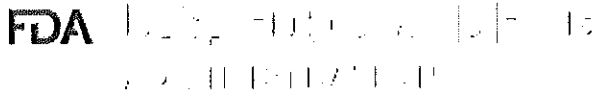


Clark P. Rosengarten
LEVY KONIGSBERG, LLP

Exhibit A

	<u>Plaintiff</u>	<u>Docket Number</u>
1	Thomas P. Arnold	BER-L-3832-16
2	Willie Butler	BER-L-3055-16
3	Joye M. Craven	BER-L-3832-16
4	Willie C. Green	BER-L-3055-16
5	Billy M. Lee, Sr.	BER-L-3055-16
6	Robert M. McConnell	BER-L-2073-16
7	Martha J. Reid	BER-L-3832-16

Exhibit B



[FDA Home](#)³ [Medical Devices](#)⁴ [Databases](#)⁵

Class 2 Device Recall Stryker LFIT Anatomic V40 Femoral Head



[510\(k\)](#)⁶ | [DeNovo](#)⁸ | [Registration & Listing](#)⁹ | [Adverse Events](#)¹⁰ | [Recalls](#)¹¹ | [PMA](#)¹² | [HDE](#)¹³ | [Classification](#)¹⁴ | [Standards](#)¹⁵ | [CFR Title 21](#)¹⁶ | [Radiation-Emitting Products](#)¹⁷ | [X-Ray Assembler](#)¹⁸ | [Medsun Reports](#)¹⁹ | [CLIA](#)²⁰ | [TPLC](#)²¹

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Class 2 Device Recall Stryker LFIT Anatomic V40 Femoral Head



Date Initiated by Firm	August 29, 2016
Create Date	November 09, 2016
Recall Status¹	Open ³ , Classified
Recall Number	Z-0378-2017
Recall Event ID	75246 ²³
510(K)Number	<u>K022077</u> ²⁴
Product Classification	<u>Prosthesis, hip, semi-constrained, metal/polymer, cemented</u> ²⁵ - Product Code <u>JD</u> 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 1/1/02 - 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. 325 Corporate Dr Mahwah NJ 07430-2006
For Additional Information Contact	Mr. Michael Van Ryn 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 Cause²	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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28. <http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm>
29. /scripts/cdrh/cfdocs/cfPMN/pmnm.cfm?start_search=1&productcode=JDI&knumber=&applicant=HOWMEDICA%20OSTEONICS%20CORP%2E

Page Last Updated: 03/02/2017

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March 6, 2017

VIA FEDERAL EXPRESS

The 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: *Reply to Howmedica Osteonics Corp.'s Response to Plaintiffs' Request for Multi-County Litigation Designation for HOC (Stryker) LFIT™ Taper Lock*

Dear Judge Grant:

I write in Reply to Howmedica Osteonics Corp.'s ("HOC") Response to Plaintiffs' Request for MCL Designation for HOC (Stryker) LFIT V40 Taper Lock Litigation, and to advocate for a Multi-County Litigation designation that consolidates all cases involving this device, in accordance with Rule 4:38A. HOC seeks to avoid an MCL altogether, or alternatively, to define it too narrowly. The MCL definition proposed by Plaintiffs – including all cases involving the HOC (Stryker) LFIT V40 head, is necessary to avoid confusion and manageability issues that would thwart the judicial efficiencies that the MCL process is specifically designed to foster.

First, HOC contends, incorrectly, that an MCL is unnecessary because the cases are already being informally coordinated before Judge Harz in Bergen County. That contention, however, ignores the realities that, absent formal coordination, LFIT V40 cases will be filed all over the State of New Jersey, with no formal consolidation possible. The result would be a waste of judicial resources, as similar cases, involving the same device, proceed through the discovery, motions and trial processes in multiple courts around New Jersey. Alternatively, multiple motions addressing venue issues would proceed in different New Jersey courts, with the likelihood that, while some courts might transfer venue to Bergen County, others would not, resulting in parallel proceedings seeking similar discovery, addressing similar motions, and likely reaching disparate results around the State.

The absence of an MCL would also render coordination between a federal court Multi-District Litigation (or MDL) and the cases pending in New Jersey haphazard, if not impossible, again

The Hon. Glenn A. Grant, J.A.D.

Reply Multi-County Litigation Designation for HOC (Stryker) LFITTM Taper Lock

March 7, 2017

Page 2

creating inefficiencies for the judicial systems and the parties, and likely precluding the ability of injured plaintiffs from being able to pursue their claims against HOC.

Second, HOC seeks to confine the MCL too narrowly, defining it to include only those LFIT V40 heads that have been recalled and those plaintiffs who have already suffered a catastrophic dissociation of the head from the femoral stem. Such a constricted MCL definition, however, would defeat the purposes of coordination, resulting in confusion, lack of manageability, and inefficiencies that would prevent injured plaintiffs from being able to seek – let alone obtain – judicial recourse.

That the Bergen County Court is already collecting data as to cases involving the HOC/Stryker LFIT V40 heads does not mean that coordination is inappropriate. Rather, it demonstrates that a single court – especially if coordination is formally ordered – has the ability to appropriately “class” cases involving the same device, to permit them to proceed together on a single track of coordinated discovery and case management, fostering the efficiencies that the MCL process envisions.

Indeed, HOC’s proposal for limited coordination would cause substantial inefficiencies. For example, the Bergen County Court would oversee an MCL and other individual cases, proceeding at different paces, substantially duplicating discovery efforts, increasing costs for all parties – not to mention the Court.

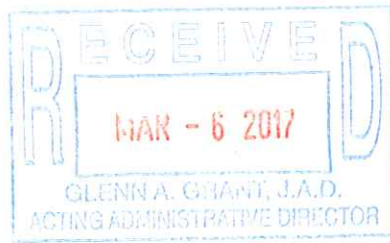
Finally, HOC’s overly-constrained MCL definition would result in confusion, delay and expense. Courts around New Jersey would struggle to evaluate whether a case should be transferred to the MCL or proceed where it was filed, and the MCL Court would have to screen all incoming cases, all based on the lot number of the specific device implanted and whether it was part of the recall (and which may not be known at the time of case filing) and the injury mode identified. Individual cases could be delayed for months while this process plays out, only to then start anew in their original courts.

In light of all the factors discussed in my March 3, 2017 correspondence and above, I respectfully join in the request that the New Jersey Supreme Court designate *all* Stryker LFIT CoCr head cases for MCL management in the Bergen County Superior Court, before Judge Rachelle Harz.

Very truly yours,



Clark P. Rosengarten
LEVY KONIGSBERG, LLP



March 6, 2017

BY HAND DELIVERY

Hon. Glenn A. Grant
Acting Administrative Director of the Courts
Attention: MCL Comments- HOC LFIT™ Taper Lock
Hughes Justice Complex, P.O. Box 037
Trenton, New Jersey 08625-0037

Re: Howmedica Osteonics Corp.'s Response to Request for Multicounty Designation of HOC LFIT™ V40™ Taper Lock Litigation

Dear Judge Grant:

Pursuant to the Court's February 6, 2017 Notice to the Bar, Howmedica Osteonics Corp. (incorrectly named as "Howmedica Osteonics Corp., a New Jersey corporation, d/b/a Stryker Orthopaedics") ("HOC") respectfully responds to Plaintiffs' "Request for Multi-County Designation of the HOC LFIT V40™ Taper Lock Litigation" ("Plaintiffs' Request").

I. Introduction

HOC objects to Plaintiffs' Request because it is both unnecessary and inconsistent with the underlying goals and benefits of centralization. A Multicounty Litigation ("MCL") designation is unnecessary as these matters already are being effectively coordinated in Bergen County, previously before Judge Martinotti and now before Judge Harz, in a way that appropriately distinguishes claims involving "taper lock failure" - or the dissociation of the head from the femoral stem to which it is "locked" - which was the subject of HOC's limited, voluntary recall of specific lots of LFIT V40 femoral heads in August 2016. Plaintiffs' proposed

Hon. Glenn A. Grant
March 6, 2017
Page 2

designation, however, improperly would include *any* claim involving *any* LFIT V40 femoral head, regardless of whether it was recalled, and regardless of the alleged failure mode or injury. That would create an unwieldy mass of disparate claims, inconsistent with both the manner in which the cases have been effectively managed to date and the goals of consolidation. Thus, should an MCL be considered by the Court, it should be defined to reflect a manageable scope consistent with those principles. In its broadest form, it would consist of only those cases involving *recalled* LFIT V40 femoral heads, but the most accurate form of an MCL would in fact consist only of those cases involving *recalled* LFIT V40 femoral heads *that exhibit taper lock failure*. If an MCL is designated, it should be assigned to Judge Harz in Bergen County.

II. Background

HOC is a worldwide market leader in total hip replacement products, offering a wide range of primary femoral hip components from which surgeons may select the most appropriate combinations. Total hip replacement systems generally consist of four primary components: (1) the acetabular cup; (2) the acetabular insert; (3) the femoral stem; and (4) the femoral head. The acetabular cup is implanted into the acetabulum (hip socket). The femoral stem fits in the femur (thigh bone). The femoral head and femoral stem mate via a “taper lock” (a connection that, upon impaction by the surgeon, firmly fastens the head to the neck of the femoral stem). The femoral head articulates with the acetabular insert, which is inserted into the acetabular cup.

Hon. Glenn A. Grant
March 6, 2017
Page 3

A. The LFIT V40 Femoral Head and the Voluntary Recall

The LFIT™ Anatomic CoCr V40™ femoral head (“LFIT V40 femoral head”), which has been marketed and sold since 2001, is one type of femoral head sold by HOC. It has demonstrated a long history of clinical success and continues to be implanted by surgeons today. This product is available in a variety of sizes and offsets¹ and a surgeon can mate the LFIT V40 femoral head with twenty different femoral stems offered by HOC. This stem/head combination can be used with a large variety of acetabular inserts and cups manufactured by HOC. The LFIT V40 femoral head is not a standalone product. It **must** be used with an entire hip replacement system containing different parts. Like all of HOC’s total hip replacement components, the LFIT V40 femoral head is a medical device that is regulated by the U.S. Food and Drug Administration (“FDA”) and can only be prescribed for use by a licensed healthcare provider.

As part of its ongoing post-marketing surveillance, HOC received several complaints describing incidence of harm secondary to taper lock failure of the femoral head to fully lock onto the stem at the stem-head taper junction, *i.e.*, “taper lock failure,” *for specific lots and specific head sizes of LFIT V40 femoral heads manufactured prior to March 4, 2011*. Taper lock failure can result in the head dissociating from the stem. As a result, on August 29, 2016, HOC sent an urgent medical device notification to its physician customers, alerting them to the issue and recommending that these physicians continue to follow their patients in accordance with

¹ The “offset” of a femoral head refers to the distance between the center of the femoral head and the mid-line of the femur.

Hon. Glenn A. Grant
March 6, 2017
Page 4

their normal protocol. On October 11, 2016, HOC sent an updated recall notification. On November 9, 2016, the FDA announced the voluntary product recall.

Notably, HOC's voluntary recall involved *less than one third of the different versions* of the LFIT V40 femoral head available, and for a specific timeframe, i.e., those manufactured prior to March 2011. Of critical importance is that the vast majority of recalled LFIT V40 femoral heads will function as intended.

B. LFIT V40 Femoral Head Cases in New Jersey

Currently, HOC is aware of a number of New Jersey state court lawsuits involving multiple and varied allegations, some of which involve recalled LFIT V40 femoral heads and, based upon the information already gathered by the Court, exhibited taper lock failure. All of these cases are pending in Bergen County and are assigned to and are being managed by Judge Rachelle L. Harz.² While HOC is also aware of a number of *other* lawsuits involving various combinations of hip components, including non-recalled LFIT V40 femoral heads, as demonstrated below, these cases do not involve common issues of fact and law, and should not be included if an MCL designation is ordered.

III. An MCL Designation is Unnecessary.

Centralization is unnecessary where the matters subject to the MCL request are already coordinated. All of the LFIT V40 femoral head actions that are the subject of Plaintiffs' MCL request -- and for that matter, every LFIT V40 femoral head action currently pending in New

² The referenced lawsuits were originally assigned to Judge Brian R. Martinotti. In July 2016, when Judge Martinotti was confirmed as a United States District Judge for the District of New Jersey, the cases were transferred to Judge Harz, who has actively handled them, as well as all new filings, since that time.

Hon. Glenn A. Grant
March 6, 2017
Page 5

Jersey state court -- are pending in Bergen County and are currently assigned to Judge Harz. Indeed, steps have already been taken to effectively coordinate these matters, including a Court order requiring case questionnaires to be completed by the parties for the then-pending cases to help define different and unique modes of injury specific to the LFIT V40 taper lock cases so that they could be properly grouped. Because the subject cases are all pending in one county before one judge and are already coordinated, an MCL is unnecessary and unwarranted.³

IV. If the Court Determines that an MCL in Some Form Is Necessary, Then Any MCL Should Be Appropriately Defined and Limited in Scope.

A. Plaintiffs' Proposed Scope of Centralization is Unwieldy and Unworkable.

A sweeping MCL designation for all cases in which an LFIT V40 femoral head was used in an HOC hip system, which is what Plaintiffs appear to request, would cause vast confusion, be unmanageable and unwieldy, and cancel out any potential benefits of coordination. Accordingly, in the event the Court designates an MCL, it should reject Plaintiffs' requested designation for *all* LFIT V40 femoral head cases in New Jersey.

As distinguished from other hip implant recalls, including the ABGII/Rejuvenate Modular litigation referenced in Plaintiffs' MCL request submission, the 2016 recall does not relate to *all* LFIT V40 femoral heads manufactured since the product's inception in 2001. Rather, it is limited to certain identified product lots and sizes that were manufactured during a specific

³ HOC has similarly objected to a request made by certain plaintiffs in federal court for the establishment of a federal multi-district litigation ("MDL") for cases involving LFIT V40 femoral heads. In response to the MDL request, HOC noted no objection to one District Court judge being assigned to similar cases filed *within a given federal district*, much like what has naturally occurred in the pending Bergen County, New Jersey cases.

Hon. Glenn A. Grant
March 6, 2017
Page 6

time period. And only very few of the LFIT V40 femoral heads in those recalled lots will ever experience taper lock failure. Accordingly, an overly broad designation to capture all New Jersey cases in which one of the implanted hip replacement components simply happens to be an LFIT V40 femoral head would result in an unmanageable and unwieldy litigation in which commonality is effectively lost. It also would lead to confusion about the overall status of the LFIT V40 femoral head and, consequently, the filing of numerous improper and unfounded lawsuits.

Some of the New Jersey LFIT V40 femoral head cases involve recalled heads that exhibited taper lock failure. Plaintiffs in those cases claim that a recalled LFIT V40 femoral head failed to completely lock onto the stem at the taper junction, causing the head to eventually dissociate from the stem altogether. It would be illogical and pointless to join those claims with cases involving a completely different situation in which an LFIT V40 head happened to be one of the hip implant components, but the mode of alleged failure was unrelated and involved a completely different component—e.g., a claim of acetabular cup loosening, or femoral stem fracture. It is accepted in the orthopaedic and scientific communities that one percent of all total hip arthroplasties will require revision unrelated to any product issues, and this revision rate increases with the number of years *in vivo*. Plaintiffs' requested designation would incorrectly capture cases involving varied and dissimilar issues of liability, causation, and damages focused on other components or combinations of components, merely because an LFIT V40 femoral head happened to be one of the several hip system components. *Cf. Hughes v. Stryker Sales Corp., et al.*, Civ. No. 08-0655-WS-N, 2010 WL 1961051, at *5 (S.D. Ala. May 13, 2010) (recognizing

Hon. Glenn A. Grant
March 6, 2017
Page 7

recall notice related to hip implant was insufficient to demonstrate causation because hip devices can fail for “innumerable possible reasons” that are “wholly divorced from, and independent of any defect that the device may have had”). Such a result would not accomplish the established goals of an MCL.

Moreover, even in cases where the component at issue is actually claimed to be the LFIT V40 femoral head, this fact, in and of itself, is not sufficient to achieve commonality for a workable MCL because there are many different and completely unrelated (and warned of) potential causes of femoral head failure that have nothing whatsoever to do with an alleged design or manufacturing defect. For example:

- A femoral head may remain affixed to the stem but dislocate from the acetabular cup. Dislocation could be related to head size, cup size, surgical technique, patient factors, or any number of other potential causal factors that have nothing to do with the taper lock issues in this litigation.
- A plaintiff might claim to have suffered osteolysis or other injury resulting from the articulation of the femoral head against the polyethylene insert.
- A plaintiff might claim that a femoral head was not properly sterilized, and therefore caused infection.
- Another plaintiff might claim allergic reaction to the cobalt chromium implant material.

Hon. Glenn A. Grant
March 6, 2017
Page 8

- Yet another plaintiff might claim that the normal corrosion process associated with any femoral head/stem modular junction construct caused some type of injury.

These are just some examples of completely different potential failure modes with different potential causes, all of which raise their own unique and complex set of issues and none of which belongs together in a coordinated litigation. However, all of these cases, and others, would be indiscriminately caught up in the overly broad MCL requested by Plaintiffs.

Given the inevitable and fundamental dissimilarities in the cases that would be lumped together, an MCL designation that simply captures all cases involving an LFIT V40 femoral head would be impossible to manage effectively. The litigation would become unwieldy as the Court's docket would likely be flooded with meritless cases filed by opportunistic (or simply confused) plaintiffs and attorneys, the vast majority of which would not share the taper lock failures involved in the recall, but rather would consist of "bandwagon" patients who were simply implanted with an LFIT V40 femoral head as part of their overall hip replacement system, regardless of actual injury. The unwieldiness of the litigation is a very real and legitimate concern given that the LFIT V40 femoral head is a popular and successful product that has been *on the market continuously since 2001 and remains on the market today.*

Not only would the criteria for centralization not be met if an MCL designation is granted for unlimited LFIT V40 femoral head cases, but centralization under such circumstances would actually reduce efficiency. Discovery would become bogged down and delayed because of the

Hon. Glenn A. Grant
March 6, 2017
Page 9

diversity of substantive issues involved in fundamentally different cases. As described above, completely different products could be the focus of the issues in any given case; and even cases in which the LFIT V40 femoral head is at issue would involve dissimilar failure modes and injuries. Many different tracks of discovery would need to be established on different timelines covering many different products, different categories of documents for the various products, different written discovery demands and responses, different fact and expert witnesses, and different issues for trial. This is precisely what an MCL is designed to *avoid*. Plaintiffs' Request for a sweeping MCL should be denied.

B. The Most Efficient MCL Designation Would Be Defined to Include Cases Involving Recalled LFIT V40 Femoral Heads *Exhibiting* Taper Lock Failure.

If the Court considers some form of MCL designation, then the problems discussed above can best be avoided if the MCL is appropriately defined to include only cases involving *recalled LFIT V40 femoral heads where the claims are for injuries relating to taper lock failure*. Such a sensibly limited and manageable scope of designation is the only potentially workable MCL designation that would satisfy New Jersey's criteria for centralization and capture a sufficient number of the existing case docket. Not only would the litigation be focused on the correct component, but unrelated issues and potential failure modes that do not belong together in litigation would be appropriately culled out. In fact, recognizing that not all LFIT V40 femoral head cases are the same, nor do they necessarily belong together, Judge Martinotti previously ordered case questionnaires to be completed by the parties to help define different and unique

Hon. Glenn A. Grant
March 6, 2017
Page 10

modes of injury specific to the LFIT V40 taper lock cases so that they could be properly grouped. His Order included the then-pending cases that are the subject of Plaintiffs' MCL request. Thus, Judge Martinotti recognized that these cases are not all similar, highlighting the importance of culling out failure modes unrelated to the recall in order to avoid confusion and facilitate manageability.⁴ Accordingly, if the Court deems an MCL designation appropriate, then defining the MCL to include only recalled LFIT V40 femoral heads involving claims relating to taper lock failure would also promote judicial efficiency and streamline the litigation.

C. If the Court Designates an MCL, It Should be Assigned to Judge Harz in Bergen County.

HOC agrees with Plaintiffs that if an MCL is established, then Judge Harz in Bergen County should preside over it. Judge Harz is uniquely qualified to manage an LFIT V40 Femoral Head Taper Lock MCL as she is familiar with the issues and the parties, having handled these very cases since July 2016. In fact, every one of the cases sought to be centralized is already pending before Judge Harz in Bergen County.

In addition, fairness, geographical location of parties and attorneys, and the existing civil and multicounty litigation caseload in Bergen County support venue there.⁵ As noted, every single case sought to be centralized has been brought by Plaintiffs in Bergen County, and

⁴ Plaintiffs may attempt to argue that some plaintiffs implanted with non-recalled LFIT V40 femoral heads allege similar injuries and should be included in an MCL. This argument is unpersuasive because the taper lock issues and the facts underlying the recall are exclusive to the recalled femoral heads manufactured prior to March 4, 2011. Opening an MCL up to non-recalled heads or to recalled heads without taper lock failure would inevitably lead to more and more disparate issues at the expense of commonality and manageability. Also, it should be noted that the cases involving non-recalled LFIT V40 femoral heads are all currently assigned to Judge Harz and can continue to be separately managed and coordinated as necessary by Judge Harz, outside of an MCL.

⁵ See Multicounty Litigation Guidelines and Criteria for Designation, Directive #08-12 (Aug. 7, 2012)

Hon. Glenn A. Grant
March 6, 2017
Page 11

Plaintiffs themselves have requested a Bergen County venue for an MCL. Moreover, HOC is headquartered in Mahwah, in northern Bergen County. The vast majority of corporate witnesses and documents are located there, and it is where many of the products at issue are manufactured. Thus, the discovery that would be relevant to common questions of fact would be centered in Bergen County. Bergen County also is in close proximity to regional and international airports and is near to the New York City metropolitan area, making it convenient to all counsel.

Bergen County is well-positioned to handle an MCL from a case load perspective. As Plaintiffs point out in their submission, most of Bergen County's seven multicounty litigations are winding down. The fact that the very cases sought to be centralized here are already being handled in Bergen County also clearly demonstrates the ability of the vicinage to handle the litigation. In fact, in a very real sense, an MCL presided over by Judge Harz in Bergen County would simply formalize the existing litigation structure, while ensuring that any cases within the scope of the MCL eventually filed outside of Bergen County will also be managed by Judge Harz.

V. Conclusion

For the reasons set forth above, HOC objects to Plaintiffs' request for an MCL relating to all LFIT V40 femoral head cases. However, if the Court grants an MCL, then in its broadest form, it should consist of only those cases involving *recalled* LFIT V40 femoral heads, but the most accurate form of an MCL would consist only of those cases involving *recalled* LFIT V40 femoral heads *that exhibit taper lock failure*. Finally, HOC agrees that if Plaintiffs' request for

Hon. Glenn A. Grant
March 6, 2017
Page 12

an MCL is granted, then it should be assigned to Judge Rachelle Harz in Bergen County, New Jersey, where the matters are currently pending.

Respectfully submitted,



Kim M. Catullo

cc: Taironda E. Phoenix, Esq., Chief, Civil Court Programs
The Honorable Rachelle L. Harz
Ellen Relkin, Esq.

CIVIL

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March 14, 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 otherwise referred to as In Re: Stryker LFIT V40 Femoral
Head Products Liability Litigation**

Dear Judge Grant:

I am writing in response to Howmedica Osteonic Corp.'s Response to Request for Multicounty Designation of HOC LFIT™ V40™ Taper Lock Litigation. As counsel for Howmedica Osteonic Corp. filed a response objecting to Multicounty designation of these cases on the last possible day of the comment period, I hope you will consider this response although the comment period has now passed.

Counsel's response somewhat mischaracterizes the status of the cases pending in Bergen County as well as the scope of the cases in which plaintiffs seek designation of a Multicounty Litigation (MCL), the mechanisms of failure associated with the V40 device, and the types of injuries sustained such that a reply is warranted.

I. Multicounty Litigation or Centralized Designation is Necessary and Warranted

While the cases were informally coordinated before Judge Martinotti and now before Judge Harz, plaintiffs maintain that such coordination is not sufficient and will require formal coordination as an MCL or a Centralization. First and foremost, the ordinary discovery end dates (DED) are a problem given the shorter time frames for non-MCL cases and the fact that there are multiple cases with varying DED's. Additionally, since there is no formal MCL or Centralization, when a new case is filed, it would not be subject to the same discovery or scheduling orders unless there is an MCL or Centralization. Numerous additional cases have been filed since the initial MCL request was submitted.

Further, up until the present, defendant was very persuasive in avoiding substantial discovery obligations urging that their time and resources were best devoted to resolving the related Stryker Rejuvenate litigation involving several thousand cases before Judge Martinotti, and the second wave of settlements that just resolved hundreds of more cases pending before Judge Harz. While the resolution of the vast number of cases is commendable, Stryker received great latitude in discovery compliance and the plaintiffs at issue in this petition are still waiting for progress in their cases. Thus, the time has come for Stryker to meaningfully respond to long outstanding discovery requests served in the many separate cases, and a coordinated discovery plan should commence as part of an MCL.

Further, since an MDL is likely to be formed by the Judicial Panel on Multi-District Litigation, there should be one MCL that can efficiently coordinate well with the MDL since inevitably; Stryker will seek to cross-notice the depositions of their witnesses in both the MCL and the MDL.

The lack of discovery progress and the setting of trial dates of the approximately 100 cases involving the LFIT V40 femoral heads and the standard accompanying stems (typically Accolade I or II, Meridian and Citation) is due to the lack of a centralization or MCL treatment. Further, there was the natural transition period from when Judge Martinotti left for federal court to when Judge Harz took over his challenging and complex docket, and since these cases were not specially denominated, they were not on a list of MCL's assigned to Judge Harz and thus there has not yet been a status conference. In fact, I asked defense counsel to agree to jointly request a status conference and was told that it was premature in light of the pending MCL application.

It is simply too chaotic to not have these cases formally assigned and managed. While plaintiffs disagree with defendant's hair splitting about which cases ought to be consolidated in an MCL, they certainly could advance those arguments within the MCL to suggest differing treatment within the litigation, and plaintiffs will present evidence why the similarities prevail.

II. Multicounty Designation of HOC LFIT™ Taper Lock Litigation Should Include All Cases Involving a Cobalt- Chromium LFIT V40 Femoral Heads

Plaintiffs solely seek designation of a MCL for cases involving cobalt-chromium LFIT V40 femoral heads. Counsel for Howmedica Osteonic Corp. d/b/a Stryker Orthopedics is correct in that in addition to the cobalt-chromium LFIT V40 femoral heads, they also sell ceramic LFIT V40 femoral heads. However, it is believed that the cases already in suit in Bergen County only

involve cobalt-chromium femoral heads. The primary basis for the litigation is the problematic fretting and corrosion interaction of the cobalt chrome heads in the taper junction (also referred to as trunnion or taper lock) connecting the head to the adjacent titanium neck/stem piece. In the unlikely event there are any cases in suit that do not involve the cobalt-chromium LFIT V 40 femoral head, then the undersigned agrees that they should not be included in the MCL.

Furthermore, the scope of the litigation should not be limited to the cobalt-chromium LFIT V40 femoral heads subject to Howmedica's inadequate recall notice. Plaintiffs in the cases currently pending underwent revision surgery of the LFIT Anatomic cobalt-chromium V40 femoral head due to corrosion at the head-neck junction (trunnionosis) from implantation with a titanium femoral stem and generally also elevated cobalt levels and tissue damage from adverse reaction to the metal debris.

While Stryker did not recall all sizes and lots of the cobalt-chromium LFIT V40 femoral head, cases filed involving revision of non-recalled LFIT V40 components have exhibited virtually identical evidence of corrosion at the head-neck junction and involve the same exact problem with other LFIT V40 femoral heads that for whatever reason did not make the narrowly defined recall list—*at least at this point in time*.

For example, Martin Parsons - BER-L-009394-14, was implanted with a cobalt-chromium LFIT V40 femoral head and Stryker Accolade TMZF Plus hip stem on May 3, 2007. He developed pain and elevated cobalt blood ion levels, and had revision surgery on May 24, 2013. During this revision, his surgeon found, "gross black debris" within the head where the trunnion inserts, and "determined that the trunnion metallosis was the likely cause of the pseudotumor." Furthermore, he noted "necrosis debris was evident at the junction of the head and the femoral stem ... confirmed gross black material in the bore of the head and adherent to the trunnion." Similarly, Nancy Anderson - BER-L-003322-16 - was implanted with a cobalt-chromium LFIT V40 femoral head and Stryker Accolade TMZF Plus hip stem on October 6, 2011. Prior to her revision surgery on November 13, 2015, she had an elevated level of cobalt. During the revision surgery, her surgeon noted "extensive corrosion between cobalt chrome femoral and titanium Accolade TMZF hip stem," and "Extensive necrosis of posterior capsule, rotators, gluteus medius and minimus, quadrature femoris." Lastly, Linda Martin - BER-L-000447-17 - was implanted with a cobalt-chromium LFIT V40 femoral head and Accolade II hip stem. Blood testing revealed elevated cobalt ion levels and an ultrasound discovered a pseudotumor. She underwent revision surgery on September 21, 2015 during which her orthopedist noted, "There was gross evidence of trunnion corrosion, roughly 20% to the gluetus medis was involved... There was extensive tissue necrosis noted deep." These examples of cases with *non-recalled* cobalt-chromium LFIT V40 femoral heads clearly demonstrate the commonality of injuries and damages of cases involving recalled and non-recalled cobalt-chromium LFIT V40 femoral heads. Both the recalled and unrecalled models can cause massive corrosion tissue damage and tissue necrosis (death), among other problems. Thus, the MCL should not be limited solely to cases involving a recalled cobalt-chromium LFIT V40 femoral head.

Counsel for Howmedica argues that Multi-County designation would incorrectly apply to any case involving an LFIT V40 head despite the mechanism of failure and also seeks to limit the type of failure to case of dramatic disassociation. The cases filed involve the problem of

fretting and corrosion in the junction where the femoral head connects to the femoral stem. Corrosion at this junction has led to disassociations which is the end state of corrosion whereby the metal so erodes that the head falls out of the taper junction. However, prior to that “catastrophic failure” as it is described in the medical literature, the corrosion also leads to tissue and bone damage from metallosis as well as elevated levels of cobalt and chromium in the blood thus requiring patients to undergo revision surgery to remove the defective device. The disassociations typically occur at around year 8 while the earlier revisions for tissue damage or elevated ions are generally closer to the time of implantation.

While it is unlikely that cases would be filed alleging some other mechanism of failure, a question of causation is not grounds for denial of an MCL petition or imposing limits on which cases would be eligible for inclusion. For example, in granting the petition to designate the Stryker Rejuvenate Hip Stem and the ABG II Modular Hip Stem components as an MCL, the order does not lay out specific criteria for inclusion in the MCL beyond implantation of the components at issue. It will be within the trial judge’s discretion to further manage and classify any meaningful differences.

The differences in the cases are over-exaggerated by counsel for Howmedica, and MCL designation would not delay or bog down discovery. Counsel’s attempt to rely on the order issued by Judge Martinotti as a means of “culling out failure modes unrelated to the recall in order to avoid confusion and facilitate manageability” is a misrepresentation of the nature of this order. First, this order was issued prior to Howmedica’s recall of the device. Secondly, the questionnaire asks for basic information about the case such as the type of device implanted, date of implantation, date of revision, and names of physician as well as the hospital where the surgeries were performed etc. Plaintiffs are not asked to explain how the device failed, and the information requested is no different than a standard preliminary disclosure form required in most MCLs. Therefore, despite Howmedica’s argument that the differences among cases are too great to warrant MCL designation, inclusion of cases involving the cobalt-chromium LFIT V40 femoral head all involve recurrent issues of law and fact as set for in the Multicounty Litigation Guidelines.

Conclusion

For the reasons stated above, it is respectfully request that the Multicounty Designation be granted.

Respectfully submitted,

/s/ Ellen Relkin

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)

Civil

March 17, 2017

VIA HAND DELIVERY

Hon. Glenn A. Grant
Acting Administrative Director of the Courts
Attention: MCL Comments- HOC LFIT™ Taper Lock
Hughes Justice Complex, P.O. Box 037
Trenton, New Jersey 08625-0037



Re: Howmedica Osteonics Corp.'s Response to Request for Multicounty Designation of HOC LFIT™ V40™ Taper Lock Litigation

Dear Judge Grant:

Late on the evening of March 15, 2017, Plaintiffs served Howmedica Osteonics Corp. (“HOC”) with a letter (incorrectly dated March 14th) purporting to reply to HOC’s Response to Plaintiffs’ “Request for Multi-County Designation of the HOC LFIT V40™ Taper Lock Litigation” (“Initial Response”), which was timely served by HOC ten (10) days earlier. Plaintiffs’ attempt to supplement *their own request* for Multicounty Litigation (“MCL”) should not be considered because it is untimely, not permitted under the Court’s Guidelines and factually incorrect as follows:

- Plaintiffs still have not provided any valid reason why Judge Harz, who is already assigned to *all* of the pending New Jersey cases involving LFIT V40 femoral heads, cannot continue her current management and coordination of those cases outside of an MCL structure.
- Contrary to Plaintiffs’ misrepresentation, Judge Martinotti’s case management order, which required questionnaires to be completed by the parties (including certain medical records), was clearly a case management tool designed to help define and group the different and unique modes of injury specific to the LFIT V40 taper lock cases.
- Plaintiffs fail to grasp and flatly ignore the important distinction between recalled heads that exhibit taper lock failure and non-recalled heads. Plaintiffs conflate normal corrosion known to occur with all hip implants, regardless of

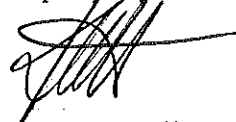
Hon. Glenn A. Grant
March 17, 2017
Page 2

manufacturer, with the different and specific phenomenon involved in the limited LFIT femoral head recall for limited specific sizes, lots and date range.

- Plaintiffs fail to distinguish between a recall that involves an entire product line (such as ABG II Modular and Rejuvenate Modular) and the LFIT V40 femoral head voluntary recall, which is limited in scope and involves only certain sizes and lots manufactured within a finite date range that ended in 2011.

For these reasons, and the reasons set forth in its Initial Response, HOC objects to Plaintiffs' request for an MCL covering all LFIT V40 femoral head cases, regardless of claimed injury, alleged failure mode or, importantly, whether recalled or not. MCL treatment is not necessary or appropriate given the prior background and existing management of these cases, but even accepting Plaintiffs' arguments, any MCL would properly include only those cases involving *recalled* LFIT V40 femoral heads *that exhibit taper lock failure, or at an absolute maximum those cases involving recalled products.*

Respectfully submitted,



Kim M. Catullo

cc: Taironda E. Phoenix, Esq., Chief, Civil Court Programs
The Honorable Rachelle L. Harz
Ellen Relkin, Esq.

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April 5, 2017

VIA FEDERAL EXPRESS

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

Civil Practice Division

APR - 6 2017

RECEIVED

*Re: Request for Multi-County Designation of HOC LFit™ Taper Loc
Litigation*

Dear Judge Grant:

I am writing with regard to the above-captioned application for a Multi-County designation to advise that an MDL, (Multidistrict Litigation), was granted today by the Judicial Panel on Multidistrict Litigation and that the litigation was sent to District of Massachusetts in Boston.

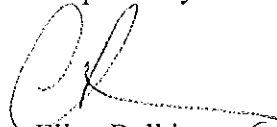
This is also to advise that at controversy before the JPML Panel was the title and scope of the litigation and the Panel decided to title the litigation, *In Re: Stryker Orthopaedics LFit V40 Femoral Head Products Liability Litigation* for the reasons set forth in the attached Transfer Order. I respectfully suggest that if the MCL is to be granted that the same title and scope used by the MDL be utilized to avoid any confusion (even though I had submitted the above-captioned title). For the reasons set forth in the opinion, I believe that *In Re: Stryker Orthopaedics LFit V40 Femoral Head Products Liability Litigation* is more appropriate. While

Ms Relkin is admitted in New York, New Jersey, Pennsylvania and the District of Columbia, and also affiliated with the following office:

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Howmedica has opposed the need for an MCL, they do agree that the cases belong before Judge Harz.

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)

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: STRYKER ORTHOPAEDICS LFIT V40
FEMORAL HEAD PRODUCTS LIABILITY
LITIGATION

MDL No. 2768

TRANSFER ORDER

Before the Panel: Plaintiffs in an action in the District of Massachusetts (*O'Hare*) move under 28 U.S.C. § 1407 to centralize pretrial proceedings in the District of Massachusetts or, alternatively, the District of Minnesota. These cases concern alleged defects in Stryker-branded LFIT Anatomic CoCR V40 femoral heads, a prosthetic hip replacement device. Plaintiffs' motion includes the six actions listed on Schedule A, which are pending in three districts. Since plaintiffs filed this motion, the parties have notified the Panel of 27 additional potentially related actions.¹

Defendant Howmedica Osteonics Corp. (HOC) opposes centralization and, as an alternative, suggests selection of the District of New Jersey or, alternatively, the Southern District of New York as the transferee district. HOC also prefers that the litigation be retitled "*In re: HOC LFIT V40 Taper Lock Litigation.*"

All responding plaintiffs support centralization. Plaintiffs in the District of Massachusetts *D'Orlando* and *Driscoll* potential tag-along actions support the motion in its entirety, while plaintiff in the District of Massachusetts *McCooe* potential tag-along action supports centralization in the District of Massachusetts. Plaintiffs in the Southern District of Indiana *Layne* action and five potential tag-along actions support centralization in the District of Minnesota. Plaintiffs in the District of Minnesota *Smith* action, as well as plaintiffs in three potential tag-along actions, support centralization in the District of Minnesota or, alternatively, the District of New Jersey. Plaintiffs in four District of New Jersey potential tag-along actions seek centralization in that district or, alternatively, the District of Minnesota. Finally, plaintiffs in a Middle District of Georgia action support centralization in that district.

After considering the argument of counsel, we find that the actions in this litigation involve common questions of fact, and that centralization in the District of Massachusetts will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation. All actions involve common factual questions about alleged defects in HOC's Stryker-branded LFIT Anatomic CoCr V40 femoral heads. On August 29, 2016, Stryker issued a voluntary recall of certain

¹ These actions, and any other related actions, are potential tag-along actions. See Panel Rules 1.1(h), 7.1 and 7.2. It appears that the Panel was erroneously notified of two actions, which do not involve an LFIT V40 device; such actions will not be placed on a conditional transfer order.

- 2 -

lots of the device manufactured before March 2011, due to harm secondary to failure of the femoral head to fully lock onto the stem at the stem-head taper junction, i.e., “taper lock failure.” Plaintiffs’ claims focus on the performance of the LFIT V40 cobalt-chromium device, in particular the alleged propensity of the device to cause corrosion at the taper junction when paired with femoral stems made from different alloys (such as HOC’s proprietary TMZF, which is an alloy of titanium, molybdenum, zirconium and iron). This corrosion allegedly leads to failure of the implant or other serious health consequences and necessitates surgery to remove and replace the implants. Centralization will avoid duplicative discovery on such complex issues as the design, testing, manufacturing, and marketing of the LFIT V40 cobalt-chromium femoral head device and related motion practice. Centralization is consistent with our past decisions in other similar hip implant dockets. *See, e.g.*, MDL No. 2441 – *In re: Stryker Rejuvenate and ABG II Hip Implant Products Liability Litigation*; MDL No. 2391 – *In re: Biomet M2a Magnum Hip Implant Prods. Liab. Litig.*

HOC opposes centralization on the grounds that there are only a few actions, informal cooperation is workable, and centralization will prove inefficient given the wide variety of combinations (stem type, different lengths and offsets) with which their modular femoral head product can be employed. We are not persuaded by these arguments. There already are a significant number of pending cases: 33 cases are pending in seventeen different districts, with at least eight groups of what appears to be competing plaintiffs’ counsel involved.

Without a doubt, there will be some individualized factual issues in each action, but these issues do not at this early stage of litigation negate the efficiencies to be gained by centralization. That a number of different combinations of sizes and types of stems can be employed with the modular LFIT V40 device is not an insurmountable barrier to centralization. Indeed, such arguments could be applied to many prior hip implant MDL dockets involving allegedly problematic metal-on-metal articulation. We have previously stated that “[a]lmost all personal injury litigation involves questions of causation that are plaintiff-specific. Those differences are not an impediment to centralization where common questions of fact predominate.” *In re: Xarelto (Rivaroxaban) Prods. Liab. Litig.*, 65 F. Supp. 3d 1402 (J.P.M.L. 2014). In addition to the specific causes of the failure of each plaintiff’s device, the cases now before us implicate numerous common issues concerning the development, manufacture, testing, regulatory history, promotion, and labeling of the LFIT V40 cobalt-chromium femoral head. We note, though, that the transferee judge might find it useful, for example, to establish different tracks for the different femoral stems that can be mated with the LFIT device.

Defendant requests that the MDL title of *In re: Stryker Orthopaedics LFIT V40 Femoral Head Products Liability Litigation* be changed to *In re: HOC LFIT V40 Taper Lock Litigation*. We will eliminate “Orthopaedics” from the title, as Stryker Orthopaedics appears to be a predecessor of defendant HOC, but we decline to change “Stryker” to “HOC,” because defendant marketed the device to physicians under the Stryker brand name. We also decline to change the title to add “taper lock” to the litigation caption or to limit the scope of the MDL only to recalled devices. Few plaintiffs specifically recite “taper lock” as an issue – they instead mention the specific problems they experienced, such as those listed as potential hazards listed in the recall notice (e.g., excessive

- 3 -

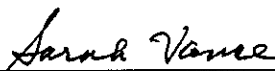
metal debris, disassociation of the head from the stem/failure, trunnion fracture) and other related descriptions, such as corrosion at the femoral head and stem junction. Since plaintiffs allege that all LFIT V40 devices are substantially similar (whether recalled or not) and experience similar problems, claims regarding non-recalled devices should be included in the MDL.

While any number of the parties' proposed transferee districts would be suitable, we are persuaded that the District of Massachusetts is the appropriate transferee district for this litigation. Five LFIT V40 cases in the District of Massachusetts are pending before Judge Indira Talwani, who has not yet had an opportunity to preside over an MDL docket. Boston offers an accessible transferee forum for this litigation, which involves a product that was distributed nationwide. Moreover, the District of Massachusetts is relatively close to HOC's Mahwah, New Jersey headquarters, where relevant documents and witnesses may be found.

IT IS THEREFORE ORDERED that the actions listed on Schedule A and pending outside of the District of Massachusetts are transferred to the District of Massachusetts and, with the consent of that court, assigned to the Honorable Indira Talwani for coordinated or consolidated pretrial proceedings;

IT IS FURTHER ORDERED that the caption of this litigation shall be changed to "In re: Stryker LFIT V40 Femoral Head Products Liability Litigation."

PANEL ON MULTIDISTRICT LITIGATION



Sarah S. Vance
Chair

Charles R. Breyer
Lewis A. Kaplan
R. David Proctor

Marjorie O. Rendell
Ellen Segal Huvelle
Catherine D. Perry

**IN RE: STRYKER ORTHOPAEDICS LFIT V40
FEMORAL HEAD PRODUCTS LIABILITY
LITIGATION**

MDL No. 2768

SCHEDULE A

Southern District of Indiana

LAYNE, ET AL. v. HOWMEDICA OSTEONICS CORPORATION,
C.A. No. 1:16-03350

District of Massachusetts

O'HARE, ET AL. v. HOWMEDICA OSTEONICS CORP., ET AL.,
C.A. No. 1:16-11510
D'ORLANDO v. HOWMEDICA OSTEONICS CORP., ET AL., C.A. No. 1:16-12253
DRISCOLL v. HOWMEDICA OSTEONICS CORP., ET AL., C.A. No. 1:17-10057

District of Minnesota

BELISLE v. HOWMEDICA OSTEONICS CORPORATION, C.A. No. 0:16-02881
SMITH, ET AL. v. HOWMEDICA OSTEONICS, ET AL., C.A. No. 0:16-03897