BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: STRYKER LFIT V40 FEMORAL HEAD PRODUCTS LIABILITY LITIGATION

MDL Docket No.: 2768

NOTICE OF POTENTIAL TAG-ALONG ACTIONS AND INTERESTED PARTY RESPONSE TO PLAINTIFF O'HARE'S TRANSFER MOTION

Oral Argument Requested

Notice of Tag-Along

The undersigned counsel represents tag-along Plaintiffs *Segerstrom*[1] *and Proue*[2] in their recently-filed cases against Howmedica Osteonics d/b/a/ Stryker Orthopaedics, Stryker Corp. and Stryker Ireland Limited ("Stryker") arising from failure of Stryker's LFIT V40 metal femoral components. A schedule referencing these actions is attached as Exhibit A and copies of the complaint face pages are attached as Exhibits B and C. Both of these cases are filed in the Western District of Wisconsin. Having reviewed the papers in other actions referenced in the Motion to Transfer, other Interested Party Responses and Defendant's Response to O'Hare's Motion to Transfer, two things appear clear. Respondents' cases qualify as tag-alongs, and all federally filed Stryker LFIT V40 failure cases should be transferred and consolidated to promote efficiency, consistency and economy.

Transfer and Coordination is Justified

Since 2010, the medical device industry has come under intense regulatory, scientific and legal scrutiny due to metal wear disease (Adverse Local Tissue Reaction or "ALTR") induced hip

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[1] *Steven M. Segerstrom and Beth A. Segerstrom v. Howmedica Osteonics d/b/a Stryker Orthopaedics, Stryker Corp. Stryker Sales Corporation and Stryker Ireland,* Case: 3:17-cv-00080 (WDWS)

[2] *Ardis M. Proue and Edward F. Proue v. Howmedica Osteonics d/b/a Stryker Orthopaedics, Stryker Corp. Stryker Sales Corporation and Stryker Ireland,* Case: 3:17-cv-00079 (WDWS)

implant failures. As a result, virtually every major manufacturer, including Defendant, issued either recalls or market withdrawals. Uniformly, patients in whom those products were implanted suffered from excessive metal wear debris, adverse tissue reaction, loss of mobility, inflammatory response and the need for premature removal of the offending device. Each of those recalls/withdrawals presented common issues of fact subject to discovery and therefore were found to justify transfer and coordination under 28 U.S.C § 1407.[3] Coordination has resulted in global settlements in all but one of those MDLs.

In the summer of 2016, Stryker issued a new voluntary recall of 44,000 metal LFIT V40 femoral heads. The femoral head is a common component in modular artificial hip replacement systems. Affixed to the femoral stem by means of a Morse taper, the head and stem together form the "leg side" once implanted into the femur. On the opposite side, a shell and liner are implanted into the acetabulum or hip bone. When combined, these four parts comprise a total hip replacement.

Stryker's new LFIT V40 metal head recall closely follows both temporally and factually its 2012 recall of the Rejuvenate and ABG II hip implants. In contemporaneous recall documents, Stryker warned in 2012 that the combination of its modular chromium/cobalt neck with its proprietary TMZF titanium alloy stem led to premature failure due to fretting and corrosion at the modular junction between the neck and stem.[4] Fretting and corrosion at the connection point between these metal components caused metal wear toxicity (ALTR) and the need for premature, unnecessary removal and replacement of the implants.

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[3] IN RE: DePuy Orthopaedics, Inc. ASR Hip Implant Products Liability Litigation (MDL 2197); IN RE: DePuy Orthopaedics, Inc. Pinnacle Hip Implant Products Liability Litigation (MDL 2244); IN RE: Zimmer Durom Cup Products Liability Litigation (MDL 2158); IN RE: Biomet M2A Magnum Hip Implant Products Liability Litigation (MDL 2391); IN RE: Wright Medical Technology, Inc., Conserve Hip Implant Products Liability Litigation (MDL 2329); IN RE: Stryker Rejuvenate and ABG II Hip Implant Products Liability Litigation (MDL 2441).

[4] A copy of Stryker's 2012 recall notice is attached as Exhibit D.

In its current recall[5], Stryker reveals its LFIT V40 chromium/cobalt metal head poses a safety hazard as evidenced by a higher than expected number of complaints of "taper lock failure" at the connection between the head and stem. Echoing hazards previously disclosed in its earlier Rejuvenate and ABG II recalls, Stryker once again warns that its metal heads can cause excessive wear debris, adverse local tissue reaction (ALTR), inflammatory response, dislocation and necessitate revision surgeries to alleviate hazardous situations. Medical literature suggests that the vast majority of these Stryker metal head failures occur with Stryker's TMZF titanium alloy stems, including the Accolade stem.[6] In essence, these new metal head failures and the resulting recall involve predominantly the same Morse taper locking combination of metals (TMZF and chrome/cobalt) as did the Rejuvenate and ABG II recalled products. In fact, the Rejuvenate, ABG II and LFIT V40 devices fail in exactly the same way just at a different location.

Defendant's attempts to distinguish its Rejuvenate and ABG II recalls from its current recall are unpersuasive. A side-by-side comparison of Defendant's 2012 and 2016 recalls (Exhibits D and E) reveals there to be far more similarities than dissimilarities. Both involve failure due to fretting and corrosion at a modular taper connection involving two parts made of dissimilar metals. In addition, the injuries and consequences for the patient are identical.

Far more troubling however, is the undue emphasis Stryker places on the LFIT V40 recall by suggesting its metal head failure problem is limited to the recalled devices. Nothing could be farther from the truth. In fact, patients are experiencing metal wear disease failures across Stryker's

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[5] A copy of Stryker's 2016 recall notice is attached as Exhibit E.

[6] Cook, Richard B., et.al., *Pseudotumor Formation Due to Tribocorrosion at the Taper Interface of Large Diameter Metal on Polymer Modular Total Hip Replacements,* Journal of Arthroplasty (2013); Craig, P. *Raised Levels of Metal Ions in the Blood in Patients Who Have Undergone Uncemented Metal-on-Polyethylene Trident-Accolade Total Hip Replacement, Bone Joint,* J. 2014;96-B:43-7 (2014); Kiran, M., *Adverse Reactions to Metal Debris in Metal-on-Polyethylene Total Hip Arthroplasty Using a Titanium-Molybdenum-Zirconium-Iron Alloy Stem,* Journal of Arthroplasty 30 (2015) 277-281.

LFIT V40 metal head line. Compelling evidence of this fact exists not only in the previously cited medical literature but more persuasively by the very cases before the courts and this Panel. Respondent *Segerstrom* and another tag-along *Smith*[7] suffered metal wear disease and revision surgery after implantation of a non-recalled LFIT V40 head and Accolade stem.

Although amounting to 44,000 units, Stryker's recall is for a limited subset of the total number of LFIT V40 heads currently implanted in patients. No LFIT V40 heads manufactured after 2011 are recalled.[8] Additionally, a limited number of head sizes with limited offsets are recalled.[9] From the early 2000's to present, the company's LFIT V40 product line has included a multitude of heads that do not qualify for the recall. The undersigned currently represents numerous patients who have undergone revision surgery due to extensive metal wear induced tissue damage who had *non-recalled* LFIT V40 heads. Some of those Plaintiffs have heads manufactured after 2011. Some are less than 36 mm. or have less than +4 offsets. Various responders have pointed to other filed cases involving non-recalled heads.

There is essentially no difference between the recalled LFIT V40 heads and non-recalled heads. First, there was no redesign of the heads in 2011. Why a head manufactured in 2010 is defective and the very same head with the exact same specifications, taper, alloy and design manufactured in 2012 is not will certainly be the subject of discovery in every failed LFIT V40 case.

While LFIT V40 heads vary in size, every head is the same alloy and has exactly the same taper angle for engagement and fixation. Every LFIT V40 head is impacted onto every Stryker

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[7] See: *Smith v. Stryker*; CASE 0:16-cv-03897-DWF-FLN currently pending before Judge Donovan Frank in the District of Minnesota.
[8] *Segerstrom's* LFIT V40 head was implanted in 2013.
[9] *Smith's* LFIT v40 was implanted before 2011 but is not recalled because it has a 0 offset.

femoral stem in the exact same way and each fits on every one of those stems exactly the same irrespective of the stem's size, alloy, shape or brand name. Once implanted all LFIT V40 heads serve the same purpose and are designed to fulfill the same function.

Defendant suggests to the court that the presence of non-recalled heads within the group of filed cases mitigates against transfer and consolidation, proposing that the failures are somehow dissimilar and pose too many "individual issues." Quite the opposite is true. The presence of cases involving non-recalled heads alleged to have failed exactly like the recalled heads suggests a problem with the *entire* product line. This is further supported by the previously-cited medical literature. It is Plaintiffs' position that this litigation is about much more than the limited number of heads Stryker chose to recall. For the sake of efficiency, consistency and economy any transfer and coordination should include all of the Stryker products within the same product line when the same design defects and failure mode have been alleged.

Defendant further attempts to suggest that if transfer and consolidation are found to be warranted the scope of the proceedings should be limited to recalled heads only. That would be manifestly unjust to those injured by non-recalled heads. Stryker's recall was voluntary, self-initiated and self-defined. This was not a Class I, FDA mandated recall. As such, Stryker should not be allowed to escape efficient, coordinated inquiry into failures of its LFIT V40 product line by self-limiting the scope of its recall. It would likewise be illogical and wasteful to have individual, non-recalled head cases proceeding on separate but parallel tracks in multiple federal jurisdictions concurrently with a limited-scope consolidated federal action. Each would be seeking identical discovery regarding the design, manufacture, marketing and post-market surveillance of the LFIT V40 product line simultaneously. The very purpose to be served by 28 U.S.C. §1407 transfer is, "to eliminate duplication in discovery, avoid conflicting rulings and schedules, reduce

litigation costs, and save the time and effort of the parties, the attorneys , the witnesses, and the courts." Manual for Complex Litigation (Fourth) §10.131 (2004) (citing *In re Plumbing Fixture Cases,* 298 F. Supp. 484 (J.P.M.L 1968)).

In summary, should this Honorable Panel see fit to order transfer and coordination as Respondents advocate, the proceedings should cover *all* Stryker LFIT V40 metal heads and not just the limited number Stryker chose to recall. Regardless of whether the heads are recalled or not, the allegations concerning defect, causation and damages are identical.

As an additional factor against transfer and consolidation, Defendant points to the number of different femoral stems it manufactures and how implant of the LFIT V40 head upon dissimilar stems poses additional "individual issues" that are not appropriate for coordinated treatment. This Honorable Panel found unpersuasive similar arguments made expressly or impliedly in one or more of the failed metal hip implant MDL arguments previously cited. The DePuy ASR, DePuy Pinnacle, Zimmer Durom, Biomet M2A, and Wright Medical Conserve metal heads could be and were mounted on a large variety of femoral stems. The Stryker Rejuvenate and ABG II stems could be used with a variety of femoral heads and bearing surfaces. Despite these supposed differences, the Panel astutely appreciated the central theme that binds all of these cases, LFIT V40 included; they all fail due to the generation of abnormally high levels of toxic metal wear debris. They hurt patients in exactly the same way and all cause the need for unnecessary, premature removal and replacement due to tissue destruction. As such, each presents common questions of fact for subject to discovery. *See* 28 U.S.C. § 1407(a); *In re Kugel Mesh Hernia Patch Products Liability Litigation* 43 F. Supp. 2nd 1371, 1372-73 (J.P.M.L 2007)

In terms of the potential number of cases that may ultimately be filed, consider the 44,000 heads Stryker is now recalling involve but a small subset of the LFit V40 metal head product line.

As described above, the recall does not address a substantial number of metal heads and nothing manufactured and implanted after 2011. Stryker has continued to manufacture the LFIT V40 heads since 2011, and they continue to fail. It is likely the denominator representing potential LFIT V40 head failures exceeds forty-four thousand. For context, Stryker's Rejuvenate recall involved just 27,000 units.

Stryker's previous implant recall resulted in both federal and state coordinated proceedings. Within two years, a global settlement for more than four thousand Plaintiffs was reached and less than ten depositions were taken. Such a result would likely not have occurred in the absence of coordination. By its own words, Stryker has declared the problem with its LFIT V40 heads to be substantially similar to its previous recall in terms of defect, failure mode and consequence.[10] In terms of numbers, this may be a larger problem. Although early to tell, Stryker's size and market share[11] suggest injured victims and resulting litigation will span the majority of our fifty states as it did in the Rejuvenate and ABG II litigation.[12]

For the above reasons, these two tag-along Plaintiffs join in the motion and urge the Panel to order transfer and coordination of this litigation.

VENUE

Our federal judiciary contains many distinguished jurists in varied venues capable of managing complex, coordinated litigation. Should however, the panel solicit counsel's input as to where or who may be uniquely qualified for *this* potential coordination, respectfully there appear to be two natural choices.

[10] *See:* Recall Notices referenced at footnotes 4 & 5.
[11] In its response at page 2 Defendant claims, "HOC is the worldwide leader in total hip replacement products…"
[12] In the Rejuvenate and ABG II litigation the undersigned represented over four hundred clients from 38 states.

Judge Donovan Frank in the District of Minnesota is currently wrapping up his very successful and efficient handling of the Stryker Rejuvenate and ABG II MDL. He is intimately familiar with the parties, defense counsel and several lawyers who have pending LFIT V40 cases. Although the undersigned has never appeared before Judge Frank,[13] the fact he could shepherd a complex Stryker hip implant recall coordination from start to successful settlement within two years speaks for itself. Although different products, the striking similarities between Rejuvenate, ABG II and LFIT V40 failures make him familiar with both the relevant science and medicine. Further, Judge Frank already has a template for case management previously employed in an almost identical case. That together with the relationships developed in his current MDL would allow him to hit the ground running. In sum, Judge Frank has both the capacity and special knowledge to move this litigation both deftly and efficiently.

The exact same could be said of Judge Brian Martinotti who presided over the New Jersey State court MCL Stryker Rejuvenate and ABG II proceedings with distinction and has since been elevated to the federal bench in the District of New Jersey. However, the undersigned is aware that Judge Martinotti has recently been assigned responsibility for a new MDL thereby limiting his current capacity.

The undersigned's recommendations are respectfully made and mindful of the bench and bar's commitment to establishing more diversity in these appointments.

SUMMARY

28 U.S.C. § 1407, the Rules of Procedure of the Judicial Panel on Multidistrict Litigation and volumes of case law provide this honorable panel broad discretion in deciding whether to order

[13] The undersigned served on the Plaintiffs' Steering Committee for New Jersey State Court coordination (MCL 296: IN RE Stryker Rejuvenate Hip Stem and ABG II Modular Hip Stem Litigation)

transfer and consolidation of pending federal actions. Upon a sufficient showing that the proposed transfer and coordination will promote efficiency, consistency and economy, transfer and consolidation is a valuable tool at the Panel's disposal to overcome one of the biggest challenges our federal courts face. When drugs and medical devices fail they tend to hurt a lot of people. Experience teaches that those injured Plaintiffs are geographically diverse. Acknowledging the burdens already placed upon our federal courts, wasting resources the courts already lack can be avoided by establishing coordinated proceedings. Experience also suggests that establishing coordinated proceedings for failed hip implant cases has been incredibly time and cost efficient and, most importantly, successful.

Dated: 2/9/2017

s/ C. Calvin Warriner, III
C. CALVIN WARRINER, III
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SCHEDULE OF POTENTIAL TAG ALONG STRYKER LFIT V40 FEMORAL HEAD PRODUCTS LIABILITY AND LITIGATION

No.	Case Name	Date Filed	District and Judge	Plaintiff's Residence	Allegations: Synopsis of Incident & Injuries
1	STEVEN M. SEGERSTROM and BETH A. SEGERSTROM v. HOWMEDICA OSTEONICS d/b/a STRYKER ORTHOPAEDICS, STRYKER CORP., STRYKER SALES CORPORATION and STRYKER IRELAND LIMITED	2/3/2017	United States District court Western District of Wisconsin Judge William M. Conley and Magistrate Judge Stephen L. Crocker 3:17-cv-00080	Mondovi, WI	Steven Segerstrom, age 59 was implanted with a non-recalled 40 mm. +0 offset LFIT V40 head and Accolade stem on 02/07/2013. In the spring of 2015 he developed throbbing hip pain and blood testing revealed his cobalt level was elevated. His revising surgeon made the following observations, "We were able to identfy the pseudocapsule and when we cut into it pus-like fluid came out. This was sent for cell count and culture. If you did not know about the negative sed rate and C-reactive protein, you would think this was infection but it is clearly not. It has that kind of tissue around that the pseudocapsule consistent with the trunnionosis. There was a blackened material with a circumferential ring around the base of the head.

EXHIBIT A

No.	Case Name	Date Filed	District and Judge	Plaintiff's Residence	Allegations: Synopsis of Incident & Injuries
2	ARDIS M. PROUE and EDWARD F. PROUE v. HOWMEDICA OSTEONICS d/b/a STRYKER ORTHOPAEDICS, STRYKER CORP., STRYKER SALES CORPORATION and STRYKER IRELAND LIMITED	2/3/2017	United States District court Western District of Wisconsin Judge William M. Conley and Magistrate Judge Stephen L. Crocker 3:17-cv-00080	Chippewa Falls, WI	Ardis Proue, age 73 was implanted with a recalled 36 mm. +5 offset LFIT V40 head and Accolade stem on 03/08/3007. She did well. On 03/30/2015 she presented to the emergency department where it was determined her LFIT V40 head had come off of the stem. Emergent surgery revealed a large 20cm. pseudotumor and extensive metallosis. The trunnion of the Accolade stem was "completely worn away" a finding described in the note as, "certainly a strange event."

EXHIBIT A

EXHIBIT B

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WISCONSIN

STEVEN M. SEGERSTROM and BETH A. SEGERSTROM, Plaintiffs, v. HOWMEDICA OSTEONICS d/b/a STRYKER ORTHOPAEDICS, STRYKER CORP., STRYKER SALES CORPORTION and STRYKER IRELAND LIMITED, Defendants.	COMPLAINT AND JURY DEMAND

COMPLAINT

COME NOW Plaintiffs, Steven M. Segerstrom ("Plaintiff") and Beth A. Segerstrom, by and through the undersigned counsel, and bring this complaint against Defendants, HOWMEDICA OSTEONICS d/b/a STRYKER ORTHOPAEDICS, STRYKER CORP., STRYKER SALES CORPORATION and STRYKER IRELAND LIMITED (hereinafter collectively "Defendants" and "Stryker"), and allege as follows:

1. This is an action for damages relating to Defendants' development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the defective product(s) sold under the names "The Accolade TMZF® Hip Stem and LFIT Anatomic V40 Femoral Head" (hereinafter, "Defective Devices").

EXHIBIT C

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WISCONSIN

ARDIS M. PROUE and EDWARD F. PROUE, Plaintiffs, v. HOWMEDICA OSTEONICS d/b/a STRYKER ORTHOPAEDICS, STRYKER CORP., STRYKER SALES CORPORTION and STRYKER IRELAND LIMITED, Defendants.	COMPLAINT AND JURY DEMAND

COMPLAINT

COME NOW Plaintiffs, Ardis M. Proue ("Plaintiff") and Edward F. Proue, by and through the undersigned counsel, and bring this complaint against Defendants, HOWMEDICA OSTEONICS d/b/a STRYKER ORTHOPAEDICS, STRYKER CORP., STRYKER SALES CORPORATION and STRYKER IRELAND LIMITED (hereinafter collectively "Defendants" and "Stryker"), and allege as follows:

1. This is an action for damages relating to Defendants' development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the defective product(s) sold under the names "The Accolade TMZF® Hip Stem and LFIT Anatomic V40 Femoral Head" (hereinafter, "Defective Devices").

EXHIBIT D

325 Corporate Drive
Mahwah, NJ 07430
201-831-5000

stryker®

Orthopaedics

URGENT UPDATE
PRODUCT RECALL

June 28, 2012

Product Remediation #: RA 2012-067 EXT

Description:	ABG II Modular Stems and ABG II Modular Necks
Catalog No.:	See attached list
Lot Codes:	All

Description:	Rejuvenate Modular Stems and Rejuvenate Modular Necks
Catalog No.:	See attached list
Lot Codes:	All

Dear Surgeon,

On May 1, 2012, Stryker Orthopaedics issued a Product Correction communication (Product Remediation reference RA2012-067) for the above products. Please be advised that Stryker has now updated this action to a voluntary product recall. Please note, however, that the potential hazards associated with Product Remediation RA2012-067 EXT have not changed from the previous communication (restated below for reference).

Issue

Ongoing analysis of the global data following the Product Correction does not yield a significant increase in the global reported rate for Adverse Local Tissue Reaction (ALTR). However, the additional data, which includes variability in ALTR rates among sites, may potentially be predictive of an increased likelihood of this condition for both the Rejuvenate and ABG II Modular Hip Systems. Based on information received to date, a product field action to remove these products is being conducted.

Potential Hazards

1. Excessive metal debris and/or ion generation. Fretting and/or corrosion at or about the modular neck junction may lead to increased metal ion generation in the surrounding joint space.
    a. Contact between metal ions and tissues and structures during an implant's service life may result in an Adverse Local Tissue Reaction (ALTR), the inflammation of associated tissues experiencing immunological response (metallosis, necrosis, and/or pain). An ALTR may result in the need for revision surgery.
    b. Patients with a heightened sensitivity to these ions may experience a hypersensitivity/allergic reaction which may result in the need for revision surgery.
2. Excessive fretting debris. Fretting may lead to increased metal debris in the joint space (concentration of debris exceeds individual patient threshold) resulting in osteolysis. Osteolysis may be asymptomatic and may result in the need for revision surgery.

Note: Stryker has not received any reports of modular neck fracture associated with fretting/corrosion.

Risk Mitigation

The risk is mitigated by the removal of products from use.

Follow-up

Surgeons should ensure that patients with ABG II Modular or Rejuvenate Modular Hip Systems are followed regularly and undergo clinical evaluation as per their surgeon and institutional protocol.

If a patient is experiencing pain and/or swelling involving the groin, buttock, lateral hip or thigh, the surgeon should rule out aseptic loosening or periprosthetic sepsis, common conditions following joint replacement surgery that are not related to an ALTR to metal wear debris. Once the surgeon has ruled out aseptic loosening and periprosthetic sepsis, the surgeon should evaluate the patient for an ALTR potentially related to metal wear debris. Testing includes blood work for metal ion levels (CR and CO levels over 7 ppb are commonly considered high) and either an MRI or ultrasound to look for soft tissue mass or fluid collection. If the results reveal an ALTR to metal wear debris, the surgeon should consider proceeding with a revision of the femoral component to a monolithic stem.

Please continue to report to Stryker all adverse events related to the products.

Our records indicate that you have received and/or used the above referenced product(s). It is Stryker®'s responsibility as the manufacturer to ensure that customers who may have received and/or used these affected products also receive this important communication. Please assist us in meeting our regulatory obligation by faxing back the attached Product Recall Acknowledgement Form at your earliest convenience to 201-831-6069.

Please note that your signature on the following form only confirms that you received this notification and does not obligate you to take any additional action beyond what is called for in this notification letter.

We regret any inconvenience this action may cause you and if you have any questions, feel free to contact me at 201-972-2100, or Jonathan Sacks, Director, Global Brand Marketing at 201-831-6398.

Sincerely,

Colleen O'Meara

Colleen O'Meara
Manager, Divisional Regulatory Compliance

NL12-FB-CO-608

RA2012-067 EXT – scope of devices covered

ABG II Modular Components

Catalog No.	Description
4845-4-101	ABGII. Modular Stem
4845-4-102	ABGII. Modular Stem
4845-4-103	ABGII. Modular Stem
4845-4-104	ABGII. Modular Stem
4845-4-105	ABGII. Modular Stem
4845-4-106	ABGII. Modular Stem
4845-4-107	ABGII. Modular Stem
4845-4-108	ABGII. Modular Stem
4845-4-201	ABGII. Modular Stem
4845-4-202	ABGII. Modular Stem
4845-4-203	ABGII. Modular Stem
4845-4-204	ABGII. Modular Stem
4845-4-205	ABGII. Modular Stem
4845-4-206	ABGII. Modular Stem
4845-4-207	ABGII. Modular Stem
4845-4-208	ABGII. Modular Stem
4845-4-410	ABGII Modular short neck
4845-4-411	ABGII Modular short neck
4845-4-412	ABGII Modular short neck
4845-4-413	ABGII Modular short neck
4845-4-414	ABGII Modular short neck
4845-4-415	ABGII Modular long neck
4845-4-416	ABGII Modular long neck
4845-4-417	ABGII Modular long neck
4845-4-418	ABGII Modular long neck
4845-4-419	ABGII Modular long neck

Rejuvenate Modular Components

Catalog No.	Description
SPT070000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 7
SPT080000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 8
SPT090000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 9
SPT100000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 10
SPT110000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 11
SPT120000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 12
NLS-301600P	LRG TAP PRI MOD NCK 16DEG 30MM
NLS-300000B	LRG TAP PRI MOD NCK 0DEG 30MM
NLS-341600P	LRG TAP PRI MOD NCK 16DEG 34MM
NLS-340000B	LRG TAP PRI MOD NCK 0DEG 34MM
NLS-381600P	LRG TAP PRI MOD NCK 16DEG 38MM
NLS-380000B	LRG TAP PRI MOD NCK 0DEG 38MM
NLS-421600P	LRG TAP PRI MOD NCK 16DEG 42MM
NLS-420000B	LRG TAP PRI MOD NCK 0DEG 42MM

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NLV-300800Y	LRG TAP PRI MOD NCK 8DEG 30MM
NLV-300800G	LRG TAP PRI MOD NCK 8DEG 30MM
NLV-340800Y	LRG TAP PRI MOD NCK 8DEG 34MM

RA2012-067 EXT – scope of devices covered (continued)

Rejuvenate Modular Components

NLV-340800G	LRG TAP PRI MOD NCK 8DEG 34MM
NLV-380800Y	LRG TAP PRI MOD NCK 8DEG 38MM
NLV-380800G	LRG TAP PRI MOD NCK 8DEG 38MM
NLV-420800Y	LRG TAP PRI MOD NCK 8DEG 42MM
NLV-420800G	LRG TAP PRI MOD NCK 8DEG 42MM

STRYKER ORTHOPAEDICS
PRODUCT RECALL ACKNOWLEDGMENT FORM

June 28, 2012

«ShipTo_Customer_Name»
«ShipTo_Address_1»
«ShipTo_Address_2_»
«ShipTo_Address_3_»
«SHIPTOCITY», «SHIPTOST» «SHIPTOZIP»

Product Remediation #: RA 2012-067 EXT

Description:	ABG II Modular Stems and ABG II Modular Necks
Catalog No.:	See attached list
Lot Codes:	All

Description:	Rejuvenate Modular Stems and Rejuvenate Modular Necks
Catalog No.:	See attached list
Lot Codes:	All

I have received the notification from Stryker Orthopaedics dated June 28, 2012 stating that they initiated a voluntary product recall of the above described products.

_____ _____

Surgeon (Signature) Date

_____

Surgeon (Print)

NL12-FB-CO-608

Please fax this signed and dated form to Aminah Crawford at 201-831-6069

EXHIBIT E

stryker

URGENT MEDICAL DEVICE RECALL NOTIFICATION
LFIT™ Anatomic CoCr V40™ Femoral Heads

August 29, 2016

Product Field Action Number: RA2016-028
Description: LFIT™ Anatomic CoCr V40™ Femoral Heads
Catalog Number(s): 6260-9-236, 6260-9-240, 6260-9-244, 6260-9-340, 6260-9-344, 6260-9-440, 6260-9-444
Lot Code(s): See attached

Dear Surgeon,

Stryker has initiated a voluntary medical device recall for the following Femoral Heads.

The intent of this letter is to describe all potential hazards associated with the below noted issue, and any risk mitigation factors associated with the use of the product.

Our records indicate that you have received the above referenced product. It is Stryker's responsibility as the manufacturer to ensure that customers who may have received these affected products also receive this important communication.

Reason for the Voluntary Recall:
Stryker has received higher than expected complaints of taper lock failure for specific lots of the following certain sizes of LFIT™ Anatomic CoCr V40TM Femoral Heads manufactured prior to 2011.

Catalog Number	Head Diameter	Offset
6260-9-236	36mm	+5
6260-9-240	40mm	+4
6260-9-244	44mm	+4
6260-9-340	40mm	+8
6260-9-440	40mm	+12
6260-9-344	44mm	+8
6260-9-444	44mm	+12

Potential Hazards may include:

- Disassociation of femoral head from hip stem
- Fractured hip stem trunnion
- Excessive metallic debris
- Insufficient ROM
- Insufficient soft tissue tension
- Noise
- Loss of implant: bone fixation strength
- Excessive wear debris (polymeric)
- Implant construct with a shortened neck length

The aforementioned potential hazards may result in one or more of the following potential patient harms:

- User annoyance
- Loss of mobility
- Pain requiring revision
- Inflammatory response
- Adverse local tissue reaction
- Dislocation
- Joint instability
- Revision to alleviate hazardous situation
- Pain associated with implant loosening
- Periprosthetic fracture
- Leg length discrepancy

Follow up:

Implanted patients with LFIT™ Anatomic CoCr V40™ Femoral Heads as described above should continue to be followed per the normal protocol established by his/her surgeon.

Required actions:

1. Hospitals/Surgeons: Please inform users of this Urgent Medical Device Recall Notification and forward this notice to all those individuals who need to be aware within your organization. Complete and sign the enclosed Business Reply Form and fax a copy to **1-888-912-8457** or email to Stericycle at strykerortho8402@stericycle.com

2. Stryker Branches/Agencies: No product is to be returned as part of this notification.

Our records indicate that you have received the above referenced product. It is our responsibility to ensure that customers who may have received this affected product also receive this important communication. **Please assist us in meeting our regulatory obligation by faxing back the attached Business Reply Form within 5 days of receipt of this letter.**

For patient questions, Stryker has established a dedicated call center at 1-888-644-2548.

We regret any inconvenience this action may cause you and if you have any questions, feel free to contact me at 1-201- 831-6693.

Sincerely,

Eric Petschler
Manager, Regulatory Compliance