BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: ZIMMER M/L TAPER HIP PROSTHESIS OR M/L TAPER HIP PROSTHESIS WITH KINECTIV TECHNOLOGY AND VERSYS FEMORAL HEAD PRODUCT LIABILITY LITIGATION	)	**MDL-**

BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR TRANSFER OF ACTIONS PURSUANT TO 28 U.S.C. §1407

ORAL ARGUMENT REQUESTED

I. INTRODUCTION AND SUMMARY OF ARGUMENT

Plaintiffs Elizabeth and Ray Hackett, and David Pastor (hereinafter "Movants") bring this motion to transfer all cases to the District of Minnesota that arise out of the Zimmer M/L Taper Hip Prosthesis ("M/L Taper") and Zimmer M/L Taper Hip Prosthesis with Kinectiv Technology ("Kinectiv") when paired with the Zimmer VerSys Hip System Femoral Head ("VerSys").

The M/L Taper and Kinectiv are modular, titanium alloy femoral stems designed, manufactured, marketed, developed, supplied, labeled, tested, sold and/or distributed by Zimmer, Inc., Zimmer US, Inc. and Zimmer Biomet Holdings, Inc., f/k/a Zimmer Holdings, Inc. (collectively referred to as "Zimmer") and used in total hip arthroplasty

surgeries. The neck portion of the stems contain a 12/14 conical trunnion taper designed to mate with the corresponding bore taper of a cobalt-chromium or ceramic femoral head. The Versys femoral head is a cobalt-chromium component having a 12/14 conical bore taper designed to mate with the corresponding 12/14 trunnion taper of a femoral stem. Movants allege in their complaints that the trunnion taper of the M/L Taper and Kinectiv femoral stems and the bore taper of the VerSys femoral head were defectively designed and/or manufactured, and promote fretting and corrosion at the junction between the femoral stem and the femoral head, resulting in personal injury and the need for revision surgery.

Movants are aware of twenty-two product liability actions involving the M/L Taper and Kinectiv stems paired with VerSys heads pending in ten different jurisdictions across the United States being prosecuted by at least fourteen different law firms. Movants are not requesting the *Adams*[1] case be consolidated, as that case is set for trial in July of 2018.

All of these cases seek damages against the same defendants based upon the same legal theories and operative facts. Upon information and belief, more than 100,000 M/L Taper and Kinectiv stems with VerSys heads have been implanted in patients across the country, and so it is inevitable that many more cases involving these

[1] *Adams v. Zimmer US, Inc., et al.* (5:17-cv-00621-EGS) is set for trial on July, 30 2018. Movants believe this case should not be consolidated because its scheduled trial will be concluded long before the Panel has the opportunity to hear arguments on consolidating these cases.

components will be filed in federal courts in the coming months. Because all of these pending lawsuits are predicated on common issues of fact, they should be consolidated, coordinated and managed for pretrial purposes through a multidistrict litigation.

The Panel has previously granted motions to transfer cases arising out of defective hip implant systems, *see In Re: Zimmer Durom Hip Cup Products Liability Litigation* (MDL No. 2158); *In Re: DePuy Orthopaedics, Inc., ASR Hip Implant Products Liability Litigation* (MDL No. 2197); *In Re: DePuy Orthopaedics, Inc., Pinnacle Hip Implant Products Liability Litigation* (MDL No. 2244); *In Re: Wright Medical Technology, Inc., Conserve Hip Implant Products Liability Litigation* (MDL No. 2329); *In Re: Biomet M2a Magnum Hip Implant Products Liability Litigation* (MDL No. 2391); *In Re: Smith & Nephew Hip Implant Products Liability Litigation* (MDL No. 2775), and has granted motions to transfer cases arising out of the specific modular junction corrosion problem present in the VerSys and M/L Taper/Kinectiv cases. *See In Re: Stryker Rejuvenate and ABG II Hip Implant Products Liability Litigation* (MDL No. 2441) and *In Re: Stryker LFIT V40 Femoral Head Products Liability Litigation* (MDL No. 2768). To promote judicial efficiency and ensure that these cases benefit from the cost savings accomplished by coordinated or consolidated pretrial proceedings, Movants respectfully submit this Brief in Support of Plaintiffs' Motion for Transfer of Actions Pursuant to 28 U.S.C. § 1407.

II. FACTUAL BACKGROUND

A total hip replacement typically involves implantation of four separate components: a femoral stem, a femoral head, an acetabular liner, and an acetabular shell. The femoral head, usually manufactured from a cobalt-chromium alloy or ceramic, is fixed on top of the femoral stem via a Morse taper. The principle of the Morse taper is that of a cone-within-a-cone. The trunnion (the male portion) and the bore (the female portion) are both uniformly tapered. When the bore in the femoral head is tapped onto the trunnion of the femoral stem, they come into intimate contact. The conical femoral taper compresses the walls in the bore as it expands. Thus, the stresses inside the materials keep both components fixed together. The contact area between the inside of the bore of the femoral head and the trunnion of the femoral stem is called the taper interface.

The surface of the femoral head bore is covered by a natural passive film ("passivation layer") consisting of cobalt oxide which protects against corrosion. Although the taper interface is designed to prevent movement of the stem trunnion within the femoral head bore when assembled, studies have demonstrated that a malfunctioning taper interface can produce micro motion of these components, resulting in a removal of the protective passivation lawyer ("fretting"), fluid ingress, and subsequent corrosion. This fretting and corrosion can cause the release of cobalt and/or chromium ions and debris which can result in adverse local tissue reactions, pseudotumor formation, tissue destruction, the need for revision surgery and, in some

cases, systemic effects of metal ion toxicity. The process by which metal ions and debris build-up in the soft tissues of the hip joint and blood is often generally referred to as metallosis.

The concern that fretting and corrosion damage could occur at the head-neck taper interface of the modular hip prosthesis was first reported in the early 1980s. Since that time, numerous studies and reports have demonstrated that a malfunctioning or defectively designed taper interface between a cobalt-chromium femoral head and a titanium alloy femoral stem may be susceptible to fretting and corrosion damage resulting in elevated serum metal ion levels, adverse local tissue reactions, pseudotumor formation, tissue destruction, metallosis, and the need for revision surgery.

The *M/L Taper* is a femoral stem/neck component with a taper wedge design constructed from a single piece of Tivanium® Ti-6Al-4V alloy with a porous coating of titanium plasma spray. The neck portion of the stem contains a 12/14 conical taper designed to mate with the corresponding bore taper of a metal or ceramic femoral head. The taper contains threading or shallow groves in order to comply with manufacturing requirements for the ceramic head option. The M/L Taper can be described as uni-modular, in that the stem contains a single modular junction between the stem and femoral head.

The *Kinectiv* stem is similar to the M/L Taper in that it has a taper wedge design and is constructed from Tivanium® with a titanium plasma spray coating. In fact, Defendants applied for 510(k) clearance for the *Kinectiv* through the Food and Drug Administration ("FDA"), naming the Zimmer M/L Taper as a predicate device upon which it relied for clearance[2].

In order to obtain 510(k) clearance, an applicant must demonstrate that the device is safe and effective by proving substantial equivalence to another legally marketed device[3]. Substantial equivalence means that the new device is at least as safe and effective as the predicate. Substantial equivalence does not mean the new device must be identical, but equivalence is established with respect to intended use, design, energy use or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable. Here, Defendants represented to the FDA that the Kinectiv stem is the substantial equivalent to the M/L Taper stem.

The primary difference between the Kinectiv stem and the M/L Taper stem is that the Kinectiv stem has an additional modular junction between the stem body and

[2] https://www.accessdata.fda.gov/cdrh_docs/pdf6/K063251.pdf The *Zimmer®* M/L Taper Hip Prosthesis with *Kinectiv™* Technology System names its predicate as the *Zimmer®* M/L Taper Hip Prosthesis with Modular Neck Technology. The *Zimmer®* M/L Taper Hip Prosthesis with Modular Neck Technology names the *Zimmer®* M/L Taper Hip Prosthesis as its predicate. In other words, the *Zimmer®* M/L Taper Hip Prosthesis is the predicate of the predicate of the *Zimmer®* M/L Taper Hip Prosthesis with *Kinectiv™* Technology System.

[3]https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm#se

an interchangeable neck which is also constructed from Tivanium®. This dual-modular stem was introduced in an effort to improve restoration of joint biomechanics (i.e. anteversion, offset, and limb length). The Kinectiv neck also contains a 12/14 conical threaded taper designed to mate with the corresponding bore taper of a metal or ceramic femoral head.

The *VerSys* femoral head is manufactured from wrought Zimaloy® (a proprietary cobalt-chromium-molybdenum alloy) and intended for use with both Tivanium® and Zimaloy® femoral stems equipped with 12/14 tapered necks.

Movants allege that in designing the M/L Taper and Kinectiv stems, and the VerSys head, Zimmer knew or should have known that pairing this combination of a cobalt-chromium femoral head with the dissimilar Tivanium® alloy stem, as well as taper size, small taper angle mismatch, trunnion surface finish, and flexural rigidity, all contribute to fretting and corrosion at the head-stem and head-neck taper interfaces.

III. ARGUMENT

A. Transfer and Coordination of the M/L Taper-VerSys and Kinectiv-VerSys Cases is Appropriate and Necessary

28 U.S.C. § 1407 authorizes the Panel to transfer federal civil actions for coordinated or consolidated pretrial proceedings, when (1) the "actions involve one or more common question of fact"; (2) transfer "will be for the convenience of parties and witnesses;" and (3) transfer "will promote the just and efficient conduct of such

actions." The purpose of Section 1407 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) § 20.131 (2004) (*citing In re Plumbing Fixture Cases*, 298 F. Supp. 484 (J.P.M.L. 1968)). *See also* David H. Herr, Multidistrict Litigation Manual § 5:16 (2010).

Multidistrict litigation serves the purpose of conserving judicial resources and promoting efficiency and consistency. *Illinois Municipal Retirement Fund. V. Citigroup, Inc.*, 391 F.3d 844, 852 (7th Cir. 2004). The objective of the legislation is to provide centralized management under court supervision of pretrial proceedings of multidistrict litigation to assure the 'just and efficient conduct' of such actions. "*Matter of New York City Mun. Sec. Litig*., 572 F.2d 49, 51 (2d Cir. 1978) (*citing* House Judiciary Committee notes, H.R. Rep. No. 1130, 90th Cong., 2d Sess., reprinted in 2 U.S. Code Cong. & Admin. News, pp. 1898, 1899-1900 (1968)). Efficient and just management is effected, in part, by eliminating the potential for conflicting contemporaneous rulings by coordinated district and appellate courts. *In re Air Crash off Long Island, N.Y. on July 17, 1996*, 965 F. Supp. 5, 7 (S.D.N.Y. 1997). Multidistrict litigation also promotes inexpensive determination of every action. *In re Nat. Student Mktg. Litig.*, 368 F. Supp. 1311, 1316 (J.P.M.L. 1972).

The M/L Taper-VerSys and Kinectiv-VerSys cases are well-suited for centralization under Section 1407. Although scattered across the country, they share

common defendants, the same basic theories of liability, and the same basic factual allegations. All of the cases will involve the same core document discovery and the same lay and expert witnesses. Transferring these cases pursuant to 28 U.S.C. § 1407 would enhance the convenience and efficiency of this litigation. Declining to transfer would almost certainly lead to inconsistent and conflicting rulings in discovery and other pretrial matters. As set-forth in detail below, these cases are suitable for transfer and centralization before a single district court.

1. The M/L Taper-VerSys and Kinectiv-VerSys Cases Involve Common Questions of Fact and Involve Common Issues for Discovery

Federal civil actions are eligible for transfer pursuant to 28 U.S.C. § 1407 if they involve "common questions of fact" subject to discovery. *See* 28 U.S.C. § 1407(a); *In re Kugel Mesh Hernia Patch Products Liability Litigation*, 493 F.Supp. 2d 1371, 1372-73 (J.P.M.L. 2007). The statute, however, does not require complete identification of common questions of fact to justify transfer. *In re Zyprexa Prods, Liab. Litig.*, 314 F. Supp. 2d 1380, 1381 (J.P.M.L. 2004).

The cases presented here share a common core of operative facts. All plaintiffs allege that the M/L Taper, Kinectiv, and VerSys implants shared the same mechanism of failure and caused similar injuries to each plaintiff, including metallosis, adverse local tissue reactions, pseudotumor formation, tissue destruction, and the need for revision surgery. While not all plaintiffs suffered the same exact injury or outcome, all injuries

are alleged to be attributable to the M/L Taper or Kinectiv stems while paired with a VerSys femoral head.

In addition, each plaintiff alleges that Defendants knew or should have known of the defective nature of these hip implant components, and yet failed to properly warn doctors and patients and failed to timely remove the products from the market when it knew of the dangers associated with these products. Plaintiffs have also asserted the same legal theories of liability, including negligence, breach of express and implied warranties, strict liability and defective design.

Plaintiffs raise common questions of fact regarding the M/L Taper-VerSys and Kinectiv-VerSys device combinations, including the following: to what extent these devices caused, or will in the future cause, harm to patients; when Defendants first learned of the harmful effects caused by these devices; whether, and for how long, Defendants concealed this knowledge from surgeons and physicians and continued to promote sales of these devices; whether Defendants defectively designed and/or manufactured these devices; whether Defendants failed to provide adequate warnings concerning these devices; whether defendants were negligent in their design and/or manufacture of these devices; whether Defendants engaged in fraudulent and illegal marketing practices regarding these devices; and the nature and extent of damages suffered by Plaintiffs as a result of these devices.

Separate, unconsolidated proceedings would increase the cost of litigation for all parties, waste judicial resources, and risk inconsistent rulings on these common questions of fact. For these reasons, Movants respectfully request this Court to consolidate these related actions.

2. Consolidation Prevents Duplicative Discovery

Preventing duplicative discovery favors consolidation. Centralization avoids repetitive discovery and depositions when there are common questions of fact. *See, e.g., In re: Pilot Flying J. Fuel Rebate Contract Litigation (No. II),* 11 F. Supp. 3d, 1351, 1352 (J.P.M.L, 2014). Centralizing also allows Plaintiffs' counsel to coordinate their efforts and share discovery and the pre-trial workload. *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 173, F. Supp.2d 1377, 1379 (2001). Small litigations are also benefited from consolidation by eliminating duplicative discovery, preventing inconsistent pretrial rulings and conserving the resources of the parties, their counsel and the judiciary. *See In re First Nat'l Collection Bureau, Inc., Tel. Consumer Prot. Act (TCPA) Litig*. 11 F. Supp. 3d 1353, 1354 (J.P.M.L. Apr. 8, 2014).

Substantial duplicative discovery will occur if each of these cases proceeds separately. It is neither cost effective nor efficient for multiple cases to proceed in various courts. Many of the same depositions, documents and discovery will be required in each jurisdiction.

Consolidating benefits both Plaintiffs and Defendants. Pretrial transfer reduces discovery delays and costs for Plaintiffs and allows Plaintiffs to share the pre-trial workload. Defendants are also benefited in that depositions of key witnesses will only be required once rather than on dozens of separate occasions. Documents can be produced to one body of plaintiffs, thereby eliminating duplicative discovery as to the common factual issues between the parties. Centralization is necessary to prevent duplicative discovery, lower the overall costs of discovery for all parties, and avoid unnecessary burdens on witnesses.

While plaintiff anticipates many more filings, even the current number of filed cases would benefit from coordination given the overlapping factual allegations and legal theories of liability.

3. Pretrial Centralization will Enhance the Convenience of the Litigation as a Whole

Transfer is appropriate when it enhances the convenience of the litigation as a whole. *See e.g. In re Library Editions of Children's Books*, 297 F. Supp. 385, 386 (J.P.M.L. 1968). As mentioned above, both Plaintiffs and Defendants benefit from consolidation. Pretrial centralization would reduce discovery costs significantly for Defendants. It would also permit Plaintiffs' counsel to coordinate their efforts and share the pretrial workload, thereby reducing costs for each individual plaintiff and her attorneys. Without centralization, Defendants will be forced to hire counsel in multiple districts across the country, respond to similar but invariably slightly different discovery

requests, and develop potentially different pretrial litigation strategies. Centralization will permit Defendants to focus their attention and energy on one forum, allow them to respond more quickly and efficiently to Plaintiffs and the transferee court, and enhance the overall efficiency of the litigation. *See, e.g., In re Baldwin-United Corp. Litigation*, 581 F. Supp. 739, 741 (J.P.M.L. 1984) ("[P]rudent counsel will combine their forces and apportion the workload in order to streamline the efforts of the parties and witnesses, their counsel and the judiciary, thereby effectuating an overall savings of cost and a minimum of inconvenience to all concerned.").

Centralization will also conserve the precious financial and time resources of the courts. One judge, rather than many, will consider issues related to discovery, privilege, expert witnesses, and other essential aspects of the cases.

In short, transferring the M/L Taper-VerSys and Kinectiv-VerSys cases for pretrial coordination or consolidation will make this litigation far more efficient and convenient for everyone involved.

4. Transfer Will Promote the Just and Efficient Conduct of These Actions

Centralization of the M/L Taper-VerSys and Kinectiv-VerSys cases promotes the just and efficient conduct of this litigation. Centralization seeks to promote justice and efficiency by eliminating duplicative discovery, preventing inconsistent pretrial rulings, and conserving the resources of the parties, their counsel and the judiciary. *See, e.g.., In re Baycol Products Liability Litigation*, 180 F. Supp. 2d 1378, 1380 (J.P.M.L. 2001).

Because every M/L Taper-VerSys and Kinectiv-VerSys case asserts the same basic liability allegations, Defendants will likely assert the same defenses to the allegations in each case. With twenty-two cases currently filed, and dozens more expected to surface in the near future, it is imperative that there not be conflicting rulings from various courts around the country. Centralization before a single court eliminates the possibility of inconsistent rulings in these cases, thereby preventing different treatment of Plaintiffs under similar legal theories and ensuring the just application of law for all Plaintiffs.

A single transferee court will be in the best position to determine the appropriate resolution of these threshold issues that will affect all actions and that could dramatically simplify the litigation. Movants therefore respectfully request this Court to centralize the M/L Taper-VerSys and Kinectiv-VerSys cases to promote the just and efficient conduct of these actions.

B. Transfer to the District of Minnesota Best Serves Convenience and the Just and Efficient Conduct of These Actions

In determining an appropriate transferee forum, the Panel balances a number of factors, including: the experience, skill and caseload of the parties; location of the witnesses and evidence; and the minimization of costs and inconvenience to the parties. *See, e.g., In re Regents of University of California*, 964 F.2d 1128, 1136 (Fed. Cir. 1992); *In re Wheat Farmers Antitrust Class Action Litig.*, 366 F.Supp. 1087, 1088 (J.P.M.L. 1973); *In re Preferential Drugs Prods. Pricing Antitrust Litig.*, 429 F.Supp. 1027, 1029 (J.P.M.L. 1977); *In*

re Tri-State Crematory Litig., 206 F.Supp. 1376, 1378 (J.P.M.L. 2002); Annotated Manual of Complex Litigation (Fourth) (2004), §20.131, at 303-304.

Movants urge the Panel to transfer the M/L Taper-VerSys and Kinectiv-VerSys actions to the District of Minnesota where these common questions of fact can be efficiently and justly managed by a judge with extensive Multidistrict Litigation experience. The District of Minnesota is the best court to effectively manage a complex products liability case like this one, in part, because of the court's familiarity and experience with the science and damages involved in orthopedic implant product liability cases.

The District of Minnesota has been host to many multidistrict litigations, including medical device products liability cases: *In Re: Stryker Rejuvenate and ABG II Hip Implant Products Liability Litigation*, MDL No. 2441; *In Re: Guidant Corp. Implantable Defibrillators Products Liability Litigation*, MDL No. 1708; *In Re: Medtronic Inc., Sprint Fidelis Leads Products Liability Litigation*, MDL No. 1905; *In Re: St. Jude Medical Inc., Silzone Heart Valves Products Liability Litigation*, MDL. No. 1396; and *In Re: Medtronic, Inc. Implantable Defibrillators Products Liability Litigation*, MDL No. 1726.

In addition, Movants believe that many of the Plaintiffs in this litigation will reside in or have connections to Minnesota, including six plaintiffs already filed in Minnesota. Additionally, the Minneapolis-St. Paul International Airport is a central hub for multiple airlines and centrally located in the country.

Although the District of Minnesota is home to many excellent judges, Movants respectfully request that this litigation be assigned to the Honorable Donovan W. Frank. Judge Frank is an immensely qualified judge and has overseen multiple MDLs. Specifically, Judge Frank presided over the *In re: Stryker Rejuvenate and ABG II Hip Implant Products Liability Litigation*, MDL No. 2441, which involved similar common questions of fact and liability alleged here, including the problem of fretting and corrosion at the modular junctions of femoral hip stems. Judge Frank has presided over complex disputes concerning science and discovery that will undoubtedly arise in this case. Judge Frank's experience, and that of his staff, in managing large and complicated medical device litigation would facilitate the efficient and just prosecution of these related cases.

IV. Conclusion

Transfer and consolidation for pre-trial proceedings of all pending and subsequently filed actions involving the M/L Taper-VerSys and Kinectiv-VerSys device combinations would promote the just and efficient prosecution of these actions by allowing national coordination of discovery and other pre-trial matters, prevent duplicative and potentially conflicting pre-trial rulings, reduce the costs of the litigation, and allow cases to proceed more efficiently to trial. For all of these reasons, Movants respectfully request the Panel to enter an order that all such actions be

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consolidated and transferred to the District of Minnesota before the Honorable Donovan W. Frank.

Dated: June 19, 2018

Respectfully submitted,