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February 3, 2023

VIA ECF FILING

Honorable Nicholas G. Garaufis, District Judge
Honorable Marcia M. Henry, Magistrate Judge
United States District Court
Eastern District of New York
225 Cadman Plaza East
Brooklyn, NY 11201

Re: MDL No. 3044, *In re: Exactech Polyethylene Orthopedic Products Liability Litigation,* 1:22-md-03044-NGG-MMH

Dear Judge Garaufis and Magistrate Judge Henry:

In advance of the Science Day presentation, and pursuant to the Court's Case Management Order No. 1 (Dkt. 87), Plaintiffs' Lead Counsel and the Exactech Defendants (collectively the "Parties") jointly submit proposed dates for Science Day and outline their proposed Science Day Protocol for the Court's consideration and adoption. The Parties also request the Court's guidance on whether outside expert witness testimony or attorney presentation is preferred by the Court because the Parties have not been able to reach an agreement on the manner of presentation at Science Day.

The Parties request a date in mid-April for Science Day. If it is convenient for the Court's calendar, in coordination with Judge Keim, the Parties propose one of the following dates: April 4, 18, 19 or 27. The Parties agree that Science Day should proceed either in person in the Courthouse in Brooklyn with Judge Keim participating remotely, or if the

Court is willing, proceed in person at the federal Courthouse in Gainesville, Florida (if feasible), so that the judges from both coordinated proceedings may attend in person.[1]

The Parties agree to the following Science Day Protocol:

- This is Science Day, a time for education on the science issues and not advocacy.
- The Parties shall provide to the Court a joint submission with general background of the case and a glossary of terms on February 3, 2023.
- The Parties will separately offer additional information to the Court regarding the products at issue and the science relevant to this litigation in-person and off-the-record at a Science Day on a day selected by the Court.
- Each side will make presentations which may incorporate the use of PowerPoints, articles, publicly available scientific data, or other demonstrative aids, which will not be exchanged by Parties in advance of Science Day, but will be provided to the Court and exchanged by the Parties at the close of Science Day. Neither confidential Defendant company documents nor Plaintiffs' medical records shall be presented or offered to the Court during Science Day.

[1] Lead counsel for both parties had experience in the Ortho Evra MDL, where the late Judge David Katz travelled to federal courthouse in Newark, NJ from Toledo, Ohio, to facilitate a joint science day. As explained by Judge Barbara Rothstein in Managing Multidistrict Litigation in Products Liability Cases A Pocket Guide for Transferee Judges (2011): "Judge David A. Katz scheduled a 'Science Day' at the Newark federal courthouse and invited state court judges handling similar cases. Approximately 125 attorneys attended, as did the New Jersey state court judge overseeing the related New Jersey state court litigation. See Case Management Order No. 19, N.D. Ohio, No. 1:06 cv40000 (June 12, 2007) (doc. no. 124); MDL No. 1742, In re: Ortho Evra Prods. Liab. Litig."

- Science Day presentations will be for the Court's benefit to gather information about the products and the science. The Federal Rules of Evidence will not be enforced during the presentations. It shall be "off the record," and closed to any person other the Parties or counsel for the Parties attending the session live, and the Court of Alachua County attending live or remotely. No recording of the presentation or telephonic access will be permitted; however, the Court may have the proceedings videotaped at its discretion for viewing in Chambers.
- No demonstrative aid or party statement or any party of the Science Day presentation shall be discoverable, admissible, used beyond the sole purpose of Science Day or shared beyond this MDL, or used for any purpose other than for this Court's benefit to gather background and technical information informally.

The parties disagree as to whether the presentations should be made by counsel or by retained experts and set forth their respective positions below.

Defendants' Position:

During the initial Status Conference, the Court stated:

> [I]t would be useful…to receive some technical information that doesn't go to liability or to reach conclusions as to whether there's premature wear of a particular device, but what are these devices and what are they advertised for or intended to do. Now, this can be done -- you can provide this to us in one of two ways. Either can you agree to provide us jointly with certain information, or if you can't agree, you can separately provide us with that kind of information in a submission that is not evidence, that will not be used at trial, that we will only use to get some basic information about what the subject matter is of this MDL. And if you object to that, let me know, but I think it would be useful since

> especially for Judge Henry, in the initial stages, so that she has, you know, a certain amount of information about what we're dealing with here. So, you can meet ask confer about that and we'd appreciate whatever you can to in that regard[.]

(Transcript, 11/16/22, p. 18). As the Court is aware, the Parties worked together successfully to negotiate many case management requirements and Court requests following the status conference. Relevant here, the Parties agreed to propose a Science Day presentation to the Court, and the Court adopted the Parties proposal in Case Management Order No. 1: "The parties shall meet and confer on the protocol for an in-person, off-the-record background tutorial regarding the products at issue and science relevant to this litigation." (Dkt. 87.)

As this submission shows, every Science Day is different, designed with the specific facts underlying the litigation and the areas of medicine in mind. The Science Days in orthopedic device litigation typically have not included expert presentations. Instead, Science Days in orthopedic device litigation have been limited to attorney presentation on the basics. This is an efficient and cost-effective way of presenting information to the Court, and the attorneys on both sides here are well-positioned to present the basic, fundamental information appropriate for Science Day, given that they have served as counsel in numerous MDLs comprising thousands of cases involving total joint replacement products over the past two decades.

What the Plaintiffs propose seems more like a mini-trial with testimony from four of their chosen experts, rather than offering a presentation on the basics of anatomy, total joint replacement, and the products at issue to help the Court get up to speed. Given that Plaintiffs have represented that they intend to call experts who can present their

experience "implanting and/or explanting the devices at issue," it is reasonable to assume that these particular experts may include treating physicians of the individual Plaintiffs (whose medical records Exactech has not seen), and that since Plaintiffs have proffered these experts, that their experiences and thoughts are likely calculated to bolster the merits of Plaintiffs' claims, not to help the Court develop fluency on the basics.

Exactech can and will meet Plaintiffs' expert testimony and science with their own to demonstrate the clinical and engineering success of its products, but the proper format for that battle is not at Science Day before any discovery on the merits, but rather after full discovery; with the benefit of both public and non-public information (including internal company research and individual Plaintiffs' medical records); and after Plaintiffs and their experts provide full notice and disclosure of their opinions under Fed. R. Civ. P. 26(a)(2) – a rule designed to ensure that defendants have a fair opportunity to prepare their expert cases and avoid the prejudices that can result from the plan Plaintiffs propose now.

As stated in the Federal Judicial Center's *Tutorials on Science and Technology,* "the court should reiterate as needed that science tutorials should remain educational and should not digress into a 'battle of the experts' or a 'Daubert hearing dress rehearsal.'"[2] Notably, this event will occur very early in the life of this MDL, long before expert disclosures and the other protections and notice afforded to the parties. Certainly, both sides can point to examples of MDLs where Science Days were presented by either expert witness testimony or attorney presentation, and counsel for both parties have proceeded

[2] *Tutorials on Science and Technology*, Melissa Whitney, Federal Judicial Center Pocket Guide Series, p. 11 (2018)

under both fashions based on *ad hoc* determinations and agreement of the parties, which were informed by the particulars of each litigation. Here, considering the early stage of this MDL and the Defendants' understanding of the Court's request for technical information about the devices, their intended use, and basic information about the subject matter of the MDL, the Court should limit party presentations to attorney presentation only as part of the Science Day Protocol consistent with other recent MDL Science Days involving orthopedic devices in their early stages (*See, e.g.*, In Re: Zimmer M/L Taper Hip Prosthesis with Kinectiv Technology and VerSys Femoral Head Product Liability Litigation, No. 1:2018mc02859 (S.D.N.Y.); In Re: Zimmer NexGen Knee Implant Products Liability Litigation, No. 1:11-cv-05468 (N.D. Ill.) (Attorney presentation only at Science Day for orthopaedic hip implant product liability litigation). If, after the attorneys' presentations at Science Day, the Court believes that further presentation is needed in the form of expert testimony, the Court can always request supplemental presentations later this year and, in fairness provide for staggered written disclosures of the intended expert content for those presentations, so that Exactech has the time and notice necessary to meet Plaintiffs' experts' testimony with that of its own experts.

Plaintiffs' Position:

Plaintiffs agree that the purpose of Science Day is for education and not argument. Thus, in this context, since implant orthopedics and related scientific issues is the subject matter, the education should come from experts, and not attorney advocates. Plaintiffs believe it would aid the Court to hear from an orthopedic surgeon who has implanted and or explanted the devices at issue, potentially an expert on

polyethylene (manufacture, storage and degradation potential), pathologist, as well as a biomechanical engineer. Plaintiffs would propose up to four experts and suggest that each side has a maximum of two and a half hours for their presentations, leaving time for the Court to query the experts. If defendants prefer not to call an expert, they should be free to have attorneys present instead. But plaintiffs want the court to have the ability to learn and ask, and plaintiffs believe in this context, live expert presentations would be more informative. Further, since this MDL selected leadership in part to provide opportunities to younger lawyers to learn about MDL practice, it would be beneficial for them to observe actual experts presenting the science so they too can better appreciate the medical and technical issues.

Notably, counsel for both parties have been involved in science days where experts were presented. In the *In Re: Xarelto (Rivaroxaban) Prods Liab. Litig.*, managed by Judge Eldon Fallon, Ms. Sharko negotiated PTO 18 CMO which stated "[t]he presentations shall be made by physicians and scientists. The presenters will not be questioned by each other or opposing counsel. The Court will have the opportunity to ask questions of the experts as the Court deems appropriate." Case 2:14-md-02592-EEF-MBN Document 925 Filed 05/21/15. Similarly, *In Re: Invokana Litigation was* managed by Judge Brian Martinotti in the District of New Jersey, and CMO 5 stated "[t]he presentations may be made by the Parties' attorneys and/or experts or a combination. The presenters will not be questioned by each other or opposing counsel. The Court will have the opportunity to ask questions of the presenters as the Court deems appropriate. Nothing in this paragraph should be

read to mean that the Parties' are required to present with an expert" Ellen Relkin, co-lead counsel herein, was on the Executive Committee of that litigation and can represent that both Plaintiffs and Defendants called witnesses in Court.

Of note, in this District, the late Judge Jack Weinstein stated "to address the court's current lack of knowledge about website design and the assistive technologies used by the blind, the court will hold a 'Science Day' featuring testimony from expert witnesses." *Andrews v. Blick Art Materials, LLC*, 268 F. Supp. 3d 381, 403 (E.D.N.Y. 2017). There are numerous other examples of various permutations of live expert presentations, lawyer presentation or a combination thereof. Plaintiffs appreciate the time this Court and Judge Keim will be devoting to this litigation and believe they will better appreciate the issues they will see in briefing and eventual trial, by live education from experts at an early juncture.

The Parties look forward to the opportunity of presenting at a Science Day with this Court and hopefully Judge Keim.

Respectfully submitted,

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
(BROOKLYN)

IN RE: EXACTECH POLYETHYLENE ORTHOPEDIC PRODUCTS LIABILITY LITIGATION	**Case No.: 1:22-md-03044-NGG-MMH**
	District Judge Nicholas G. Garaufis **Magistrate Judge Marcia M. Henry**
This Document Relates to All Cases	**MDL No. 3044**

JOINT STATEMENT OF CASE FOR SCIENCE SUBMISSION

This orthopedic device litigation involves hip, knee, and ankle joint replacement systems designed, manufactured, and sold by Exactech, Inc. and Exactech U.S., Inc. ("Exactech") (collectively the devices at issue are referred to as "Hip, Knee, and Ankle Devices", "Exactech Devices", or "Devices."). While each of these Devices is distinct, common among them is that they all incorporate Exactech's ultra-high molecular weight polyethylene ("UHMWPE") inserts or liner components. Plaintiffs allege that these polyethene inserts/liners are defective due to an alleged increased risk of accelerated wear and degradation, thereby necessitating early replacement of the components (often referred to as a "revision surgery") and other personal injuries. Exactech denies that the Devices, including the polyethylene components, are defective and denies that they caused Plaintiffs' claimed injuries.

This joint submission is broken out into the following four sections: (1) the factual background of the Devices at issue, including their function and purpose; (2) a brief summary of the voluntary recall; (3) a brief summary of Plaintiffs' claims and Exactech's defenses; and (4) a glossary of terms and figures describing the Devices, science, and medicine involved in this litigation.

I. FACTUAL BACKGROUND OF THE EXACTECH DEVICES AT ISSUE

A. Background on Total Hip, Knee, and Ankle Arthroplasty

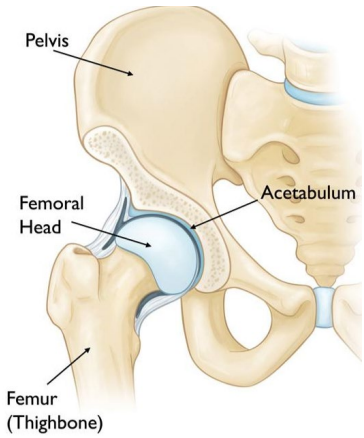
There are numerous conditions that may contribute to the deterioration of the healthy, native joint.[1] Some of the main ones include osteoarthritis, rheumatoid arthritis, congenital conditions, trauma, neoplasms, and osteonecrosis. Of these, osteoarthritis is by far the most common. Osteoarthritis is a degenerative disease that occurs when the cartilage cushioning the bones of the joint starts to wear away. The bones then rub against each other, causing joint pain and loss of mobility. When the cartilage has been completely worn away, the patient is said to have end stage, or "bone-on-bone" arthritis. Total joint replacement surgery is indicated for patients who have failed conservative treatment options and continue to complain of persistent, debilitating pain and significant impairment to activities of daily living. Total joint replacement (including hip, knee, and ankle replacement) is an operative procedure in which the diseased and damaged joint is resected and replaced with prosthetic components. The goal of total joint replacement surgery is to alleviate pain, improve function, and enhance quality of life.

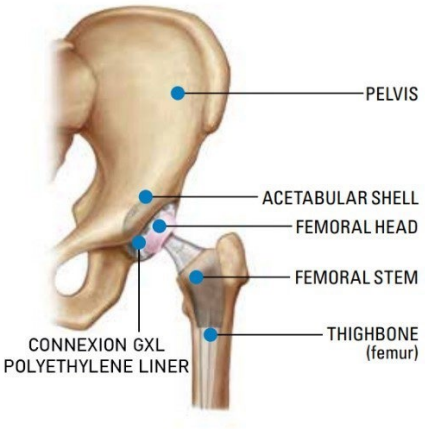
1. Total Hip Arthroplasty

The hip joint connects the leg bone to the bones of the pelvis and its primary function is to support the weight of the body and allow for movement. The hip is part of a special class of joints called "ball and socket" joints. On the pelvis side of the hip, the cup-like depression that forms the socket is referred to as the acetabulum. On the leg side, the top of the thighbone, or femur, forms a rounded ball referred to as the femoral head. The surfaces of the femoral head and acetabulum are coated with a smooth, tough material called articular cartilage, which cushions the bones and facilitates smooth and pain-free movement of the hip joint. Surrounding the hip joint, an articular

[1] A joint is a place where two bones meet.

capsule creates a defined, fluid-filled joint cavity, which further lubricates the joint.



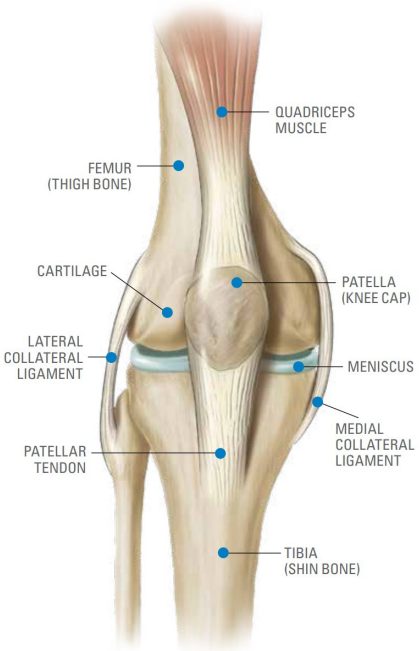


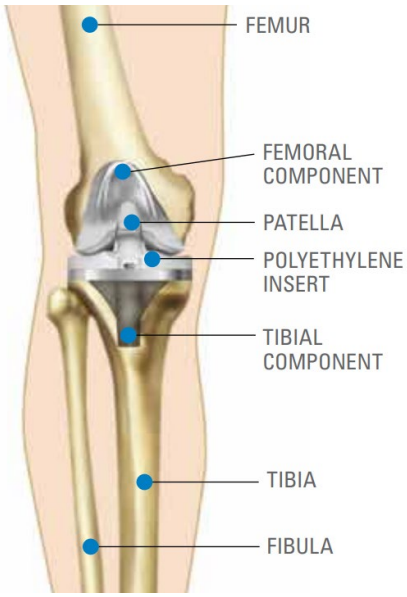
Hip replacement, also called hip arthroplasty or total hip replacement, is a surgical procedure to resurface a hip that has become damaged due to, for example, arthritis. Most total hip devices are comprised of a metal acetabular component ("acetabular shell" or "acetabular cup"), a plastic liner, a metal femoral stem, and a femoral head comprised of either metal or ceramic. During a total hip arthroplasty ("THA"), the hip joint is opened up, the patient's damaged femoral head is removed and the femur is reamed or hollowed out to allow for insertion of a metal stem into the hollow center of the femur. The femoral stem may be either cemented or "press fit" into the bone. A prosthetic femoral head is then placed on the proximal end of the stem, replacing the damaged femoral head that was removed. On the acetabular side, the damaged cartilage surface is removed with a reamer in order to uncover healthy bone. A metal socket is then impacted into the acetabulum. Screws are sometimes used to hold the socket in place for initial fixation. A "liner" is then inserted between the new ball and the socket to allow for a smooth gliding surface. Most often this liner is comprised of plastic, but it may also be comprised of ceramic or metal.

2. Total Knee Arthroplasty

The knee joint connects the bones in the upper and lower leg. It is made up of three bones: the lower end of the femur (thigh bone), the upper end of the tibia (shin bone), and the patella

(knee cap).[2] These bones work together to allow for flexing and extending the leg at the knee joint. The knee joint acts like a hinge, but with some rotation as well. The lower part of the femur connects to the upper part of the tibia and to the patella with ligaments, tendons, and other connective tissues. Amongst these connective tissues is a two-part structure called the meniscus. The two parts are the inner (medial) side and the outer (lateral) side. The meniscus helps to reduce friction, balance out the weight distribution in the knee, and acts as a shock absorber. Articular cartilage covers the surfaces at the ends of the femur and tibia where they meet in the knee joint. This cartilage is very strong and smooth and acts to reduce the friction in the knee joint even more. Surrounding the knee joint, as in the hip, an articular capsule creates a defined, fluid-filled joint cavity, which further lubricates the joint.





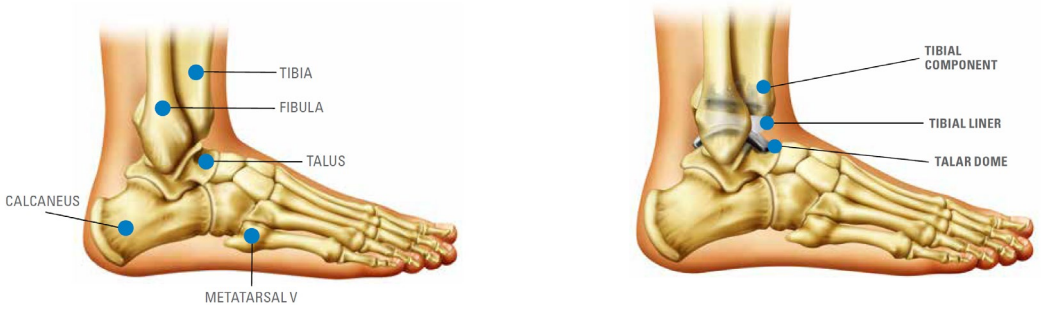
[2] There is a fourth bone, the fibula which lies along the side of the tibia, but it has only a small role in the function of the knee joint.

Knee replacement, also called knee arthroplasty or total knee replacement, is a surgical procedure to resurface a knee that has become damaged due to, for example, arthritis. Most total knee devices are comprised of a metal femoral component, a plastic tibial insert which attaches to a stemmed metal tibial tray, and a plastic patellar component. During total knee replacement, the knee joint is opened up, the patella is moved out of the way, and the damaged bone and cartilage at the bottom of the femur are first cut away. The femur is then measured and cut to fit into the femoral prosthetic component, and the femoral component is attached to the femur. Next, damaged bone and cartilage at the top of the tibia are cut away and the tibia is measured and cut to fit into the stemmed tibial component. A metal tray is fit against the flat cut top of the tibia with its stem inserted down into the bone. A plastic insert is snapped into the tibial tray. The femoral component then slides on to the tibial component when the knee is bent. The damaged portion of the kneecap may also be replaced by a mushroom-shaped prosthesis made of plastic. The resected patella and prosthesis are then attached to the other components of the total knee replacement.

3. Total Ankle Arthroplasty

The ankle joint connects the leg and the foot. It is made up of three bones: the lower end of the tibia (shin bone), which forms the medial, or inside portion of the ankle; the lower end of the fibula (the thinner bone going along the tibia), which forms the lateral, or outside portion of the ankle; and the talus (foot bone) underneath. Like the knee, the ankle is a hinge joint. The bones of the ankle work together to allow the foot to move up and down and adapt to the surface on which a person walks during ambulation. Articular cartilage covers the ends of the bones in the ankle joint, reducing friction and allowing the bones of the ankle to glide smoothly against each other with motion. Surrounding the ankle joint, an articular capsule creates a defined, fluid-filled joint cavity, which further lubricates the joint. Bands of tough fibrous tissue known as ligaments

also surround the ankle joint and attach the bones of the leg to each other and to the bones of the foot. The major stabilizing ligaments of the ankle are the anterior tibiofibular ligament, which connects the tibia to the fibula; the lateral collateral ligaments, which attach the fibula to the calcaneus and gives the ankle lateral stability; and, on the medial side of the ankle, the deltoid ligaments, which connect the tibia to the talus and calcaneus and provide medial stability.



Ankle replacement, also called ankle arthroplasty or total ankle replacement, is a surgical procedure to resurface an ankle that has become damaged due to, for example, arthritis. Most total ankle devices are comprised of three different parts: a titanium tibial component or tibial tray, a cobalt-chrome talar dome, and a plastic tibial liner. During total ankle replacement, an incision is made in the front of the ankle to expose the ankle joint. The damaged bone and cartilage at the bottom end of the tibia and the top end of the talus are then removed. Next, under the guidance of C-arm fluoroscopy (live-action X-rays), special surgical instruments are used to cut the talus and tibia to precisely accommodate the new protheses. The new metal parts of the artificial joint are then attached to the prepared bony surfaces of the talus and the tibia. The titanium tibial tray is inserted into the tibia and the cobalt-chrome talar done is inserted into the talus. Finally, a plastic tibial liner is inserted in between the two metal parts. It acts like an artificial cartilage and prevents the metal parts from rubbing against each other.

B. The Exactech Devices

1. The Connexion GXL Liner

The Exactech Connexon GXL liner is a moderately crosslinked polyethylene acetabular liner that has been used in a variety of Exactech's different hip replacement systems for over a decade. The basic components associated with these hip systems include: (1) an acetabular cup/shell, (2) an acetabular liner (the Connection GXL) that fits inside the acetabular shell; (3) a femoral stem that fits inside the femoral shaft; and (4) a femoral head or ball that connects to the femoral stem. The Connexion GXL liner options include a range of internal diameters and face configurations. The Connexion GXL liner is manufactured with ultra-high molecular weight polyethylene (UHMWPE).

2. The Optetrak Classic, Optetrak Logic, and Truliant Knee

The Exactech Optetrak Classic, which was first introduced in 1994, is a prosthetic knee system that includes cruciate retaining, posterior stabilized, and constrained condylar options. The Optetrak Logic was introduced in 2009. The Truliant was introduced in 2017. The basic components associated with the Optetrak Classic, Optetrak Logic, and Truliant total knee systems include a (1) patellar cap, (2) femoral cap, (3) tibial insert, and (4) tibial tray. The tibial inserts for these knee systems are all made of Exactech's net compression molded polyethene, which is sterilized with gamma radiation (2.5-4.0 Mrad) in a vacuum.

3. The Vantage Ankle

The Exactech Vantage Total Ankle System is an anatomic total ankle system. The basic components associated with the Vantage Total Ankle System include a (1) tibial plate, (2) tibial insert, (3) locking piece, and (4) a talar component. The tibial component is an anatomic design that is right and left specific to respect the native anatomy of the tibia as well as provide articulation

of the fibula. It utilizes a press-fit central cage and plasma pegs to achieve initial fixation. The talar component is designed with a bicondylar articulating surface with the goal of reproducing the natural biomechanics during the gait cycle.

II. VOLUNTARY RECALL

On June 29, 2021, Exactech initiated a voluntary recall for certain Exactech Hip Devices that utilized Exactech's Connexion GXL polyethylene acetabular liner because Exactech had observed early linear and volumetric wear in certain patients who had received the Connexion GLX liner and were between 3-6 years out from their implant surgery.

On August 30, 2021, Exactech initiated a voluntary recall for its Knee and Ankle polyethene inserts labeled with an 8-year shelf-life because those inserts were packaged in oxygen resistant vacuum bags that contained only a nylon barrier to limit oxygen transmission, but not a secondary oxygen barrier consisting of ethylene vinyl alcohol ("EVOH") as specified in Exactech's packaging drawings. On February 7, 2022, the knee and ankle voluntary recall was expanded to include all knee and ankle polyethylene inserts packaged in the oxygen resistant single-barrier bags regardless of label or shelf-life.

On August 11, 2022, Exactech expanded the scope of its hip recall to all Connexion GXL liners and conventional non-crosslinked polyethene liners manufactured since 2004 that were packaged in the oxygen resistant single-barrier bags, but not a secondary oxygen barrier consisting of ethylene vinyl alcohol ("EVOH") as specified in Exactech's packaging drawings.

III. CLAIMS AND DEFENSES

A. PLAINTIFFS' STATEMENT

Plaintiffs who were implanted with Exactech Devices allege they were put at an increased and undue risk of, and have suffered from adverse events associated with accelerated wear and

degradation of UHMWPE, including but not limited to inflammation causing bone destruction (known as osteolysis), implant component loosening, adverse local tissue reaction, implant failure, pain, swelling, destruction of the hip, knee, and ankle bone and muscular structure, and permanent alteration of gait.

Plaintiffs bring strict liability and negligence claims against Exactech alleging that the Devices were defectively designed, manufactured, packaged, and sold. Plaintiffs further allege that Exactech negligently and/or fraudulently misrepresented aspects of these Devices to surgeons and/or omitted material information known to Defendants about risks associated with these Devices. Plaintiffs allege Exactech sold and distributed these Devices, and they were defective in that the Devices were irradiated without proper thermal treatment of the UHMWPE to rid the polyethylene of free radicals, without proper packaging to protect against in vitro oxidation, without proper quality control of aging inventory, without a safe expiration date, and without proper warnings to surgeons concerning the risks of these Devices. Additionally, Plaintiffs allege that the Knee Devices' utilization of Exactech's polyethylene tibial insert in conjunction with its tibial tray component, which have a proclivity for loosening, contributes to micromotion, wear, osteolysis, and failure.

B. DEFENDANTS' STATEMENT

Exactech denies that the Devices are defective, denies any liability, and denies that it caused Plaintiffs' claimed injuries. Exactech further denies that cases where the failure mode is alleged to related to the tibial insert should be included in this MDL, which was created to address claims of premature polyethylene wear.

Although modern total hip, total knee, and total ankle replacement surgeries are associated with a high rate of success, there is no such thing as a risk-free total joint replacement surgery.

There is also no such thing as a risk-free total joint replacement device. Complications necessitating revision surgery can and do arise. A revision surgery is a procedure to re-do or replace one or more of the components in the total joint construct. There are many potential reasons why a patient may need to undergo revision surgery. The leading cause for revision of total joint replacement devices over the past 50 years has been wear of the polyethylene component. Other common reasons for failure include prosthesis or bone fracture, loosening, infection, dislocation, and patient size and level of activity. The bottom line is that as with any major surgery, there are risks associated with total joint replacement and surgical outcomes can never be guaranteed. At this time, science cannot offer a perfect substitute for the healthy, native hip, knee, and ankle joint

The evidence will show that the Devices at issue were state-of-the-art, industry-leading components that are safe, effective, and have a long successful clinical history in patients. The evidence will further show that the packaging non-conformity leading to the voluntary recall, which was initiated out of an abundance of caution, does not render the Devices defective or unreasonably dangerous.

IV. GLOSSARY OF TERMS AND FIGURES

A. Joint Anatomy

Acetabulum – Cup-shaped socket of the hip joint. In total hip replacement, it holds the acetabular component (cup).

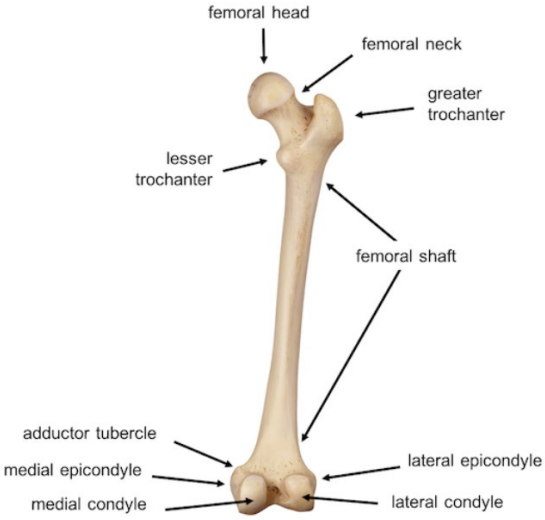
Cartilage – The firm, whitish, flexible connective tissue that protects the bones and joints. It surrounds the ends of bones and cushions the space in the joint where the bones meet thereby reducing how much stress an impact puts on the bones. It also acts as a lubricant which reduces friction between the bones and helps the joint keep its shape while moving.

Condyle – A smooth, rounded prominence at the end of some bones where they form a joint with another bone. For example, the knee joint is formed by the femoral lateral and medial condyles and the tibial lateral and medial condyles.

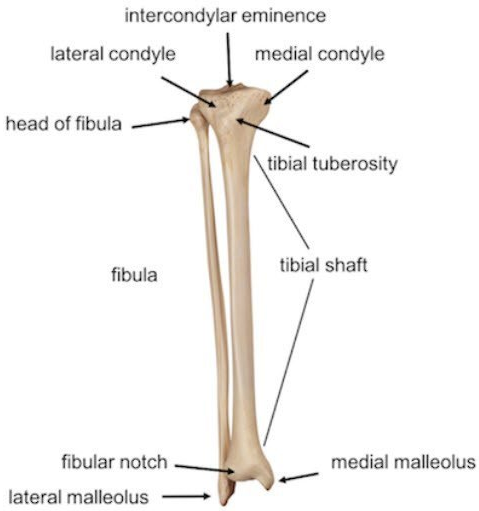
Femoral condyles – Two rounded prominences at the distal end of the femur that form part of the knee joint.

Femur – The thigh bone. The femur contains two distinct anatomical landmarks: the head of the

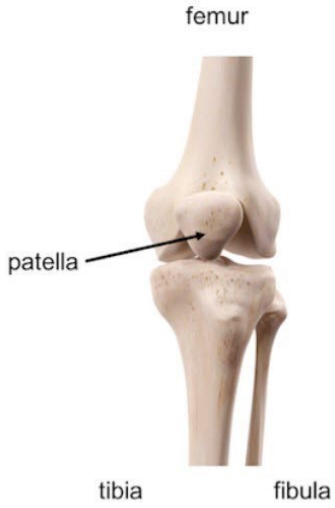
femur which articulates with the socket or acetabulum of the pelvic bone, and the two femoral condyles.



Fibia – The lateral and smaller of the two bones of the lower leg; it does not bear weight and articulates with the tibia above and the tibia and talus below. It is also known as the calf bone.



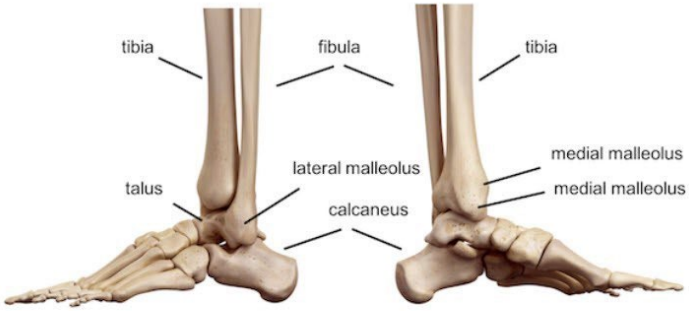
Patella – Also known as the knee-cap, the patella is a small, rounded, triangular-shaped bone located in the front of the knee joint where the femur and tibia meet.



Posterior cruciate ligament (PCL) – The PCL runs along the back of the knee and connects the femur (upper leg) to the tibia (lower leg). The PCL helps stabilize the knee by preventing the tibia from slipping too far back in relation to the femur, especially when the knee is flexed (bent).

Synovial joint – A joint is where two bones come together. A synovial joint (e.g. the hip, knee, and ankle) is the type of joint found between bones that move against each other. In synovial joints, the bones are able to move or articulate against each other because they are not directly connected. Instead, they are surrounded by an articular capsule that defines a joint cavity filled with synovial fluid. The articular surfaces of the bones are covered by a thin layer of articular cartilage, which allows for smooth movements between the two adjacent bones.

Talus – The talus is the bone that makes up the lower part of the ankle joint (the tibia and fibula make up the upper part). The talus also sits above the heel bone (calcaneus).



Tibia – The leg bone or shin bone.

B. Anatomical Positioning

Anterior – Referring to the front of the body.

Distal – A point situated or positioned further away from the center (trunk) of the body, or to the

point of attachment to the body. The opposite of proximal.

In situ – Refers to something be in its originating place or where it should be.

In vitro – Refers to something that is performed or taking place in a test tube, culture dish, or elsewhere outside the body.

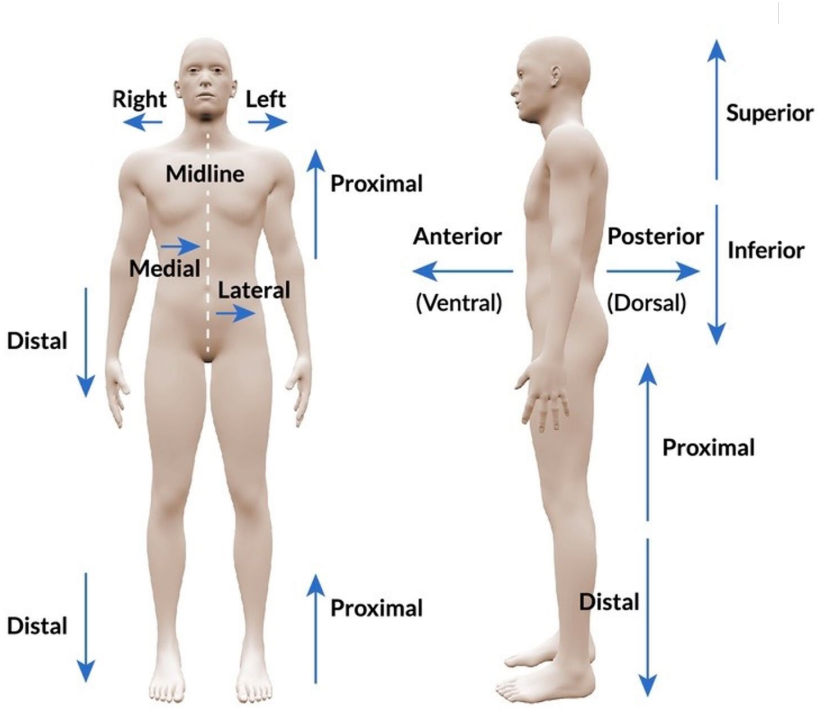
In vivo – Refers to something that is performed or taking place in the body.

Medial – Refers to a part of the body situated or directed toward the middle or center of the body. The opposite of lateral.

Lateral – Refers to a part of the body situated or directed away from the middle or center of the body; to the side. The opposite of medial.

Posterior – Referring to the back of the body.

Proximal –A point situated or positioned closer to the center (trunk) of the body, or to the point of attachment to the body. The opposite of distal.



C. Indications for Total Joint Replacement

Avascular necrosis – The death of bone tissue due to a loss of blood supply. If left untreated, it can cause the bone and surrounding joint to collapse.

Osteoarthritis – A progressive degenerative joint disease that occurs when the protective cartilage that cushions the ends of the bones wears down over time. Osteoarthritis often follows a history of injury or overuse of a joint and is characterized by cartilage deformation and eventual

bone deformation, with or without inflammation of the joint. It causes motion of the affected joint to be painful.

Rheumatoid arthritis – A chronic autoimmune condition that occurs when a person's immune system doesn't work properly and attacks the lining of the joints causing a painful swelling that can eventually result in bone erosion and joint deformity.

D. Joint Replacement Procedures

Arthroplasty – The surgical reconstruction or replacement of a joint.

Cruciate Retaining (CR) – The cruciate retaining knee implant does not require the removal of either the anterior or posterior cruciate ligaments for attachment. Cruciate-retaining implants do not have the center post and cam design. This implant may be appropriate for a patient whose posterior cruciate ligament is healthy enough to continue stabilizing the knee joint.

Minimally Invasive – *In contrast to a traditional open surgery with a large incision, a minimally invasive* procedure involves smaller incisions.

Posterior Stabilized (PS) – The posterior stabilizing knee requires removal of the anterior and posterior cruciate ligaments. Posterior stabilized implants do include a center post and cam design.

Revision – Replacement of a prosthesis. A revision can either be total (replacement of all components) or partial (replacement of one or some of the components).TAA – Total ankle arthroplasty, also called total ankle replacement, is a surgical procedure in which the lower end of the tibia and the talus are replaced with metal and plastic components.

THA – Total hip arthroplasty, also called total hip replacement surgery, is a surgical procedure in which the upper end of the thigh bone (femur) and the acetabulum (socket of the pelvis) are replaced with metal, plastic or ceramic components.

TKA – Total knee arthroplasty, also called total knee replacement, is a surgical procedure to remove damaged or worn parts of the knee joint by replacing the lower end of the thigh bone (femur), upper end of the shin bone (tibia) and back of kneecap (patella).

E. Materials Used in Joint Replacement

Bone cement – A material, Polymethyl Methacrylate (PMMA), that fills the space between the bone and the implant, acting as a type of "grout," holding the implant against the bone.

Conventional UHMWPE (Ultra High Molecular Weight Polyethylene) – Polyethylene that has been manufactured by compression molding or ram extrusion but has not been intentionally cross-linked.

HXLPE (highly crosslinked polyethylene) – Refers to UHMWPE that has been extensively crosslinked.

Moderately cross-linked polyethylene – Refers to UHMWPE that has been crosslinked but not to the same extent as HXLPE.

Polyethylene – One of the most widely produced plastics in the world, also referred to as a

polymer. There are several types of polyethylene, and each one is best suited for a different set of applications

UHMWPE (Ultra-high molecular weight polyethylene) – An engineering polymer that is commonly used as a bearing material in total joint arthroplasty due to its high wear resistance, toughness, durability, and biocompatibility.

F. Potential Treatments for Materials used in Joint Replacement

Crosslinking – The general term for forming, through exposure to gamma radiation or peroxides, covalent bonds or relatively short sequences of chemical bonds to join adjacent polyethylene chains together.

Direct Compression Molding (DCM) – A process by which polyethylene resin is converted to a finished part using individual molds and by applying heat and pressure.

Gamma radiation – A commonly used method of sterilization in the medical industry that involves the use of gamma rays to ionize the medical device in question, thereby destroying any microorganisms that are present.

Sterilization – Sterilization refers to the removal of microorganisms and other pathogens from an object or surface such as an implant by treating it with chemicals or subjecting it to high heat or radiation. Sterilization is essential when using biomaterials in the human body to avoid infection, which may result in implant failure and/or serious illness.

G. Clinical Evaluation of the Native and/or Reconstructed Joint

Abductor Muscles – A muscle group whose contraction moves a limb from the midline of the body.

Antalgic gait – A gait that develops as a way to avoid pain while walking. It is a form of gait abnormality where the stance phase of gait is abnormally shortened relative to the swing phase. It can be a good indication of pain with weight-bearing.

Aseptic loosening – Mechanical or biological loss of fixation of the implant or inadequate initial fixation of the implant in the absence of infection.

Aspiration – A medical procedure that involves withdrawing fluid, tissue or another substance from an area of the body.

Extension – It describes a straightening movement that increases the angle between body parts. For example, when standing up, the knees are extended. The opposite of flexion.

Flexion – It describes a bending movement that decreases the angle between body parts. Bending the leg at the knee is an example of flexion. The opposite of extension.

Foreign Body Reaction – The body's response to an exogenous substance.

Girdle stone – A very rare salvage hip procedure to address problems arising from failed hip surgery including peri-prosthetic infections or recurrently dislocating prostheses. It is reserved for those in which revision surgery(s) have failed to restore hip function often due to infection,

abductor muscle loss, and severe bone destruction.

Implant fixation – Refers to the nature of the bond between the prosthetic component and host bone. Implant fixation can be achieved via cemented or cementless means.

Innate Immune Response –The body's non-specific response to certain substances and conditions.

Joint Dislocation – The separation of two bones where they meet at a joint.

Joint Effusion - An increased accumulation of fluid in the joint space.

Laxity – Refers to looseness or instability of a joint.

Lysis – The disintegration of a cell by rupture of the cell wall or membrane.

Necrotic Tissue – Dead tissue.

Osteolysis – Bone resorption or loss of bone that occurs as the result of an active biological cascade induced by an underlying inflammatory condition.

Phagocytic Process – A cellular process for ingesting foreign and endogenous materials.

Radiolucency – A dark or black area on a conventional radiograph indicating a void or area of tissue that is less dense than surrounding tissue.

Range of Motion (ROM) – The arc, in degrees, through which one part of a joint may move.

Synovitis – The inflammation of the joint lining.

Trendelenburg Gait – An altered gait as a result of weakness of the hip abductor muscles.

Valgus deformity – Outward angulation of the distal segment of a bone or implant component (away from the midline).

Varus deformity – The inward angulation of the distal segment of a bone or implant component (toward the midline.

H. Processes that May Impact the Mechanical Properties of Polyethylene

Abrasion – A specific type of wear damage to polyethylene that results in the disintegration of the material on the surface due to the influence of a harder particle in contact with the surface. It is characterized by a shredded appearance.

Burnishing – A specific type of wear damage to polyethylene characterized by heavily polished areas with loss of machining marks.

Delamination – A specific type of wear damage to polyethylene characterized by the removal of sheets of material from the implant surface.

Embedded debris – A specific type of wear damage to polyethylene characterized by the presence of irregular material pressed into the polyethylene surface.

Free Radicals – Highly reactive unstable molecules.

Implant wear – The release of particles or debris from the implant surface that occurs when implants are placed in the body. The extent to which an implant wears can be influenced by numerous factors.

kGy (Kilo Grays) – is the unit of absorbed energy from ionizing radiation.

Oxidation – A chemical reaction that takes place when a substance comes into contact with oxygen or another oxidizing substance.

Oxidative Degradation – Refers to a change in the mechanical properties of a polymer (here, polyethylene) that can occur when a certain level of oxygen containing molecules interact with the hydrogen which forms the long chains in the polymer (resulting in oxidation), and causes the chains to break into smaller molecules.

Pitting – A specific type of wear damage to polyethylene which results in small, crater-like surface defects.

Plastic deformation – A specific type of wear damage to polyethylene characterized by irreversible cold flow structural changes or irregularities.

Scratches – A specific type of wear damage to polyethylene characterized by thin, shallow linear defects.

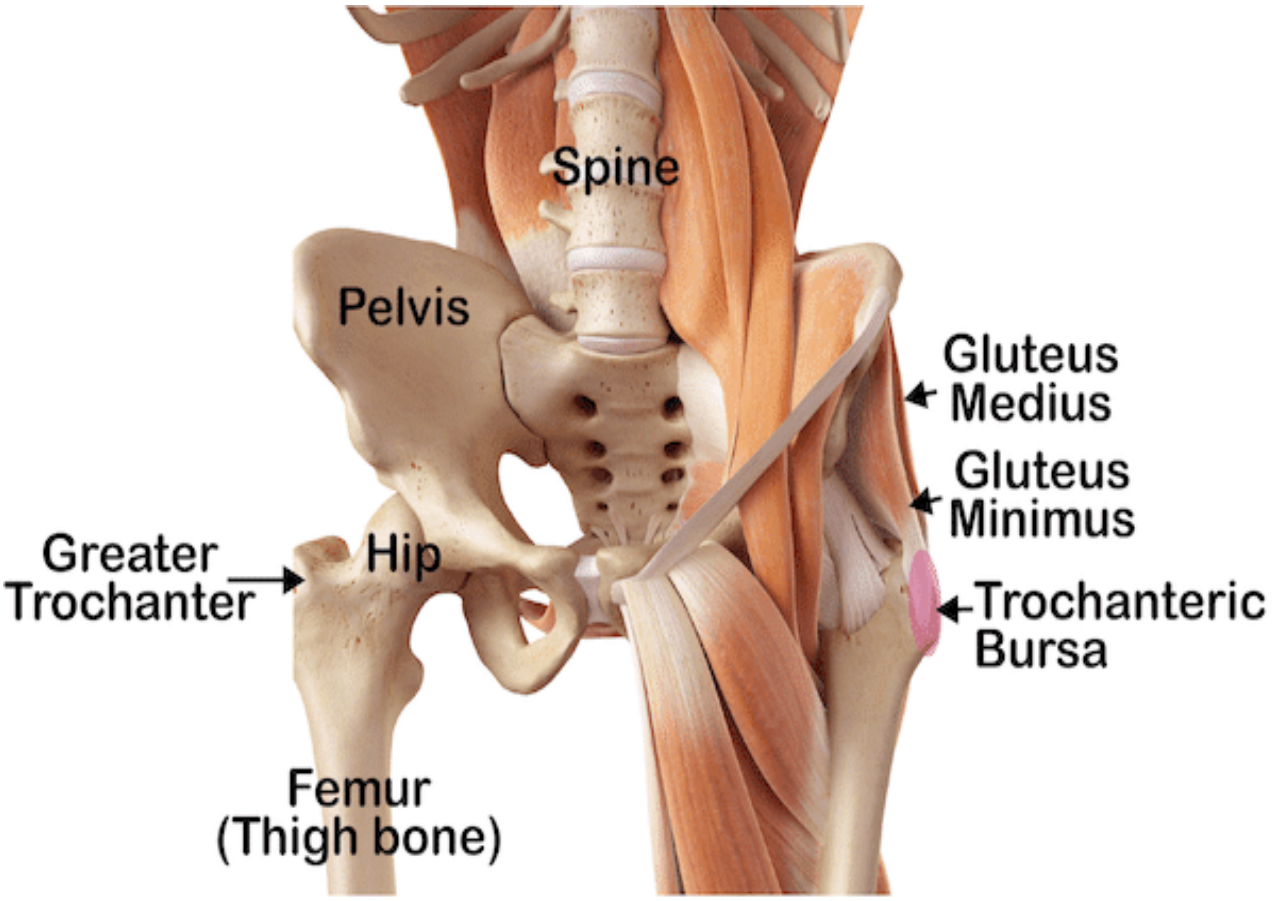
Thermal Treatment of UHMWPE – Exposing irradiated UHMWPE to heat in an effort to reduce free radicals generated by the crosslinking process.

Vitamin E – An additive that may be used with UHMWPE prosthetic components as an antioxidant in an effort to reduce oxidation of the polyethylene.

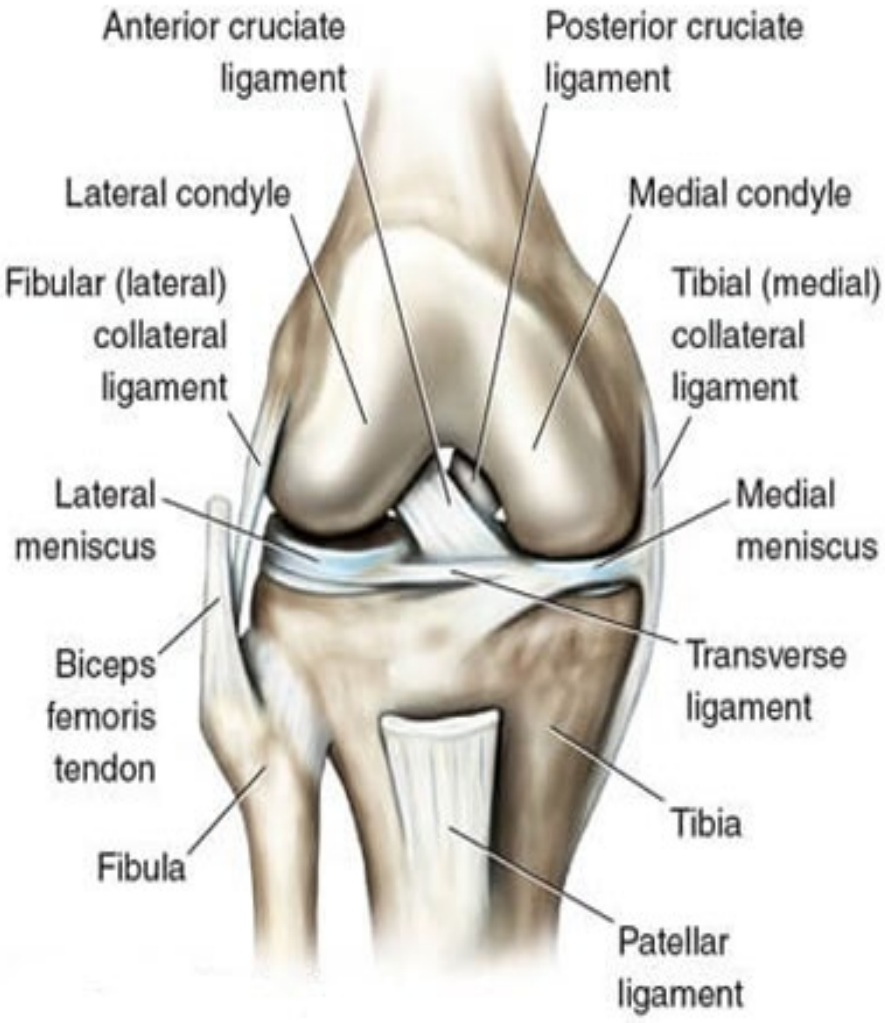
Wear damage – Refers to the change in surface texture or morphology that is caused by the action of wear mechanisms (i.e. burnishing, abrasion, scratches, plastic deformation, pits, delamination, and embedded third bodies).

Wear Debris – In articulating prosthetic joints, particles created from friction between component parts.

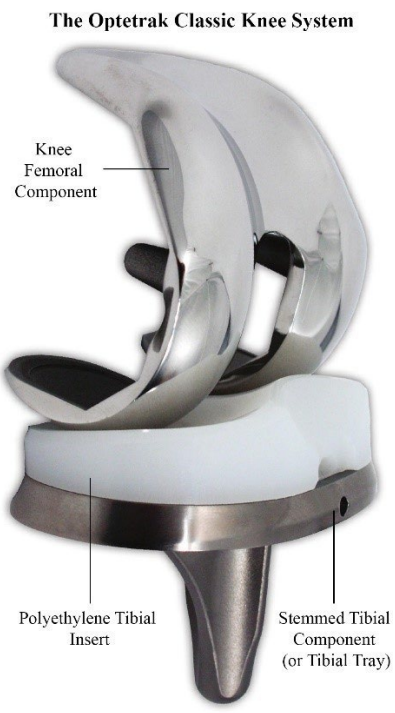
Hip Joint

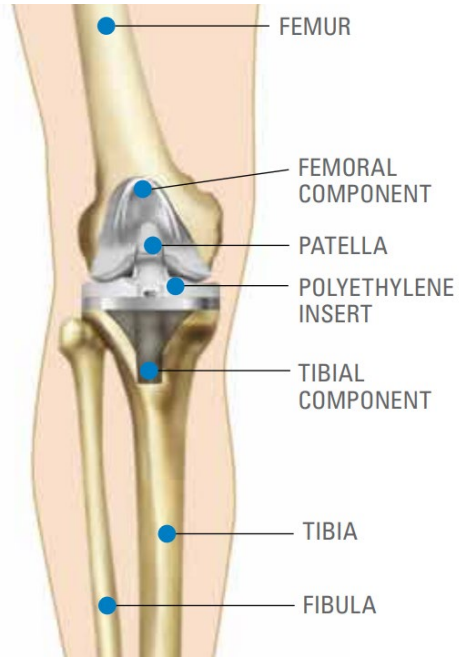

Spine
Pelvis
Gluteus Medius
Gluteus Minimus
Greater Trochanter
Hip
Trochanteric Bursa
Femur (Thigh bone)

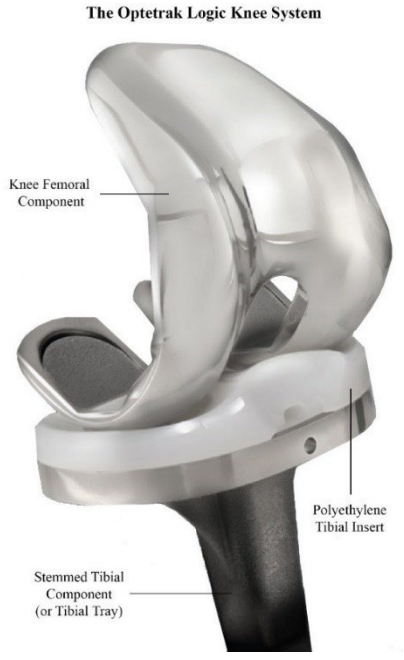
Knee Joint


Anterior cruciate ligament
Posterior cruciate ligament
Lateral condyle
Medial condyle
Fibular (lateral) collateral ligament
Tibial (medial) collateral ligament
Lateral meniscus
Medial meniscus
Biceps femoris tendon
Transverse ligament
Tibia
Fibula
Patellar ligament

Optetrak Total Knee Systems

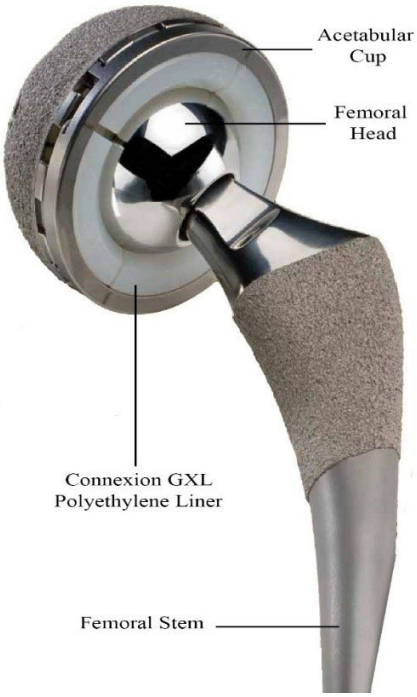


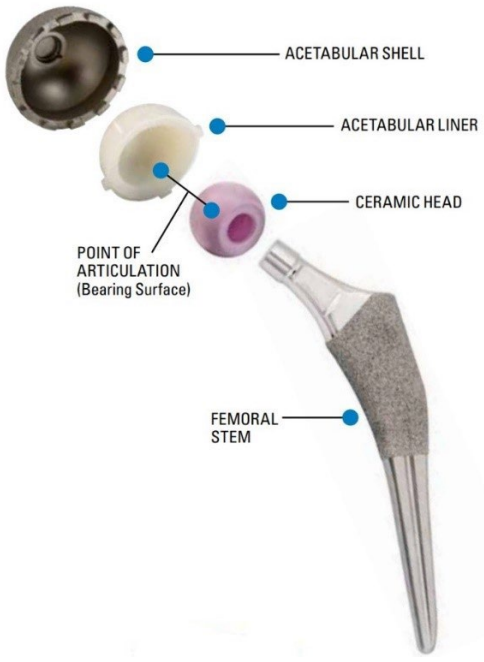


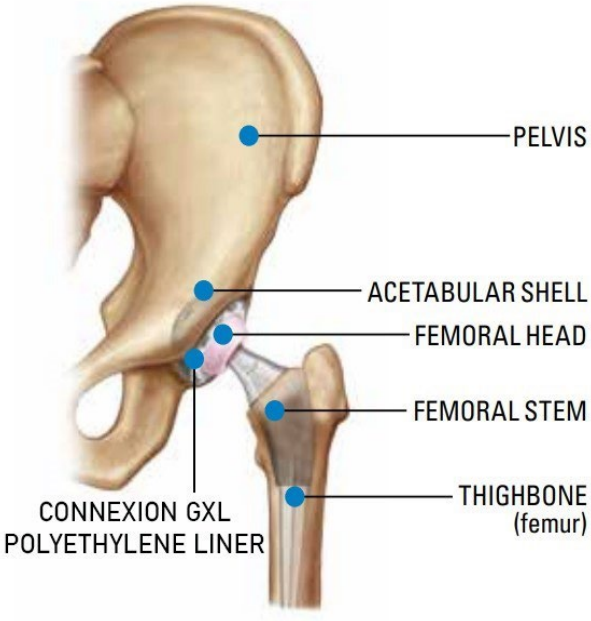


Truliant Total Knee System

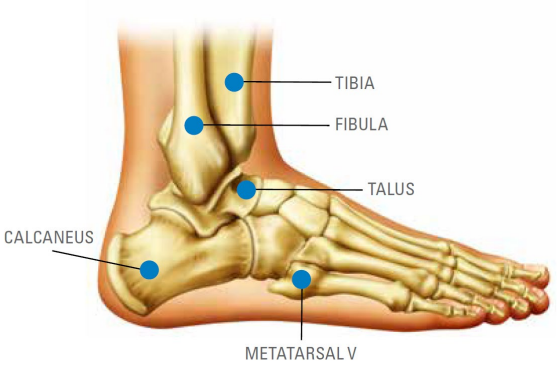
Connexion GXL Polyethylene Liner for Use in Total Hip Replacement

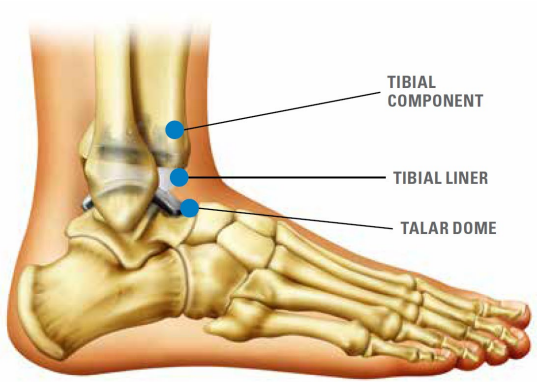


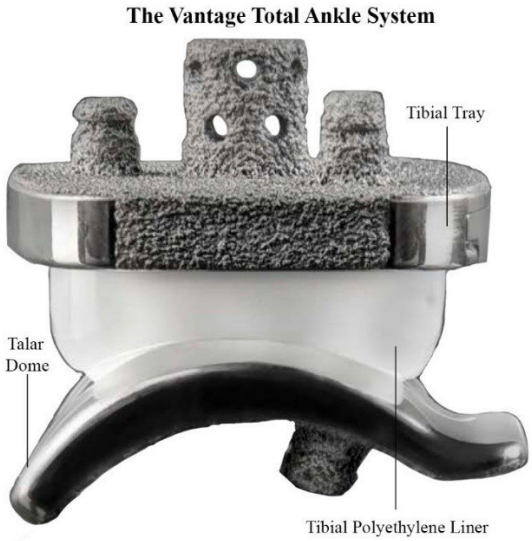




The Vantage Total Ankle System







Dated: February 3, 2023

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