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Exactech Knee Replacement Inserts Lawsuits

Results achieved in prior matters are not meant to be a guarantee of success as the facts and legal circumstances vary from matter to matter.

While we no longer handle Exactech cases, we continue to advocate for clients in related areas. Visit our Defective Drugs and Device Injuries page to view all of the current cases we are handling.

In August 2021, knee implant manufacturer Exactech initiated a recall of its polyethylene knee inserts after confirming that approximately 80% of inserts manufactured since 2004 were packaged in out-of-specification (non-conforming) vacuum bags. In April 2022, the company expanded the earlier recall to nearly 150,000 polyethylene inserts used in knee replacements.

The reason for the recall is that Exactech used non-confirming packaging that would allow oxygen to interact with and degrade the plastic insert before it was implanted in the knee, causing oxidation before the insert is implanted. The Exactech recall letter to clients states:

During a recent review of its knee implant manufacturing process, Exactech learned that one of the packaging layers for the plastic insert has been out of specification and may allow oxygen from the air to diffuse into the plastic insert prior to it being implanted in your knee. If a large amount of oxygen diffuses into the plastic insert while it's being stored and before it is implanted, this can lead to a process called oxidation, which can cause the plastic to wear out earlier than expected or to become damaged after it is implanted into the patient's body. See Exactech recall notice to patients.

For more information, see the Exactech recall notice to healthcare professionals.

How the Exactech Knee Replacements Fail

Oxidation can wear out prematurely and cause damage to the plastic after it is implanted in the patient's body, causing injury to the patient. In addition, without the plastic insert, there is no cushioning to absorb the impact of movement, causing metal-on-metal or metal-on-bone articulation, resulting in pain and injury to the patient.

The four parts of a standard total knee replacement include:

1. The femoral component – a metal piece that attaches to the thigh bone.
2. The tibial tray – a metal piece that fits into the shin bone.
3. The patellar component – a piece of plastic that fits onto the kneecap.
4. The tibial polyethylene insert – a plastic insert that fits between the femoral component and the tibial component and acts as the new cushion for the replaced knee joint.

A standard total knee replacement consists of three parts:

1. The tibial component – a metal piece that attaches to the shin bone.
2. The talar component – a metal piece that girls into the foot bone.
3. The polyethylene insert – a plastic insert that fits between the tibial component and the talar component and acts as the cushion or cartilage for the replaced ankle joint.

Complications associated with polyethylene wear include:

- Loosening/Instability
- New or worsening pain
- Inability to bear weight
- Grinding, clicking, or other noise
- Swelling
- Osteolysis (Bone Loss)
- Cracking or fracture

Patients Who Believe They May Have an Exactech Knee Device

According to the recall notice, patients who have had a knee implant should see their doctor for a clinical exam and x-rays.

Devices Affected by the Exactech Recall

- OPTETRAK® Posterior Stabilized Knee - Available since 1994
- OPTETRAK Logic® - Available since 2009
- TRULIANT® Tibial Inserts – Available since 2017