

Answers to your Questions about Hip and Knee Replacements (Revised 2-26-14)

Consumers Union's Safe Patient Project is urging major manufacturers of hip and knee devices to warranty their products so consumers have clear actions to take if their implants fail. A warranty also will encourage manufacturers to be upfront with consumers about the life-expectancy of artificial hips and knees, and make sure these devices are safe and effective before they go on the market.

Q: Why should hip and knee implants be warranted?

A: Unlike most expensive products on the market today – cars, computers, major appliances – the vast majority of knee and hip implants are not warranted by their manufacturers. In fact, most patients get little to no written information prior to surgery about how long the device inside their body will last, or even its maker or model number. Compounding the problem is that most devices are exempted from safety testing before they are put on the market, and there is no national registry that tracks who has which implant in case of failure.

When an implant fails, the patient often has no idea what company made the device inside them, or how to get it fixed. Worse, most failures will require revision surgery, which entails chipping out the old device and replacing it with another – a costly surgery that the patient, or his or her insurance, or Medicare – is on the hook for. Requiring manufacturers to state how long their products will last and back that up with a warranty, will improve the safety and effectiveness of hip and knee implants.

Q: Is there a history of these implants failing?

A: Yes. A review of medical device recalls over the past decade reveals that all major hip and knee implant manufacturers have recalled a product, or line of products, for defects.

Consumer Union reviewed complaints from the last 10 years concerning hip and knee devices in the FDA's Medwatch database, where patients, physicians and others can register problems with medical devices.

We found that common complaints from both hip and knee replacement patients include difference in leg length, continued joint pain, instability and limited range of motion, nerve damage, devices that did not adhere to the bone and tissue, and reaction to the materials that make up the device. For instance, patients have had debilitating reactions to metal toxicity from all-metal hip implants. In the last ten years the six to selling hip and knee implant companies collectively issued 1,334 recalls.

Q: Aren't joint replacements rare? Is this really a big problem?

A: As the population ages, and adults in their 40s and 50s want to play longer and harder, the popularity of hip and knee implant surgery has skyrocketed. Last year alone there were nearly 1.2 million of these surgeries in the United States. That number is expected to quadruple by 2030, and more than half of those patients will be under the age of 65.

Right now, revision surgery (replacing or repairing a failed implant) makes up 18 percent of hip replacements, and 8 percent of knee replacements. Patients with hip and knee revisions are more likely to undergo additional revisions as compared to those with those who have had only one replacement.¹

Since companies are marketing hip and knee replacements to very active people, including athletes and people in their 40s and 50s, it is critical to for manufacturers to tell consumers how long these joints will last so they can avoid multiple revision surgeries, and to back that up with a warranty.

Q: I don't need an artificial knee or hip, so why should I care?

A: Because as a taxpayer, you contribute to Medicare – the national health care program for Americans over 65 – and you will be paying for many of these hip and knee surgeries. The average cost of hip implant surgery is \$19,000 and \$17,500 for a knee replacement. If you need knee revision surgery, replacing the first implant with a new one, the average cost is 25,000. And the average cost of a hip revision is \$24,500.²

As more Baby Boomers get implants, as well as revision surgeries for failed products, joint replacements could make up a significant percentage of all Medicare spending. The cost of the actual hip or knee implant can be as much as 50 percent of the cost of the entire procedure.³

Q: Do any companies warranty their hip and knee implants now?

A: Currently, the only warranty in the U.S. market is for Biomet's Oxford Partial Knee.⁴ Biomet offers a lifetime warranty, which is limited to one full replacement. It comes with a disclaimer of any liability outside of what is included in the warranty, such as pain and suffering, medical expenses and lost earnings. Consumers Union thinks Biomet's warranty should cover the medical expenses required to replace its knee, just as "labor costs" are typically included in other warranties.

Q: What should a warranty cover?

A: We are asking device makers to offer a warranty that meets the following requirements:

- Manufacturers should provide a warranty specifying how long they intend to stand by their product.
- Cover the full replacement costs of a flawed device, including the device, surgeon, and hospital costs, as well as the related patient out-of-pocket costs for a
- Give the consumer the option to replace the failed device with another manufacturer's product if the implant has been recalled by the FDA or the company, is the subject of FDA warnings, is under investigation by the FDA, or if the product is no longer being sold by the company.
- Establish a clear system for patients to use, including a toll-free number and a registration number to track the claims process. Physicians will charge the device company, not the patient.
- Not require the patient pay out-of-pocket expenses. For example, the patient should not have to pay the device maker or surgeon first and get reimbursed later.
- Provide the patient with full information concerning a warranty claim denial and a process to allow the patient to appeal the decision.
- Not limit or eliminate a patient's right to sue if he or she uses the warranty.
- Not disqualify patients across the board if they have specific diseases or illnesses that are not related to the failure of a device.
- Not disqualify patients for normal activities, including falls.
- Not disqualify patients due to information that is not routinely available to them, such as information that is on the device packaging or placed into their medical records.

Q: What kinds of problems or flaws would the warranty cover?

A: The warranty should cover full replacement costs of implants that fail, including those that break, crack, cease to function as intended or emit toxins into the body. A good warranty should clearly explain the process for its activation, clarifying and streamlining the process for a patient to pursue revision surgery and repair the hip or knee quickly.

Q: What should I ask if I'm getting a hip or knee replacement?

A: We found that people who shared their device stories with Consumers Union did not choose the device that was implanted in them. Patients are most likely to end up with a device that their orthopedic surgeon prefers and has experience installing,⁵ which may or may not be the best fit for a particular patient.

We suggest asking your doctor:

- Is a hip or knee replacement completely necessary?
- What is the make and model of the device the doctor plans to use?
- Will I be able to maintain my current activity level?
- What is the success/complication rate of the device?

- Will a representative from the medical device manufacturer be present during your operation and if so, what is their role?
- Has the device been recalled? Don't feel silly asking this question -- recalled devices can continue to be implanted in people.
- What materials are used to make the device? You may have an allergy to materials used.
- How many times has the doctor performed the surgery with this particular device?
- Does the doctor have a financial interest in the device company?
- What are the infection rates at the hospital? You can also find this information at: <http://www.hospitalcompare.hhs.gov/?AspxAutoDetectCookieSupport=1>
- Are there any warranties or guarantees that the surgeon is offering on the surgery and/or device?
- What are all of the long-term complications from particulate wear debris, and in particular, the long-term implications from exposure to metal ions from aging and degrading medical devices?
- Ask for documentation about the device implanted, including the manufacturer and model name, and any written information available about your device. Keep this information with your personal medical records.

Who are the top sellers of hip and knee implants?⁶

1. Zimmer
2. Johnson & Johnson (Depuy Orthopedics is a subsidiary)
3. Stryker
4. Smith & Nephew
5. Biomet

¹ Ong KL, Lau E, Suggs J, Kurtz SM, Manley MT.; Risk of subsequent revision after primary and revision total joint arthroplasty.; Clin Orthop Relat Res. 2010 Nov;468(11):3070-6. doi: 10.1007/s11999-010-1399-0. Epub 2010 May 25.

² Steiner C, Andrews R, Barrett M, Weiss A. *HCUP Projections: Mobility/Orthopedic Procedures 2011 to 2012*. 2012. HCUP Projections Report # 2012-03. ONLINE September 20, 2012. U.S. Agency for Healthcare Research and Quality. Available: <http://www.hcup-us.ahrq.gov/reports/projections/2012-03.pdf>.

³ A Surgeon's Look at Costs In Total Joint Arthroplasty; LAING RIKKERS, MARCH 31, 2006; Orthopedic and Dental Industry News: http://www.healthpointcapital.com/research/2006/03/31/a_surgeons_look_at_costs_in_total_joint_arthroplasty/

⁴ Biomet, "Lifetime Limited Warranty Terms and Conditions," <http://www.biomet.com/lessIsMore/warrantyTerms.pdf>

⁵ "Hip and Knee Implants: Current Trends and Policy Considerations"; Natalia A. Wilson, Eugene S. Schneller, Kathleen Montgomery and Kevin J. Bozic; Health Affairs; May 2013.

⁶ Fierce Medical Devices; "After tough times, hip implant revenue projected to grow again," May 16, 2013.