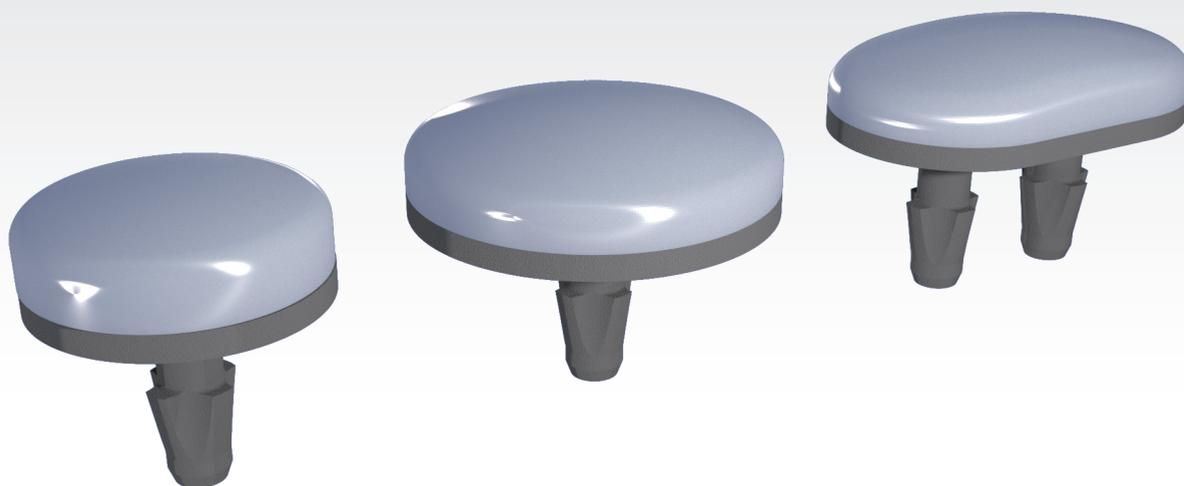


FAQs

BioPoly[®] RS
Distal Femur



Advancing Materials. Advancing Outcomes.™

BioPoly® RS

Distal Femur

Frequently Asked Questions

General Information

- Q:** What are the indications for BioPoly® RS Knee Implants?
- A:** Intended for the replacement of symptomatic abnormal or severely abnormal (ICRS Grade 2, 3 or 4) chondral or osteochondral focal lesions located in the weight bearing regions of femoral condyles and trochlear facets.
- Q:** What size lesions can BioPoly® RS Knee Implants accommodate?
- A:** Lesion size should not exceed 3.1 cm² and must be circumscribed by a 1.5 or 2.0 cm circle or 1.5 by 2.4 cm oval of normal or nearly normal (ICRS Grade 0 or 1) cartilage, with an overall cartilage depth less than 4 mm from the articulating surface. Subchondral bone quality must be deemed sufficient to secure the implant.
- Q:** What type of patient would benefit from the use of BioPoly®?
- A:** Patients with knee pain who are too young for a TKR who want to regain active lifestyle. They must be over 21 years of age. In addition to being the primary treatment of focal chondral or osteochondral lesions, BioPoly® can also be used in patients who have failed debridement, microfracture, OATS, ACI, MACI, or other biologic procedures provided that the subchondral bone is adequate.
- Q:** Can BioPoly® be used on patients with nickel allergies?
- A:** Yes, nickel allergies are not contraindicated because none of the implant materials contain significant amounts of nickel.

Materials

- Q:** What is BioPoly®?
- A:** BioPoly® is a next generation orthopaedic biomaterial, combining Hyaluronic Acid (Bio) and ultra high molecular weight polyethylene (Poly or UHMWPE). This proprietary material is hydrophilic (water attracting) and interacts favorably with native tissues to support anatomical loads. (HA refers to Hyaluronic Acid, NOT Hydroxyapatite.)
- Q:** How long does the Hyaluronic Acid (HA) remain in the implant?
- A:** The HA is permanently locked in place by crosslinking the HA to itself within the UHMWPE network. Accelerated aging and degradation testing have shown no degradation even beyond 10 years.
- Q:** Does BioPoly® oxidize?
- A:** BioPoly® is not exposed to gamma irradiation during its manufacturing or sterilization. Therefore, there are no free radicals present and, thus, premature aging due to oxidation does NOT occur. Accelerated aging to beyond 10 years demonstrated this.
- Q:** What metal is used for the stem of BioPoly® RS Implants?
- A:** The implant stem is made of titanium alloy (Ti 6-4) with a roughened surface finish for optimal bone on-growth. The surface finish is that same as that of hip prostheses that have been implanted for over a decade.

Design

- Q:** How is BioPoly® fixed to the stem?
- A:** BioPoly® is direct compression molded onto a titanium stem. A series of crossing dove-tail channels within the stem platform provide mechanical locking of the BioPoly® to the stem.
- Q:** Is there a chance BioPoly® will pop off the stem in the patient?
- A:** Extensive testing has been performed to ensure that the BioPoly®-stem interface is robust and will handle the anatomical loading.
- Q:** How many implant sizes are available?
- A:** There are three sizes of implants – 15mm, 20mm and 15x24mm.
- Q:** Why only three sizes?
- A:** Compared to metal, BioPoly® is a very forgiving material, so the need for replicating the exact curvature is not needed. Second look arthroscopies have shown that cartilage tissue grows around and, depending on the depth of the implant, may even grow over the material, creating a smooth articulating surface.
- Q:** Will the implant stay in place?
- A:** Human clinical radiographic evidence beyond 6 years continues to show no signs of loosening, migration, or radiolucency.
- Q:** How is BioPoly® RS sterilized?
- A:** Ethylene Oxide (EtO)

Clinical Data & Testing

Q: What human studies have been performed?

A: A post market registry is underway in the UK with follow up at 6-months, 1, 2, 3, 4, and 5-years. Published results show patients returning to pre-injury activity and improved quality of life scores.

Q: What in vivo studies have been performed?

A: A large animal (goat) study was conducted with time points at 3, 6, and 12 months with no indication of implant wear or degradation nor damage to opposing articular cartilage. ISO 10993 Biocompatibility testing was also successfully performed that included in vivo studies in rabbits and mice.

Q: Were mechanical tests performed?

A: In order to obtain the CE mark, BioPoly® had to go through extensive mechanical testing on the material and implants to demonstrate safety and performance. The implant was subjected to an equivalent of 10-years of fatigue mechanical loading resulting in no sign of damage and no degradation in mechanical properties.

Q: How long will BioPoly® last?

A: Accelerated aging studies to beyond 10 years were performed as well as degradation (hyaluronidase) testing, resulting in no degradation in material properties nor any degradation of the hyaluronic acid in the implant. The implant is intended to be permanent.

Surgical Technique

Q: How should implant size be determined?

A: Place the appropriate sized trial instrument over the defect and ensure that the defect is surrounded by cartilage. The implant corresponding to the trial instrument is the proper size.

Q: At what depth should BioPoly® RS Implants be implanted?

A: BioPoly® should be implanted 0.5mm below the surrounding cartilage surface. This will enable the implant to share the load with adjacent cartilage. Please note: BioPoly® should not be implanted to a depth greater than 2.0mm nor should it ever be implanted proud.

Q: How is implant depth controlled?

A: BioPoly® RS Instruments are designed to reference off of the articulating surface of the patient's anatomy. Drilling until the reamer stops on the appropriately sized reaming cannula will ensure that the proper reaming depth is achieved. To verify the implant site is acceptable, the appropriately sized trail can be inserted into the defect.

Q: Can BioPoly® RS Implants be implanted arthroscopically?

A: BioPoly® implantation can be arthroscopically assisted. In other words, the defect size can be determined and the appropriateness of BioPoly® can be established arthroscopically; however, the defect bed and implantation of the BioPoly® device should be done through a mini-arthrotomy incision.

Q: Can BioPoly® implants be cemented?

A: Yes, BioPoly® RS Knee implants are indicated for use with bone cement.

Cartilage Repair Market

Q: How many cartilage repair procedures are performed in Europe annually?

A: Clinical data indicates there are roughly 202,000 cartilage procedures performed annually.

Q: What types of cartilage procedures are performed?

A: The articular cartilage repair market can be divided into two segments: (a) debridement and microfracture, which is very cost effective; however, these procedures have not proven to be very effective long-term; and (b) those that require an implant. Implants can further be segmented into biologic (i.e., rely on patient's biology for successful repair tissue, e.g., collagen or polymers) or synthetic implant (metallic and polymer replacement of chondral or osteochondral defects).

Q: What percentage of the market would be amenable to a BioPoly® implant?

A: Clinical data shows that of the approximately 174,000 debridement and microfracture procedures performed annually, approximately 30% fail after the first 18-months. As a first source of patients, these failures would be good candidates for a BioPoly® implant. If, however, we factor in all 202,000 cartilage procedures, it is estimated that approximately 38% (76,760) could be potential BioPoly® candidates. Actual applicability will depend on defect size and location and on the status of the adjacent cartilage. We intend for BioPoly® to be the standard of care to treat the defects that are currently being microfractured or debrided.



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