Surgical Technique

BioPoly® RS
Knee System

Bio
Hyaluronic Acid

Poly
UHMWPE

Advancing Materials. Advancing Outcomes.™
Assessment

1. Proper implant sizing is determined by placing the appropriate sized trial over the defect and ensuring complete coverage. Important: The defect must be shouldered on all sides by normal cartilage. When the defect is located in the femoral condyle, the defect must be within the weight bearing region, especially if the defect is near the posterior edge of the weight bearing region (Fig. 1).

Preparation

1. Firmly press the drill guide against the articular cartilage, centered about the defect. Check to make sure the guide is sitting flush on the articular cartilage surface, ensure that the long axis of the guide is normal (perpendicular) to the curvature of the articular cartilage (Fig. 2). Important: The implant must match the surrounding anatomy. Placing the drill guide and pilot nail(s) determines the final location of the implant. Therefore, when implanting in the femoral condyle, care should be taken at this step to ensure that all edges of the implant will be within the weight bearing region, especially when the defect reaches near the posterior edge of the weight bearing region.

2. Insert and lightly tap or drill the pilot nail until the radial etch line marked FEM is even with the top of the drill guide (Fig. 3). Technique Tip: Insert nail 1-2mm into the bone, check alignment and adjust as necessary to achieve perpendicularity. 15x24 Implant: When using the 15mm x 24mm implant, insert 2 pilot nails using the 15mm x 24mm drill guide that has 2 holes (Fig. 4).

3. Remove the drill guide and place the appropriate sized guide tube over the pilot nail. Place the cutting cannula over the guide tube and with a twisting motion, cut through the cartilage to the subchondral bone (Fig. 5). 15x24 Implant: For the 15mm x 24mm implant, first remove one of the pilot nails and then proceed with steps above.
4. Remove the cutting cannula and place the reami ng cannula over the guide tube, making sure the protective edge is inserted into the previously cut cartilage (Fig. 6). **Important:** Ensure the shoulder of the reaming cannula is resting on top of the cartilage surface (Fig. 7). Not having the cannula flush on the cartilage surface will result in improper reaming depth.

5. Remove the inner guide tube. While pressing the reaming cannula against the cartilage surface, place the appropriate sized cannulated reamer over the pilot nail. Drill until the shoulder of the reamer makes contact with the top of the reaming cannula (Fig. 8) (It is recommended to use saline lavage during the drilling process). Remove cannula and reamer. Irrigate site. **Note:** If cementing, ream defect site to appropriate size and depth ensuring subchondral bone quality is sufficient for cementing.

6. **15X24 Implant**

When using the 15mm x 24mm implant, insert the 2nd pilot nail into the open hole (the 15mm x 24mm drill guide may need to be used to find the open hole), remove 1st pilot nail (Fig. 9) and repeat preparation steps 3, 4 and 5 (Fig. 10). **After Drilling:** Use a sharp osteotome or knife to remove the small triangular shaped cartilage and bone between the two drill holes to create the shape of the 15mm x 24mm implant (Fig. 11).
Implantation

1. To verify implant site is acceptable, insert the appropriately sized trial over the pilot nail (Fig. 12). Both pilot nails must be removed prior to inserting the 15mm x 24mm trial (Fig. 13). Important: The trial edge must not be proud relative to the articulating surface. If the trial is proud, remove and re-insert the cannulated reamer and carefully re-drill by hand until proper fit and orientation is achieved. The ideal placement is for the top of the trial to be **0.5mm recessed** below the articulating cartilage. Important: The implant must match the surrounding anatomy. Therefore, when implanting in the femoral condyle, care should be taken to ensure that all edges of the implant are within the weight bearing region, especially when the defect reaches near the posterior edge of the weight bearing region.
2. Remove trial and pilot nail.

3. To insert the implant, press the distal end of the appropriate sized inserter over the implant (Fig. 14) and align stem(s) with the previously created pilot hole(s). Once aligned properly, gently push the implant into the implant site. Using the soft insertion tamp, gently tap on the implant while pulling back on the insertion guide making sure to fully seat the implant (Fig. 15). **Important: Only use the provided insertion tamp when inserting the implant as other instruments or materials can cause damage to the implant surface.** Use care so the implant inserter and tamp do not slip during insertion and damage the surrounding tissue. **Note:** If cementing, follow the bone cement manufacturers’s instructions. Place implant into the defect site and press until the implant is **0.5mm recessed** from the articulating surface. Carefully remove all of the extruded cement.
Device Description

The BioPoly® RS Partial Resurfacing Knee Implant is a long-term, surgically invasive device for replacement of focal osteochondral defects in the knee not exceeding 3.1cm².

Materials

The implant is made of BioPoly® material (ultra-high molecular weight polyethylene and crosslinked hyaluronan) and titanium alloy (Ti-6Al-4V).

Intended Use

The BioPoly® RS Partial Resurfacing Knee Implant is 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 the femoral condyle or in the trochlear facets. Lesion size should not exceed 3.1cm² and must be circumscribed by a 1.5 or 2.0cm circle or 1.5 by 2.4cm oval of normal or nearly normal (ICRS Grade 0 or 1) cartilage, with an overall cartilage depth less than 4mm from the articulating surface. For use with or without bone cement. Subchondral bone quality must be deemed sufficient to secure the implant.

Contraindications

1. Body mass index > 35
2. Generalized degenerative or autoimmune arthritis
3. Gout
4. Uncorrected chronic malalignment of the knee
5. Uncorrected ligamentous instability
6. Uncorrected mechanically symptomatic meniscal tear or total meniscectomy
7. Kissing lesion on tibia or patella
8. More than one implant required to accommodate lesion
9. Allergy to titanium alloy (Ti-6Al-4V), Ultra-high molecular weight polyethylene (UHMWPE), or hyaluronic acid (HA)
10. Use with opposing articulating tibial or patellar components.
Warnings

1. Prior to use, the surgeon should thoroughly read and understand all aspects of the surgical technique.

2. This device is provided STERILE as a single use product. If sterile barrier is broken or the package otherwise damaged, the device may not be administered. Re-sterilization of the device is not permitted.

3. During removal of the device from the packaging, special care should be taken to preserve the articulating surface finish.

4. In case of damage to the implant, including scratches or indentations on the articulating surface, bending of the fixation stem, or any other disfigurement, the device may not be administered.

5. Any alteration or modification to the device prior to the surgical implantation is prohibited.

6. Excessive insertion force can damage the articulating surface of the implant.

7. Implant articulation with non-cartilage or abnormal anatomic surface may damage the implant.

8. Do not reuse device. Risks of reuse include: damage to implant, loss of performance, and infection.

9. MR Image quality may be compromised if the area of interest is in the same position or relatively close to the position of the device.

10. Care should be taken to ensure that the BioPoly® RS Partial Resurfacing Knee Implant is not placed posteriorly beyond the weight bearing region when using in the femoral condyle due to potential mismatch with anatomy.

Adverse Effects

Infections, allergies, or other reactions to implant materials.

Packaging and Sterilization

The BioPoly® RS Partial Resurfacing Knee Implant is provided sterile and for single use.

1. Do not use if the sterile packaging has been breached or damaged.

2. Do not attempt to re-sterilize the implant.

3. Do not use if the expiration date has elapsed.
The BioPoly RS Partial Resurfacing Knee Implant surgical technique and instrumentation have been developed in cooperation with Vladimir Bobic, M.D., FRCSEd, Chester, UK, Matthew Matava, M.D., St. Louis, MO, USA, and Samuel Tabet, M.D., Albuquerque, NM, USA.