Surgical Technique

Advancing Materials. Advancing Outcomes.

BioHyaluronic Acid
PolyUHMWPE

BioPoly® RS Patella System
Assessment

1. Using the depth probe, determine the appropriate implant size (thickness) for use. The probe must touch the subchondral bone for proper cartilage thickness measurement. If the top edge of the articular cartilage exceeds the radial etch line on the probe use a size 1 (SZ1) implant; otherwise use a size 0 (SZ0) implant (Fig. 1). **Important:** If cartilage depth is greater than 4mm, the BioPoly® RS Patella Implant cannot be used.

2. Using the trial drill guides, determine whether a 15mm or 20mm diameter implant is needed. Place the appropriate side (SZ0 or SZ1) of the trial drill guide over the defect and ensure complete coverage (Fig. 2). **Important:** The defect must be shouldered on all sides by normal or near-normal cartilage (ICRS Grade 0 or 1).

Preparation

1. Firmly press trial drill guide against the medial or lateral facet of the patella, centered about the defect. Check to make sure the trial is sitting flush on the articular cartilage surface, and ensure that the long axis of the guide is normal (perpendicular) to the surface of the medial or lateral facet.

2. Insert and lightly tap or drill the pilot nail until the radial etch line marked PAT is even with the top of the drill guide (Fig. 3). **Technique Tip:** Insert nail 1-2mm into bone, check alignment and adjust as necessary to achieve perpendicularity.
3. Remove the trial and place the BioPoly® Knee 15mm or 20mm guide tube over the pilot nail. Place the BioPoly® Knee 15mm or 20mm cutting cannula over the guide tube and with a twisting motion, cut through the cartilage to the subchondral bone (Fig. 4). **Important:** 15mm or 20mm guide tube and cutting cannula can be located in the BioPoly®RS Knee System Instrument Kit.

4. Remove the cutting cannula and place the appropriately sized BioPoly® Patella reaming 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 BioPoly® Knee 15mm or 20mm cannulated reamer over the pilot nail. Ream until the shoulder of the reamer makes contact with the top of the patella reaming cannula (Fig. 8) (It is recommended to use saline lavage during the drilling process). Remove cannula and reamer. Irrigate site. **Important:** 15mm or 20mm cannulated reamer can be located in the BioPoly® RS Knee System Instrument Kit.
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6. Remove pilot nail

7. Firmly place BioPoly® Patella stem drill on the subchondral bone surface, centered about the implant site. Drill until bottom shoulder of the stem drill makes contact with the subchondral bone (Fig. 9). Remove stem drill. Irrigate site.

Implantation

1. To verify that the implant site is acceptable, insert the appropriate side of the trial drill guide into the implant site (Fig. 10). **Important:** The trial drill guide top edge must be recessed relative to the articulating surface. If the trial drill guide is not recessed, remove and use the BioPoly® Patella reaming trial without a reaming cannula to carefully re-ream by hand until proper fit and orientation is achieved, or re-insert the pilot nail and repeat steps 5-7. The ideal placement is for the top of trial to be **0.5mm recessed** below the articulating cartilage.
2. Prepare bone cement and apply to the prepared implant site and the distal end (back) of the implant according to the bone cement manufacturer’s instructions.

3. Carefully place implant into prepared defect site and press until the implant is **0.5mm recessed** below the surface of the articulating cartilage (Fig. 11). Remove all extruded cement with a curette.
Device Description

The BioPoly® RS Partial Resurfacing Patella Implant is a long-term, surgically invasive device for replacement of focal chondral or osteochondral defect in the patella less than 3.1cm².

Materials

The implant is made of BioPoly® material (ultra-high molecular weight polyethylene and cross-linked hyaluronan).

Intended Use

The BioPoly® RS Partial Resurfacing Patella 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 medial and/or lateral facet of the patella in patients over 21 years of age. Lesion size may not exceed 3.1cm² and must be circumscribed by a 1.5 or 2.0 cm circle of normal or nearly normal (ICRS Grade 0 or 1) cartilage, with an overall cartilage depth less than 4mm from the articulating surface. Subchondral bone quality must be deemed sufficient to secure the implant with bone cement.

Contraindications

1. Body mass index ≥ 35
2. Generalized degenerative or autoimmune arthritis
3. Gout
4. Uncorrected malalignment of the patella
5. Uncorrected ligamentous instability
6. Kissing lesion on the femur
7. More than one implant required to accommodate lesion
8. Allergy to ultra-high molecular weight polyethylene (UHMWPE), or hyaluronic acid (HA)
9. Use with opposing articulating femoral 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 packaging is 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 indentation on the articulating surface, bending of the fixation stem, or any other disfigurement, the device may not be administered.

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

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

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

8. Implant articulation with non-cartilage or abnormal anatomic surface can damage the implant.

Adverse Effects

Infections, allergies, or other reactions to implant materials.

Packaging & Sterilization

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

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

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

3. Do not use if expiration date has elapsed.
The BioPoly® RS Partial Resurfacing Patella Implant surgical technique and instrumentation have been developed in cooperation with Dinesh Nathwani MB ChB, MSc, FRCS (TR & Orth), London, UK, Jack Farr, M.D., Greenwood, IN, USA, and Vladimir Bobic, M.D., FRCSEd, Chester, UK.