Surgical Technique

BioPloy® RS
Shoulder System

Bio
Hyaluronic Acid

Poly
UHMWPE

Advancing Materials. Advancing Outcomes.™
Assessment

1. Proper implant diameter is determined by placing the appropriately sized trial over the defect and ensuring complete coverage. **Important: The defect must be shouldered on all sides by normal cartilage (ICRS Grade 0 or 1)** (Fig. 1).

2. Determine proper implant radius of curvature ("Small" or "Large") by placing the appropriate end of the Shoulder Radius Gauge over the defect (Fig. 2).

Preparation

1. Firmly press the drill guide against the humeral head, centered about the defect. Check to make sure the guide is fully seated on the articular cartilage surface, and ensure that the long axis of the guide is normal (perpendicular) to the curvature of the humeral head (Fig. 3).

2. Insert the pilot nail through the drill guide until the radial etch line is even with the top of the guide (Fig. 4). **Important: Ensure the nail is inserted through both the medial cortex of the humeral head and the lateral cortex of the humerus. Technique Tip:** Insert nail 1-2mm into the bone, check alignment and adjust as necessary to achieve perpendicularity.
3. Remove the drill guide and place the appropriately sized guide tube over the pilot nail. Place the cutting cannula over the guide tube and cut with a twisting motion through the cartilage to the subchondral bone (Fig. 5).

4. Remove the cutting cannula and place the 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 fully seated on the top of the cartilage surface (Fig. 7).** Not having the cannula fully seated 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 (25mm or 30mm diameter, “Small” or “Large” radius of curvature) cannulated reamer over the pilot nail (Fig. 8). Ream until the reamer stop makes contact with the cannula (Fig. 9) (It is recommended to use saline lavage during the reaming process). Remove cannula and reamer. Irrigate site.
Implantation

1. To verify implant site is properly prepared, insert the appropriately sized trial over the pilot nail and into the implant site (Fig. 10). **Important:** The trial edge must not be proud relative to the articulating surface. If the trial is proud, remove and re-insert the trial reamer and carefully re-ream by hand until proper fit is achieved. The ideal placement of the trial is **0.5mm recessed** below the articulating cartilage as indicated below.

2. Insert the cruciate punch over the pilot nail and gently impact until the tip of the punch fully engages the bone (Fig. 11).

3. Remove cruciate punch and pilot nail.

CORRECT

INCORRECT
4. To insert the implant, press the distal end of the appropriately sized inserter over the implant (Fig. 12) and align stem punched hole ensuring the fins mate properly with the prepared bone. Once aligned, gently push the implant in 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. 13). **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.
Surgical Technique

Device Description

Device Description: The BioPoly® RS Partial Resurfacing Shoulder Implant is a long-term, surgically invasive device for replacement of focal osteochondral or chondral defect in the shoulder less than 7cm².

Materials

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

Intended Use

The BioPoly® RS Partial Resurfacing Shoulder Implant is intended for the replacement of symptomatic abnormal or severely abnormal (ICRS Grade 2, 3, or 4) osteochondral or chondral focal lesions located in the humeral head in patients over 21 years of age. Lesion size may not exceed 7cm² and must be circumscribed by a 2.5 or 3.0 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. For use without bone cement. Subchondral bone quality must be deemed sufficient to secure the implant.

Contraindications

1. Generalized degenerative or autoimmune arthritis
2. Gout
3. Uncorrected malalignment of the shoulder
4. Uncorrected ligamentous stability
5. Uncorrected mechanically symptomatic labral tear
6. Kissing lesion on glenoid
7. More than one implant required to accommodate lesion
8. Allergy to titanium alloy (TI-6AI-4V), ultra-high molecular weight polyethylene (UHMWPE), or hyaluronic acid (HA)
9. Use with opposing articulating glenoid components
Warnings

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

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

3. During removal of the device from 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 can 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 area or relatively close to the position of the device.

Adverse Effects

Infections, allergies, or other reactions to implant materials.

Packaging & Sterilization

The BioPoly® RS Partial Resurfacing Shoulder 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 Shoulder Implant surgical technique and instrumentation have been developed in cooperation with Carl Basamania, M.D., Seattle, WA, USA, Keith Kenter, M.D., Cincinnati, OH, USA, and Richard Evans, BMed.Sci. (Hons) BM, BS, MScFRCS, FRCS (Tr & Orth), Cardiff, UK.