BioPoly® RS
Trochlea System

Surgical Technique

Bio
Hyaluronic Acid

Poly
UHMWPE

Advancing Materials. Advancing Outcomes.™
Pre-Operative Planning

Prior to implantation of the BioPoly® RS-Trochlea Implant, pre-operative planning will be helpful for approximating implant size and determining if concomitant therapies are required. Successful treatment of femoral trochlear groove lesions with the BioPoly® RS-Trochlea Implant requires consideration of any possible joint damage outside of the femoral trochlear groove, the shape of the femoral trochlea, and the stability of the patellofemoral joint.

The BioPoly® RS-Trochlea Implant is ideally suited for treatment of Isolated Patellofemoral Osteoarthritis (PFOA) that is localized to the femoral trochlear groove. Use of the RS-Trochlea implant in patients with patellar kissing lesions or patellar prostheses (e.g. Patellar Button) is strictly contraindicated, and if joint damage is present within the tibiofemoral joint, appropriate treatment must be considered to prevent progression of Tibiofemoral Osteoarthritis (TFOA). Progression of TFOA has been shown as the most common cause of revision after Patellofemoral Arthroplasty\(^1\); therefore, it is critical that the tibiofemoral joint is considered prior to surgery. Pre-operative assessment of the defect(s) via MRI or arthroscopy is highly recommended prior to surgery. A brief assessment of the femoral trochlea shape is also recommended prior to surgery. Specifically, evaluation of the sulcus angle via “skyline” MRI or X-Ray is recommended to help anticipate implant size. The chart below estimates the appropriate implant size based upon sulcus angle. If the femoral trochlea sulcus angle or depth does not fit within the ranges listed below, use of the RS-Trochlea Implant is not recommended.

<table>
<thead>
<tr>
<th>Sulcus Angle(^\wedge)</th>
<th>Trochlear Depth(^\wedge)</th>
<th>Estimated Implant Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>135° – 145°</td>
<td>4.5 – 5.5mm</td>
<td>Standard</td>
</tr>
<tr>
<td>145° – 155°</td>
<td>3.5 – 4.5mm</td>
<td>Shallow*</td>
</tr>
<tr>
<td>155° – 165°</td>
<td>2.5 – 3.5mm</td>
<td>Dysplasia*</td>
</tr>
</tbody>
</table>

*Trochlear dysplasia can be diagnosed by a sulcus angle > 150°; therefore, care should be taken that joint stability is maintained when using these implant sizes (see explanation below).

\(^\wedge\)The methodology described in studies from Huyssteen\(^2\) and Pfirrmann\(^3\) is recommended for measurement of sulcus angle and trochlear depth respectively.

Prior to the surgical technique, the appropriate implant size and knee status (no patellar kissing lesions or untreated tibiofemoral lesions, etc.) must be confirmed intra-operatively.

The patellofemoral joint must also remain stable post-surgery for treatment success. Isolated PFOA has been historically linked with trochlear dysplasia\(^4\), and trochlear dysplasia has been linked with increased risk of patellar instability\(^5\). While the BioPoly® RS-Trochlea Implant replaces damaged cartilage in the femoral trochlear groove, it does not significantly alter the natural femoral anatomy or stabilizing tissues. Appropriate realignment procedures should be performed in cases where patients demonstrate significant risk of patellar instability due to malalignment, trochlear dysplasia, patellar mal-positioning, ligamentous instability, or other appropriate indications.

References:
Assessment

1. Proper implant diameter 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 (Fig. 1).

2. Proper implant shape (Standard, Shallow, or Dysplasia) is determined by trialing the defect site with the gauge tool. **Important:** The implant shape chosen with the gauge tool must be able to fully contact both the trochlear groove and facets (Fig. 2). If the gauge tool does not sufficiently contact the trochlear groove and facets after multiple trials, the BioPoly® RS-Trochlea implant must not be used.

Preparation

1. Firmly press the drill guide against the femoral trochlea, centered on the groove. 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 superior-inferior curvature of the trochlear groove (Fig. 3).

2. Insert the pilot nail through the drill guide until the FEM radial etch line is even with the top of the guide. **Technique Tip:** Insert nail 1-2mm into the bone, check alignment and adjust as necessary to achieve perpendicularity prior to fully inserting the nail to the FEM radial etch line (Fig. 4).
3. Remove the drill guide and place the appropriately sized guide tube over the pilot nail. Place the cutting cannula over the guide tube (Fig. 5) and cut with a gentle rocking motion through the cartilage to the subchondral bone (Fig. 6). **Technique Tip:** Do not attempt to twist the cutting cannula because the angular geometry of the trochlear groove restricts this type of motion.

4. Remove the cutting cannula and place the appropriately sized reaming cannula over the guide tube, making sure the protective edge is inserted into the ring in the cartilage that was cut in the prior step (Fig. 7). **Important:** Ensure the shoulder of the reaming cannula is fully seated on the top of the cartilage surface (Fig. 8). 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 cannulated reamer over the pilot nail (Fig. 9). Ream until the shoulder of the reamer stop makes contact with the top of the reaming cannula. (It is recommended to use saline lavage during the reaming process). **Technique Tip:** It is recommended to ream slowly at first as the uneven shape of the femoral trochlea may cause the reamer to move irregularly. 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 (Fig. 12), 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 (Fig. 11).

2. Remove the pilot nail and place the punch guide into the implant site (Fig. 13). Align the barbs of the punch guide with the superior-inferior orientation of the trochlear groove (Whiteside’s Line) (Fig. 14).

3. While firmly holding the punch guide, insert the punch into the punch guide and gently impact until the tip of the punch fully engages the bone (Fig. 15).
4. Remove punch and punch guide.

5. Gently place implant inside of holder (Fig. 16). Press the distal end of the appropriately sized inserter over the implant, aligning the orientation marks of the inserter with the holder (Fig. 17).

6. To insert the implant, align stem with the punched hole ensuring the fins mate properly with the prepared bone slots. Once aligned, gently push the implant in the implant site with the implant inserter; however, stop pushing once the implant fins have engaged with the bone and are stable. Once the implant is stable, the inserter can be removed, leaving the implant at the proper orientation in the prepared bone slots. Using the soft insertion tamp, gently tap on the implant until it is fully seated (Fig. 18). **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 manufactures’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 Trochlea Implant is a long-term, surgically invasive device for replacement of focal osteochondral defects in the femoral trochlear groove ranging no larger than 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 Trochlea 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 femoral trochlear groove in patients over 21 years of age. Lesion size may not exceed 3.1cm² and must be circumscribed by a 1.5 or 2.0cm 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 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 stability
6. Kissing lesion on patella
7. More than one implant required to accommodate lesion
8. Allergy to titanium alloy (TI-6Al-4V), ultra-high molecular weight polyethylene (UHMWPE), or hyaluronic acid (HA)
9. Use with opposing articulating patellar 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.