BioPoly®

Radial Head

Surgical Technique

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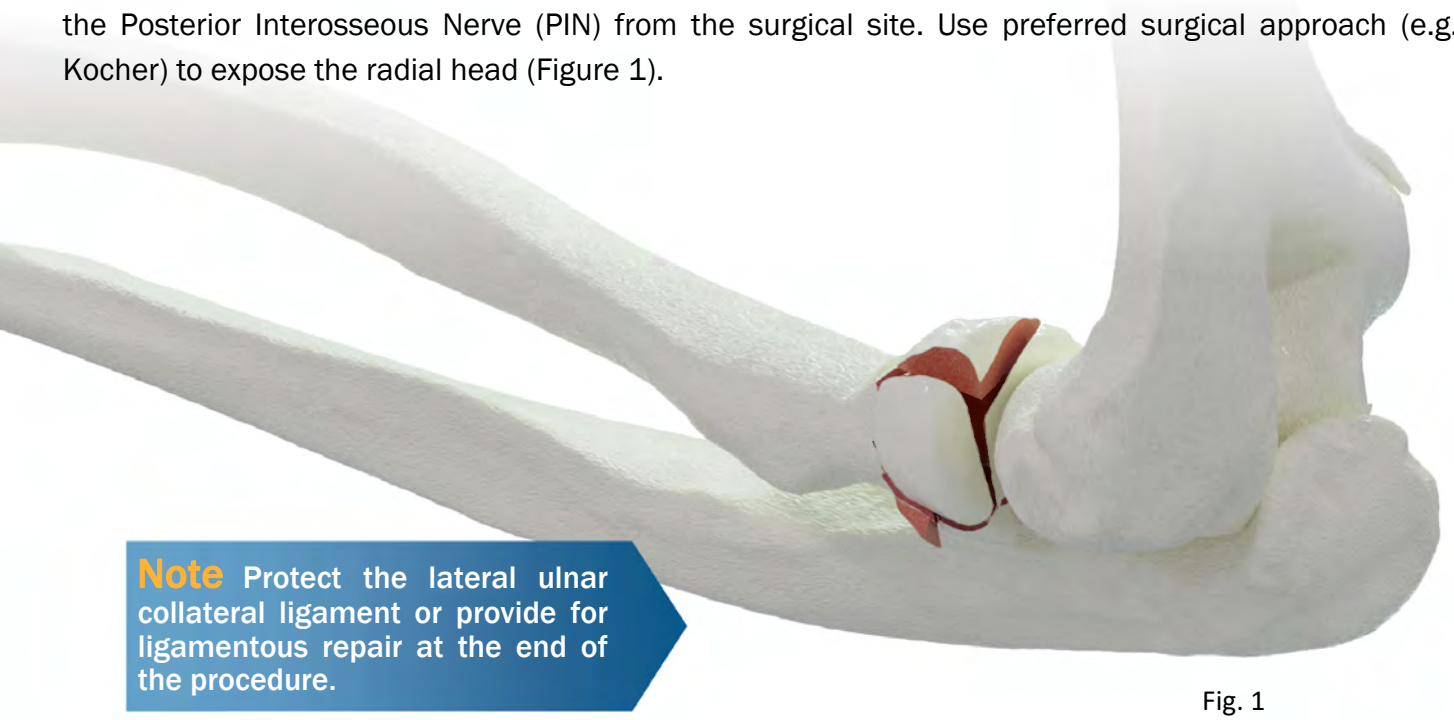
Incision and Dissection

With the patient in a supine position, prepare the elbow using sterile technique. Pronate the forearm to distance the Posterior Interosseous Nerve (PIN) from the surgical site. Use preferred surgical approach (e.g. Kaplan or Kocher) to expose the radial head (Figure 1).

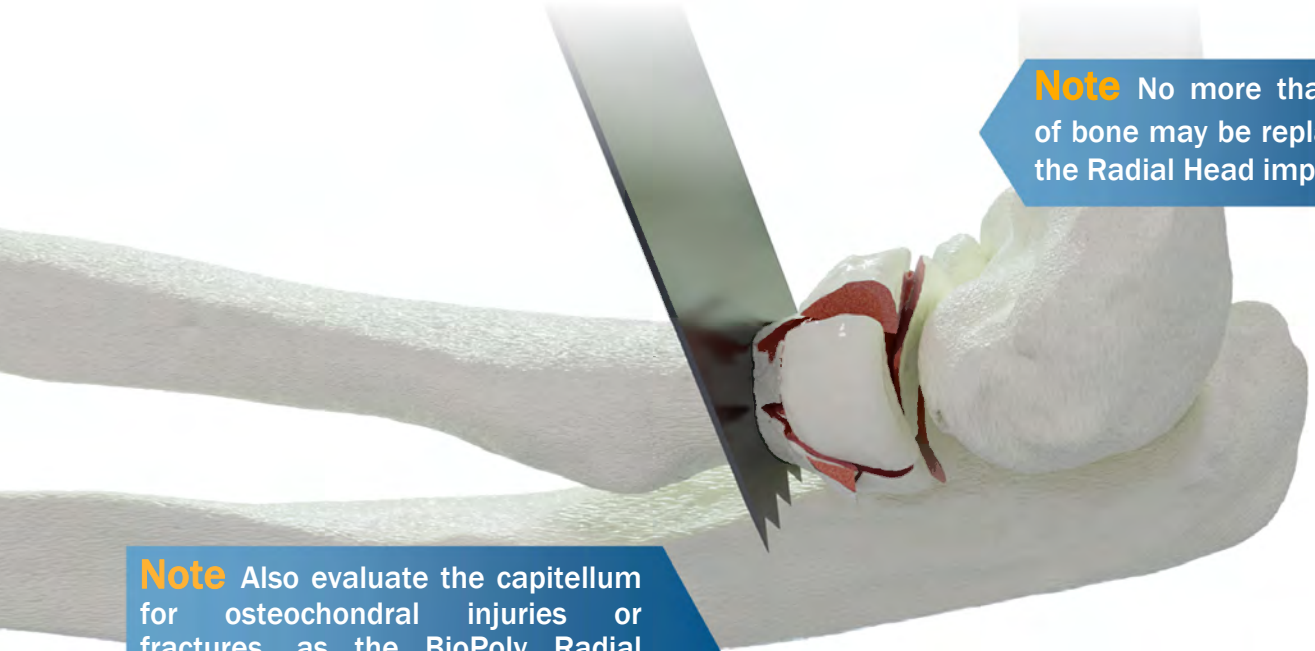


Note Protect the lateral ulnar collateral ligament or provide for ligamentous repair at the end of the procedure.

Fig. 1

Resect Radial Head

Remove all fragments of the radial head, irrigating to remove any loose debris. The osteotomy of the radius should be performed perpendicular to the neck (Figure 2).



Note No more than 17mm of bone may be replaced with the Radial Head implant.

Note Also evaluate the capitellum for osteochondral injuries or fractures, as the BioPoly Radial Head Implant is not indicated for use against non-cartilage surfaces.

Fig. 2

Retract Radius

As necessary during the procedure, the radius may be retracted laterally (Figure 3). A Radius Retractor instrument is provided to assist with retraction. Avoid contact with the anterior aspect of the radius, to protect the interosseous nerve. Take care to avoid prolonged traction or pressurization of the PIN.

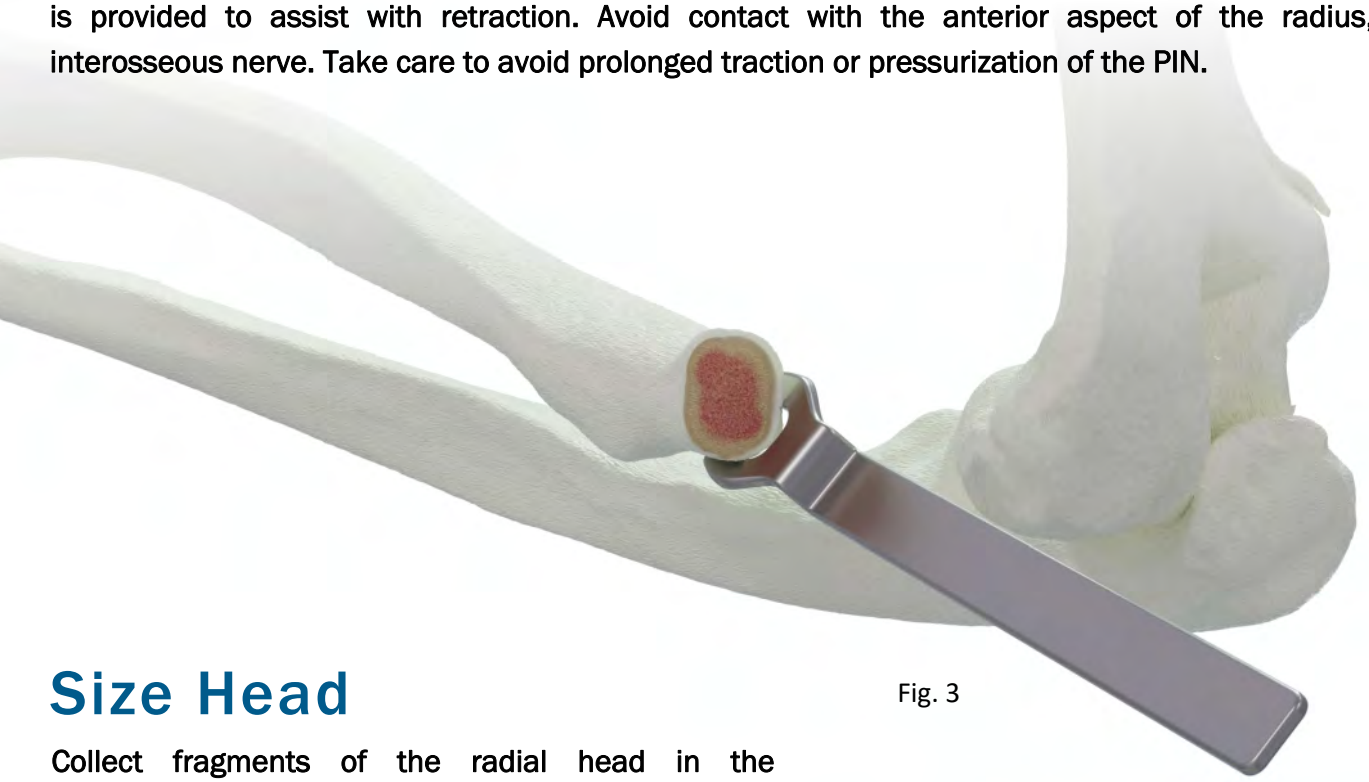


Fig. 3

Size Head

Collect fragments of the radial head in the diametric gages of the Sizing Tray (Figure 4) and select the Head Trial based on the smallest diameter of the head. Then, move the fragments to the corresponding height gage and select the smallest matching Offset Trial (Figure 5).

Note If any dimensions are between sizes, downsize to the lower option to avoid overstuffing.

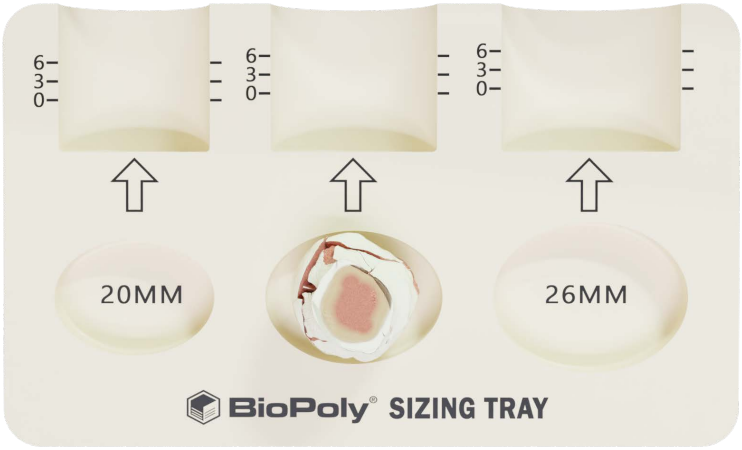


Fig. 4

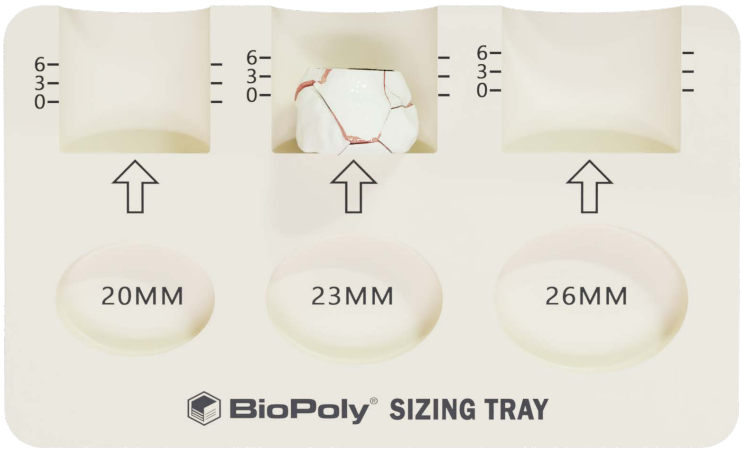
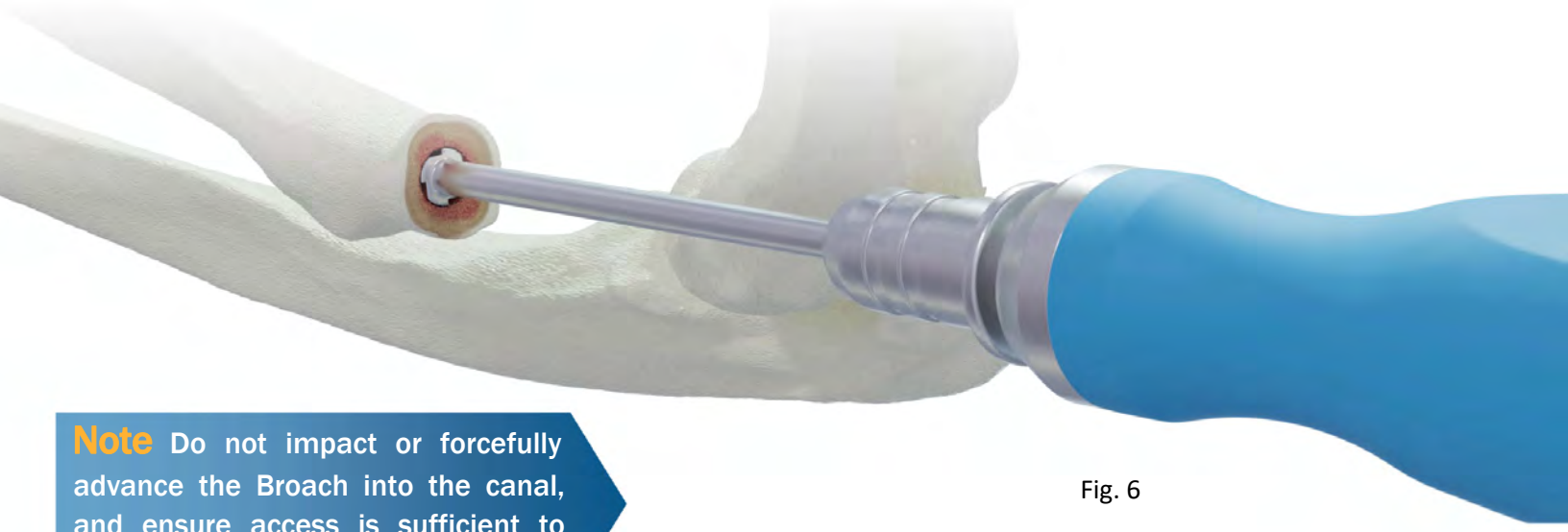


Fig. 5

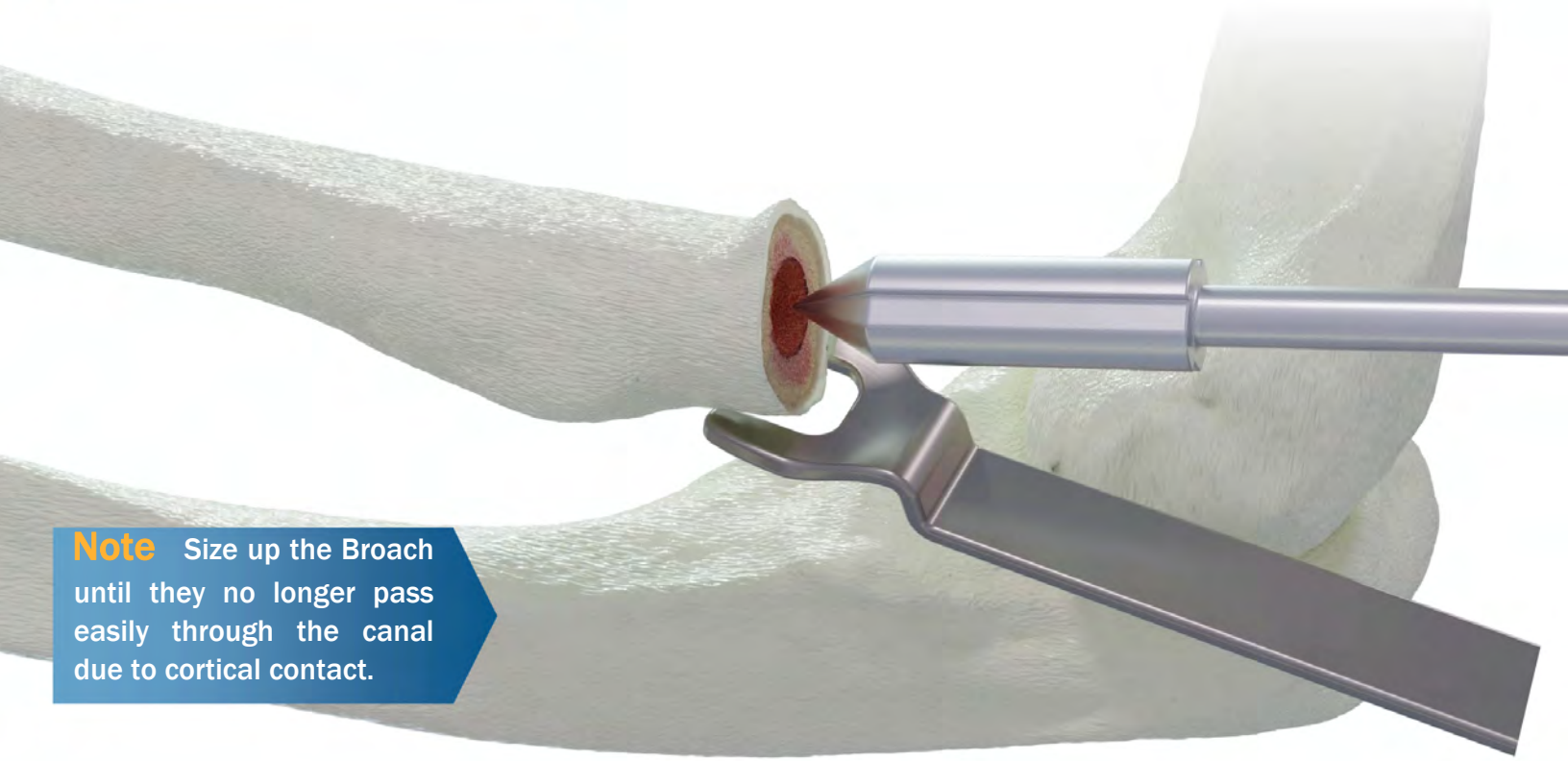
Broach Radial Canal

Using the Instrument Handle, open the medullary canal with the smallest Broach (6mm), inserting until the back of the broaching head is fully inserted. Sequentially insert larger sizes of the Broach until they no longer pass easily through the canal due to cortical contact (Figures 6-7). Note the size of the final Broach used.



Note Do not impact or forcefully advance the Broach into the canal, and ensure access is sufficient to avoid damage to the radial neck.

Fig. 6



Note Size up the Broach until they no longer pass easily through the canal due to cortical contact.

Fig. 7

Plane Radial Neck

Insert the Planer tool into the cleared canal. Rotate gently to smooth the surface for contact on the radial neck, ensuring it remains perpendicular to the canal axis (Figures 8-9).

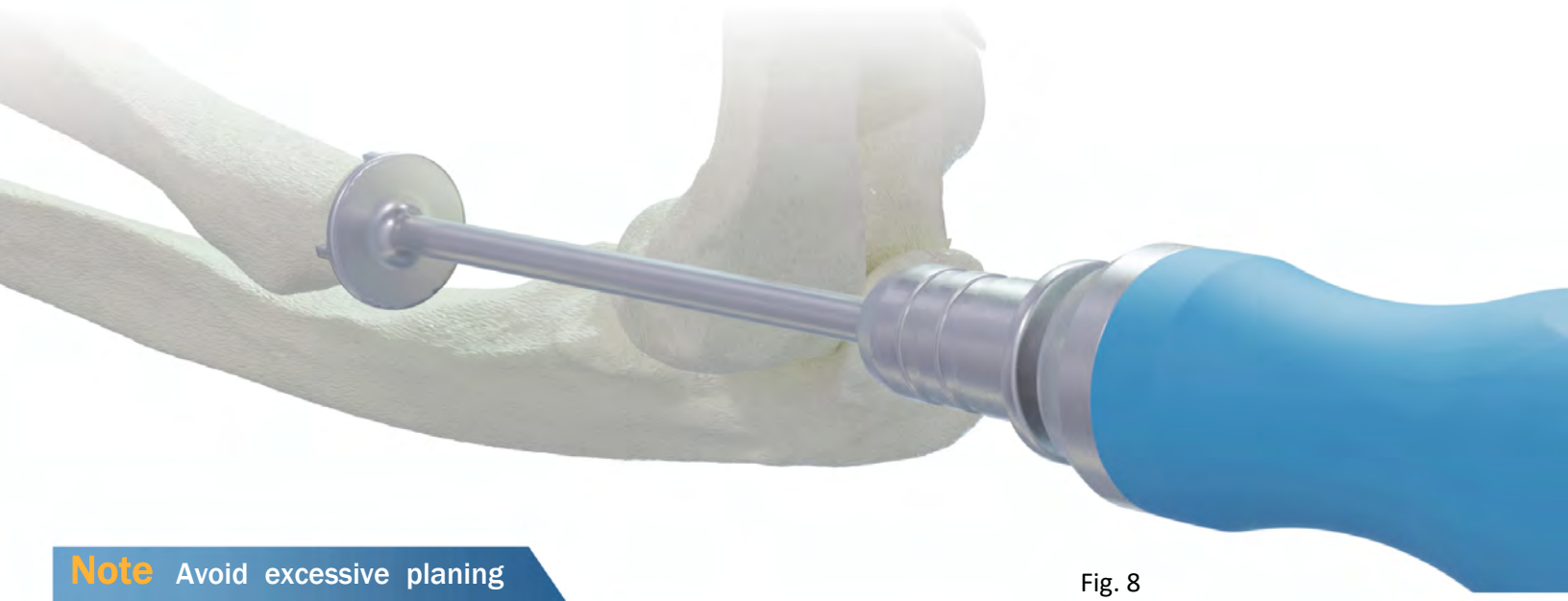


Fig. 8

Note Avoid excessive planing as it may increase the measured head resection.

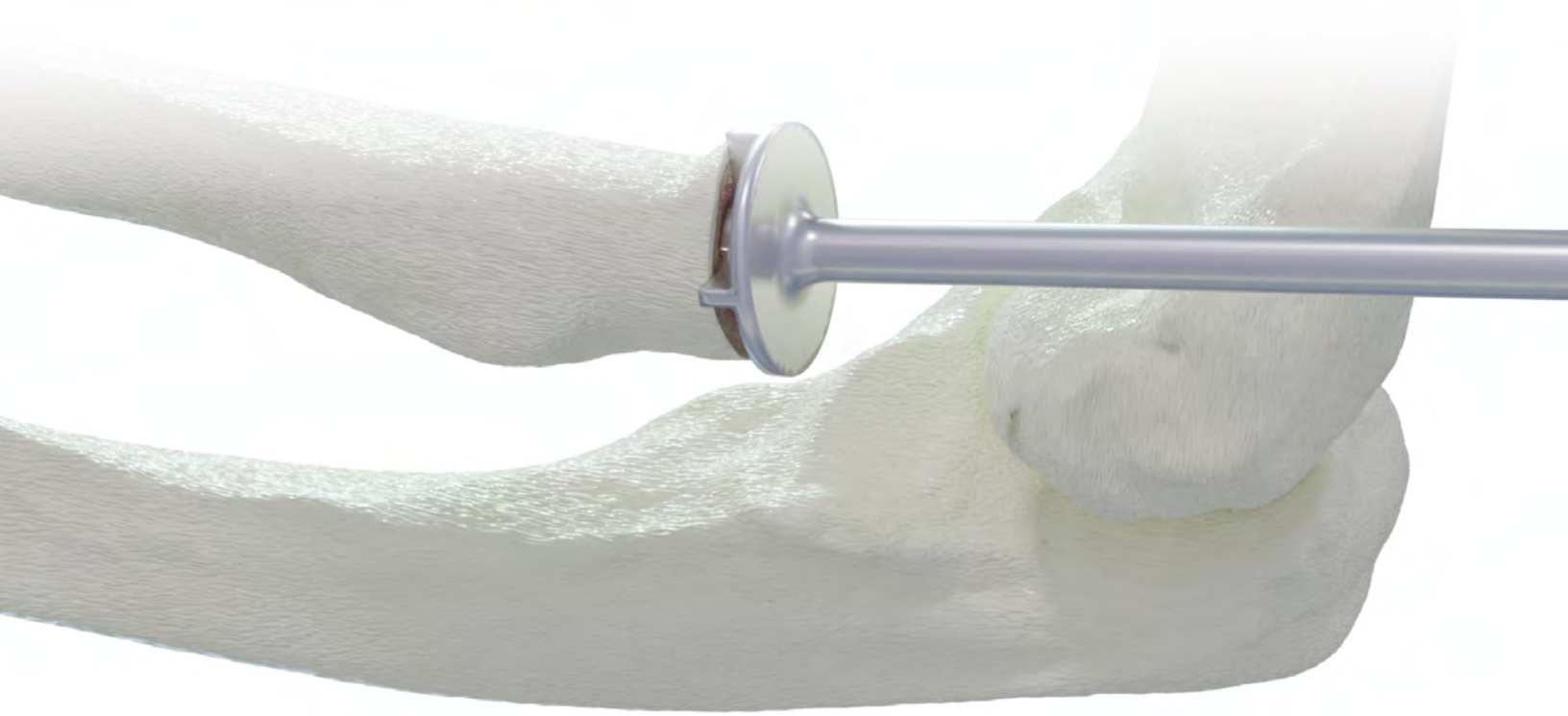


Fig. 9

Optional Assemble and Place Initial Trial

Assemble the Head Trial (see Sizing step) to the planned Stem Trial (Figure 10). Use this assembly in conjunction with the Height Trial to test and select the final offset for the final Implant (Figure 11). This may also be verified by comparing the total height of the Head Trial and Height Trial/Offset Trials to the resected radial head, directly. The Insertion Tamp may be used to assist in placing the trials and final implant along with the Radius Retractor.

An image intensifier should be used to evaluate effect of the trial on joint spacing. Avoid overstuffing the radiocapitellar joint. On anteroposterior imaging, the medial and lateral ulnohumeral joint should be symmetrically spaced. A tall implant will cause varus alignment, reducing parallelism of the space, and making it appear wider laterally. On lateral imaging the deep portion of the head replacement should be parallel to the proximal edge of the lesser sigmoid notch of the ulna. Visually, the radial head replacement should be barely touching the capitellum with the forearm in full pronation and the ulnohumeral joint reduced.

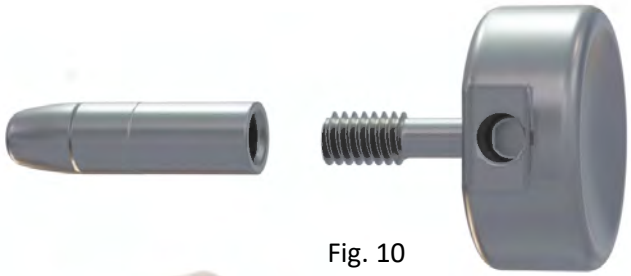


Fig. 10

Fig. 11

Note The Height Trial may be used in conjunction with the Head and Stem Trial to determine the appropriate offset height prior to the complete Implant Trial assembly with the offset washers

Final Trialing Step

Assemble a final trial, using the appropriate Head Trial (found during head sizing), Stem Trial (found during broaching), and Offset Trial (found during head sizing and the first trialing step) (Figure 12). Insert this trial into the canal and perform full analysis of range of motion (Figure 13).

An image intensifier may be used to evaluate effect of the trial on range of motion. Pronating the forearm allows compensation for the lateral destabilization of the surgical approach. Poor tracking against the capitellum may indicate a smaller stem size is necessary to allow ligamentous control of the motion. Note that metallic trials will appear larger on x-ray than native structures because cartilage is radiolucent. Ensure that each trialing step is performed, and that full range of motion is evaluated. Assess that ligaments may be repaired at closure.

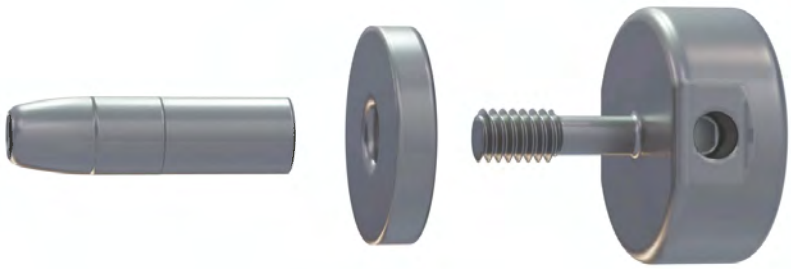


Fig. 12

Fig. 13

Implant Preparation

Remove the trial. Carefully remove the appropriately sized Implant from the packaging.

Implant Insertion

Carefully insert the Implant into the proximal radius canal. The arm may be extended and pronated to allow the implant to fit around the capitellum. The Insertion Tamp may be used to tap the implant into place, taking care not to scratch the articular surface.

Closure

Repair the annular ligament and perform other soft tissue repairs as necessary based on the integrity of the joint structure. Perform another test of range of motion of the joint, evaluating for elbow stability. Close the exposure of the joint.

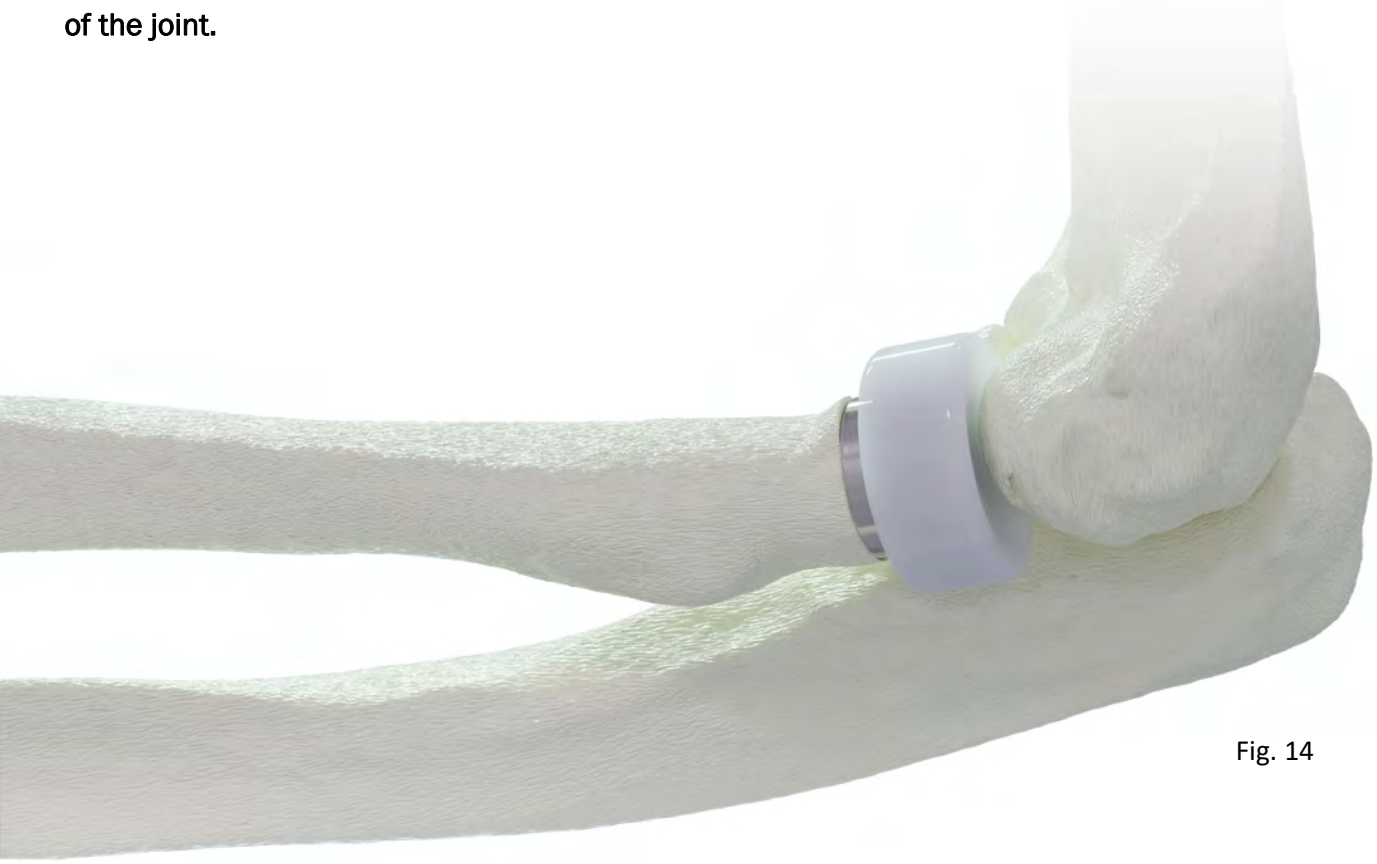


Fig. 14

Extraction

The BioPoly Radial Head Implant is intended for permanent implantation. In the event of necessary removal of the implant, the implant should be removed through careful exposure and retraction of the radial head. Contact the manufacturer using the contact information provided in this surgical technique for instructions on return of the explanted device.

Surgical Technique

Device Description

The BioPoly Radial Head Implant is a hemiarthroplasty device specifically designed to restore the articular surface and spacing of the proximal head of the radius in patients following fracture, resection, and/or degenerative disability. The implant is supplied with head diameters of 20mm, 23mm, and 26mm; and stem diameters of 6mm, 7mm, 8mm, and 9mm with +0mm, +3mm, and +6mm height offsets for selection by the physician.

Materials

The BioPoly Radial Head Implant is made of BioPoly material (ultra-high molecular weight polyethylene and crosslinked hyaluronan) and Ti-6Al-4V.

Intended Use

The BioPoly Radial Head Implant is intended to restore the articular surface of the proximal radial head. BioPoly medical devices are intended to be surgically implanted in a sterile environment by a surgeon.

Indications for Use

The BioPoly Radial Head Implant is indicated for:

- Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and or proximal radio-ulnar joint with:
  - joint destruction and/or subluxation visible on x-ray; and/or
  - resistance to conservative treatment.
- Primary replacement after fracture of the radial head.
- Symptomatic sequelae after radial head resection.
- Revision following failed radial head arthroplasty.

Contraindications

- Inadequate bone stock
- Inflammatory or rheumatoid arthritis, infection, sepsis, and osteomyelitis
- Osteoporosis
- Metabolic disorders which may impair the formation or healing of bone
- Infections at remote sites which may spread to the implant site
- Chronic instability or deficient soft tissues and other support structures
- Vascular or muscular insufficiency
- Allergy to titanium, ultra-high molecular weight polyethylene (UHMWPE), or hyaluronan
- Use with opposing capitellar components
- Patients who are unwilling or incapable of following post-operative care instructions.

Caution

Federal (USA) law restricts this device to sale by or on the order of a physician.

Storage and Handling

Store in a cool, dry place and in a manner that protects the integrity of the packaging of the implant. Prior to use, inspect product packaging for signs of damage and/or tampering.

Disposal

After use, this product may be a potential biohazard. Handle and dispose in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

Warnings and Precautions

- Prior to use, the surgeon should thoroughly read and understand all aspects of the surgical technique.
- This device is provided STERILE as a single use product. If sterile barrier is broken or the packaging otherwise damaged, the device may not be administered. Re- sterilization of the device is not permitted.
- During removal of the device from the packaging, special care should be taken to preserve the articulating surface finish.
- In case of damage to the implant, including scratches or indentations on the articulating surface, bending of the stem, or any other disfigurement, the device may not be administered.
- Any alteration or modification to the device prior to the surgical implantation is prohibited.
- Implant articulation with non-cartilage or abnormal anatomic surface can damage the implant.
- Do not reuse device. Risks of reuse include damage to implant, loss of performance, and infection.
- Improper implant selection, placement, positioning, or depth can lead to migration or loss of constraint.
- The implant is intended to be used with the corresponding BioPoly instrument set. Use of other instruments may result in implant failure.
- 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.
- Use of an implant size larger than the native radial head is not allowed

Possible Adverse Effects

- Infections
- Allergies or other reactions to implant materials
- Subsidence, migration, or loss of constraint
- Pain or discomfort
- Wear and damage to the implant articulating surface
- Wear and damage to the adjacent and opposed articular cartilage surfaces or soft tissue support structures
- Intraoperative or postoperative bone fracture
- Incomplete range of motion due to improper selection or positioning of the implant
- Embolism
- Soft tissue damage/impingement

Packaging and Sterilization

The BioPoly Radial Head Implant is sterilized using ethylene oxide. The implant is provided sterile and for single use.

- Do not use if the sterile packaging has been breached or damaged
- Do not attempt to re-sterilize the implant
- Do not use if the expiration date has elapsed

MRI Safety Information

The BioPoly Radial Head Implant has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the BioPoly Radial Head Implant in the MR environment is unknown. Performing an MR exam on a person with this medical device may result in injury or device malfunction.

Implants

Description*	Part #
Radial Head Implant, 20 x 6(+0)mm	160-5060
Radial Head Implant, 20 x 6(+3)mm	160-5063
Radial Head Implant, 20 x 6(+6)mm	160-5066
Radial Head Implant, 20 x 7(+0)mm	160-5070
Radial Head Implant, 20 x 7(+3)mm	160-5073
Radial Head Implant, 20 x 7(+6)mm	160-5076
Radial Head Implant, 20 x 8(+0)mm	160-5080
Radial Head Implant, 20 x 8(+3)mm	160-5083
Radial Head Implant, 20 x 8(+6)mm	160-5086
Radial Head Implant, 23 x 6(+0)mm	160-5360
Radial Head Implant, 23 x 6(+3)mm	160-5363
Radial Head Implant, 23 x 6(+6)mm	160-5366
Radial Head Implant, 23 x 7(+0)mm	160-5370
Radial Head Implant, 23 x 7(+3)mm	160-5373
Radial Head Implant, 23 x 7(+6)mm	160-5376
Radial Head Implant, 23 x 8(+0)mm	160-5380
Radial Head Implant, 23 x 8(+3)mm	160-5383
Radial Head Implant, 23 x 8(+6)mm	160-5396
Radial Head Implant, 23 x 9(+0)mm	160-5390
Radial Head Implant, 23 x 9(+3)mm	160-5393
Radial Head Implant, 23 x 9(+6)mm	160-5396
Radial Head Implant, 26 x 7(+0)mm	160-5670
Radial Head Implant, 26 x 7(+3)mm	160-5673
Radial Head Implant, 26 x 7(+6)mm	160-5676
Radial Head Implant, 26 x 8(+0)mm	160-5680
Radial Head Implant, 26 x 8(+3)mm	160-5683
Radial Head Implant, 26 x 8(+6)mm	160-5686
Radial Head Implant, 26 x 9(+0)mm	160-5690
Radial Head Implant, 26 x 9(+3)mm	160-5693
Radial Head Implant, 26 x 9(+6)mm	160-5696

***[Head Ø x Stem Ø (offset)]**

Instruments

Description	Part #
Instrument Set	160-5500
Sizing Tray	160-2010-01
Instrument Handle	160-2010-02
Radius Retractor	160-2010-03
Broach – 6mm	160-2011-06
Broach – 7mm	160-2011-07
Broach – 8mm	160-2011-08
Broach – 9mm	160-2011-09
Planer - 6/7mm	160-2012-06
Planer - 8/9mm	160-2012-08
Height Trial	160-2013-01
Stem Trial - 6mm	160-2014-06
Stem Trial - 7mm	160-2014-07
Stem Trial - 8mm	160-2014-08
Stem Trial - 9mm	160-2014-09
Head Trial - 20mm	160-2015-20
Head Trial - 23mm	160-2015-23
Head Trial - 26mm	160-2015-26
Offset Trial - +3mm	160-2016-03
Offset Trial - +6mm	160-2016-06
Tamp	160-2017-01

BioPoly®

Advancing Materials. Advancing Outcomes.™

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