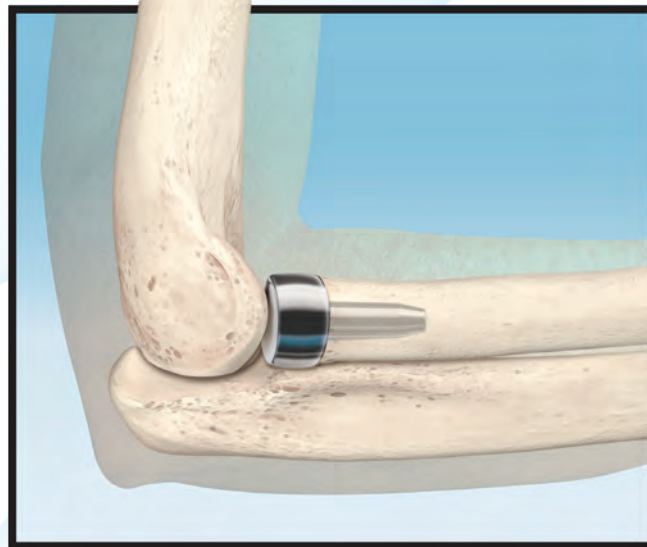


MODULAR DESIGN

Avenger Radial Head System™

Smooth Articular Surface with Tapered Stem



Modular

Ease of Insertion

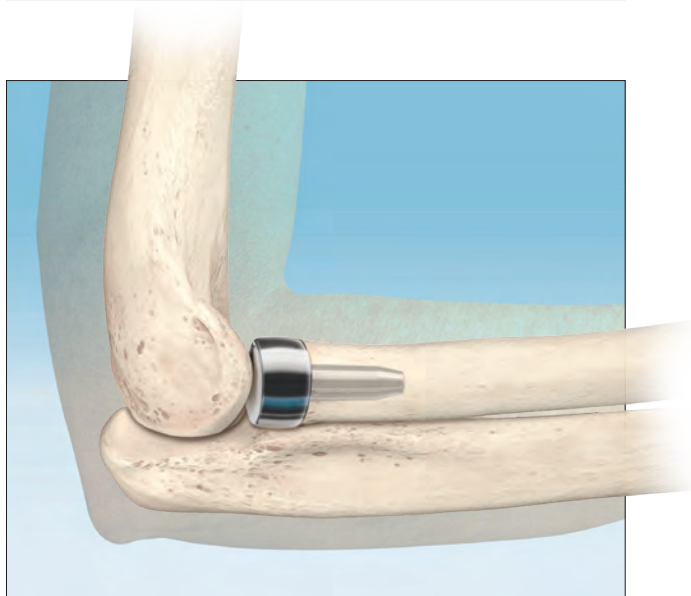
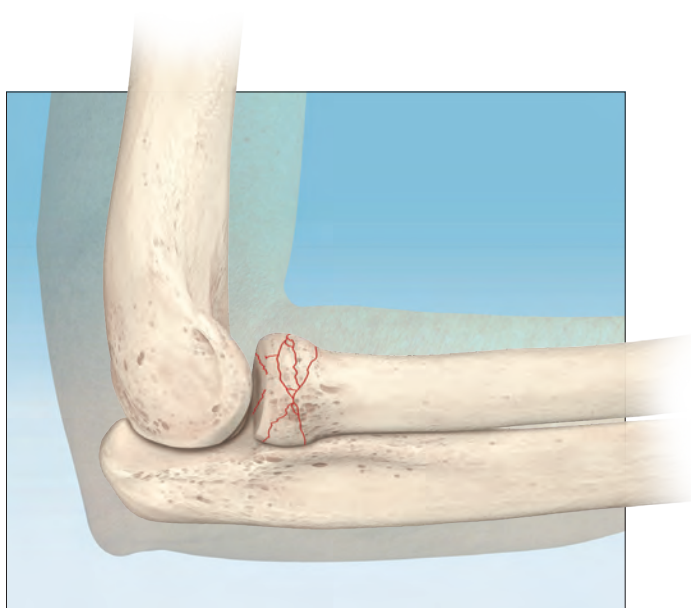
Smooth Stem



A GLOBAL EXTREMITY COMPANY

Avenger Radial Head System

SMOOTH ARTICULAR SURFACE WITH TAPERED STEM



“The indications for surgical management of radial head fractures are not well defined in the literature. Fragment size, number, degree of displacement, and bone quality influence decision making regarding optimal management. Associated injuries and a block to motion are also important factors to consider. Good results have been reported after ORIF for selected non-comminuted displaced radial head fractures. Radial head fragment excision and early or delayed radial head excision all have a role in the management of these common injuries. Radial head fractures that are displaced, but are too comminuted to be anatomically reduced and stably fixed with ORIF and which are too large to consider fragment excision (fracture involves greater than $\frac{1}{4}$ of the radial head), should be managed by radial head excision or arthroplasty. Patients known to have or likely to have an associated ligamentous injury of the elbow or forearm should undergo a radial head arthroplasty because radial head excision is contraindicated.”¹

1. King GJ, Management of Radial Head Fractures with Implant Arthroplasty. Journal of the American Society for Surgery of the Hand. February,2004; vol 4, no 1: 11-26

Modular

Highly polished articular surface in 12 Head sizes with 10 Stem sizes to address fracture specifics and patient anatomy.

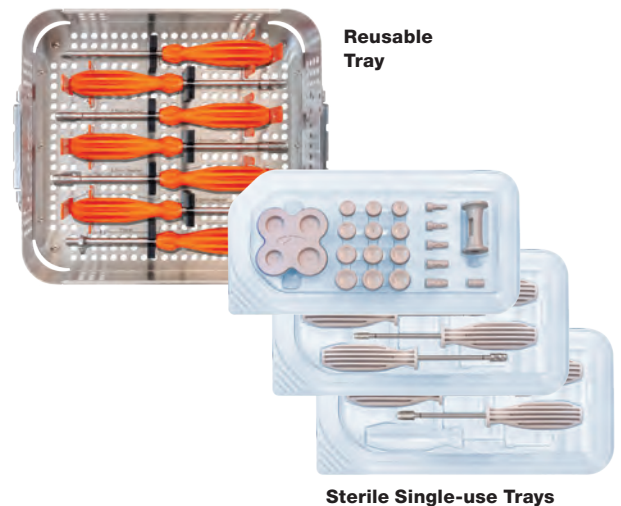
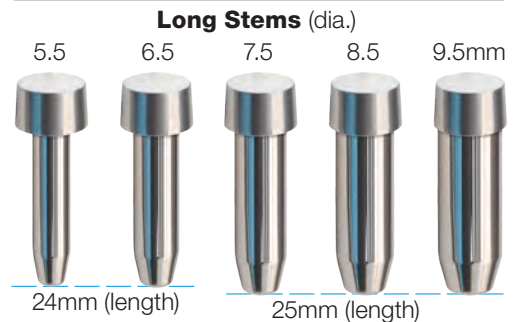
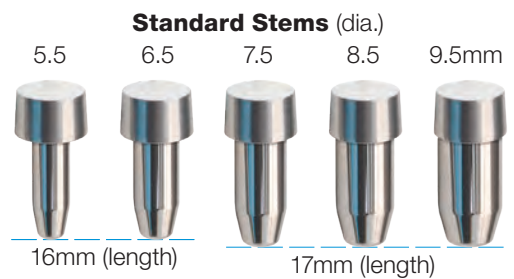
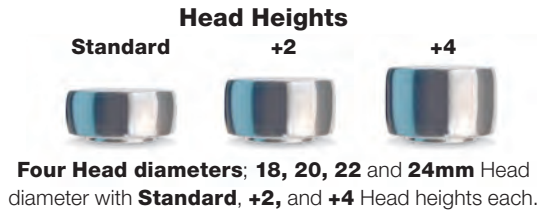


Simple Assembly

Simple, Morse-taper assembly; 120 combinations.

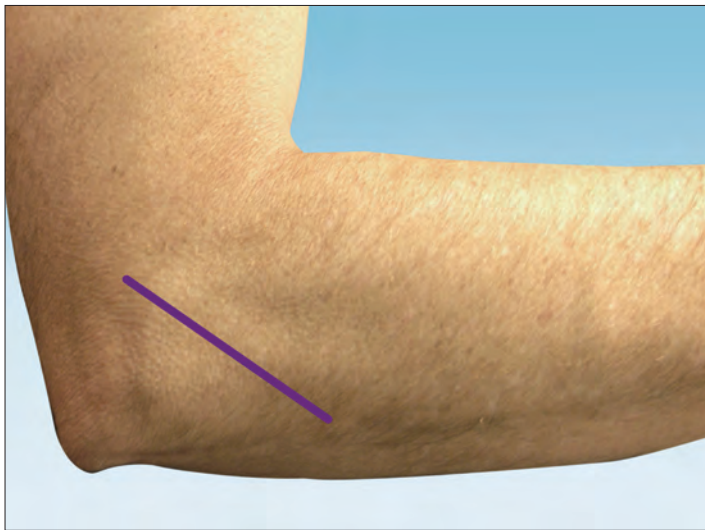
Single Use or Reusable Instruments

Avenger Instrumentation is provided in either a Reusable tray or Sterile Single-use Trays. See page 7 or 8 for detailed descriptions of trays and contents.



Avenger Radial Head System™

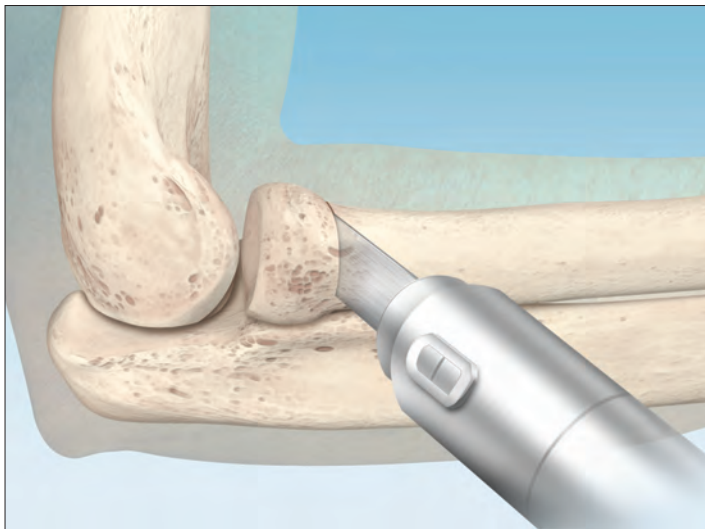
SMOOTH ARTICULAR SURFACE WITH TAPERED STEM



INCISION / EXPOSURE

With the patient in a supine position, a midline posterior incision is made just lateral to the tip of the olecranon. A full thickness lateral flap is elevated on the deep fascia. The use of this incision decreases the risk of cutaneous nerve injury and permits access to the medial side of the elbow in case repair of the collateral ligament is needed for stability. Alternatively, a lateral approach to the elbow can be used as depicted.

The radiocapitellar joint is exposed via the fascial interval between the anconeus and extensor carpi ulnaris (Kocher approach). Continue to open the joint to expose the radial head. The posterior interosseous nerve (the motor branch of the radial nerve) passes around the radial neck and can be protected by keeping the forearm pronated during the exposure and by limiting the distal dissection. Dissection into the supinator muscle should be avoided.

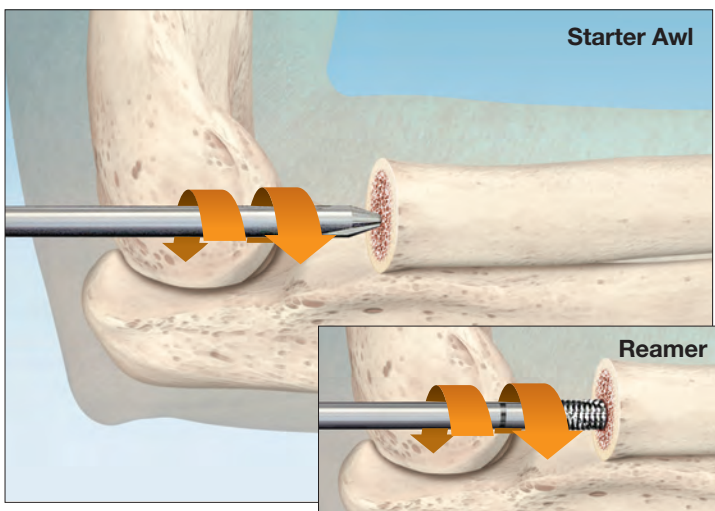


HEAD RESECTION

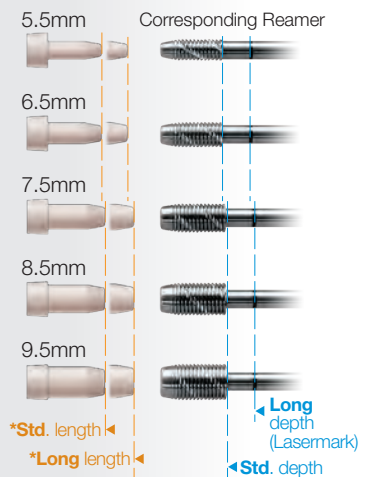
The radial head and fragments are resected and removed. The resection should be perpendicular and at the level of the radial neck fracture. Excessive resection should be avoided. Retract the radial shaft to improve exposure.

REAMER AND STEM SIZING

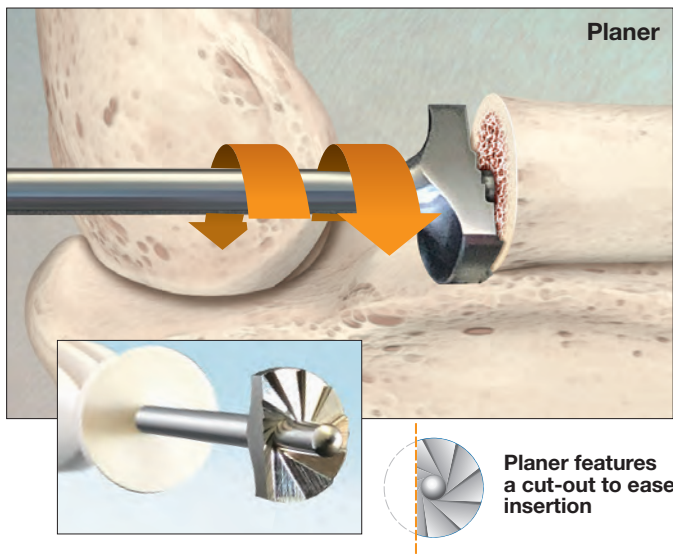
Create an opening in the medullary canal using the Starter Awl. The smallest Reamer (5.5mm) is then used in the medullary canal. Each Reamer is used sequentially until the largest Reamer that creates an easy fit is used. This “largest fitting diameter” Reamer will correspond to the diameter of the Stem Trial and Implant. The length of the cutting teeth area is equivalent to the standard Stem Implants. A laser mark line on the Reamer shaft corresponds to the long Stem Implants.



Sequential Reamers diameters match Stem diameters



*5.5-6.5mm Std. Stems are 16mm long.
7.5-9.5mm Std. Stems are 17mm long.
5.5-6.5mm Long Stems are 24mm long.
7.5-9.5mm Long Stems are 25mm long.

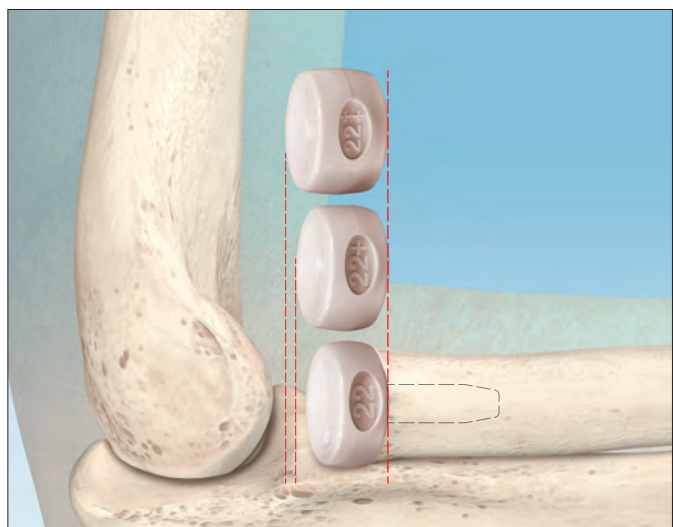


PLANER USE

After the canal has been reamed and the appropriate size Stem diameter has been selected, it may be necessary to use the Planer to create a smooth contact surface on the radial neck. The Planer features a cut-out to ease insertion.

HEAD SIZING

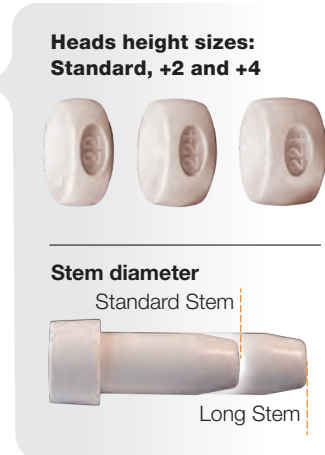
Using the gathered radial head fragments, use the Head Sizer /Assembly Tray impressions to determine the closest diameter Head Trial and Implant. In cases where 2 diameters may work, select the smaller size.



TRIAL VALIDATION

The selected Trial Stem and Head are assembled and placed into the joint space. The joint is reduced and the sizing is assessed through a full range of motion.

In some cases, it may be necessary to adjust the height of the Head to facilitate proper joint spacing. Plus height sizes (+2mm and +4mm) of the Heads can be used for this purpose.

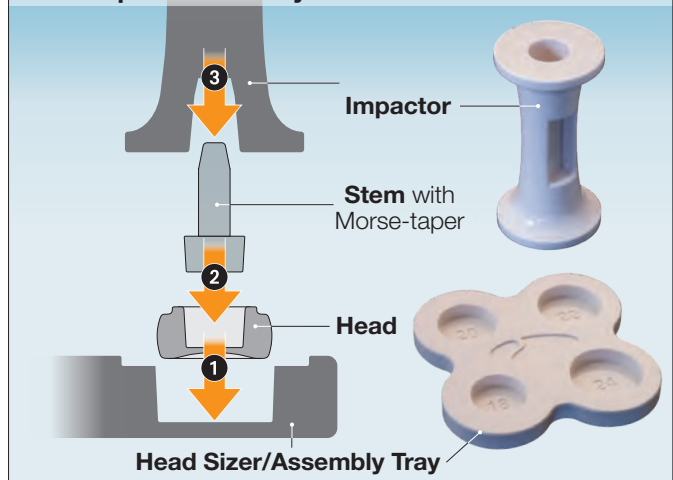


The Stem Implants are provided in standard and long (8mm longer than standard) lengths to facilitate stability if necessary. A laser mark line on the Reamer shaft corresponds to the long Stem Implants. For this reason, only standard Stem diameter Trials are provided for diameter validation.

Before deciding on the final Implant combination, the size and spacing should be confirmed using fluoroscopy. The lateral and medial sides of the humeroulnar joint space should be symmetric and the coronoid and trochlea should be in contact.

NOTE: It is important to ensure that the joint has not been over-stuffed.

Final Implant assembly



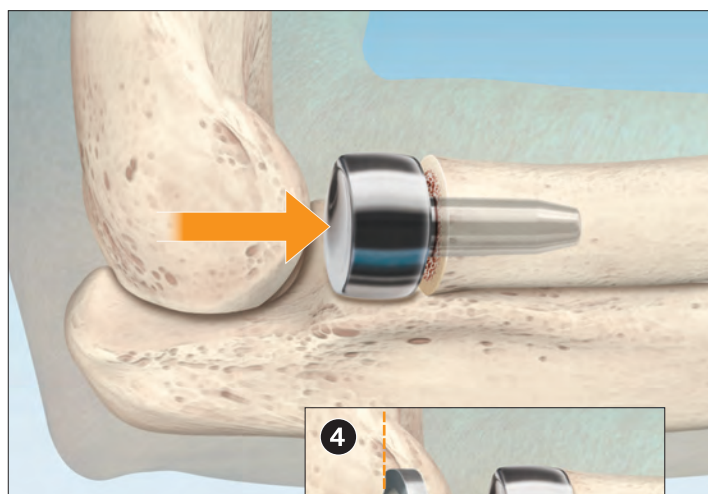
Do not use Impactor to assemble Trials. Hand insert only.

IMPLANT ASSEMBLY

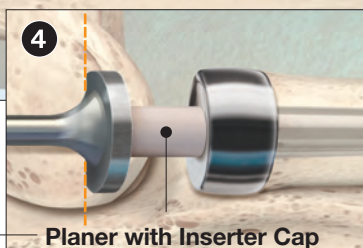
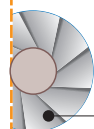
Prior to insertion, the final Implant Head/Stem combination is assembled using the Implant assembly instruments. ① The Head is placed in the Head Sizer/Assembly Tray and the ② Stem Morse-taper is inserted into the mating head taper. ③ The Impactor is placed over the stem and firmly struck approximately two to four times with a mallet.

Avenger Radial Head System

SMOOTH ARTICULAR SURFACE WITH TAPERED STEM



Planer features a cut-out to ease insertion



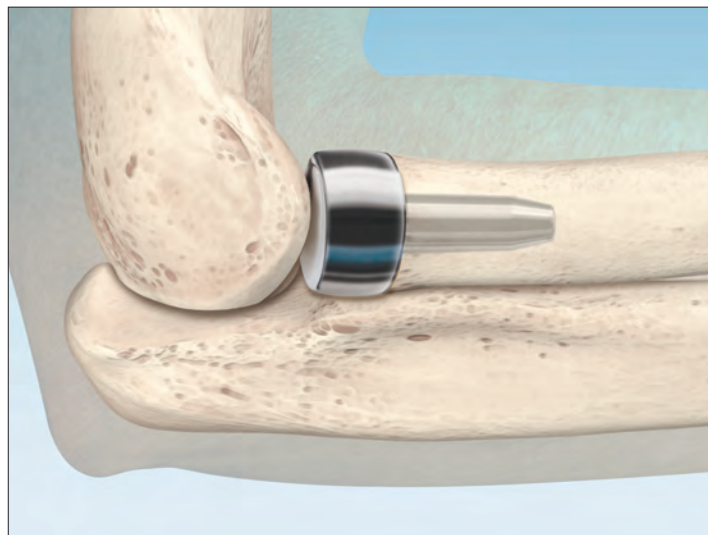
IMPLANT INSERTION

Retract the radial shaft to improve exposure. Using finger control, the Implant is placed into the joint space. If necessary, place the Inserter Cap over the end of the Planer 4 and use this to push the Implant into place. As a final check, manipulate the elbow through its full range of motion. This is done to confirm Implant alignment. Additional confirmation may be done using fluoroscopy. The proximal edge of the Implant should not be more proximal than the most proximal aspect of the radial notch of the ulna (at the PRUJ).

REPAIR SOFT TISSUES AND CLOSURE

The annular and radial collateral ligaments are repaired. The fascial interval between the anconeus and extensor carpi ulnaris muscles is closed. Repair the lateral collateral ligament and extensor muscle origins back to the lateral condyle. Then place the elbow through an arc of flexion-extension. If elbow instability is present, perform additional ligament repair.

The skin and subcutaneous tissues are repaired in layers.



AVENGER RADIAL HEAD™ INSTRUMENTS

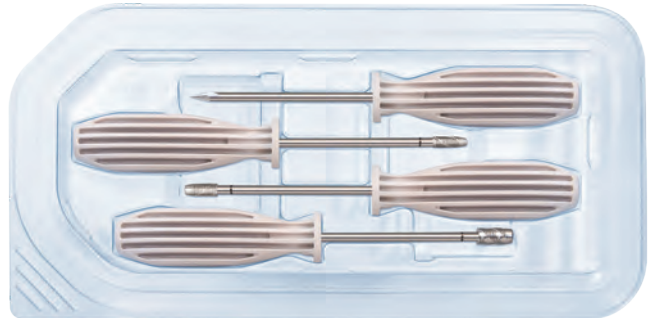
Sterile, Single-Use Trials Tray

- Head Trials in 18, 20, 22 and 24mm diameters with standard, +2, and +4 heights each
- Standard Stem Trials in 5.5, 6.5, 7.5, 8.5 and 9.5mm
- Head Sizer / Assembly Tray
- Impactor
- Inserter Cap



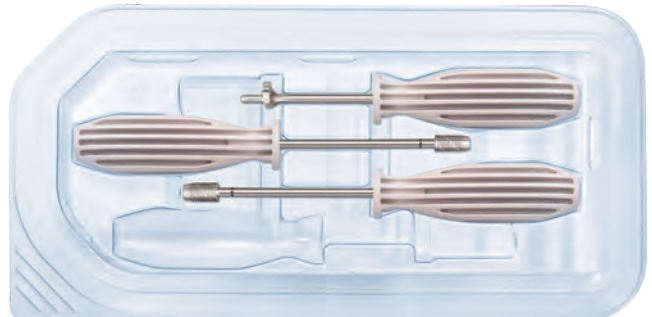
Sterile, Single-use Kit, Tray 1

- Starter Awl Assembly, Single-Use
- Reamer Assembly, Size 5.5mm, Single-Use
- Reamer Assembly, Size 6.5mm, Single-Use
- Reamer Assembly, Size 7.5mm, Single-Use



Sterile, Single-use Kit, Tray 2

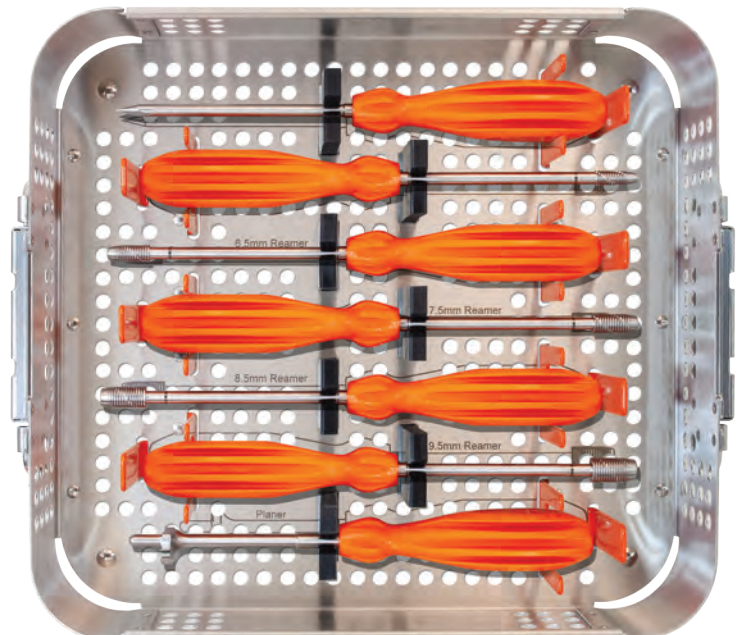
- Planer Assembly, Single-Use
- Reamer Assembly, Size 8.5mm, Single-Use
- Reamer Assembly, Size 9.5mm, Single-Use



Reusable Tray / Sterile, Single-use Trials

- Starter Awl Assembly, Reusable
- Reamer Assembly, Size 5.5mm, Reusable
- Reamer Assembly, Size 6.5mm, Reusable
- Reamer Assembly, Size 7.5mm, Reusable
- Reamer Assembly, Size 8.5mm, Reusable
- Reamer Assembly, Size 9.5mm, Reusable
- Planer Assembly, Reusable

Reusable Tray is accompanied by Sterile, Single-use Trials Tray



MODULAR DESIGN

Avenger Radial Head System

Smooth Articular Surface with Tapered Stem



Avenger Modular Heads

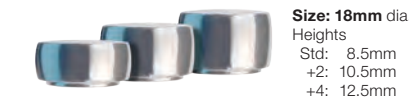
CATALOG NO DESCRIPTION / SIZE

- M70 HC018Head Implant, 18mm
- M70 HC118Head Implant, +2 18mm
- M70 HC218Head Implant, +4 18mm
- M70 HC020Head Implant, 20mm
- M70 HC120Head Implant, +2 20mm
- M70 HC220Head Implant, +4 20mm
- M70 HC022Head Implant, 22mm
- M70 HC122Head Implant, +2 22mm
- M70 HC222Head Implant, +4 22mm
- M70 HC024Head Implant, 24mm
- M70 HC124Head Implant, +2 24mm
- M70 HC224Head Implant, +4 24mm

Avenger Modular Stems

- M70 SC055Stem Implant, Standard 5.5mm
- M70 SC065Stem Implant, Standard 6.5mm
- M70 SC075Stem Implant, Standard 7.5mm
- M70 SC085Stem Implant, Standard 8.5mm
- M70 SC095Stem Implant, Standard 9.5mm
- M70 SC155Stem Implant, Long 5.5mm
- M70 SC165Stem Implant, Long 6.5mm
- M70 SC175Stem Implant, Long 7.5mm
- M70 SC185Stem Implant, Long 8.5mm
- M70 SC195Stem Implant, Long 9.5mm

Heads: Standard / +2mm / +4mm



Size: 18mm dia.
Heights
Std: 8.5mm
+2: 10.5mm
+4: 12.5mm



Size: 20 dia.
Heights
Std: 9.0mm
+2: 11.0mm
+4: 13.0mm

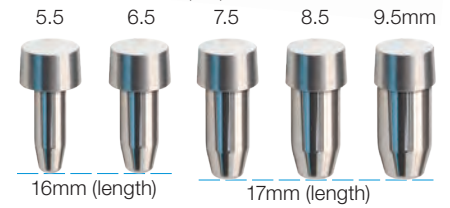


Size: 22 dia.
Heights
Std: 9.5mm
+2: 11.5mm
+4: 13.5mm

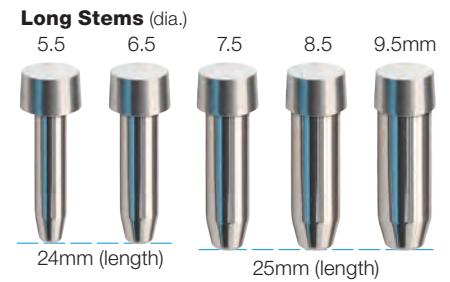


Size: 24 dia.
Heights
Std: 10.0mm
+2: 12.0mm
+4: 14.0mm

Standard Stems (dia.)



16mm (length) 17mm (length)

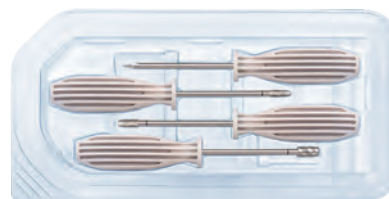


24mm (length) 25mm (length)



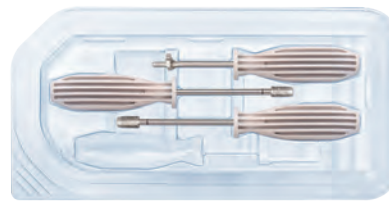
Sterile Single-Use Trial Kit M07 S0001

- Head Trial, 18mm
- Head Trial, 20mm
- Head Trial, 22mm
- Head Trial, 24mm
- Head Trial, 18 +2mm
- Head Trial, 20 +2mm
- Head Trial, 22 +2mm
- Head Trial, 24 +2mm
- Head Trial, 18 +4mm
- Head Trial, 20 +4mm
- Head Trial, 22 +4mm
- Head Trial, 24 +4mm
- Standard Trial Stem, Size 5.5 x 16mm
- Standard Trial Stem, Size 6.5 x 16mm
- Standard Trial Stem, Size 7.5 x 17mm
- Standard Trial Stem, Size 8.5 x 17mm
- Standard Trial Stem, Size 9.5 x 17mm
- Head Sizer/Assembly Tray
- Impactor
- Insertor Cap



Sterile Single-Use Tray: Awl, Reamers 5.5 -7.5mm M07 S002A

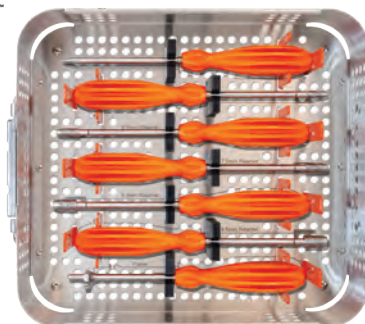
- Starter Awl Assembly
- 5.5mm Reamer Assembly
- 6.5mm Reamer Assembly
- 7.5mm Reamer Assembly



Sterile Single-Use Tray: Planer, Reamers 8.5 & 9.5mm - M07 S002B

- Planer Assembly,
- 8.5mm Reamer Assembly
- 9.5mm Reamer Assembly

Reusable, Avenger Radial Head Instrument Tray



Avenger Radial Head® Reusable Instruments

- M07 N0001Tray with instruments listed below
- M07 N0011Starter Awl Assembly, Reusable
- M07 N0021Reamer Assembly, Size 5.5mm, Reusable
- M07 N0022Reamer Assembly, Size 6.5mm, Reusable
- M07 N0023Reamer Assembly, Size 7.5mm, Reusable
- M07 N0024Reamer Assembly, Size 8.5mm, Reusable
- M07 N0025Reamer Assembly, Size 9.5mm, Reusable
- M07 N0031Planer Assembly, Reusable

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