stryker

Evolve® Proline Radial Head System

Operative technique

Evolve Proline
Radial Head System

Contents

This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

Important

- The patient should be advised that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma and that the device has a finite expected service life.
- Removal or revision of the device may be required sometime in the future.
- Cleaning and sterilization information is provided in the applicable instructions for use.
- Non-sterile devices, including implants and instruments, must be cleaned and sterilized prior to use, in accordance with validated methods.
- Devices that are able to be disassembled should be disassembled prior to point-of-use processing. Additionally, devices with movable components that do not facilitate disassembly should be manually articulated during the point-of-use processing step in order to evacuate additional soils.
- Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.
- Consult Instructions for Use (https://ifu.wright.com) for a complete list of potential adverse effects and adverse events, contraindications, warnings and precautions.
- The surgeon must advise patients of surgical risks, and make them aware of adverse effects and alternative treatments.
- An implant whose packaging is open or damaged or whose expiration date has passed must not be used. Every precaution must be taken to ensure sterility when opening the packaging of the implant and during implantation.

Introduction

The Evolve Radial Head prosthesis was designed to reduce abnormal kinematics and therefore problems with articular wear and pain and utilizes a spacer concept with a smooth stem. The smooth stem can move slightly in the proximal radius so that the radial head tracks with the articular surfaces, reducing abnormal kinematics and therefore problems with articular wear and pain.[1]

Conceptually, the annular ligament guides the motion of the Evolve Radial Head prosthesis optimally with the capitellum and the proximal radial ulnar joint rather than relying on the motion patterns of the radial neck. Given that the native radial head is not circular and the articulation with the capitellum is usually offset from that of the radial neck, there is a natural cam effect which occurs during forearm rotation that is difficult for an off-the-shelf axisymmetric implant to replicate.

The Evolve Proline RH System is a two-part, modular implant design that gives surgeons the ability to appropriately match the patient's anatomy. The Evolve Proline RH System head sizes range from 18 to 28mm in diameter and stem sizes range from 4.5 to 9.5mm diameter (Figure 1). Furthermore, the system has three head heights and three stem heights that enable precise replication of the native radial head articulation with the proximal radioulnar joint.

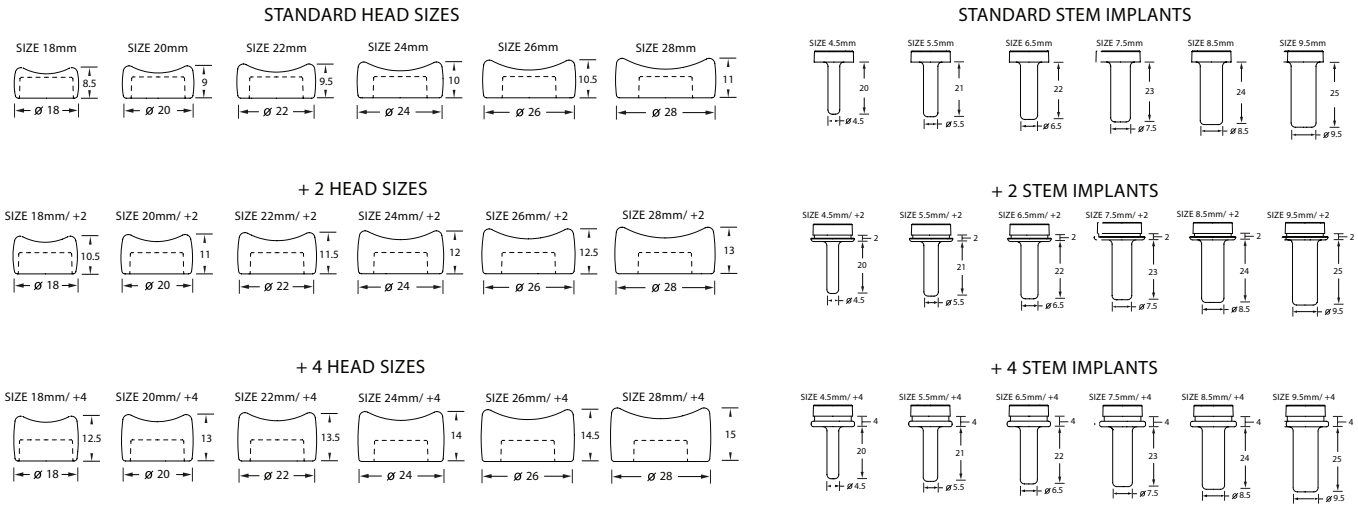


Figure 1

1. **King GJ, Zarzour ZD, Rath DA, Dunning CE, Patterson SD, Johnson JA. Metallic radial head arthroplasty improves valgus stability of the elbow. Clinical Orthopedics and Related Research 368:114-25, 1999.**

Indications and warnings

Indications

Use of the radial head implant may be considered 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

- Infection
- Physiologically or psychologically inadequate patient
- Inadequate skin, bone, or neurovascular status
- Irreparable tendon system
- Possibility for conservative treatment
- Growing patients with open epiphyses
- Patients with high levels of activity
- Growing children with open epiphyses
- Dislocations of radius on ulna that would not allow a radio-humeral articulation
- Rheumatoid arthritis. Evidence of joint narrowing secondary to radio-humeral joint synovitis is not a contraindication to radial head implant replacement combined with elbow synovectomy.

Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the package insert is available on the website listed.

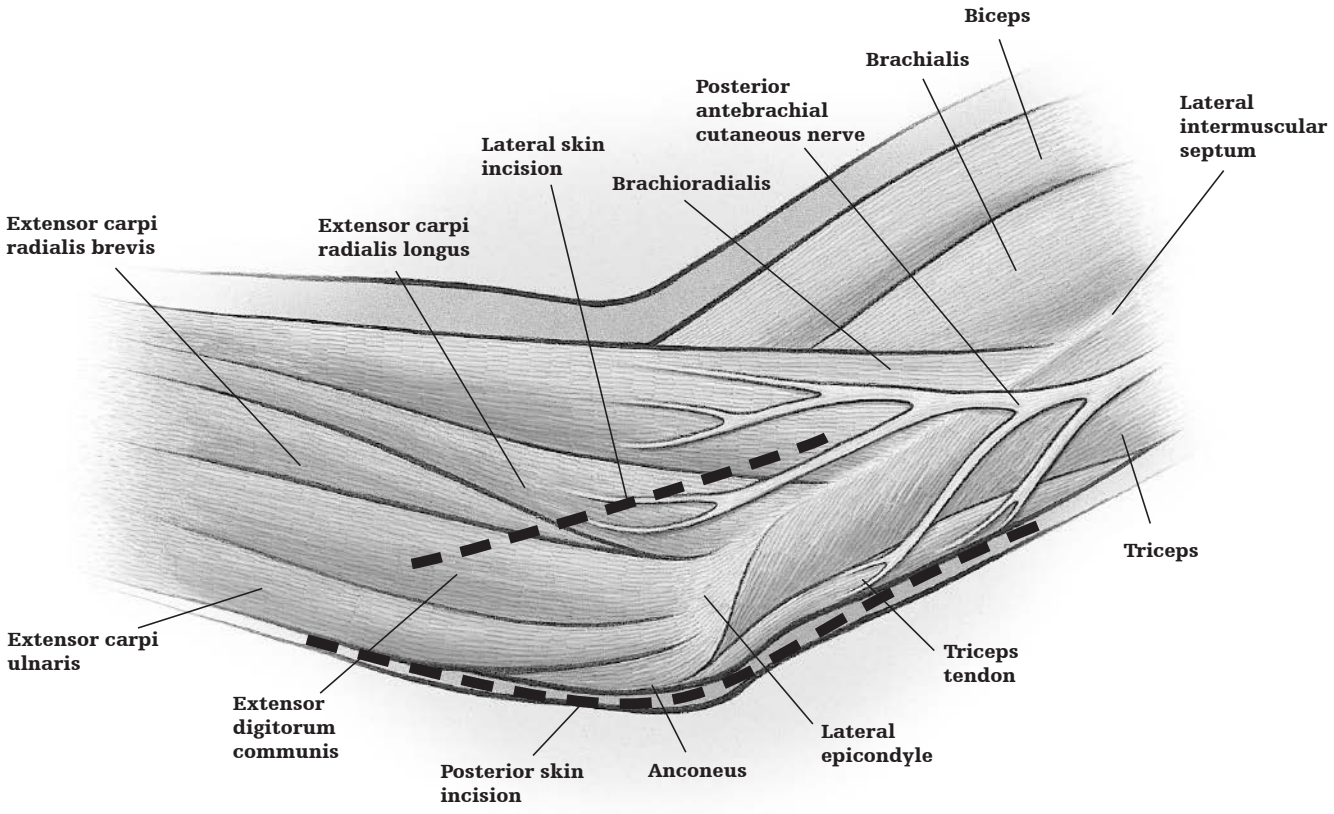
Operative technique

Skin incision

Radiographs of the contralateral elbow and both wrists are helpful in preoperative planning, particularly if the radial head has previously been excised.

With the patient in either the supine or lateral decubitus position, make a posterior midline longitudinal skin incision just lateral to the tip of the olecranon. Elevate a full thickness lateral flap (fasciocutaneous) on the deep fascia to protect the cutaneous nerves. The posterior midline incision permits access to the medial side of the elbow if repair of the medial collateral ligament is necessary to restore elbow stability. It is also more cosmetic than a laterally-based incision. In patients with isolated injuries to the radial head, a traditional lateral skin incision may be employed. However, first identify and protect the cutaneous nerves which usually cross the incision (Figure 2).

Figure 2

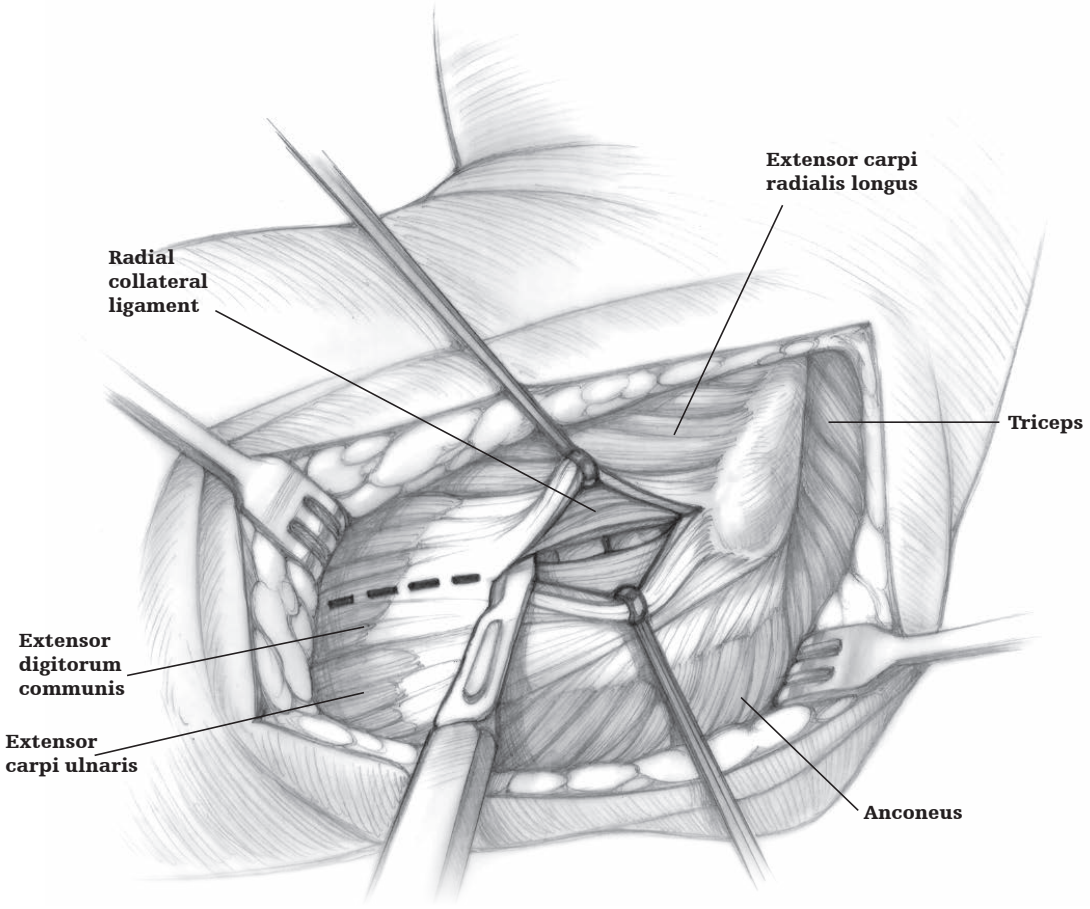


Operative technique

Direct lateral dissection

Pronate the forearm to move the posterior interosseous nerve more distal and medial during the surgical approach. Split the extensor digitorum communis tendon longitudinally at the midaspect of the radial head and incise the underlying radial collateral and annular ligaments (Figure 3). Keep dissection anterior to the lateral ulnar collateral ligament to prevent the development of posterolateral rotatory instability. If additional exposure is needed, elevate the humeral origin of the radial collateral ligament and the overlying extensor muscles anteriorly off the lateral epicondyle and lateral supracondylar ridge. In the unusual circumstance where further exposure is required, consider releasing the posterior component of the lateral collateral ligament (including the lateral ulnar collateral ligament). However, careful ligament repair is required at the end of the procedure in order to restore the varus and posterolateral rotatory stability of the elbow. In many circumstances, the radial head is easily visualised after opening the subcutaneous tissue due to avulsion of the lateral collateral ligament and common extensor muscles from the lateral epicondyle during the injury.

Figure 3



Operative technique

Resection

Remove and retain all fragments of the radial head. Using a sagittal saw, resect the remaining radial head at the level of the radial neck fracture, perpendicular to the neck to make a smooth surface for seating the prosthetic radial head (Figure 4). Confirm complete radial head excision with an image intensifier and by reassembling the resected radial head in the Sizing and assembly dish (p/n 24981005) (Figure 5). It is recommended that at least 60% of the native radial neck be in contact with the implant. If not, make the radial neck cut more distal and use a thicker head/stem prosthesis. Copiously irrigate the joint to remove all loose intra-articular debris. Evaluate the capitellum for chondral injuries or osteochondral fractures. Manage associated fractures of the coronoid as indicated prior to radial head replacement. Carefully place a hohman retractor around the posterior aspect of the proximal radial neck to deliver the radial neck laterally (Figure 6). Avoid placing the retractor anteriorly due to the risk of injury to the posterior interosseous nerve from pressure.

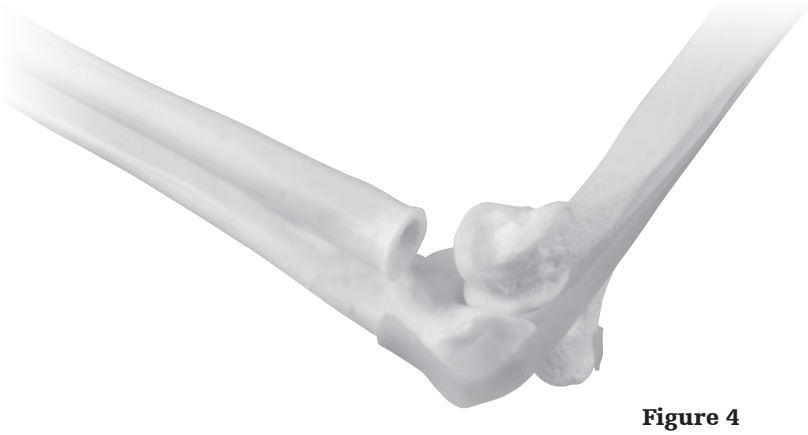


Figure 4

Figure 5

Sizing and assembly dish
(p/n 24981005)

Figure 6

Operative technique

Trial head selection

Select the appropriate trial head (p/n 2499H018-2499H428) diameter based on backtable reassembly of the radial head fragments. For elliptically shaped radial heads, select the minimum rather than the maximum diameter (Figure 7). Pay special attention to replicate the size of the articular dish rather than the outside diameter of the native head (Figure 8). Select the prosthesis height based on the thickness of the flatter articular portion of the native radial head that articulates with the proximal radial ulnar joint (Figure 9). If the native radial head is between available implant sizes in diameter or height, downsize the implant in the appropriate dimension.

Figure 7

Figure 8

Stem broaching

Create an opening in the medullary canal using the starter awl (p/n 24987100). Sequentially ream the radial neck by inserting the stem broaches (p/n 2497145-2497105) to the depth indicators on the broaches (Figure 10) until the stem broaches no longer pass easily into the canal due to cortical contact.

Figure 9

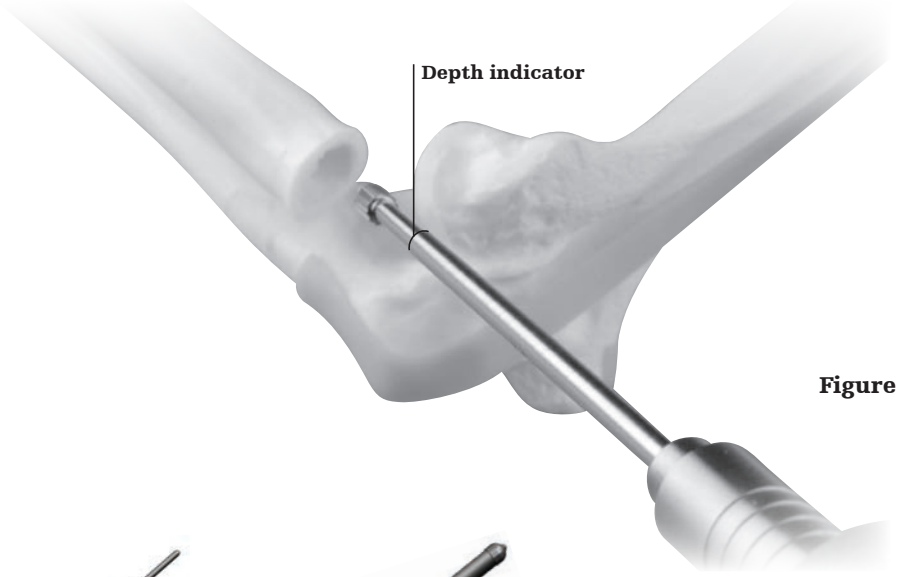


Figure 10

Trial head
(p/n 2499H018-2499H428)

Starter awl
(p/n24987100)

Stem broach
(p/n 2497145-2497105)

AO driver handle
(p/n 44112009)

Operative technique

Neck planing

Leave the last stem broach in the canal and remove the handle. Slip the neck planer (p/n 24981003) over the stem broach (Figure 11a). Gently rotate the neck planer to create a smooth contact surface on the radial neck, perpendicular to the longitudinal axis of the radial neck (Figure 11b). Avoid excessive planing as it may increase the height of the stem required.

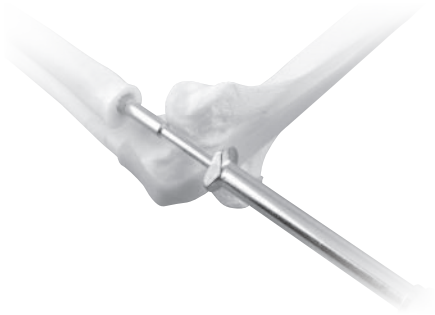


Figure 11a

Trial Stem Selection

Select the appropriate trial stem (p/n 2499S045-2499S495) diameter based on the largest stem broach that easily fits in the canal. The trial stem should fit into the radial neck (Figure 12) without force and have a slightly loose but not sloppy fit in the medullary canal of the radius. **Undersizing the trial stem diameter by one size is recommended in most cases to allow for the implant to toggle and precisely conform with the capitellum during range of motion.** Select the stem collar height by placing the trial stem into the trial head and comparing the total height with that of the native radial head that was excised (Figure 13).

Figure 11b

Figure 12

Neck planer
(p/n 24981003)

Trial stem
(p/n 2499S045-2499S495)

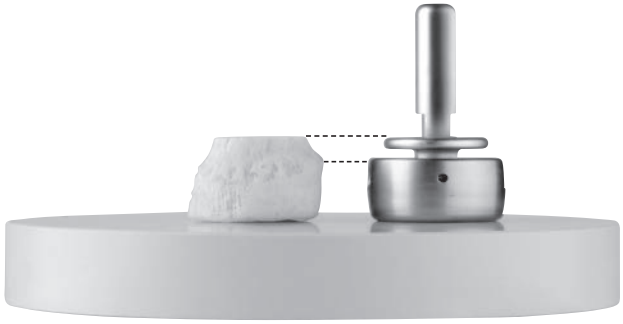


Figure 13

Operative technique

Trial stem and head insertion

Grasp the trial stem with the trial stem handle (p/n 24981002) so that the handle sits below the trial head. Insert the trial stem into the medullary canal. Screw the trial head onto the trial head handle (p/n 24981001). Holding the trial head handle in line with the trial stem handle, slide the trial head over the trial stem platform (Figure 14a). Once the trial head is completely seated on the trial stem platform, rotate the trial handles 90º apart (Figure 14b) to lock the trial head and trial stem together via a ball plunger connection (Figure 14c). If the trial handles do not rotate easily, reconfirm that the trial head is completely seated on the trial stem platform.

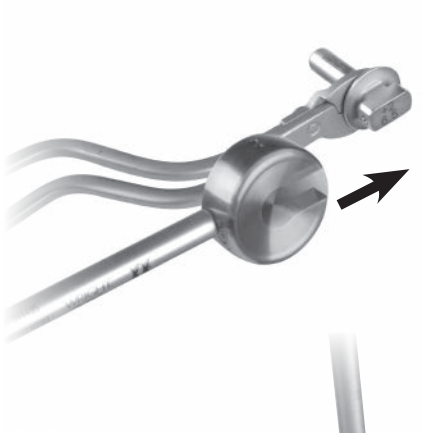


Figure 14a

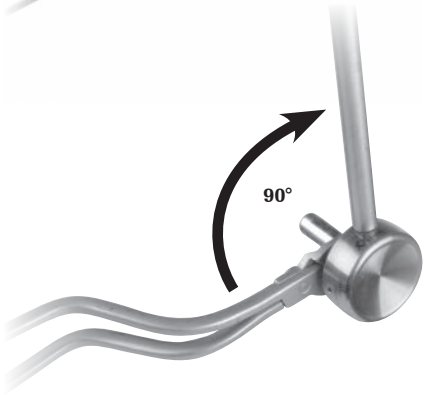


Figure 14b

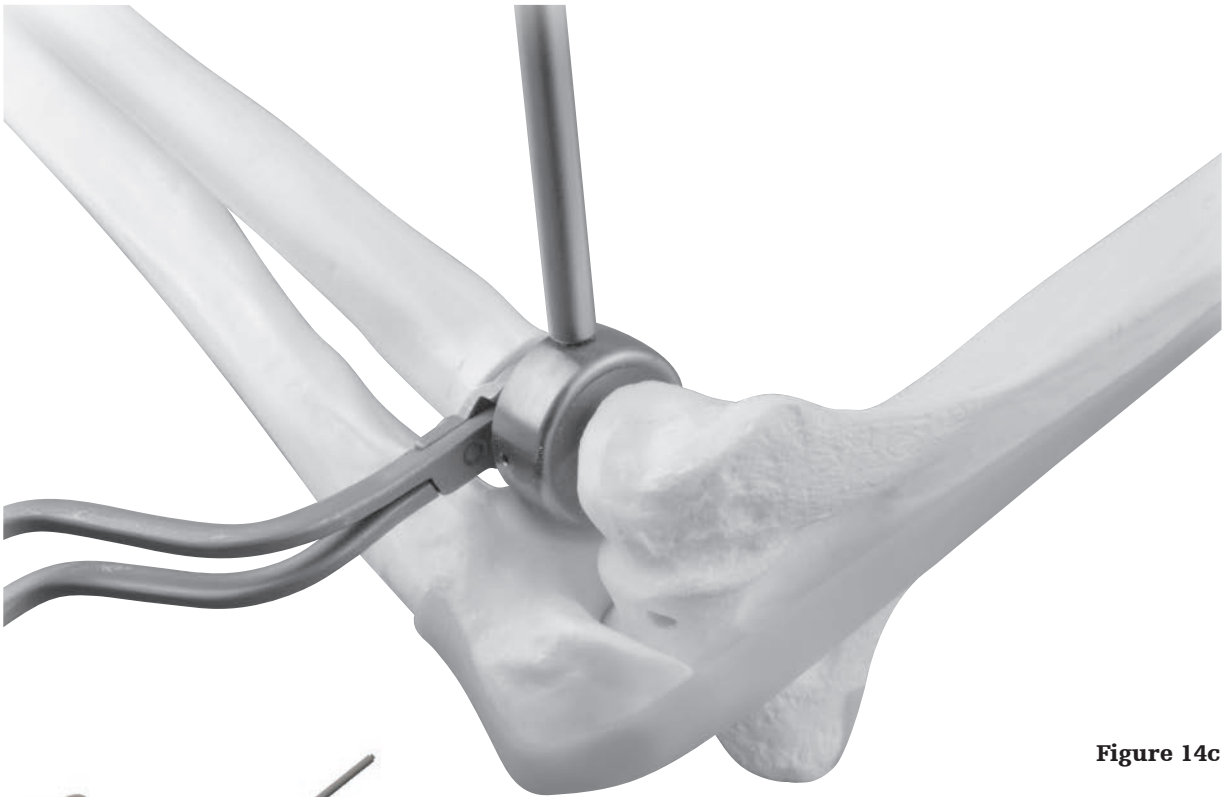


Figure 14c

Trial stem handle
(p/n 24981002)

Trial head handle
(p/n 24981001)

Operative technique

Validate trial sizing

Unscrew the trial head handle from the trial head and remove the trial stem handle. Reduce the elbow with the trials in place. Verify smooth motion in passive flexion and extension of the elbow and rotation of the forearm. Some translation of the trial head relative to the capitellum is normal with forearm rotation. Assess the appropriate implant height by pronating the forearm to compensate for the lateral destabilization induced by the surgical approach or injury. The trial head should articulate with the most proximal margin of the proximal radioulnar joint approximately 1 mm distal to the coronoid process.

Note:
To reduce the risk of cartilage wear on the capitellum from excessive pressure, avoid overstuffing the radiocapitellar joint with a radial head implant that is too thick. To avoid overstuffing the radial-capitellar joint, use the combined trial head and trial Stem collar height to approximate the height of the native radial head and radial neck portion that was resected, not the gap between the radial neck and the capitellum. There is often a small gap between the trial head and capitellum; particularly in cases with lateral ligament injuries. Do not increase the implant thickness to compensate for the ligament injuries. Repairing the collateral ligaments prior to closure will stabilize the joint.

Use an image intensifier to evaluate ulnar variance at the wrist. An implant that is too thick will have ulnar negative variance and an implant that is too thin will have ulnar positive variance relative to the contralateral wrist. Visualize the medial ulnohumeral joint in an anteroposterior view with an image intensifier to ensure that the joint space is symmetrical (Figure 15). An implant that is too thick will result in varus alignment and a non-parallel medial ulnohumeral joint space that is wider laterally. If the prosthesis is tracking poorly on the capitellum with forearm rotation, trial a smaller stem size to ensure that the articulation of the radial head with the capitellum is controlled by the annular ligament and articular congruency, and not dictated by the motion pathways of the proximal radial shaft.

Note:
A metallic radial head will appear larger on x-ray than the native radial head because it is replacing radiolucent cartilage as well as radiographic bone.

Trial head and stem removal

Once optimal sizing has been determined, reattach the trial handles to the trials. Unlock the trial head from the trial stem by realigning the handles. Remove the trial head from the joint space and then remove the trial stem. Irrigate the joint thoroughly.

Implant insertion using back table implant assembly

In most acute injuries, the proximal radius is sufficiently mobile or the lateral ligaments have been compromised such that the implant can be assembled on the back table and inserted as a monoblock implant. To do this, insert the stem implant (p/n 496S045-496S495) into the head implant (p/n 496H018-496H428) and place onto the sizing and assembly dish. Place the appropriately sized stem impactor (p/n 24981007-24981009) over the stem and strike it firmly three times with a mallet (Figure 16). Insert the assembled implant into the proximal radius by retracting the proximal radius laterally (Figure 6).

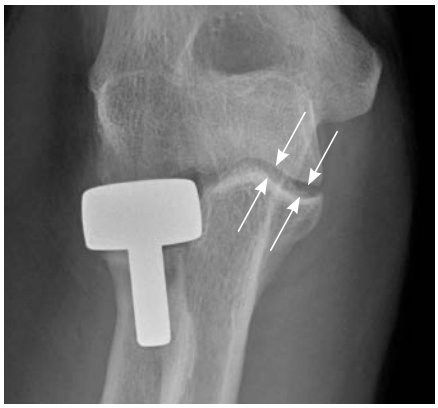


Figure 15

Figure 16

Stem impactor
(p/n 24981007-24981009)

Operative technique

Implant insertion using in situ assembly

When the lateral ligaments are intact in acute injuries and in cases of late reconstruction, insertion of the assembled implant may not be possible due to insufficient mobility of the proximal radius. In these settings, the two components of the implant should be inserted separately and then coupled in situ using the supplied locker.

While retracting the proximal radius with a retractor, insert the stem implant into the medullary canal. It should slide in easily (Figure 17a). Using finger control, slide the head implant into the joint space with the head implant female taper over the stem implant male taper (Figure 17b).

Figure 17a

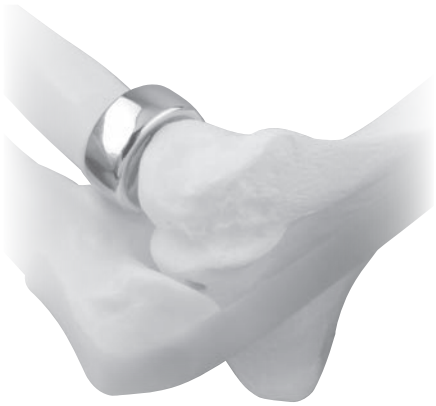


Figure 17b

Locker assembly

Assemble the locker by first inserting the stem paddle post (p/n 24991001) into the locker body (p/n 24991000). Screw the locker assembly knob (p/n 24982005) onto the stem paddle post. Insert the appropriately sized head paddle (p/n 24991018-24991028) into the jaw on the locker body. Insert the appropriately sized stem paddle (p/n 24991045-24991095) into the jaw on the stem paddle post (Figure 18).

Note:
The locker is the only recommended device for in situ assembly. A tamp and/or mallet will not generate enough force to adequately secure the morse taper and disassociation may occur.

Locker assembly

1. **Insert stem paddle post (A) into locker body (B)**
2. **Screw locker assembly knob (C) onto stem paddle post (A)**
3. **Snap head paddle (D) into locker body (B)**
4. **Snap stem paddle (E) into stem paddle post (A)**

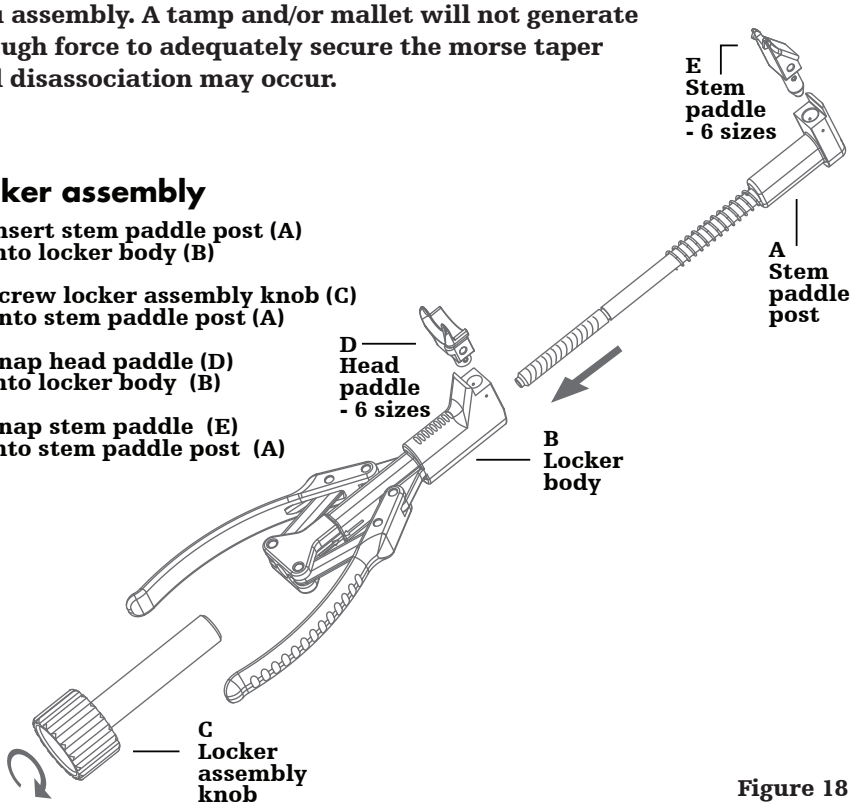


Figure 18

Operative technique

Implant locking

With traction on the arm, gently slide the stem and head paddles into the joint space to avoid damaging the capitellum. Once the locker is properly seated on the implant (Figure 19a), tighten the locker assembly knob and give the Locker one firm squeeze (Figure 19b). Unscrew the locker assembly knob to disengage the locker from the now assembled implant.

Note:
Because of the tremendous load being applied by the In situ locker, on some occasions, after assembling the implant, the locker jaws will not release freely. In those cases, loosen the locker assembly knob 2-3 turns and lightly tap the end of the locker assembly knob with a small mallet.

Figure 19a

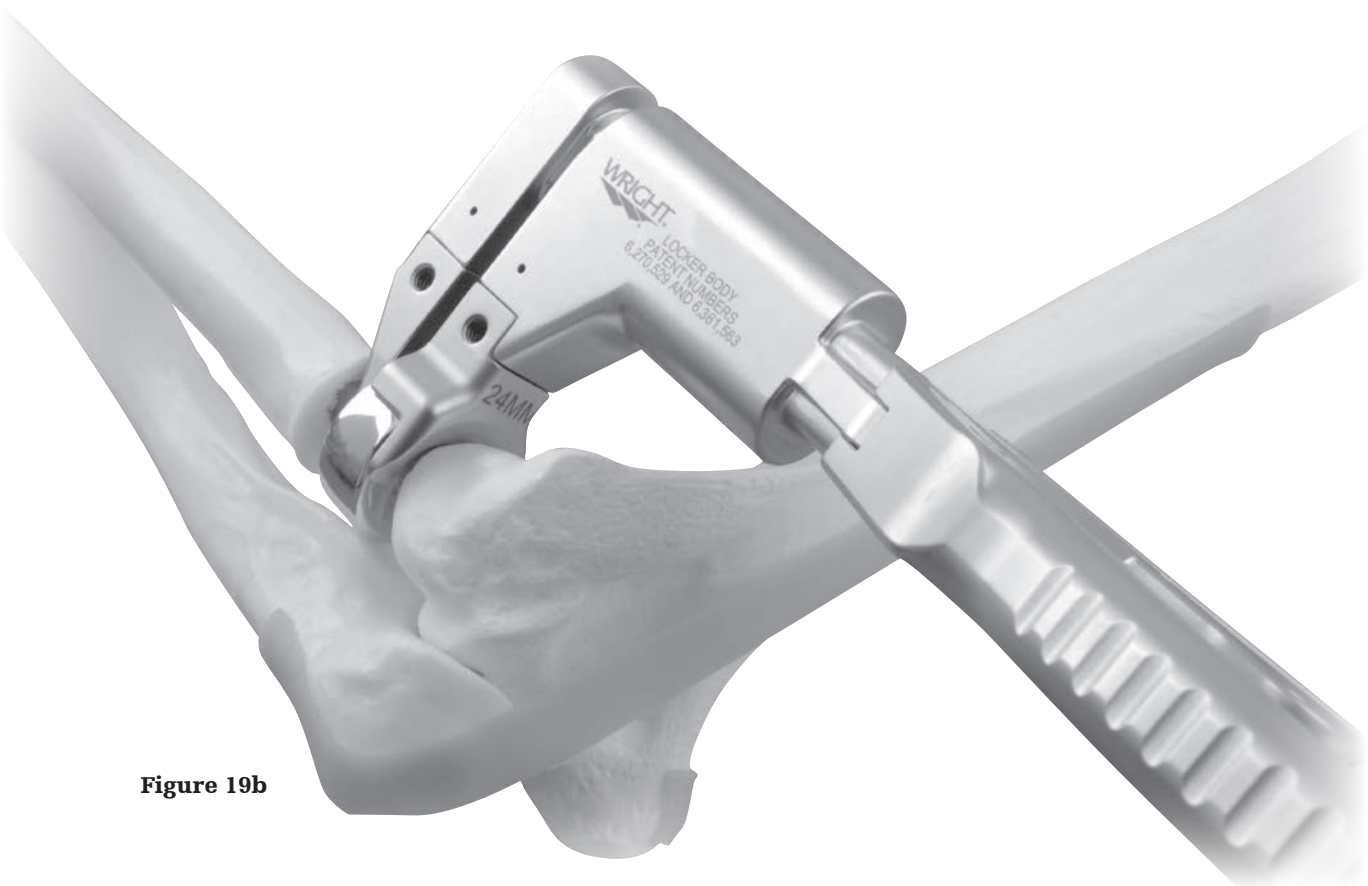


Figure 19b

Operative technique

Locker insertion in very tight elbows (optional)

In some cases, the elbow joint may be too small or tight to allow both the head paddle and stem paddle to be inserted concurrently. In those situations, a consecutive approach can be used. Instead of snapping the stem paddle into the stem paddle post (Figure 18, step 4), use the trial head handle to hold onto the stem paddle (Figure 20a). Insert the stem paddle underneath the stem implant collar. Carefully guide the head paddle, attached to the locker body, onto the head implant while also guiding the stem paddle post onto the stem paddle (Figure 20b). Once the locker is positioned correctly, tighten the locker assembly knob and give the locker one firm squeeze.

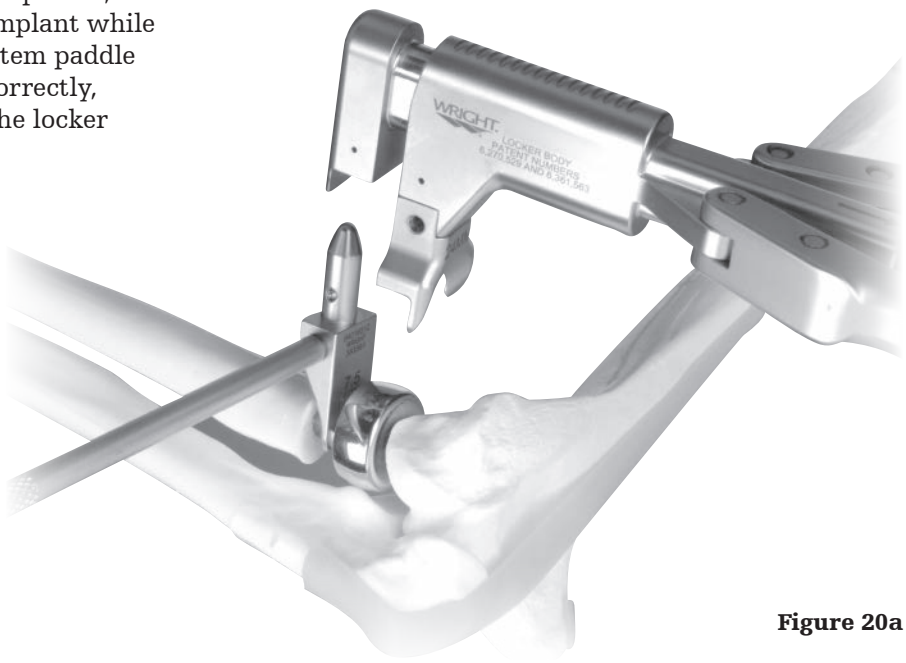


Figure 20a

Figure 20b

Operative technique

Closure

Following radial head replacement, repair the lateral collateral ligament and extensor muscle origins back to the lateral condyle. If the posterior half of the lateral collateral ligament is still attached to the lateral epicondyle, repair the anterior half of the lateral collateral ligament (the annular ligament and radial collateral ligament) and extensor muscles to the posterior half using interrupted absorbable sutures (Figure 21). If the lateral collateral ligament and extensor origin have been completely detached either by the injury or surgical exposure, securely repair them to the lateral epicondyle using drill holes through bone and non-absorbable sutures or suture anchors. Place a single drill hole at the axis of motion (the centre of the arc of curvature of the capitellum) and two drill holes placed anterior and posterior to the lateral supracondylar ridge. Employ a locking (krackow) suture technique to gain a secure hold of the lateral collateral ligament and common extensor muscle fascia. Pull the ligament sutures into the holes drilled in the distal humerus using suture retrievers. Pronate the forearm and avoid varus forces while tensioning the sutures prior to tying. Leave the knots anterior or posterior to the lateral supracondylar ridge to avoid prominence.

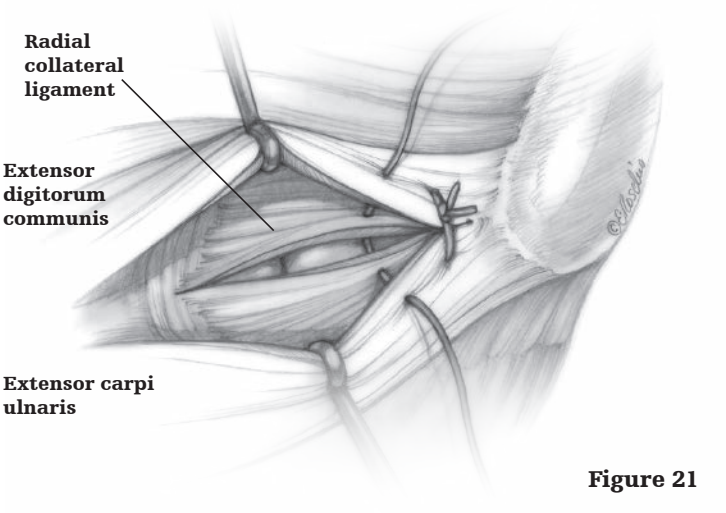


Figure 21

Following replacement arthroplasty and lateral soft tissue closure, place the elbow through an arc of flexion-extension while carefully evaluating for elbow stability in pronation, neutral, and supination. Pronation is generally beneficial if the lateral ligaments are deficient, supination if the medial ligaments are deficient and neutral position if both sides have been injured.

In patients who have an associated elbow dislocation, perform additional repair of the medial collateral ligament and flexor pronator origin if the elbow subluxates at 40° or more of flexion. After tourniquet deflation and secure hemostasis, the subcutaneous tissues and skin are closed in layers.

Postoperative care

Postop care is the responsibility of the surgeon.

Explant Information

If the removal of the implant is required due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located on the back cover of this surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation.

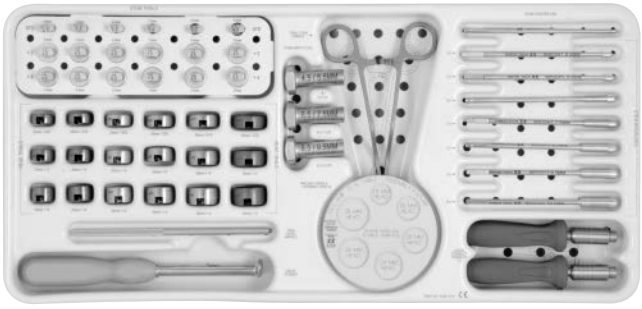
Appendix: ordering information

Evolve Proline implants

2499KITA

Item #	Description	Kit qty
496H018	Head 18mm	1
496H218	Head 18mm +2	1
496H418	Head 18mm +4	1
496H020	Head 20mm	1
496H220	Head 20mm +2	1
496H420	Head 20mm +4	1
496H022	Head 22mm	1
496H222	Head 22mm +2	1
496H422	Head 22mm +4	1
496H024	Head 24mm	1
496H224	Head 24mm +2	1
496H424	Head 24mm +4	1
496H026	Head 26mm	1
496H226	Head 26mm +2	1
496H426	Head 26mm +4	1
496H028	Head 28mm	1
496H228	Head 28mm +2	1
496H428	Head 28mm +4	1

Item #	Description	Kit qty
496S045	Stem 4.5mm	1
496S245	Stem 4.5mm +2	1
496S445	Stem 4.5mm +4	1
496S055	Stem 5.5mm	1
496S255	Stem 5.5mm +2	1
496S455	Stem 5.5mm +4	1
496S065	Stem 6.5mm	1
496S265	Stem 6.5mm +2	1
496S465	Stem 6.5mm +4	1
496S075	Stem 7.5mm	1
496S275	Stem 7.5mm +2	1
496S475	Stem 7.5mm +4	1
496S085	Stem 8.5mm	1
496S285	Stem 8.5mm +2	1
496S485	Stem 8.5mm +4	1
496S095	Stem 9.5mm	1
496S295	Stem 9.5mm +2	1
496S495	Stem 9.5mm +4	1



Proline instrument tray

Locker instrument tray

Appendix: Ordering Information

Evolve Proline instruments

2499KIT1

Item #	Description	Kit Qty
44112009	AO Driver Handle	2
24981007	Impactor 4.5/5.5mm	1
24981008	Impactor 6.5/7.5mm	1
24981009	Impactor 8.5/9.5mm	1
24981003	Neck planer	1
24981005	Sizing & assembly dish	1
24987100	Stem starter awl	1
24987145	Stem broach 4.5mm	1
24987155	Stem broach 5.5mm	1
24987165	Stem broach 6.5mm	1
24987175	Stem broach 7.5mm	1
24987185	Stem broach 8.5mm	1
24987195	Stem broach 9.5mm	1
24987105	Stem broach 10.5mm	1
24981001	Trial head handle	1
24981002	Trial stem handle	1
496XR01	Proline x-ray template	1
24981010	Instrument tray	1
2499H018	Trial head 18mm	1
2499H218	Trial head 18mm +2	1
2499H418	Trial head 18mm +4	1
2499H020	Trial head 20mm	1
2499H220	Trial head 20mm +2	1
2499H420	Trial head 20mm +4	1
2499H022	Trial head 22mm	1
2499H222	Trial head 22mm +2	1
2499H422	Trial head 22mm +4	1
2499H024	Trial head 24mm	1
2499H224	Trial head 24mm +2	1
2499H424	Trial head 24mm +4	1
2499H026	Trial head 26mm	1
2499H226	Trial head 26mm +2	1
2499H426	Trial head 26mm +4	1
2499H028	Trial head 28mm	1
2499H228	Trial head 28mm +2	1
2499H428	Trial head 28mm +4	1
24981011	Proline replacement lid	0

Item #	Description	Kit Qty
2499S045	Trial stem 4.5mm	1
2499S245	Trial stem 4.5mm +2	1
2499S445	Trial stem 4.5mm +4	1
2499S055	Trial stem 5.5mm	1
2499S255	Trial stem 5.5mm +2	1
2499S455	Trial stem 5.5mm +4	1
2499S065	Trial stem 6.5mm	1
2499S265	Trial stem 6.5mm +2	1
2499S465	Trial stem 6.5mm +4	1
2499S075	Trial stem 7.5mm	1
2499S275	Trial stem 7.5mm +2	1
2499S475	Trial stem 7.5mm +4	1
2499S085	Trial stem 8.5mm	1
2499S285	Trial stem 8.5mm +2	1
2499S485	Trial stem 8.5mm +4	1
2499S095	Trial stem 9.5mm	1
2499S295	Trial stem 9.5mm +2	1
2499S495	Trial stem 9.5mm +4	1

Evolve locker instruments

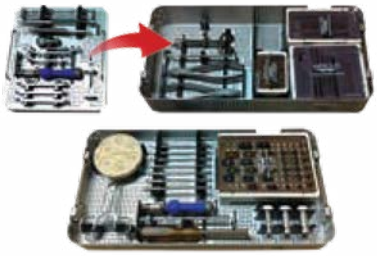
2499KIT2

Item #	Description	Kit Qty
24982005	Locker assemb knob	1
24991000	Locker body	1
24981012	Locker tray	1
24991001	Stem paddle POST	1
24991045	Stem paddle 4.5mm	1
24991055	Stem paddle 5.5mm	1
24991065	Stem paddle 6.5mm	1
24991075	Stem paddle 7.5mm	1
24991085	Stem paddle 8.5mm	1
24991095	Stem paddle 9.5mm	1
24991018	Head paddle 18mm	1
24991020	Head paddle 20mm	1
24991022	Head paddle 22mm	1
24991024	Head paddle 24mm	1
24991026	Head paddle 26mm	1
24991028	Head paddle 28mm	1
24981013	Locker replacement lid	0

The **Evolve** family of radial head products

Evolve Proline System
18 head sizes and 18 stem sizes
2499KIT1/A

Evolve Locker
for use with Evolve Proline System or Evolve System
2499KIT2



Evolve Proline Plus
Radial Head System
4955KIT1/A/B

KIT/A is the sterile packed radial head implants. KIT/B has the non-sterile packed plates and screws, in the tray.

Radial head plate

Radial neck plate

Evolve Triad
Fixation System
4951KIT1/A

Includes radial head instruments. Radial head implants are sterile packaged in 2499KITA.

Evolve EPS
Elbow Plating System
4954KIT1/A

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for cleaning and sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

The instructions for use, operative techniques, cleaning instructions, patient information leaflets and other associated labeling may be requested online at ifu.wright.com or wright.com. If saving the instructions for use, operative techniques, cleaning instructions from the above mentioned websites, please make sure you always have the most up to date version prior to use.

Content ID: AP-013241C_11-2021

Manufactured by:

Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117

161 Rue Lavoisier
38330 Montbonnot Saint Martin
France

stryker.com