EndoRelease™

ENDOSCOPIC CUBITAL TUNNEL RELEASE SYSTEM

SURGICAL TECHNIQUE

UPPER EXTREMITY SOLUTIONS

INTEGRA™
Extremity Reconstruction

EndoRelease™

ENDOSCOPIC CUBITAL TUNNEL RELEASE SYSTEM

Description:

The EndoRelease™ Endoscopic Cubital Tunnel Release System provides specialized instrumentation for performing minimally invasive decompression of the ulnar nerve. The system consists of a disposable Blade, a double slotted Cannula, Obturator, and Spatula and is designed to aid in precision cutting while reducing the risk of damaging the ulnar nerve and surrounding soft tissue.

System Benefits:

- Safe and Reliable Technique[1] – an endoscopic procedure with a specialized Cannula design allowing for constant visualization and protection of the ulnar nerve during decompression
- Rapid Patient Recovery[2] – minimally invasive system results in less patient scarring and postoperative pain
- Safe and Fast – efficient surgical technique through system designed specifically for cubital tunnel release

System Features:

- Double slotted Cannula with flat undersurface to ensure constant visibility of ulnar nerve during the decompression
- Retractor built into Cannula to hold superficial nerves out of harms way
- Disposable precision Blade slides through Cannula slot while dividing fascia surrounding nerve
- Additional instruments included to ensure efficient and reliable procedure

1. Tsai TM, Chen IC, Majd ME, Lim BH. : Cubital tunnel release with endoscopic assistance: results of a new technique. J Hand Surg [Am]. 1999 Jan;24(1):21-9.

2. Cobb TK, Lemke J, Tyler J, Sterbank, P: Complications and Failures in Endoscopic Cubital Tunnel Release: AAOS 2008 San Francisco, CA.

Surgical Technique

THIS TECHNIQUE HAS BEEN DEVELOPED BY TYSON COBB, M.D.

As the manufacturer of this device, Integra does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate techniques in each patient.

Caution: Federal law restricts this device to sale by or on the order of a physician or practitioner.

Indications:

The EndoRelease™ Endoscopic Cubital Tunnel Release System is intended for use in the endoscopic surgical treatment of cubital tunnel syndrome by releasing the fascia around the ulnar nerve.

Contraindications:

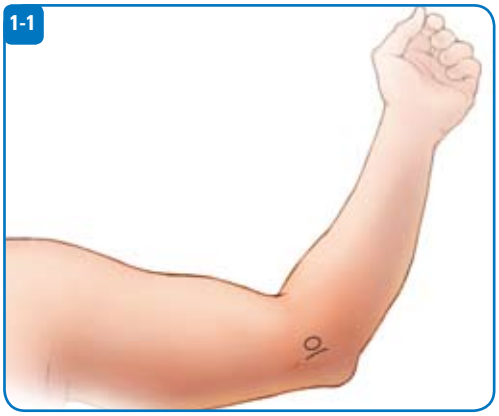
- Repeat cubital tunnel release
- Distortion of anatomy
- Previous soft tissue injury at the surgical site

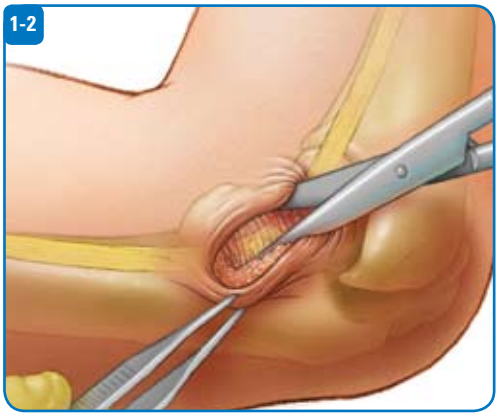
See Package Insert for full prescribing information

Step 1 • Surgical Approach

1-1 Patient is placed supine on the operating table with the operative extremity placed on a hand table. Elevate the arm sufficiently to enhance access to the cubital tunnel. Identify and mark the medial epicondyle. Mark out an approximate 2cm incision over the cubital tunnel, posterior to the medial epicondyle (Figure 1-1). Make an incision just through the dermis, placing the incision in the skin crease to minimize the scar.

1-2 Use scissors and forceps to dissect down to the deep fascia and medial epicondyle (Figure 1-2). Protect any superficial nerves you encounter.



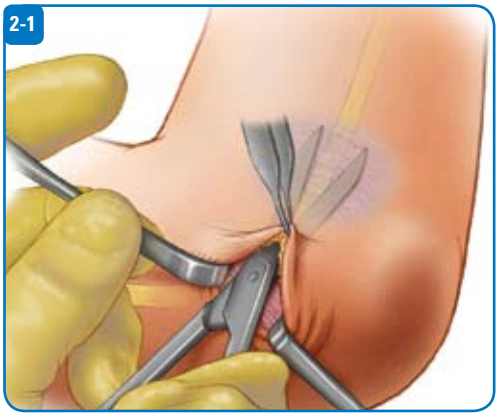


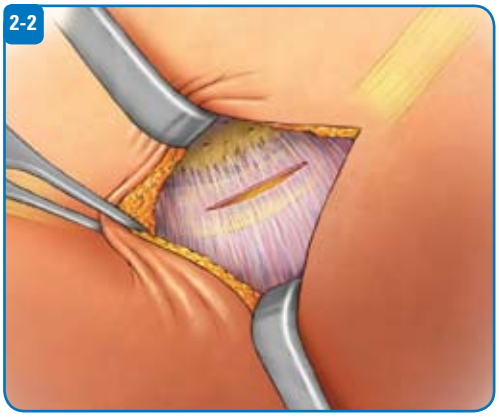
Step 2 • Expose Cubital Tunnel

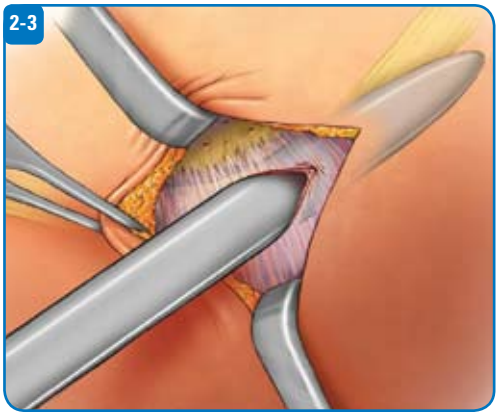
2-1 Use scissors to elevate the subcutaneous tissue and create space between the deep fascia and the subcutaneous tissue/nerves proximally and distally. Retract the skin using standard retractors (Figure 2-1).

2-2 Use the medial epicondyle for orientation and palpate the cubital tunnel and ulnar nerve. Lift the roof of the cubital tunnel with forceps and open the tunnel with a 15-blade. Identify and protect the ulnar nerve (Figure 2-2).

2-3 Use scissors to open the cubital tunnel several centimeters. The Spatula may be used to facilitate access to the cubital tunnel and assist separating the ulnar nerve from the roof of the cubital tunnel (Figure 2-3). Care should be taken to stay superficial to the nerve. The cubital tunnel must be opened sufficiently to allow atraumatic placement of the Cannula along the course of the ulnar nerve.







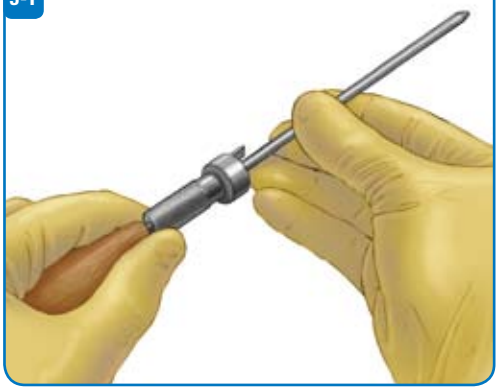
Step 3 • Proximal Cannula Insertion

3-1 Connect the Obturator to the Obturator Handle (Figure 3-1) and insert into the Cannula, engaging the flange on the Obturator into the Cannula slot.

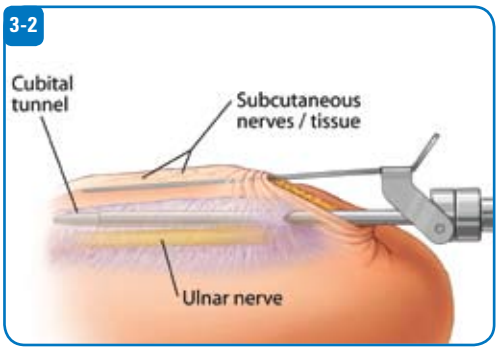
3-2 Lift the skin and subcutaneous tissue and insert the Obturator and Cannula into the cubital tunnel and advance it proximally between the ulnar nerve and the roof of the cubital tunnel. (Figure 3-2). **Do not force the Cannula into the cubital tunnel.**

Simultaneously, as the Cannula is placed in the cubital tunnel, the retractor is advanced superficial to the deep fascia and deep to the subcutaneous nerves/tissues. Remove the Obturator with Handle.

3-1



3-2



Step 4 • Endoscopic Visualization - Proximally

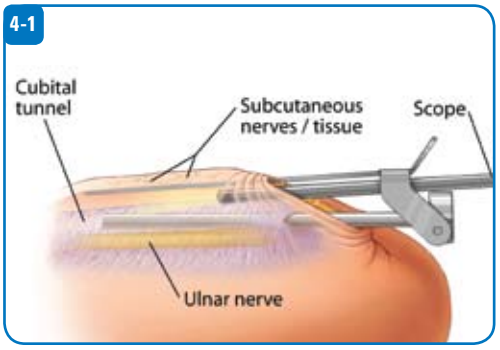
4-1 Insert the endoscope between the Cannula and retractor (Figure 4-1).

4-2 Use the endoscope to confirm that no superficial nerves are in harms way (Figure 4-2).

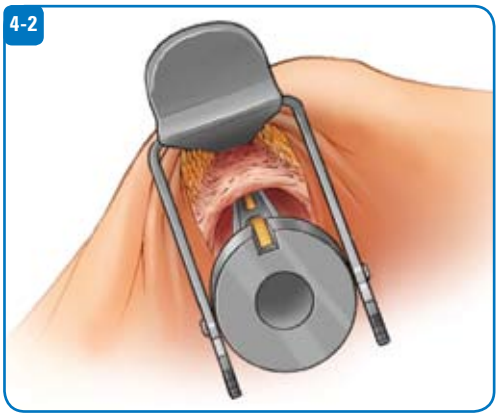
4-3 Insert the endoscope into the Cannula (Figure 4-3a). Look through the series of slots at the inferior surface of the Cannula to confirm that the ulnar nerve is located directly beneath the Cannula (Figure 4-3b). The Cannula may need to be rotated slightly to capture the nerve beneath the flat surface of the Cannula. Use the endoscope to visualize the fascia stretched above the Cannula.

If the nerve is not clearly identified, pull the endoscope back to the open portion of the exposure and identify the nerve with a probe visually through the open incision and then through the endoscope. Then, trace the nerve proximally with the endoscope. **Make sure the nerve is under the Cannula throughout the entire length of the Cannula.**

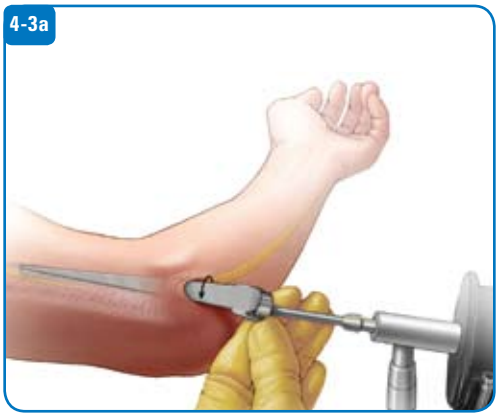
4-1



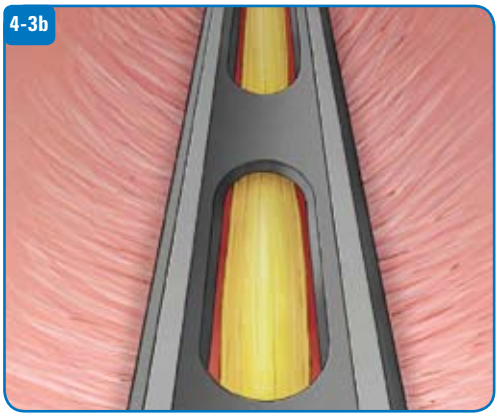
4-2



4-3a



4-3b

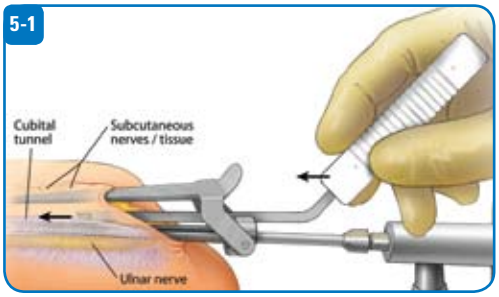


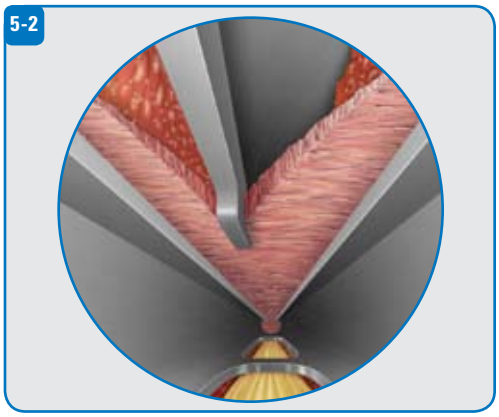
Step 5 • Incision of the Fascia - Proximally

5-1 Insert the Blade into the slot on the Cannula (Figure 5-1).

5-2 Use the endoscope to visualize the fascia and the Blade. Divide the fascia above by carefully advancing the Blade proximally under direct endoscopic visualization (Figure 5-2). **Under no circumstances should the fascia be divided unless the ulnar nerve is clearly visualized through the slots below the Cannula.**

Remove the Blade and confirm with the endoscope that the fascia is incised along the tunnel and that the nerve is completely released. Remove endoscope and the Cannula.

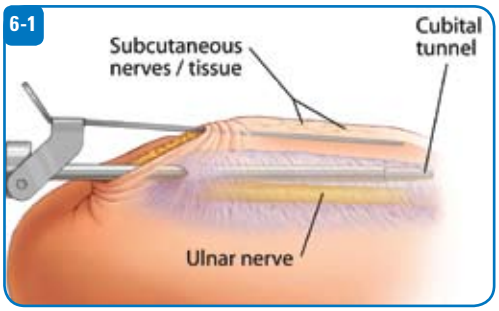




Step 6 • Distal Cannula Insertion

6-1 At the distal portion of the incision, create access to the cubital tunnel and locate the ulnar nerve. The Spatula may be used to create a space between the ulnar nerve and the roof of the cubital tunnel. Care should be taken to stay superficial to the nerve. Insert the Obturator with Handle into the Cannula. Lift the skin and subcutaneous tissue and insert the Cannula and Obturator distally into the cubital tunnel (Figure 6-1). **Do not force the Cannula into the cubital tunnel.**

The retractor is simultaneously advanced external to the cubital tunnel and deep to the subcutaneous nerves/ tissues. Remove the Obturator with Handle.

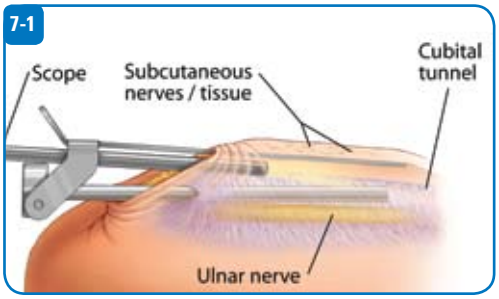


Step 7 • Endoscopic Visualization - Distally

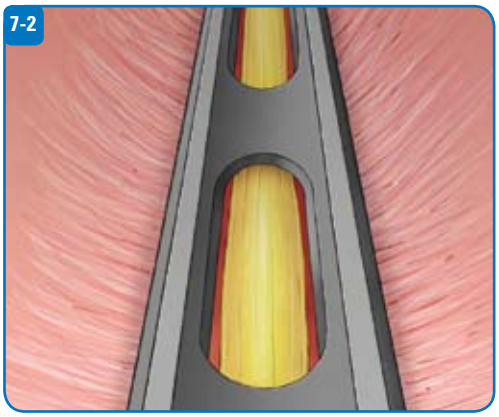
7-1 Insert the endoscope between the Cannula and Retractor to confirm that no superficial nerves are in harms way (Figure 7-1).

7-2 Insert the endoscope into the Cannula. Look through the series of slots at the inferior surface of the Cannula to confirm that the ulnar nerve is located directly beneath the Cannula (Figure 7-2). The Cannula may need to be rotated slightly to capture the nerve beneath the flat surface of the Cannula. Confirm that the ulnar nerve is under the Cannula throughout the entire length of the Cannula. Use the endoscope to visualize the fascia stretched above the Cannula.

7-1



7-2



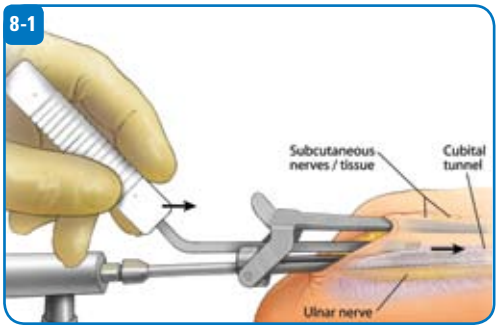
Step 8 • Incision of the Fascia - Distally

8-1 Insert the Blade into the slot on the Cannula (Figure 8-1).

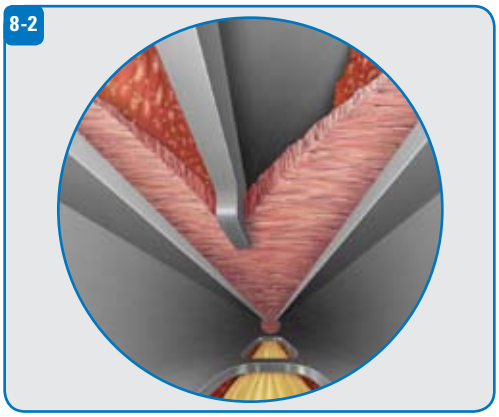
8-2 Use the endoscope to visualize the fascia and the Blade. Divide the fascia above by carefully advancing the Blade distally under direct endoscopic visualization (Figure 8-2). **Under no circumstances should the fascia be divided unless the ulnar nerve is clearly visualized through the slots below the Cannula.**

Remove the Blade and confirm with the endoscope that the fascia is incised along the tunnel and that the nerve is completely released. Remove endoscope and the Cannula.

8-1



8-2



Step 9 • Surgical Closure

9-1 The tourniquet is dropped and hemostasis is accomplished through a short period of compression. If bipolar cautery is necessary, this can be performed with retraction of the skin and subcutaneous tissue and visualization with the endoscope. After obtaining hemostasis, elevate the skin and insert a 20-gauge Angiocath through the skin and into the wound under direct visualization, taking care not to injure the ulnar nerve. Withdraw the needle from the Angiocath (leaving the Angiocath) and tightly close the skin with absorbable subcuticular sutures, followed by Steri-Strips. Tight closure is mandatory due to considerable stress placed on the incision during postoperative range of motion exercises. Following closure, infiltrate (if no contraindications) with 15-20 cc of 0.25% Marcaine with Epinephrine through the Angiocath, which is then removed. Standard soft postoperative dressing is applied with compressive Ace.

Step 10 • Postoperative Care

10-1 The patient is instructed prior to surgery for active and passive range of motion of the elbow with the expectation of having full range of motion on the first postoperative visit in 7-10 days. The patient is instructed to de-bulk the dressing as necessary to allow for full range of motion. Patients are allowed to return to full activity as tolerated, with many patients obtaining full or near full activity by the end of the first week.

EndoRelease System - Full Instrument Tray

1. Obturator Handle
2. Small Cannula (2.7mm Endoscope)
3. Small Locking Obturator
4. Large Cannula (4.0mm Endoscope)
5. Large Locking Obturator
6. 7mm Spatula
7. 5mm Spatula

EndoRelease™

ENDOSCOPIC CUBITAL TUNNEL RELEASE SYSTEM

Instruments

EndoRelease Endoscopic Cubital Tunnel Release System

09-2000	Instrument Tray
09-5160	Small Locking Obturator
09-5250	Large Locking Obturator
21-1700	Obturator Handle
09-5070	5mm Spatula
09-5080	7mm Spatula
09-5090	Small Cannula (2.7mm Endoscope)
09-6020	Large Cannula (4.0mm Endoscope)
ENDORELSTD	EndoRelease System - Standard Instrument Set *

Blades

EndoRelease Endoscopic Cubital Tunnel Release System

09-6000	EndoRelease Blade
09-6005	EndoRelease Blades - 5 Pack

* Standard Instrument Set (not shown) includes Instrument Tray (09-2000), Large Locking Obturator (09-5250), Large Cannula (09-6020), 7mm Spatula (09-5080) and Obturator Handle (21-1700).
All other items must be purchased separately.

09-9006

INTEGRA™
Extremity Reconstruction

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