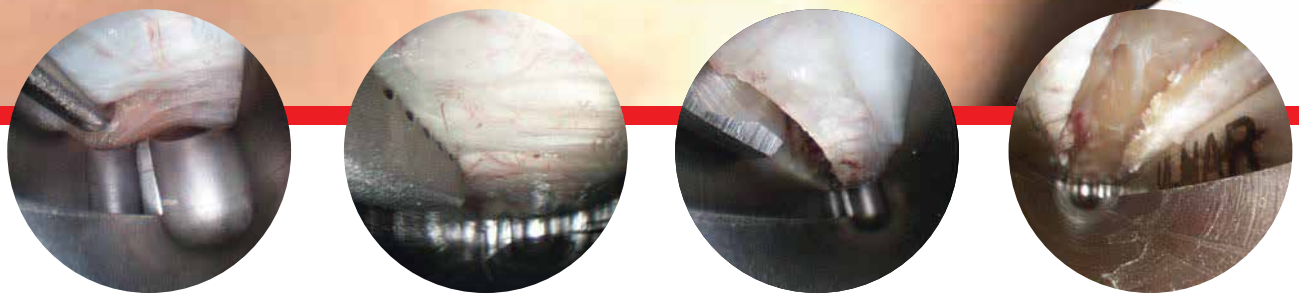
SegWAY
ORTHOPAEDICS, INC.

SURGICAL TECHNIQUE

Synchronized Endoscopic Guide System for Endoscopic Carpal Tunnel Release

ULNAR ZONE GUIDE SYSTEM™
The Safer Approach to E.C.T.R



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SYNCHRONIZED ENDOSCOPIC GUIDE SYSTEM

Minimally Invasive E.C.T.R. System

SegWAY is the first E.C.T.R. system designed to position the blade on the Ulnar side of the transverse carpal ligament. Its uniportal entry gives surgeons a wider endoscopic field of view while making a small and cosmetically appealing incision.

The scope functions independently from the knife, probe and RASP. This gives the surgeon the ability to easily probe and identify uncut fibers under direct endoscopic visualization.

Instrument Overview

A Synovial Dilator/Elevator

B Dilator

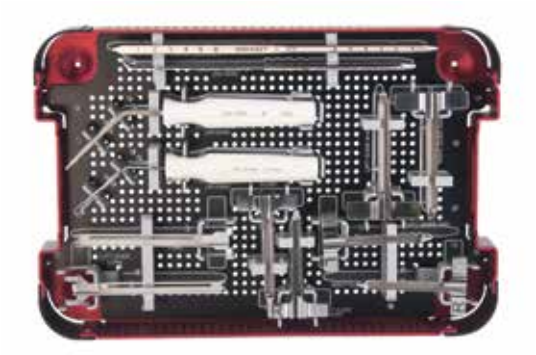
C Ligament Probe

D Ligament Rasp

E Left Guide - Medium and small*

F Right Guide - Medium and small*

G Retrograde Knife (Single Use)**



*Different size SegWAY guides allow the surgeon to use a 2.7mm or 4mm scope.
**Not included in SegWAY instrument tray

Sterile Field Setup

The following instruments are needed for an endoscopic carpal tunnel procedure using the SegWAY Endoscopic Guide System:

- Ragnall retractors
- Scalpel
- 4mm, 30° scope (standard knee scope) or 2.7 mm wrist scope
- Arthroscopic tower (light source, camera, screen, printer)
- Stevens tenotomy scissors
- Hemostat
- Addison forceps

In addition, the following items should be made available for the procedure:

- Cotton swabs
- Anti-fog wipes, for scope
- Marking pen
- Lead hand or rolled towel

Anesthesia Options

In endoscopic carpal tunnel surgery, most surgeons employ Monitored Anesthesia Care (MAC) with addition of local or regional anesthesia to the extremity. Local and regional anesthesia are available in the following forms:

- Local infiltrate
- Regional I.V. bier block
- Proximal median nerve block

In addition to the above anesthesia options, some surgeons prefer to perform the technique under general anesthesia.

Note: When using a local infiltrative anesthetic, the surgeon should avoid injecting into the carpal canal as fluid could impair visualization of the carpal ligament when using the scope.

Operating Room Setup

The operating room should be set up to enable the surgeon to have a clear view of the video monitor and proper access to the patient's hand.

The assistant should also be seated opposite the surgeon and must have a clear view of the monitor as he/she will assist in the operation of the scope.

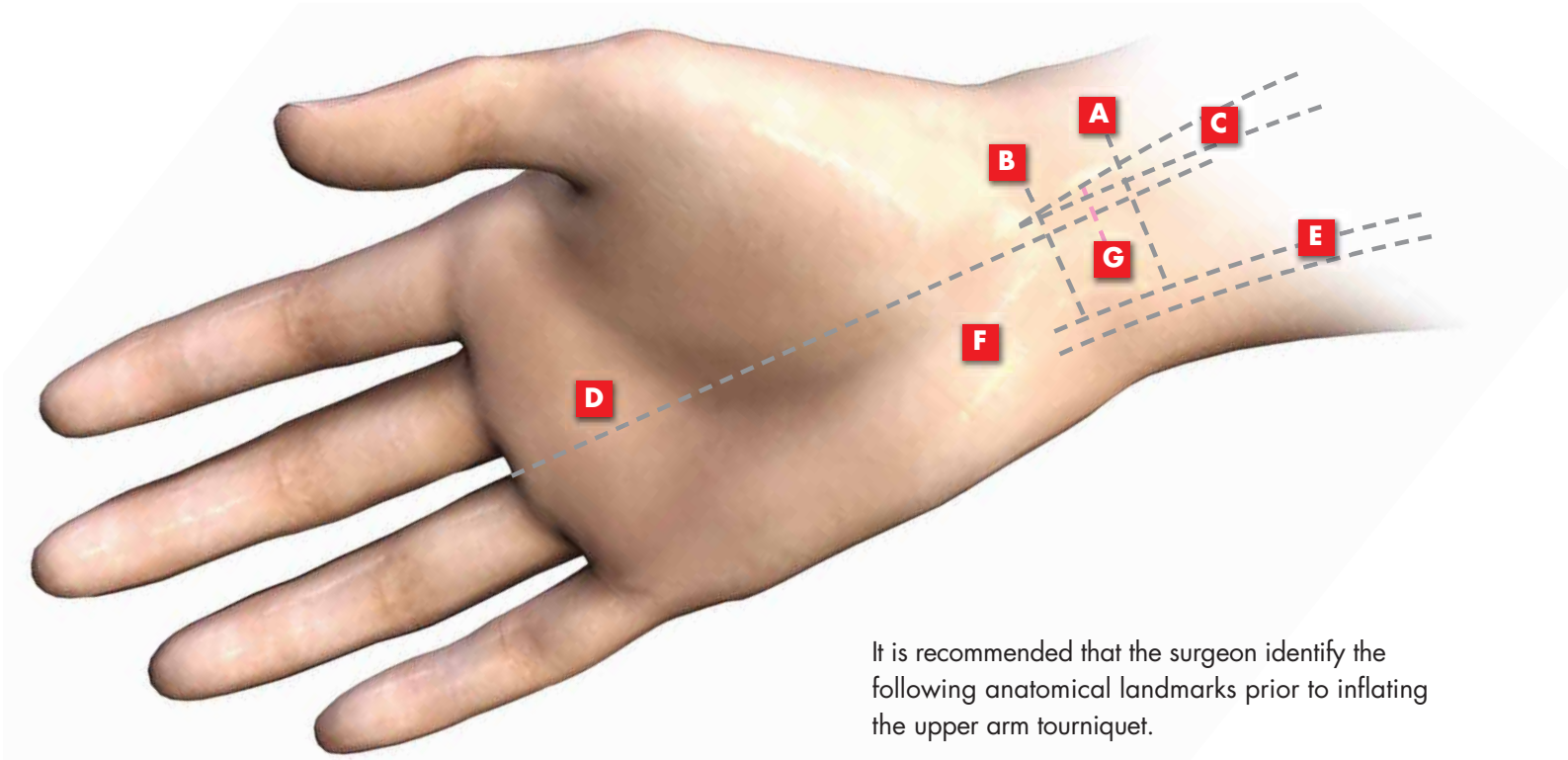
The patient is positioned supine on the operating room table. A hand table is used for the operative arm, which is positioned palm up.

Surgical Preparation

An upper arm tourniquet is recommended as visualization is crucial for a successful procedure. Forearm tourniquets are not recommended as they will obstruct the scope and guide as well as put increased tension on the flexor tendons, crowding the carpal canal.

The Esmarch bandage is used to exsanguinate the upper extremity prior to inflation of the tourniquet. The arm is then prepped and draped in the usual sterile fashion.

Entry Portal Surface Anatomy



It is recommended that the surgeon identify the following anatomical landmarks prior to inflating the upper arm tourniquet.

A Proximal wrist crease

B Distal wrist crease

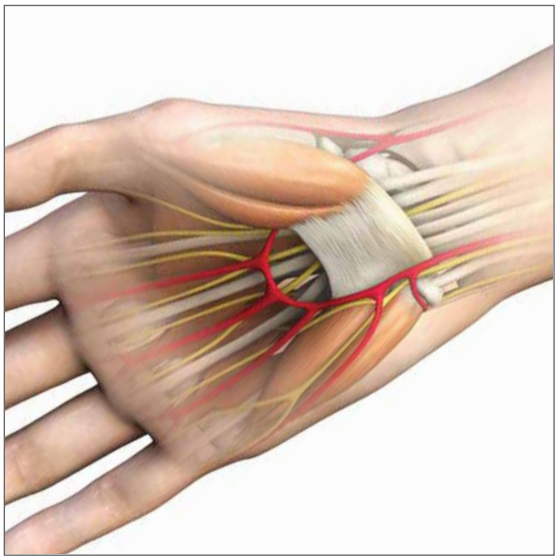
C Palmaris Longus (if present)

D Line from Radial Ring Finger to Wrist Crease

E Flexor Carpi Ulnaris

F Hook of Hamate

G Entry portal
The entry portal is a 1cm transverse line in between the proximal and distal wrist flexion creases centered about the radial aspect of the ring finger line (starting over Palmaris Longus and extending 1cm ulnarward).



1 Portal Creation – To View Carpal Tunnel

Make Incision

- Make a 1cm transverse skin incision on the predetermined entry portal line. *(Figure 1-1)*

Expose Forearm Fascia

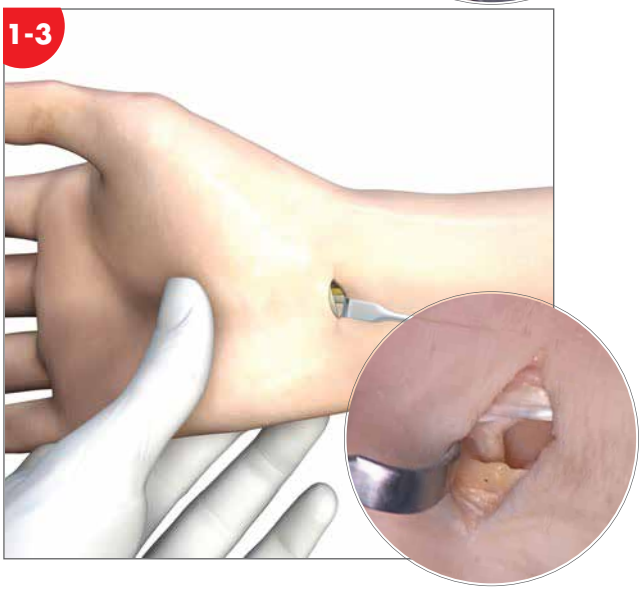
- Expose the distal forearm fascia by dissecting the soft tissue in a longitudinal manner. *(Figure 1-2)*
- Retract Palmaris Longus tendon radially if present.

Note: Dissection through the forearm fascia is critical in order to gain access to the carpal tunnel.

Expose Median Nerve

- Divide the distal forearm fascia transversely to expose the median nerve.
- Retract distal soft tissues to provide clear visualization of the carpal tunnel. *(Figure 1-3)*

Technique Tip: To allow for easier access to the carpal tunnel and to provide added decompression of the median nerve, the surgeon can: (1) Release the proximal forearm fascia 1cm under direct visualization; Then (2) release the proximal end of the transverse carpal ligament approximately 4mm to 5mm.



2 Create Path for the SegWAY Guide

Insert Synovial Dilator

- Insert 6mm Synovial Dilator into the carpal tunnel. *(Figure 2-1)*

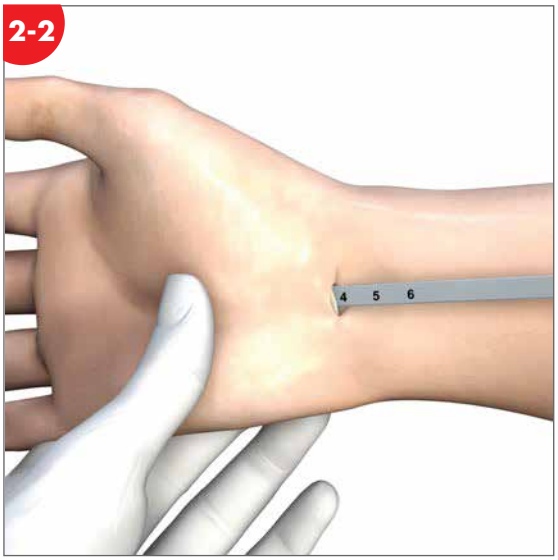
Technique Tip: Aim for the web space between the 3rd and 4th metacarpals while feeling the hook of hamate ulnarly. This will confirm you are in the carpal tunnel not Guyon's canal.

Insert Elevator

- Insert the curved elevator until the tip is easily palpated in the mid palm, just distal to the transverse carpal ligament. *(Figure 2-2)*

Note: Depth of insertion of the elevator is determined by noting the measurement on the instrument (usually between 3cm and 4cm).

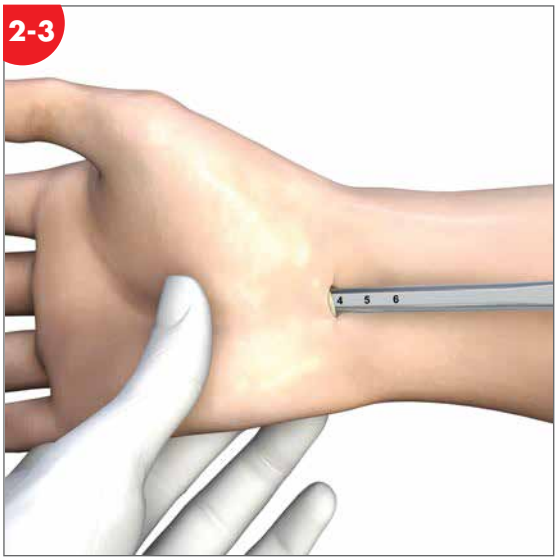
Technique Tip: Move the elevator longitudinally along the bottom of the transverse carpal ligament, feeling the washboard effect. Do this several times to remove the synovium off the undersurface of the ligament.



Insert Dilator

- Further dilate the canal using the 7mm and 8mm dilators to the previously measured depth to create sufficient space to accomodate the SegWAY guide. One pass should be sufficient to open the guide pathway. *(Figure 2-3)*

Note: The 8mm dilator equals the exact size of the 4mm guide.



3 SegWAY Guide Insertion

Choose Appropriate Guide

- Ensure that you have the appropriate guide. there is a right and left guide to match the hand on which you are operating. *(Figure 3-1)*

Note: Depth markings are located on the ulnar side of each guide.

3-1

Insert Guide

- Insert the appropriate guide through the created path in the carpal tunnel, slightly deeper than the previously measured depth during use of the elevator and dilators. *(Figure 3-2)*
- The tip of the guide should be palpated in the palm just distal to the transverse carpal ligament.

Note: The guide should insert easily and smoothly. If there is resistance or the patient experiences pain or parasthesias, repeat the elevation/dilation steps and reposition the guide so that it inserts easily.

Technique Tip: The tip of the guide should pass along the undersurface of the transverse carpal ligament. This will help displace the flexor tendons, median nerve and synovium away from the ligament and help avoid entrapment of these structures. The wrist and fingers should already be placed in extension to help avoid their entrapment as well.

3-2

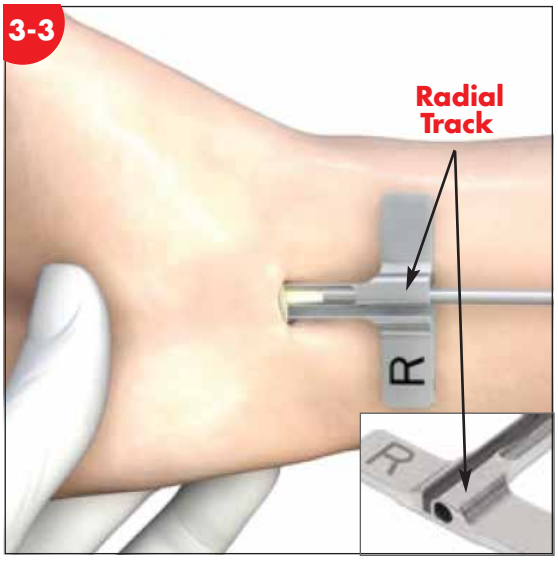
Insert Scope

- Insert scope into the radial track of the guide.
- Rotate the light source as far radial as possible. This provides the best visualization of the undersurface of the transverse carpal ligament. *(Figure 3-3)*

Note: To confirm a clear, unobstructed visualization of the transverse carpal ligament's undersurface, the transverse oriented fibers of the ligament should be clearly visualized as well as the fat pad distal to the ligament. If there is any interposed tissue such as median nerve or flexor tendon, the guide must be removed and reinserted until the field of vision is clear. If the field cannot be cleared after three attempts at insertion, it is generally recommended to convert to an open release.

Note: It is sometimes necessary to use an antifog agent on the lens of the arthroscope to achieve optimal visualization.

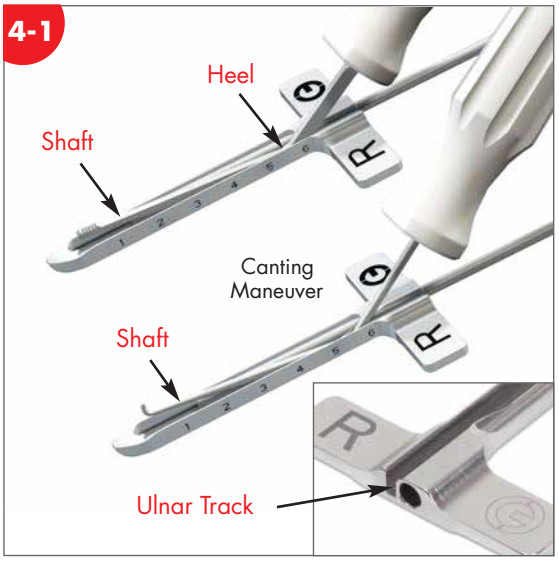
3-3



4 Preparation for Release

Instrument Placement

- When inserting the instruments into the ulnar track of the guide, the shaft of the instrument should be in full contact with the guide. They are maneuvered by canting the tip of the instrument and then sliding it while the heel remains in contact with the guide. *(Figure 4-1)*



Insert Probe

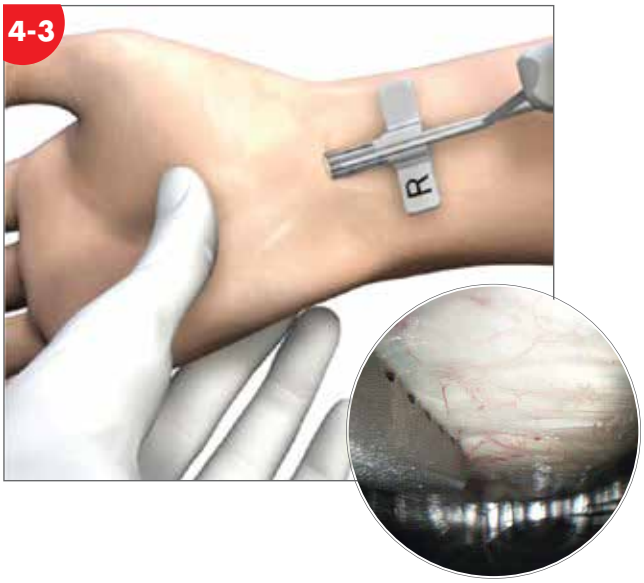
- Insert the probe in the ulnar track to the distal end of the ligament.
- Cantilever the instrument to allow the tip of the probe to hook the distal end of the ligament. Lightly pull in the proximal direction to verify the distal end of the ligament. *(Figure 4-2)*

Technique Tip: The probe can be used to palpate the undersurface of the ligament and dissect through the synovial membrane layer.

Insert Rasp

- Insert the rasp in a similar manner to the probe. Use it to clear the remaining synovial tissue from the undersurface of the ligament for better visualization of the release area. *(Figure 4-3)*

Technique Tip: Throughout the procedure, sterile cotton swabs may be used to sweep away remaining soft tissue or absorb fluid that may be obstructing the field of view.

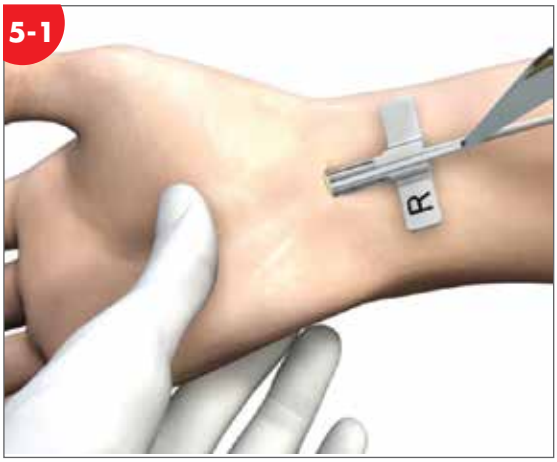


5 Carpal Tunnel Release

Insert SegWAY Retrograde Knife

- Insert the SegWAY retrograde knife (packaged separately) in the ulnar track of the guide. *(Figure 5-1)*
- Insert the SegWAY retrograde knife to the distal edge of the ligament previously delineated by the probe.

5-1



Release Transverse Carpal Ligament with SegWAY Retrograde Knife

- Cantilever the SegWAY retrograde knife to allow the tip of the knife to hook onto the distal edge of the ligament.
- Keep the heel of the SegWAY retrograde knife against the guide and pull the knife in the proximal direction to incise the ligament.
- Move the scope with the SegWAY retrograde knife to maintain constant visualization of the tip of the knife while cutting the ligament. *(Figure 5-2)*

5-2

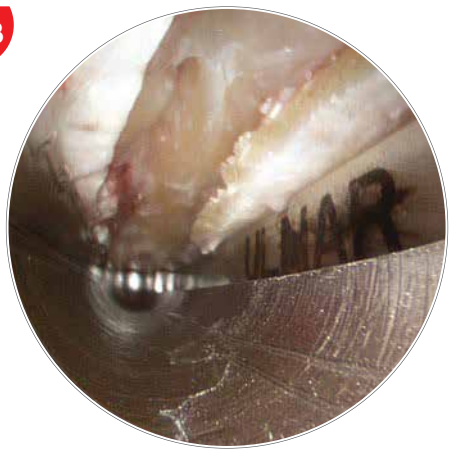
Note: Several passes with the SegWAY retrograde knife may be required depending on the thickness of the ligament.

Technique Tip: A 2mm proximal edge of the ligament may be left intact for a later release after guide removal. This can help protect the patient's skin from getting cut during removal of the SegWAY retrograde knife.

Confirm Release with Probe

- Insert the probe into the ulnar track of the guide to check for uncut fibers. *(Figure 5-3)*
- Once release is complete, remove the scope and guide.

5-3



Note: If uncut fibers are identified, reinsert the SegWAY blade to cut remaining fibers.

Technique Tip: There should be parallel separation of the cut edges of the ligament, interceding fat from the palm and a loss of tension on the guide.

Technique Tip: Insert the scope without the guide. By dimming the overhead lights in the OR, the scope light should now be easily visible underneath the skin and can be used to confirm release of the ligament.

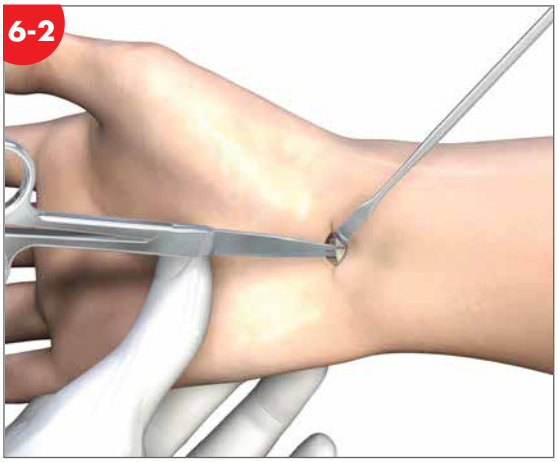
6 Completing the Procedure

Proximal Edge of the Transverse Carpal Release

- Under direct visualization, the remaining 2mm proximal edge of the transverse carpal ligament can be sectioned using a Stevens tenotomy scissor. *(Figure 6-1)*

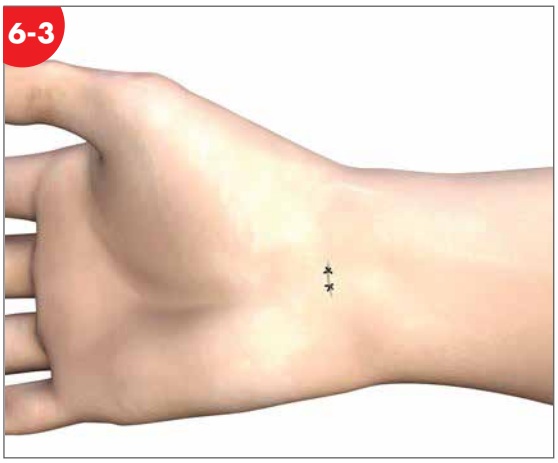
Forearm Fascia Release

- If the forearm fascia release was not completed at the beginning of the procedure, the surgeon may choose to perform a 1 cm release at this time. This provides added decompression of the median nerve. *(Figure 6-2)*



Closure

- Using a small bulb or 10cc syringe, irrigate the wound and carpal canal with sterile saline.
- Wound closure should be skin only, with surgeon choosing the suture material and method of their choice (interrupted or subcuticular type closure). *(Figure 6-3)*
- Apply a small, soft dressing to cover the wound. Splinting is neither necessary or desirable.
- Allow for thumb movement when a soft dressing is applied to the hand and wrist.



Postoperative Care

The postoperative care is as usual, allowing the patient full finger range of motion the next day with use of the hand for activities as tolerated. Allow at least four weeks before heavy work or other strenuous activity. Assuming no pain, the patient can perform functional activities as tolerated.

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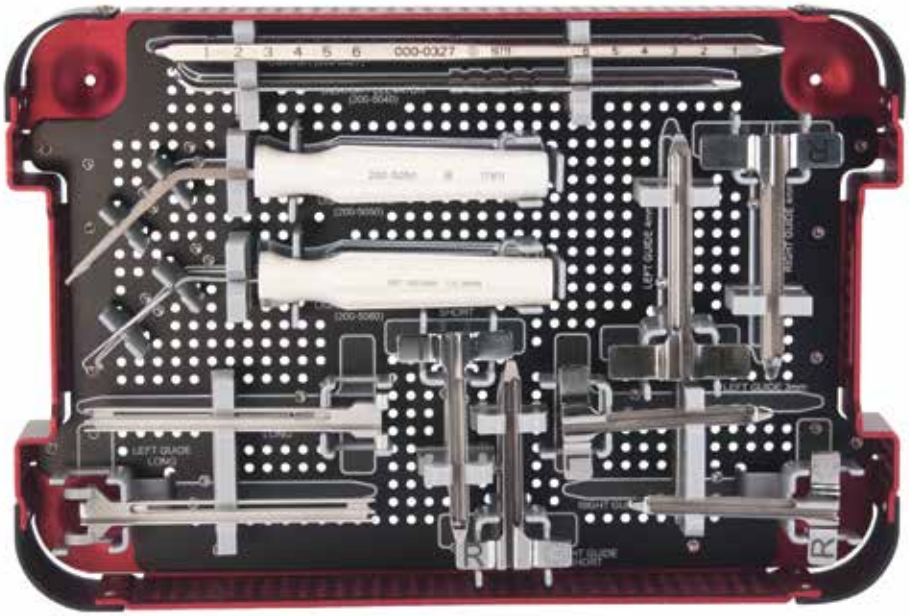
PRODUCT LINE INFORMATION

Description	Part #
SegWAY Instrument Set (Complete Set)	200-5560
Left Large SS Knife Guide (4mm)	200-5012
Right Large SS Knife Guide (4mm)	200-5022
Left Small SS Knife Guide (2.7mm)	200-5014
Right Small SS Knife Guide (2.7mm)	200-5024
Synovial Dilator / Elevator	200-5040
Rasp, Ligament	200-5050
Probe, Ligament	200-5060
Dilator	000-0327
Retrograde Ligament Knife (SINGLE USE)	200-1003



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