Integra™
SafeGuard® Mini Carpal Tunnel Release System
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Surgical Technique

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 for using the device in each patient.

Description

A two-component system that simplifies the “Mini Open” surgical technique while providing a high-level of control and median nerve protection.

The SafeGuard System

Simple
• Instrumentation - protective guide and knife.
• SafeGuard Knife provides high level of control.

Safe
• Direct visualization of median nerve.
• Defines the “Safe Zone” for carpal tunnel release.

Cost Effective
• Eliminates the need and cost for endoscopic equipment.
• Reduces O.R. set-up and time.

Indications

The SafeGuard Mini Carpal Tunnel Release System is used for the treatment of carpal tunnel syndrome in patients who fail to respond to conservative treatment.

Contraindications

• Repeat carpal tunnel release
• Distortion of anatomy
• Neurologic defects
• Previous soft tissue injury at the surgical site

Precautions

Surgeons using this device should be familiar with the recommended surgical technique and the required surgical instrumentation.

Packaging and Sterility

• Each knife is provided sterile in packaging and is a single-use, disposable product.
• The guide is non-sterile and must be removed from packaging and autoclaved prior to surgery.
Step 1 • General Recommendations

1-1 If local anesthesia is elected, 10 cc of anesthetic mixture (5 cc of 1% lidocaine without epinephrine plus 5 cc of .25% Marcaine® without epinephrine) are injected into the midline of the proximal palm to the proximal flexion wrist crease.

1-2 Anesthesia should infiltrate both the carpal tunnel and subcutaneous tissues, taking care not to injure the median nerve.

Step 2 • Pre-Operative Planning

2-1 Draw a line across the palm from the proximal-most extent of the first web space toward the hook of the hamate (Kaplan’s line).

2-2 Draw a second line longitudinally from the radial border of the ring finger proximally.

2-3 The junction of these lines represents the center of the incision. Draw a 1.5-2 cm line through this junction to mark the incision. It should stop about 2 cm distal to the wrist flexion crease (slightly ulnar to the thenar crease).

Step 3 • Incising Skin And Palmar Aponeurosis

3-1 After tourniquet exsanguination of the upper extremity, use a #15 blade to incise the palmar skin, coursing through skin and subcutaneous fatty tissue exposing the palmar aponeurosis.

3-2 Spread the palmar aponeurosis exposing the transverse carpal ligament at its distal portion. Care should be taken not to damage the vascular arch.

3-3 Use either a self-retaining retractor or two Senn retractors transversely and one Ragnell retractor proximally, to expose and identify the distal portion of the transverse carpal ligament.
Step 4 • Incising Distal Portion of Transversal Carpal Ligament

4-1 Under direct visualization, divide the transverse carpal ligament longitudinally as far proximally as possible with dissecting scissors taking care to avoid injury to the carpal tunnel contents.

Step 5 • Aligning Cutting Guide

5-1 Pass either the large or small end of the Knife Guide proximally underneath the remaining portion of the transverse carpal ligament.

5-2 The curved tip of the guide should pass proximally and always be in contact with the undersurface of the transverse carpal ligament until it reaches beyond the proximal extent of the ligament itself. Keep the guide as ulnar in the carpal tunnel as possible and avoid pointing it radially.

Step 6 • Cutting Knife Alignment

6-1 After ensuring an appropriate passage of the guide, (without tissues between the ligament and the guide itself) hold the guide closely against the transverse carpal ligament. Place the carpal tunnel knife into the dedicated guide’s knife groove.
Step 7 • Complete Release

7-1 Advance the knife along the groove proximally to complete the release of the transverse carpal ligament. The knife should not advance past the end of the groove on the guide.

Step 8 • Ensuring Complete Release

8-1 After the knife has been retracted, use the guide to probe the transverse carpal ligament to ensure complete release.
Step 9 • Closure

After the wound is irrigated, the tourniquet is released and hemostasis is achieved. Close the wound with nonabsorbable suture and apply a soft sterile dressing that permits full motion of the digits.

Postoperative Care

Patients are encouraged to perform range of motion exercises postoperatively, although heavy lifting should be avoided.

Sutures are generally removed in 7-14 days at which time patients are counseled in the progressive use of their hand over the ensuing weeks.
Features

Simple
- Simple instrumentation—protective guide and knife.
- Integra SafeGuard Knife provides high level of control.

Safe
- Direct visualization of median nerve.
- Defines the “Safe Zone” for carpal tunnel release.

Cost Effective
- Eliminates the need and cost for endoscopic equipment.
- Reduces O.R. set-up and time.

Integra™ SafeGuard® Mini Carpal Tunnel Release System

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>GUIDE</td>
<td>Integra™ SafeGuard® Guide</td>
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<td>08-0001</td>
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<table>
<thead>
<tr>
<th>CUTTING KNIFE</th>
<th>Integra™ SafeGuard® Knife</th>
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<tbody>
<tr>
<td>08-0003</td>
<td>Integra™ SafeGuard® Knives (set of 5)</td>
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Component Materials

<table>
<thead>
<tr>
<th>GUIDE</th>
<th>316L Stainless Steel as per ASTM A276</th>
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<tbody>
<tr>
<td>KNIFE</td>
<td>HANDLE: Polyethylene PE955l</td>
</tr>
<tr>
<td></td>
<td>BLADE: Stainless Steel (modified AISI.SAE 51440 A)</td>
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Instrument Set

For more information or to place an order, please contact:
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877-444-1122 USA • 609-936-5400 outside USA • 866-800-7742 fax
integralife.com