

## Instructions for Use

Dev4 SurePass™ CTR

## Description

The Dev4 SurePass™ CTR System is provided as a sterile single use kit in one configuration. Each kit contains a sterile SurePass™ CTR guide, and CTR knife blade.

## Intended Use

The Dev4 SurePass™ CTR is intended for use in minimally invasive ligament or fascia release.

## Indications for Use

The Dev4 SurePass™ CTR is indicated for:

- Carpal Tunnel release in the wrist

## Contraindications

- Active infection
- Abnormalities of the wrist or carpal tunnel that may affect anatomy
- Conditions that limit the patient's ability or willingness to follow postoperative instructions

## Instructions for Use

- Infiltrate 10 cc of anesthesia mixture (5cc of 1% lidocaine without epinephrine plus 5 cc of .25% Marcaine without epinephrine) by injecting into the middle of the proximal palm to the proximal distal wrist crease.
- Anesthesia should infiltrate both the carpal tunnel and subsequent tissues, taking care not to injure the median nerve.
- Position the hand on a sterile rolled towel allowing a natural wrist extension.
- The distal edge of the transverse carpal ligament is estimated by measuring and marking a point at 4.5 cm from the distal wrist crease along the longitudinal trajectory line from the third web space. This point coincides with the junction of the longitudinal and Kaplan's lines. A 2 cm incision line is drawn from this point proximally and slightly ulnar of the thenar crease.
- The extremity is exsanguinated, and the tourniquet inflated.
- Using a #15 blade incise a 2 cm superficial incision through palmar skin. Use two Senn, or a self-retaining retractor, and a Ragnell retractor proximally for incision exposure. Continue to course through subcutaneous fatty tissue exposing Palmar Aponeurosis.
- Incise the palmar aponeurosis to expose the transverse carpal ligament.
- Under direct visualization, begin incising from the most distal edge of the transverse carpal ligament longitudinally and as far proximal as incision allows.
- Introduce the SurePass™ CTR guide curved tip under the transverse carpal ligament, above the median nerve, and ensure there is no soft tissue entrapment.
- Apply downward pressure on the handle of the guide (handle trajectory should be positioned in the third web) and advance the guide proximally, always keeping the distal tip of the guide in contact with the undersurface of the transverse carpal ligament.
- Continue to advance the SurePass™ CTR guide beyond the most proximal edge of the transverse carpal ligament while ensuring that the guide tip is positioned just ulnar to the Palmaris Longus tendon.
- Confirm that the distal tip of the guide is positioned beyond the proximal transverse carpal ligament, can be palpated with your

finger, and is free of any tissues between the transverse carpal ligament.

- Maintain downward CTR guide handle tension creating upward pressure on underside of transverse carpal ligament.
- Engage the carpal tunnel blade within the dedicated groove of the guide.
- Advance the carpal tunnel blade proximally in one smooth motion, dividing the transverse carpal ligament.
- After the carpal tunnel blade has been removed from the surgical field, use the guide in an upward sweeping motion to probe any remaining undivided transverse carpal ligament fibers.
- Close the surgical incision in a standard manner with a non-absorbable suture and apply a soft sterile dressing that allows the fingers and thumb an active range of motion while in a splint.
- Patients can remove their dressing in 3-4 days and allow the wound/sutures covered by a band-aid strip. Sutures are removed in 7-14 days at which time patients are counseled on post operative progress by their physician.

## Warnings




- SurePass™ CTR is a sterile single use kit. Do not reuse.
- Do not sterilize or cold soak devices for reuse.
- Do not expose to excessive heat.
- Knowledge of surgical techniques is extremely important.
- Pre- and intra-operative planning are always suggested.
- Patients should strictly follow post operative instructions.
- SurePass™ CTR has not been evaluated for safety and compatibility in the MRI environment.
- SurePass™ CTR is designed for single use only and must never be reprocessed for additional use. Risks of reuse or reprocessing include contamination and mechanical failure of components.










## Packaging and Sterility

- The kit supplied is sterile. Method of sterilization is Gamma irradiation.
- The kit is intended for single (one time) use only.
- Do not use the kit if the packaging has been previously opened or damaged.

## Material Specifications

- SurePass™ CTR guide, 17-4 S.S. and ABS
- SurePass™ CTR blade, 420 S.S. and ABS

	Catalog number
	Batch code
	Consult electronic instructions for use at <a href="http://www.dev-4.com">www.dev-4.com</a>

	Caution
	Sterilized using irradiation
	Unique device identifier
	Manufacturer
	Prescription Use Only
	Do not use if package is damaged and consult instructions for use
	Do not re-use
	Single sterile barrier system
	Use by date