SurePass™ CTR NS

Carpal Tunnel Release

Instructions for Use

Dev4 Sure**Pass**™ CTR NS

Description

The Dev4 Sure**Pass**™ CTR NS System is provided as a non-sterile kit in two configurations. One kit contains 1 non-sterile Sure**Pass**™ CTR NS guide. Another kit contains 10 non-sterile Sure**Pass**™ CTR NS knife blades.

Intended Use

The Dev4 Sure**Pass**™ CTR NS is intended for use in minimally invasive ligament or fascia release.

Indications for Use

The Dev4 Sure**Pass**™ CTR NS 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 palmer 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 Sure**Pass**™ CTR NS 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 Sure**Pass**™ CTR NS 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 NS 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 to get wet during showers only, thereafter, keeping 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

- Sure**Pass**™ CTR NS is a non-sterile kit.
- Knowledge of surgical techniques is extremely important.
- Pre- and intra-operative planning are always suggested.
- Patients should strictly follow post operative instructions.
- Sure**Pass**™ CTR NS has not been evaluated for safety and compatibility in the MRI environment.

Cleaning and Decontamination

1. Removal of gross contaminants should be accomplished by manually submerging items in water or mechanically, or by a combination of both methods. Either method should be effective, should not impede functionality of the device and be safe for employee performing the task.
2. Scrub the parts with a brush to remove visible contaminants.
3. Instruments should be submerged in a detergent solution or the combination of detergent and enzymatic solution. Any solution or detergent should be easily removable from the medical device by rinsing with water so that the device does not retain residual chemicals that could harm patient or damage device.
4. Following cleaning, instruments should be thoroughly rinsed using quality water that does not contribute to staining.

Packaging and Sterility

- The kit supplied is non-sterile.
- The devices are intended to be sterilized by steam sterilization only.

Sterilization Cycle Parameters

- Sterilization Type: Gravity
  - 30 minutes at 121˚C or 250˚F; 25 minute dry time
- Sterilization Type: Prevacuum
  - 4 minutes at 132˚C or 270˚F; 20 minute dry time

Material Specifications

- Sure**Pass**™ CTR NS guide, 17-4 S.S.
- Sure**Pass**™ CTR NS blade, 420 S.S.

SurePass™ CTR NS

Carpal Tunnel Release

REF Catalog number

LOT Batch code

Consult electronic instructions for use at www.dev-4.com

Caution

Non-sterile

UDI Unique device identifier

Manufacturer

Rx ONLY Prescription Use Only

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