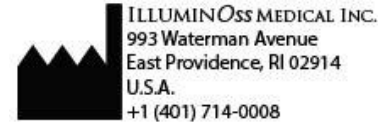




CT-0200-01, CT-0205-01, CT-0243-01
CT-0307, CT-0308, CT-0309, CT-0310, CT-0311, CT-0312, CT-0313
CT-0314, CT-0315, CT-0316, CT-0317, CT-0318, CT-0329



Device Description

Single use, sterile pouched stainless steel ball tipped guidewires (CT-0200-01, CT-0205-01, CT-0243-01).

Single use, sterile pouched stainless steel trocar tipped guidewires (CT-0307, CT-0308, CT-0309, CT-0310, CT-0311)

Single use, sterile pouched stainless steel cannulated drill bits (CT-0312, CT-0313, CT-0314, CT-0315, CT-0316, CT-0317, CT-0318)

Single use, sterile pouched stainless steel deep tissue scorer and low-profile stabilizer (CT-0329)

Contents

CT-0200-01, CT-0205-01, CT-0243-01:

- (1) Single use disposable ball tipped guidewires per pouch.
- (5) Pouches per box.

CT-0307, CT-0308, CT-0309, CT-0310, CT-0311:

- (1) Single use disposable trocar tipped guidewire per pouch.
- (1) Pouch per box.

CT-0312, CT-0313, CT-0314, CT-0315, CT-0316, CT-0317, CT-0318:

- (1) Single use disposable cannulated drill bit per pouch.
- (1) Pouch per box.

CT-0329:

- (1) Single use disposable deep tissue scorer and
- (1) Single use disposable low-profile stabilizer per pouch.
- (1) Pouch per box.



For Full Indications, Warnings, Cautions, Risks, Contraindications, and complete procedure instructions, refer to the Photodynamic Bone Stabilization System Instructions for Use (PN 900365) provided at this web address: www.illuminoss.com

- These are single use devices provided sterile by ethylene oxide (EO) sterilization.
- Please report any serious incident that has occurred in relation to the device to the manufacturer (via www.illuminoss.com)

Warnings



Do not re-use or attempt to re-sterilize disposable components, doing so may result in injury or death.



Discard and do not use opened or damaged packages.



 Do not utilize any components after the expiration date.

Precautions

- Read instructions prior to use.
- Prior to using the IlluminOss product, surgeons should go through specific training and experience, be thoroughly familiar with the properties, handling characteristics, and application of the product.

Instructions For Use

Refer to the IlluminOss Medical IFU and Surgical Technique Guides for the Photodynamic Bone Stabilization System for additional information (www.illuminoss.com).

Using Trocar Tipped Guidewires and Cannulated Drill Bits

1. Select desired sizes of trocar tipped guidewire and cannulated drill bit.
2. Insert and secure guidewire into a cannulated power drill. Drill trocar tipped end of guidewire into bone safely using image guidance if necessary. Use of drill guide and tissue protector is recommended.
3. Leave guidewire in bone and remove power drill from guidewire.
4. Attach and secure the cannulated drill bit to the power drill.
5. Insert the proximal end of the guidewire previously inserted in bone into the cannulation of the drill bit and advance the drill bit over the guidewire to the bone.
6. Safely drill the cannulated drill bit the desired distance into bone. Image guidance may be necessary. Use of drill guide and tissue protector is recommended.
7. Remove the cannulated drill bit and guidewire from bone and discard using standard methods for sharps and biohazard waste.

NOTE: Use of excessive force while drilling may break or bend the guidewire or drill bit.

Using Deep Tissue Scorer and Low-Profile Stabilizer (CT-0329)

1. Attach and secure Scorer tube to Stabilizer Handle (CT-0188)
2. Slide the Scorer tube over the catheter shaft and advance it forward to contact the proximal end of the implant.
3. Rotate the handle knob back and forth several times while applying moderate pressure to the Scorer tube to score the end of the PET balloon. Remove the Scorer tube from the catheter shaft.
4. Slide the tube at the distal end of the Low-Profile stabilizer over the catheter shaft and advance it forward to contact the proximal end of the implant.
5. Attach and clamp the tip of the Separator to the exposed catheter. With one hand, hold the stabilizer handle and apply slight forward pressure against the proximal end of the balloon.
6. With the second hand, grasp the sliding “hammer” portion of the Separator instrument. Quickly move the hammer from distal to proximal in one quick full, sharp stroke, separating the catheter from the implant. Remove the stabilizer from the incision.



Using Deep Tissue Scorer with Power Drill for catheter separation (CT-0329)

1. Attach and secure Scorer tube to the chuck of a power drill.
2. Insert and slide the Scorer tube over the catheter shaft and advance it forward to contact the proximal end of the implant.
3. Activate the power drill trigger to rotate the Scorer about 5 sec to score the balloon / catheter junction. With the drill off, angle the DTS in all directions (about 30-45° from the as-cured axis of the flow tube) for about 3 full rotations (about 15-30 seconds). With the drill at an angle (about 30-45°), pull the trigger and apply slight pressure to separate the catheter.
4. Remove the Scorer along with the separated catheter and discard.

NOTE: The IlluminOss instrument, its container and any packaging are not made with natural rubber latex.