

TACTOSET®

INJECTABLE BONE SUBSTITUTE DELIVERY CANNULA

INSTRUCTIONS FOR USE



Sterilized by Ethylene Oxide



Do Not Reuse

Not Made
With Natural
Rubber Latex

DESCRIPTION AND INTENDED USE:

Stainless Steel Outer Cannula, Stylus, Inner Cannulas, and Push Rod with ABS Plastic luer lock connections. The Injectable Bone Substitute Delivery Cannula is a sterile, single-use device, intended for delivery of bone substitute material to a surgical site. Injectable Bone Substitute Delivery Cannulas allow for either end delivery or side delivery of the bone substitute material, depending on the inner cannula used. The surgeon must choose the appropriate delivery direction based on individual patient anatomic and surgical procedure requirements.

WARNINGS AND PRECAUTIONS:

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Inspect the device and packaging carefully for damage; do not use if device or package is damaged.

Single Use Only device. Do not reuse. Do not re-sterilize. Do not use after expiration date.

The surgeon is to be thoroughly familiar with the device and surgical procedure prior to use. Refer to Surgical Technique Guide for effective use of the device or see directions for use at www.anikaifu.com

Use of the device for a technique other than that for which it is intended may result in damaged or broken cannula(s) or patient injury.

Exercise caution when handling the cannula, stylus, and push rod to avoid inadvertent needle sticks. The cannulas, stylus, and push rod are potential biohazards after use; discard used devices in an appropriate biohazard sharps container.

Insert the outer cannula into bone with the stylus fully engaged to avoid damage; use a surgical drill with appropriate attachments.

Avoid excessive or prolonged drilling into bone as it may cause increased temperatures in the cannula and surrounding bone. Before injection, allow the device to cool to body temperature.

Do not bend or exert unnecessary force during insertion to avoid damaging or breaking the cannula.

Do not attempt to redirect the cannula while in bone. Remove the device from the bone and redirect to the desired trajectory through the same opening. Avoid creating additional channels to reduce extravasation.

Always monitor and confirm appropriate placement of cannula using fluoroscopy. Delivery holes must be in bone to avoid extravasation.

Use proper techniques to remove cannula from bone to avoid damage. Remove the inner cannula and fully insert the stylus into the outer cannula, then remove device with a surgical drill in reverse.

Not made with natural rubber latex.

Store at room temperature.

MARKETED AND DISTRIBUTED BY:



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