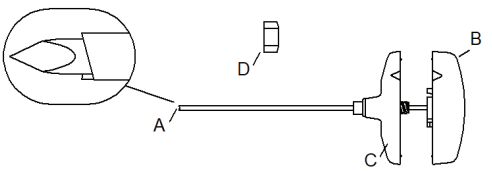
ENGLISH

PRESTON™

Transpedicular Introducer

INSTRUCTIONS FOR USE



PRODUCT DESCRIPTION

The Preston™ Transpedicular Introducer is designed for accessing and traversing vertebral bone. The access provided allows for a subsequent bone biopsy and/or vertebroplasty cement delivery (supplied separately, see Table #1). The Preston Transpedicular Introducer has the following contents.

A	Cutting (Access) Cannula 11G x 10cm
B	Stylet with Trocar Tip Ø2.4mm x 14cm
C	Cannula Handle (removable)
D	Wing Nut

INDICATIONS FOR USE

Transpedicular bone access needle with the intent to then perform a bone biopsy and/or vertebroplasty cement delivery (supplied separately, see Table #1).

PRECAUTIONS

The device must only be used by a physician trained to carry out biopsies or radiology interventions, or under his/her supervision. The device is supplied in a sterile state and should be considered as such unless the packaging has been opened or is damaged. Do not use if the packaging is damaged. When using equipment from other suppliers, check that their length and diameter are compatible with the components of the device. When in use, only apply pressure with your fingers and ensure that you do not apply excessive axial pressure or bend the elements. Do not use a hammer. After use, this product may pose a potential biological risk. All products of this type must be handled and destroyed in accordance with accepted medical practices, legislation and applicable provisions.

STORAGE

Store in a cool, dry place (below 26° C), away from humidity and direct heat. Do not use after the expiry date.

REUSE PRECAUTION STATEMENT

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

CONTRAINDICATIONS

Contraindicated for use on patients who are receiving heavy anticoagulant therapy or who have a severe bleeding problem. Prior to carrying out the procedure, the medical condition of the patient under anti-coagulant treatment or suffering from haemorrhagic issues must be carefully established.

DIRECTIONS FOR USE

The following is a suggested method for using the device. The approach should be accurately planned using diagnostic imaging and clinically approved techniques.
Disinfect the skin, make a small skin incision, and perform anesthesia until in contact with bone.

FIG. 1 Introduce, rotating counterclockwise, the assembled Cutting Cannula with Handle and Stylet (A+B+C) until vertebral pedicle is reached.
Note 1 : To protect soft tissue, a counterclockwise rotation must be applied during insertion through the soft tissue.

With careful but firm turns, rotate the assembled Cutting Cannula with Handle and Stylet (A+B+C) clockwise until desired position is obtained.
Note 2 : If the insertion process is difficult due to dense bone, the Stylet with Trocar Tip (B) may be removed and replaced with the Merit Preston™ Transpedicular Drill (MV1110 supplied separately, see Table #1).

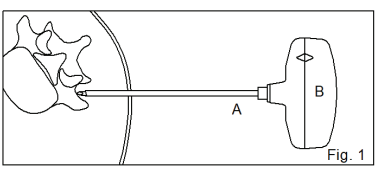


Fig. 1

FIG. 2 Firmly hold the Cutting Cannula with Handle (A+C), unscrew the Stylet with Trocar Tip (B) and remove. The Cutting Cannula and Handle (A+C) is now ready to be used as a fixed pathway for bone biopsy with the Merit Preston™ Bone Biopsy Needle and/or vertebroplasty cement delivery with the Merit Preston™ Bone Filler (CD1110 and/or CR1320 supplied separately, see Table #1).

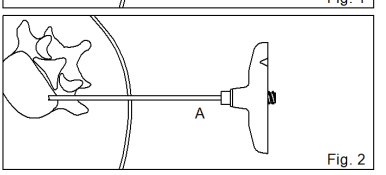


Fig. 2

FIG. 3 If desired, the Cannula Handle (C) may also be removed by placing two fingers under the handle and pressing the luer end of the Cutting Cannula (A) with the thumb.
Note 1: To replace the Stylet (B) back in the Cutting Cannula (A), first replace the Handle (C) on the luer lock end of the Cutting Cannula (A), with regards to the alignment and slots. Then insert the Stylet (B) in the assembled Cannula and Handle (A+C) and screw until it clicks into place.
Note 2: To remove the Cutting Cannula (A) from the bone without replacing the Stylet (B), place back the Handle (C) on the luer lock of the Cutting Cannula (A), with regards to the alignment and slots, and screw the Wing Nut (D) on the luer end to assemble. Then remove the assembled Cutting Cannula and Handle with Wing Nut (A+C+D).

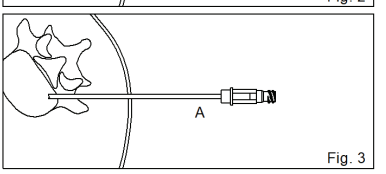


Fig. 3

#1	TV1110
	MV1110
	CD1110
	CR1320

	DO NOT USE A HAMMER
	Single use
	Do not resterilize
	Caution: consult accompanying documents
	Sterilized using ethylene oxide
	Do not use if package is damaged
	For electronic copy scan QR code, or go to www.merit.com/ifu and enter IFU ID number. for printed copy, call U.S.A or E.U. Customer Service
	Temperature limitation
Rx ONLY	Federal (USA) law restricts this device to sale by or on the order of a physician.

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