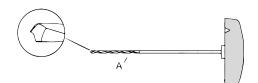


INSTRUCTIONS FOR USE



PRODUCT DESCRIPTION

The Preston™ Transpedicular Drill is designed for use with the Preston™ Transpedicular Introducer for traversing vertebral bone. The Preston Transpedicular Drill has the following contents:



INDICATIONS FOR USE

The Drill is intended for use with the Preston Transpedicular Introducer (TV1110 – supplied separately, see Table #1) for traversing vertebral bone.

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 procedure, patient's medical records should be carefully checked for any history of hemorrhagic activity.

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.

- FIG. 1 Follow the instructions for use for the Preston Transpedicular Introducer (TV1110, supplied separately). If while using the Preston Transpedicular Introducer, traversing the vertebral bone is difficult due to dense bone, the Stylet with Trocar Tip (B) may be removed and replaced with the Merit Preston Transpedicular Drill as follows. Note: The Preston Transpedicular Drill must only be used once the TV1110 is engaged in the bone.
- FIG. 2 Firmly hold the tip of the Cutting Cannula with Handle (TV1110), unscrew the Stylet with Trocar Tip (TV1110) and remove.

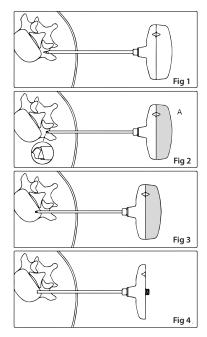
Insert the Drill (A) into the Cutting Cannula (TV1110). Rotate and lock the handle of the Drill (A) to assemble with the handle of the Cutting Cannula (TV1110).

Note: It may be necessary to withdraw the Cutting Cannula (TV1110) by approximately 2mm in order to connect the handles.

- FIG. 3 With careful but firm turns applying finger force only, rotate the assembled Cutting Cannula (TV1110) and Drill (A) clockwise until desired position in reached. During drilling, to maintain penetration efficiency, it is recommended to remove the Drill (A) from time to time and remove any bone debris from the drill grooves.
- FIG. 4 Once the tip of the Drill (A) is close to the lesion or desired position, firmly hold the Cutting Cannula (TV1110) and unscrew the Drill (A).

The Cutting Cannula (TV1110) is now ready to be used as a fixed pathway for bone biopsy using the Preston™ Bone Biopsy Needle (CD1110 supplied separately, see Table #1).

#1	MV1110
	TV1110
	CD1110



\otimes	DO NOT USE A HAMMER
2	Single use
an dema	Do not resterilize
	Caution: consult accompanying documents
STERILEEO	Sterilized using ethylene oxide
	Do not use if package is damaged
i	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
26°C	Temperature limitation
F_XONLY	Federal (USA) law restricts this device to sale by or on the order of a physician.



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403939002_001 ID 2023-12-04