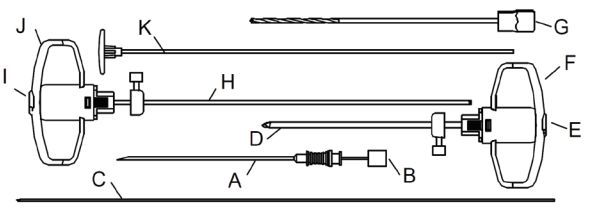
HUNTINGTON™

Guided, Perforating Bone Biopsy System with Drill

INSTRUCTIONS FOR USE



PRODUCT DESCRIPTION

The Huntington™ Guided, Perforating Bone Biopsy System with Drill is designed for accessing bone, traversing bone when necessary, and performing bone biopsies. The system has the following contents. For specific sizes, see Table #1.

A	Anesthesia Needle	**F & J**	Handle (detachable)
B	Anesthesia Needle Stylet	**G**	Drill Insert
C	Guide Wire	**H**	Biopsy Needle with Clockwise Tip
D	Cutting (Access) Cannula	**I**	Biopsy Hub (with Stiffener)
E	Grooved Stylet (with Tri-Angled Tip)	**K**	Ejector Pin

INDICATIONS FOR USE

Bone access and biopsies of bone lesions.

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. 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 approach should be accurately planned using diagnostic imaging and clinically approved techniques. Disinfect the skin, make a small skin incision, and perform local anesthesia. The following is a suggested method for using the device with a guided approach over the Guide Wire (C). For a direct approach, go to Fig. 4.

FIG. 1 Introduce the Anesthesia Needle and its Stylet (A+B) through the soft tissue, until in contact with bone.
Note: Perform additional anesthesia with the Anesthesia Needle (A) to the periosteum if desired.

FIG. 2 Withdraw the Anesthesia Needle's Stylet (B) and introduce the Guide Wire (C) in the Anesthesia Needle (A) until in contact with the bone.

FIG. 3 Withdraw the Anesthesia Needle (A), while holding the Guide Wire (C) firmly against the bone. Place the assembled Cutting Cannula with Grooved Stylet and optional Handle (D+E+F) over the Guide Wire (C).

FIG. 4 Introduce the assembled Cutting Cannula with Grooved Stylet and optional Handle (D+E+F) by rotating counterclockwise until in contact with bone. Remove Guide Wire (C) if present.
Note 1: To protect soft tissue, a counterclockwise rotation must be applied during insertion through the soft tissue.

Move the depth gauge forward until in contact with the skin, then withdraw it by the desired depth, using the centimeter markings on the Cutting Cannula (D) to provide a visual guide. With careful but firm turns, rotate the Cutting Cannula with Grooved Stylet and optional Handle (D+E+F) clockwise until the depth gauge reaches the skin and/or desired position is obtained.
Note 2: If traversing the bone is difficult, remove the optional Handle (F), remove the Grooved Stylet (E), insert the Drill (G) in the Cutting Cannula (D) and screw the two parts together to assemble. Add optional Handle (F) to the Drill (G) as desired. Restart drilling with clockwise turns. During drilling, to maintain penetration efficiency, it is recommended to remove the Drill (G) from time to time and remove any bone debris from the drill grooves.

FIG.5 Remove the optional Handle (F) if applicable, then unscrew and withdraw the inner Grooved Stylet/Drill (E/G).

FIG. 6 Adjust the depth gauge on the Biopsy Needle (H) to the appropriate centimeter marker and tighten to provide a visual guide.
Note: The selected centimeter marker (see Fig. 6) will represent the Biopsy Needle protrusion beyond Cutting Cannula (D).

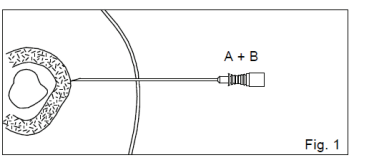


Fig. 1

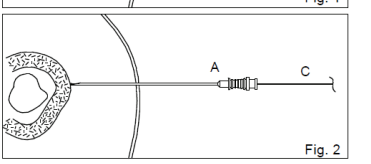


Fig. 2

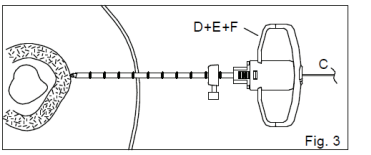


Fig. 3

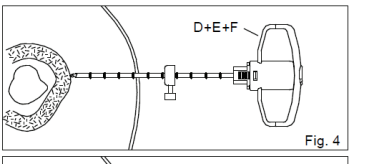


Fig. 4

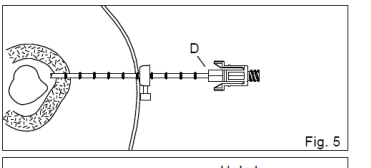


Fig. 5

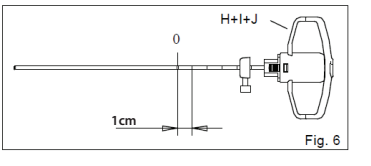


Fig. 6

FIG. 7 Insert the assembled Biopsy Needle and optional Handle (H+I+J) through the Cannula (D).
Carefully rotate clockwise until desired biopsy depth is achieved, or until the depth gauge of the Biopsy Needle (H) reaches the Cannula (D) luer end. Then rotate Biopsy Needle and optional Handle (H+I+J) counterclockwise and remove. Remove the Handle (F), if applicable, and the Hub (I) from the Biopsy Needle (H); insert the Ejector Pin (K) through the Biopsy Needle (H) from the luer end and eject the sample.
Note 1: Repeat process from Fig.6 if desired and anatomically safe.
Note 2: A syringe can be connected to the luer end of the Biopsy Needle (H) and light aspiration may be applied during removal of the Biopsy Needle (H) if desired.
Note 3: In the case of sclerotic lesions, taking several incremental, smaller, samples are recommended to avoid crushing tissue within Biopsy Needle (H).

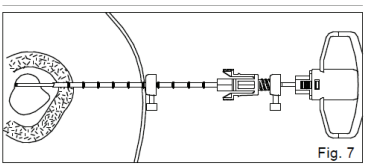


Fig. 7

#1	OM1165	OM1110	OM1115
A	18G x 7cm	18G x 10cm	18G x 15cm
C	Ø1mm x 21cm	Ø1mm x 25cm	Ø1mm x 29.5cm
D	11G x 6.5cm	11G x 10.8cm	11G x 15cm
E	Ø2.4mm x 10cm	Ø2.4mm x 14cm	Ø2.4mm x 19cm
G	Ø2.4mm x 10cm	Ø2.4mm x 14cm	Ø2.4mm x 19cm
H	Ø2.35mm x 16cm	Ø2.35mm x 20cm	Ø2.35mm x 24cm
K	Ø1.7mm x 19.3cm	Ø1.7mm x 23.4cm	Ø1.7mm x 27.4cm

	Single use
	Do not resterilize
	Caution: consult accompanying documents
STERILE EO	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
℞ ONLY	Federal (USA) law restricts this device to sale by or on the order of a physician.

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CE 2797

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