



**IZI Medical**

## **MDT Navigable Brain Biopsy Cannula (compatible with Medtronic® navigation system)**

**Rx only**

Manufactured For:

**IZI Medical Products, LLC**

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### **Components**

The MDT Navigable Brain Biopsy Cannula contains:

- One navigable biopsy cannula (1)
- One biopsy cannula stop with screw (2)
- One stop adjustment tool (3)
- One aspiration tube (4)

### **Indications for Use**

The MDT Navigable Brain Biopsy Cannula is for use in stereotaxic biopsy of cranial tissue. The MDT Navigable Brain Biopsy Cannula is a pre-sterilized, single-use, side-cutting cannula where the cutting action is achieved by rotation of an inner cannula within an outer cannula. The device is compatible with Medtronic's StealthStation® Image Guided Surgery System.

### **Warnings**

- All components in the MDT Navigable Brain Biopsy Cannula are pre-sterilized, single –use components. Do not re-sterilize or reuse.
- The product is MR UNSAFE.
- Inspect all components for any shipping damage prior to procedure. Do not attempt to use the product if any component appears to be bent or otherwise damaged.
- The product must only be used by or under the guidance of a skilled, duly qualified physician trained in the use of the StealthStation® system manufactured by Medtronic Inc.
- This operating manual is not a reference to stereotaxic technique.
- The product must be used according to the instructions given by this operating manual.
- Do not modify the device. Any modification may compromise device safety and efficacy. Surgeons must decide on the appropriate use of the MDT Navigable BRAIN BIOPSY CANNULA depending on the patient's disease.



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- The use of biopsy instruments involves the removal of intracranial material and entails some risk of hemorrhage.
- Patients or their representatives should be informed of possible complications associated with the use of the device.

## Cautions

- Federal Law (U.S.A) restricts this device to sale by or on the order of a physician.

## Handling and Application Information

The MDT Navigable Brain Biopsy Cannula has a side window-type cutter at its tip. The cutting window is opened by rotating the proximal handle piece of the MDT Navigable Brain Biopsy Cannula until the green panel is completely visible in the viewing window of the hub. The cutting window is closed by rotating the proximal handle piece of the MDT Navigable Brain Biopsy Cannula by 180° until the red panel is completely visible in the viewing window of the hub. The inner cannula can be removed in this position. The MDT Navigable Brain Biopsy Cannula may be used with the Trajectory Guide Kit, the Vertec® Articulating Arm and Precision Aiming Device.

## Set Up

1. Insert the probe in the guide stem (or Precision Aiming Device) and click [Set Entry] to update the entry point to its actual location.
2. When using the Trajectory Guide Kit, hold the probe in the guide stem, loosen the trajectory guide locking ring, and use the trajectory views and guidance view to aim the guide assembly along the planned surgical trajectory. Tighten the locking ring to secure the assembly so the guide stem cannot move during the procedure.

**Caution:** Failure to loosen the locking ring before attempting to align the guide stem along the surgical plan will result in stress on the assembly.

(When using the Vertec II Articulating Arm, hold the probe in the Precision Aiming Device, loosen the adjustment screws, and use the trajectory views and guidance view to aim the precision aiming device along the planned surgical trajectory. Tighten the screws to secure the assembly so the precision aiming device cannot move during the procedure.)

3. With the probe in the guide stem (or Precision Aiming Device), press the footswitch to lock the trajectory

**Warning:** Always use the 2.2 mm adapter (or reducing tube) with the passive biopsy needle.

4. Remove the probe and insert the adapter (or reducing tube) into the guide stem (or Precision Aiming Device).
5. While the trajectory is locked, the system reports the Stop Position necessary to deliver the needle to the target point. Use the stop adjustment tool (3) to position either the needle tip or cutting window at the Stop Position. The needle's cutting window begins 2.5 mm from the tip and is 10 mm long.

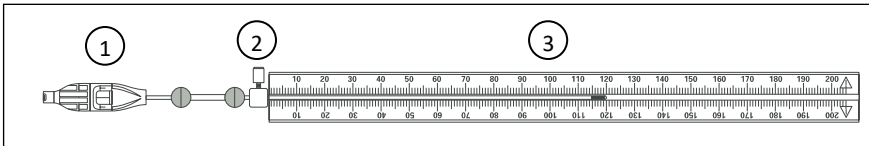


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The Stop Position is the sum of two quantities:

- the length of the adapter [50 mm] (or reducing tube [70 mm])
- the length of the surgical plan

Note: When the adapter is fully seated in the guide stem, the tip of the adapter is at the center of the guide stem's spherical end. In a previous step you redefined the entry point of the surgical plan at the center of the spherical end of the guide stem; therefore the length of the adapter [50 mm] is added to the length of the surgical plan to obtain the Stop Position. (Similarly, the length of the reducing tube [70 mm] is added to the length of the surgical plan to obtain the Stop Position.)



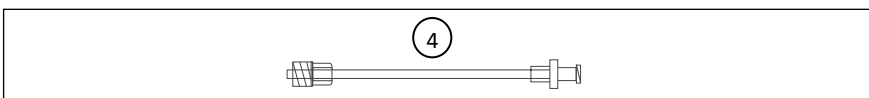
6. Review the following warnings. Then, connect the provided aspiration tube (4), carefully advance the biopsy needle through the adapter (or reducing tube) until the depth stop contacts the top of the adapter (or reducing tube). The system reports the distance to target as the needle advances.

**Warning:** Make sure that the BRAIN BIOPSY CANNULA (1) is closed before inserting the cannula (1) into the adapter. The red panel of the cannula (1) must be visible. Visually confirm that the cutting window is closed before advancing or retracting the needle. Moving the needle while the cutting window is open could cause unnecessary patient trauma.

**Warning:** The system tracks the location of the needle tip. The software displays a graphical representation of the needle cutting window in all views to assist you in determining the cutting window's position.

7. To take the biopsy sample, rotate the proximal handle piece of the BRAIN BIOPSY CANNULA (1) until the green panel is completely visible in the viewing window of the hub. Connect an aspiration syringe to the Luer-Lock connection of the aspiration tube (4) and suck a tissue sample into the open window using the syringe. Close the cutting window and shear off the tissue sample by rotating the proximal handle piece until the red panel is completely visible. Gently withdraw the inner cannula (or the entire device if procedure is complete) containing the tissue sample. If desired, reposition the cannula (1) and repeat the procedure. Make sure the biopsy window is closed and then carefully retract the inner cannula to retrieve the sample.

Note: You may draw suction using the aspirator tube and a syringe, or by attaching a syringe directly to the inner cannula hub.



Note: Do not remove the guide assembly from the patient until a satisfactory sample is acquired. If you wish to acquire a sample from a new location, create a new surgical plan and repeat the process.



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Do not use if package is damaged.



Manufacturer



Protect from sunlight.



Do not reuse!



Store in a dry place.



Do not resterilize!



Storage temperature range.



Catalog number.



Use by - month & year



Lot number.



Warning



Quantity



Sterile, unless the package is damaged or opened. Method of sterilization - EO