



IZI Medical

BL Navigated Biopsy Needle

Rx only

Manufactured For:

IZI Medical Products, LLC

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Set Components

The BL Navigated Biopsy Needle contains:

- One navigated biopsy needle
- One biopsy needle stop with screw
- One stop adjustment tool
- One aspiration tube

Indications for Use

The BL Navigated Biopsy Needle is for use in stereotactic biopsy of cranial tissue. The Navigated Biopsy Needle is a pre-sterilized, single-use, side-cutting needle where the cutting action is achieved by rotation of an inner cannula within an outer cannula. The device is compatible with Brainlab's navigation system.

Warnings

- All components in the Navigable Brain Biopsy Needle are pre-sterilized, single-use components. Do not re-sterilize or reuse.
- Inspect the Set components for any shipping damage prior to procedure. Do not attempt to use the Set if any component appears to be bent or otherwise damaged.
- The Product is MR UNSAFE.
- The product must only be used by or under the guidance of a skilled, duly qualified physician trained in the use of the Brainlab navigation systems manufactured by Brainlab.
- This operating manual is not a reference to stereotactic technique.
- The Set must be used according to the instructions provided in this operating manual.
- Do not modify the device. Any modification may compromise device safety and efficacy.
- Surgeons must determine the appropriate use of the BL Navigated Biopsy Needle depending on the patient's disease.
- The use of biopsy instruments involves the removal of intracranial material and entails some risk of hemorrhage.



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- Patients or their representatives should be informed of possible complications associated with the use of the device.

Cautions

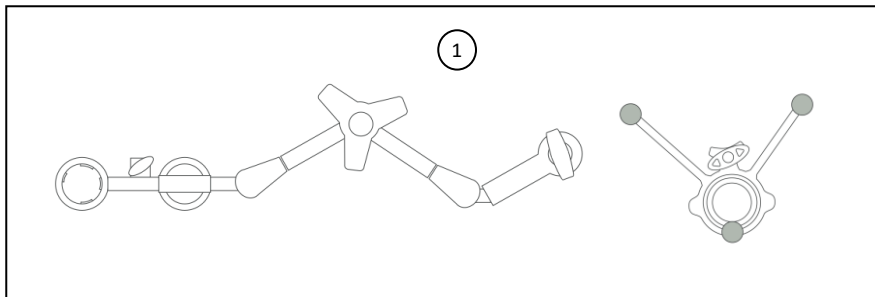
- Federal Law (U.S.A) restricts this device to sale by or on the order of a physician.

Handling and Application Information

The BL Navigated Biopsy Needle has a side window-type cutter at its tip. The cutting window is opened by rotating the proximal handle piece of the Biopsy Needle 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 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 Biopsy Needle's insertion trajectory and insertion depth is pre-determined in a surgical plan. The Biopsy Needle will be mounted on the VarioGuide™ or other compatible fixation devices after the proper trajectory has set up by the user in the BrainLab navigation system.

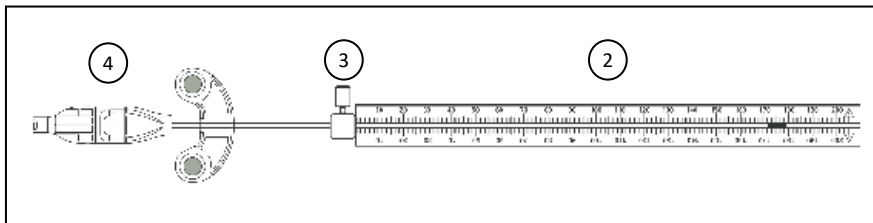
Instructions for use with the BrainLab Navigation System

1. Follow the BrainLab manual for patient registration and treatment plan creation as well as for the fixation, adjustment of the VarioGuide™ aiming device (1).



Set the stop (3) of the biopsy needle (4) to the depth of the penetration

indicated in the navigation system. Use the provided Stop Adjustment Tool (2) to set accurate depth. The user can set the stop position (3) either to the tip of the needle or to the center of the side window. The side window starts 3mm away from the tip of the needle and has a length of 10 mm. Secure the stop (3) by gently fixing the stop screw.





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2. Connect the provided aspiration tube (5). Gently insert the Brain Biopsy Needle (4) into the VarioGuide™ (1) until the stop position is reached.



Caution: Make sure that the VarioGuide™ is set to a diameter of 2.1 mm.

Caution: Make sure that the Brain Biopsy Needle (4) is closed before inserting the needle into the VarioGuide™. The red panel of the biopsy needle must be visible. The position of the needle (4) as well as the distance to the target point is shown on the screen.

3. To take the biopsy sample, rotate the proximal handle piece of the Biopsy Needle (4) 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 (5) and aspirate 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.

Note: Do not remove the VarioGuide™ 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 steps above.

4. Gently withdraw the inner cannula (or the entire device if procedure is complete) containing the tissue sample. If desired, reposition the cannula (4) and repeat the procedure from step 3.



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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