



CLEARPOINT®
NEURO

Bladed Lancet

INSTRUCTIONS FOR USE

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I. Intended Use

The Bladed Lancet is intended to pierce or cut tissue during a neurosurgical procedure, in or near an MR scanner of 3T maximum field strength. The Bladed Lancet is intended to be used only when the scanner is not performing a scan. The Bladed Lancet is intended for single use only.

Warning: This device is intended for single use only. Contents of unopened, undamaged package are sterile. Do not re-sterilize.

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

II. Device Description

Package Contents:

NGS-BL-01: **Bladed Lancet**
Bladed Lancet, Depth Stop, Ruler

III. General Warnings and Precautions

The device is intended for single-use-only and is provided sterile. Do not re-sterilize.

Warning: DO NOT perform an MRI Scan while the Lancet is being held or in contact with tissue. Use the Lancet only when the MRI scanner is not running a scan. The Lancet may cause injuries from RF-induced heating if it is near tissue during a scan.

Warning: There are no known and reliable means of cleaning, disinfecting, repairing, and sterilizing this device that returns it to original specifications and renders it safe and effective for reuse.

Warning: Visually inspect all sterile barriers prior to use to determine if breaches to the sterile barrier system are evident. Do not use the device if any damage to the sterile barrier system is identified during visual inspection.

Caution: Grasp the Lancet only on the smooth shank section. Do not grasp the Lancet by the point or point edges.

General Precautions:

Handle all components using standard hospital sterile practices.

IV. MRI Safety Information

- Non-clinical testing has demonstrated the Bladed Lancet is MR Conditional. It can be used in or near an MRI scanner safely under the following conditions:
 - Static Magnetic field of 1.5 Tesla and 3 Tesla
 - Spatial gradient field of 517 Gauss/cm (5.17 T/m) or less
 - DO NOT perform an MRI Scan while the Lancet is in the scanner.
 - DO NOT perform an MRI Scan while the Lancet is being held or in contact with tissue. Use the Lancet only when the MRI scanner is not running a scan. The Lancet may cause injuries from RF-induced heating if it is near tissue during a scan. REMOVE the Lancet from the scanner before performing an MRI scan.

V. Use Instructions

A. Preparation

Examine the Lancet for any signs of damage or corrosion. Do not use a Lancet if it is damaged or if corrosion is present.

B. Using the Lancet

A Depth Stop is provided in case the Lancet is inserted through a guide.

To attach the Depth Stop, slide it over the proximal (blunt) end until it is at the desired distance from the tip. See Figure 1.

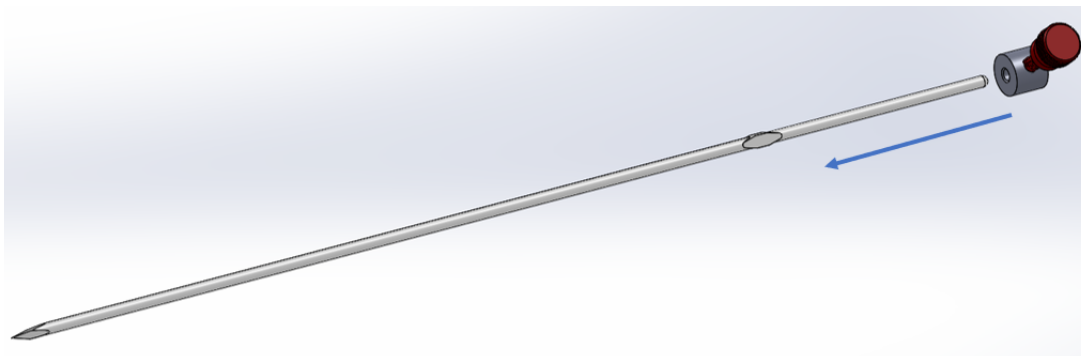


Figure 1

Tighten the thumbscrew until the Depth Stop is secure on the Lancet. See Figure 2.

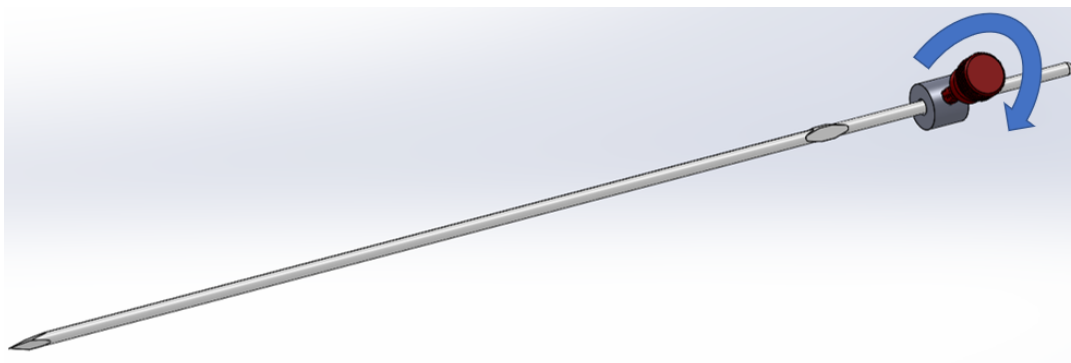


Figure 2

The Lancet may be held anywhere along the body. However, avoid touching the Lancet on or near the point or point edges.

The Lancet has a region in its body that is slightly larger than the rest of the body (see **Figure 3**). This provides a surface that acts as an integrated stop if the Lancet is inserted through guide with ID no larger than 2.1 mm. Note that the Depth Stop can slide over this feature.

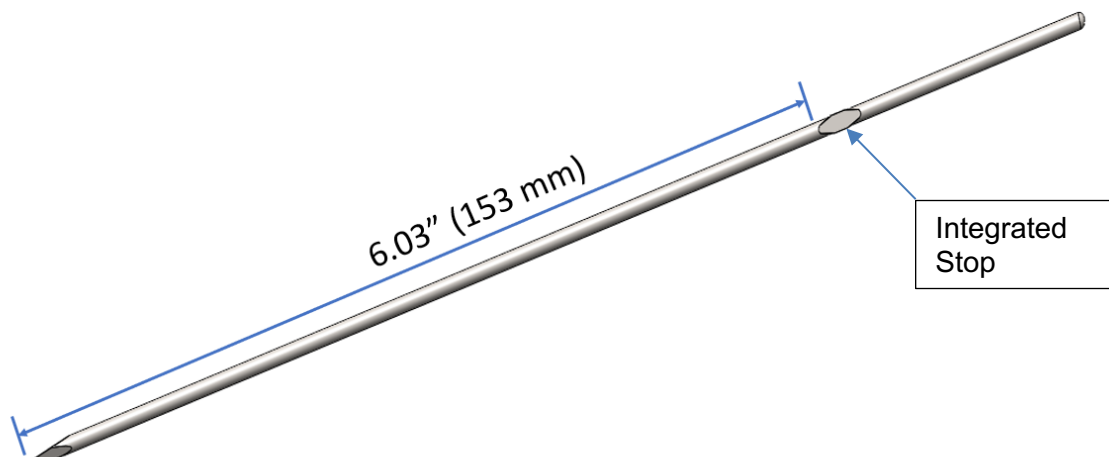


Figure 3

If inserting the Lancet through a guide, an inner diameter of 2.1 mm is recommended.

Push the tip of the Lancet through the tissue (for example, the dura and/or pia) to pierce and cut it as necessary. Apply force gently at first, using additional force as required to cut tissue.

Warning: DO NOT perform an MRI Scan when the Lancet is in contact with tissue or being held by hand. The Lancet may cause the tissue to heat, resulting in injury.

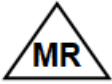
C. Storage and Technical Specifications

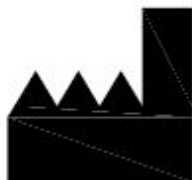
Storage

- Store in a cool dry place

Technical Specifications

Product Name	Length (in/mm)	Diameter (in/mm)	Mass (g)
Bladed Lancet	8.00 / 203	0.08 / 2.0	12

SYMBOL	DEFINITION	SYMBOL	DEFINITION
	MR Conditional		Sterilized through ethylene oxide
	Consult instructions for use		Manufacturer
	Catalogue number		Date of Manufacture
	Batch code		Keep dry
	Use by date		Keep away from sunlight
	Non-pyrogenic		Single use
	Double sterile barrier system		Not made with natural rubber latex
	Do not use if the product sterilization barrier or its packaging is compromised		



Manufactured by:

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