NICO meniGLIDE™ Instructions for Use

Caution: Federal (US) Law restricts this device to sale by or on the RXOnly

order of a physician.

Please read all information carefully. Failure to properly follow these instructions may lead to unintended surgical consequences. Important: This package insert is designed to provide instructions for use for the NICO meniGLIDE. It is not a reference to surgical techniques.

Indications

The NICO meniGLIDE is intended to be used to cut an opening in the meninges for access purposes during neurosurgery.

Contraindications

• None

Warnings

- Prior to use, inspect the device for gross damage such as bends, cracks, etc. Do not use the device if it is damaged or defective.
- Handling of device prior to use can affect performance during use.
 Ensure that the cutting edge of the blade does not become damaged once removed from its packaging (e.g., dropping the device into a metal bowl).

Precautions

- Device is single use only. Resterilization may compromise integrity, which may result in malfunction. Reuse of device may result in patient infection and/or malfunction.
- Use device only in accordance with its intended use. Read and follow the instructions for use.
- The device is a sharp instrument. Take the proper precautions in handling the device to avoid injury to yourself or others before, during, or after use.
- Device should be used prior to stated expiration on the label.

Symbols

RxOnly	Symbol indicating that the device is for prescription use only
	Symbol indicating that the device is not made with natural rubber latex
2	Symbol indicating that the device is for single use only and should not be reused
\triangle	Attention consult accompanying documents
LOT	Symbol indicating the lot/control number for a device
REF	Symbol indicating the catalog number for the device
STERILE R	Symbol indicating that the device has been sterilized via gamma radiation processes
	Symbol indicating the "use by" date for a device
•••	Symbol indicating the manufacturer of the equipment
<u></u>	Do not use if package is damaged

For more information on the NICO meniGLIDE, contact your NICO representative or NICO Customer Service at 317-660-7118 ext.100. Additional information may be found at www.niconeuro.com.

Device Description

The NICO meniGLIDE is a single-use disposable scalpel, specifically designed and developed to be used during neurosurgery. It is intended to be used to cut an opening in the meninges for access purposes during neurosurgery.

Instructions for Use

- Obtain access to the desired membrane, make a small 5mm incision with a scalpel in order to create the starting location for cutting of the membrane.
- 2. Introduce the meniGLIDE into the incision with the foot plate underneath the membrane.
- Elevate to separate the membrane from the brain with the foot plate.
- With the meniGLIDE blade positioned perpendicular to the membrane, begin cutting through the membrane until the desired length of cut is attained.

How Supplied

The meniGLIDE is supplied sterile and packaged for single patient use. This item is sterilized using gamma irradiation. Discard into an appropriate container after use.

For More Information

For more information contact your NICO representative or NICO Customer Service at **317-660-7118 ext.100**. Additional information may be found at www.niconeuro.com.

Patents pending worldwide.

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