

## LeadLoc Depth Stop

### Directions For Use

L011-67 (Rev D0, 17-11-13)

Contains directions for the following products:

66-AC-DC

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EC REP



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Edificio LUGO Oficina 1406  
Medellin-Colombia

### Indications For Use

The LeadLoc Depth Stop is a part of the microTargeting™ STar™ Drive System which is intended to be used with commercially available stereotactic systems for neurosurgical procedures which require the accurate positioning of microelectrodes, stimulating electrodes, or other instruments in the brain or nervous system.

### Intended Use

The LeadLoc Depth Stop is intended for use with the microTargeting™ Drive, STar™ Drive, or STar™ Inserter by a neurosurgeon in a standard operating room environment.

### Symbol Key



WARNING / Caution, consult documents



Read usage instructions

Rx Only

**Caution-** Federal law (USA) restricts this device to sale by or on the order of a physician.

USA

In reference to "Rx only" symbol; this applies to USA audiences only



Indicates a medical device that should not be used if the package has been damaged or opened



Do not re-use: intended for one use on a single patient, during a single procedure.



Indicates a medical device that is not to be resterilized.



Indicates the date after which the medical device is not to be used.



Medical Device manufacturer, As defined in EU directives 90/385/EEC, 93/42/EEC and 98/79/EC.



Telephone number

EC REP

Authorized Representative in the European Community



European Conformity. This device fully complies with MDD Directive 93/42/EEC and legal responsibilities as a manufacturer are with FHC, Inc., 1201 Main Street, Bowdoin, ME 04287 USA

STERILE EO

Indicates a medical device that has been sterilized using ethylene oxide.

REF

Indicates the manufacturer's catalogue number so that the medical device can be identified.

LOT

Indicates the manufacturer's batch code so that the batch or lot can be identified.

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## Warnings & Cautions



**WARNING:** Handle all components with extreme care. They may be damaged if excessive force or incorrect handling occurs.



**WARNING:** User must examine unit prior to use to ensure it has no shipping damage.



**CAUTION:** LeadLoc Depth Stops are for single patient use only. Do not reuse any single use components.

Rx Only

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician.

STERILE EO

**CAUTION:** Sterilized by ethylene oxide



**CAUTION:** Sterile Medical Device - Do NOT resterilize



**CAUTION:** Do not use the contents if there is any evidence of damage to the package or package seal that could compromise sterility.

## Specifications

Material: Clear Lexan HP4R

Lead Diameters: 1.27-1.40mm

Packaging: Box of 10, individually bagged, sterile

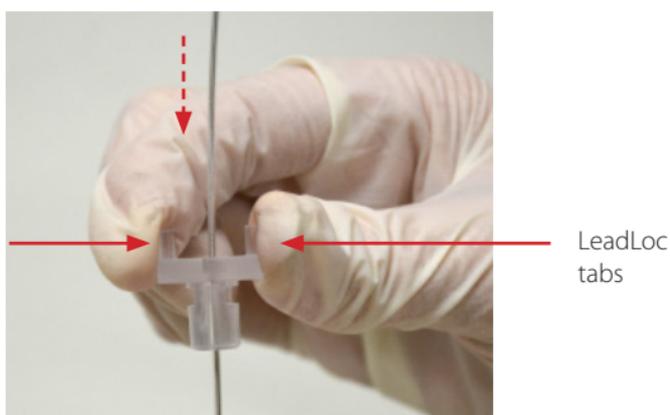
## Storage & Cleaning

Store all components at temperatures between  $-34^{\circ}\text{C}$  ( $-29^{\circ}\text{F}$ ) and  $57^{\circ}\text{C}$  ( $135^{\circ}\text{F}$ ). Do not exceed  $135^{\circ}\text{F}$  for long-term storage.

## Preparing the Lead for Implant



1. Secure the lead holder to the measurement fixture.

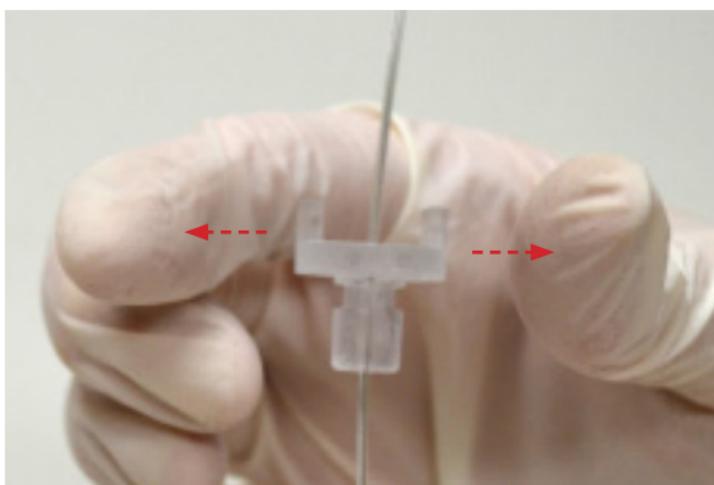


2. Pinch the tabs of the LeadLoc together slightly and push the distal end of the lead through the top of the LeadLoc to approximately 25 mm from the stylet handle making sure the lead is in the center notch of the LeadLoc.

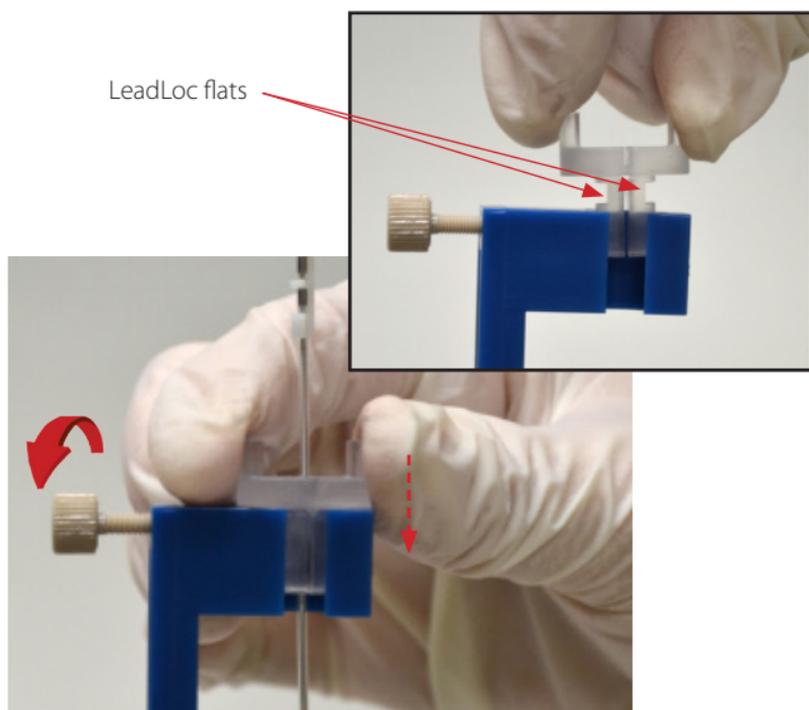


**WARNING:** Do NOT over-pinch the tabs. Over-pinching the tabs could result in the LeadLoc not holding the lead.

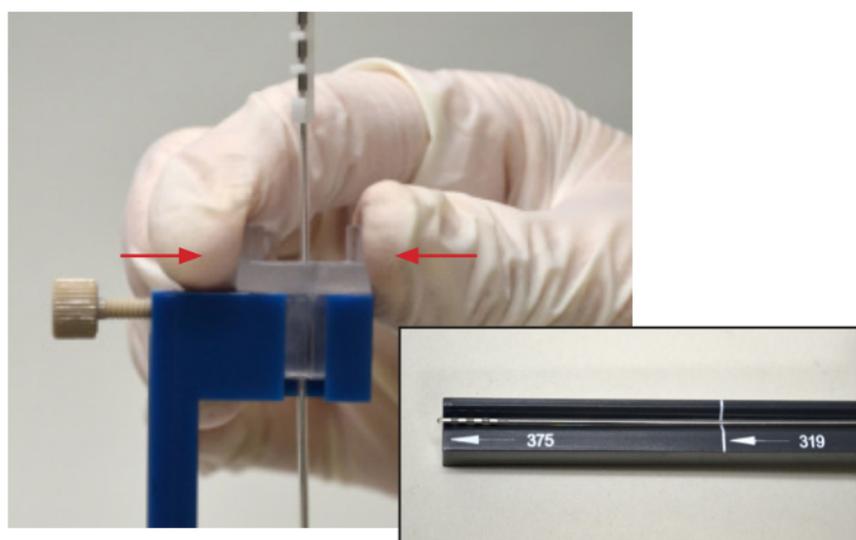
**CAUTION:** When sliding the lead inside the LeadLoc, ensure the lead is inserted from the top hole down through the bottom hole of the LeadLoc and does not come out of the center slot.



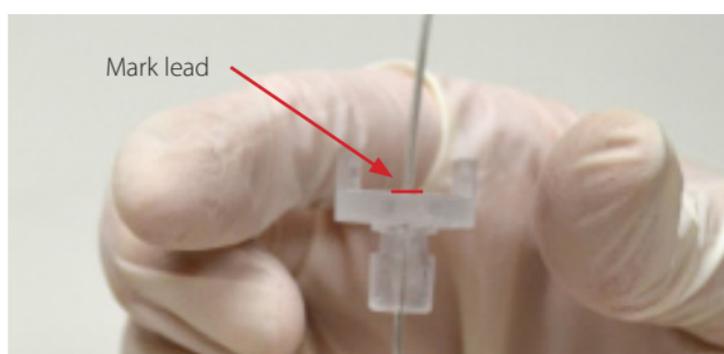
3. Release pressure on the LeadLoc.



4. Insert the lead and the LeadLoc into the lead holder making sure one of the flats of the LeadLoc are aligned with the thumbknob on the lead holder. Gently tighten the thumbknob to secure the LeadLoc into the holder then loosen slightly, ensuring that the LeadLoc cannot move vertically.



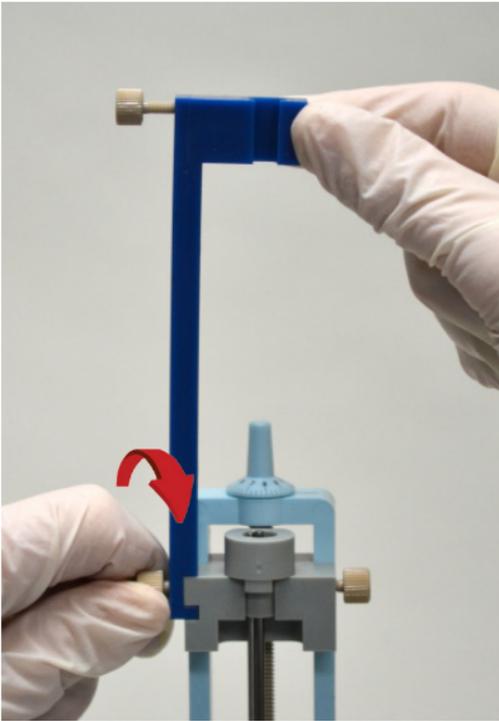
5. While pinching the LeadLoc, move the lead so that the contacts are in the desired position relative to target depth.



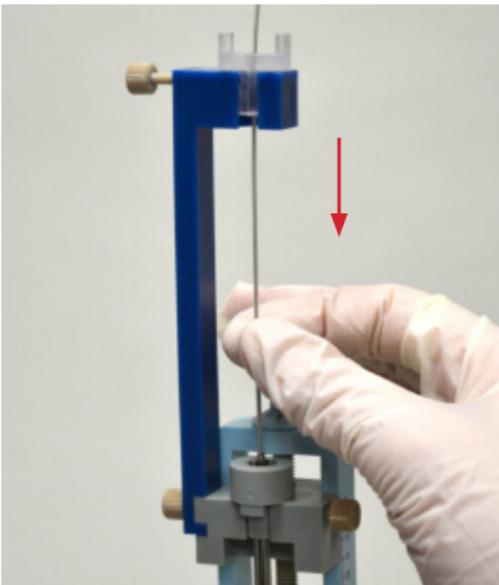
6. Release pressure on the LeadLoc to secure the lead. To confirm the lead does not move during the insertion process, use an appropriate (sterile) pen to make a mark on the lead just above where it comes out of the LeadLoc.
7. Loosen the lead holder and remove from the measurement fixture.
8. Remove the LeadLoc with lead from lead holder.
9. Set aside lead holder and lead with preattached LeadLoc in a sterile area for later use.

## Implanting the Lead

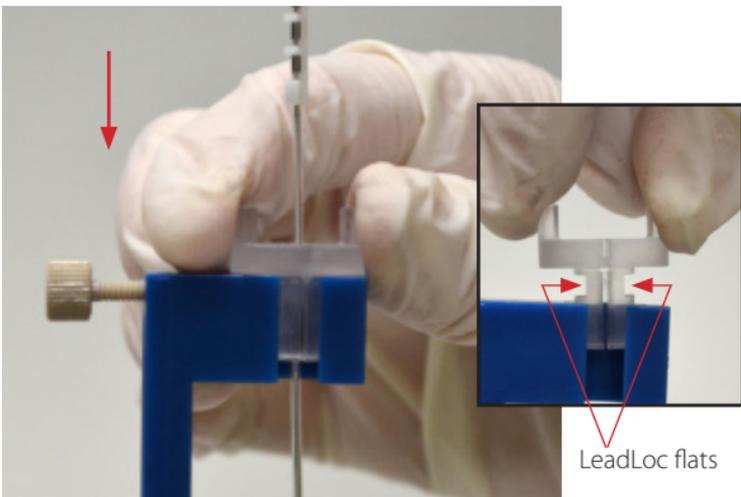
1. Re-check the lead position. (Confirm LeadLoc has not moved on lead by checking the pen mark.)



2. Secure the lead holder to the drive positioning platform.



3. Insert the preset lead into the insertion tube and into the brain.

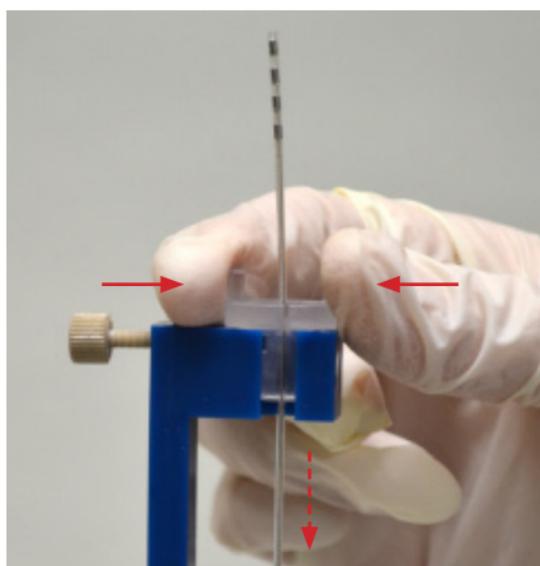


4. Carefully secure the LeadLoc (and lead) in the lead holder as shown, making sure one of the flats of the LeadLoc align with the thumbknob on the lead holder.

5. Confirm the lead location.
6. Loosen and raise the lead insertion tube out of the skull and secure.



7. Secure the lead next to the skull with smooth tweezers or the selected securing device.
8. Remove the stylet from the lead.



9. Loosen the lead holder thumbknob then pinch the LeadLoc and pull the lead down through the drive.



**WARNING:** Trying to pull the LeadLoc over the lead may dislodge the lead from its implantation location.

10. Remove the drive system.



