

## LeadLoc Depth Stop Directions for Use

66-AC-DCM  
66-AC-DCS

L011-63 (Rev B0 April 2015)



**FHC, Inc.**  
1201 Main Street  
Bowdoin, ME 04287  
Fax +1-207-666-8292  
www.fh-co.com

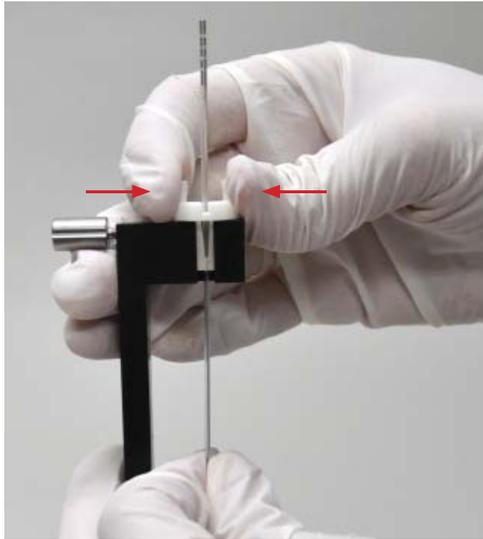


**FHC Europe**  
(TERMOBIT PROD srl)  
42A Barbu Vacarescu Str, 3rd Fl  
Bucharest 020281 Sector 2  
Romania



24 hour technical service:  
1-800-326-2905 (US & Can)  
+1-207-666-8190

**FHC Latin America**  
Calle 6 Sur Cra 43 A-200  
Edificio LUGO Oficina 1406  
Medellín-Colombia



- 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.

- Remove the drive system.

**Indications For Use:** The LeadLoc Depth Stop is intended to be used with the microTargeting™ or STar™ Drive System for neurosurgical procedures which require the accurate positioning of microelectrodes, stimulating electrodes, or other instruments in the brain or nervous system.

### Warnings



**WARNING:** Federal law restricts this device to sale by or on the order of a physician.



**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.

### Cautions

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

## 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. Note that LeadLoc Depth Stops should not be cleaned prior to use. These components should only be sterilized following the protocol on page 2.

## Sterilization

LeadLoc Depth Stops should be sterilized in the STar™ Drive container using the following sterilization parameters:

### Gravity Steam Sterilization:

Minimum Temperature,  
Wrapped:  $132^{\circ}\text{C}$   
Full Cycle Time: 30 minutes  
Minimum Dry Time: 35 minutes

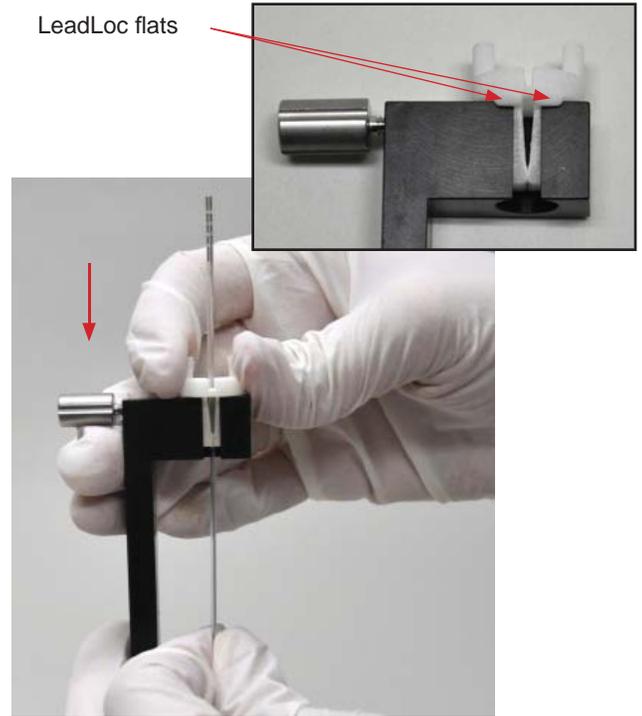
### Prevacuum Steam Sterilization:

Preconditioning Pulses: 3  
Minimum Temperature,  
Wrapped:  $132^{\circ}\text{C}$   
Full Cycle Time: 12 minutes  
Minimum Dry Time: 30 minutes



**WARNING:** Users should be aware that the effects of unvalidated sterilization protocols could result in damage to the components and affect their functioning or performance. The components of this system are not validated for use with alternative sterilization protocols, and FHC does not recommend or endorse their use. Users with questions regarding this safety issue should contact FHC's Technical Service Department at 1-207-666-8190.

LeadLoc flats



4. Carefully secure the LeadLoc (and lead) in the lead holder making sure the flats of the LeadLoc align with the opening 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.

## 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.

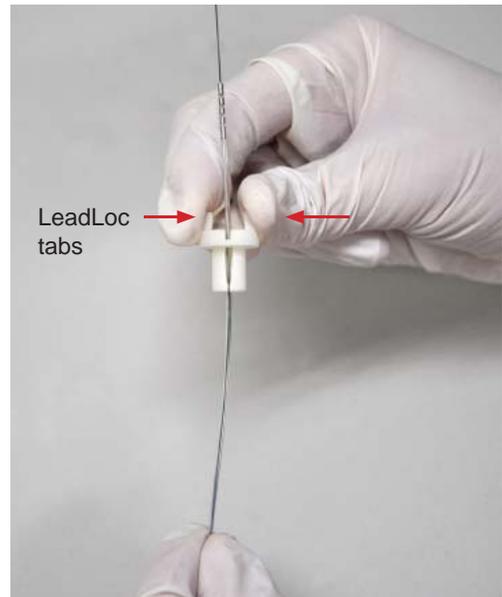


3. Insert the preset lead into the insertion tube and into the brain.

## Preparing the Lead for Implant



1. Secure the lead holder to the measurement fixture.

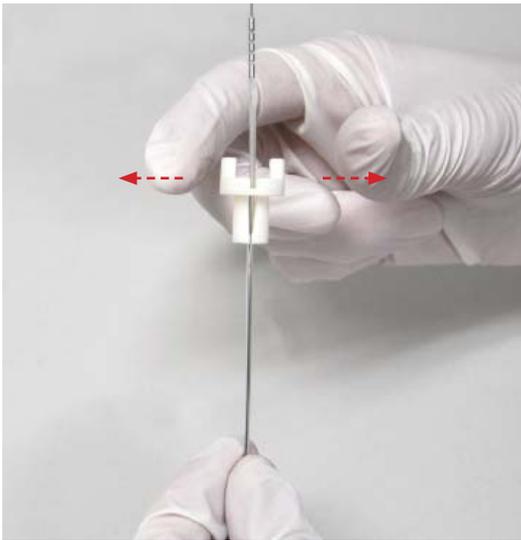


2. Pinch the tabs of the LeadLoc together slightly and slide the distal end of the lead through the top of the LeadLoc to approximately 25 mm from the stylet handle making sure the lead is in the center notch of the LeadLoc.

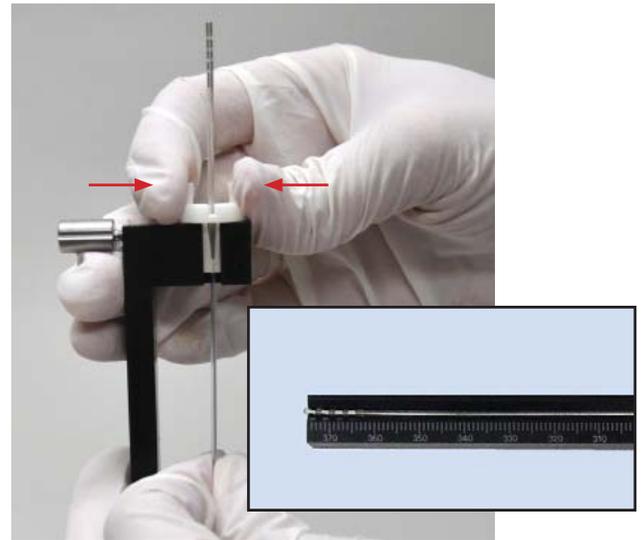


**WARNING:** Do NOT overpinch the tabs. Overpinching the tabs could result in the LeadLoc holding the lead.

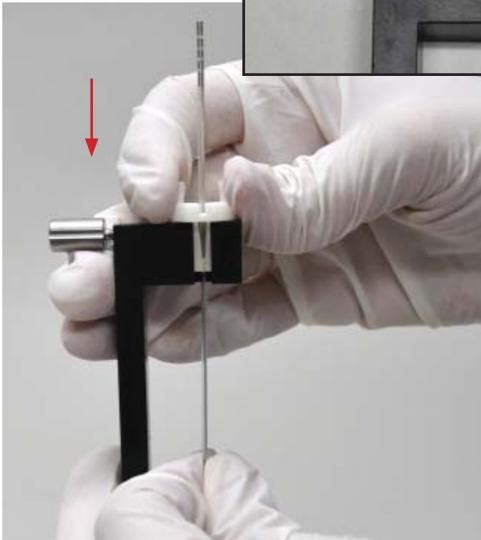
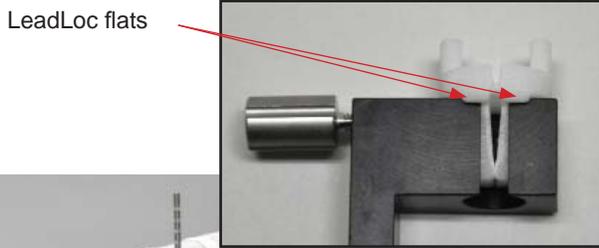
**CAUTION:** When sliding the lead inside the LeadLoc, ensure the lead is inserted from the top hole down through the bottom hole of the LeadLoc and does not come out of the center slot.



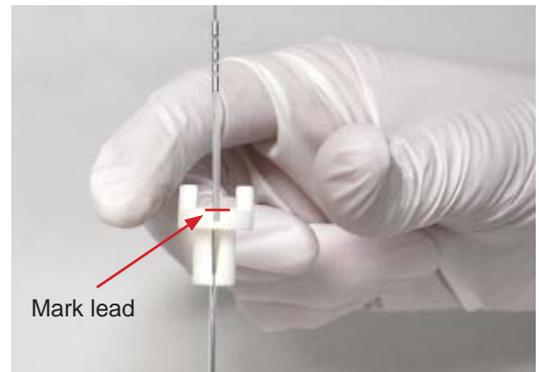
3. Release pressure on the LeadLoc.



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



4. Insert the lead and the LeadLoc into the lead holder making sure the flats of the LeadLoc are aligned with the opening 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.



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.