microTargeting™

Loom Cable Management System Directions For Use

L011-64 (Rev A0, March 2013)

FHC
Neural microTargeting™ Worldwide

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

EC REP **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
Carrera 43 A # 1sur 31
Ed. BBVA oficina 401
Medellín-Colombia

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

Warnings

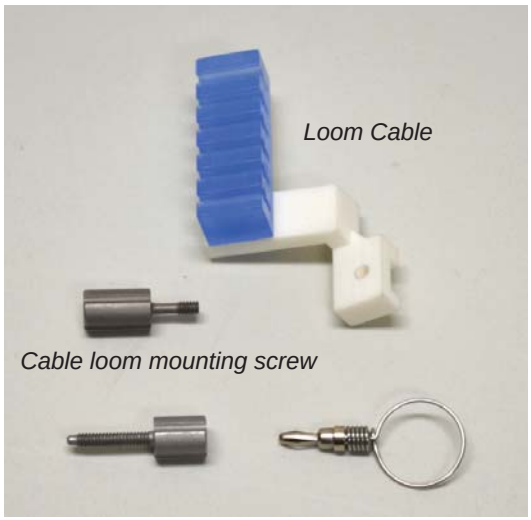
WARNING: Federal law restricts the device to sale by or on the order of a physician.

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

Cautions

CAUTION: Cable Looms are for Single patient use only. Do not reuse any single use components.

CAUTION: Patient Common Rings with receptacle screw have been validated for 10 uses. Do not use more than 10 times.



Patient Common Ring receptacle thumbscrew

Patient Common Ring

Storage

Store all components at temperatures between –34°C (-29°F) and 57°C (135°F). Do not exceed 135°F for long-term storage. Note that the Cable Looms should not be cleaned prior to use.

Cleaning

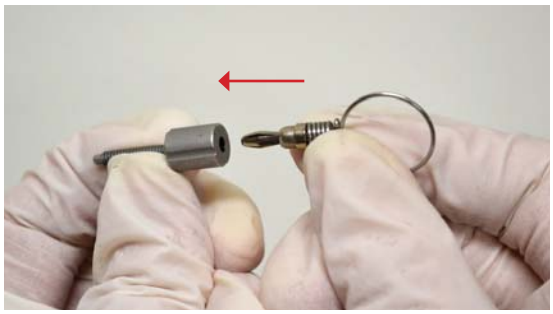
Patient Common Ring and screws should be cleaned either manually or through an automatic washing cycle. For cleaning instructions, refer to the STar™ Drive or microTargeting™ Drive Directions For Use.

Sterilization

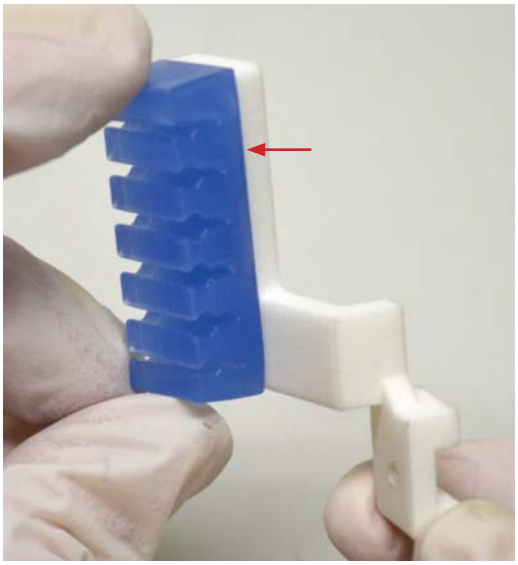
The Cable Loom, Patient Common Ring and thumbscrews should be sterilized in the STar™ Drive or microTargeting™ Drive sterilization tray container. For sterilization instructions, refer to the STar™ Drive or microTargeting™ Drive Directions For Use.

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.

Pre-Use Check

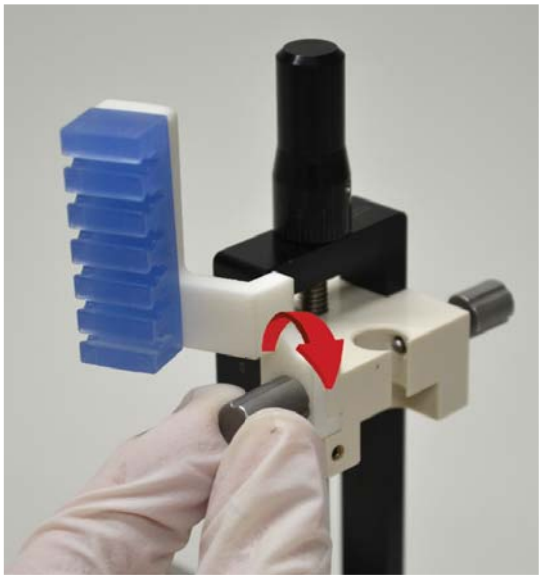


1. Confirm the banana plug of the patient common ring fits snugly inside the hole of the electrode carrier thumbscrew.

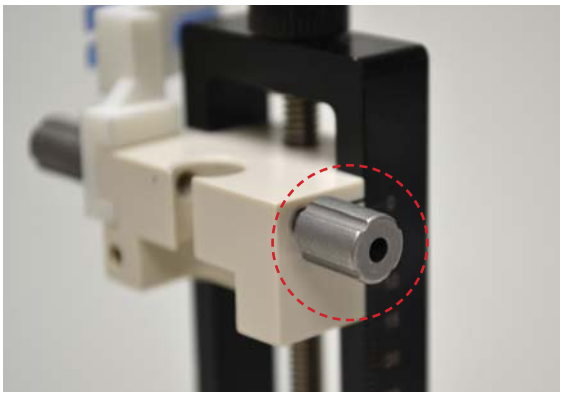


2. Check the loom is fully secured to its bracket.

Illustrative Procedure



1. Before the drive is mounted on the stereotactic system, secure the cable Loom to the drive positioning platform with the provided thumbscrew, as shown.

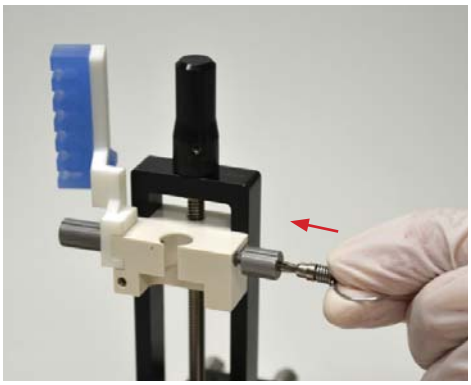


2. Confirm the electrode carrier locking thumbscrew installed on the drive positioning platform has a hole as shown. If not, install thumbscrew with hole provided with patient common ring.

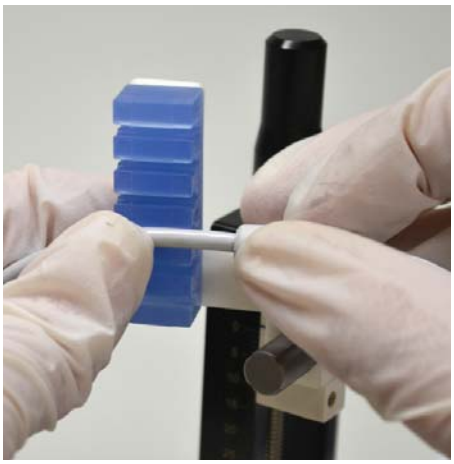
3. Mount the drive to the stereotactic system.

4. Proceed with mounting the electrode carrier, insertion tubes and microelectrodes per microTargeting™ Drive or STar™ Drive Directions For Use.

WARNING: When there is an insertion tube/ electrode in the brain, every effort should be made to minimize lateral forces to the microTargeting™ Drive or STar™ Drive system as it can translate into significant lateral movements of the tube/electrode in the brain.



5. Plug patient common ring into electrode carrier locking thumbscrew as shown.



6. Attach cable to the loom starting in the mid section of the loom. To attach cable, press length of cable adjacent to junction mold into the groove to secure the cable in place as shown on picture.

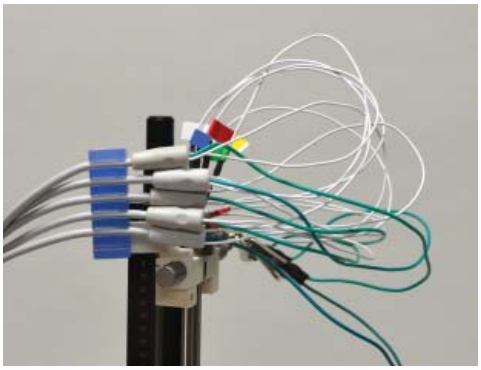
CAUTION: Do not use any lubricant on the cables.

7. Establish electrical connection to the microelectrode per microTargeting™ Electrode Directions For Use.

> **WARNING: Improper cable connections may cause erroneous results including unintended stimulation through metal contacts in the brain.**

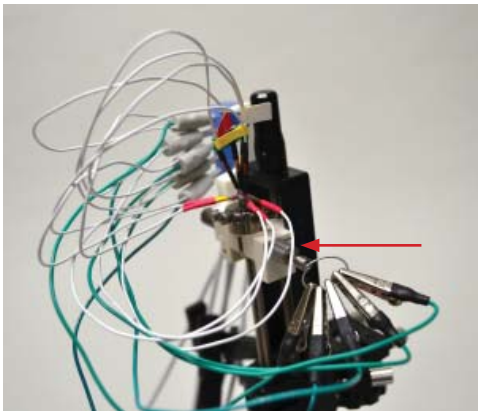
8. Attach alligator clip to the patient common ring as shown.

> **WARNING: For electrical continuity, make sure the teeth of the alligator clip are engaged with the patient common ring.**



9. Repeat steps 6-8 as many times as there are micro-electrodes/cables. Consecutive cables should be attached in consecutive open grooves in the cable loom until all the cables are attached to the loom.

> **CAUTION: Leaving empty grooves in between filled ones could cause the cables to get dislodged from their groove during the procedure.**



10. Confirm tightness of the electrode carrier thumbscrew.

11. Proceed with drive advancement and microelectrode recordings.

12. When the anatomical areas have been confirmed, detach alligator clips from the patient common ring.

13. Remove the electrode connections and disconnect the loom from the drive by loosening the thumbscrew.

14. Proceed with Lead implant.

15. At the end of the surgery discard Cable Loom.

16. Set thumbscrews and patient common ring aside with drive system for cleaning and sterilization.