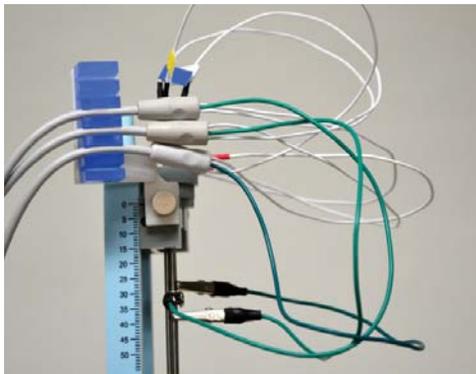


- Attach cable to the loom starting in the mid section of the loom. To attach cable, press length of cable adjacent to junction mold into the groove to secure the cable in place as shown on picture.

CAUTION: Do not use any lubricant on the cables.

- Establish electrical connection per STar™ Inserter Directions For Use.



- Repeat step 4 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.

- Proceed with drive advancement and microelectrode recordings.
- When the anatomical areas have been confirmed, remove the electrode connections and disconnect the loom from the drive by loosening the thumbscrew.
- Proceed with Lead implant.
- At the end of the surgery discard Cable Loom.

Loom Cable Management Fixture Directions For Use

L011-65 (Rev A0, March 2013)



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Indications For Use: The Loom Cable Management Fixture is intended to be used with the STar™ Inserter for neurological procedures which require the accurate positioning of micro-electrodes, 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.



Loom Cable Management Fixture with peek mounting screw

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.

Sterilization

The Cable Loom should be placed in a suitable container and sterilized as described below.

Gravity Steam Sterilization (Flash)

Minimum Temperature, unwrapped: 132°C
 Full Cycle Time: 10 minutes
 Minimum Dry Time: none

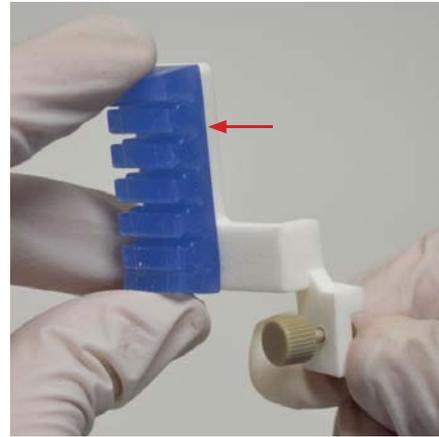
Prevacuum Steam Sterilization

Preconditioning Pulses: 3
 Minimum Temperature, wrapped: 132°C
 Full Cycle Time: 4 minutes
 Minimum Dry Time: 40 minutes



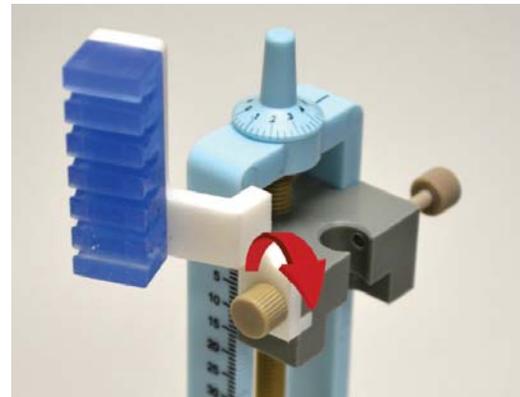
WARNING: Users should be aware that the effects of unvalidated sterilization protocols could result in damage to the components and affect their functioning or performance. The components of this system are not validated for use with alternative sterilization protocols, and FHC does not recommend or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

Pre-Use Check



1. 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. Mount the drive to the stereotactic system.
3. Proceed with mounting the electrode carrier, insertion tubes and microelectrodes per STar™ Inserter 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 STar™ Inserter as it can translate into significant lateral movements of the tube/electrode in the brain.