

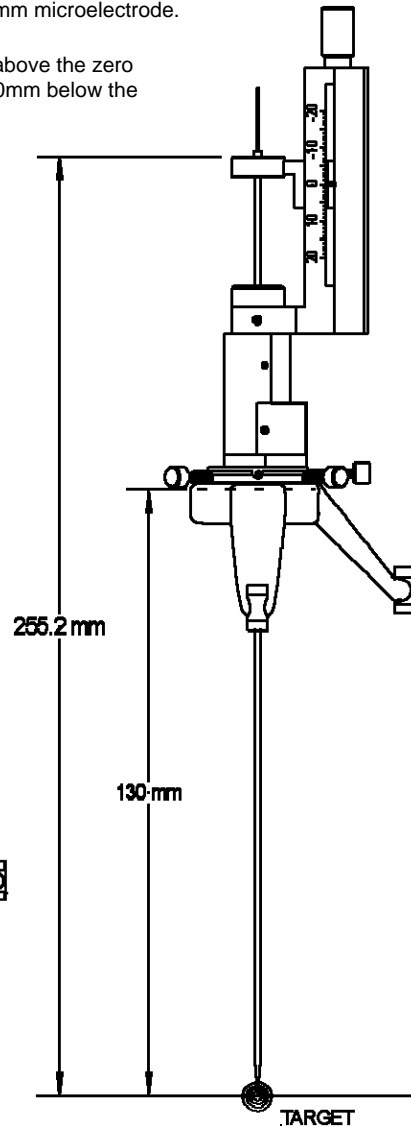
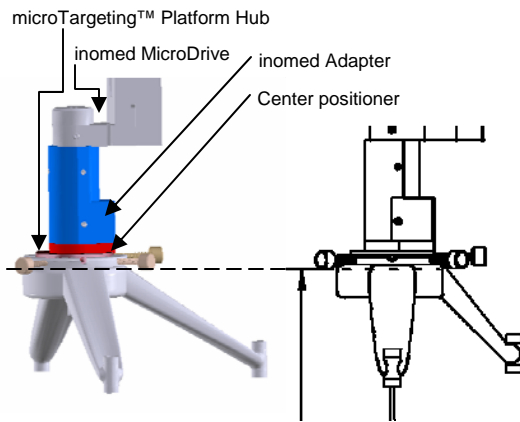
4. If the Platform is a 130 mm target Platform, the inomed MicroDrive will be at target at its zero point on the scale with a 255.2mm microelectrode.

A 120mm targeted platform will be at target at 10 above the zero point, and a 140 mm platform will be at target at 10mm below the zero point.

The combination of the positioning pin on the inomed MicroDrive and the 8 positions available in the Platform hubs will allow the MicroDrive and Microgun to be placed as desired.

Proceed using the Microdrive as it would be used with other stereotactic systems following the MicroDrive IFU. Should an alternate track be needed, refer to the STar Drive Platform Adapter Kit Directions For Use.

System shown with 130mm platform



inomed MicroDrive Adapter for microTargeting™ Platform

For use with the RM/ZD inomed MicroDrive

Directions For Use

L011-73 (Rev. A0, November 2013)

Indications for use: The inomed MicroDrive Adapter for microTargeting™ Platform is intended for use in neurosurgical procedures which require the accurate positioning of microelectrodes, stimulating electrodes, or other instruments in the brain or nervous system.

Compatibilities: The inomed MicroDrive Adapter for microTargeting™ Platform is specifically designed to be used with the microTargeting™ Platform adapter kit AND the inomed MicroDrive. Use with other components or systems is not authorized and may result in mechanical failure or injury.

General Warnings

- ⚠ WARNING: The inomed MicroDrive Adapter for microTargeting™ Platform is shipped non-sterile and must be sterilized before use.
- ⚠ WARNING: Prior to use, the inomed MicroDrive Adapter for microTargeting™ Platform should be completely assembled and correct operation verified to ensure that all components function properly. Improper set-up of equipment may lead to serious patient injury.
- ⚠ WARNING: The inomed MicroDrive Adapter for microTargeting™ Platform is 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.



FHC, Inc.
1201 Main Street
Bowdoin, ME 04287 USA
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



FHC Latin America
Carrera 43 A # 1sur 31
Ed. BBVA oficina 401
Medellín-Colombia

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



www.fh-co.com

General Cautions

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

CAUTION: The inomed MicroDrive Adapter for microTargeting™ Platform is specifically designed to be used with the microTargeting™ Platform Adapter kit AND the inomed MicroDrive.

CAUTION: Use with other components or systems is not authorized and may result in mechanical failure or injury.

CAUTION: Always check the securing thumbscrews and knobs to prevent loosening and movement of the adapter and other components

CAUTION: The inomed MicroDrive Adapter for microTargeting™ Platform is not MRI compatible.

Symbol Key



Warning or caution notices, using the symbol at the left, or **bold type highlighting** denote a potential hazard to the health and safety of users or patients or a need for special attention or care to be taken. These notices clearly state the nature of the respective hazard and the means by which it can be avoided.

Warranty and Service

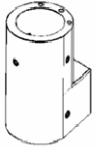
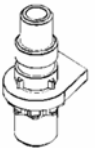
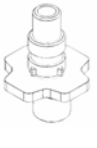
All FHC microTargeting™ products are unconditionally guaranteed against defects in workmanship for one year from date of shipment as long as they have been exposed to normal and proper use.

Should service or repair be required, please contact our 24 hour Technical Service for return authorization and shipping instructions (207-666-8190) or visit www.fh-co.com/FHC_Services.htm

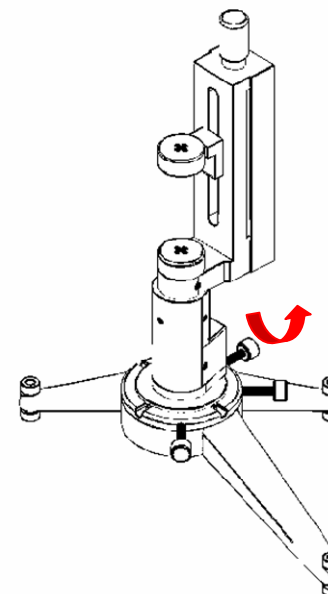
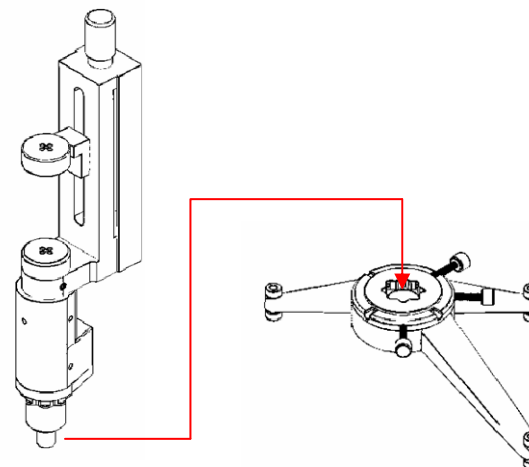
Please include a note indicating:

1. The model number, serial number, and purchase date of the instrument.
2. The name of the Purchaser
3. The name and contact information of a person to contact if questions arise.
4. The "symptoms" indicating that repair is necessary.
5. A statement that the instrument is being shipped free of any biological contamination.

Inventory

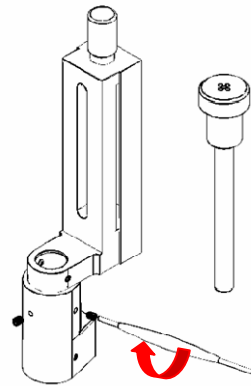
<p>66-WP-IN</p>	<p>inomed MicroDrive Adapter for microTargeting™ Platform: includes parts needed to adapt the inomed MicroDrive to the microTargeting™ Platform Adapter kit.</p>	 <p>SA10-60 inomed MicroDrive Adapter (w 5ea M3X.5, 5mm Setscrews for use with the inomed hexwrench)</p>	 <p>SA8-56-03 Center Positioner</p>	 <p>SA8-57-03 Offset Positioner</p>
------------------------	--	---	--	--

3. Insert the positioner into the microTargeting™ Platform hub and secure (refer to the STar™ Drive Platform Adapter Kit Directions For Use).

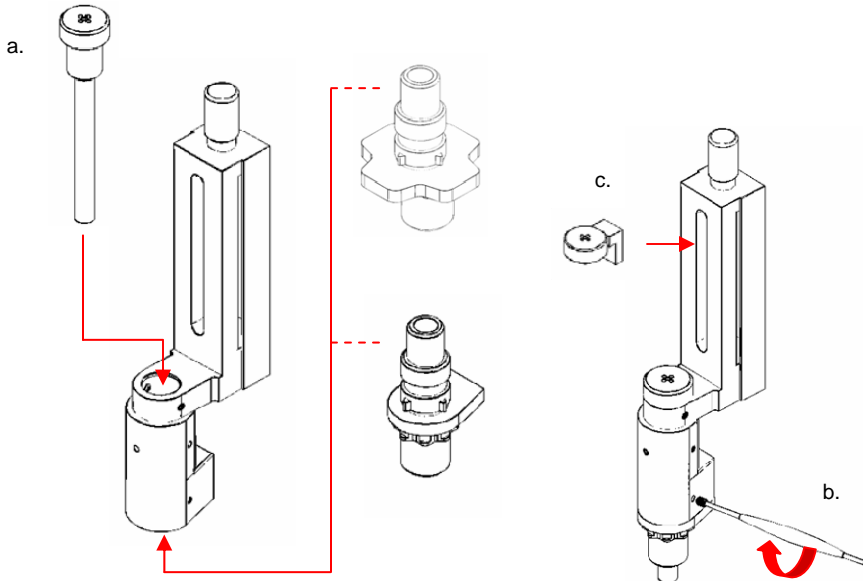


(Illustrated Procedure continued)

- 1b. Using the inomed hexwrench secure the adapter to the MicroDrive with the two of the 5 included M3 x .5 setscrews in the most accessible of the three available locations.

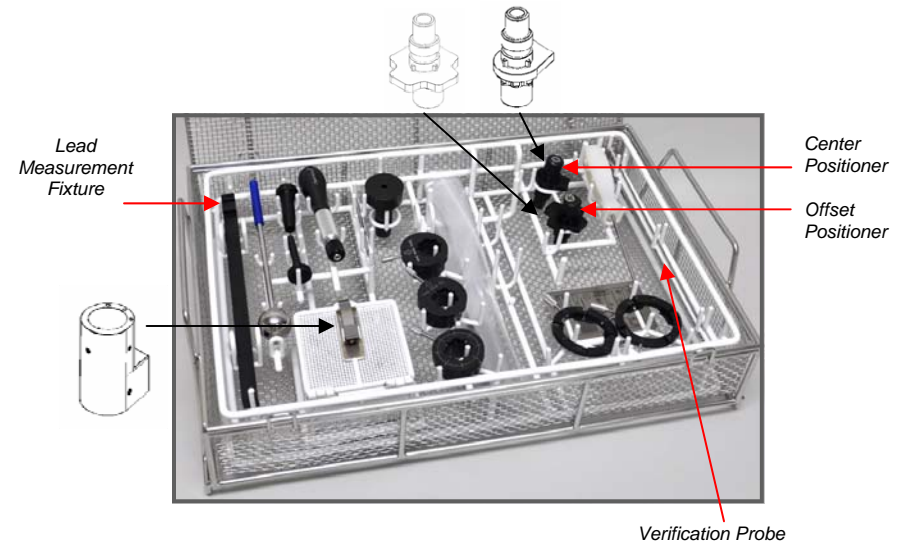


2. The Microgun may be installed in the MicroDrive at this point or later as directed by the MicroDrive Instructions For Use (IFU). Slide the desired positioner into the bottom of the adapter and secure the 2 setscrews using inomed hexwrench. Attach the microelectrode holder to the inomed MicroDrive.



Installation

Remove from the SteriSuite case the following 4 labeled hardware components from 70-FA-SF: offset positioner, center positioner, verification probe, lead measurement fixture and place the components of the inomed MicroDrive Adapter for microTargeting™ Platform as shown below for cleaning, sterilization and storage.



Functional Checkout

The inomed MicroDrive Adapter for microTargeting™ Platform includes: the inomed MicroDrive adapter provided with 5 setscrews, center positioner and offset positioner.

To perform a functional check out:

- Confirm all 5 setscrews are present on the inomed MicroDrive adapter.
- Secure the adapter to the inomed MicroDrive.
- Secure the positioners to the inomed MicroDrive adapter.
- Secure the positioners into the microTargeting™ Platform hub.

Cleaning

Manual Cleaning

1. Prepare the detergent according to manufacturer's recommendations: Asepti Wash Plus liquid (2.5 ml per liter or 1/4 oz per gal), using warm tap water.
2. Separate the MicroDrive, positioners, adapter and immerse them in the wash solution for a minimum of 5 minutes.
3. Using a clean soft cloth that has been soaked in the detergent, wipe the tray, and its insert, to remove any visible soil. Use a soft bristle brush and syringe to reach hard-to-clean areas.
4. Prepare the detergent in a sonication unit according to manufacturer's recommendations: Asepti Wash Plus liquid (2.5 ml per liter or 1/4 oz per gal).
5. Place the parts back in the tray.
6. Immerse the tray in the sonication unit and sonicate for a minimum of 10 minutes.
7. Rinse all components with running reverse osmosis/de-ionized water to remove any residual detergent.
8. Dry components using a clean soft cloth.
9. Visually inspect to ensure all visible soil is removed.

Automated Cleaning

Validated protocol is detailed below.

Protocol				
Phase	Recirculation Time (min)	Water Temperature	Ecolab Inc. detergent (2.5 ml/l or 1/4 oz/gal)	Ecolab Inc. detergent (2.5 ml/l or 1/4 oz/gal)
Pre-Wash 1	2:00	Cold Tap Water (16°C max)	N/A	N/A
Enzyme Wash	2:00	Hot Tap Water (43°C min)	Asepti Wash Plus	Sekusept AR
Wash 1	2:00	65.5°C (Set Point)	Asepti Wash Plus	Sekusept AR
Rinse 1	2:00	Heated Water (66.0°C)	N/A	N/A
Pure Water Rinse	0:10	Heated (66.0°C)	Asepti Rinse	Sekusept FNZ or Sekumatic Multiclean
Dry Phase	7:00	115°C	N/A	N/A

Sterilization

Sterilization should be performed in the Sterisuite.

Gravity Steam Sterilization

Minimum Temperature,
Wrapped: 132°C
Full Cycle Time: 30 minutes
Minimum Dry Time: 35 minutes

Prevacuum Steam Sterilization

Preconditioning Pulses: 3
Minimum Temperature,
Wrapped: 132°C
Full Cycle Time: 12 minutes
Minimum Dry Time: 30 minutes

Maintenance

The inomed MicroDrive Adapter for microTargeting™ Platform is designed to match the microTargeting™ Platform Adapter kit maintenance schedule. It should be inspected visually prior to each use for physical damage, missing screws or poor fit due to wear or residue buildup. If any component shows wear or damage that could interfere with proper function, please contact the manufacturer for repair or replacement. None of the components require lubrication of any kind.

Illustrated Procedure

