

inomed MicroDrive Adapter for microTargeting™ Platform

Directions For Use

L011-73 (Rev C0, 2021-05-14)

Contains directions for the following products:

66-WP-IN

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EC REP



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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.















Intended use

The inomed MicroDrive Adapter for microTargeting Platform is intended for use by a neurosurgeon in an operating environment to position and move devices relative to a planned stereotactic system trajectory and target.

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. A microTargeting Platform Adapter Kit and inomed MicroDrive are required to use this device.

Symbol Key

	WARNING/Caution, Consult instructions for important cautionary information.		Medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC, 98/79/EC and Medical Device Regulation (EU) 2017/745.
	Consult instructions for use.		Telephone number
	In reference to "Rx Only" symbol; this applies to USA audiences only.		European Conformity. This device fully complies with Medical Device Regulation (EU) 2017/745 and legal responsibilities as a manufacturer are with FHC, Inc., 1201 Main Street, Bowdoin, ME 04287 USA.
Rx Only	Caution - Federal law (USA) restricts this device to sale by or on order of a physician		Authorized Representative in the European Community.
	Indicates the catalog number so that the medical device can be identified.		MR Unsafe - an item that is known to pose hazards in all MRI environments.
	Indicates the model number so that the model of the medical device can be identified.		Indicates the use of Radio-Frequency Identification (RFID).
	Indicates Medical Device		
	Instructions for end of life disposal.		
	Date when the medical device was manufactured.		

microTargeting™ and STar™ are trademarks of FHC, Inc.

Warnings and Cautions

-  **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.
-  **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 MR unsafe.

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.

If service or repair is required, please contact a member of Customer Support for return authorization and shipping instructions (207-666-8190).

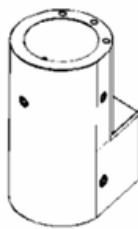
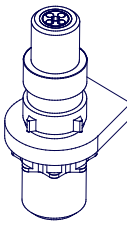
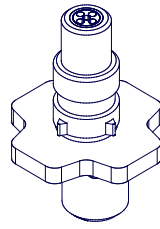
Please provide the following information:


1. Item code and serial number
2. Name and contact information if questions arise
3. Letter indicating issues experienced
4. Decontamination Statement - include in shipment

Disposal

Equipment may be returned to FHC, In Bowdoin, Maine, USA, freight pre-paid for proper disposal/recycling.

Inventory

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

 The products referenced in this document satisfy the FDA's Unique Device Identification Direct Marking requirement through the use of Radio-Frequency Identification (RFID). The RF air protocol is compliant with ISO-18000-6C EPC Global Class 1 Generation 2, and operates at frequencies in the band of 902-928MHz (UHF). The Unique Device Identification number retrieved from the RFID can be used to access product information through the FDA's Global Unique Device Identification Database (GUDID), which is available on the FDA's website.

Installation

Remove from the SteriSuite case the following 4 labeled hardware components from 70-FA-SF-01: 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. Separate the positioners and adapter from the MicroDrive. The MicroDrive and its components should be cleaned and sterilized according to the manufacturer's specifications.
2. 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.
3. Separate the positioners and adapter and immerse them in the wash solution for a minimum of 5 minutes.
4. 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.
5. 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).
6. Place the parts back in the tray.
7. Immerse the tray in the sonication unit and sonicate for a minimum of 10 minutes.
8. Rinse all components with running reverse osmosis/de-ionized water to remove any residual detergent.
9. Dry components using a clean soft cloth.
10. 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 Wash Plus	Sekusept FNZ or Sekumatic Multiclean
Dry Phase	7:00	115°C	N/A	N/A

Sterilization

Sterilization should be performed in the SteriSuite.

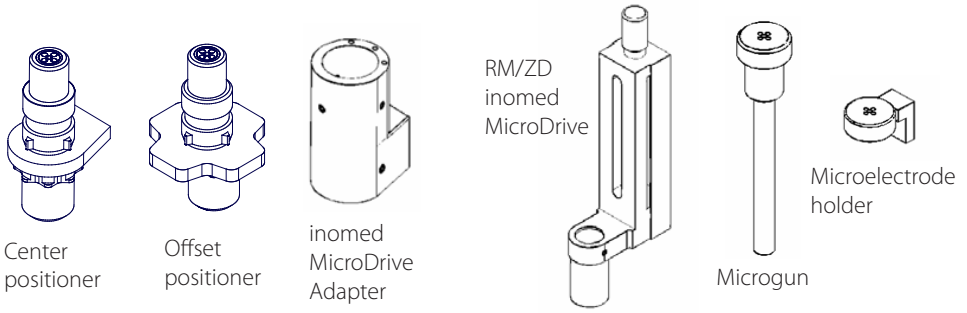
Method	Protocol	
Steam	Gravity wrapped: (in 2 Layers of 1-ply Polypropylene wrap ^[1]) Exposure Time: 30 minutes at 132°C (270°F) Minimum Dry Time: 60 minutes [1] Cycle was validated using Halyard Health H300 wrap	Prevacuum wrapped: (in 2 Layers of 1-ply Polypropylene wrap ^[2]) Preconditioning Pulses: 3 Exposure Time: 4 minutes at 132°C (270°F) Minimum Dry Time: 60 minutes [2] Cycle was validated using Halyard Health H400 wrap
	Prevacuum wrapped: (in 2 Layers of 1-ply Polypropylene wrap ^[3]) Preconditioning Pulses: 3 Exposure Time: 18 minutes at 134°C (273°F) Minimum Dry Time: 60 minutes [3] Cycle was validated using Halyard Health H300 wrap	

User should be aware that the effects of unvalidated sterilization protocols could result in damage to the components and affect their functioning or performance. The Inomed MicroDrive Adapter 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.

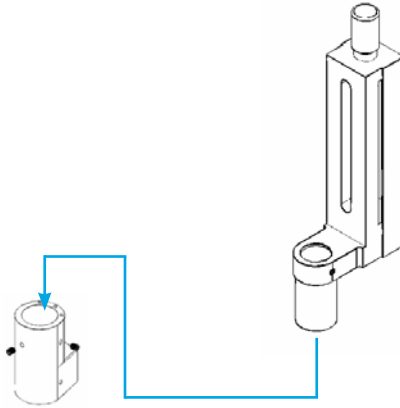
Maintenance

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.

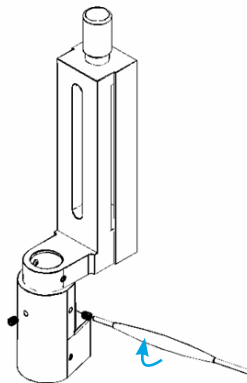
Illustrated Procedure



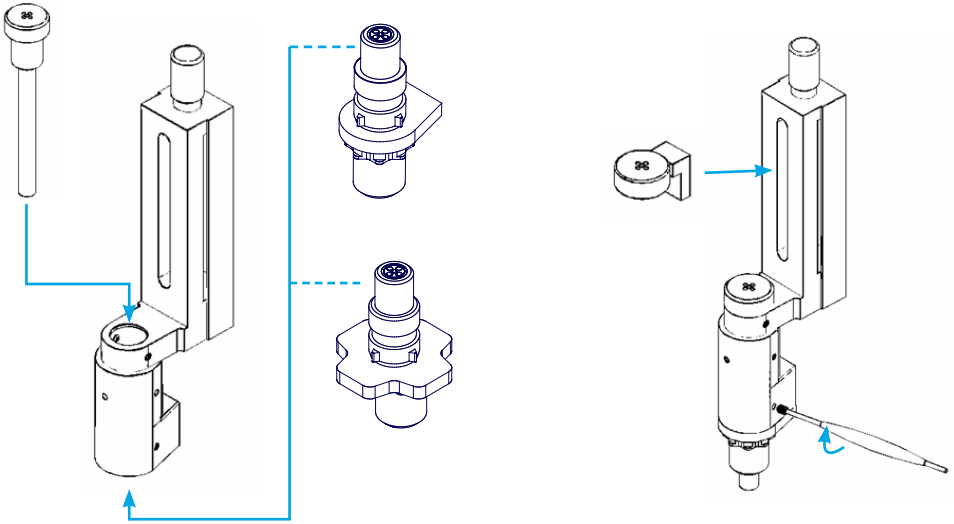
1. Insert the inomed MicroDrive Baseplate fixation ring into the top of the adapter, ensuring that the baseplate positioning pin is engaged on the correct recess for the drive angle desired.



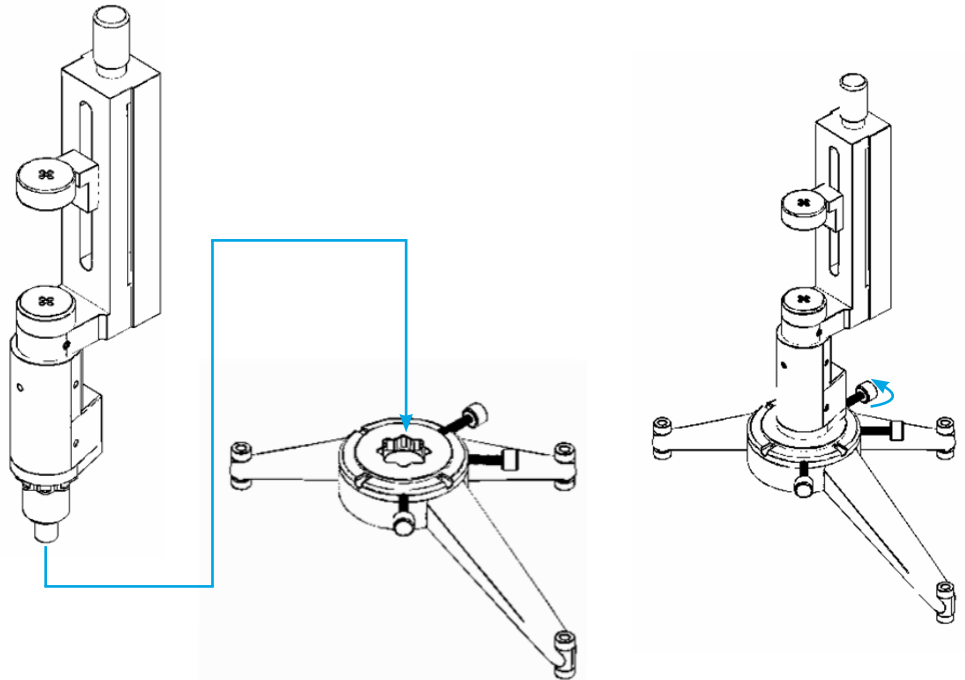
2. Using the inomed hexwrench secure the adapter to the MicroDrive with the two of the 5 included M3 x .5 setscrews in the most accessible of the three available locations.



3. 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.



4. Insert the positioner into the microTargeting Platform hub and secure (refer to the STar™ Drive Platform Adapter Kit Directions For Use L011-44).



5. 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 (L011-44).

System shown with 130mm platform

