microTargeting™

microTargeting™ STar™ Drive System

Directions for Use

Including:
Motor Assembly
Encoder Assembly
Controller/Display Module
Stereotactic Adapters

L011-1007
(Rev. D1, February 2012)

FHC

"Innovation through collaboration"

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

CE 0413

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

EC REP

FHC Europe
(TERMOBIT PROD srl)
129 Barbu Vacarescu Str, Sector 2
Bucharest 020272
Romania

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

Contents

Directions for Use of the STar™ Drive M/E and Manual version are similar. Illustrations herein show the M/E version with accessories. Manual drive users should disregard the sleeved Motor shown in pictures and any instructions labeled with ■ *.*

microTargeting™ STar™ Drive System, Accessories and Stereotactic Adapters

Indications for use: The microTargeting™ STar™ Drive System is intended to be used with commercially available stereotactic systems for neurosurgical procedures which require the accurate positioning of microelectrodes, stimulating electrodes, or other instruments in the brain or nervous system.

Contraindications: Follow the general guidelines concerning the suitability of neurosurgery involving the insertion of electrodes, instruments or devices.

Warnings

WARNING: If any error or erratic function is observed, discontinue use of the Drive System immediately and evaluate the potential impact to patient safety before continuing its unmitigated use.

WARNING: Prior to use, the microTargeting™ STar™ Drive System 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: Always confirm the tightness of thumbknobs, especially those holding the frame adapter, before beginning the procedure. The stereotactic adapter must be securely held in the frame mount so that the drive system cannot move or rotate.

Cautions

CAUTION: The microTargeting™ STar™ Drive M/E System Motor and Encoder Accessories are specifically designed to be used with the microTargeting™ STar™ Drive M/E. Use with other components or systems is not authorized and may result in mechanical failure or injury.

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

CAUTION: FHC's regulatory clearance requires that microTargeting™ STar™ Drive Systems and components be factory evaluated by an authorized representative on an annual basis or serviced and recalibrated every 100 uses, whichever comes first.

CAUTION: Do not use non-approved stereotactic system adapters, insertion tubes or other medical or electronic devices with the microTargeting™ STar™ Drive System.

CAUTION: Handle the Drive and, when applicable, its Motor and Encoder Accessories with extreme care. These components may be damaged if excessive force or incorrect handling occurs.

CAUTION: The Drive System and its associated insertion tubes are not MRI compatible.

CAUTION: When tightening the STar™ Array Locking Carrier screws that are difficult to reach by hand, use only the tool provided. When tightening all other screws and thumbknobs, hand tighten only. Overtightening can cause damage to the Drive System and adversely affect targeting.

Symbol Key

Warnings should be read carefully because if they are not heeded they could lead to situations which may result in serious injury or death.

! USA Rx Only

Hand Tighten Securely

Type BF Equipment
(electrically isolated from patient)

Zero

Retract

Advance

Retract to Zero

0 I Off/On

Remote Control

Power Assist or Display Assembly

Serial Communications Port

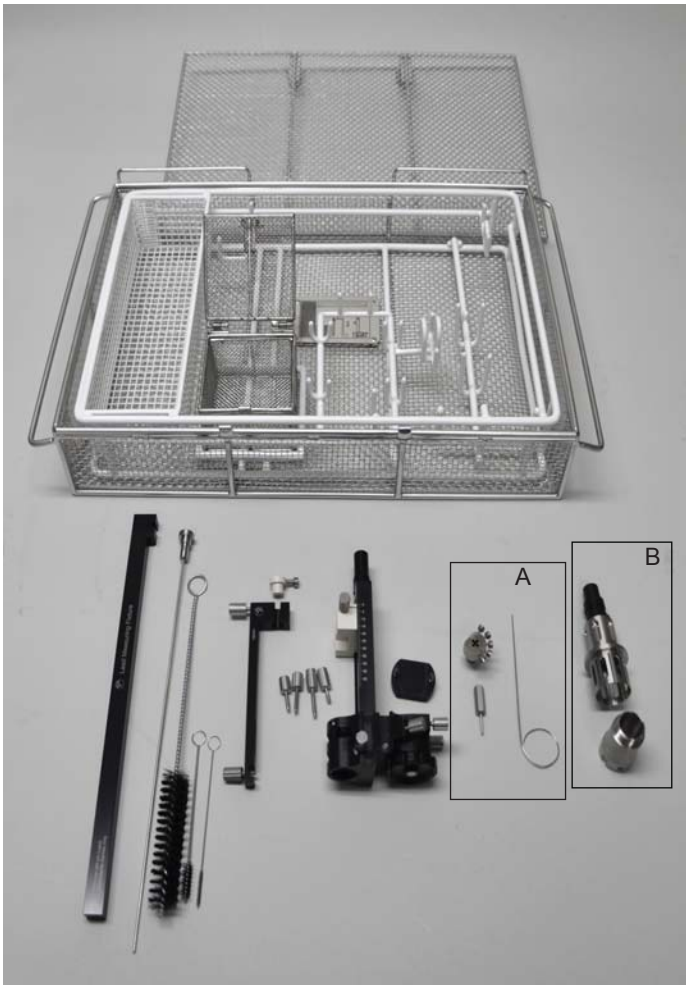
STERILE Sterile

STERILE Non-sterile

Storage

Store the microTargeting™ STar™ Drive System and, when applicable, the Motor/Encoder Accessories at temperatures between –34°C (-29°F) and 57°C (135°F). Do not exceed 135°F for long-term storage.

Sterilizable components

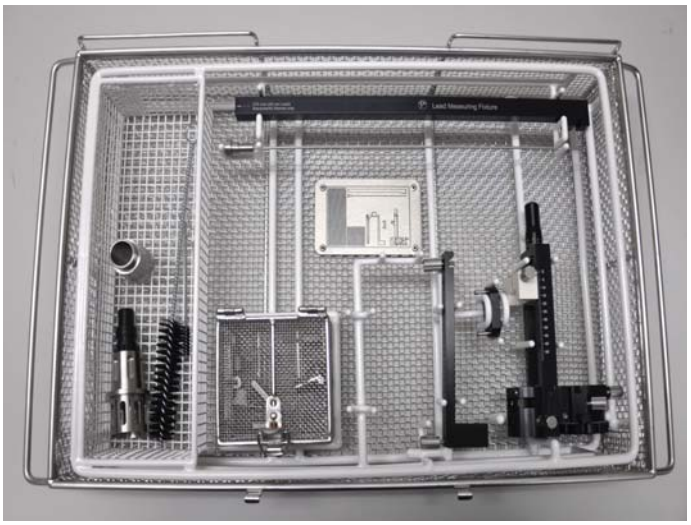


microTargeting™ STar™ Drive System components (Drive, carrier and frame adapter) that require sterilization. Shown with [A] STar™ Array locking carrier and [B] STar™ Frame Adapter for Radionics CRW™.

Disassembly for Cleaning and/ or Sterilization

Using a clean soft cloth that has been soaked in the detergent solution (page 6). Wipe the tray and its insert to remove any visible soil. Use the soft bristle brushes to reach hard-to-clean areas, especially the lumen of the Frame Adapter Guide Tube.

Remove and put the small extra parts in the basket, then position the other components as shown below.

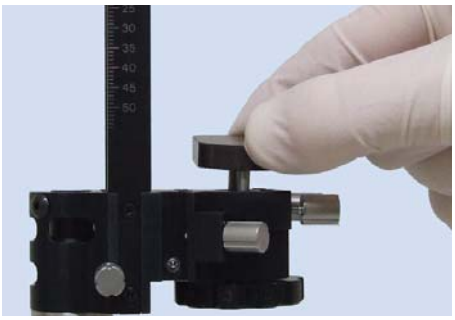


Tray with correct positioning of all sterilizable components.

Cleaning of Sterilizable Components

CAUTION: The cover is provided to protect the opening of the STar™ Drive M/E when an accessory is not attached. Failure to use the cover could allow debris to enter the drive mechanism. The cover should be removed during cleaning and sterilization to allow proper drainage from this mechanism.

The cover should be kept in the sterilization tray basket so that it is available in case the drive is to be transported or stored in the tray without the sterile wrap.



WARNING: None of the Drive Electronic Accessories should be cleaned or sterilized using the methods described on pages 6-7; use the sterile draping system as described on pages 11-12 to assure they do not contaminate the sterile field, and the procedure on page 38 to remove any soiled materials.

* *Refer to system diagram on pages 19-20 for the components identified with letters, listed below.*

Manual Cleaning

	Items Covered	Protocol
STar™ SteriSuite case needed (L)	**Drive and its Components** * **STar™ Drive M/E with cover removed** (J) **STar™ Drive** (I) **Lead Holder** (M) **Electrode Depth Stops** (O, Y, X, SA, SB) **Measuring Fixture** (N) **Frame Adapter** (S, T, U, V, YY, ZZ) **Verification Probe** (A)	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 Drive, stereotactic adapter, and Lead Holder and immerse them in the wash solution for a minimum of 5 minutes. Actuate the devices during the soak. 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. Place the Drive and its components back in the tray. 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. 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.
	Insertion Tubes and Spacer Tubes (AA, BB, CC, KK, LL, SAA, SBB, SCC, SDD)	1. Immediately following use, thoroughly rinse each tube and other components separately under tap water. Repeatedly insert the Stylet or Spacer Tube cleaning tool in and out of the tube under running tap water to dislodge any debris or coagulated fluid. 2. Soak all components in wash solution, then repeat step one (as above) then rinse in distilled water. 3. Insertion Tubes, Spacer Tubes, and Stylets MUST be steam sterilized as separate items (not assembled).

Automated Cleaning - Use tray with disassembled components (page 5)

	Items Covered	Protocol				
		Phase	**Recirculation Time (min)**	**Water Temperature**	**Ecolab Inc. detergent** (2.5 ml/l or 1/4 oz/gal)	**Ecolab GmbH detergent** (2.5 ml/l or 1/4 oz/gal)
STar™ SteriSuite case needed (L)	**Drive and its Components *** ***ONLY*** **STar™ Drive M/E with cover removed** (J) **STar™ Drive** (I) **Lead Holder** (M) **Electrode Depth Stops** (O, Y, X, SA, SB) **Measuring Fixture** (N) **Frame Adapter** (S, T, U, V, YY, ZZ) **Verification Probe** (A)	**Pre-Wash 1**	2:00	Cold Tap Water (16°C maximum)	N/A	N/A
		Enzyme Wash	2:00	Hot Tap Water (43°C minimum)	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

WARNING: The use of unvalidated sterilization protocols could result in damage to components and affect their functioning or performance.

Method	Container	STar™ Drive	Tubes	Protocol
Steam		✓		**Prevacuum (Wrapped)** preconditioning pulses: 3 minimum temperature: 132°C (270°F) full cycle time: 12 min minimum dry time: 30 min **Gravity (Wrapped)** minimum temperature: 132°C (270°F) full cycle time: 30 min minimum dry time: 35 min
Steam			✓	**Prevacuum (Wrapped)** preconditioning pulses: 3 minimum temperature: 132°C (270°F) full cycle time: 4 min minimum dry time: 20 min **Gravity (Unwrapped)** minimum temperature: 132°C (270°F) full cycle time: 10 min

Following sterilization, before reassembling the Drive System, use a cloth dampened with sterile distilled water to wipe off surfaces to prevent residue build up. The system should be examined after each sterilization cycle for damage and function.

Maintenance and Calibration of the Drive

All components of the Drive should be thoroughly cleaned, then rinsed with distilled water following each use. None of the system's moving parts require lubrication. Do not oil or lubricate.

Before each use, thoroughly examine the microTargeting™ STar™ Drive System for function, cleanliness, and calibration. Any noticeable change in accuracy, in ease of movement, or any buildup of residues, looseness, damage, or difficulty of fitting components will require return to the manufacturer for refurbishing and recalibration.

Specifications

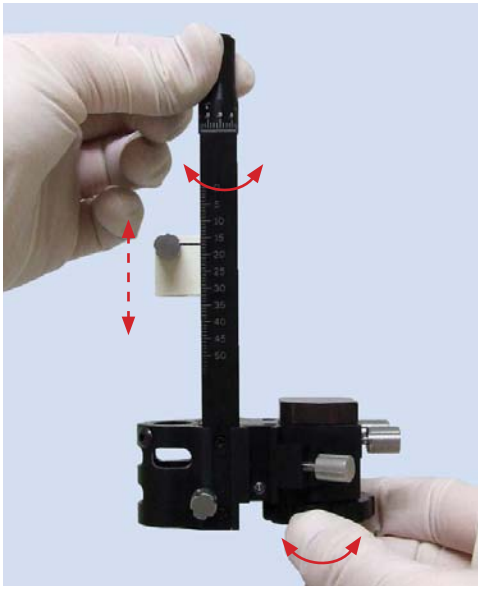
Usability

Drive Platform Travel: 50 mm, graduated in 1mm increments from 0 to 50 mm.
Drive advancement knobs: 1mm movement/revolution, 0.025mm graduation
Array spacing: 2.00 mm from center:
Array guide hole diameter: 1.88mm
Electrical requirements (Controller module): 100-240 volts, 50-60Hz, 0.8 Amps

Emitted Radiation

All electrical components have been tested to certify they meet requirements of ISO 60601.

Pre-Use Assembly and Checkout



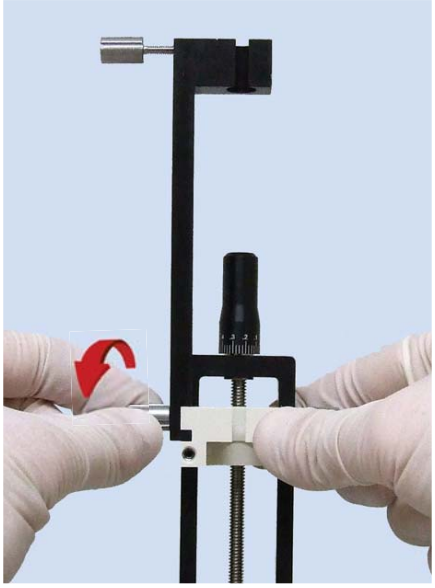
1. Confirm there are no contaminants or debris on the Drive. Turn both knobs separately, confirm that the Drive screw rotates and that the electrode platform moves. Confirm that there are no stiff spots, skipping, free play or backlash present when turning the knob. Confirm that the knob(s) turn easily without excessive resistance.

WARNING: If any error or erratic function is observed, discontinue use of the Drive immediately and evaluate the potential impact to patient safety before continuing its unmitigated use.

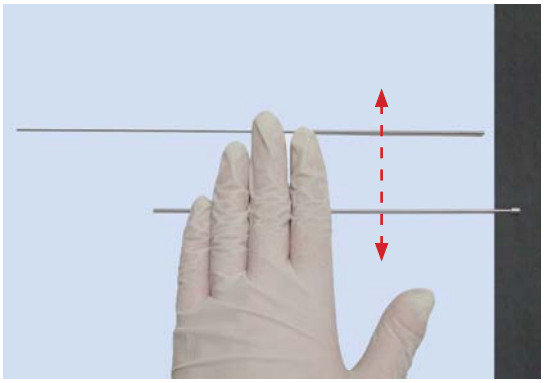
WARNING: While often snug, all tubes used with the microTargeting™ STar™ Drive System have been designed to be inserted and removed by hand or by using the STar™ Insertion Tube Extractor. Any other tool should be used only as a last resort and indicates system repair may be necessary.

WARNING: Do not use the STar™ Insertion Tube Extractor with any other tube than the STar™ Array Insertion Tube.

2. Confirm all thumbknobs are present.



3. If using the 40cm lead, test mount the Lead Holder on the positioning platform, confirm there are no stripped threads or looseness.



4. Inspect the Insertion Tubes.

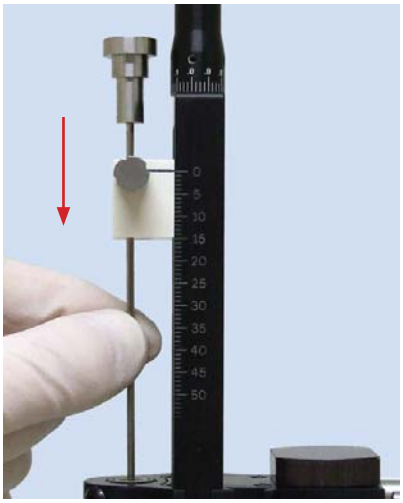
WARNING: As the most critical component of a procedure, delicate Insertion Tubes should always be carefully inspected before use because damage to them can cause targeting errors and impact patient safety. Handle Insertion Tubes and Spacer Tubes carefully to prevent bending.

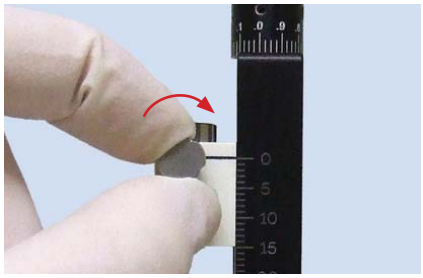
WARNING: Check to be certain that tubes are straight; with the collar over the edge, roll the Insertion Tube over a flat surface or in the Measuring Fixture slot.

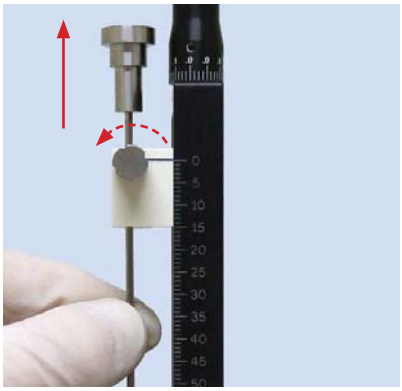
5. Secure the Stereotactic Adapter to the Drive. (See pages 39-52 for appropriate type.)

6. Install the Verification Probe onto the positioning platform; tighten the locking screw. When the stereotactic system and the Drive are set up correctly, the tip of the Verification Probe will be exactly at the predicted target. If the stereotactic system used has a phantom, confirm the targeting coordinates at this step. If not, proceed.

> ⚠ **WARNING: The verification probe should never enter the brain.**







7. Remove the Verification Probe.

Motor/Encoder Accessories: Sterile Draping

Draping the Assembly can be accomplished by one person, but is facilitated if an assistant is present. The one-person method will require a sterile gloved hand (STERILE) for the drape. The other hand will be a non-sterile hand (STERILE) after handling the module. Most will find that the module hand should be the least favored hand. A practice draping should be done before first surgical use.

1. STERILE (or prior to putting on sterile gown and gloves): Remove the protective storage cap from the Coupling Unit. To remove any debris, wipe the alignment and center drive pins with an isopropyl alcohol dampened, lint free cloth or wipe. Coil the assembly's cable and place it on a flat surface so that it can be picked up with its cable in one hand.

2. STERILE : Remove the drape from its sterile packaging and expand the opening to allow entry of a hand. Do not pull any of the folds out at this time. (If one person, remove the included elastic bands from their tape holder and place on a sterile surface.)

3. STERILE : Holding the non-sterile assembly with the pins pointing away from you, and the coiled cable in the same hand, slide it into the drape, being careful not to touch the outside of the drape.

4. STERILE : Push the drape over the STERILE hand so the assembly and cable are all the way at the end of the sleeve. Note that the draping process results in the alignment and motor drive pins, which are non-sterile, protruding from the sterile drape.

> ⚠ **WARNING: After draping the accessories, do not touch the mounting or drive-plate pins against any sterile field elements. These pins should only be allowed to contact the top of the STar™ Drive M/E, and will be inaccessible when fully assembled.**

5. STERILE and STERILE : Maneuver the drape and assembly so that the two alignment pins and the center drive plate are entering the cutouts in the end of the drape.

6. STERILE and STERILE : Push the pins and the center drive plate through the cutouts and smooth the stretchable end of the drape over the assembly.

7. Take the elastic bands and stretch them over the assembly, using at least two wraps. Be careful to smooth any wrinkles from the mating flat surface of the assembly as this is done. Do not touch the pins or drive plate. Ensure the wraps are above the flanges on the assembly to prevent slipping.

8. STERILE : Hold the drape with the assembly inside while STERILE hand pulls the cable from the drape. Be careful not to touch the pins protruding from the end of the drape.

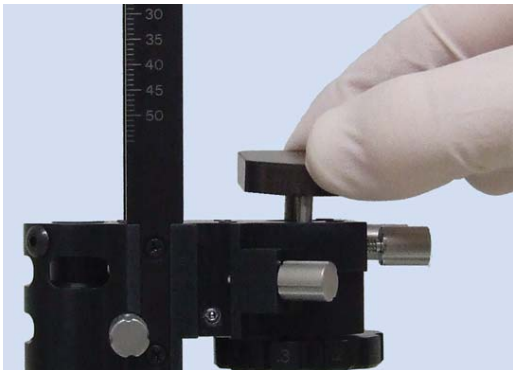
9. STERILE : Unfold the drape carefully as the cable is withdrawn. When the cable is out of the sterile envelope distance, the STERILE hand can hold both the cable and the drape.

10. STERILE : Using the tape that the elastic bands came in, pull in the folds of the drape tightly above the assembly and tape neatly. If no assistant is helping, this can be done after changing the non-sterile glove.

11. STERILE : The assembly cable can be plugged into its receptacle, or

    STERILE : The whole draped apparatus set aside on a sterile surface awaiting the surgery. In this case, it is best to leave the cable inside the drape and to not unfold the drape more than necessary until it is needed.

Motor/Encoder Accessories: Mounting the Draped Assembly



1. Remove the protection cover of the Drive.

2. Pick up the assembly and insert the two long alignment pins slightly into the holes in the top cover. There is no incorrect way to align the pins. Do not force the assembly any further at this time.

3. Push down lightly on the Assembly while turning the Drive advancement knob slowly.

   Since the center drive plate of the Encoder Assembly, if used, turns so easily it may be necessary to pull it away from the turning plate in the Drive slightly and push down lightly several times before alignment occurs. Do not attempt to force engagement as damage to the mechanism can occur.

4. When the pins are felt to engage, gently push the Assembly all the way down to the top cover of the Drive. Make sure no folds of the sterile drape are caught between surfaces.

WARNING: Always confirm the Encoder or Motor Assembly seats squarely on the Drive. A misalignment may result in a stall. (See page 16.)

CAUTION: Never turn the manual advancement knob on the microTargeting™ STar™ Drive M/E while a motor is engaged. This can damage both the motor and the Drive.

5. Tighten the Assembly locking knobs securely and test the Assembly for secure attachment.

Motor/Encoder Accessories: Controller/Display Module

WARNING: Position connecting cables and leads where they will not be inadvertently pulled or tangled.

WARNING: Do not operate the controller unit in the presence of flammable anesthetics.

WARNING: Do not connect simultaneously an Encoder Assembly and a Remote Control into the microTargeting™ Controller or this will result in display errors.

Warning: If motor or drape sleeve sterility is compromised at any time during the procedure it must be replaced and the process begun again as described on Page 11.

CAUTION: The accessory components should be inspected visually prior to each use for physical damage, frayed or kinked cables or damaged connectors.

1. It is assumed at this point that either the Encoder or Motor Assembly is draped and attached to the Drive.
   - Ensure the power supply's line cord is plugged into a power outlet.
   - Connect the Assembly to the Module by inserting its connector into the corresponding socket on the front panel labeled with the following symbol.

   - If using the Motor Assembly, connect the Remote Control to the Module front panel mating connector labeled with the following symbol.

   - Connect the power supply to the Module (back panel).

CAUTION: Alternative power supplies and sources are not authorized for use with this equipment and may cause malfunction or injury.

2. Activate the ON/OFF switch in the back panel of the Module.

CAUTION: If the Retract to Zero button on the Remote Control is inadvertently pressed for at least 5 seconds before the next step, the Module will go into its Remote calibration mode. The calibration procedure described on page 16 must be followed before the Remote will function normally.

- For the Encoder Assembly, advance or retract the Drive using the advancement knob.
- For the Motor Assembly, turning the Remote Control knob clockwise advances the Drive towards the target, turning the knob counterclockwise retracts the Drive away from the target location. The further the knob is turned, the faster the Drive will advance or retract. Full clockwise position will advance the Drive at the highest possible speed, full counterclockwise position will retract the Drive at highest possible speed.
- If there is any movement of the Drive when the Remote Control knob is in the center (resting) position, follow the calibration procedure on page 16.

⚠ **WARNING: Be careful when moving the Drive above the zero mark or below 50mm prior to pressing the zero button. It is possible to move the Drive into its physical limits. Carefully observe travel direction when using the Remote Control before the Drive is zeroed. After the Drive is zeroed, the Controller will not allow movement beyond the Drive limits of 0.00 and 50.0mm.**

CAUTION: Never turn the manual advancement knob on the microTargeting™ STar™ Drive M/E while a motor is engaged. This can damage both the Motor and the Drive.

CAUTION: Pre-use check should include retracting or advancing the Drive Motor using the handheld remote. Confirm that the knob can be turned to its clockwise (advance) and counterclockwise (retract) limits and when released returns to the center position. No movement of the Drive should occur when the remote control knob is in the center resting position. If there are any abnormalities, perform the calibration procedure.
(See page 16.)

3. If a Motor is used, set the Drive to zero by using the remote control. If an Encoder is used, turn the advancement knob to zero. Press the zero button, labeled ⌀, (front panel on the Module) to set the LED display to 00000µm.

⚠ **WARNING: Always confirm that the microTargeting™ STar™ Drive M/E is set at 0mm when zeroing the microTargeting™ Controller. (As a safety feature, the Display Unit cannot be re-zeroed without powering off the Module.) Not doing so will cause the Drive limit to be incorrect and also will cause the Controller Display to be out of sync with the drive position as read on the drive scale.**

CAUTION: Do not zero the Display Unit until prompted. Failure to do so will result in display errors.

4. When the Drive is advanced, the position report on the LED will be updated and will show either the real distance traveled from the zero position, or the distance from the target location depending on the distance mode. Distance is shown in microns or millimeters, depending on the operator's preference. The arrow symbol in front of the position number indicates direction of travel or will point to the position readout at rest.

⚠ **WARNING: In the event of any Drive Accessory failure, erratic function or motor stall, remove it and proceed using the microTargeting™ STar™ Drive M/E manually.**

⚠ **WARNING: During the procedure, periodically compare the physical scale depth reading with Controller reading to ensure proper operation. If the two scales differ by more than 25 microns, discontinue use of the Display Unit and proceed manually.**

⚠ **WARNING: The microTargeting™ Controller has been factory set to enforce a software drive limit of 50mm which corresponds with the maximum travel of the microTargeting™ STar™ Drive M/E. This limit may be changed through the serial interface of the microTargeting™ Controller. However, setting the limit beyond 50mm could result in drive travel beyond the range of the Drive.**

Remote Control Calibration *(If needed)*

With the Motor Assembly and Remote Control connected and the power on, press on the Retract to Zero button on the Remote Control for at least 5 seconds to enter the calibration menu. The display will show “REMOTE CALIBRATION...ADVANCE”.

Turn the knob in the fully clockwise position then while holding the knob in the full clockwise position, press and release the retract to zero button. The display will show “RETRACT”.

Turn the knob all the way counterclockwise and hold it while pressing the Retract to Zero button.

This calibration procedure may need to be repeated several times.

Check again for correct function, and if any errors are noted the units should be returned to FHC for service.

microTargeting™ Controller Stall Detection

In the event of a stall, make certain there is no physical obstruction.

A stall algorithm has been provided so that if a stall is detected during Drive movement, the word “STALL” will appear on the display, and the Drive will stop moving, then the position number will be redisplayed but the Drive will not continue moving. To restart turn the knob of the remote control.

The number displayed should be checked against the Drive’s physical scale. A small discrepancy of less than 25 microns is not a cause for concern.

Discrepancies of over 25 microns or frequent stall warnings indicate repair is necessary. In order to complete the procedure, disconnect accessories and proceed using the manual advancement knob.

FHC should be contacted for service or repair.

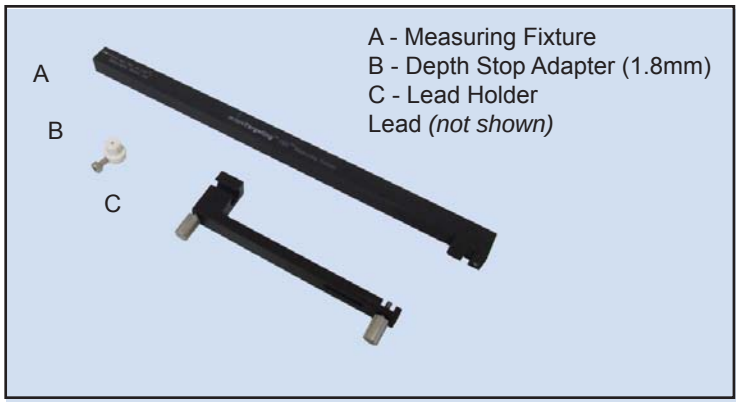
Mounting the Drive on the Stereotactic System

Mount the assembled system onto the stereotactic system and secure it as shown on pages 39-52. Make sure the securing screws are tight to prevent movement or rotation. Confirm that the Drive mounts securely on the frame mount.

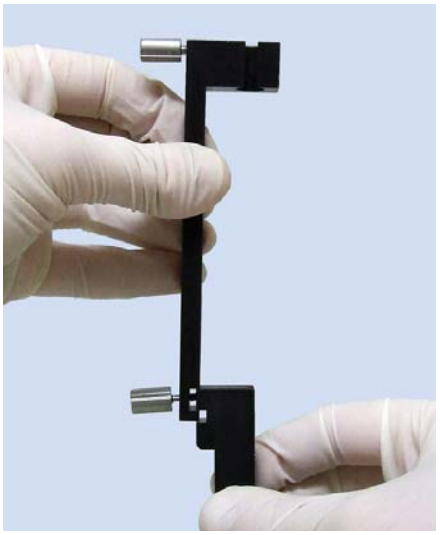
WARNING: Always confirm the tightness of thumbknobs, especially those holding the frame adapter, before beginning the procedure. The stereotactic adapter must be securely held in the frame mount so that the STar™ Drive System cannot move or rotate.

WARNING: The Motor/Encoder should be attached to the Drive before it is mounted on the stereotactic system to avoid exposing the assembly mounting pins to the patient sterile field.

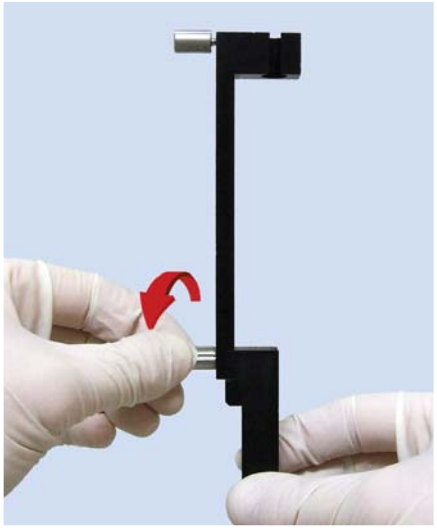
Preparing the 40cm Lead for Implant



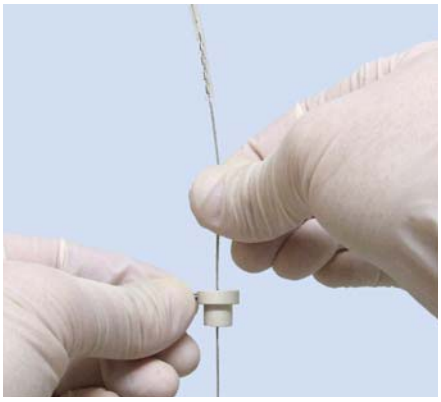
Note: Preparation should be done in a sterile area.



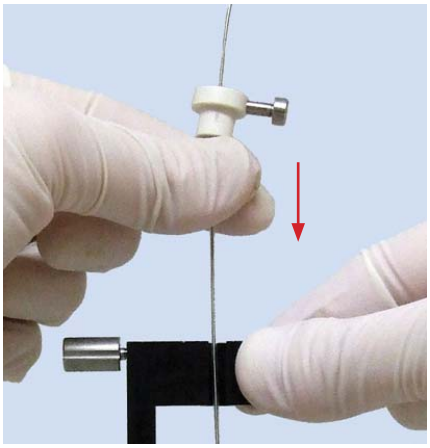
1. Attach the Lead Holder to the Measuring Fixture.



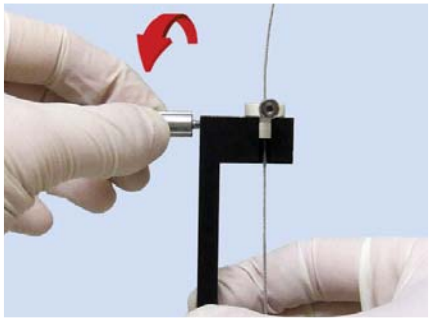
2. Secure the Lead Holder to the Measuring Fixture.



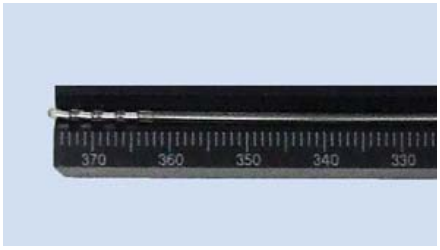
3. Place the Depth Stop Adapter (1.8mm) loosely on the lead.



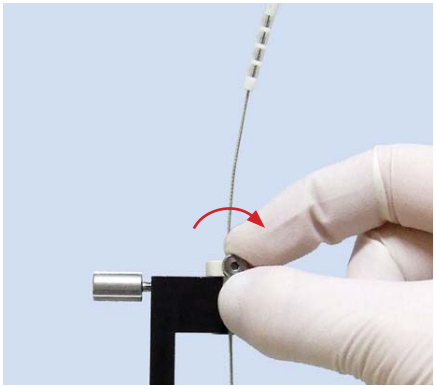
4. Insert the lead and Depth Stop Adapter (1.8mm) into the Lead Holder.



5. Secure the Depth Stop Adapter (1.8mm).

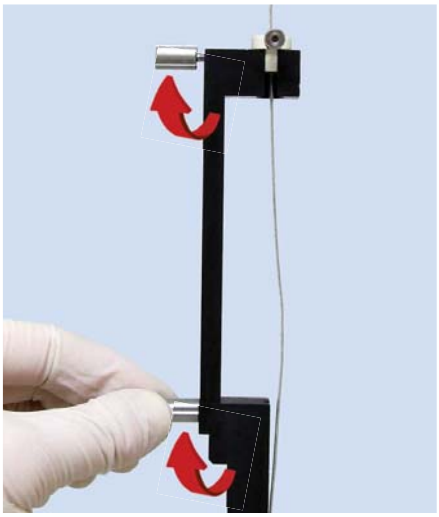


6. Position the lead contact area at the end of the Measuring Fixture.

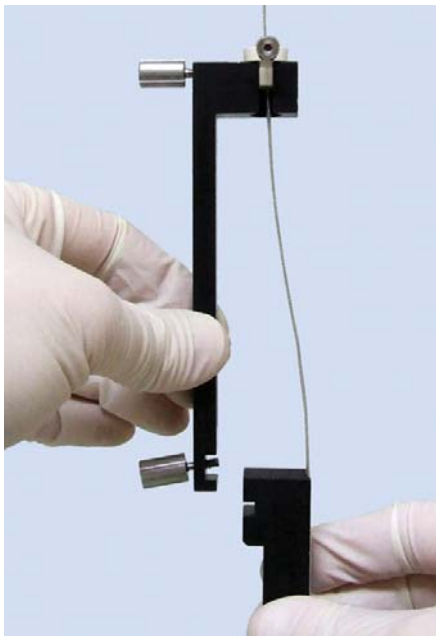


7. Tighten the lead.

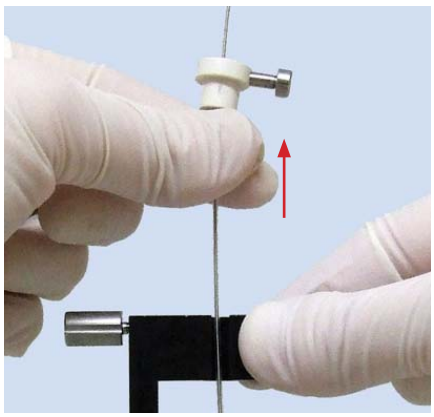
> ⚠ **WARNING: Do not over tighten this screw as it may damage the lead.**



8. Loosen the Lead Holder.



9. Remove the Lead Holder and lead with preattached Depth Stop Adapter (1.8mm) from the Measuring Fixture.



10. Remove the Depth Stop Adapter (1.8mm) from the Lead Holder, and set aside in a sterile area for later use.

microTargeting™ STar™ Drive System - Stereotactic frame configuration

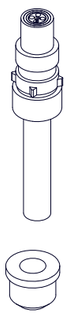
Ordering information **FHC** - Medtronic

A	Verification Probe,	**66-IT-VP**
B	Positioning platform	
C	Electrode carrier locking screw	
D	Drive advancement knob (upper)	
E	Drive advancement knob (lower), M/E version only	
F	Stereotactic positioner locking knob	
G	Lower Guide (for 70-ZD-ME only)	**70-LG-01**
H	Lower guide locking knob, M/E version only	
I	STar Drive manual	**70-ZD-MA**
J	STar Drive Motor/Encoder	**70-ZD-ME**
K	Cleaning brushes	**66-CN-BR**
L	STar Steri Suite	**67-00-7**
M	Lead Holder	**70-CN-DB** *(includes M,O)*
N	Lead measurement fixture	**70-AC-MT**
O	1.8 mm Depth Stop Adapter	**66-AC-DS(1.8)**
P	Protection Cover, M/E version only	
Q	Accessory locking knobs, M/E version only	

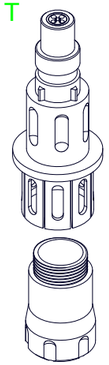
Frame Adapters - one needed but not included - Ordering Information

S	STar™ Frame Adapter for Leksell Stereotactic System w/ lower arm bushing,	**70-FA-LX /** FC8003
T	STar™ Frame Adapter for Radionics CRW™	**70-FA-RD /** FC8004
U	STar™ Frame Adapter Leibinger RM™	**70-FA-RM /** FC8005
V	STar™ Frame Adapter for Leibinger ZD™	**70-FA-ZD /** FC8006
W	STar™ Frame Adapter for BrainLAB/MICROMAR	**70-FA-BL**
YY	STar™ Offset Frame Adapter for Leksell Stereotactic System	**70-FA-LX-01**
ZZ	STar™ Offset Frame Adapter for Radionics CRW ™	**70-FA-RD-01**
	STar™ microTargeting Platform Adapter Kit (not shown)	**70-FA-SF**

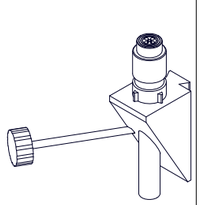
STar™ Frame Adapter for Leksell Stereotactic System with Lower Arm Bushing
S



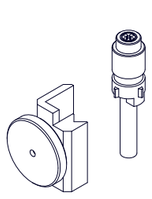
STar™ Frame Adapter for Radionics CRW ™
T



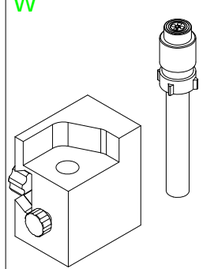
STar™ Frame Adapter Leibinger RM™
U



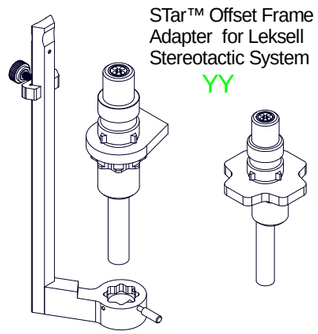
STar™ Frame Adapter for Leibinger ZD™
V



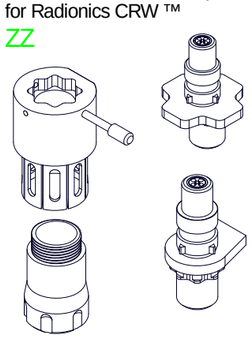
STar™ Frame Adapter for BrainLAB/ MICROMAR
W



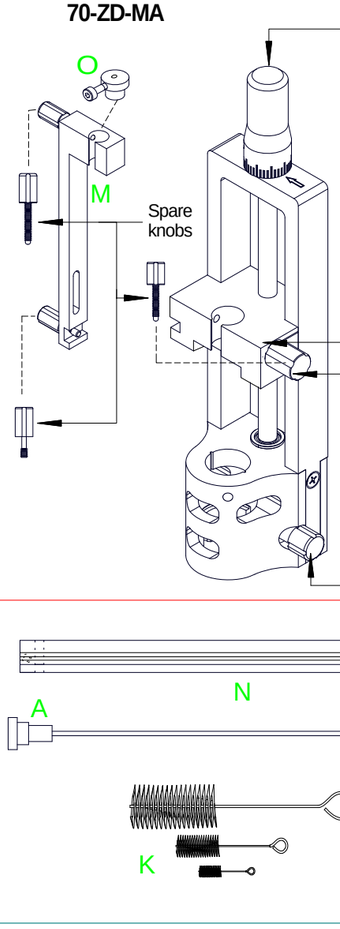
STar™ Offset Frame Adapter for Leksell Stereotactic System
YY



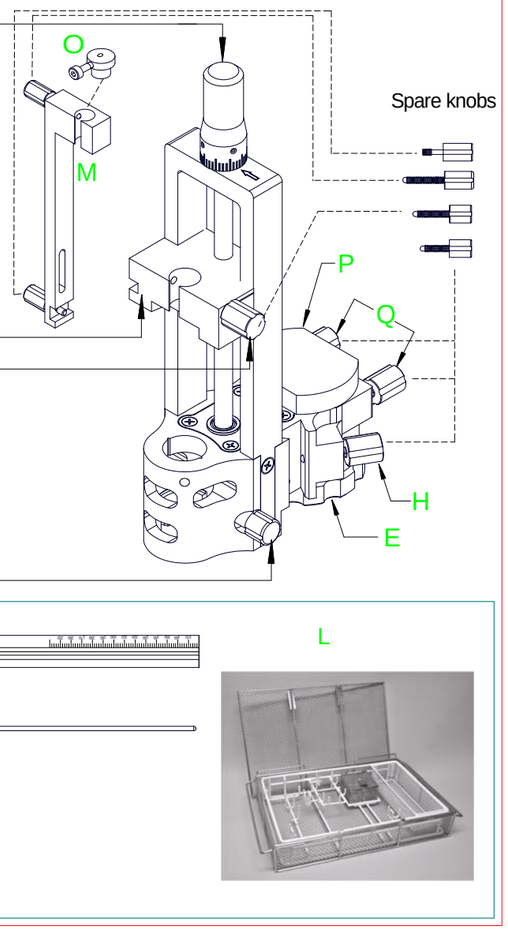
STar™ Offset Frame Adapter for Radionics CRW ™
ZZ



I STar Drive Manual
70-ZD-MA



J STar Drive Motor/Encoder
70-ZD-ME



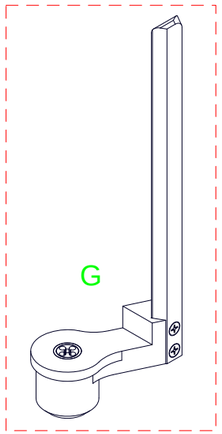
L

microTargeting™ STar™ Drive System ordering information:

ST-DS-MA / FC8001 includes I, A, K, L, N

ST-DS-ME / FC8002 includes J, A, K, L, N

Optional Equipment
G Lower Guide (for use with 70-ZD-ME only), **70-LG-01 /** FC8007

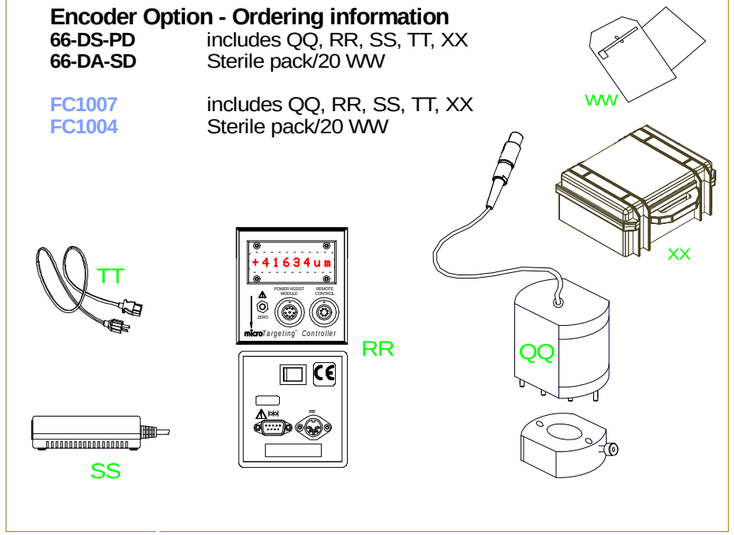


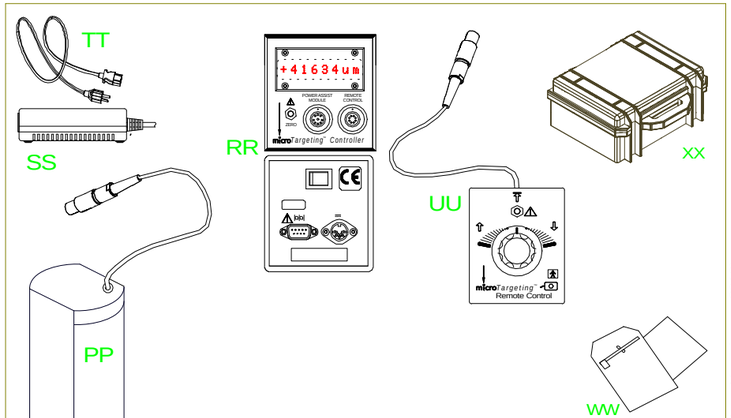
Drive Motor and Encoder Accessories

PP	Power Assist with Display Assembly (motor)	**66-DA-ME**
QQ	Position Display Assembly (encoder)	**66-DA-EN-02**
RR	Power Assist Controller/Display Module	**66-EL-MS**
SS	Power supply	
TT	Power Cord	
UU	Remote Control	**66-EL-RM**
WW	Sterile Drapes Sleeves	**66-DA-SD**
XX	Storage Case	**66-DA-SC**

Encoder Option - Ordering information

66-DS-PD	includes QQ, RR, SS, TT, XX
66-DA-SD	Sterile pack/20 WW
FC1007	includes QQ, RR, SS, TT, XX
FC1004	Sterile pack/20 WW





Motor Option - Ordering information

66-DS-PA	includes PP, RR, SS, TT, UU, XX
66-DA-SD	Sterile pack/20 WW
FC1008	includes PP, RR, SS, TT, XX
FC1004	Sterile pack/20 WW

See reverse for Insertion Tube and microelectrode Sets: Single and Array

Single Electrode frame configuration

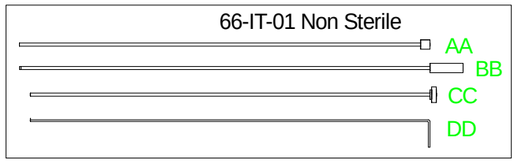
Ordering information

70-AC-01 / FC1010	**Non Sterile STar Single Electrode Carriers** includes 2ea Y
66-IT-01P	**Sterile Single Electrode Insertion Tubes** includes AA, BB, CC (pk 5) 40 mm above target
66-IT-01	**Non Sterile Single Electrode Insertion Tube Set** includes AA, BB, CC, DD - Standard tube ends at 40 mm above target. See table with additional lengths →
66-IT-05P / FC1036	**Sterile Single Electrode Insertion Tubes** includes AA, BB, CC (pk 5) 20 mm above target
34685Z	Sterile single mT electrode (pk 5) DZAP
34685L / FC2002	Sterile single mT electrode (pk 5) DZAP Leadpoint
FC1011	Non Sterile Single Electrode Insertion tube Kit includes X, Y, AA, BB, CC, DD
FC1002	Non Sterile single mT electrode (pk 5)
34680	Sterile single mT electrode (pk 5)

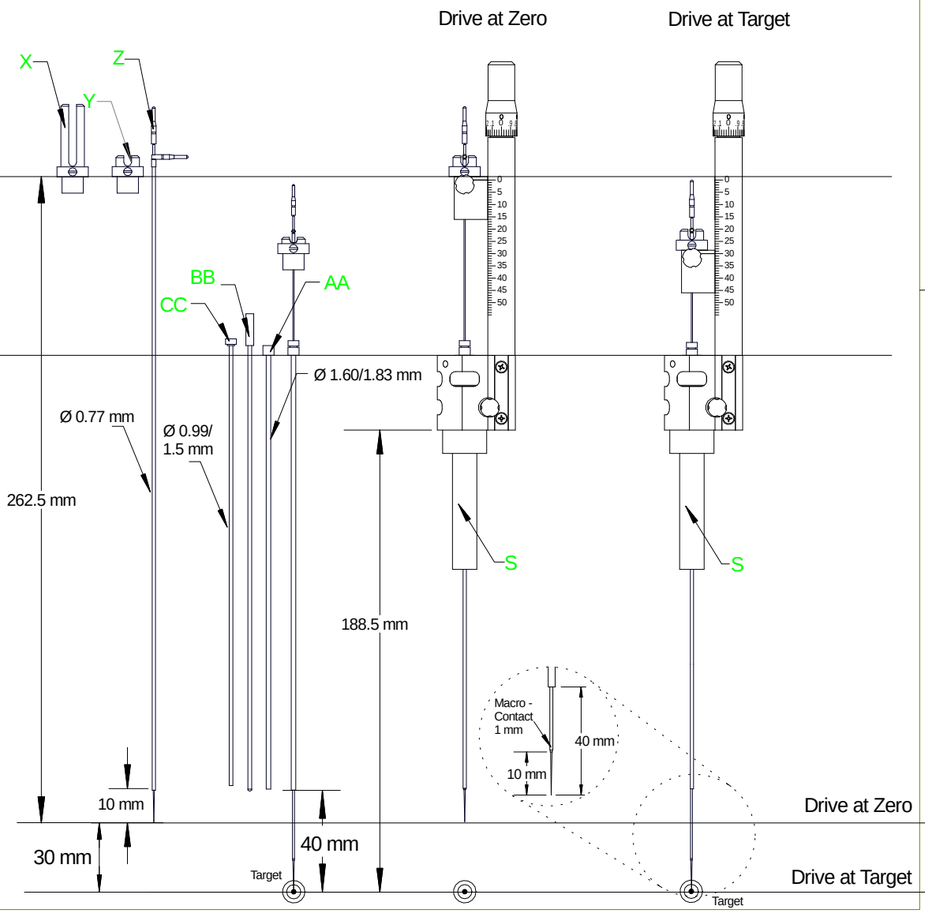
Cat # Non Sterile Set	Distance to Target (mm)
66-IT-01	40mm
66-IT-09	30mm
66-IT-13	25mm
66-IT-05	20mm
66-IT-07	15mm
66-IT-14	10mm
66-IT-08	At Target

70-AC-01 / FC1010

X Shielded Single Electrode Carrier
Y STar Single Electrode Carrier
Z Single mT electrode Medtronic # 34680/FC2002 FHC # 34685L/Z
AA Insertion Tube (66-IT-01 shown)
BB Stylet
CC Spacer Tube
DD Spacer Cleaning Rod

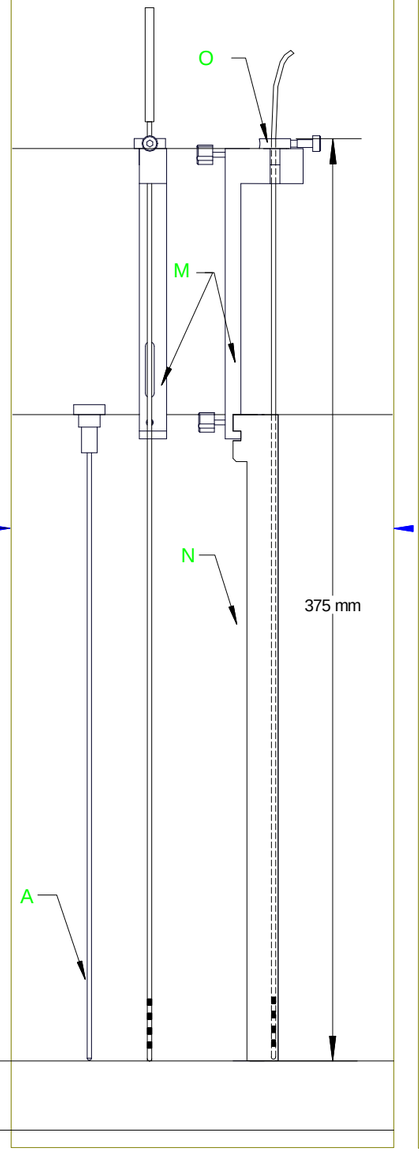


MA Drive shown with STar™ Frame Adapter for Leksell Stereotactic System S



Ordering information
FHC - Medtronic

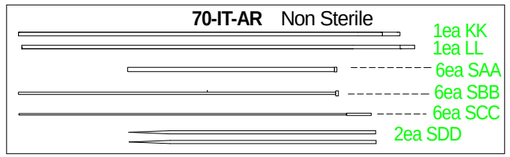
40cm Lead Implant

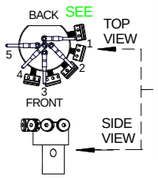


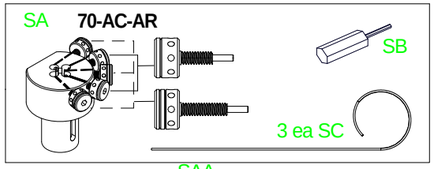
STar™ Array Electrode frame configuration

Ordering information

70-IT-ARP / FC8009	**Sterile STar™ Array Electrode Insertion Tube (pk 5)** includes 5ea SAA, 5ea SBB and 5ea SCC
66-IT-1019 / FC1019	**Sterile lead Insertion tube (pk 5)** includes 5ea KK, 5ea LL
70-CN-ET / FC8011	**Sterile STar™ Array Insertion Tube Extractor (pk 5) i**ncludes 5ea SDD
70-IT-AR	**Non Sterile STar™ Array Electrode Insertion Tube Set** includes 6ea SAA, 6ea SBB, 6ea SCC, 2 ea SDD, 1ea LL, 1ea KK
70-AC-AR / FC8008	**STar™ Array Locking Carrier** includes 1ea SA (w/ 2 spare screws), 1ea SB
FC1003	Non Sterile Array mT Electrode (pk 5)
22670	Sterile Array mT Electrode (pk 5)
22675L / FC2001	Sterile Array mT Electrode (pk 5)DZAP Leadpoint
22675Z	Sterile Array mT Electrode (pk 5) DZAP

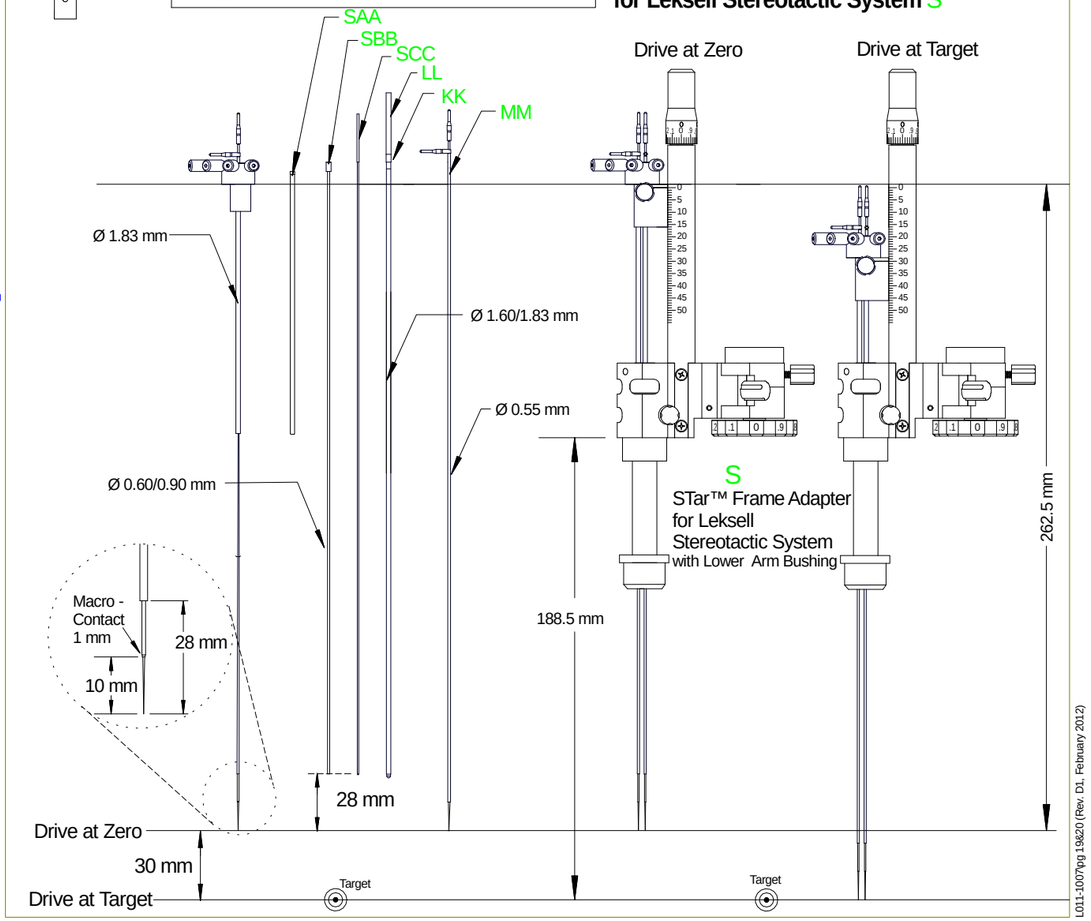






SA STar™ Array Locking Carrier w/ 2 extra screws
SB STar™ Array Hex Wrench
SC STar™ Array Wire Tool
SAA STar™ Array Insertion Guide Tube
SBB STar™ Array Electrode Insertion Tube
SCC STar™ Array Electrode Insertion Tube Stylet
SDD STar™ Array Insertion Tube Extractor
SEE Array Electrode pin positions in slots
KK Array Lead Insertion Tube
LL Array Lead Insertion Tube Stylet
MM Array microelectrode Medtronic # FC2001 FHC # 22675L/Z

M/E Drive shown with STar™ Frame Adapter for Leksell Stereotactic System S



L011-1007pg 19&20 (Rev. D1, February 2012)

(Dimensions may vary for other adapters)

1. Adjust the Drive to zero; use the Remote Control if a motor is attached, otherwise turn the knob.

Directions for Use of the STar™ Drive M/E and Manual version are similar. Illustrations herein show the M/E version with accessories. Manual Drive users should disregard the sleeved Motor shown in pictures and any instructions labeled with ■ .

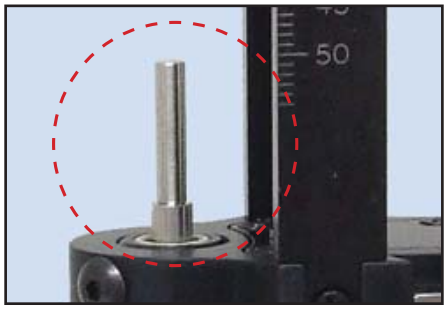
Position the Insertion Tube

WARNING: The Insertion Tube will enter the brain at this stage.

WARNING: Never move the Insertion Tube in the brain without a Stylet or electrode inside.

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

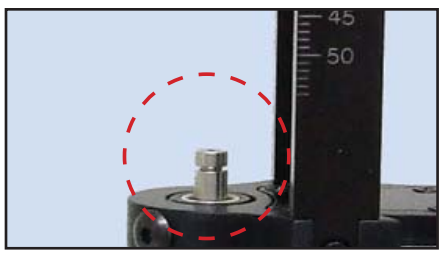
2. Insert the Insertion Tube and Stylet in the desired track.



2a. The Insertion Tube and Stylet are inserted.

3. Remove the Stylet.

4. Insert the Spacer Tube.

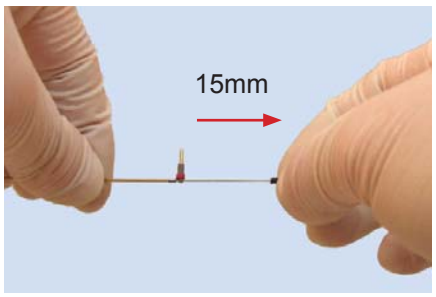


4a. The Insertion Tube and Spacer Tube are inserted.

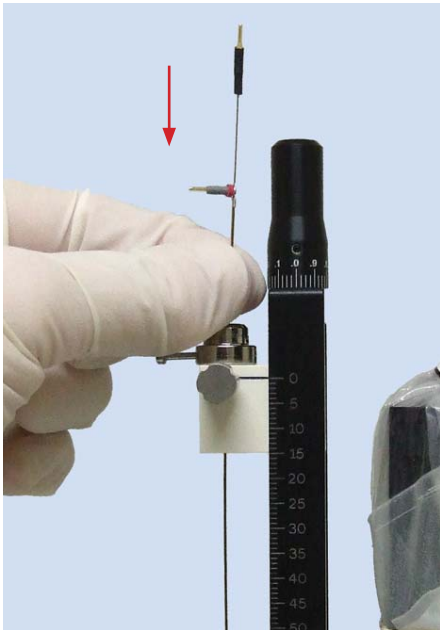
Position the Microelectrode

5. Insert the Electrode Carrier, making sure the holes align with the bushing holes.

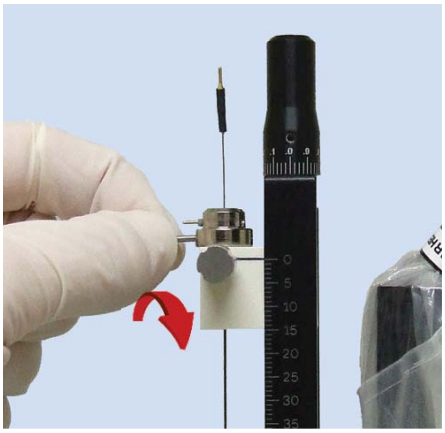
6. Secure the Electrode Carrier.



7. Retract the microelectrode 15mm.



8. Insert the microelectrode in the Carrier and the Spacer Tube until the micro-electrode stop comes flush to the Carrier.

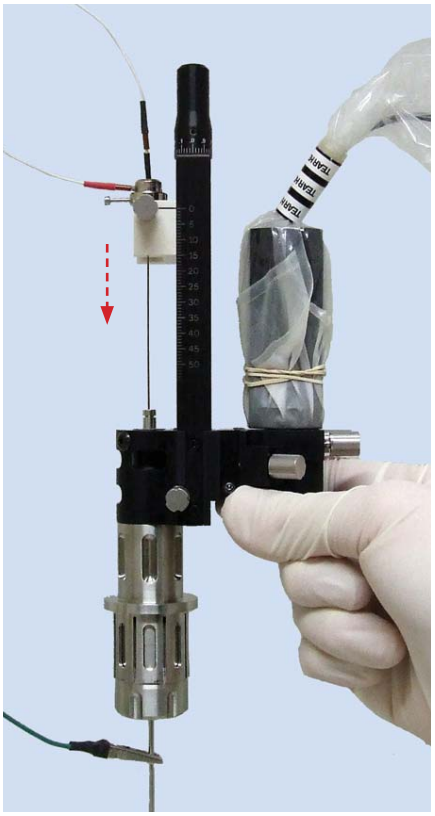


9. Secure the microelectrode in the Carrier; push the microelectrode down.

CAUTION: Do not over tighten this screw as it may damage the microelectrode.

Establish Electrical Connections and Begin Microelectrode Recording

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

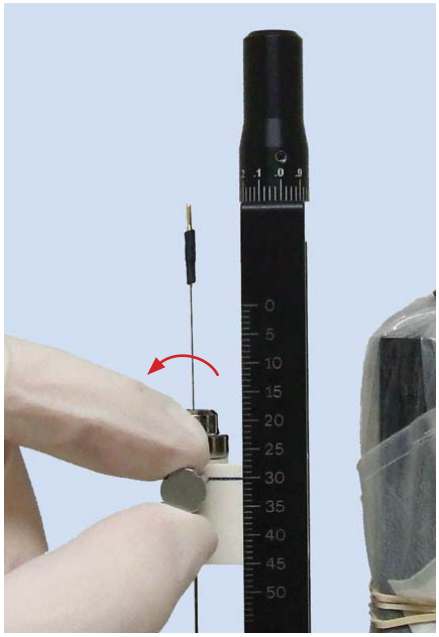


10. Establish electrical connections and advance the Drive. Use the Remote Control if a Motor is attached, otherwise turn the knob.

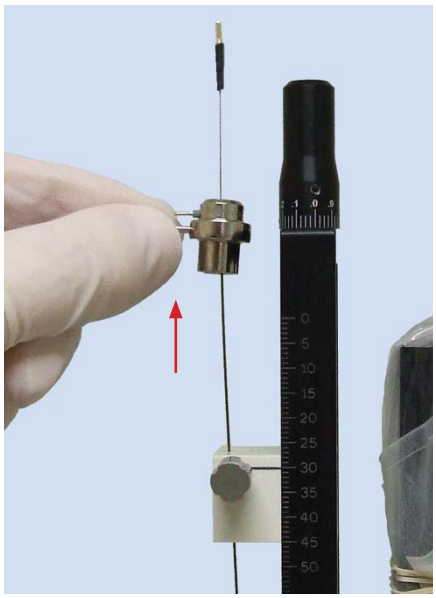
11. Begin recording.

12. Confirm the anatomical areas.

Removing Electrodes



13. Remove electrical connections and loosen the Carrier Locking Screw.



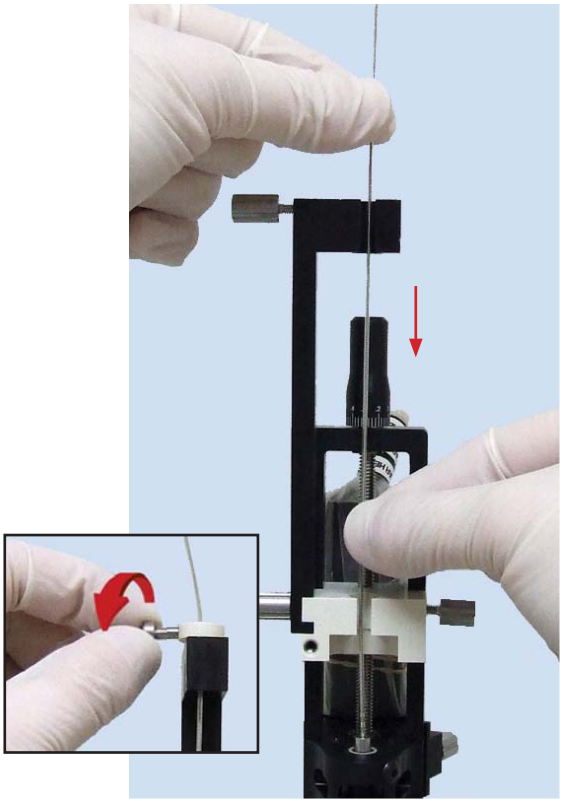
14. Remove the microelectrode and the Carrier.

15. Remove the Spacer Tube.

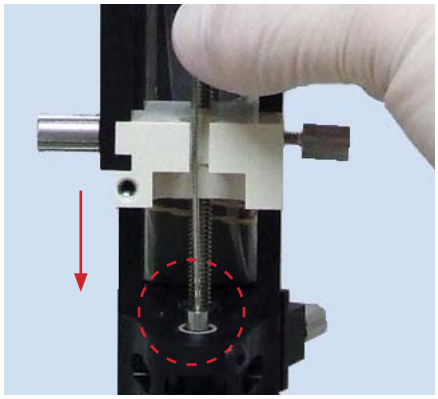
16. Additional tracks are available and require the Insertion Tube to be removed, and steps 1-15 repeated.

Begin the 40cm Lead Implant

17. Attach the Lead Holder to the Drive positioning platform.



18. Insert the preset lead into the tube and secure the Depth Stop Adapter (1.8mm) in the Lead Holder.



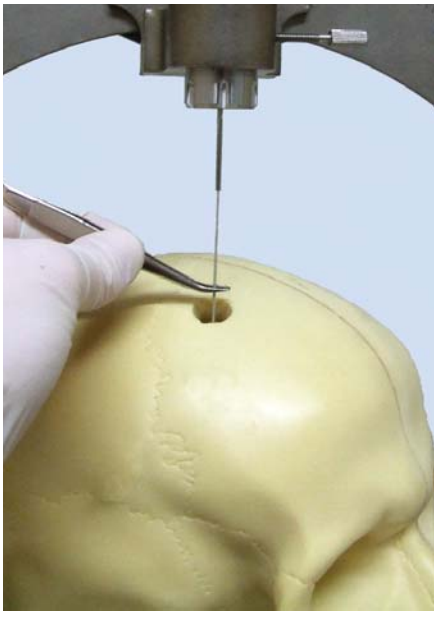
19. The lead is inserted into the tube.

20. Confirm the lead location. Use the Remote Control if a Motor is used, otherwise turn the knob.

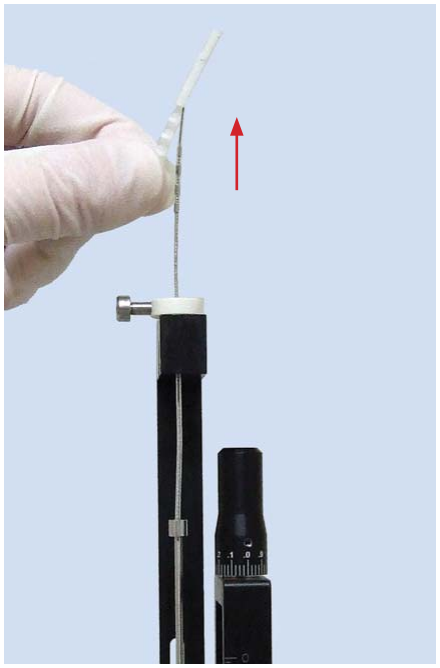
> **WARNING: Observe the exposed segment of the lead while advancing the Drive and ensure it advances into the Insertion Tube without binding or bending.**

Remove the Drive and Insertion Tube

21. Raise the Insertion Tube.

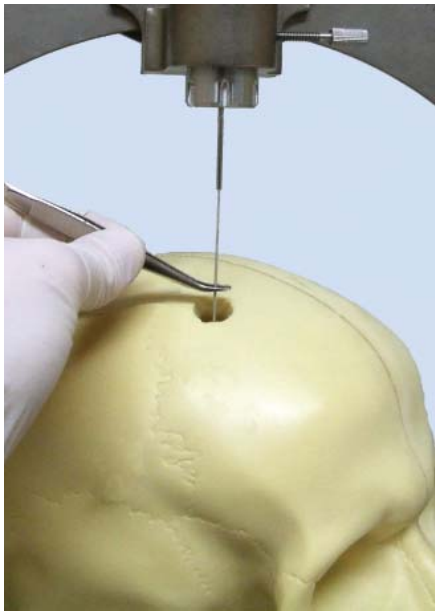


22. Hold the lead with smooth tip, rubber coated tweezers next to the skull.



23. Remove the Stylet from the lead.

24. Loosen the Depth Stop Adapter (1.8mm) screw.



25. Hold the lead with smooth tip, rubber coated tweezers or use the lead locking device.

26. Remove the Drive System (several methods may be used). If the lower guide is used it may be necessary to remove it from the Drive prior to removing the Drive System. Proceed to Page 38 for instructions on dismantling equipment after use.

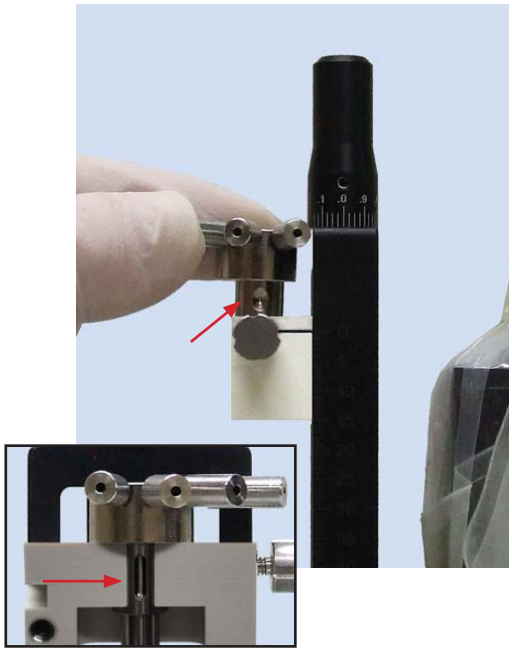
Array Electrode Insertion Tube Set Procedure

WARNING: In the Array Electrode Insertion Tube Procedure, the Drive System is designed to be used with the STar™ Array Insertion Tube Set (refer to chart on page 20). If you are using other tubes you need to purchase a Lower Guide for the Drive (see page 19) and refer to the Lower Guide Directions for Use.

1. Advance the Drive to the initial start position; use the Remote Control if a Motor is attached, otherwise turn the knob.

Directions for Use of the STar™ Drive M/E and Manual version are similar. Illustrations herein show the M/E version with accessories. Manual drive users should disregard the sleeved Motor shown in pictures and any instructions labeled with ■ .

Position the Insertion Tube



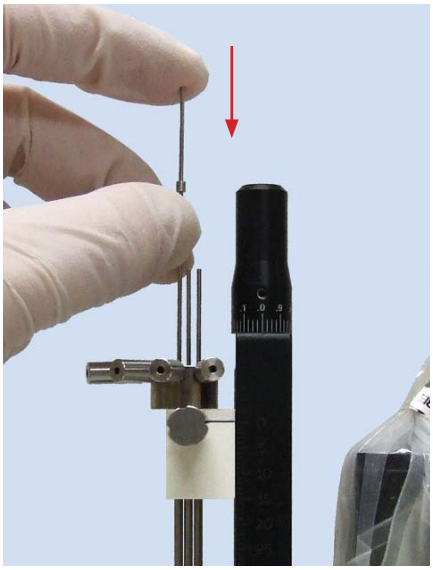
2. Make sure the screws of the array carrier are partially manually tightened such that they only have to be turned a small fraction (45 to 90° of a turn) to secure the tubes in place. Insert the STar™ Array Locking Carrier, making sure the indent is aligned with the locking thumb screw and the slot is aligned with the opening of the drive positioning platform.

3. Secure the Carrier by tightening the thumbscrew.

WARNING: The Insertion Tube will enter the brain at this stage.

WARNING: Never move the Insertion Tube in the brain without a Stylet or electrode inside.

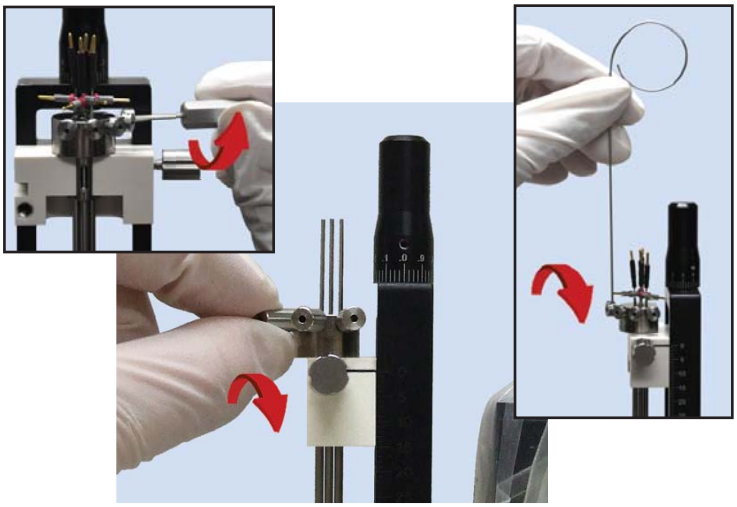
4. Insert the STar™ Array insertion guide tube(s). Ensure it is fully seated in its recess.



5. Insert the STar™ Array Insertion Tube(s). The top of the collar should come flush with the top surface of the STar™ Array Locking Carrier.

   Note: For multiple tubes, repeat steps 4 and 5. As many as 5 microelectrodes may be used for simultaneous recording.

5a. The guide tube(s), Insertion Tube(s) and Stylet(s) are inserted.



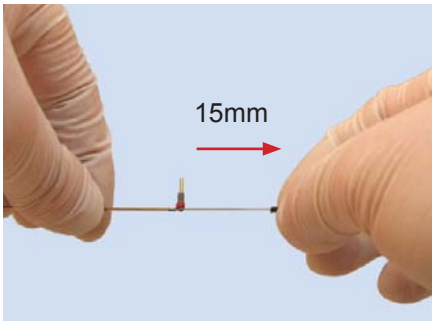
6. Secure the Insertion Tubes(s) by tightening the screw(s) of the carrier. Use the hexwrench or the wire tool provided for hard-to-reach screws, as shown above.

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

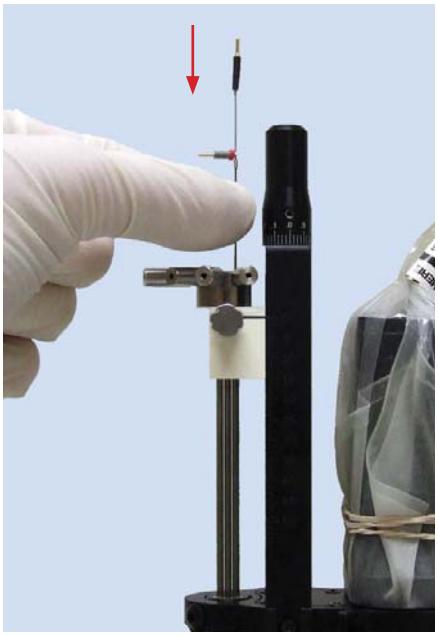
CAUTION: Do not over tighten these screws as it may damage the Insertion Tubes.

7. Remove the Stylet(s).

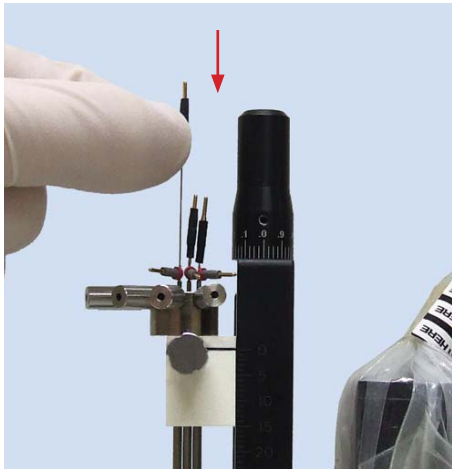
Position the microelectrode



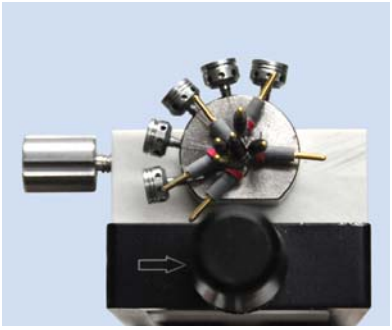
8. Retract the microelectrode 15mm.



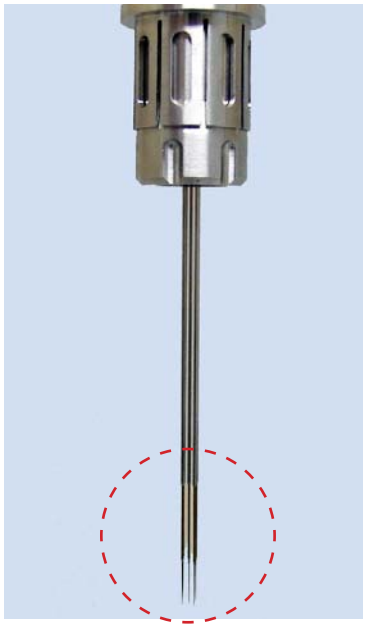
9. Insert the microelectrode(s).



10. Push the microelectrode(s) down.



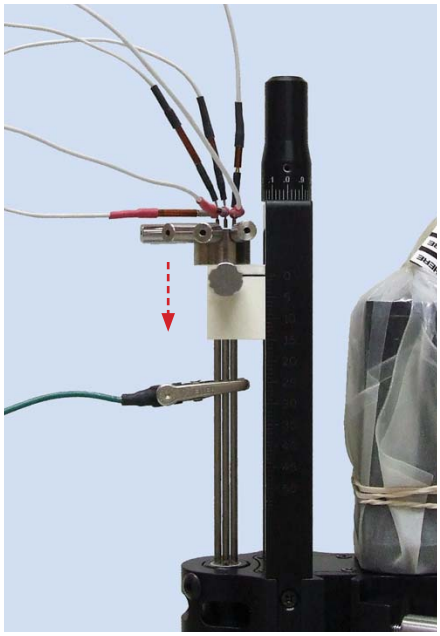
10a. The top view of a five microelectrode setup.



10b. Five microelectrodes are extended.

Establish Electrical Connections and Begin Microelectrode Recording

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

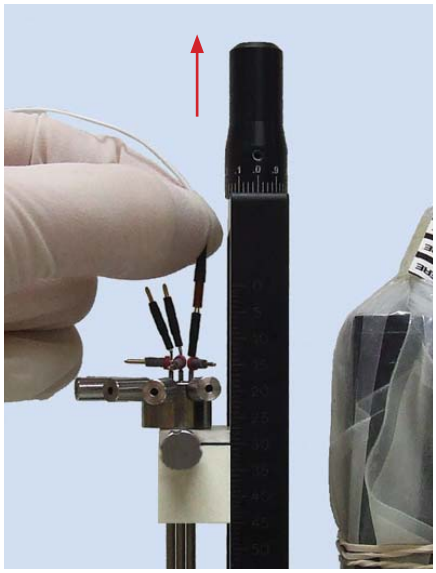


11. Establish electrical connections and advance the Drive. Use the remote control if a motor is attached, otherwise turn the knob.

12. Begin recording.

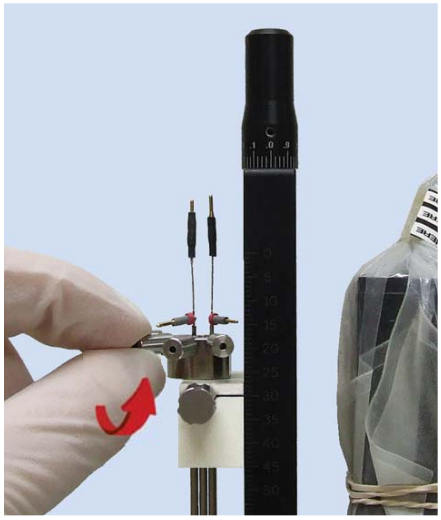
13. Confirm the anatomical areas.

Removing Electrodes

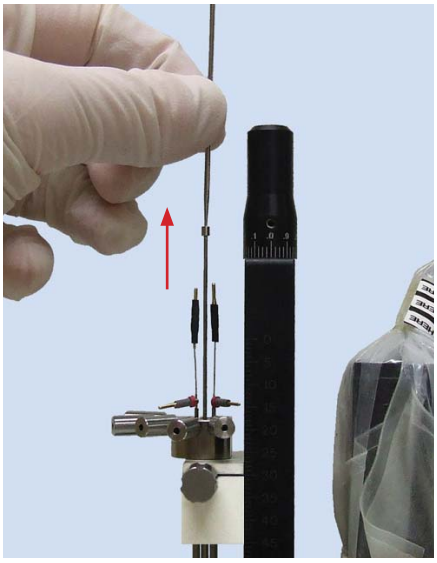


14. Remove electrical connections.

15. Retract all microelectrodes and remove the microelectrode of the selected track.



16. Loosen the screw of the carrier holding the Insertion Tube of the selected track.



17. Remove the Insertion Tube of the selected track by inserting the tube extractor with slight force into the Insertion Tube and pulling upwards.

18. Repeat step 17 to remove the insertion guide tube of the selected track.

19. Remove all remaining microelectrodes.

Begin the 40cm Lead Implant

20. Insert the lead Insertion Tube and Stylet.

21. Loosen the screw(s) of the carrier holding the remaining Insertion Tube(s).

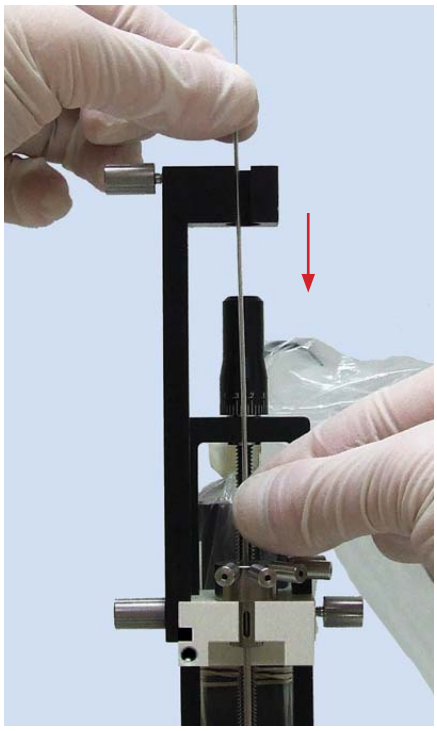
22. Remove the remaining Insertion Tube(s) by inserting the Tube Extractor with slight force into the Insertion Tube and pulling upwards.

23. Repeat step 22 to remove the remaining guide tubes.

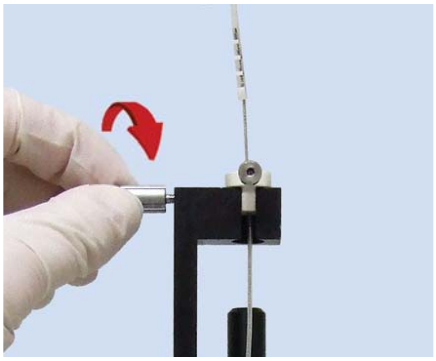
24. Tighten the screw of the carrier to secure the lead Insertion Tube.

25. Remove the Stylet.

26. Attach the Lead Holder to the Drive positioning platform.



27. Insert the preset lead into the Insertion Tube.

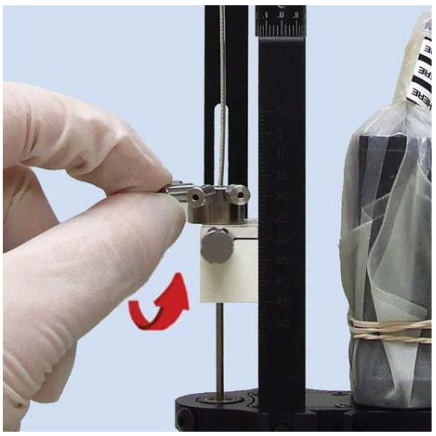


28. Secure the Depth Stop Adapter (1.8mm) in the Lead Holder.

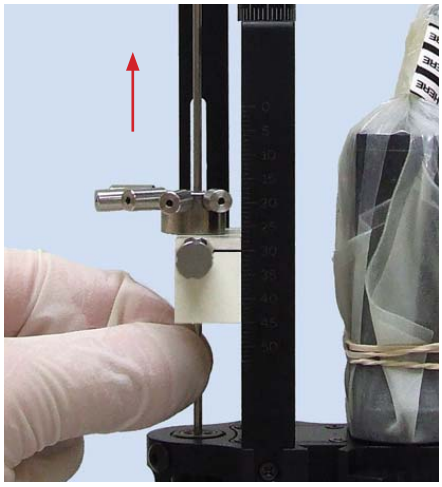
29. Confirm the lead location. Use the remote control if a motor is attached, otherwise turn the knob.

WARNING: Observe the exposed segment of the lead while advancing the Drive and ensure it advances into the Insertion Tube without binding or bending.

Remove the Drive and Insertion Tube



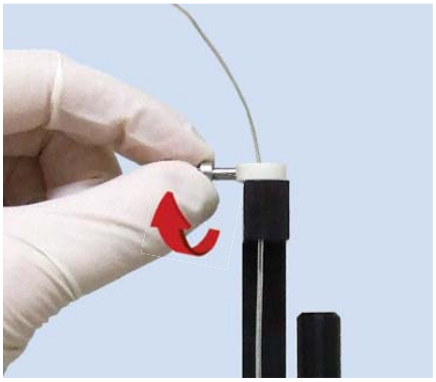
30. Loosen the screw holding the lead Insertion Tube.



31. Raise the lead Insertion Tube.

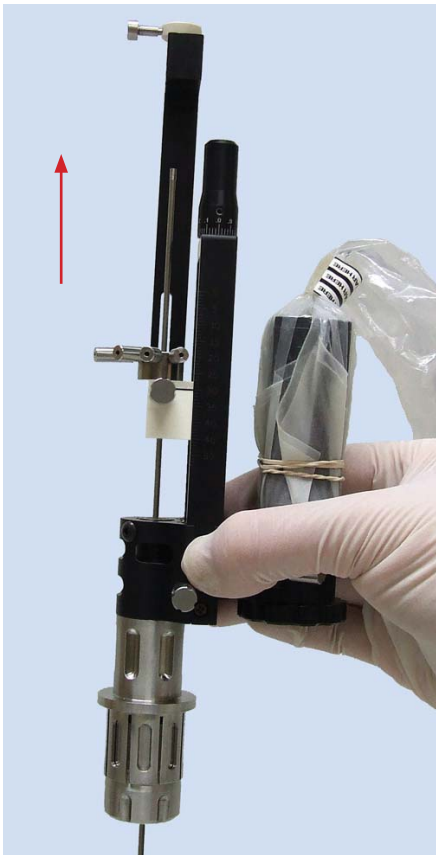
32. Hold the lead with smooth tip, rubber coated tweezers next to the skull.

33. Remove the Stylet from the lead.



34. Loosen the Depth Stop Adapter (1.8mm) screw.

35. Hold the lead with smooth tip, rubber coated tweezers next to the skull or use the lead locking device.



36. Remove the Drive System (several methods may be used).

Dismantling Equipment After Use

1. If a STar™ Drive M/E is used with the Motor or Encoder Accessory, remove it from the drive and unplug it and the Remote Control from the Controller. Disconnect the Power Supply from the Controller and the Line Cord from the power receptacle. Discard the sterile drape.

   In the event these accessory components become soiled they should be wiped clean with an Isopropyl Alcohol dampened cloth, then dried. Do not immerse Accessories in fluids or allow excessive moisture to remain.

2. Set aside the microTargeting™ STar™ Drive, the Carrier and the Stereotactic Frame Adapter, in the sterilization tray, including the verification probe and spare parts, for disassembly and cleaning (page 5-7).

This equipment should be stored where it's available for the next procedure.

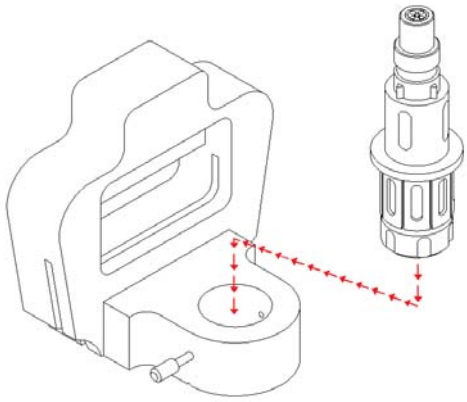
Radionics CRW™ Adapter

Radionics Inc. 22 Terry Ave Burlington, MA 01803 USA

WARNING: Separate collet and adapter prior to cleaning and sterilization.

CAUTION: Due to sharp edges and pinch points, handle collet and adapter carefully.

II.



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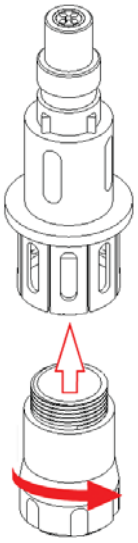

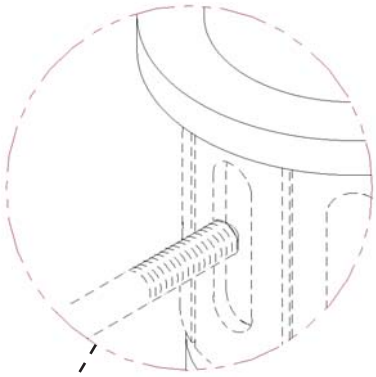

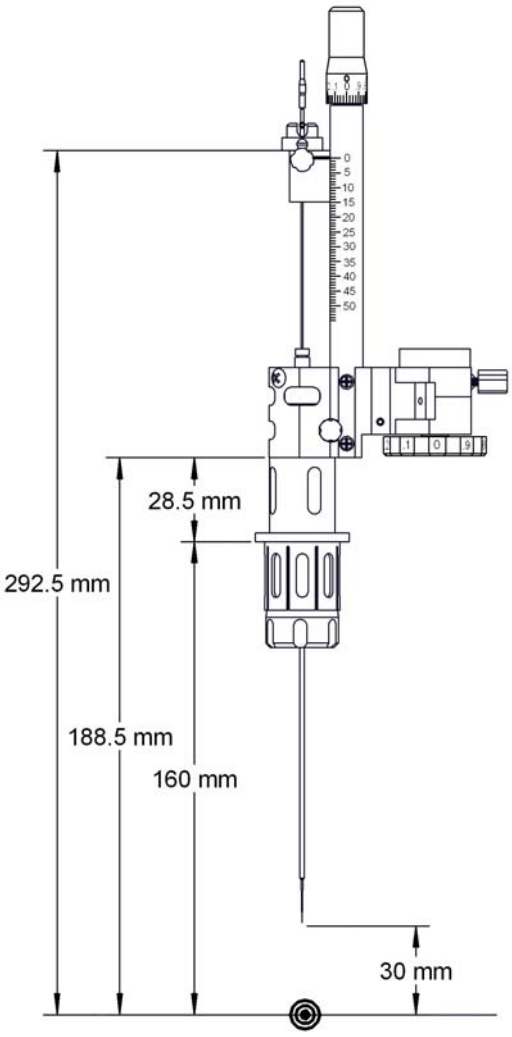

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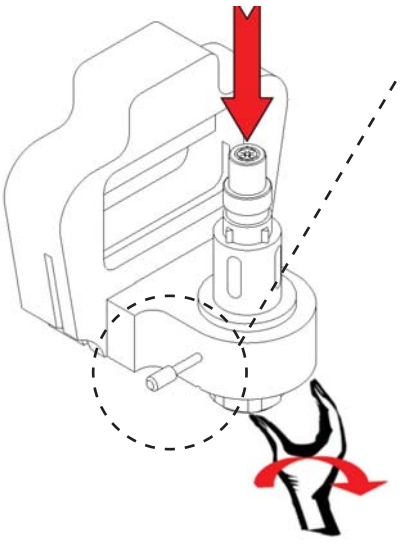

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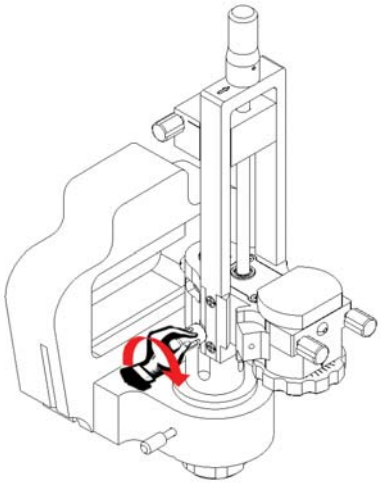

Elekta AB Birger Jarlsgatan 53 Box 7593, SE-103 93 Stockholm Sweden

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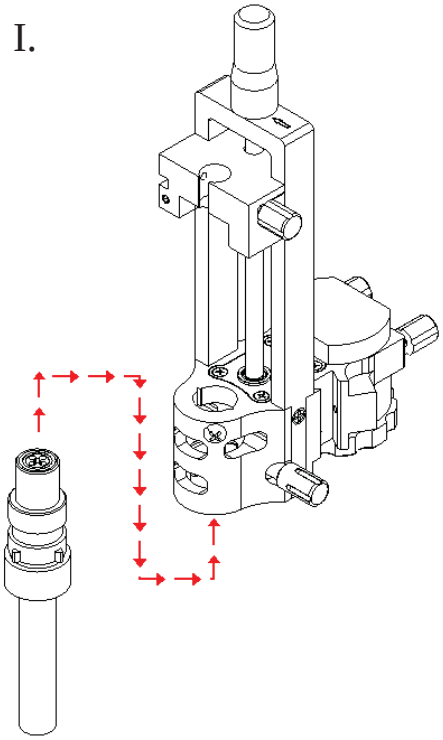

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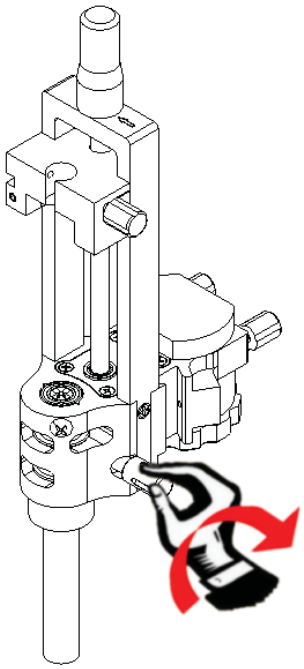

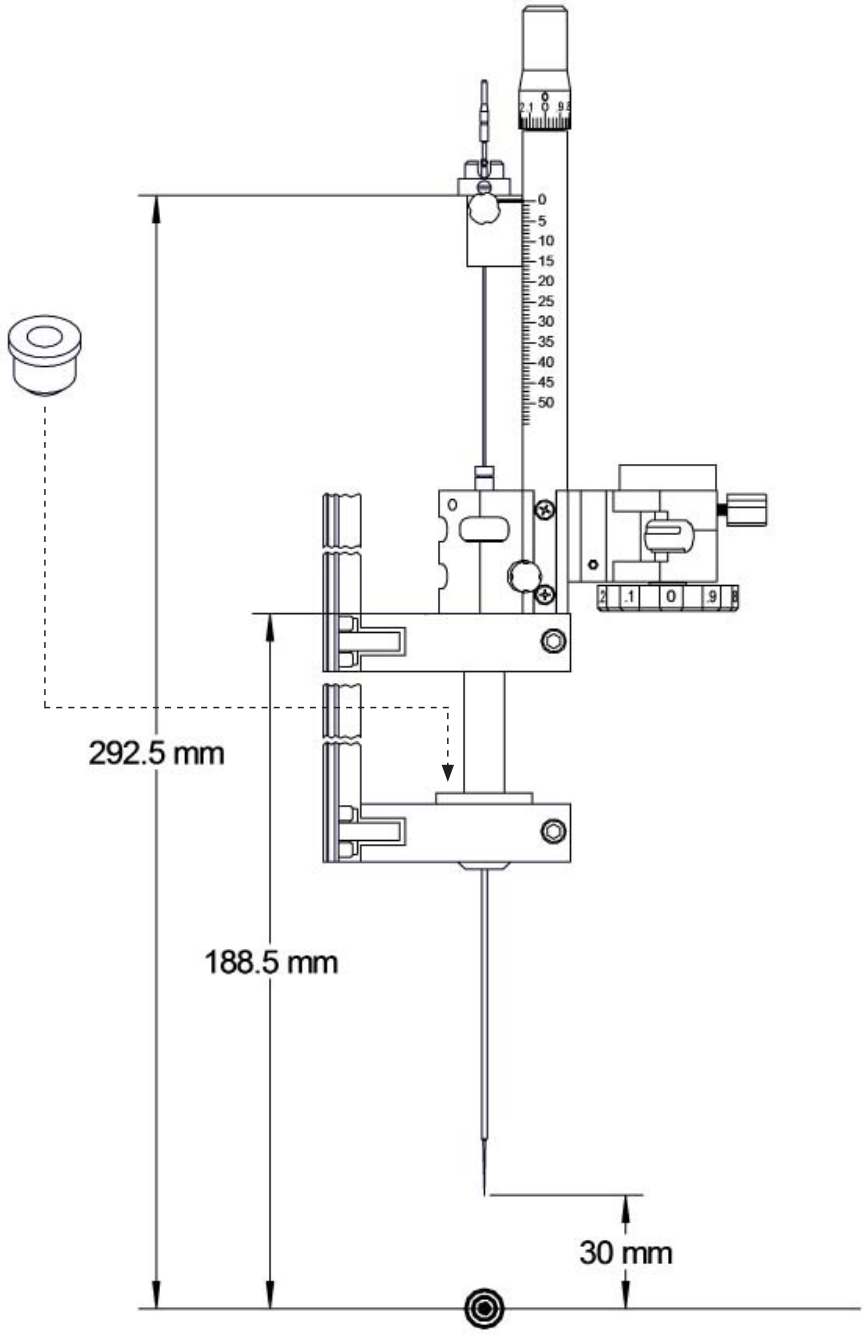

Stryker Leibinger GmbH& Co KG Bötzinger Straße 41 D-79111 Freiburg Germany

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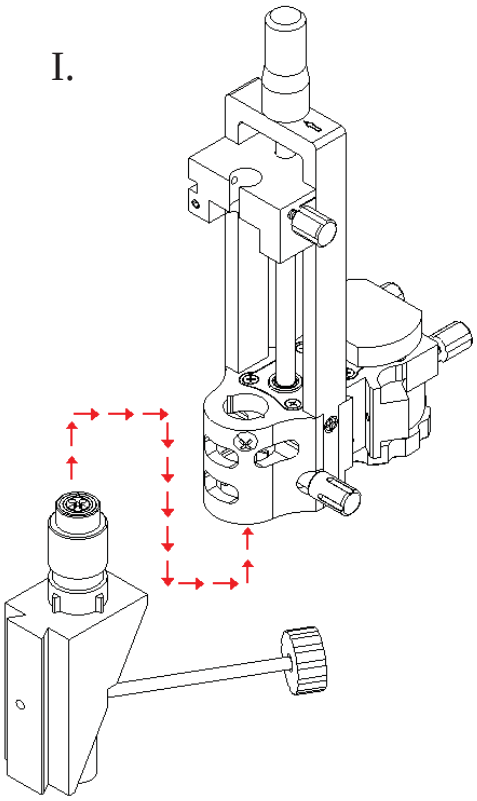

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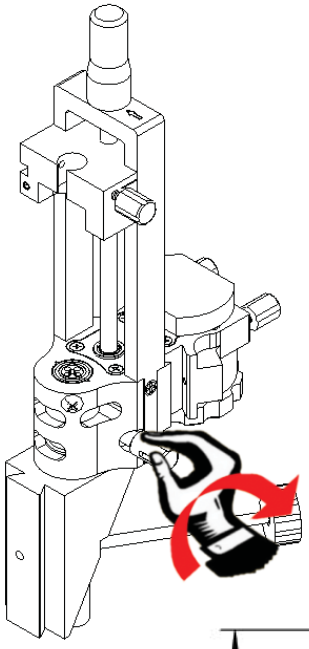

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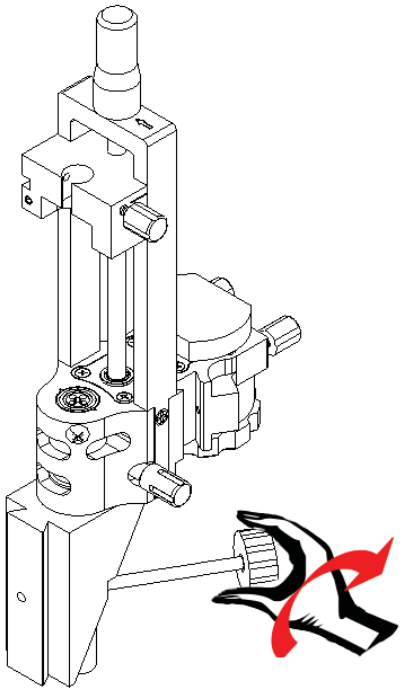
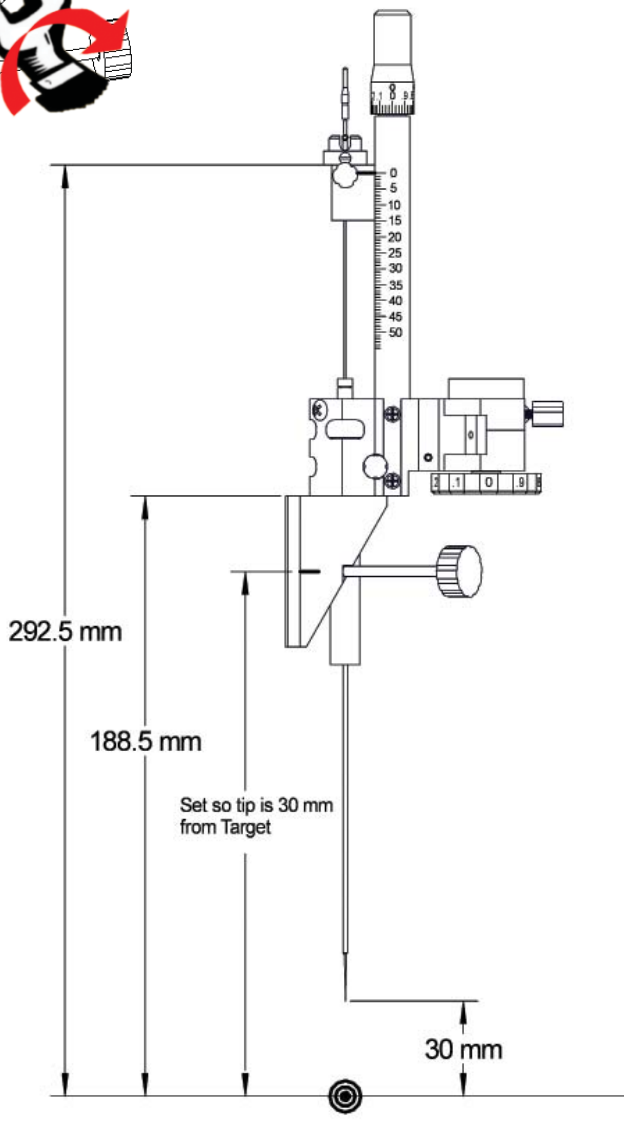
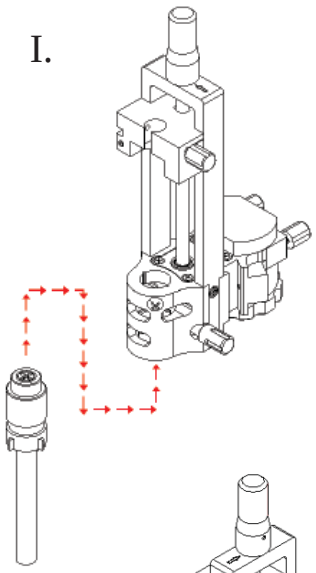




Leibinger ZD™ Adapter

Stryker Leibinger GmbH& Co KG Bötzinger Straße 41 D-79111 Freiburg Germany

I.



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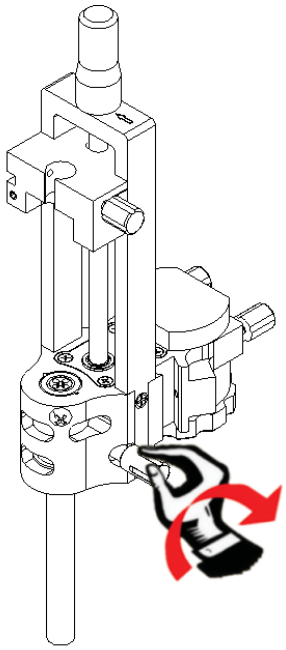
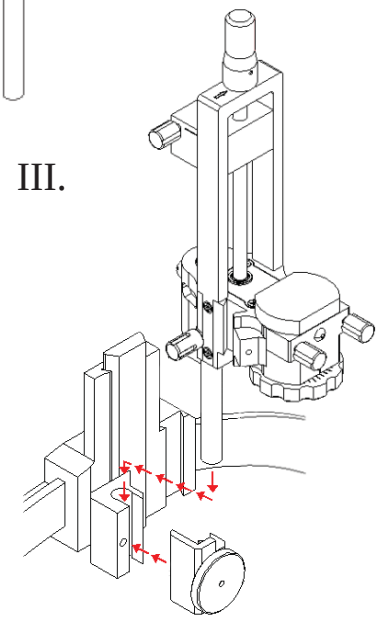


WARNING: Leibinger ZD-devices are provided with different instrument holders. Refer to the Leibinger ZD User Manual to confirm settings. Failure to do so may cause a deviation from the planned target point.

III.



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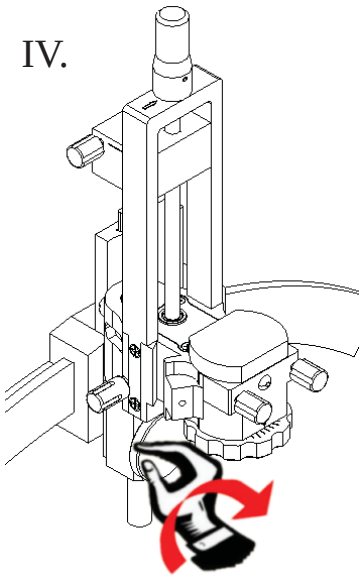

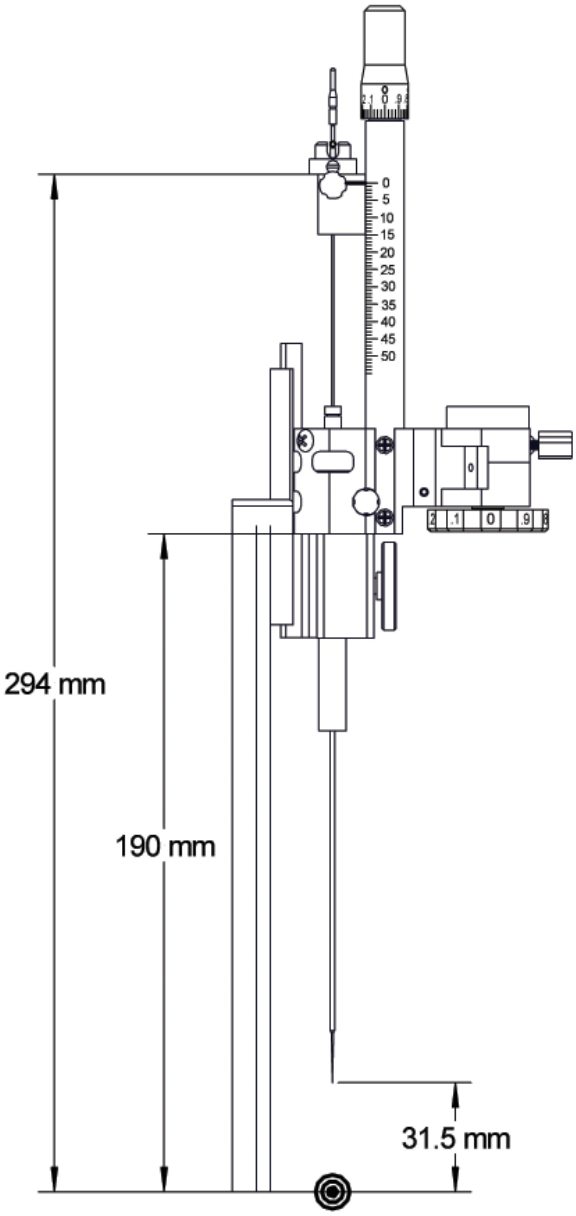

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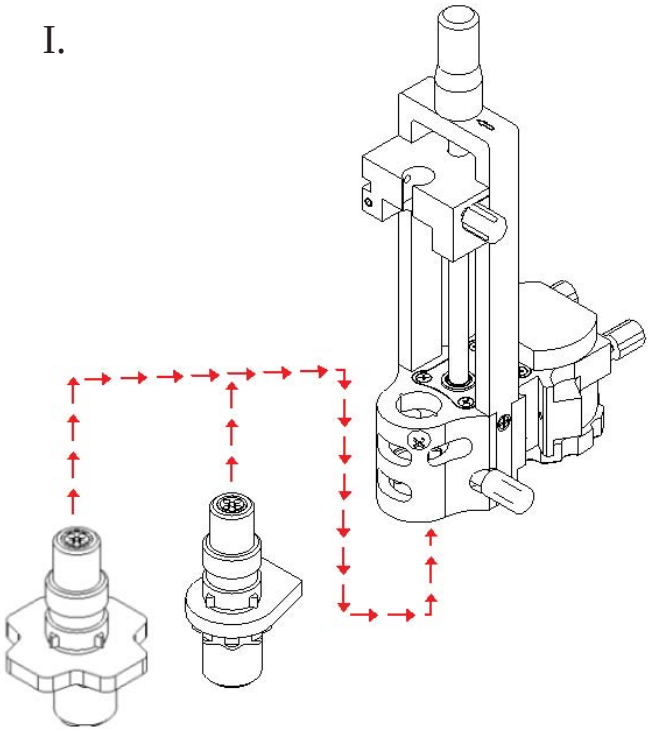

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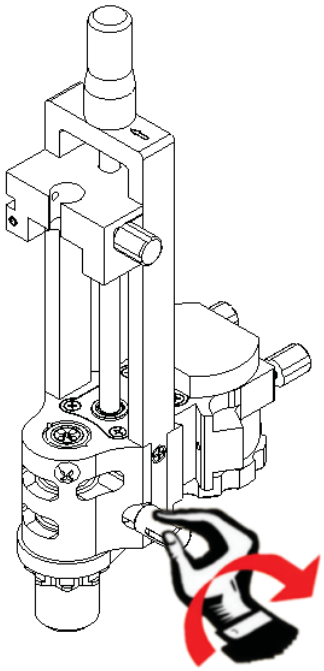
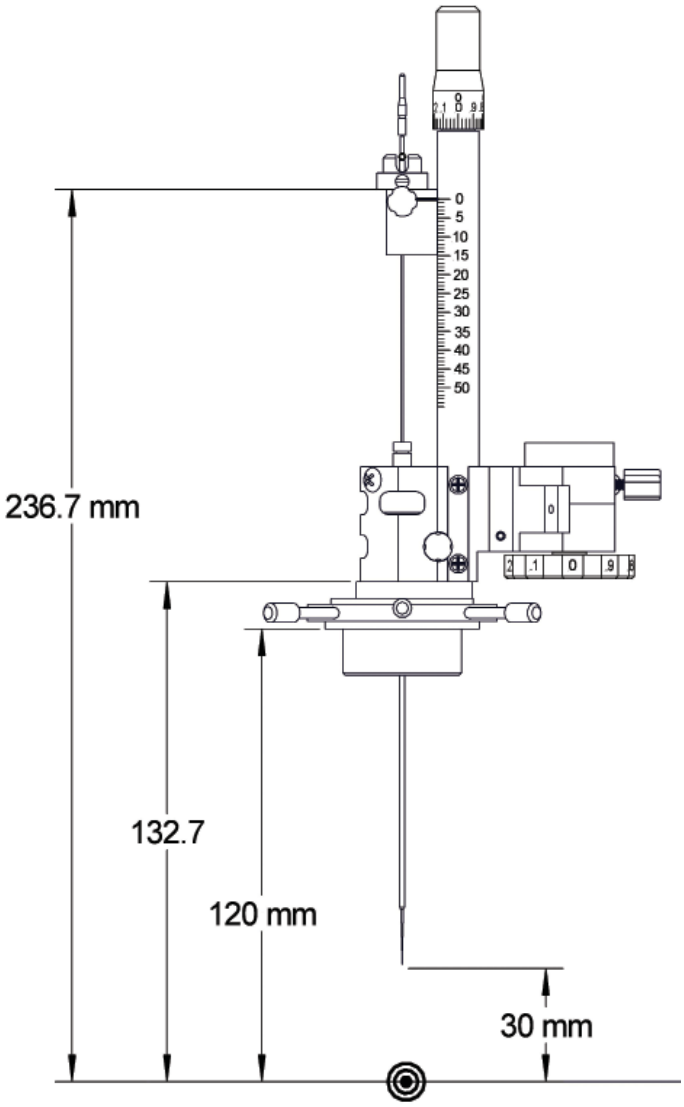
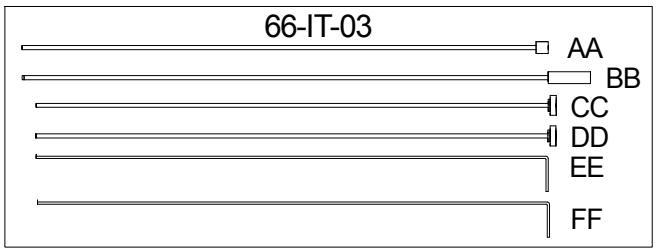


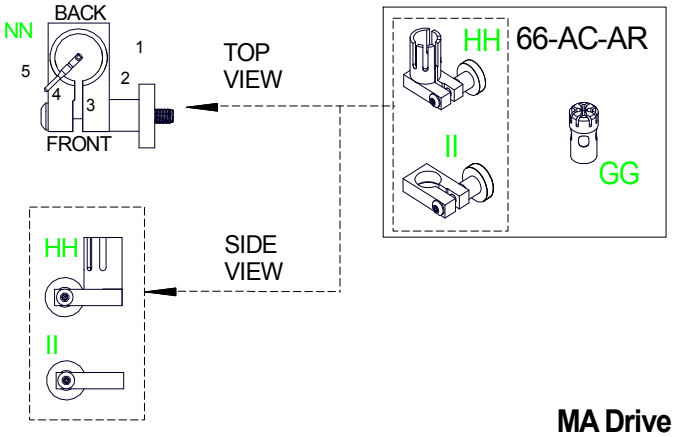


Single Electrode Platform configuration

Ordering information

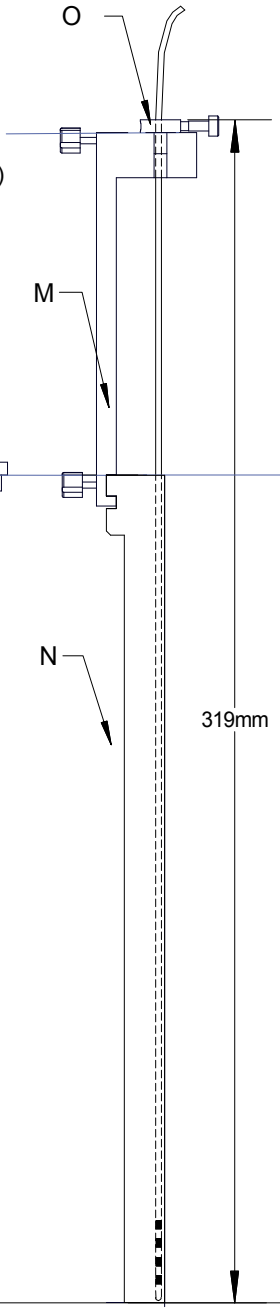
66-AC-AR	Non Sterile Array Carrier and Clamp Includes GG, HH, II
66-IT-03P	Sterile Single Insertion Tube Set Includes AA, BB, CC
66-IT-03	Non Sterile Single Insertion Tube Set Includes AA, BB, CC, DD, EE, FF
44970R	Sterile Tungsten Platform mT Electrode (pk 5)
44975Z	Sterile Tungsten Platform mT Electrode D.ZAP (pk 5)
44975L	Sterile Tungsten Platform mT Elec. D.ZAP Leadpoint (pk 5)
mTDPBN(BP)(MP1)	Non Sterile Pt/Ir Platform Single mT Electrode (pk 6)





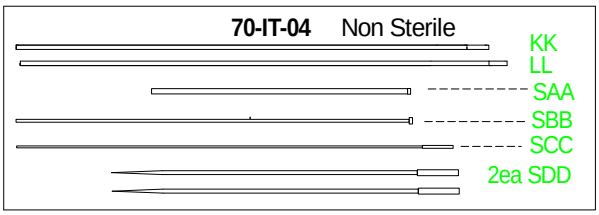
AA	Insertion Tube
BB	Stylet
CC	Spacer Tube for tungsten microelectrodes
DD	Spacer Tube for Pt/Ir microelectrodes
EE	Tungsten microelectrodes Spacer cleaning Rod
FF	Pt/Ir microelectrodes Spacer cleaning Rod
GG	Array Electrode Carrier
HH	Shielded Array Clamp
II	Non shielded Array Clamp
MM	Single tungsten mT electrode
NN	Single Electrode pin position in slot
A	Verification Probe
M	Lead Holder 70-CN-DB
N	Measuring Fixture 70-Ac-MT-01
O	Depth Stop Adapter (1.8 mm) 66-AC-DS(1.8)

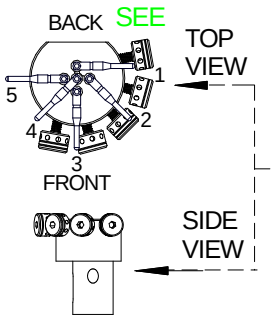
40CM Lead Implant

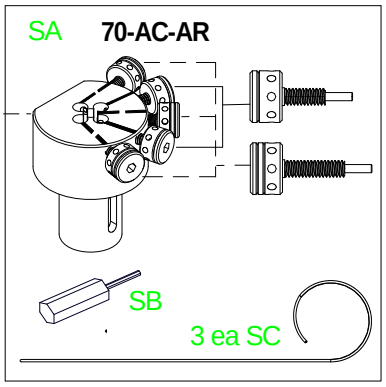


MA Drive shown with 120mm model mT platform

STar Array Electrode Platform configuration





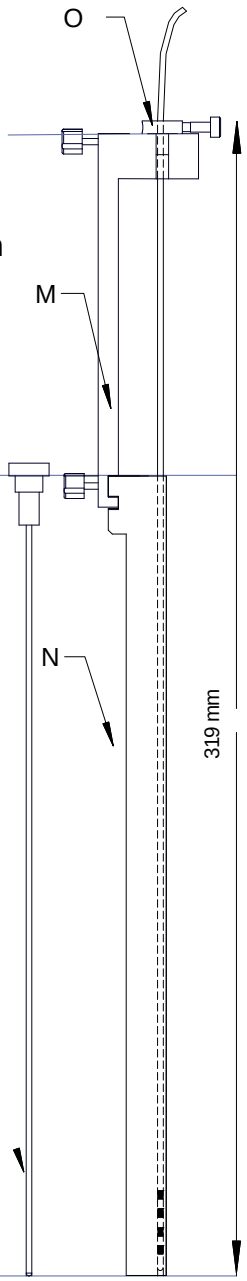


Ordering information

70-IT-AR5P	Sterile STar Array Electrode Insertion Tube (pk 5) includes 5ea SAA, 5ea SBB, 5ea SCC
66-IT-AR4P	Sterile Lead Insertion Tube (pk 5) includes 5ea KK, 5ea LL
70-CN-ET	Sterile STar™ Array Insertion Tube Extractor (pk 5) includes 5 ea SDD
70-IT-04	STar Array Electrode Insertion Tube Set for mT Platform includes 6ea SAA, 6ea SBB 6ea SCC, 1ea LL, 1ea KK, 2 ea SDD
70-AC-AR	STar Array Locking Carrier includes 1ea SA (w 2 spare screws), 1ea SB, 3ea SC
44970R	Sterile Array Tungsten Platform mT Electrode (pk 5)
44975Z	Sterile Array Tungsten Platform mT Electrode D.ZAP (pk 5)
44975L	Sterile Array Tungsten Platform mT Electrode D.ZAP Leadpoint (pk 5)

SA	STar Array Locking Carrier w/ 2 extra screws
SB	STar Array Hex Wrench
SC	STar Array Wire Tool
SAA	STar Array Platform Insertion Guide Tube
SBB	STar Array Platfrm Electrode Insertion Tube
SCC	STar Array Platform Electrode Insertion Tube Stylet
SDD	STar Array Insertion Tube Extractor
SEE	Array Platform Electrode pin positions in slots
KK	Array Platform Lead Insertion Tube
LL	Array Platform Lead Insertion Tube Stylet
MM	Array Platform microelectrode # 44970R

40CM Lead Implant



M/E Drive shown with 120 mm model Platform

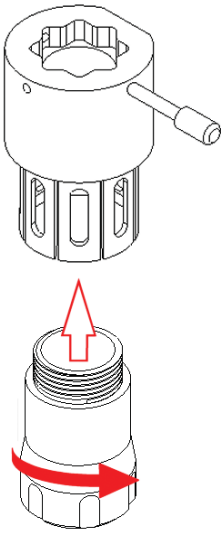
Radionics Offsetting Adapter

Radionics Inc. 22 Terry Ave Burlington, MA 01803 USA

WARNING: Separate collet and adapter prior to cleaning and sterilization.

CAUTION: Due to sharp edges and pinch points, handle collet and adapter carefully.

I.



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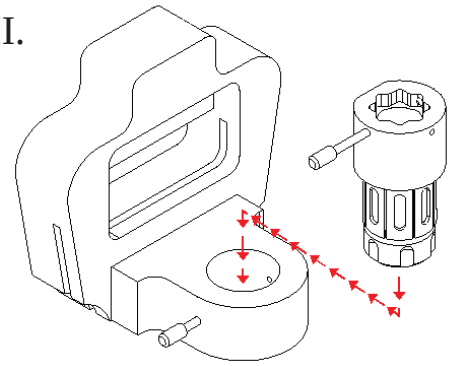

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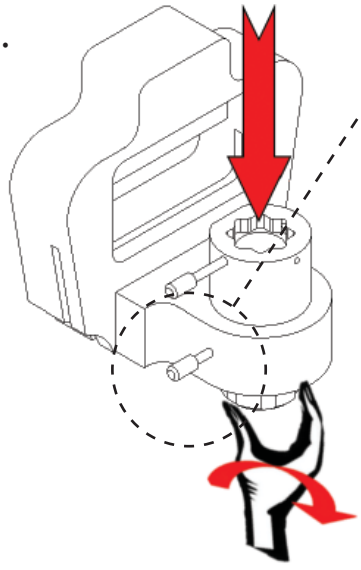

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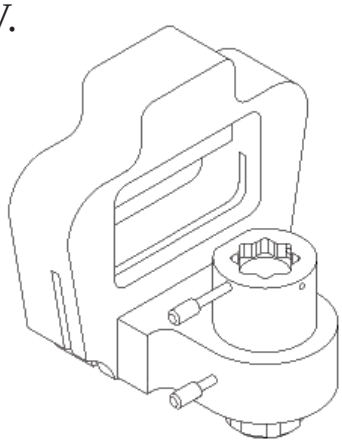

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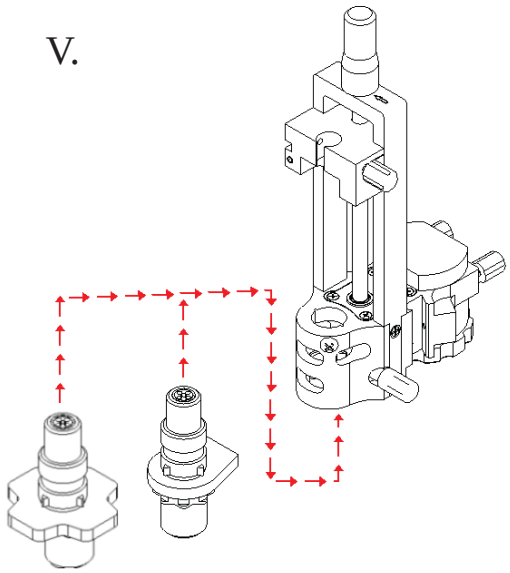
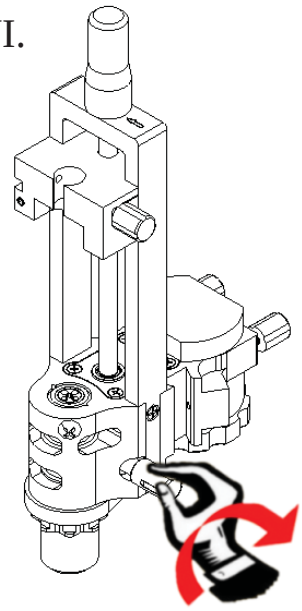
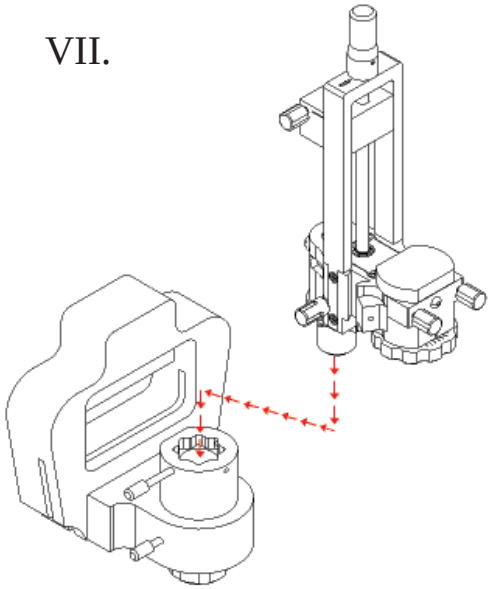


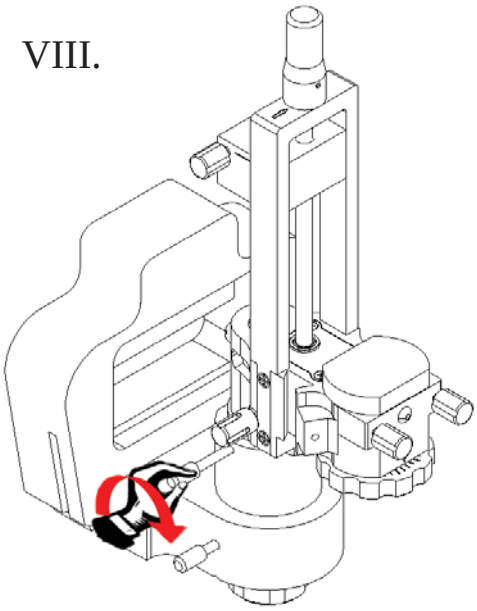
VI.

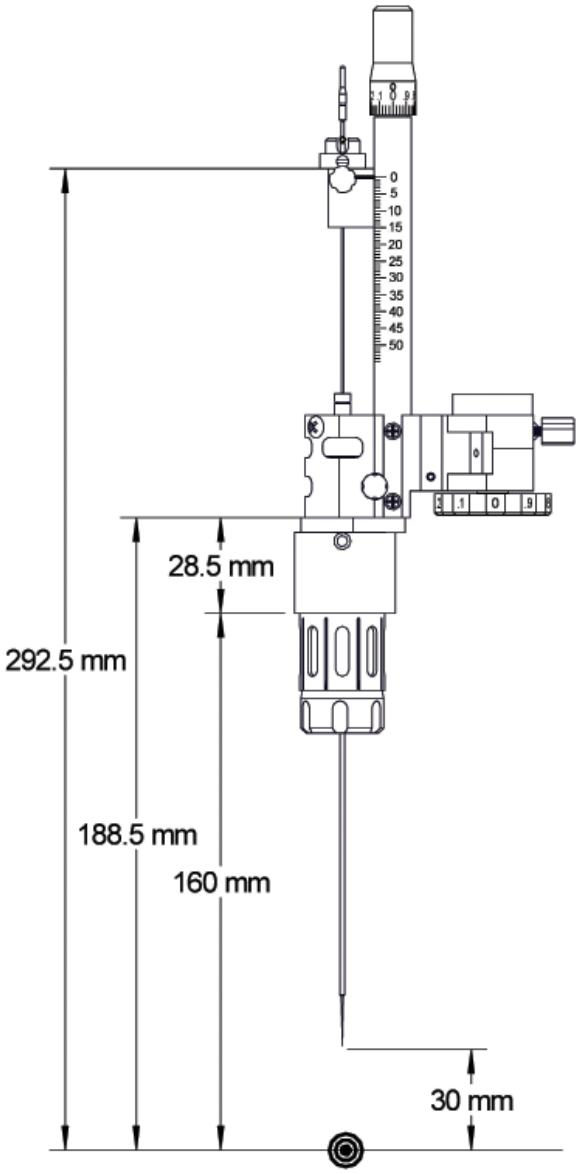


VII.



VIII.

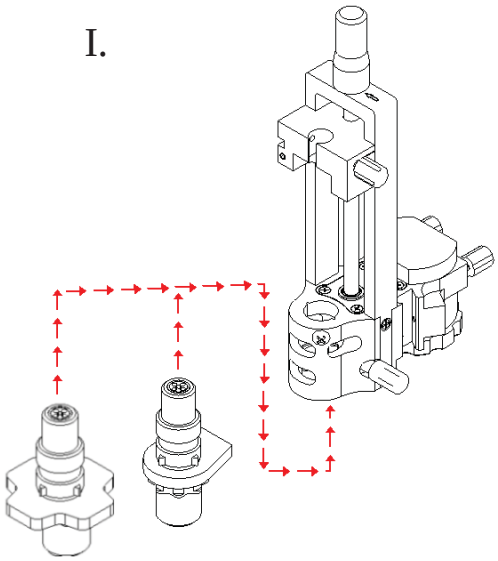




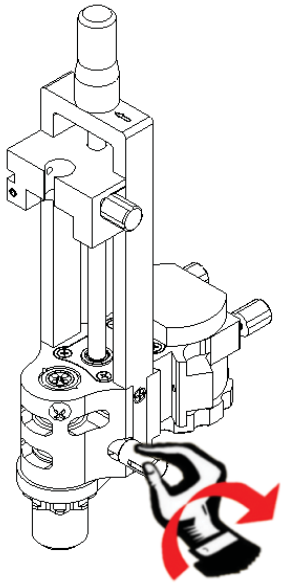
Leksell Offsetting Adapter

Elekta AB Birger Jarlsgatan 53 Box 7593, SE-103 93 Stockholm Sweden

I.



II.



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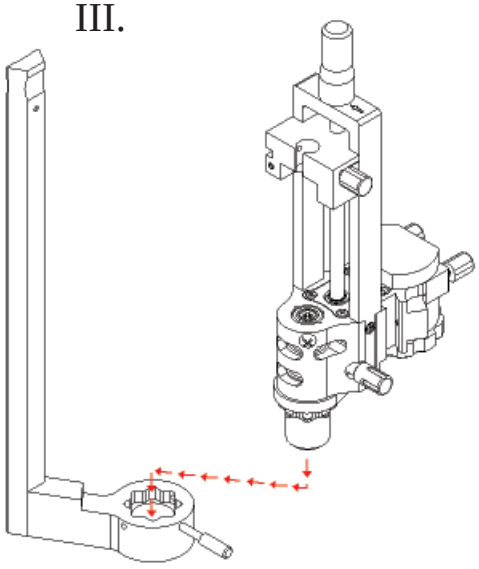

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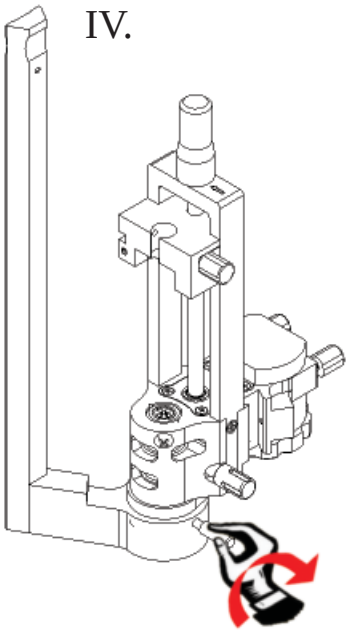
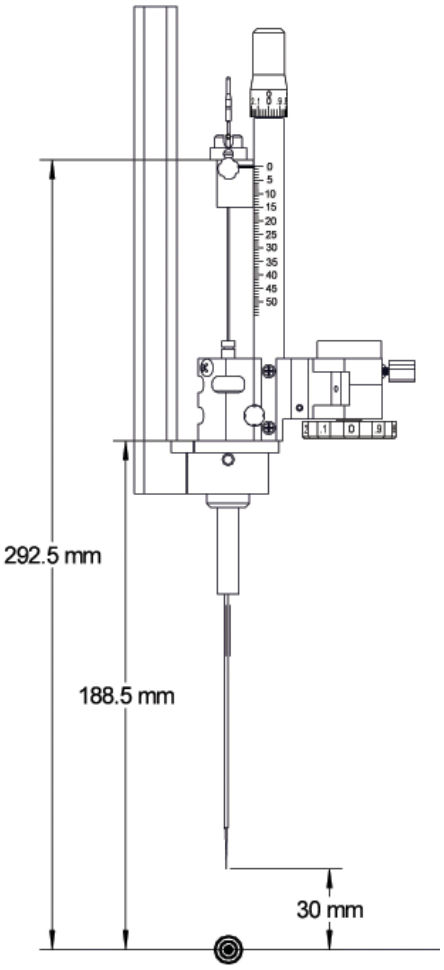
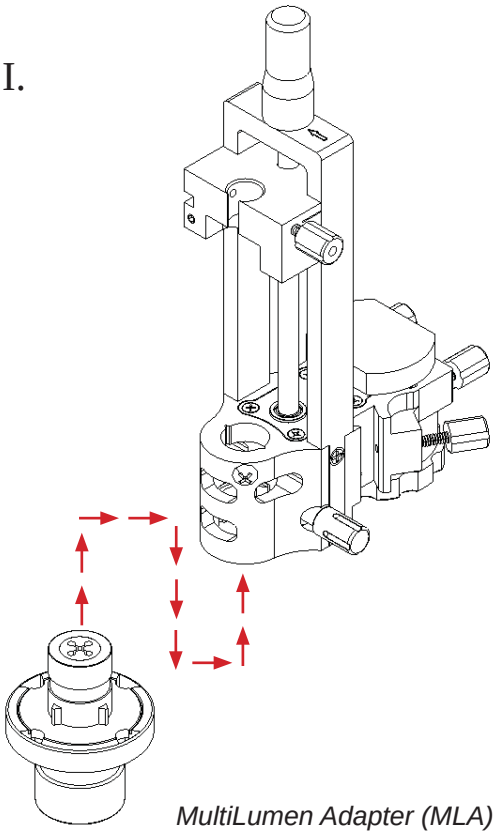




Nexframe® Adaptation

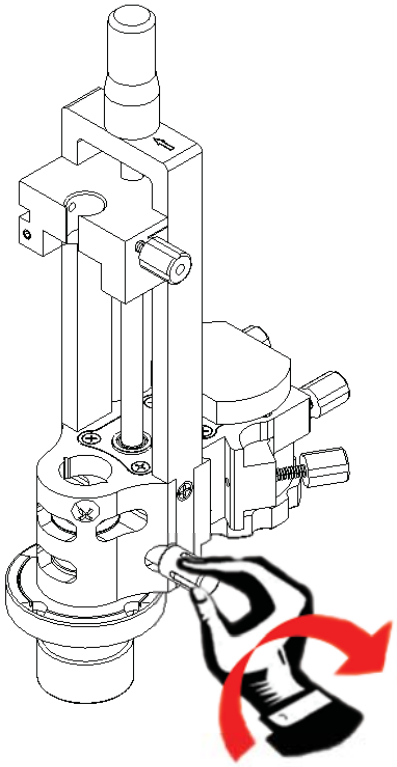
⚠ ATTENTION: See Nexframe® System manual

I.



MultiLumen Adapter (MLA)

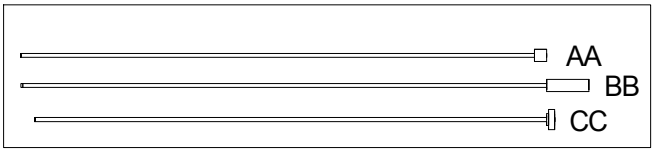
II.

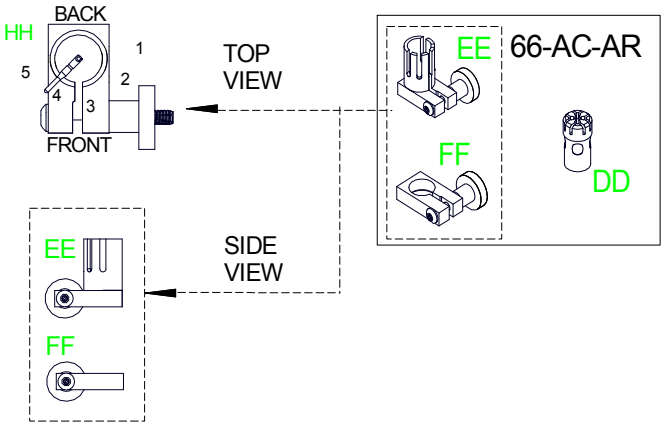


⚠ **WARNING: Nexframe® / STar™ Drive Insertion Tubes and microelectrodes should not be used with any other drive or stereotactic system.**

⚠ **WARNING: Do not use Insertion Tubes and microelectrodes other than those which have been specifically designed for use with Nexframe® / STar™ Drive.**

STar™ Single Electrode Nexframe configuration

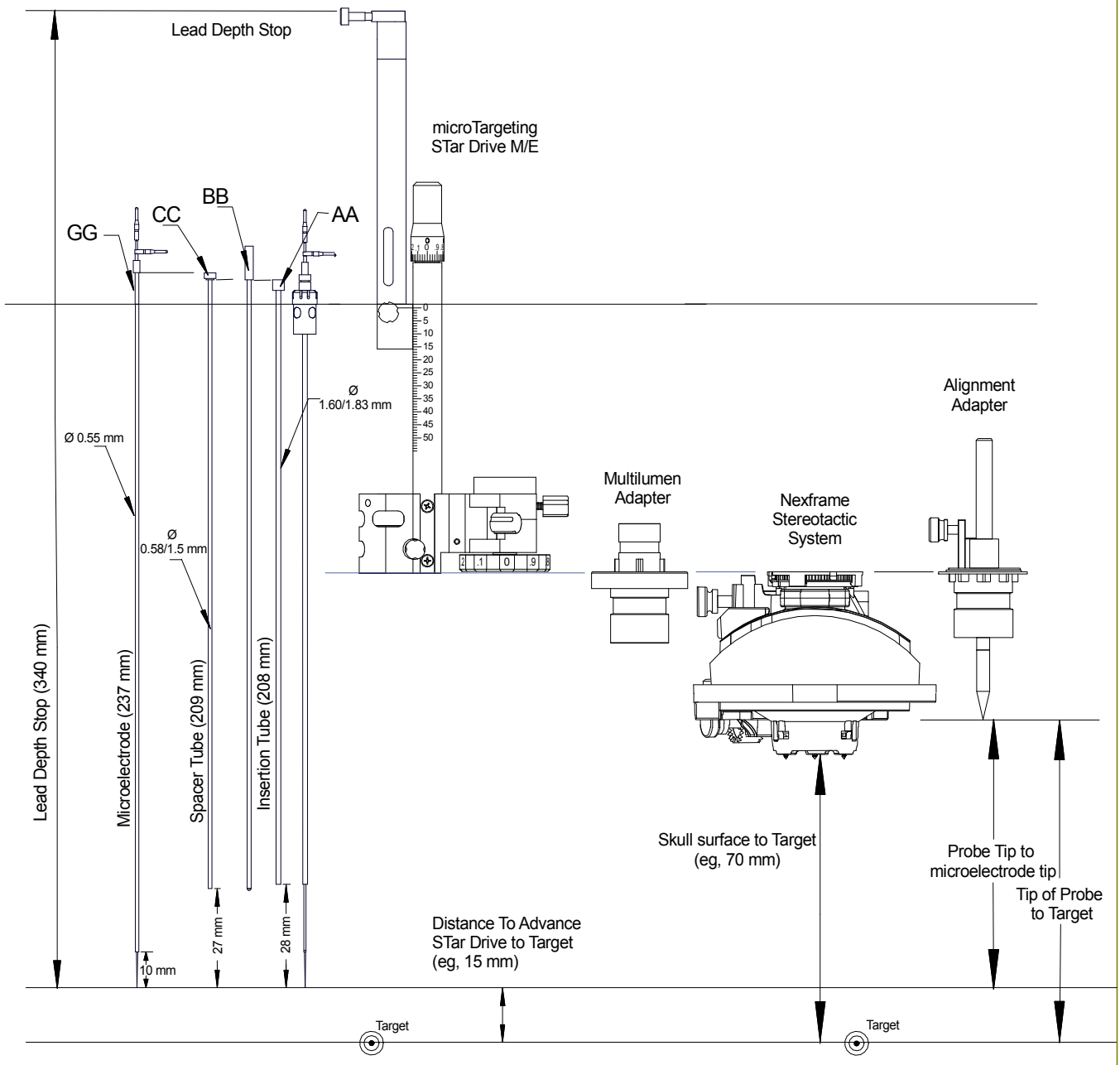




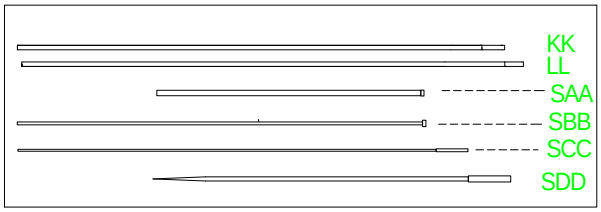
Ordering information FHC / Medtronic

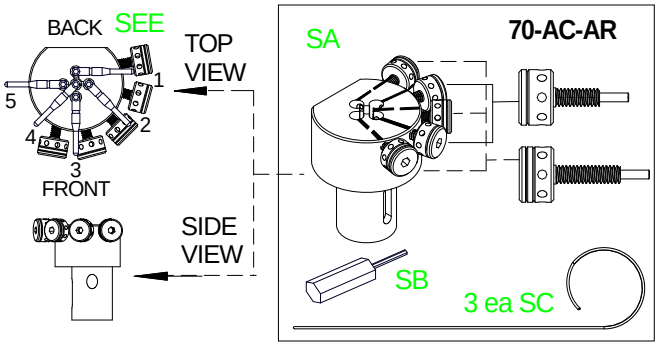
66-AC-AR	**Non Sterile Array Carrier and Clamp** Includes DD, EE, FF
70-IT-3007 / FC9003	**Sterile Single Insertion Tube Set (pk 5)** Includes AA, BB, CC
5700R	**Sterile Nexframe STar Drive mT Electrode (pk 5)**
5705L / FC2004	**Sterile Nexframe STar Drive DZAP Leadpoint mT Electrode (pk 5)**
5705Z	**Sterile Nexframe STar Drive DZAP mT Electrode (pk 5)**

AA	Insertion Tube	
BB	Stylet	
CC	Spacer Tube for Nexframe microelectrodes	
DD	Array Electrode Carrier	66-AC-EC
EE	Shielded Array Clamp	66-AC-SC
FF	Non shielded Array Clamp	66-AC-NC
GG	Sterile Nexframe STar Drive mT Electrode	
HH	Single Electrode pin position in slot	



STar™ Array Electrode Nexframe configuration

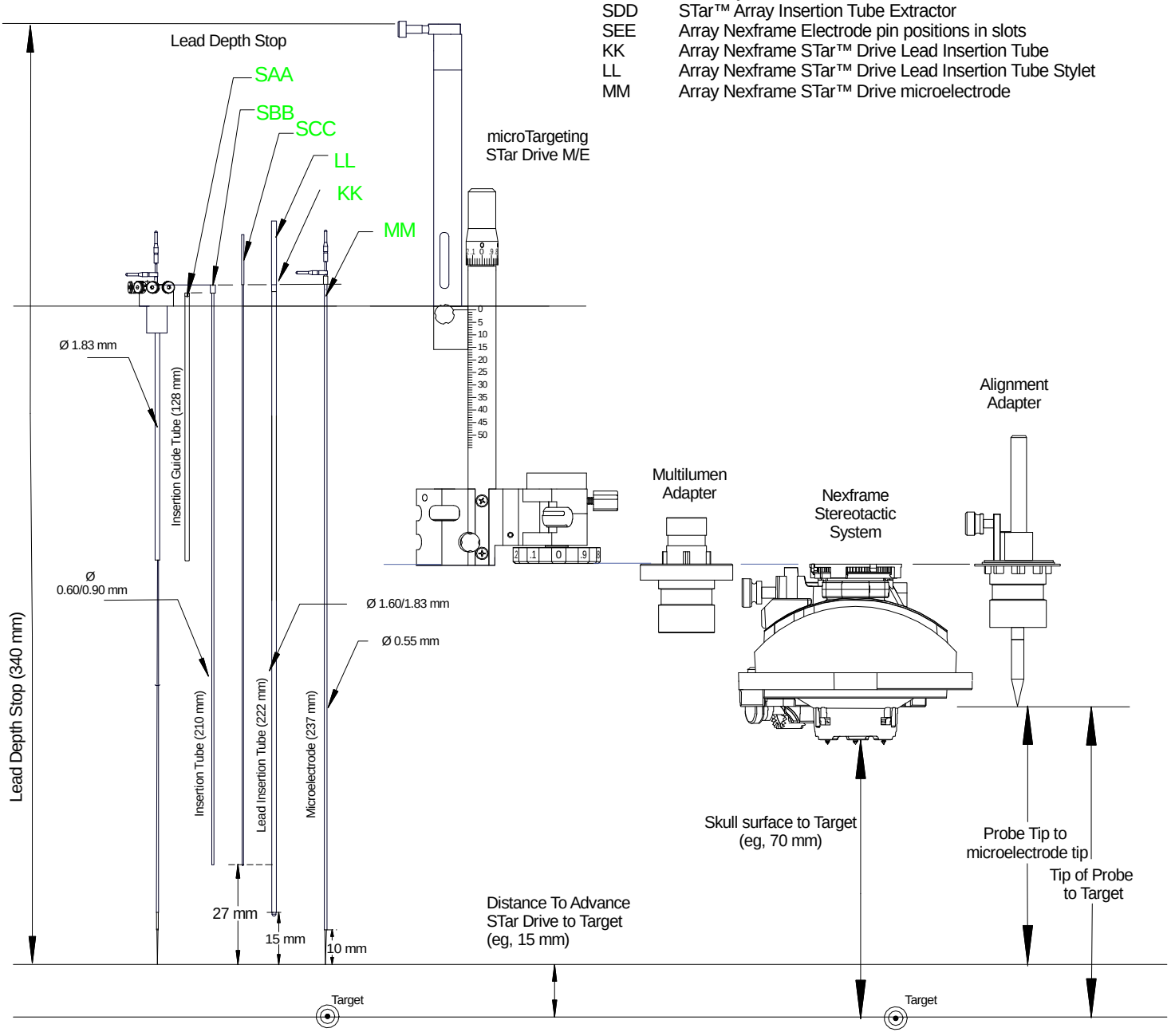




Ordering information FHC / Medtronic

70-IT-7107 / FC9001	**Sterile STar™ Array Electrode Insertion Tube Nexframe STar™ Drive (pk5)** includes 5ea SAA, 5ea SBB, 5ea SCC
70-IT-7147LI / FC9002	**Sterile Lead Insertion Tube Nexframe STar™ Drive (pk5)** includes 5ea KK, 5ea LL
70-CN-ET / FC8011	**Sterile STar™ Array Insertion Tube Extractor (pk5)** includes 5ea SDD
70-AC-AR / FC8008	**STar™ Array Locking Carrier** includes 1ea SA (w 2 spare screws) , 1ea SB
5700R	**Sterile Nexframe STar™ Drive mT Electrode (pk 5)**
5705L / FC2004	**Sterile Nexframe STar™ Drive DZAP Leadpoint mT Electrode (pk 5)**
5705Z	**Sterile Nexframe STar™ Drive DZAP mT Electrode (pk 5)**

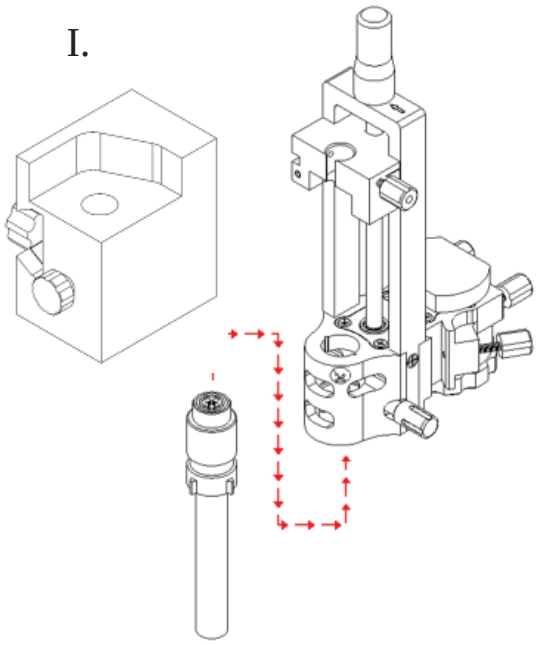
SA	STar™ Array Locking Carrier w/ 2 extra screws
SB	STar™ Array Hex Wrench
SC	STar™ Array Wire Tool
SAA	STar™ Array Nexframe Insertion Guide Tube
SBB	STar™ Array Nexframe Electrode Insertion Tube
SCC	STar™ Array Nexframe Electrode Insertion Tube Stylet
SDD	STar™ Array Insertion Tube Extractor
SEE	Array Nexframe Electrode pin positions in slots
KK	Array Nexframe STar™ Drive Lead Insertion Tube
LL	Array Nexframe STar™ Drive Lead Insertion Tube Stylet
MM	Array Nexframe STar™ Drive microelectrode



BrainLAB®/Micromar Adapter

BrainLAB AG Ammerthalstrasse 8 85551 Heimstetten Germany

I.



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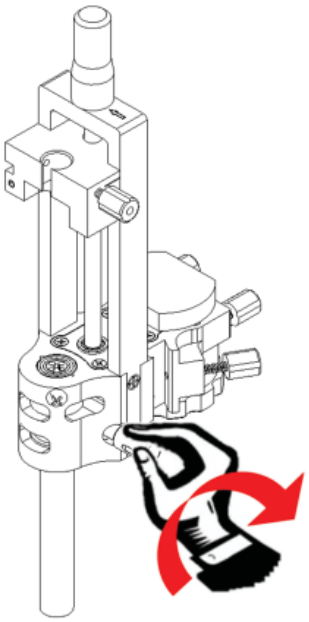
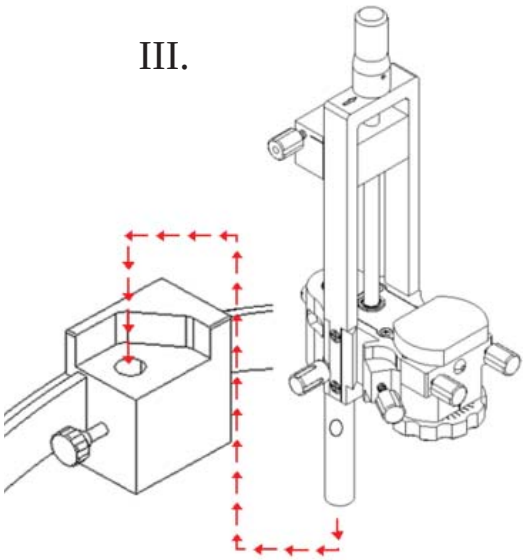
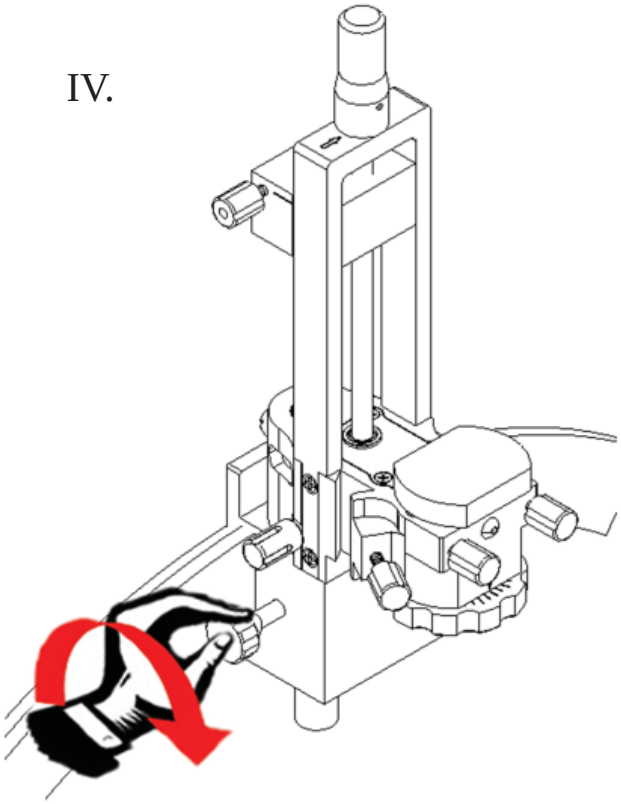
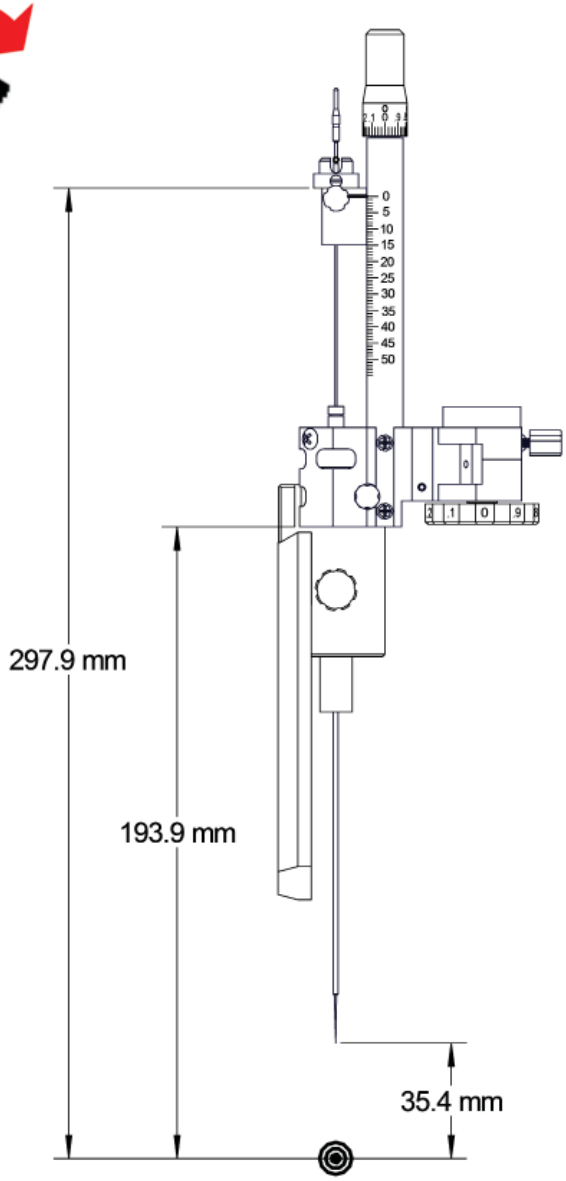


III.



IV.





Warranty and Service

CAUTION: Unauthorized field repairs may affect calibration and function. Units requiring repair should be returned to FHC or an authorized representative for service.

All FHC 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, or visit www.fh-co.com/FHC_Service.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.

Disposal at End of Product Life Cycle

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

FHC

"Innovation through collaboration"

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

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

EC REP **FHC Europe**
(TERMOBIT PROD srl)
129 Barbu Vacarescu Str, Sector 2
Bucharest 020272
Romania

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