



microTargeting™ XL STar™ Drive System: Catalog # ST-DS-DF

Directions for Use

L011-1007-XL
(Rev A0, November 2011)

Indications for use: The microTargeting™ XL STar™ Drive 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.

System Components:

70-ZD-ME-XL	STar™ Drive XL
66-DA-ME	Motor Assembly
66-EL-MS	Controller Module (V1.10XL)
70-FA-RD-XL	Radionics Frame Adapter
70-FA-LX-XL	Leksell Frame Adapter
66-EL-RM	Remote Control
67-00-6-XL	XL Wash/Sterilization Basket
66-EL-LC-USA	Line Cord (USA version)
66-DA-SD	Sterile Drapes 20/pk
70-AC-KT-XL	Spare Parts Kit
66-IT-VP-XL	Verification Probe

Replacement Parts not listed:

66-CN-BR Cleaning Brushes

Accessories: None provided by FHC

Components required, not included but not limited to:

- Suitable instrument of length and diameter to fit through frame adapter guide tube (ID=0.067in [1.7mm])
- Suitable carrier to mount instrument on XL Drive carriage
- Radionics CRW or Leksell stereotactic frame system

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"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



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

General Warnings

-  **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:** Prior to use, the microTargeting™ XL STar™ Drive 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.

General Cautions

- CAUTION:** The microTargeting™ XL STar™ Drive System must be used by a trained individual under the supervision of a neurosurgeon thoroughly familiar with its function and having carefully read this DFU.
- CAUTION:** The Motor Accessory is specifically designed to be used with the microTargeting™ XL STar™ Drive. 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™ XL STar™ Drive and components be serviced and recalibrated every 100 uses or evaluated by a factory authorized representative on an annual basis, whichever occurs sooner.
- CAUTION:** Do not use non-approved stereotactic system adapters, insertion tubes or other medical or electronic devices with the microTargeting™ XL STar™ Drive.
- CAUTION:** Handle the Drive and, when applicable, its Motor Accessory with extreme care. These components may be damaged if excessive force or incorrect handling occurs.
- CAUTION:** The microTargeting™ XL STar™ Drive is not MRI compatible.
- CAUTION:** When tightening 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.

 Rx Only	 Zero	 Off/On
 Hand Tighten Securely	 Retract	 Remote Control
 Type BF Equipment (electrically isolated from patient)	 Advance	 Motor Assembly
	 Retract to Zero	 Serial Communications Port
		 Sterile  Non-sterile

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.

System Components Diagram

Ordering information

- A XL STar Drive M/E
- B Positioning platform
- C Drive advancement knob (upper)
- D Instrument carrier locking screw
- E Protection Cover
- F Accessory locking knobs
- G Drive advancement knob (lower)
- H Stereotactic positioner locking knob
- I XL Sterilization Case incl cleaning brushes
- J Verification Probe
- K XL STar CRW Frame Adapter 70-FA-RD-XL
 - T-CRW expansion screw
 - U-Protective sleeve
- L XL STar Leksell Frame Adapter
 - U-Protective sleeve
 - V-Lower Guide Bushing
- M Spare Parts Kit
- N Motor with Display Assembly (motor)
- O Controller Module (including power supply P)
- Q Line Cord, USA
- R Remote Control
- S Sterile Drapes Sleeves (Sterile pack/20)

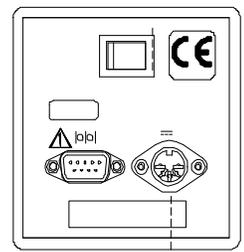
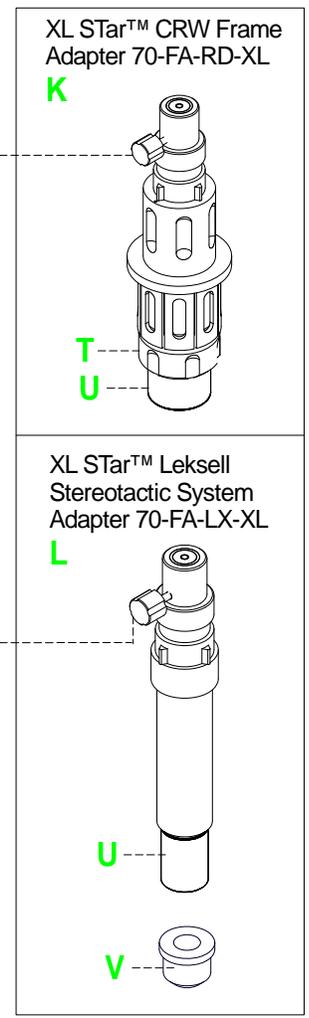
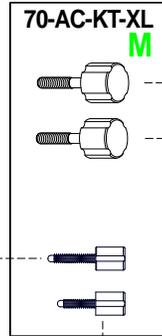
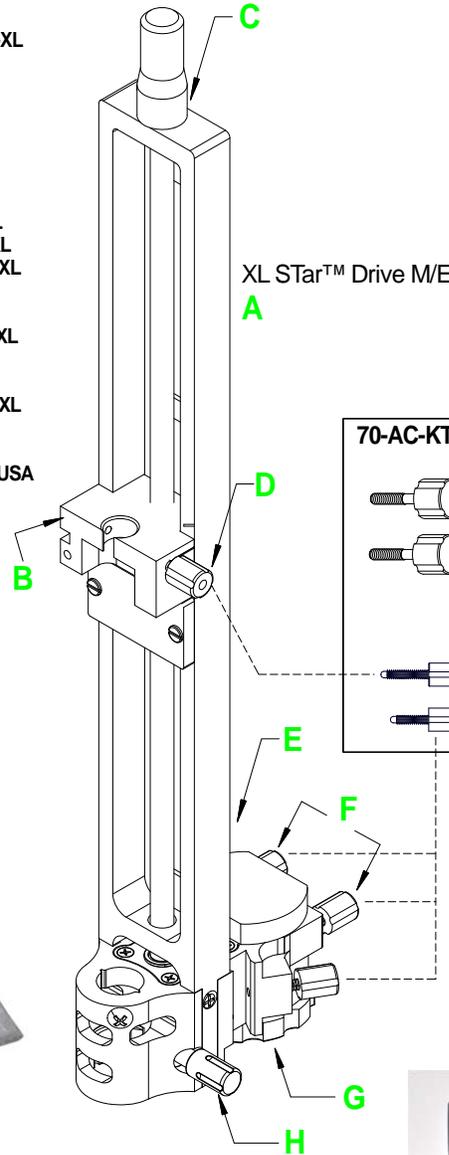
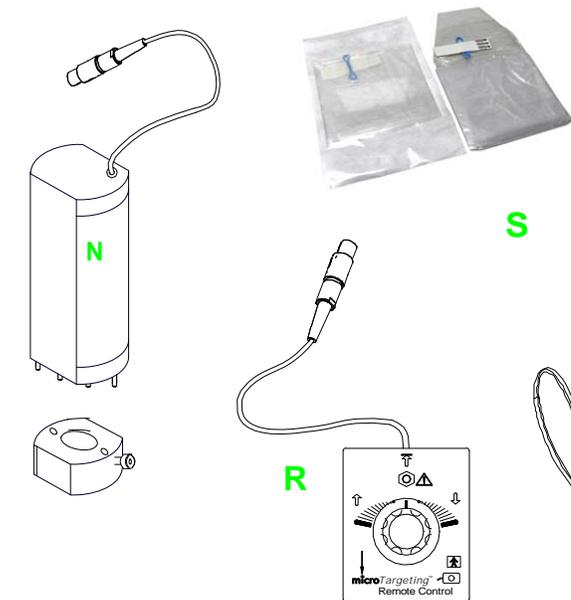
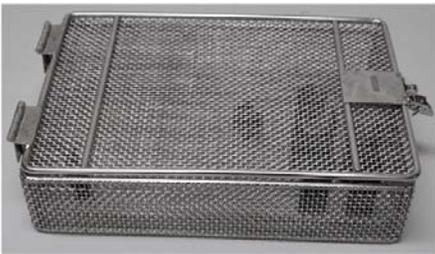
70-ZD-ME-XL

67-00-6-XL
66-IT-VP-XL
70-FA-RD-XL

70-FA-LX-XL

70-AC-KT-XL
66-DA-ME
66-EL-MS
66-EL-LC-USA
66-EL-RM
66-DA-SD

67-00-6-XL, XL Sterilization Case I



P (included with O)

Specifications

Usability

Drive Platform Travel: 120mm, graduated in 1mm increments from +15 to -110mm. Travel limited by mechanical stop at +8
 Drive advancement knobs: 1mm movement/revolution; 0.025mm graduation with 0.0 and 0.5 labeled on knob
 Platform Carrier mounting dimensions: 0.343"
 Instrument size: <.067" (1.7mm) = 1.0 of Adaptor Guide Tube
 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.

Storage

Store the microTargeting™ XL STar™ Drive and the Motor Accessory at temperatures between -34°C (-29°F) and 57°C (135°F). Do not exceed 135°F for long-term storage.

Sterilizable Components



1. XL Drive System components that require sterilization.

Disassembly for Cleaning &/or Sterilization



1. Using a clean soft cloth that has been soaked in the detergent solution (page 5). 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 the Frame Adapter protective sleeves, the CRW expansion screw, and put, with other extra small parts, in the basket as shown.

Place the verification probe in the basket as shown, before positioning the Drive.



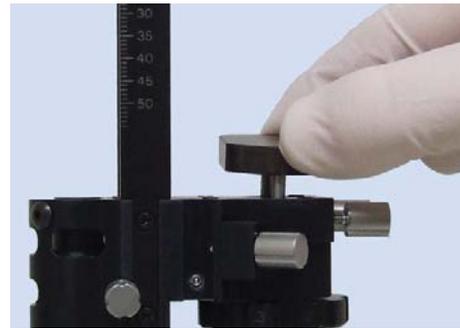
2. Tray with correct positioning of all sterilizable components.

Cleaning

* Refer to page 3 to correlate letters listed below with components.

CAUTION: The cover is provided to protect the coupling mechanism of the XL Star™ Drive when the Motor is not attached or when the Drive is not in the tray covered with sterile wrap. Failure to use the cover could allow debris to damage the mechanism. The cover should be removed during cleaning and sterilization to allow proper drainage from this mechanism.

The Frame Adapter protection sleeves are provided to protect the guide tube from misalignment and must also be removed during cleaning/sterilization and sterile storage. The cover and protection sleeves should be kept in the sterilization tray basket so they are available in case the Drive is to be transported or stored in the tray without the sterile wrap.



Manual Cleaning

Method	Items Covered	Protocol
XL Sterilization case needed (I)	<p>Drive and its Components *</p> <hr/> <p>XL STar™ Drive with cover removed (A)</p> <p>Frame Adapters (K, L)</p> <p>Verification Probe (J)</p>	<ol style="list-style-type: none"> 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. Immerse the tray filled with the disassembled drive components (page 4) in the wash solution for a minimum of 2 minutes. Remove the Drive and advance and retract it several times. Reposition the drive in the tray. 3. Repeat step 2 two more times. 4. Immerse the tray in a sonication unit filled with detergent solution and sonicate for a minimum of 10 minutes. 5. Rinse all components with running reverse osmosis/de-ionized water to remove any residual detergent. 6. Dry components using a clean soft cloth. 7. Visually inspect to ensure all visible soil is removed.

Automated Cleaning - Use tray with disassembled components (page 4)

XL Sterilization case needed (I)	<p>Drive and its Components *</p> <hr/> <p>XL STar™ Drive with cover removed (A)</p> <p>Frame Adapters (K, L)</p> <p>Verification Probe (J)</p>	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)
		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		

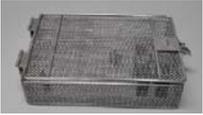
Sterilization



WARNING: The Motor Assembly should not be sterilized; use the draping system as described on page 7 prior to use in the sterile field.



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

Method	Container	XL STar™ Drive	Protocol	
Steam		✓	<u>Prevacuum (Wrapped)</u> preconditioning pulses: 3 minimum temperature: 132°C (270°F) full cycle time: 12 min minimum dry time: 30 min	<u>Gravity (Wrapped)</u> minimum temperature: 132°C (270°F) full cycle time: 30 min minimum dry time: 35 min

Following sterilization, before reassembling the Drive, 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.

Drive Maintenance, Calibration, Reuse Information

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

The XL Drive System should be calibrated by an FHC authorized service representative after every 100 uses or every year, whichever occurs sooner.

Sterile Draping the Motor Assembly



WARNING: If during the process of draping the motor the sterility of the drape is compromised, the drape should be discarded and a new drape used.

Draping the Motor 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 Motor. 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 Motor 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 accessory, 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 XL STar™ Drive motor coupling, 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 band 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 motor inside while **STERILE** hand pulls the cable from the drape. Be careful not to touch the pins protruding from the end of the drape.

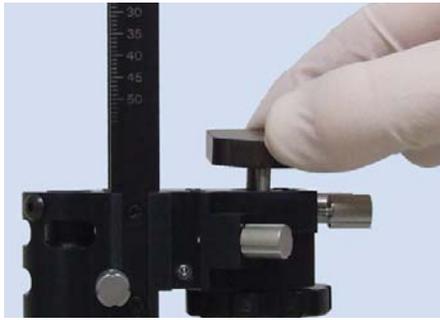


9. **STERILE** : Unfold the drape carefully as the cable is withdrawn. When the cable is out of the sterile envelope distance, the **STERILE** hand can hold both the cable and the drape.



10. **STERILE** : Using the tape that the elastic bands came in, pull in the folds of the drape tightly above the Motor and tape neatly. If no assistant is helping, this can be done after changing the second hand to a sterile glove.
11. **STERILE** : The whole draped assembly should be set aside on a sterile surface awaiting the surgery. It is best to leave the cable inside the drape and to not unfold the drape more than necessary until it is needed.

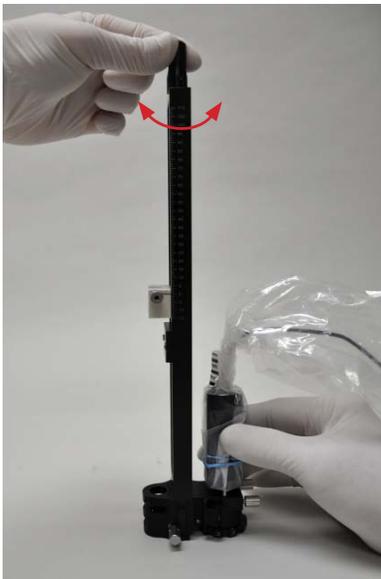
Mounting the Draped Motor Assembly on the Drive



1. Remove the protection cover of the Drive.



2. Pick up the Motor 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 Motor while turning the Drive advancement knob slowly.



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 Motor Assembly seats squarely on the Drive. A misalignment may result in a stall. (See page 14)

CAUTION: Never turn the manual advancement knob on the microTargeting™ XL STar™ Drive while the 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 and operation.

Connecting the Motor Assembly to the Controller Module

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

 **WARNING: Do not operate the Controller in the presence of flammable anesthetics.**

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 the 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.



- 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.



Assembly and Pre-Use Checkout

Before each use, thoroughly examine the microTargeting™ XL STar™ Drive for function, cleanliness, and calibration.

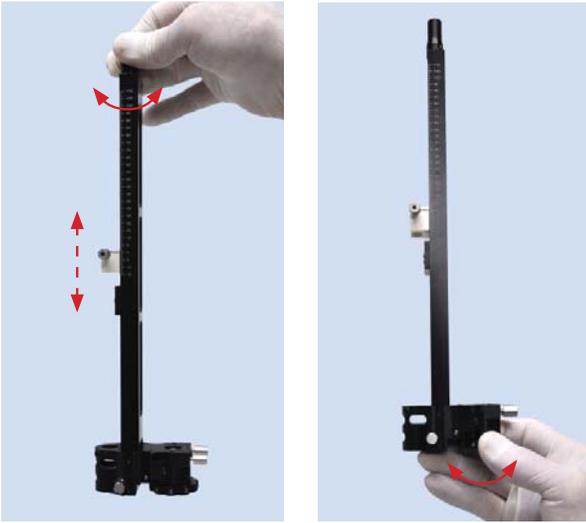
Any noticeable change in accuracy, in ease of movement, or any buildup of residues, looseness, damage, or difficulty of fitting components will require return to the manufacturer for refurbishing and recalibration.

 **WARNING: Watch for pinch points or edges that might pierce the gloves and cause sterility to be compromised.**

 **WARNING: Avoid Drive contact with any electrical current source during any stage of Drive use.**



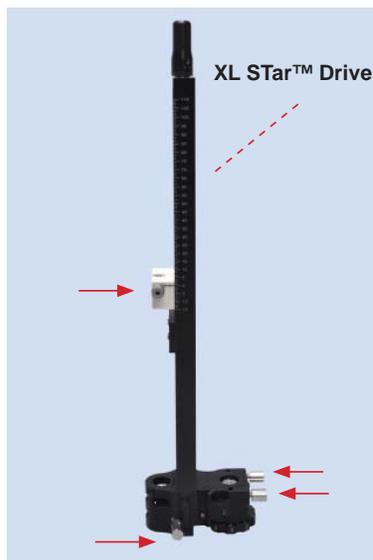
1. Check the motor transfer belt tension by grasping the upper drive adjustment screw knob ("C" on page 3) firmly. Then try to rotate the lower drive adjustment screw knob ("G" on page 3). There should be no "elasticity". If any "play" is noted, the transfer belt must be replaced. (Refer to the procedure provided with the spare parts kit 70-AC-KT-XL.)



2. Confirm there are no contaminants or debris on the Drive. Turn both knobs separately, confirm that the Drive screw rotates and that the positioning 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.

CAUTION: Pre-use check should include retracting or advancing the Drive Motor using the handheld remote. This must be done before the Drive is zeroed. Confirm that the Remote Control 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 14.)

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.



3. Confirm all thumbknobs are present.



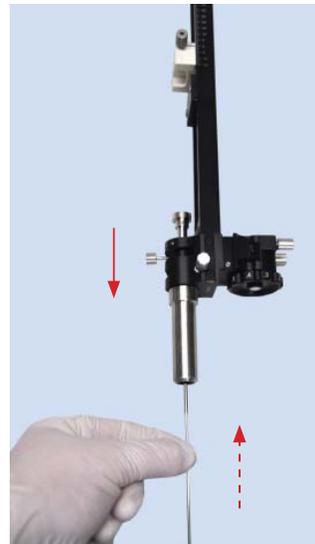
4. Secure the Stereotactic Adapter to the Drive. (See pages 15-16 for appropriate type.)

5. Install the Verification Probe onto the base of the drive. 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.



WARNING: The verification probe is for confirmation only and should never enter the brain.

6. Remove the Verification Probe.



Mounting the Drive on the Stereotactic Frame

Mount the assembled system onto the stereotactic frame and secure it as shown on pages 15-16. 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 XL STar™ Drive cannot move or rotate.



WARNING: The draped Motor 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.

Operating Procedure Including Handling Instructions for Compromised Sterility



WARNING: If motor drape sleeve sterility is compromised at any time during the procedure it must be replaced and the process begun again as described on page 9.

1. Activate power using the on/off switch on the back panel.

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

2. Set the Drive to zero by using the remote control. Press the zero button, labeled 0, (front panel on the Controller) to set the LED display to 0.000mm.
3. Push the 0 button on the Controller front panel a second time to see the Insertion Point and Retraction Point displayed.

CAUTION: Turning the knob briefly <1 second clockwise will show the Insertion Point (+7.00mm), turning the knob briefly counter-clockwise will show the Retraction Point (-100.00mm). However this method is NOT recommended since turning the knob for longer than a second will cause movement of the platform.

CAUTION: If the Retract to Zero button on the Remote Control is inadvertently pressed for at least 5 seconds before the next step, the Controller will go into its Remote calibration mode. The calibration procedure described on page 14 must be followed before the Remote will function normally.

- 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 14.

CAUTION: Never turn the manual advancement knobs on the microTargeting™ XL STar™ Drive while a motor is engaged. This can damage both the motor and the Drive.

WARNING: Always confirm that the microTargeting™ XL STar™ Drive is set at 0mm when zeroing Controller. Not doing so will cause the Drive limit to be incorrect and also will cause the Controller to be out of sync with the drive position as read on the drive scale.

WARNING: DO NOT press the zero button longer than 3 seconds after the initial zeroing, as this will reset the current position to 0.000mm.

- When the Drive is advanced, the position report on the LED will be updated. Distance is shown in millimeters. The sign in front of the position number indicates if the Drive is above or under the zero point: "+" indicates the Drive has been advanced (under zero point), "-" indicates it has been retracted (above zero point).

WARNING: In the event of any Drive Accessory failure, erratic function or motor stall, remove it and proceed using the microTargeting™ XL STar™ Drive 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 0.5 mm, discontinue use of the Controller and proceed manually.

WARNING: The microTargeting™ Controller has been factory set to enforce a software drive limit of +7mm and -100mm, which corresponds with the maximum travel of the microTargeting™ XL STar™ Drive from the zero point in each direction. These limits may be changed through the serial interface of the microTargeting™ Controller.

- Mount the carrier with instrument on the Drive positioning platform.

WARNING: Avoid exerting any lateral forces on the Drive when adjusting the Drive or positioning carrier or instruments onto the Drive positioning platform.

5. Starting motion

If the remote knob is held clockwise for more than approximately 1 second the display will repeatedly scroll: "Advance to +7.00mm - Press the remote button to initiate." Releasing the knob, and/or pressing the remote control button will cause the drive to advance towards the insertion point.

If the remote knob is held counter-clockwise for more than approximately 1 second the display will repeatedly scroll: "Retract to -100.00mm - Press the remote button to initiate." Releasing the knob and/or pressing the remote control button will cause the drive to retract towards the retraction point.

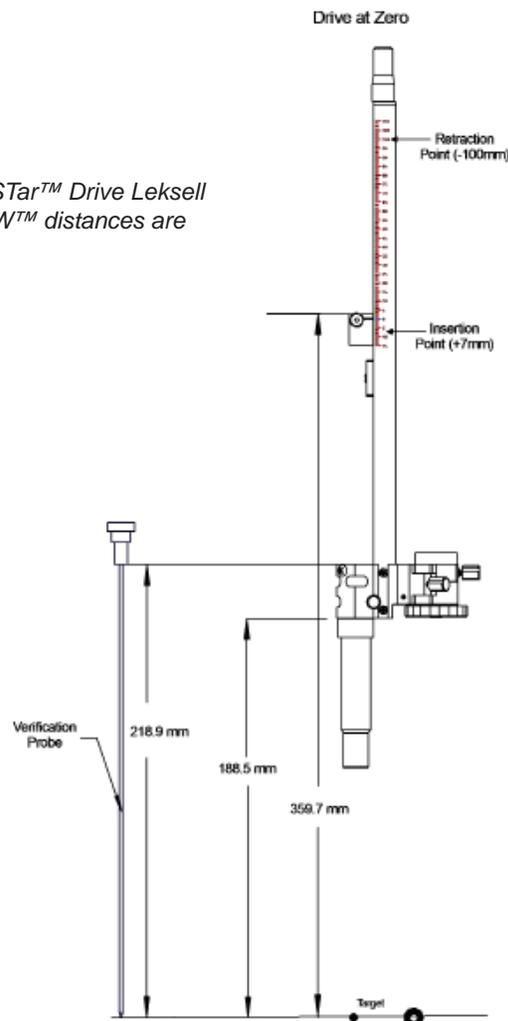
CAUTION: The initial movement of the platform when retracting from the Insertion Point is very slow; it may not be apparent that the Drive is moving for approximately 20 seconds. The time for complete retraction is approximately 7 min.

6. Stopping motion

Note: When the drive is advancing or retracting towards a set point, it can be stopped either by pressing the remote control button or the zero button on the module.

To restart the Drive, refer to section 5 above.

Shown with STar™ Drive Leksell Adapter: CRW™ distances are identical.



Remote Control Calibration

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 (refer to section 5, page 13).

The number displayed should be checked against the Drive's physical scale. A small discrepancy of less than 0.5mm is not a cause for concern.

Discrepancies of over 0.5mm 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.

Dismantling Equipment After Use

1. Remove the Drive with Stereotactic Frame Adapter from the frame. Remove the Motor from the Drive and discard the sterile drape. Set aside the Drive and Stereotactic Frame Adapters, with the sterilization tray, including the verification probe and spare parts, for disassembly and cleaning (page 4).

2. Unplug the Motor and Remote Control from the Controller. Disconnect the Power Supply from the Controller and the Line Cord from the lines receptacle.

In the event the Motor or another components not listed on page 4 as equipment for sterilization have become contaminated or soiled, they should be wiped clean with an isopropyl alcohol dampened cloth, then dried. Do not immerse in fluids or allow excessive moisture to remain.

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

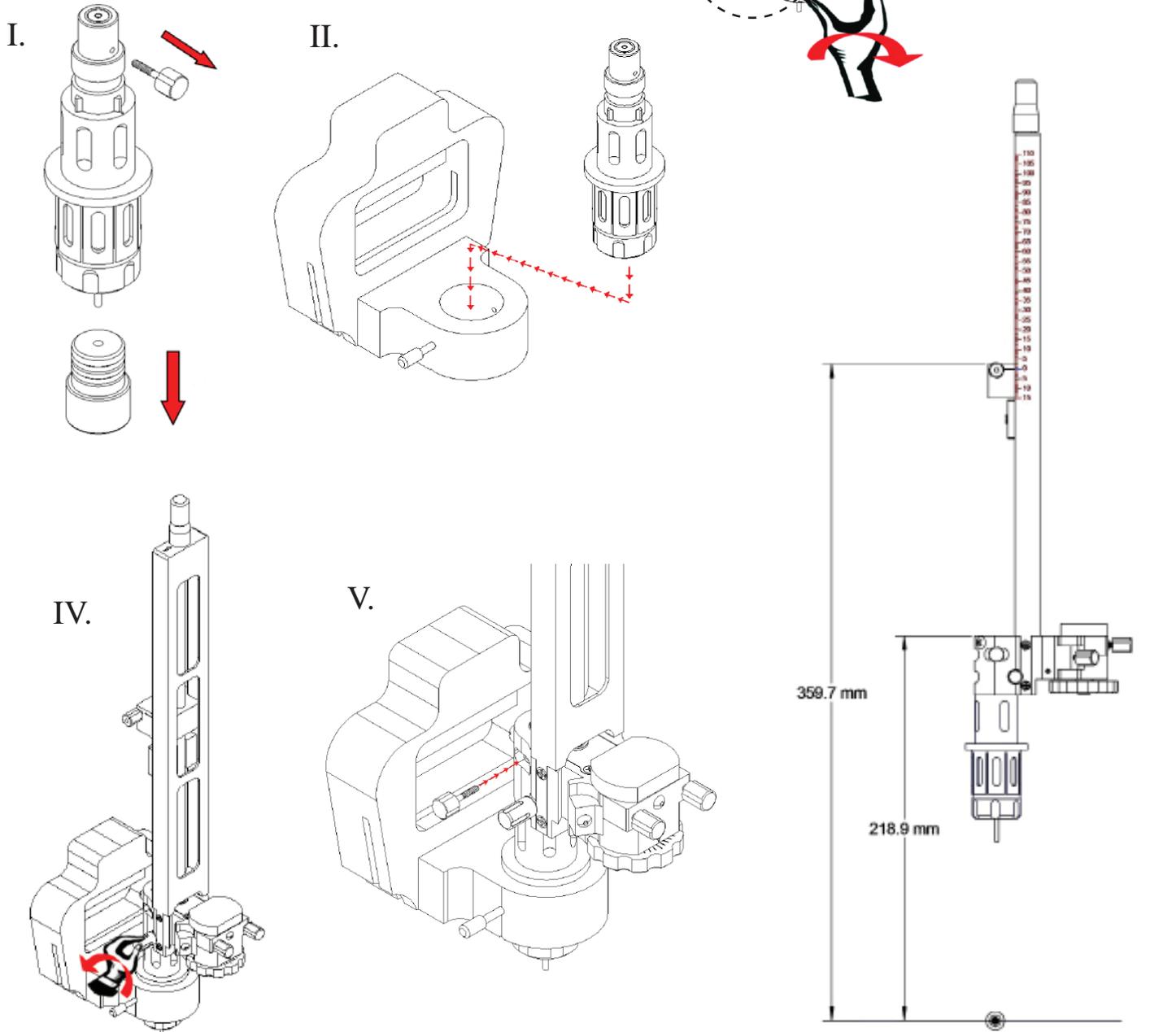
Frame Adapters

Radionics CRW™ Adapter

Radionics Inc. 22 Terry Ave Burlington, MA 01803 USA

⚠ WARNING: Separate protection sleeve and adapter prior to cleaning and sterilization.

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



Leksell Stereotactic System® Adapter

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

