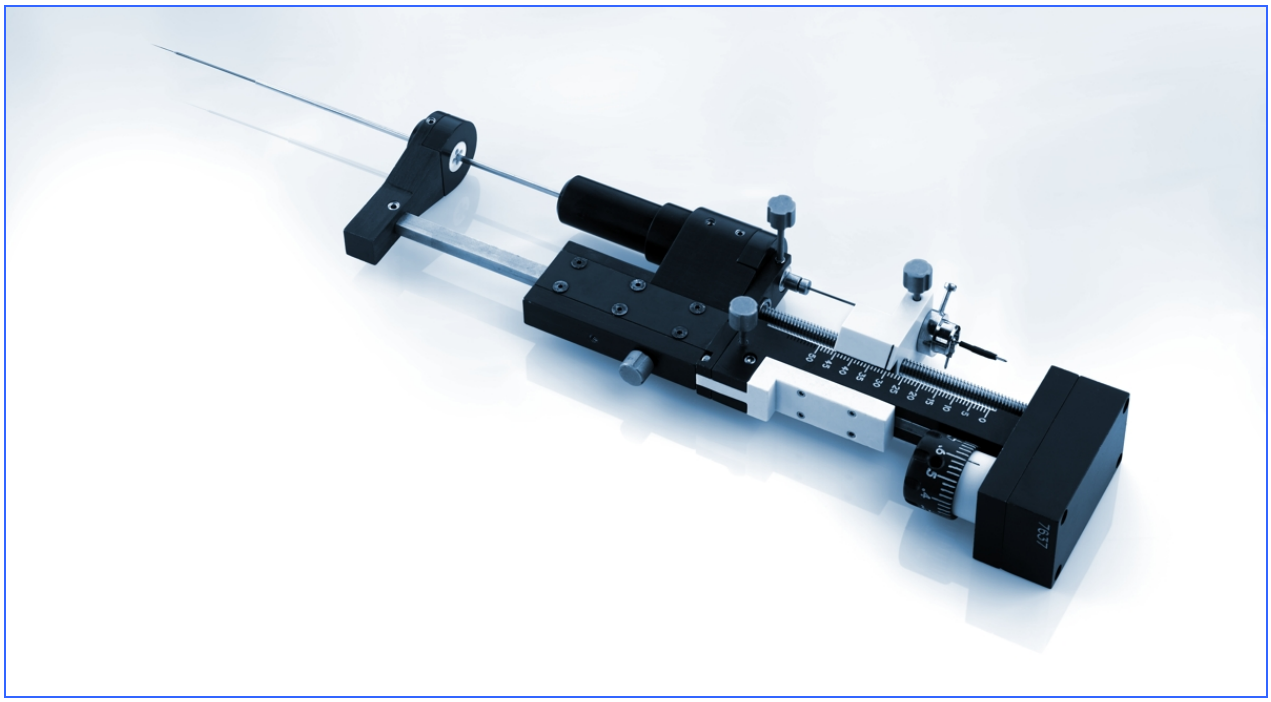
Medtronic

# microTargeting® Drive

## System for Stereotactic Positioning



# User Guide

**CAUTION** In the United States, Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner.

CE

At the time of printing / transfer to the CD-ROM, this manual correctly described the software and its functions. However, as modifications may have been carried out since the production of this manual, the system package may contain one or more addenda to the manual. This manual including any such addenda must be thoroughly read, before using the software.

The following situations void any guarantee(s) and obligations for Medtronic A/S:
- The software is not used according to the enclosed manuals and other accompanying documentation
- The software is installed or modified by persons other than Medtronic A/S service technicians

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# Table of Contents

# Introduction

The microTargeting® Drive System with maTrix™ Mount is adaptable to all major stereotactic systems and allows the neurosurgeon to position probes, or instruments such as microelectrodes, stimulating electrodes, or DBS™ electrodes precisely and efficiently in the brain. When the drive system is equipped with the maTrix™ guides, these electrodes can be positioned in 5 positions: a central track aligned with the stereotactic Z axis and 4 parallel tracks offset by 2 mm (on center) from the center track.

The microTargeting® System is set up so that it can be used to position DBS™ electrodes after microelectrode recording without removing the drive. MicroTargeting electrodes are available, which include micro and macro recording surfaces and which feature protective tube design to prevent tip damage.

Two Insertion Tube Sets are available for use with the maTrix™ drive: the Single Electrode System and the Array Electrode System:

The Single Electrode System includes an insertion tube/stylet and two electrode carriers. An electrode (ordered separately) can be positioned in any one of the five tracks and then, if additional data are required, it can be repositioned in one of the other tracks. A spacer tube provided and used to assure alignment of the thinner recording electrode is removed prior to positioning the DBS™ electrode. Depth stops for custom electrodes are also available.

The Array Electrode System is designed to minimize the insertion tube/electrode volume. The electrode and the insertion tube move together in this configuration. When a track is selected, the electrode insertion tube and lower guide must be removed and a DBS™ insertion tube/stylet is then positioned in the same track.

When the microTargeting® drive system is used with the Medtronic microTargeting® electrodes, distances are factory preset using stops so no adjustment or calibration is necessary.

The Stereotactic Adapter, Insertion Tube sets and microTargeting electrodes must be ordered separately.

# Safety Information

## General

### Indications

The microTargeting ® Drive System is intended to be used with commercially available stereotactic systems for neurosurgical procedures which require the accurate positioning of microelectrodes, stimulation 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.

**WARNING** Field disassembly of components beyond the major assemblies may affect calibration and function. Units requiring repair should be returned to the manufacturer for overhaul.

**WARNING** The device is not compatible for use in an MRI magnetic field.

## Precautions

### Storage

Store the microTargeting® Drive System and its accessories at normal room temperatures between –34°C (-29°F) and 57°C (135°F). Do not exceed 135°F for long-term storage.

### Components

The use of non-approved stereotactic system adapters, insertion tubes or other medical or electronic devices with the microTargeting® System may result in damage to components or incorrect functioning.

### Component Failures

While a high degree of reliability is designed into the system, unexpected failure of components is always possible if improper storage or handling occurs.

### Handling Components

Handle the drive and its accessories with extreme care. These components may be damaged if excessive force or incorrect handling occurs.

- Do not bend the insertion tubes or the stylets.
- Always keep the stylets inside the insertion tubes when the tubes are not in use.

**WARNING** When there is an insertion tube in the brain, every effort should be made to minimize lateral forces to the microTargeting® Drive System. Abrupt movement, or excessive handling force can translate into significant lateral movements of the tube in the brain.

## Adverse Events

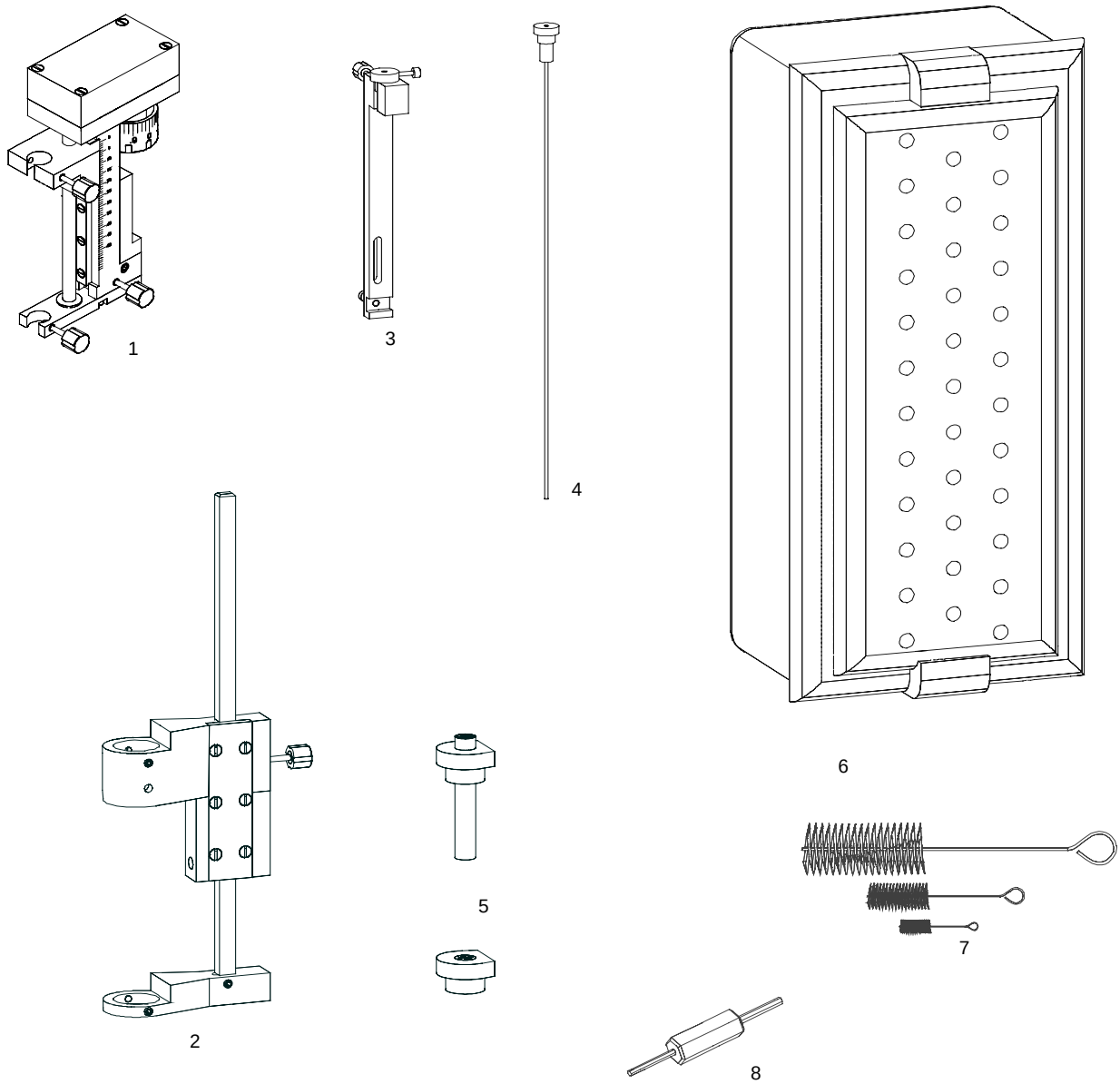
Adverse events correspond to those associated with the placement of electrodes and instruments during functional neurosurgery.

# Included Items

## microTargeting® Drive

The microTargeting® Drive System consists of the following:
microTargeting ® Drive, maTrix™ Drive Mount and Lower Guide*, maTrix™ Guide Bushings*, DBS™ Holder with DBS (1.9 mm Ø)* Verification Probe*, Sterilization Case, Cleaning Brushes* Hex Wrench*, mT$^{tm}$ Accessories Kit* (*Also Available Individually)

*Figure 1 microTargeting® Drive System*




| | | | |
|---|---|---|---|
| **1** | microTargeting® drive | **2** | MaTrix™ drive mount and lower guide |
| **3** | DBS Holder | **4** | Verification Probe |
| **5** | maTrix™ Guide Bushings | **6** | Sterilization Case |
| **7** | Cleaning Brushes | **8** | Hex Wrench |

# Stereotactic adaptor*)

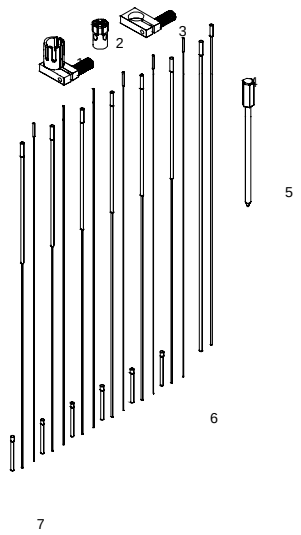
*) One required.

See Appendix A for available adaptations to commonly used stereotactic frames and systems.

## *Insertion Tube Set (one required)*

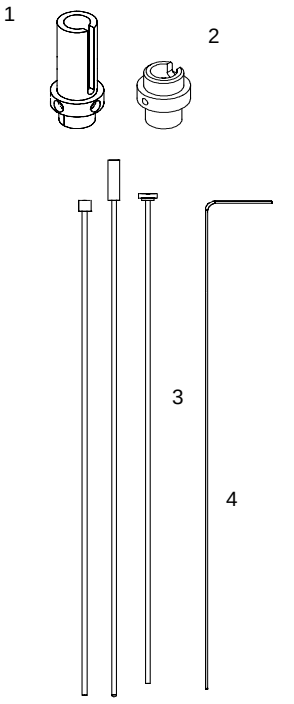
9033G0621
**Array Electrode Insertion Tube Set**
**(One required)**

1. Shielded Array electrode clamp*.
2. Array Electrode carrier*.
3. Unshielded Array electrode clamp*.
4. DBS Insertion Tube and Stylet.
5. Insertion Tool*.
6. Insertion Tubes and Stylets
7. Lower Guide Spacer Tube*.




9033G0611
**Single Electrode Insertion Tube Set**

1. Shielded Single Electrode Carrier*.
2. Unshielded Single Electrode Carrier*.
3. Insertion Tube, Stylet, Spacer Tuber
4. Cleaning Tool*.




* Available individually.

# Accessories Available

- microTargeting® Accessories Kit 9033G0801, (not shown) includes extra thumb knobs, fixing screws and hex wrench.

***Also required:***
Microelectrodes such as:

- 9013S0831 microTargeting electrode 291
- 9013S0842 microTargeting electrode 291A

# Individual Components Available

- microTargeting® drive including Sterilization Case, DBS™ Holder with Depth Stop, Cleaning Brushes and Hex Wrench
- microTargeting® Accessories Kit.
- Drive Mount with Lower Guide.
- Verification Probe.
- maTrix™ Guide Brushings.
- Single Electrode Insertion Tube Set including one insertion tube and stylet, one spacer tube with cleaning tool.
- Single Electrode Carriers.
- Array Insertion Tube Set including six insertion tubes and stylets, six lower guide spacer tubes, one DBS™ insertion tube and stylet, one insertion tool.
- Array Electrode Carrier and Clamp.
- Array Insertion Tube Cleaning Tool.
- Cleaning Brushes (set of three).
- DBS® Holder and Depth Stop.
- Array Electrode Insertion Tool.
- Hex Wrench.
- Lower Guide Spacer Tube.

# Sterilization

## Before the Sterilization

### *Drive Components (Steam or EtO Sterilize)*

After use, separate the Drive, the Mount, the Stereotactic Adapters and the DBS Adapter. These components of the microTargeting® Drive System should be thoroughly wiped with disinfectant solution such as Betadine™ ; and the seams, grooves, screw heads and other devices should be scrubbed using the cleaning brushes provided, and then wiped clean with a distilled water cloth, before sterilization is performed.

While these Drive Components may be steam autoclaved, the use of EtO sterilization is recommended, when time is not an issue. All components can be put into the sterilization case provided with the microTargeting® Drive System. This case has been validated for steam autoclave and gas sterilization, but not for Sterrad™. The system should be examined after each sterilization cycle for damage and function.

### *Insertion Tubes, Spacer Tubes and Electrode Depth Stops (Steam Sterilize only).*

**CAUTION** Handle the insertion tubes carefully to prevent bending the tubes

- Thoroughly rinse the components separately under tap water.
- Then, under running tap water, repeatedly insert the stylet, or spacer tube cleaning tool in and out of the tube to dislodge any debris, or coagulated fluid.
- Soak all components in the cleaning solution, and then repeat the tube reaming (as above) first in the cleaning solution, then under running tap water, and then in distilled water.
- Rinse the other components in distilled water.

Insertion tubes, spacer tubes, and stylets should be steam sterilized separately.

## Validated Sterilization Protocols

### *Steam autoclaving*

Minimum temperature, wrapped: 132°C
Cycle time gravity: 10 min;
Cycle time pre-vacuum: 4 min
Minimum dry time: 0 min

### *Unwrapped Gravity Steam Sterilization (Flash)*

**NOTE** To be used only during the surgical procedure in the event that the drive should get contaminated.

Temperature set point: 132°C
Half cycle time: 5 min
Minimum dry time: 0 min

### *EtO Gas*

#### Preconditioning

Temperature, wrapped: 54+/- 2°C
Relative humidity: 40 +/- 20%
Vacuum set point: 1.5psia
Steam partial pressure: 2.18psia
Preconditioning set point: 2.37psia
Preconditioning time: 1 hr

#### Sterilization

Temperature wrapped: 54+/- 2°C
Relative humidity: 40 +/- 20%
Pressure set point: 8.87 psia
EtO concentration: 725 +/- 25 mg/L
Gas exposure time: 2 hr
Detoxification and drying time: 12 hr

**CAUTION** Following sterilization, before reassembling the drive system, use a damp sterile distilled water cloth to wipe off the pylon of the drive mount, so that the residue does not affect the sliding of the pylon into the drive. Use the same cloth to wipe off other surfaces to prevent residue build up.

# Maintenance and Calibration

- Following each use, all components of the system should be thoroughly cleaned, and then rinsed with distilled water.
- None of the system moving parts require lubrication. Do not oil, or lubricate.
- Every 10 sterilization cycles, thorougly examine the microTargeting Drive system for function, cleanliness and calibration as described in the Installation section below. 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. After 100 sterilization cycles, the entire system should be returned for inspection and recalibration.

# *Procedural Information*

## System Terminology

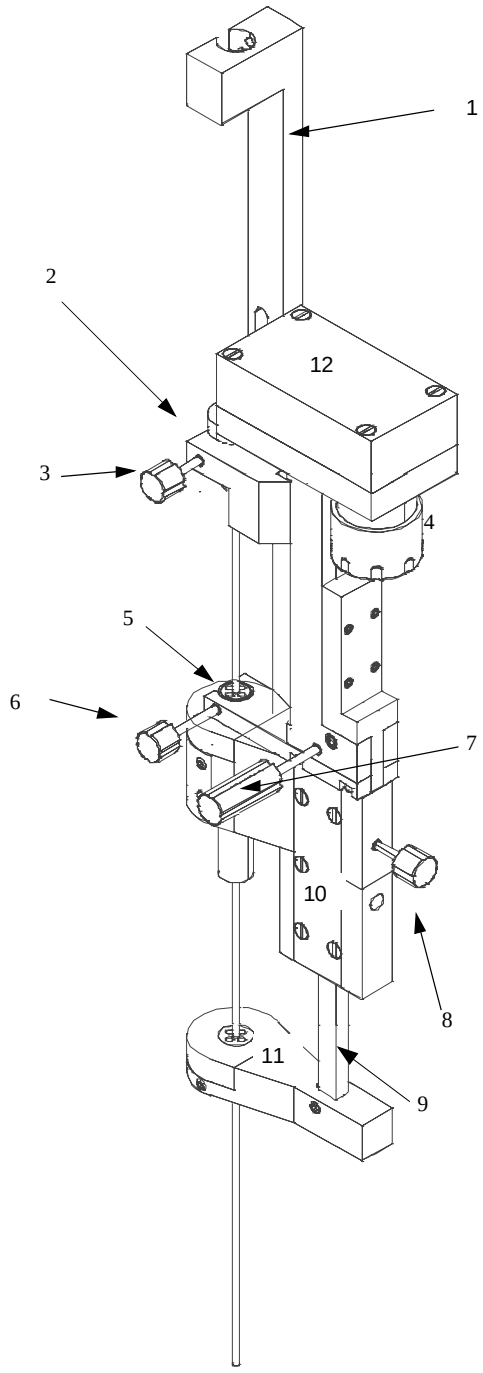



*Figure 2*

**1** DBS Holder
**2** Positioning Platform
**3** Electrode Carrier Locking Screw
**4** Drive Advancement Knob
**5** maTrix Bushing
**6** Drive Mount Locking Screw
**7** Drive Locking Screw
**8** Pylon Locking Screw
**9** Pylon
**10** Drive Mount
**11** Lower Guide
**12** microTargeting Drive

## Installation

**NOTE** General, see Appendix A for specific stereotactic system directions.

**1** Secure the stereotactic adapter to the drive mount using the hex wrench provided. (Make sure the detent of the adapter is on the same side as the locking screw).

**2** Slide the drive onto the pylon and secure it with the pylon locking screw and the drive locking screw.

**3** Mount the assembled system onto the stereotactic system and secure it. Make sure the securing screws are tight to prevent movement or rotation.

**4** Adjust the stereotactic system on its calibration base, (where used), so that the predicted target is located in the center of the arc or the selected target location of the system.

**5** Install the verification probe until its depth stop rests onto the positioning platform.

**6** Secure the verification probe in place by tightening the locking screw on the platform.

7 The verification probe exactly simulates the length of the electrodes. Advance the drive to the target distance specified for the stereotactic adapter to be used. (See Appendix A).

8 When the stereotactic system and the drive are set up correctly, the tip of the verification probe will be exactly at the predicted target.

**CAUTION** Always check the tightness of screws and knobs, before inserting electrodes, insertion tubes, or instruments. The drive and mount securing knobs should not normally require loosening during the procedure.

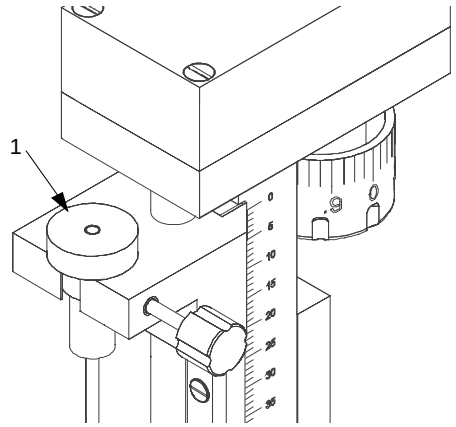



*Figure 3: 1 Verification Probe*

# Assembly

1 After sterilization assemble the components as described in steps 1-4 in the section on installation.

2 Pre-operatively set the depth stop on the recording electrode (if required), and on the DBS™ lead electrode. The dimensional considerations are shown in figure 4.

3 After placement of the fiducial rings or markers on the patient, the patient is scanned. By using standard imaging techniques (procedures provided by the stereotactic system manufacturer), the predicted target coordinates are determined and the stereotactic system is adjusted for the appropriate track.

4 If the stereotactic system includes a phantom, mount the microTargeting ® Drive System. Use the verification probe to confirm the correct track and target location.

5 Remove the Drive and the verification probe and position the stereotactic system on the fiducial rings or markers.

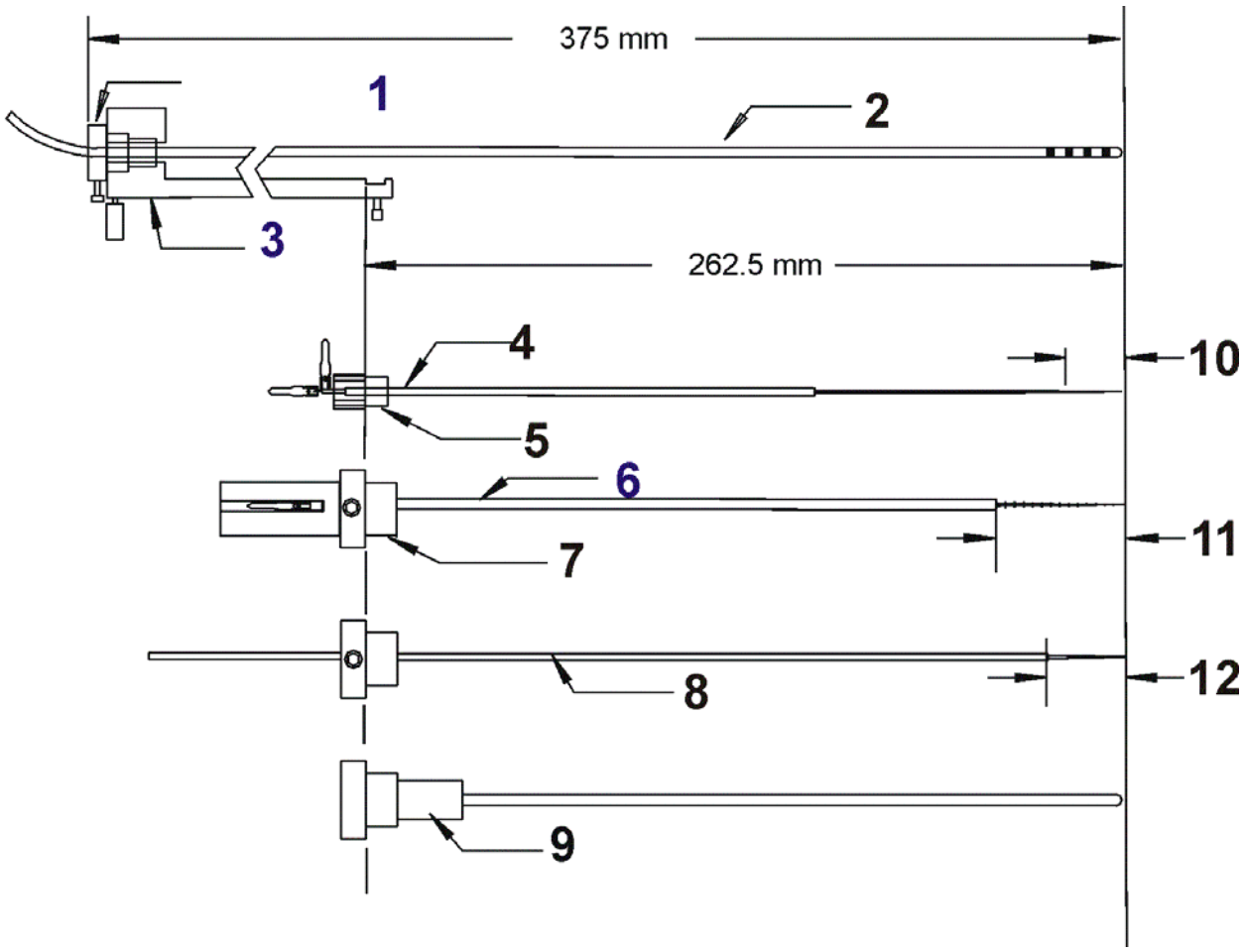
6 A burr hole or appropriate smaller cranial hole is then drilled.

7 Secure the microTargeting ® Drive System onto the stereotactic system.

**CAUTION** The stereotactic adapter must be securely held in the frame mount, so that the drive system cannot move, or rotate. Make sure that the knobs, or screws are secured tightly.

8 If a DBS™ burr hole ring is to be used, position it in the skull.

*Figure 4 Stop Placement Dimensions*




| | | | |
|---|---|---|---|
| **1** | DBS Depth Stop | **2** | DBS Electrode |
| **3** | DBS Holder | **4** | Array Electrode and Insertion Tube |
| **5** | maTrix Electrode Carrier | **6** | Single Electrode |
| **7** | Single Electrode Carrier | **8** | Generic Electrode |
| **9** | Verification Probe | **10** | Macro-electrode 10.0mm |
| **11** | Macro-electrode 10.0mm | **12** | Determine Macro-electrode Contact Distance if appropriate |

# Single Electrode Insertion Tube Set Procedure

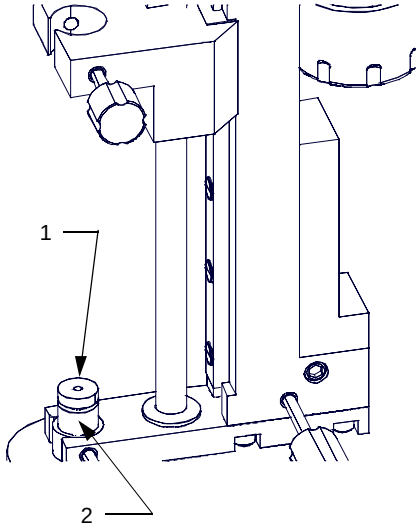



*Figure 5*

**1** Spacer Tube Collar. **2** Insertion Tube Collar.

**1** Adjust the microTargeting® Drive System to 0.00 by aligning the index marks with the 0 marks on the scales on the side of the drive and on the advancement knob. The knob is graduated in 25micron increments.

**CAUTION** The insertion tube will enter the brain during the following procedure.

**2** Push the insertion tube with its mating stylet into the hole of the upper maTrix™ bushing corresponding to the selected track, then through the lower guide bushing (the insertion tube may need to be directed into the correct lower guide hole). Pushing on the stylet will ensure it is not forced away from the insertion tube tip by fluid pressure. The insertion tube collar should rest on the upper maTrix™ bushing when fully inserted.

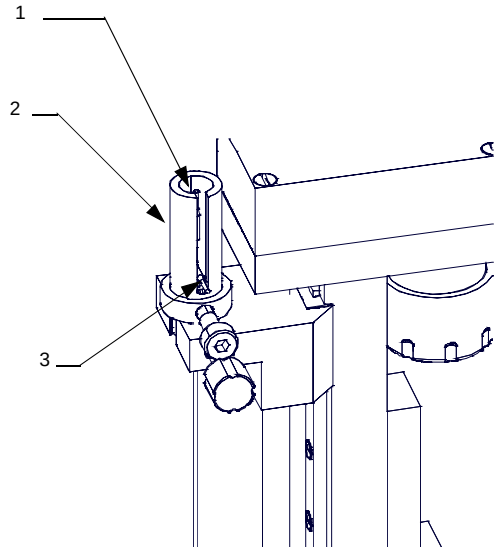



*Figure 6*

**1** Micro-electrode, which is part of the microTargeting electrode.

**2** Single Electrode Shielding Carrier.

**3** Macro-electrode, which is part of the microTargeting electrode.

**3** Remove the stylet and insert the spacer tube into the insertion tube until the spacer tube collar rests on the insertion tube collar. Please see Figure 5.

**4** Insert the electrode assembly (with the microelectrode, which is part of the microTargeting electrode, retracted into its macro-electrode, which is part of the microTargeting electrode), into the hole of the single electrode carrier corresponding to the selected track (this will normally be the center hole which will align with the selected stereotactic track) and position the macro-electrode pin in the slot of the single electrode carrier until its stop hits the bottom of the carrier. Tighten the electrode carrier set screw to lock the macro-electrode in place.

**CAUTION** Do not over tighten the electrode carrier set screw as it may distort the tube and interfere with the movement of the microelectrode, or damage the insulation between them.

**NOTE** Two carriers are provided. The version with the higher wall provides better electrical shielding and more cable strain relief for the microTargeting electrode connector.

5 Thread the electrode assembly down through the insertion tube until the single electrode carrier is fully positioned into the drive-positioning platform.

6 Secure the carrier by tightening the electrode carrier locking screw.

7 Establish the electrical connections.

8 Push the microelectrode (which is part of the microTargeting electrode) down to its maximum extension. Its stop collar will be against the macro-electrode (which is part of the microTargeting electrode) stop.

9 Advance the drive towards the predicted target. As the drive is advanced toward the target, the location of anatomical areas is confirmed by identifying typical cell firing patterns and by stimulation.

10 When the track has been examined, pull the microelectrode (which is part of the microTargeting electrode ) back into its macro-electrode and remove the microelectrode assembly, electrode carrier and spacer tube.

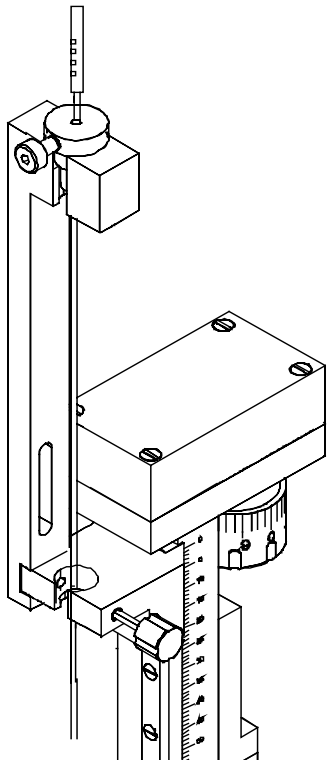


*Figure 7*

11 If additional parallel tracks are necessary, remove the insertion tube, go to step 1 and select another track. The appropriate 2 mm offset hole is chosen and a setscrew position is used which will not interfere with the mechanism. It may be necessary to rotate the carrier 90 degrees.

12 If additional parallel tracks are necessary at a distance other than 2 mm from the original track, remove the microelectrode, the electrode carrier, the spacer tube and the insertion tube from the brain. Adjust the stereotactic frame to select a new set of tracks.

**CAUTION** Observe the free length of the DBS electrode while advancing the drive, and ensure it advances into the insertion tube easily and without binding.

13 Attach the DBS holder to the drive-positioning platform. Insert the DBS lead with its depth stop pre-operatively attached into the insertion tube (note: the spacer tube must be removed). Secure the depth stop into the DBS holder. Advance to the selected target.

14 Confirm the DBS location.

The system is designed with sufficient space above the insertion tube, so it can be retracted and pulled up into the DBS holder with the lead in position. When the lead is exposed, hold it with tweezers near the skull, and remove the stylet.

Remove the drive system by sliding it up over the lead connection after loosening the depth stop screw, or alternatively pull the lead down through the drive system, and then remove it.

# Array Electrode Insertion Tube Set Procedure

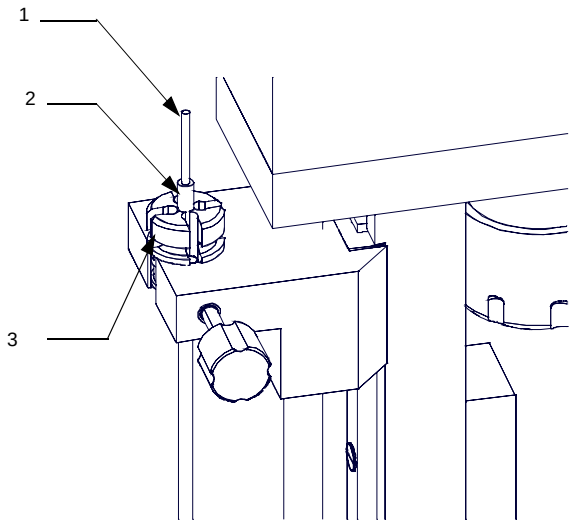



*Figure 8*

**1** Stylet.

**2** Insertion Tube Collar.

**3** Array Electrode Carrier.

**1** Position the Array Electrode Carrier in the drive-positioning platform; four detents are provided to ensure correct alignment. Tighten the electrode carrier locking screw in a detent.

**2** Position the short spacer tubes into the lower guide (this may be done pre-operatively).

**CAUTION** The insertion tube will enter the brain during the following procedure.

**3** Push the insertion tube with mating stylet through the array electrode carrier, then through the upper maTrix™ bushing, and the lower guide spacer tubes.

**4** Slide the array electrode clamp over the array electrode carrier, (see figure 10 for orientation), and tighten it to hold the insertion tube in place. (An alternative unshielded clamp is also provided for use, if desired. Use of the shielded clamp is recommended, if more than one electrode will be used).

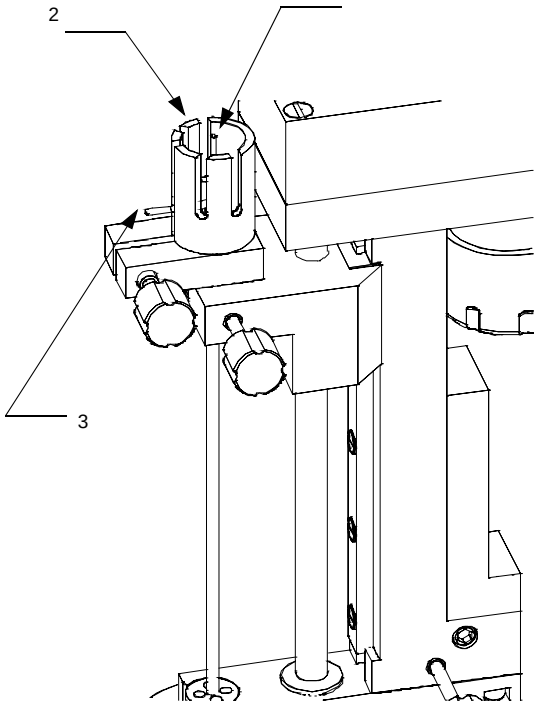



*Figure 9*

**1** Micro-electrode, which is part of the microTargeting electrode.

**2** Array Electrode Clamp.

**3** Macro-electrode, which is part of the microTargeting electrode.

**5** Remove the stylet and thread the electrode assembly (with microelectrode retracted into its macro-electrode) through the array electrode carrier down through the insertion tube until the macro-electrode stop rests on the insertion tube collar. Position the macro-electrode pin in the correct slot hole in the array electrode clamp (see figure 10). Use the insertion tool to assist in positioning.

**6** Establish the electrical connections.

**7** Push the microelectrode (which is part of the microTargeting electrode) to its maximum extension. The tip of the microelectrode is now at the distance from the predicted target specified for the stereotactic adaptor. (Please, see Appendix A).

8 Advance the drive toward the predicted target. As the drive is advanced toward the target, the location of anatomical areas is confirmed by identifying typical cell firing patterns and by stimulation.

9 When the track has been examined and the target location confirmed, loosen the array electrode clamp and remove the microelectrode assembly, insertion tube and lower guide spacer tube.

10 If additional investigation of parallel tracks is required, the array maTrix™ configuration allows insertion of up to 4 more electrodes at 2 mm orthogonal to the center track. Optionally leave the initial electrode in place or remove it. Return to step 3.

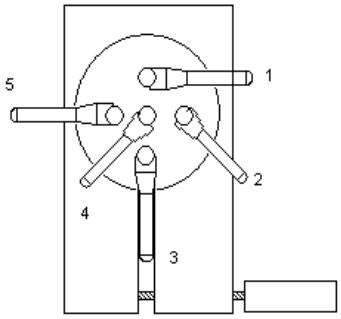
11 If additional parallel tracks are necessary at a distance other than 2 mm from the original track remove the microelectrode and the insertion tube. Adjust the stereotactic frame to select a new set of tracks. Go to step 1.

12 Push the DBS insertion tube with mating stylet in the corresponding hole in the array electrode carrier. Attach the DBS holder to the positioning platform. Tighten the array electrode clamp to retain the insertion tube. Remove the DBS insertion tube stylet. Insert the DBS lead with its depth stop preoperatively attached into the insertion tube. Secure the depth stop into the DBS holder. Advance to the selected target. Confirm the DBS location.

The system is designed with sufficient space above the insertion tube, so it can be retracted and pulled up into the DBS holder with the lead in position. When the lead is exposed, hold it with tweezers near the skull and remove the stylet.

Remove the drive system sliding it up over the lead connection or alternatively pull the lead down through the drive system and then remove it.

**Back**




**Front**

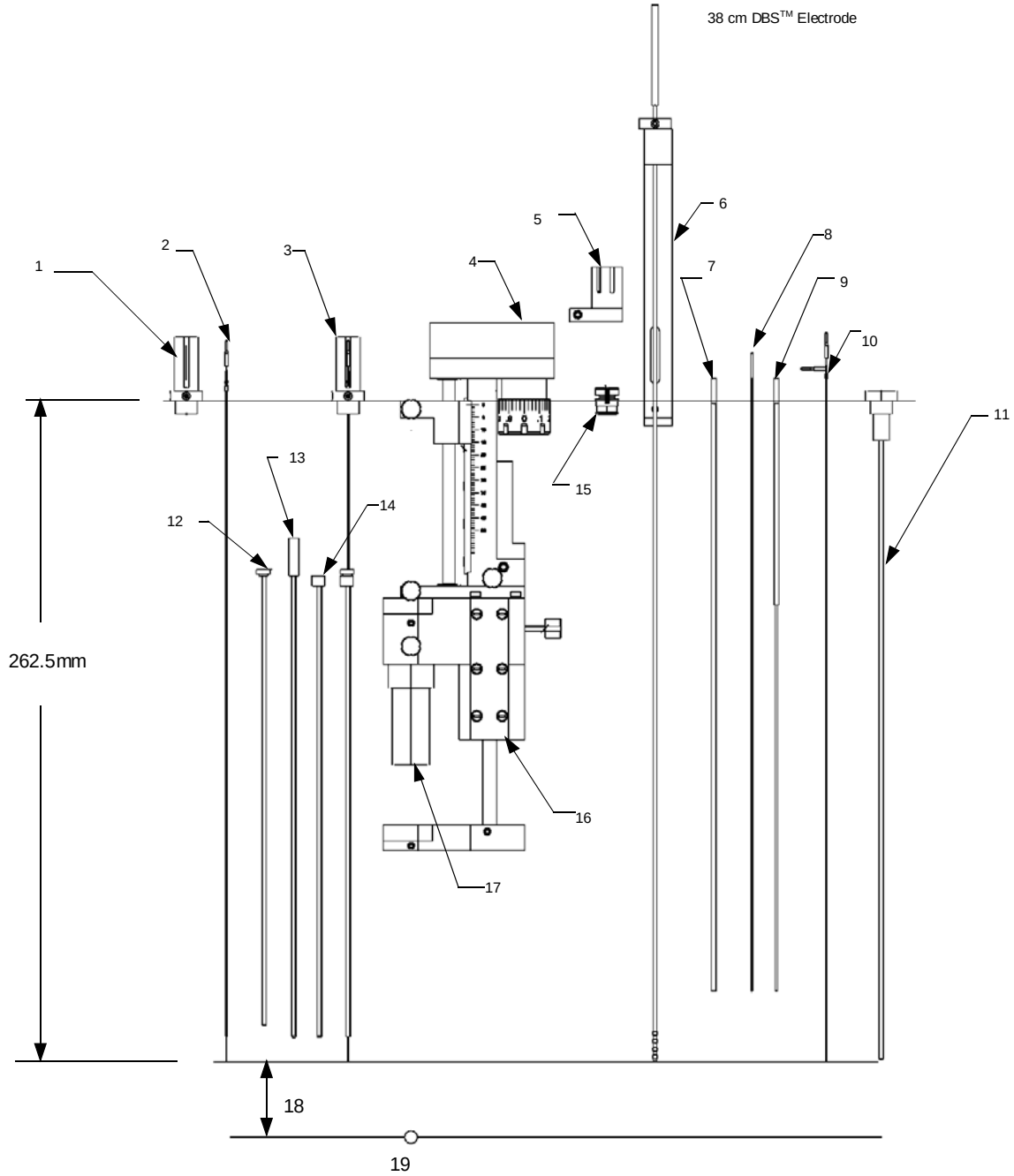
*Figure 10*

**1-5** Electrode positions in slots

**6** Array Electrode Clamp

# microTargeting® Electrode Positioning System

*Figure 11*




**1** Shielded Single Electrode Carrier with 2mm offset Possible

**2** microTargeting Electrode 291

**3** Single Electrode Assembly

**4** microTargeting Drive

**5** Array Clamp

**6** DBS Holder

**7** Array DBS Insertion Tube

**8** Array Stylet

**9** Array Insertion Tube

**10** microTargeting Electrode

**11** Verification Probe

**12** Spacer

**13** Stylet

**14** Insertion Tube

**15** Array Electrode Carrier

**16** maTrix Drive Mount and Lower Guide

**17** Frame Adaptor

**18** Distance to Target (see Appendix A)

**19** Target

# *Technical Data*

## microTargeting® Drive with maTrix™

***Drive Travel:***
50mm

***Drive advancement knob:***
25µm graduation, 1 mm movement/revolution.

***Micro- or DBS™ electrode position:***
Known distance (see Appendix A) from predicted target when drive retracted to 0.00 with electrode fully extended and stops set as shown in figure 3.

***Macro-electrode position:***
Position determined from electrode configuration dimensions (see figure 4).

***maTrix™ spacing:***
2.00 mm from center.

***maTrix™ guide hole diameter:***
1.88mm.

***Guide configuration:***
Center guide hole on stereotactic axis with 4 holes offset by 2.00 mm on center and orthogonal to the center hole.

***Materials:***
Type 6061 aluminum with Anodizing and Nickel plating, Radel, Rulon, Type 304 Stainless Steel, Type 17-4PH Stainless Steel.

## Single Insertion Tube Set

***Insertion tube dimensions/material:***
1.8 mm OD, 1.6 mm ID/ type 304 Stainless Steel.

***Spacer tube dimensions/material:***
1.5 mm OD, 1mm ID/ type 304 Stainless Steel.

***Electrode carrier material:***
Nickel plated brass

***Electrode stops material:***
Radel with type 304 Stainless Steel fastener.

## Array electrode insertion tube set

***Insertion tube dimensions/material***
1.8mm OD upper tube, 0.89mm OD lower tube (portion which enters the brain), 0.6mm ID/type 304 Stainless Steel.

***Lower guide spacer tube dimensions/material***
1.9mm OD, 0.96mm ID/ Type 304 Stainless Steel

***DBS™ insertion tube dimensions/material***
1.8mm OD 1.6mm ID/type 304 Stainless Steel.

***Array electrode carrier material***
Nickel plated brass

***Array electrode clamp material***
Nickel plated type 6061 aluminum

# Index

## *Service Centers*

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