



microTargeting™ Multi-Oblique Guides and Accessories

Directions For Use

L011-84 (Rev H0, 2020-05-11)

Contains directions for the following products:

Tool Guides: 66-MO-01, 66-MO-02, 66-MO-03, 66-MO-04, 66-MO-05, 66-MO-06, 66-MO-07

Application Guides: 66-MO-20, 66-MO-21

Depth Control: 66-DH-40, 66-DS-IT, 66-DS-MO

Sterilization/Storage: 66-ST-MO

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Indications for Use

The WayPoint™ Stereotactic 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 systems.

Intended Use

The microTargeting™ Multi-Oblique Guides and Accessories are intended for use with the microTargeting™ Multi-Oblique Platform by a neurosurgeon in a standard operating room environment in conjunction with the WayPoint™ Anchor/Locator System, WayPoint™ Planner and WayPoint™ Navigator.


Symbol Key


	WARNING / Caution, consult instructions for important cautionary information		Authorized Representative in the European Community		Medical device manufacture, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	Indicates the need for the user to consult the Instructions for use.		European Conformity. This device fully complies with MDD Directive 93/42/EEC and legal responsibilities as a manufacturer are with FHC, Inc., 1201 Main Street, Bowdoin, ME 04287 USA.		Telephone number
	An item that is known to pose hazards in all MRI environments.				In reference to "Rx only" symbol; this applies to USA audiences only
Rx Only	Caution - Federal law (USA) restricts this device to sale by or on the order of a physician.		Indicates the batch code so that the batch or lot can be identified.		Indicates the catalog number so that the medical device can be identified.

Handling and Storage

Storage: Store the microTargeting™ Multi-Oblique Guides and Accessories at normal room temperatures between -34°C (-29°F) and 57°C (135°F). Do not expose to temperatures below -34°C (-29°F) or greater than +70°C (158°F), or a relative humidity of less than 10% or more than 100%, including condensation.

Handling and use: Handle the microTargeting™ Multi-Oblique accessories with extreme care. These components may be damaged if excessive force or incorrect handling occurs. Do not force engagement during pre-operative assembly or when positioning the implantation tools through microTargeting™ Platform. Follow the assembly and use instructions carefully.

 **WARNING:** All parts are shipped non-sterile and must be sterilized before use. Follow sterilization protocols below.

 **WARNING:** Components should be examined after each sterilization cycle for damage and function. Users should be aware that the effects of unvalidated sterilization protocols could result in damage to the components and affect their function or performance.

Disposal: Dispose of accessories according to hospital protocol.

Cleaning Instructions

Manual Cleaning

FHC has validated and recommends the following manual cleaning protocol:

1. Immediately following use, thoroughly rinse the tool guides under tap water. Repeatedly insert a soft bristle brush in and out of the tool guides under running water to dislodge any debris or coagulated fluid.
2. Immerse the tool guides in enzymatic wash solution for 1 minute. After soaking, and while immersed in wash solution, insert the soft bristle brush in and out of the tool guides.
3. Remove from the wash solution and repeat under tap water, then distilled water.
4. Dry tool guides using a clean soft cloth.

There is no restriction on the number of reuses providing user performs pre-use check.

Sterilization Instructions

Load items to be sterilized into multi-oblique sterilization tray as shown on page 12, then sterilize using one of these validated protocols:

Method	Protocol	
Steam	Gravity wrapped: (in 2 layers of 1-ply polypropylene wrap ^[1]) Exposure time: 10 minutes at 132°C (270°F) [1] Cycle was validated using Halyard Health H600 wrap	Prevacuum wrapped: (in 2 layers of 1-ply polypropylene wrap ^[2]) Preconditioning Pulses: 3 Exposure time: 4 minutes at 132°C (270°F) Minimum Dry Time: 40 minutes [2] Cycle was validated using Halyard Health H200 wrap
	Prevacuum wrapped: (in 2 layers of 1-ply polypropylene wrap ^[1]) Preconditioning Pulses: 3 Exposure time: 18 minutes at 134°C Minimum Dry Time: 30 minutes [1] Cycle was validated using Halyard Health H300 wrap	

Maintenance and Repair

Scheduled maintenance: The microTargeting™ Multi-Oblique accessories should be inspected visually prior to each use for physical damage, or poor fit due to wear or residue buildup. If any component shows wear or damage that could interfere with proper function, please contact FHC for repair or replacement. None of the components require lubrication of any kind.

Repair: All FHC products are unconditionally guaranteed against defects in workmanship for one year from the date of shipment provided they have been exposed to normal and proper use. Should service or repair be required, please contact FHC for return instructions at 1-800-326-2905 (US & Canada) or +1-207-666-8190.

Pre-Use Check

The following steps should be taken prior to performing the actual procedure:

1. Verify all tools pass through the appropriate guides to expected depth.
2. Verify all bushings are secure and free of damage.
3. Verify fit of guides in each platform hub.

Usability Guide

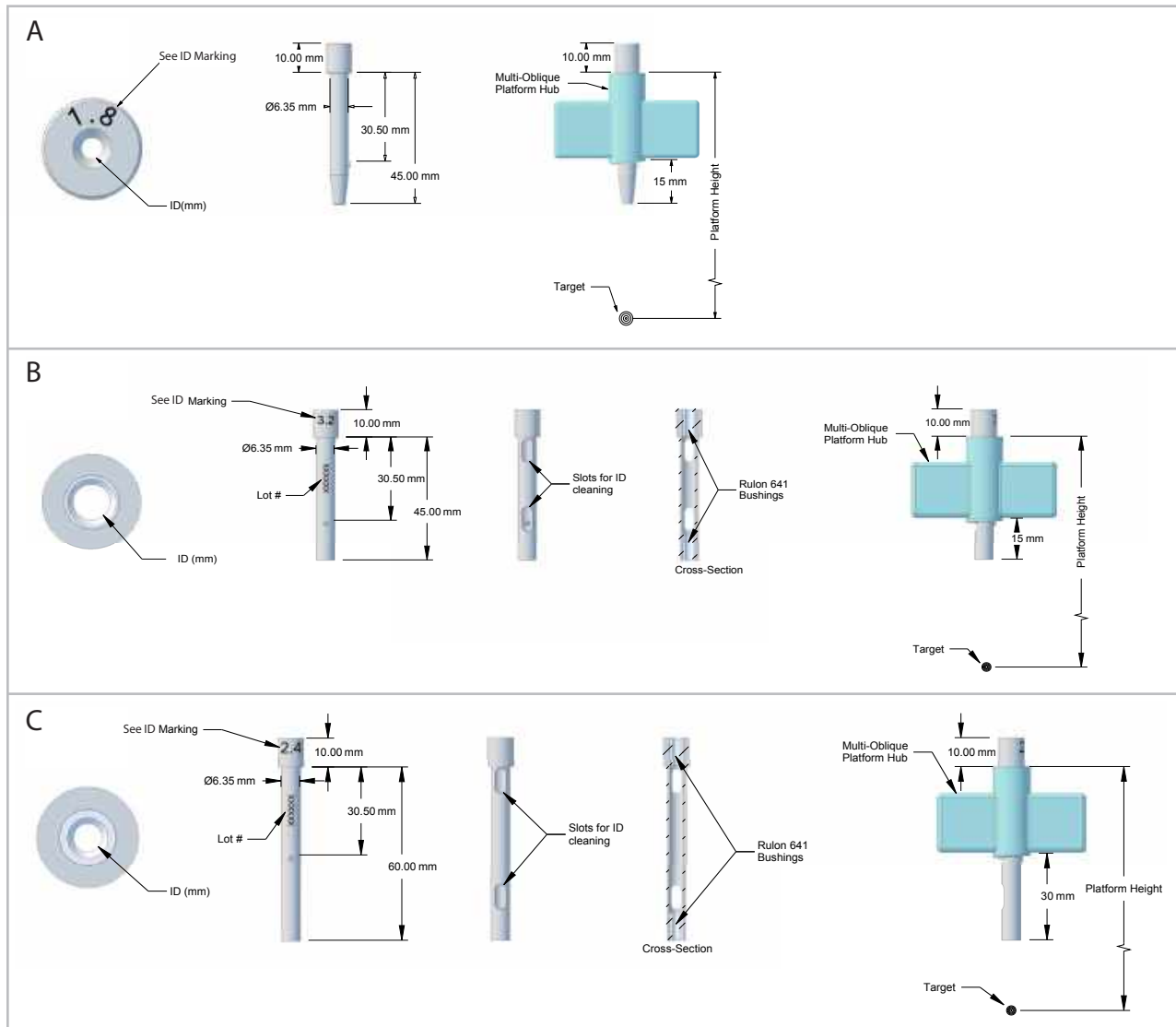
Note: When using tool guides that guide drill bits, take care to align the axis of the drill bit with the center axis of the tool guide during insertion and retraction. Inserting a spinning drill bit non-axially can cause damage to the bushings.



Specifications and Procedures

Tool Guides (66-MO-0x)

Multi-oblique tool guides are used to guide tools of varying diameters along a trajectory of the multi-oblique platform. Consult the tool manufacturer documentation to determine the appropriate guide to use for a specific tool.



Specifications

- Material: 304 stainless steel body, Rulon 641 bushing
- Body: 6.35 ± 0.05 mm OD
- Collar: 8.66 ± 0.025 mm OD; $10 \pm .13$ mm tall

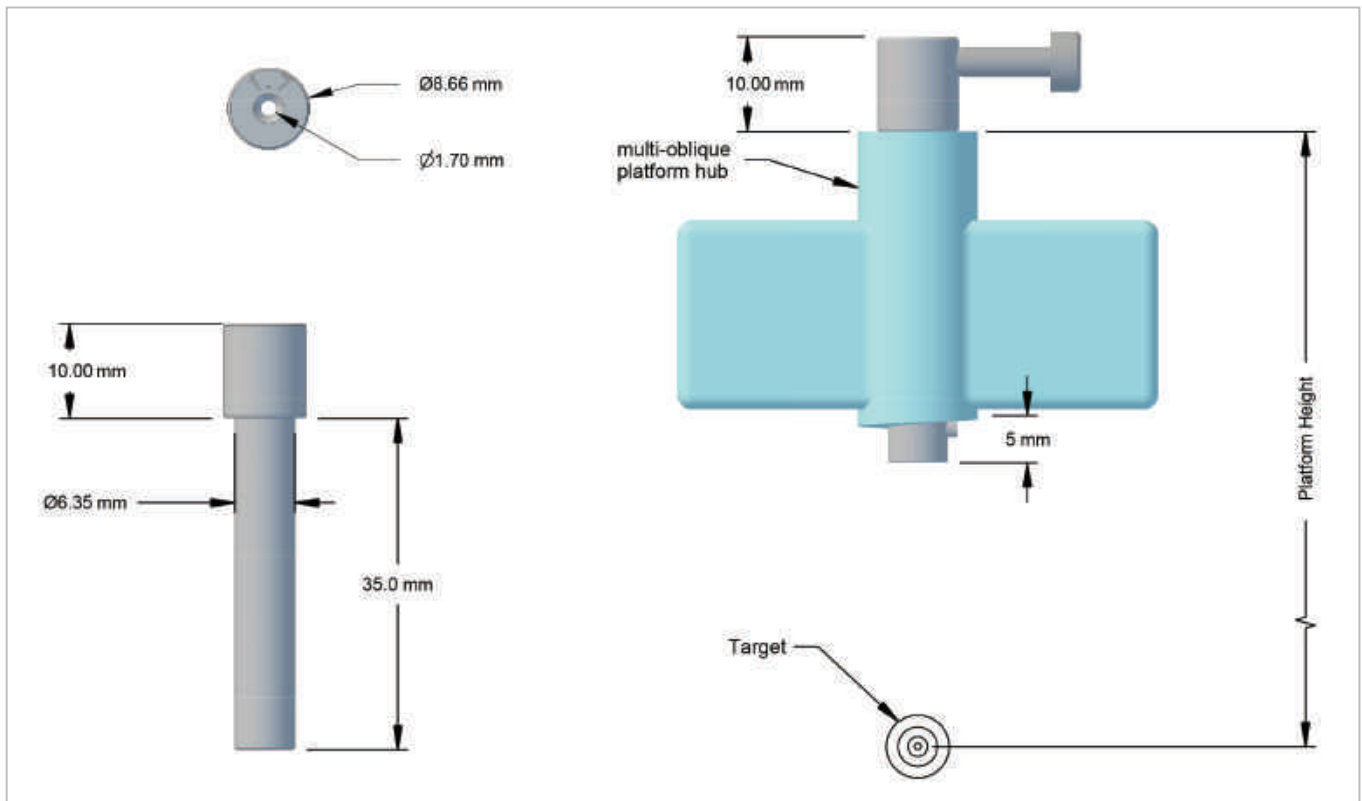
Catalog #	Reference	ID Marking	ID (mm)
66-MO-01	Figure B	3.2	3.25 +/- .025
66-MO-02	Figure A	1.8	1.85 +/- .04 - .00
66-MO-03	Figure A	2.2	2.21 +/- .025
66-MO-04	Figure B	2.4	2.44 +/- .025
66-MO-05	Figure B	2.5	2.57 +/- .025 - .00
66-MO-06	Figure C	2.4	2.44 +/- .025
66-MO-07	Figure C	3.2	3.25 +/- .025

Procedure

1. Align pin on tool-guide with slot in multi-oblique platform hub, and insert until tool-guide sits flush on platform hub
2. Turn tool clockwise so pin rides up ramp, locks, and prevents tool-guide from falling out
3. Use separately provided tool that is appropriately sized for tool-guide inner diameter
4. (Optionally) attach depth stop holder to tool-guide collar, see dual depth stop holder (66-DH-40) on page 9
5. Perform procedure
6. Turn tool-guide counterclockwise until it stops, then pull out to remove

Visualase® Alignment Rod Guide (66-MO-20)

The Visualase alignment rod guide is used to place the Visualase skull bolt along a trajectory of the multi-oblique platform.



Specifications

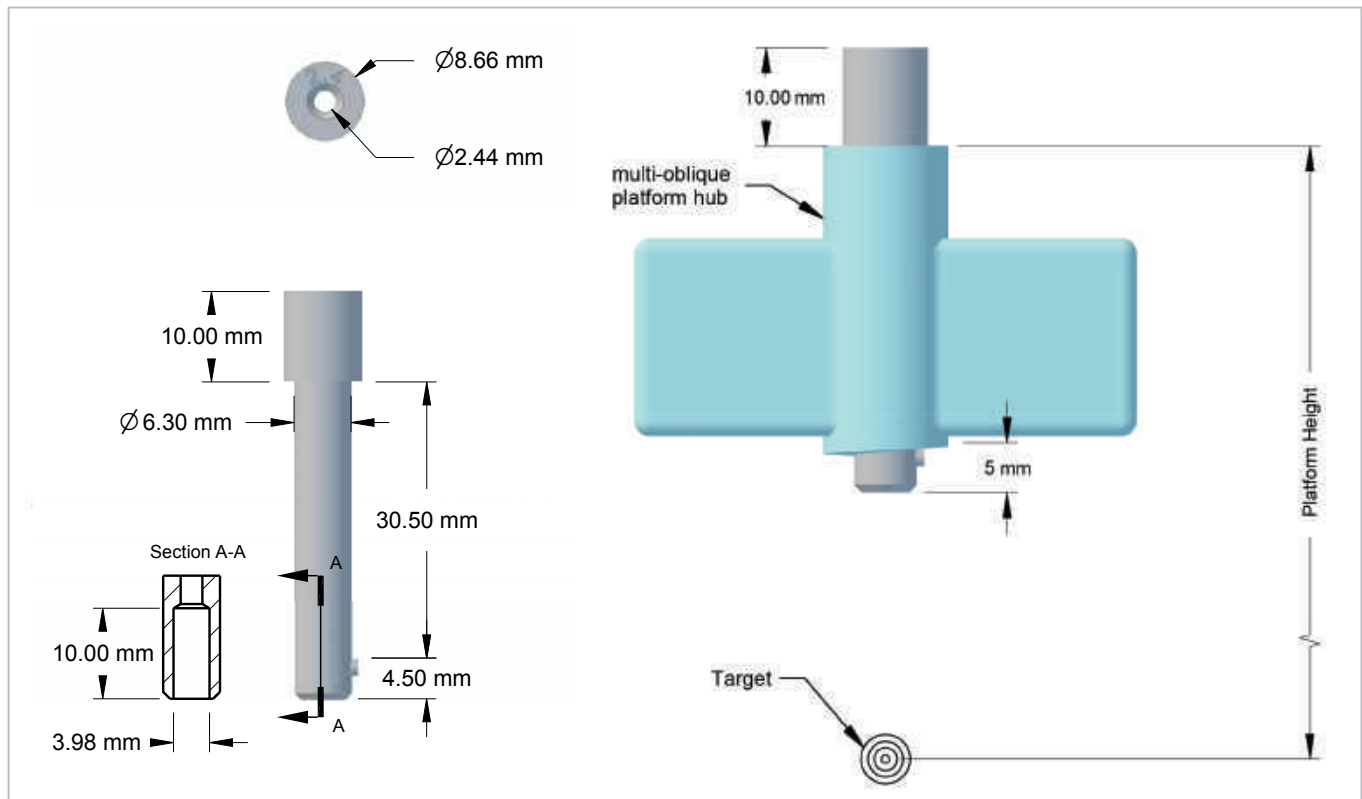
- Material: 304 stainless steel
- Collar: 8.66 ±0.025mm OD; 10±.13mm tall
- Body: 6.35+0-0.05mm OD x 30±.13mm below hub, no locking pin
- ID: 1.70±.025mm
- Locking screw: side mounted 4/40 thread
- Tool clearance below hub: 5mm

Procedure

1. Insert Visualase alignment rod guide into platform hub, turn clockwise to lock
2. Loosen screw then insert alignment rod through guide until it is slightly into hole in skull, tighten screw
3. Lift guide/rod up enough to place Visualase skull bolt into skull hole
4. Slide guide/rod into skull bolt until guide rests on platform hub, lightly tighten
5. Screw Visualase skull bolt into skull
6. Loosen alignment guide screw and Visualase bolt then lift alignment rod until it is even with top of skull bolt, tighten alignment guide screw
7. Turn counterclockwise to remove guide/rod and measure the distance from tip of rod to bottom of collar, which is the target offset
8. Subtract target offset from platform height to determine distance from top of skull bolt to target

Ad-Tech® Bolt Guide (66-MO-21)

The Ad-Tech bolt guide provides additional clearance under the platform for placement of Ad-Tech skull bolts along a trajectory of the multi-oblique platform.



Specifications

- Material: 304 stainless steel
- Collar: 8.66 ± 0.025 mm OD; 10 ± 0.13 mm tall
- Body: $6.35 + 0 - 0.05$ mm OD x 35 ± 0.13 mm below hub, locking pin
- ID: $2.44 \text{mm} \pm 0.025$ mm
- Counter Bore: 3.8mm ID minimum, 10.0 ± 0.13 mm deep
- Tool clearance below hub: 5.0mm physically, -5.0mm for bolts with OD less than 3.8mm

Procedure

1. Insert Ad-Tech bolt wrench through guide
2. Insert Ad-Tech bolt onto wrench
3. Place guide/wrench/bolt through platform hub and into skull
4. Turn guide clockwise to tighten into platform hub
5. Tighten bolt

Dual Depth Stop Holder (66-DH-40)

The dual depth stop holder is used to place a 1.8mm cannula and a 1.6mm or smaller depth electrode along a trajectory of the multi-oblique platform.

Specifications

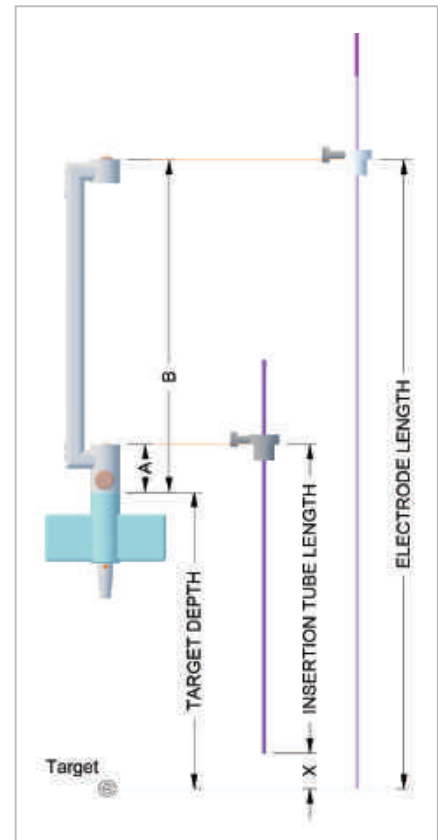
- Material: Duraform PA Nylon holder; PEEK Thumbknobs
- Single use
- Tool Guide Mount: 8.75mm ID, 11.75mm tall
- Lower Stop mount: 8.75mm ID, 7.30mm tall
- Upper Stop Mount: 8.75mm ID, 10mm tall
- Lower depth stop offset (A): 20.0mm
- Upper depth stop offset (B): 140.0mm

Required for Use

- Insertion tube depth stop – 66-DS-IT
- Lead depth stop – 66-AC-DS(1.8)
- Insertion tube – 66-IT(AO10)

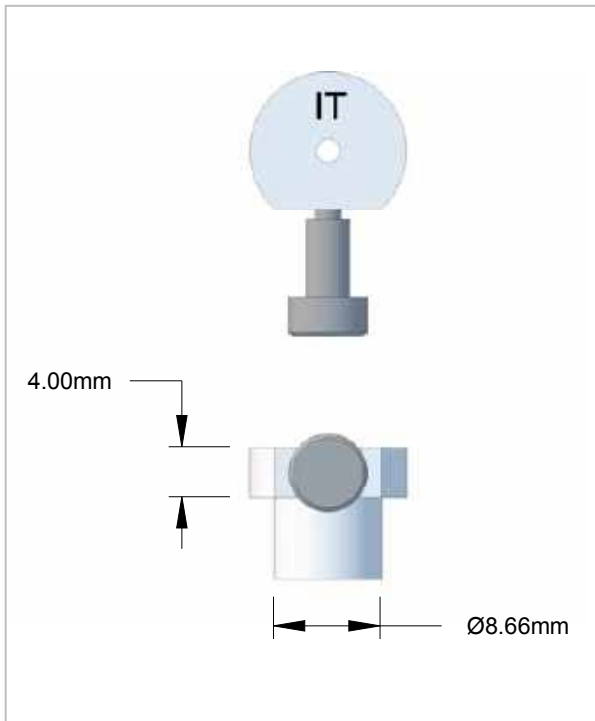
Procedure

1. Place insertion tube depth stop (66-DS-IT) on insertion tube so distance from bottom of collar to tip of tube = Platform Height (T) + Lower Depth Stop Offset (A) - Insertion tube distance above target (X)
2. Place lead depth stop (66-AC-DS(1.8)) on lead so distance from bottom of collar to point on lead, to place at target = Platform Height (T) + Upper Depth Stop Offset (B)
3. Position depth stop holder over collar of 1.8mm tool guide (66-MO-02), positioned in platform, until depth stop holder rests on top of platform, and lightly tighten thumb knob
4. Insert insertion tube and stylet with depth stop into tool guide and into brain until depth stop collar rests in lower depth stop holder
5. Remove stylet
6. Insert lead through stylet until depth stop collar rests in upper depth stop holder
7. Loosen insertion tube depth stop holder and raise tube up lead until above scalp, and tighten depth stop holder
8. Secure lead
9. Loosen lead depth stop and remove lead from cannula
10. Loosen depth stop holder and remove from guide



Insertion Tube Depth Stop (66-DS-IT)

The insertion tube depth stop is used to set insertion depth of a 1.8mm cannula that is used with a dual depth stop holder (66-DH-40), and attached to a 1.8mm tool guide (66-MO-02) in a trajectory of the multi-oblique platform.



Specifications

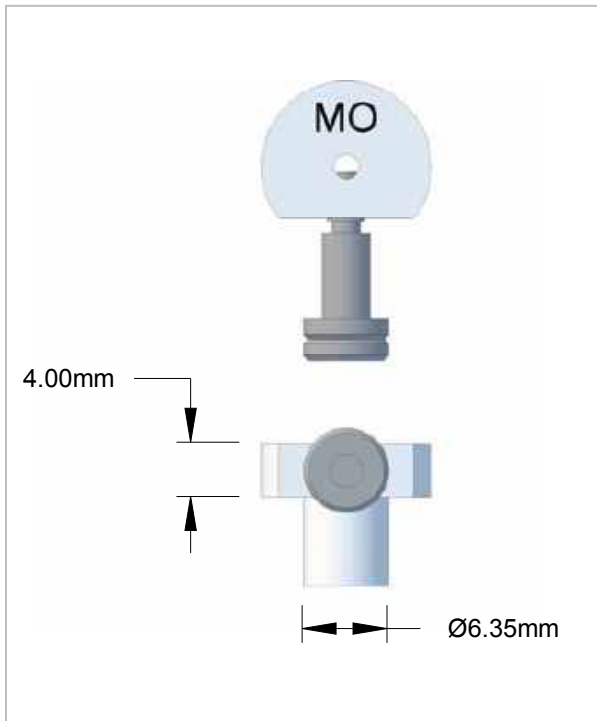
- Material: Radel (thumbknob), stainless steel (screw)
- ID: 1.93mm
- Base OD: 8.66mm
- Collar height: 4 ± 0.13 mm

Procedure

1. Loosen screw and slide insertion tube and stylet through hole
2. Measure distance to end of insertion tube as appropriate
3. Lightly tighten screw – do not over tighten and prevent movement of stylet
4. Assure depth stop does not easily move on insertion tube

Multi-Oblique Depth Stop (66-DS-MO)

The multi-oblique depth stop is used to position a depth electrode in the multi-oblique platform while it is being secured using a vendor supplied skull bolt.

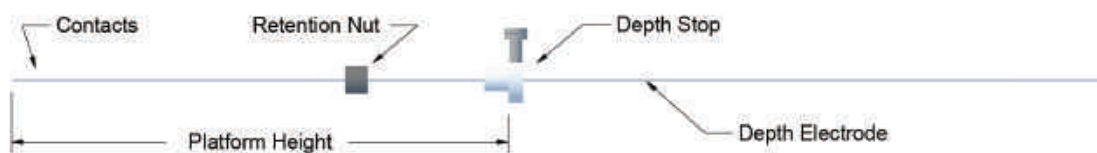


Specifications

- Material: Radel (thumbknob), stainless steel (screw)
- ID: 1.85mm
- ID (screw fully tightened): 0.46mm
- Base OD: 6.35mm
- Collar height: 4 ± 0.13 mm

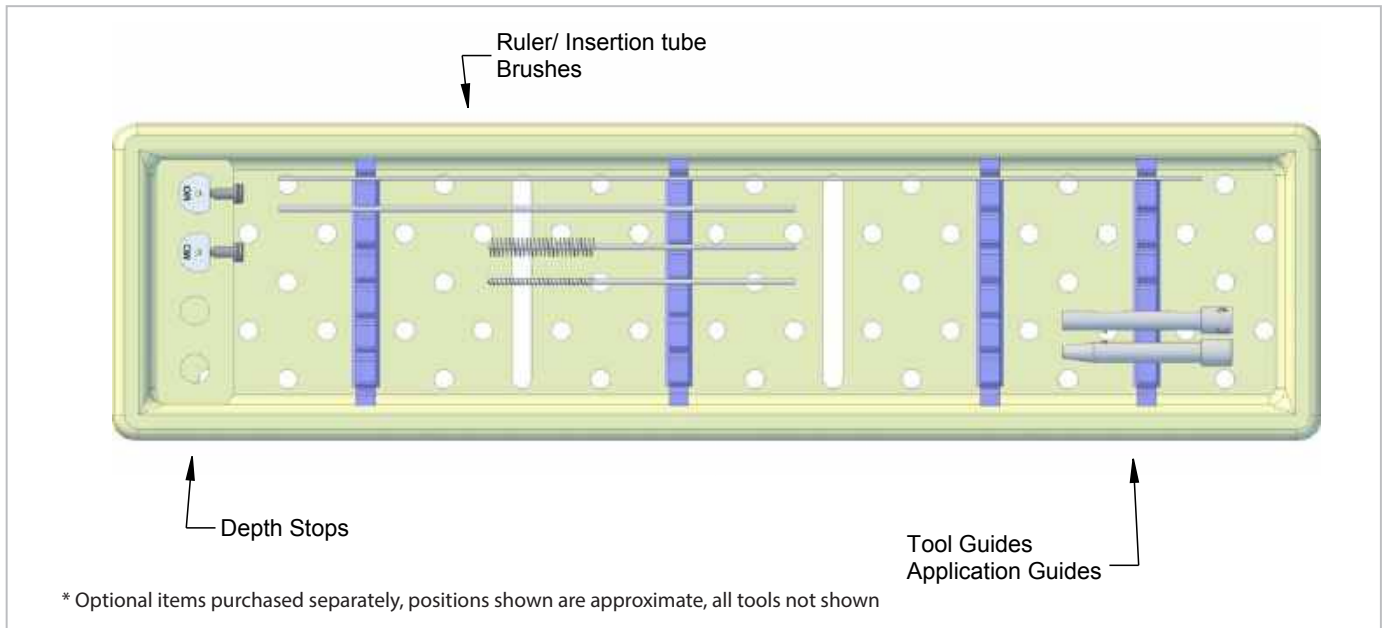
Procedure

1. Place depth stop on sEEG depth electrode and measure so the distance from the bottom edge of the collar to the point on the tip of the lead that you want to place at target equals the platform hub height. Lightly tighten screw to secure lead.
2. Place skull bolt retention nut on lead (as shown) or on skull bolt as directed by skull bolt manufacturer



3. Insert lead with depth stop through platform hub and into skull bolt until depth stop collar rests in multi-oblique hub
4. Tighten skull bolt to secure lead
5. Loosen depth stop screw and gently pull lead through depth stop

Multi-Oblique Sterilization Tray and Tools (66-ST-MO)



Specifications

- Case base: Radel with Silicone inserts
- Case lid: Radel with stainless steel clamps
- Ruler: Stainless steel - 30 cm range with 0.5mm markings
- Brushes: Stainless steel stem and nylon bristles

Procedure

1. Press rulers, brushes, tool guides, and optional depth stop(s) and insertion tube(s) into the support slots to avoid shifting when transporting or sterilizing
2. Secure the lid to the base using the 2 latches
3. Sterilize using approved protocol listed in this manual