

CE-DECLARATION OF CONFORMITY

CE 0473



Manufacturer:

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Medical Device:

TC Model 12mm/8mm/3cm	Part No. TC120803
TC Model 12mm/8mm/5cm	Part No. TC120805
TC Model 12mm/8mm/7cm	Part No. TC120807
TC Model 17mm/11mm/3cm	Part No. TC171103
TC Model 17mm/11mm/5cm	Part No. TC171105
TC Model 17mm/11mm/7cm	Part No. TC171107
TC Model 21mm/15mm/3cm	Part No. TC211503
TC Model 21mm/15mm/5cm	Part No. TC211505
TC Model 21mm/15mm/7cm	Part No. TC211507
TC Model 28mm/20mm/3cm	Part No. TC282003
TC Model 28mm/20mm/5cm	Part No. TC282005
TC Model 28mm/20mm/7cm	Part No. TC282007
EC Model 34mm/14mm/5cm	Part No. EC341405

The devices listed above meet the Essential Requirements of the Medical Device Directive EC Directive 93/42/EEC Annex V, Article 3. A conformity Assessment procedure as described in the directive has been performed by the manufacturer.



Targeting Solutions in Neurosurgery.

VYCOR VIEWSITE BRAIN ACCESS SYSTEM (VBAS) TC and EC Models

Instructions for Use



Manufacturer and ordering info:

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WARNINGS and CAUTIONS

VYCOR VIEWSITE BRAIN ACCESS SYSTEM

- Check the attachment device prior to use. Be sure that the spring mechanism and latch mechanism are functioning properly. Failure to do so may result in separation of the working channel from the introducer and damage to brain tissue at the leading edge of the advancing working channel.
- Do not advance the working port without first replacing the introducer. Failure to do so can result in tissue damage at the advancing leading edge.
- Do not advance the assembled access system unless the latch assembly is functioning properly.
- Do not use if there are cracks or defects at the leading edges or along the working channel.
- The devices are designed for single use only. Materials used in the manufacture of the device may not withstand reprocessing. Potential risks of infection/cross contamination and or failure to perform as intended may result from re-use. Do not re-sterilize or re-use device.
- Do not over-tighten the fixation device to the VYCOR VIEWSITE BRAIN ACCESS SYSTEM (VBAS) attachment piece. This may result in cracking of the attachment handle.
- Do not force the device into a tight bony/mucosal access channel, as the surrounding tissues may cause the polycarbonate material to fracture.

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

VYCOR VIEWSITE BRAIN ACCESS SYSTEM

(VBAS) TC AND EC MODELS have been designed to serve as a self-retaining retractor system for brain tissue.

SYMBOLS:



Caution



Do Not Re-use



Do Not Re-sterilize



Lot #



Sterilized With Gama Radiation



Use By



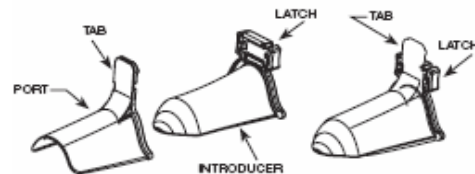
Manufacturer

CE 0473 CE Marking of Conformity

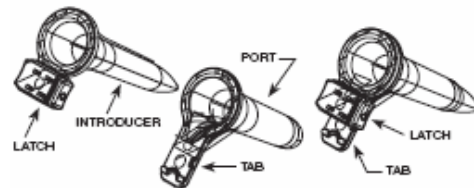


Catalog #

EC MODEL:



TC MODEL:



The assembled VYCOR VIEWSITE BRAIN ACCESS SYSTEM (VBAS) consists of an introducer and a working channel port. The two are integrated and held together by a spring-controlled latch.

Both the TC and EC devices of the Vycor ViewSite

Brain Access System (VBAS) have identical Tabs that can attach to clamps or fixation devices. See Figure.



The devices are designed to maximize stability and integration with a standard fixation arms. It is advisable to confirm secure mounting compatibility with your fixation system prior to use. Non-sterile test fit samples are available from your Vycor representative.

Preoperative planning:

It is best to plan the placement of the craniotomy and the tracking path of the device preoperatively. Plan a path that is “straight line” to the targeted site.

Each device allows for gentle retraction of tissue, visualization of the surgical site and for smooth manipulation of introduced instrumentation. The range of device sizes provides

various working channel sizes. Preoperative planning should consider both surgical site access and the instrumentation access requirements to determine proper device size.

The diameter of the craniotomy should be 1-2 cm greater than the diameter of the device to allow for angulation of the device as needed during the procedure.

When using the TC Model:

In order to eliminate the possibility of brain shift during placement, the planning line should be set at 90° to the tangent of the plane of the centered surface of the operative site.

Preoperative IGS planning should identify a cortical sulcus whenever possible, to allow for minimal brain disruption. By planning in IGS 3-D mode, the deepest “straight line” sulcus allowing the shortest traversal of brain tissue should be chosen.

The corticotomy should be slightly larger than the opening at the aperture of the device.

After the dura is opened, and the arachnoid incised, position the device with its axis along the “straight line” approach obtained during preoperative planning.

The TC model has an elliptical aperture so that binocular vision is maintained. Therefore, orient the working channel and introducer so that the elliptical diameter is parallel to the intrapupillary line of the user and the binocular microscope.

It is recommended that the device be moistened with sterile saline prior to insertion.

Prior to advancing the device, incise the cortical surface and aspirate the exposed 2mm ellipse of brain tissue. The introducer is perforated at the tip to allow for dissection during insertion.

Advance the assembled apparatus through the tissue toward the target in increments (approximately 1 cm) and repeat aspiration as necessary.

Once the access system is localized to the target tissue, lock the fixation arm in a neutral position. The polycarbonate material of the device is optically clear. Visually inspect the surrounding tissue to be sure that the device is not pulling in any direction, but is in a “neutral” position. The surrounding arterioles/veins within the brain should be red in color and not blanched.

Remove the introducer and begin working. If further advancement of the working channel is required, reposition the introducer and then advance the apparatus to the new target.

Inspect the surrounding brain tissue from time to time once the working channel has been positioned to look for inadvertent focal retraction that may have occurred while working. Be sure that the system is in a “neutral” position so that retraction pressures are equalized in a circumferential manner.

During use, the surrounding brain can be visually inspected through the transparent plastic of the working channel.

When work has been completed, detach from the fixation arm and remove the working channel slowly and inspect the surrounding brain for venous bleeding etc. Dispose of the device in accordance with your institution’s policies

When Using the EC Model:

After the dura is opened, and the arachnoid incised, position the device with its axis along the “straight line” approach obtained during preoperative planning.

The EC model has a hemi-elliptical aperture so that binocular vision is maximized. Therefore, orient the working channel and introducer so that the elliptical diameter is parallel to the intra-pupillary line of the user and the binocular microscope.

It is recommended that the device be moistened with sterile saline prior to insertion.

Advance the assembled apparatus through the tissue toward the target in increments (approximately 1cm) and inspect the overlying cortical tissue and surrounding venous structures.

Once the access system is localized to the target tissue, lock the fixation arm in a neutral position. The polycarbonate material of the device is optically clear. Visually inspect the overlying cortical tissue to be sure that the device is not causing blanching of the cortex. The surrounding arterioles/veins within the brain should be red in color.

Remove the introducer and begin working. If further advancement of the working channel is required, reposition the introducer and then advance the apparatus to the new target.

Inspect the surrounding brain tissue from time to time once the working channel has been positioned to look for inadvertent focal retraction that may have occurred while working. During use, the surrounding brain can be visually inspected through the transparent plastic of the working channel.

When work has been completed, detach from the fixation arm and remove the working channel slowly and inspect the surrounding brain for venous bleeding etc. Following use dispose of the device properly. The device is intended for single use only.