

NEUROSURGERY:

Brain Access System advances safety and efficacy

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Recent surgical advancements are many, yet tools used to access surgical locations haven't kept pace. Consider this: existing retractors can cause brain damage and prolonged patient recovery with the incidence of contusion or infarction from brain retraction being approximately 10% in cranial surgery and 5% in intracranial procedures. Pressure at the retractor blade tip is said to be responsible for 22% of infarctions as determined by CT scans. Given that there is an estimated 600,000 brain surgeries annually in the U.S. and internationally, this amounts to a very sizeable problem and possible addressable market.

Brain Access System (VBAS)

In response to this disturbing reality, the Vycor Brain Access System (VBAS) was developed.

The VBAS series of disposable products are used by neurological surgeons to access the surgical sites. This is done by inserting the VBAS gently into the brain and then removing the VBAS introducer, leaving the remaining hollow working channel in place to provide the surgeon with access to the precise location desired for surgery.

The VBAS is available in multiple sizes and is a single-use product. The current series consist of 12 disposable products,

offered in four different port diameters of 17mm and 21mm, 12mm, and 28 mm and a choice of three lengths for each of 3, 5, and 7cm. A further broadening of this product range is planned.

Clinical benefits

Field reports from surgeons and a growing hospital customer list support these VBAS benefits:

- Reduction of venous pressure.** Normal surgical procedures utilizing standard retractors require the pulling away of healthy tissue to expose the target site. Current retractors have low surface areas that in turn lead to high focal pressure. This increased venous pressure can at times exceed safe levels. Prolonged venous pressure may lead to permanent brain damage and/or post operative delays in recovery. With the VBAS, local surface pressure is minimized due to the increased surface area of its elliptical shape. The shape of the device is key. The VBAS was designed to evenly disperse the brain tissue so there is no focal pressure that is exceeded at any given point. Being elliptical also significantly reduces leakage or tissue creeping that otherwise would occur. The lack of edges on the VBAS that are inevitably present in current retraction systems avoids severe traumatization of the retracted tissue. Most existing retractor injuries occur not under the retractor blade but under the edge of the retractor where the gradient of pressure is highest.

- Superior field of view.** The VBAS is made of polished polycarbonate. The transparency of the device allows for the continual monitoring of the surrounding tissue and structures during surgery. The optical clarity of the polished polycarbonate provides significantly superior viewing of the surrounding tissue to easily detect any bleeding or changes in tissue color that may occur immediately. Standard retrac-



The VBAS series of disposable products are used by the neurological surgeon to access the surgical site.



tors and the cotton or foam materials used in unison are opaque so bleeding or tissue trauma may not be spotted right away.

The elliptical shape of the VBAS allows a 360° distribution of the brain tissue similar to the effect of a round device while providing a widened working channel in one axis to give a better field of view and working room while keeping the other axis smaller to be less invasive. The clear nature of the VBAS means that as the device is inserted, oncoming vessels can be seen through the optically clear introducer and avoided. Furthermore the risk of electronic transmission from electrocautery through the retractor is eliminated.

- **Reduction in target shift to target.** Normal surgical procedures utilizing standard retractors require the pulling back of healthy tissue to expose the targeted site. The degree of pulling can result in the target area to shift away from what is seen on the IGS system. This shifting of the target requires the surgeon to spend time repositioning the retractors as they work towards re-locating the target.

With the VBAS there is minimal target shift as the elliptical shape distributes uniform pressure to the surrounding brain tissue. The VBAS has the opportunity to adapt to IGS systems. In fact with the IGS-enabled VBAS the tip of the introducer can serve as the pointer on the IGS system, meaning that the surgeon knows his exact location in the brain during the entire procedure.

- **Minimization of size of the craniotomy-less invasive procedure.** Due to the shape and uniquely designed introducer, smaller craniotomies are feasible. To give an indication of the significance of this one should consider that in a “typical” brain procedure using standard blade retractors in a procedure involving the removal of a 7cm cystic astrocytoma, an access site (corticotomy) of approximately 20mm would normally be required. However, the same procedure performed utilizing the company’s VBAS product required a corticotomy of only 2mm.

Cost benefits

A typical Craniotomy is reimbursed at 40% of an average billed cost of \$115,000¹, with fixed allowances for surgery, post op recovery, etc. Retractors, along with OR consumables, are not reimbursed as specific devices.

The VBAS is able to potentially offer significant savings for each case in three areas: OR consumables; OR time; and post-operative recovery time. These potential savings are driven primarily by the key clinical advantages of VBAS. ▼

¹ HealthGrades cost index and Pharmetrics, Inc.

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