

Intracranial Introduction of Ultrasound Imaging Fluid

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Neurosurgery

Longstanding Unmet Need in Brain Tumor Treatment

- All intra-axial (within the brain) tumors face similar treatment challenges for localization and assessing extent of resection
 - Benign or malignant
 - Primary or metastatic
- Glioblastoma (GBM) is one of the most complex, deadly, treatment-resistant cancer types
 - Five-year survival rate: 6.9%
 - Average length of survival: 8 months (estimated)
 - Survival rates and mortality statistics for GBM virtually unchanged for decades
 - Extent of resection correlates with survival

Imaging Challenges During Brain Tumor Surgery

- Brain tumor resection requires precise localization and continuous assessment of residual during surgery to maximize safe removal
- Pre-operative imaging becomes less reliable intraoperatively due to brain shift
- Surgeons need real-time guidance to distinguish tumor from healthy tissue

Current Intraoperative Neurosurgery Imaging Options Suboptimal

Intraoperative MRI

- ↑ Accurate
- ↑ No pre-planning
- ↓ Requires 1.5 hours per scan
- ↓ Infection risk
- ↓ Requires dedicated staff
- ↓ Brain shift issue
- ↓ Expensive infrastructure

Gleolan (5 ALA)

- ↑ Effective only in high-grade glioma
- ↑ Adjunct diagnostic versus imaging mode
- ↓ Requires pre-planning
- ↓ Taken 3 hours prior to procedure
- ↓ Limited to directly visualized tissue

Intraoperative Ultrasound

- ↑ Always available, all tumor types
- ↑ Real time intraoperative imaging
- ↑ 5-minute scan time
- ↑ No pre-planning required
- ↑ Portable
- ↑ Can visualize deep tissue
- ↓ Low image quality

Use of Intraoperative Ultrasound Increasing

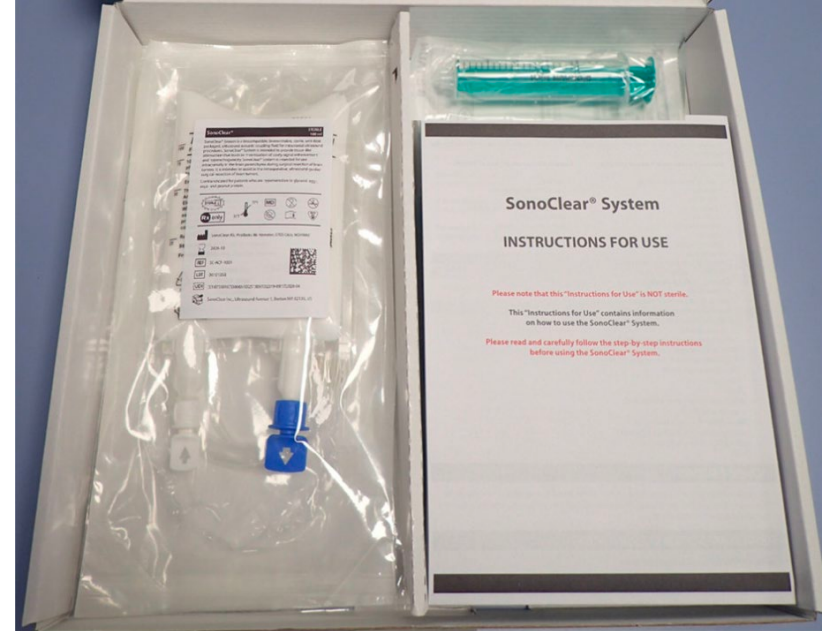
- Why the increase?
 - Easier to use
 - Able to obtain repeat imaging throughout surgery
 - Lower resource utilization
- What can further drive adoption?
 - Improve images by reducing unintended artifact
 - Improve visual delineation of tumor and margins
 - Enhance real time imaging capabilities of 3D US
 - No additional safety risk

Why SonoClear?

- Lipid emulsion is a better suited ultrasound agent compared with irrigation fluids (normal saline or lactated ringers)
- Acoustic properties similar to brain tissue
- Closer match between agent and tissue = less degradation in intraoperative imaging
- Organic matter matches many properties of cerebral spinal fluid
 - Physiologic
 - Osmolality
 - Ph
 - Bio-excretable

The SonoClear® System

- Sterile fat emulsion, single use
 - 1 * 100ml SonoClear® (fluid)
 - 1 * SonoClear® Spike set
 - 9 * B Braun Injekt® 20ml Piston Syringes
 - 1 * Indications For Use



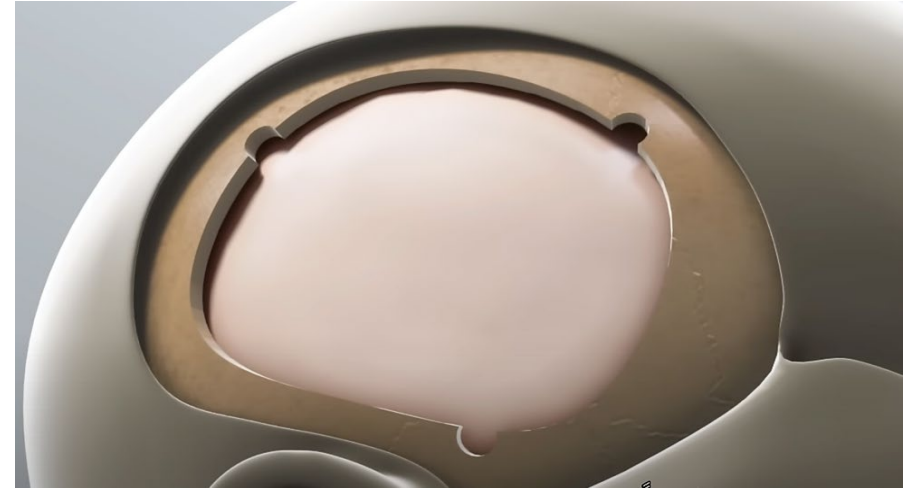
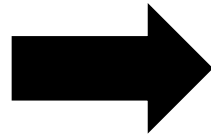
Transferred into sterile field
Delivered to the cavity via syringe(s)



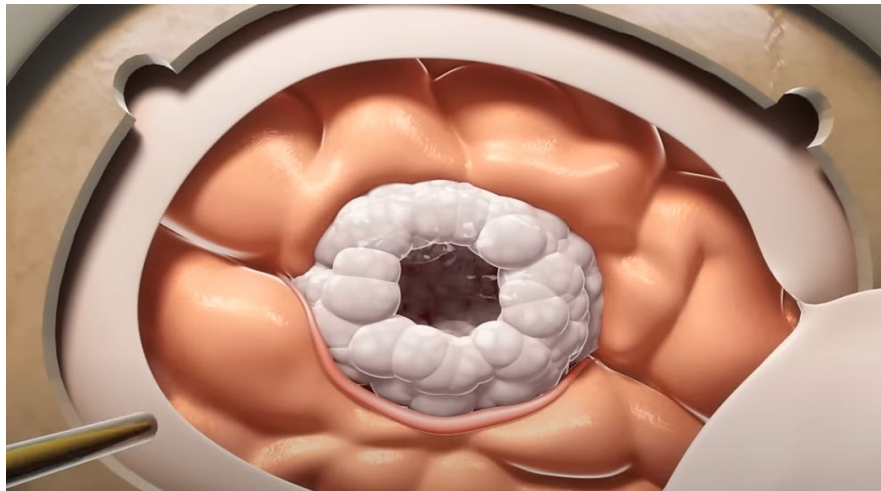
Procedural Steps to Expose the Brain Tumor



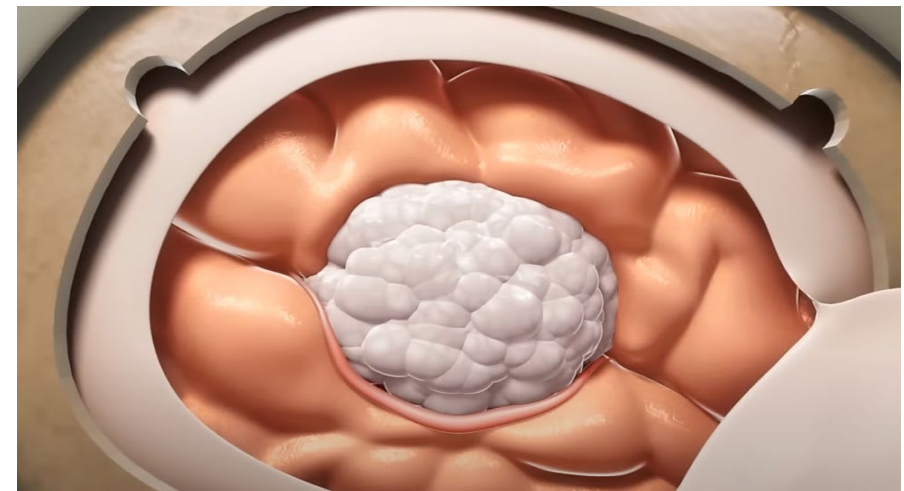
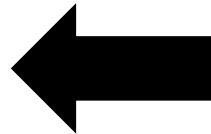
1. Tumor localized



2. Craniotomy – Dura exposed



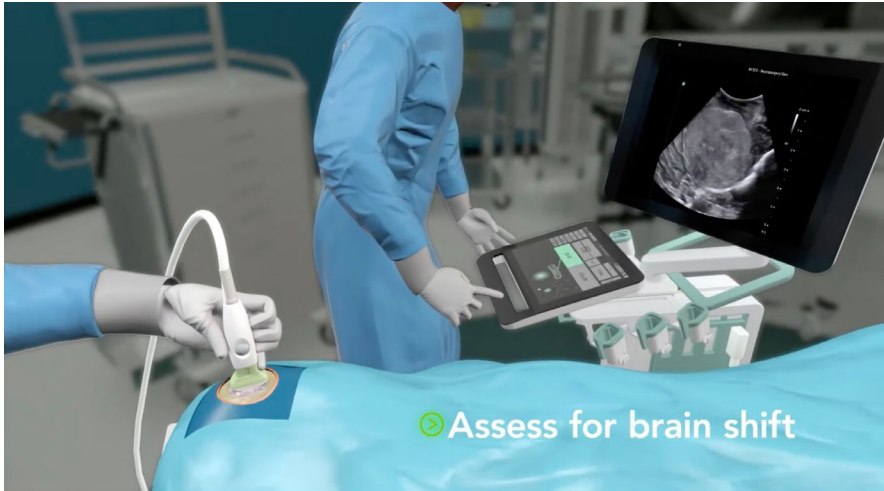
4. Initial tumor resection – cavity created



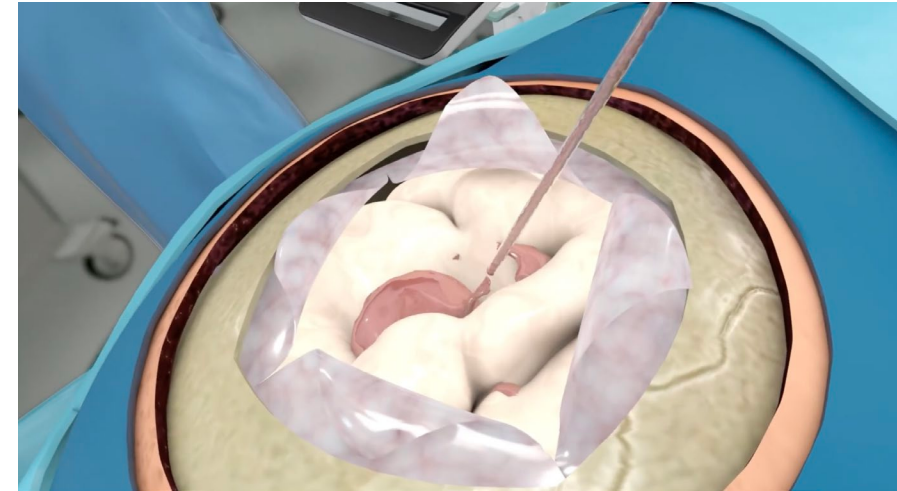
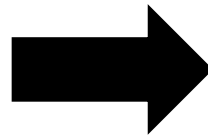
3. Dura opened – tumor exposed



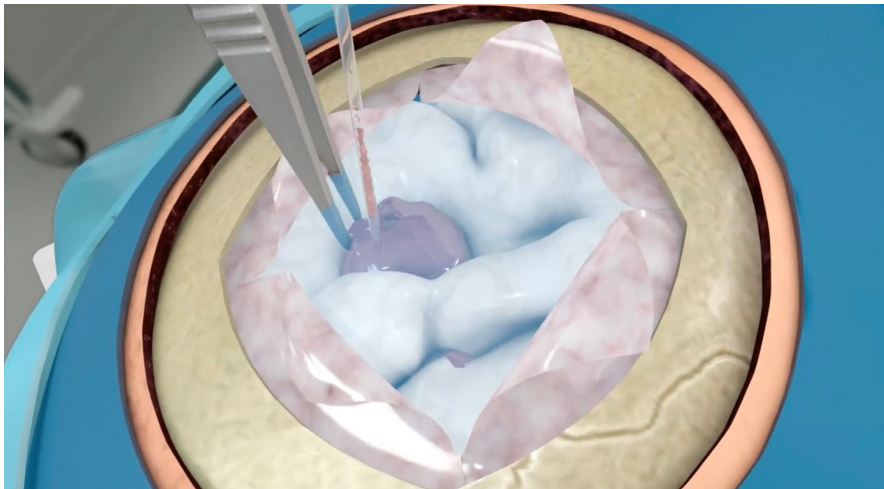
Procedural Steps with Intraoperative Ultrasound



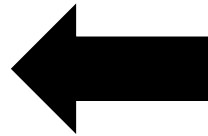
1. Pre ioUS assessment



2. Gross tumor removal



4. Removal of remanent tumor

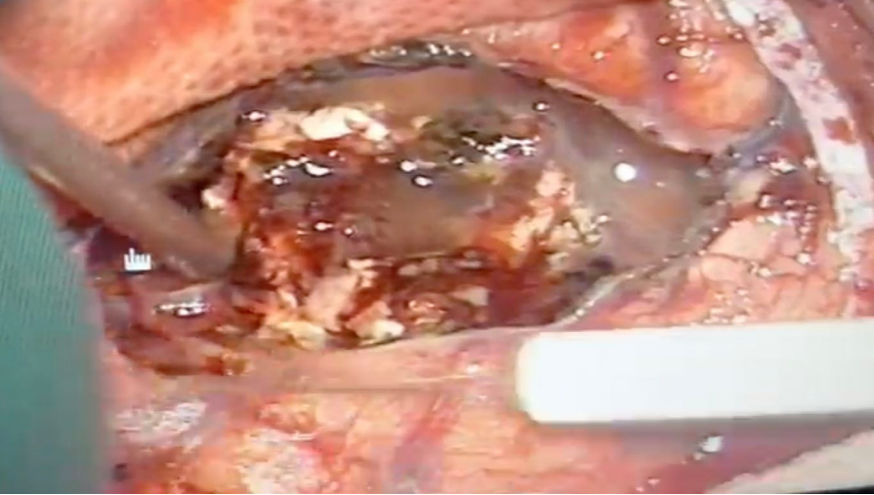


Cavity filled
with irrigation
fluid

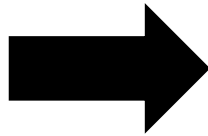


3. Ultrasound assessment of remanent tumor

SonoClear® (fluid) for Ultrasound Imaging



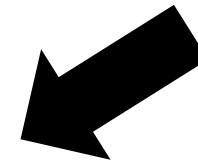
1. Resected tumor cavity



2. SonoClear® in the cavity



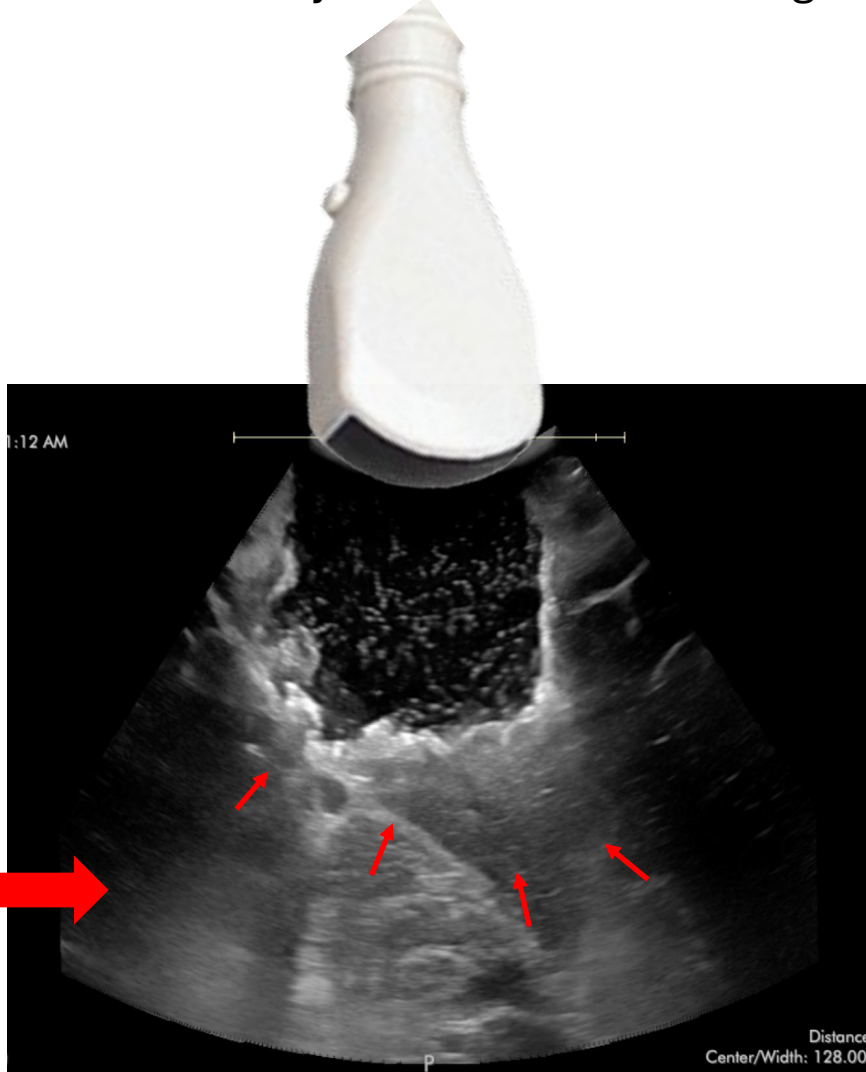
3. SonoClear® with ultrasound probe



SonoClear® impacts the physical properties of ultrasound

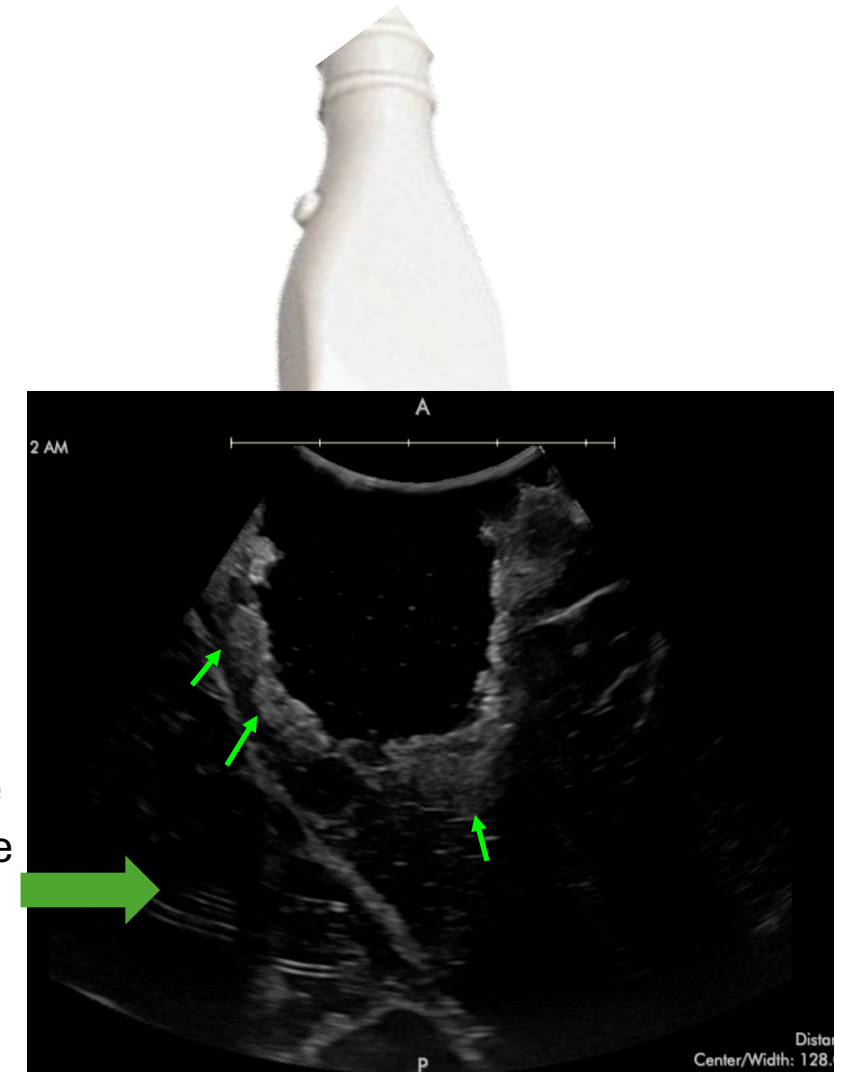
SonoClear® mimics healthy brain tissue – removing acoustic noise

Acoustic noise
degrading the
image



Irrigation fluid

Acoustic noise
removed by the
physical effect
of SonoClear®



SonoClear®

Breakthrough Device Designation – Indications For Use

”SonoClear[®] System is a biocompatible, bio-excretable, sterile, unit dose packaged, ultrasound acoustic coupling fluid for intracranial ultrasound procedures.

SonoClear[®] System is intended to provide tissue-like attenuation that leads to minimization of cavity signal enhancement and hyper-echogenicity. SonoClear[®] System is intended for use intracranially in the brain parenchyma during surgical resection of brain tumors. It is intended to assist in the intraoperative, ultrasound-guided surgical resection of brain tumors.”

Identifying SonoClear® in the Medical Record

- Documentation of the use of SonoClear® will be included in the operative and imaging report
- Key words
 - Ultrasound couplant
 - SonoClear®
 - Acoustic couplant
 - Tissue mimicking couplant
 - Acoustic Coupling Fluid (ACF)