ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI-29
STORES SECTION(CNC)

T. No. 167/CNC/NS/2025-26/St. **Dated: 29.06.2026**

Sub:- Purchase of "Surgical Navigation System (Buyback-01 No.) and server-Based Treatment Planning Software or Contouring and Data Enrichment with two concurrent session for Gamma Knife and Neurosurgery Planning-01 Unit" for department of Neurosurgery on proprietary basis-Inviting comments thereof.

The CNC (AIIMS) is in the process to purchase of Surgical Navigation System (Buyback-01 No.) and server-Based Treatment Planning Software or Contouring and Data Enrichment with two concurrent session for Gamma Knife and Neurosurgery Planning-01 Unit" for department of Neurosurgery, CNC, AIIMS, New Delhi-29 on proprietary basis from M/s. Brainlab SE, Germany through Indian agent M/s. Brainlab India Pvt. Ltd. The proposal submitted by M/s. Brainlab India Pvt. Ltd. and PAC documents are attached.

The above documents are being uploaded for open information to submit Suggestion/objections/comments, if any, by any manufacturer/Supplier firm regarding proprietary nature of the equipment/item, within 15 days of issue of this document on AIIMS website by giving Tender No. **167/CNC/NS/2025-26/St.** The comments/ objections should be submitted in the office of Stores Officer (CNC), Room No. 3, 1st Floor, New Pvt. Ward, CNC at AIIMS, New Delhi-29 on or before **14.07.2026 upto 03.00 PM**, failing which it will be presumed that any other vendor is having no comment to offer and purchase process will be initiated further for purchase of item as per procedure. No suggestions/objections will be considered after 14.07.2026.

29/6/2026

STORES OFFICER
(CNC, AIIMS, N.DELHI-29)

Encl: Related documents enclosed.

29/6/2026

DEPARTMENT OF NEUROSURGERY
ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DLHI-110 029

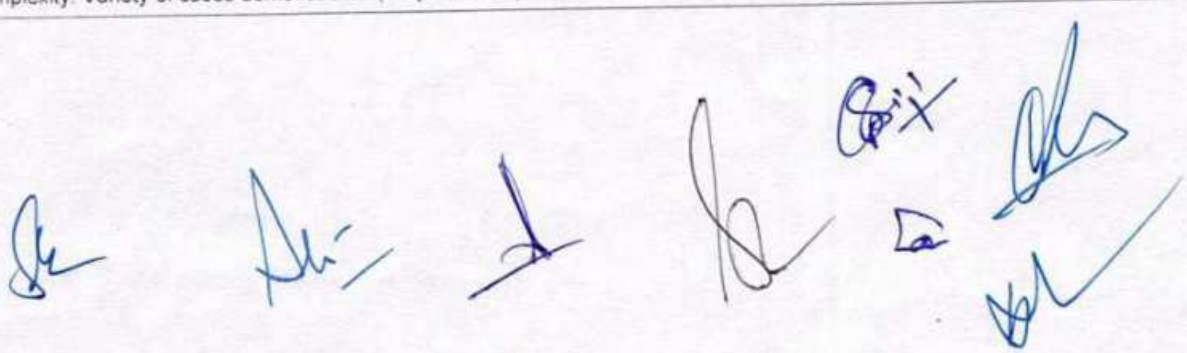
Date- 13/08/2025 & 17/12/2025

Sr. No.	Specification of Surgical Navigation System (Buyback-01 No.) and Server-Based Treatment Planning Software for Contouring and Data Enrichment with two Concurrent Session for Gamma Knife and Neurosurgery Planning – 01 Unit. Approx. Estd. Cost in INR 6 Crores + 10 Crores = Total Cost 16 Croes.
	TECHNICAL SPECIFICATIONS
	High End Navigation System for Neurosurgical Use
	Mandatory Requirements
1	**High End Navigation System**
a.	The system should be wireless based on Passive Marker Technology.
b.	The Navigation platform should have 4K UHD touch screen monitor of minimum 27 inch or greater and advanced technology will be given preference.
c.	Display should be of medical grade and of high resolution. It will be preferable to have good display quality with 4K UHD resolutions (3840 x 2160 pixels).
d.	System should have Mobile camera cart with telescopic stand and motorized joints for remote-controlled camera alignment. The Infrared camera should be extremely flexible in terms of providing for various adjustments to allow for various positions with camera height (100-250 cm) to allow flexible patient positioning & registration along with Integrated HD video camera for recording.
e.	System should have connection panel for plug & play connectivity e.g. with surgical microscopes, fluoroscopes, endoscopes, ultrasound etc. via state-of-the-art digital and analog video inputs supporting up to full HD resolution: 4 x 3G-SDI Video-In/DVI Video-In/ Display Port
g.	Direct/Fast Patient data transfer from/to with USB 3.0
h.	The system should have fast simultaneous access to e.g. PACS/hospital network via LAN network with existing PACS or future PACS, which is in use by the Department of Neurosurgery. The responsibility the vendor supplying the navigation machine.
i.	System should have high-performance computer (Intel® Core™ i9-10900X X-series 10-core Processor 3.7/4.7 GHz, 32 GB RAM memory and 1 TB SSD or better specification). The processing speed should be good enough to match the requirement of the user department.
j.	The navigation system should use passive markers without batteries. No disposal of hazardous materials is required after the use of the system.
k.	All requisite applications should be on the Navigation System and can be controlled with touch and/or with mouse and should not require any additional computer.
l.	Navigation system should have a smart software home button to ensure interchangeability between multiple windows at any given point of time as per surgeon discretion. Any changes made on attached window gets automatically updated into navigation window
m.	It should have Digital Recording capabilities inbuilt into the navigation system without requiring any other devices thus keeping the OT clutter free
2	**Cranial Navigation Software**
a.	System should be capable of performing wide range of cranial procedures with optical tracking technology. Electromagnetic navigation technology should be quoted as optional and price of it along with all the accessories required for each case must be quoted separately. If the user departments will require, then they will procure this in future, as EM navigation is used in very cases.
b.	The system should have marker based point registration with accuracy prediction system.
c.	The system should have marker less surface based registration with accuracy prediction system.
d.	System should have skin sensitive registration to avoid issues like skin shift inaccuracies specially for difficult patient positioning like prone positioning surgeries. With skin sensitive device, point acquisition will be precise as points will not be acquired in air.
e.	System should incorporate rescue points to recover navigation registration during surgery in case of registration accuracy loss during surgery
f.	If the option of touchless registration exists with the supplied system then preference will be given. Cost of this must be quoted separately and its should be supplies with the system. Touchless laser based registration device must also be supplied. No physical contact should be there with patient and device during registration to avoid errors due to skin shift.
h.	The probe should have capability to show images at -20mm to 180mm in front of it (Tool Tip Extension).
i.	System should integrate the existing rigid instruments based on 3D geometry of instruments of various companies, with respect to their diameters, length & vector. Ex 3rd party Biopsy Needles & Stylets. For Navigation purpose, full 3D views of these integrated instruments should be available. 4 instruments simultaneously can be visualized with different colors
j.	The system should be able to have options like Zoom-in, Zoom-out, different layouts, different viewing options, taking screen shots etc.

k.	System should be provided with 10 pieces of pre-calibrated stylet for shunt placement surgeries
3A	**Advanced 3D Contouring Software**
a.	Should be a Quick and easy interactive 3D contouring tool for outlining of pathologies and anatomical structures in medical images
b.	Software should offer an Instant volume generation by outlining on just two orthogonal slices using multi-modal Side by Side or axial, coronal and sagittal view configurations
c.	It should offer Intelligent contour propagation with ambient edge detection supporting various CT, MR or PET sequence
d.	Should also have Slice-by-slice contour review using Gallery View layout
e.	Should have Automatic creation of "Volumetric Report" PDF files per object with representative screenshots and details on geometrical measurements like volume, RECIST and Macdonald criteria
f.	It should have fast contour adaptation and should have Intuitive user interface with both mouse and touch control compatibility
3B	**Advanced Image Fusion Software**
a)	Software should offer fast and precise fusion based on mutual information algorithm and helps enables to exploit all anatomical & functional data sets simultaneously
b)	Software should offer fusion of numerous modalities including CT, MRI (T1, T2, FLAIR, MRA), PET, SPECT
c)	It should have automatic pair selection with instantaneous pre-alignment and fusion. A possibility of manual fine-adjustments in all dimensions should also be provided
d)	It should have definition of a "Region of Interest" in all dimensions to exclude areas from fusion
e)	Software should offer Color overlay in amber-blue and Spyglass functionality for reviews
f)	It should have ability to fuse a series of image datasets from different modalities and points of time
3 C	**DTI SOFTWARE:**
a)	DTI software should facilitate the processing of diffusion imaging, providing detailed information about eloquent white matter structures using both deterministic DTI and probabilistic CSD-based tractography algorithms.
b)	Software should support multiples views like Brain Projection View, 3D-view, ACS-view, Interactive Tracking, ROI Templates. The Brain projection views should be available while visualization of fiber tracts
c)	Software should have Fiber tracking ROI templates for specific cranial white matter tracts, based on universal atlas. Templates to be included: Arcuate Fasciculus left, CST Motor Right, CST Motor Left, DRT Left, DRT Right, Full Brain, Hand Motor Right, Hand Motor Left, Optic Radiation Left, Optic Radiation Right. It should also have feature of user defined Fiber templates
d)	It should have Fully automated DICOM DTI Data Preprocessing including De-noising, Motion- and Eddy Current Correction
e)	It should have Region-of-interest based tracking of DTI data
f)	Software should have capability for conversion of results into 3D objects for use and export to Navigation.
g)	It should have intuitive user interface for manual adjustment of tracking parameters and instant update of fiber tracking results
h)	It should have Automatic calculation of colored fractional anisotropy (FA) and anisotropic diffusion coefficient (ADC) maps
i)	It should support of DICOM DTI data from Siemens, Philips, GE and other manufacturers using standard DICOM MR diffusion information (at least 6 and up to 256 directions)
j)	Software should provide multicolor output to fibertracts according to their diffusion direction, i.e. separate fiber color for each tracts from (1) "Left-Right", (2) "Anterior-Posterior", (3) "Head-Foot".
k)	Software should be provided with manual adjustment of parameters which are fiber angulation adjustment, minimum FA threshold ,minimum fiber length to track the particular (or interested) fiber tracts with more precision
l)	Software should be provided with live fiber tracking functions for more interactive and real time.
3D	**Distortion Correction Cranial**
a)	Software should have more accurate anatomical co-registrations through local deformations based on multi-ROI rigid fusions Image Fusion with distortion correction possibilities for cranial MR data sets. There should be direct comparison corrected with conventional results through toggling
b)	Software should ensure inherent distortions of the short DTI MR sequences are corrected based on higher resolution MR scan to provide DTI data for fiber tracking with improved anatomic precision, ultimately resulting in fibers being more accurately visualized.
c)	Should have Adaptation of distorted MR against reference MR (e.g. DTI to T1) as well as MR to CT
d)	Should support Generation of an adapted, artificial DICOM data set co-registered to the reference data set
e)	It should have Automatic content update like objects and landmarks according to the new registration field
f)	Should Supports automatic and interactive segmentation on new data sets

g)	It should have Colored deformation grid highlights local deformations for detailed inspection
h)	Software should have Amber-blue color overlay and spyglass functionality complement the verification tools
3E	**Software for BOLD MRI MAPPING**
a)	Software for BOLD MRI mapping showing motoric & speech functional areas of brain should be provided
b)	It should have Automatic import of DICOM BOLD MRI data
c)	It should do Pre-processing of data incl. motion correction, slice time correction and smoothing
d)	Software should provide flexible definition of different functional paradigms
e)	It should support block-designed paradigms for motoric and speech areas
f)	It should provide automatic detection of functional activations
g)	It should provide time series view for verification of signal to paradigm correlation.
h)	It should provide Interactive selection and display of functional areas and regions of interest
i)	It should have capability for conversion into 3D objects for use with other applications including navigation
j)	It should have brain surface (Cerebrum) segmentation for enhanced orientation in 3D view
k)	It should support BOLD MRI data from Siemens (incl. Mosaic DICOM image format), GE and Philips (incl. Enriched DICOM) MR scanners
5	**Ultrasound Integration:**
a)	The Navigation software should have compatibility with existing 3D Ultrasound from BK Medical that have color map & Doppler capabilities. Digital Integration of Navigation with BK5000 should be there to avoid attenuation of signal during transmission. This feature is must.
b)	Ultrasound navigation software should be provided with plug and play facility i.e. there is no need to Integrate or calibrate ultrasound probe with navigation software each time during surgery.
c)	Ultrasound navigation software should have ultrasound inline view (real-time ultrasound data superimposed over pre-operative e.g. CT, MRI data) which enables the clinician to diagnose the brainshift intra-operatively at any point during the course of surgery. Also, ultrasound Inline view should facilitate to view pre-operative plans such as fiber bundles, tumor contouring etc.
d)	Software should be able to acquire 3D Ultrasound volumetric data (ACS) intra-operatively and further should be able to navigate on this acquired real-time 3D Ultrasound data.
e)	Software should be able to merge two recently acquired 3-D ultrasound datasets and then, overlay the same on any available imaging data to navigate with enlarged volume of real-time ultrasound data.
f)	Software should be capable of viewing the resection progress i.e. software should have facility to view two most recent 3D ultrasound datasets superimposed over the CT/MR data in axial, coronal & sagittal views.
g)	Software should have the adjustment for Increased transparency view for projecting underlying MRI
	With ULTRASOUND image overaly TO MRI automated rigid fusion between the preop MRI image and the intraoperative 3D ultrasound image, allowing you to update the registration and navigate on the most up-to-date patient anatomy. It Should Provides functionality for an automated rigid US-MR fusion with a sufficient accuracy to update the US-MR registration
h)	Software should have threshold adjustment view for highlighting echogenic structures.
6	**Instruments for Cranial Optical Navigation:**
a)	Reference frames: Unsterile:1, Sterile:1. The cost must be quoted upfront for each frame.
c)	Navigation Pointers: 3; Unsterile 2 and Sterile 1. The cost must be quoted upfront for each navigation pointer.
d)	Touchless Laser Navigation Pointer: 1. The cost must be quoted upfront for laser pointer.
e)	Surgical instrument integration with diameter, length and instrument trajectory using instrument adapters (S, M, L, XL clamps and ML, L, XL arrays) - 1 Set. The cost must be quoted upfront for each item.
f)	Caliberated Adapter for Cylindrical Instruments. The cost must be quoted upfront
g)	Navigable stylet for Ventricular catheter for Shunt Placement: 2 The cost must be quoted upfront for each stylet.
h)	Fiducial Markers- 100 Pcs. The cost must be quoted upfront for a pack of 50 fiducial.
i)	180 Glions/ Marker spheres. - The cost must be quoted upfront for a pack of 50 Glions/marker spheres.
j)	All sterilizable instrument sets must be supplied with auto-clavable instrument tray. The tray must be customized for the instruments so that instruments are not damaged. There should be slots for each item and must have protective rubberised material to avoid any damage to instruments.
7	**Integrated Biopsy Solution must be provided with the system. The system should include a frameless biopsy system with navigable needles**
	1. It should have Fine-adjustment for navigated frameless biopsies, shunt placements & endoscopic examination guided by the navigation system.
	2. It Should allow precise online tracking according to the pre-planned trajectory

	3. Should adapt to fit cylindrical instruments, including biopsy needles and endoscopes, of 1.8-2.0mm,2.0-2.5mm,2.5-3.0mm,3.0-4.0mm and 4.0-5.0mm,5.0-6.0mm,6.0-7.0mm,7.0-8.0mm(1.8mm - 8.0mm)and up to 300g; Holds instruments with a length of up to 35 cm.
	4. Software wizard should be user friendly and allow the surgeons to easily perform the biopsy with the desired accuracy.
	1. It will be preferable to have a system that allows the integration of recalibrated biopsy needles as well as autoclavable reusable needles available in the hospital.
	2. 10 Biopsy needles must be supplied with the system.
1	**General Terms & Conditions**
a)	System should have a 2 year warranty followed by annual CMC with spares for 3 to 10.
b)	The principal has to certify that spares and support shall be available for next 10 years.
c)	Demonstration of the navigation system is a must to the satisfaction of the user. The demonstration is to be held in neurosurgery OT of C. N. Center. Machine must be provided for 15 days or more so that it can be evaluated by all the faculty members. Neuro navigation system during the demonstration will be assessed for -
	1. Accuracy and Precision
	- Fiducial Registration Error (FRE): Measurement of the error between the physical fiducial markers and their digital representation.
	- Target Registration Error (TRE): Accuracy in reaching target points within the brain.
	- Overall System Accuracy: Assessment of the system's ability to maintain accuracy throughout the procedure.
	2. Ease of Use and User Interface
	- User Interface Intuitiveness: Evaluation of the ease of navigation and user-friendliness of the interface.
	- Customization Options: Availability of customizable settings for different surgical procedures.
	- Learning Curve: Assessment of the time required for the surgical team to become proficient in using the system.
	3. System Integration
	- Imaging Modality Compatibility: Compatibility with different imaging modalities (CT, MRI, DTI, BOLD etc.).
	- Seamless Integration with Operating Room Equipment: Integration with microscopes, endoscopes, C-arm, and other relevant equipment.
	- Data Import/Export: Efficiency in importing/exporting patient data and imaging for preoperative planning and postoperative analysis
	4. Real-Time Tracking and Feedback
	- Tracking Accuracy: Assessment of the system's ability to accurately track instruments and anatomy in real-time.
	- Latency: Evaluation of any delay between instrument movement and system response.
	- Feedback Mechanisms: Availability of visual, tactile, or auditory feedback during procedures. Eg. overshooting a target while doing biopsy.
	5. Workflow and Procedure Planning
	- Preoperative Planning Tools: Quality and variety of tools available for preoperative planning (segmentation, trajectory planning, etc.).
	- Intraoperative Workflow: Evaluation of the system's support for intraoperative adjustments and decision-making.
	- Procedure Documentation: Capability to document and record procedures for training and review.
	- Ergonomics of the cart and camera arm etc.
	- Quality of cart, camera arm etc. and their sturdiness.
	6. Safety and Reliability
	- Error Handling and Alerts: Assessment of the system's mechanisms for detecting and alerting errors.
	- Sterility and Hygiene Compliance: Compliance with sterilization standards and ease of maintaining sterility.
	7. Support and Service
	- Training and Support: Availability of training programs and technical support.
	- Service and Maintenance: Evaluation of the service and maintenance plans offered by the vendor.
	- Warranty and Upgrades: Assessment of warranty coverage and options for future software/hardware upgrades.
	8. Demonstration Scenarios
	- Case Complexity: Variety of cases demonstrated (simple to complex).



	- Clinical Relevance: Demonstration's relevance to typical and challenging neurosurgical cases.
	- Integration of the machine with existing ultrasound in the neurosurgery operation theater and its user friendliness will also be assessed
d)	Proper training to OT technical staff should be provided.
e)	Service engineer should be made available as and when required within 24 Hours for onsite support in Neurosurgery OT of the C. N. Center of AIIMS. Service team should be based in Delhi/NCR region. The vendor should have a good service and application backup along with instruments to provide an effective troubleshooting and support.
f)	The cost of all spares and consumables -Brain biopsy needle, Jamshidi needle, reflective/marker spheres, navigation arms, navigation pointers, batteries etc. should be quoted upfront and should be valid for 10 years. In case the cost is not quoted upfront and the part is required after consumption or after damage then the company will be bound to supply it free of cost.
g)	Manufacturer or their subsidiary or authorized dealer who is quoting should be present in India Having Selling experience of more than 5 years with at least 5 installations in government institutes/hospitals.
h)	In no case the instrument should remain in non-working condition for more than 7 days, beyond which a penalty as the per the rules of the institute will be levied
i)	All technical bids comparative statements to the tender specifications must be enclosed along with reference no. paragraph no. from original catalog of the instrument.
j)	The L1 bidder will be calculated based on the cost of machine and software for the mandatory requirement plus the cost of 100 fiducials/glions/markers and cost of 10 biopsy needles.
k)	The company is obligated to provide the latest version of the aforementioned software, including any upgrades or newer versions, to the Department of Neurosurgery at AIIMS at no additional cost during the period of use of the above machine i.e. 2 + 8 years.
l)	Machine must have USFDA/CE/Equivalent Indian certification for neurosurgical use
	Items given below are optional. The cost of each software or hardware should be quoted upfront in the tender. In case the need and requirement is there, the department can purchase these at the later date
	Optional Advance Add on Upgrade Hardware and Software on Navigation System
1	System can be used as a standalone navigation system and also as per clinical requirement can be added with Robotic Positioning Arm as per brief given below.
2A	**Robotic Positioning Arm for Cranial and Spine with ROBOTIC ALIGNMENT MODULE**
a)	Should have articulated arm with seven joints enabling seven degrees of freedom
b)	Should have kinematic design with human arm dimensions suitable for efficient draping
c)	Should have fully integrated computer unit and is ready to use within seconds due to a short booting time.
d)	Should be O.R. table mount with a stabilization brace which gets attached to the contralateral OR table rail to increase stability
e)	Should have lightweight design (Less than 20 Kgs) for effortless setup and use
f)	Should have seven LED rings display joint status
g)	Should have manual retraction from surgical site in case of emergency
h)	Should have automatic locking of individual arm joints once target position is reached
i)	Interface software between the robotic arm system and the navigation system, handles communication, serving interface of the arm and attached modules. Automatic detection of arm system via network connection, Selection of movement control modes (touch strip settings),Locking of arm to avoid unintended movement
j)	Alignment Software should provide Visual guidance for alignment to closest trajectory
k)	There should be warning and display of deviation if there is any unintended movement
l)	Instruments allowing the ability to perform transpedicular drilling with the robot/articulated Arm should also be supplied
m)	Alignment Software should also have Visual guidance for return to previously stored end position
n)	It should have automatic locking of individual arm joints once target position is reached
o)	Should have no positional shift after loss of power
p)	One set of MIS instruments should be provided.
q)	System should integrate the existing rigid instruments based on 3D geometry of instruments of various companies, their diameters and length.
r)	Disposable drapes for sterile use of the Robot should be provided (20 pcs)
s)	One stop emergency power off button
2 B	**ROBOTIC ALIGNMENT MODULE**

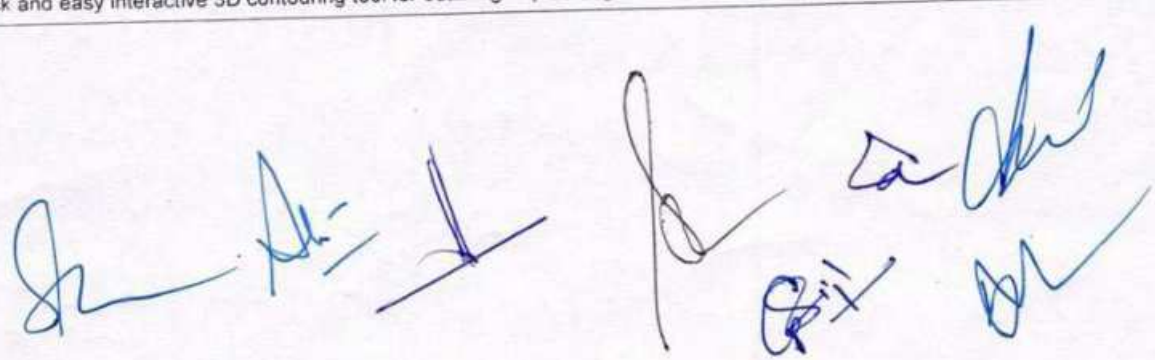
a)	The robotic module should be able to align a working channel to a preplanned trajectory made possible by additional four degrees of freedom which are motorized.
b)	The module should portable and light weigh less than 1.5KG with the working space: +/- 10 mm and +/- 10°
c)	portable and light weight design - less than 1.4 kg
d)	It has multiple buttons to control navigation workflow steps with the Module
e)	Power and data supply are handled by the Arm System, no additional cables are needed
2 C	**CRANIAL Robotic Alignment SOFTWARE**
a)	Robotic alignment software for Cranial provides visual guidance towards region of interest with a dedicated drill guide and helps keeping incisions small. Special biopsy anchor for the skull adds stability to the setup and pre-calibrated biopsy needle with guide tube facilitate seamless performance
b)	Surgeon can select pre-planned/active trajectory from sterile field and Bone-ruler enables measurements of the skull thickness at the current trajectory
c)	Real-time tracking of robotic instruments (and biopsy needles) allows uninterrupted verification of effector accuracy. Deviation monitoring with adjustable threshold warns user in case of deviations from planned trajectory
2. D	**CRANIAL INSTRUMENTS**
a)	**Device for instant intraoperative calibration of length, diameter and vector of a rigid instrument (if required for the third party instruments).**
b)	Depth stop for Cranial biopsy drill bit
c)	Pre-calibrated marker geometry tracking array cranial for cranial robotics
d)	Sterilization tray for safe, efficient sterilization (autoclaving) and storage of the cranial biopsy accessories for robotics
2. E	**CRANIAL DISPOSABLES (10 cases)**
a)	**Disposable biopsy needle (5 PCS x 2)**
b)	Disposable kit with Robotic alignment module and a sterile drape (5 qty x 2)
c)	Biopsy guide tube cranial for robotics (10 qty)
d)	**Biopsy bone anchor Cranial for Robotics**
e)	Drill bit Cranial 3.4mm/3.8mm (10 qty)
2. F	**CRANIAL SEEG Alignment SOFTWARE**
a)	Should have the Image-guided surgery software for placement of SEEG anchor bolts with Robotic Arm
b)	Should have the Graphical guidance for easy positioning of the Robotic Alignment Module.
c)	Real-time tracking of instruments mounted on robotic arm (and SEEG needles) allows uninterrupted verification of instrument accuracy.
d)	Deviation monitoring with adjustable threshold warns user in case of deviations from planned trajectory.
f)	Switching between active trajectories with the buttons of the Robotic Alignment Module.
g)	Bone-ruler enables measurements of the skull thickness at the current trajectory
2.G	**SEEG instruments (10 cases)**
a)	Cranial Instrument Holder and Tracking Array with 7.5 mm guiding diameter
b)	SEEG Drill kit PMT 2.1 MM/2.4mm / DIXI/ AD-TECH (10 CASES)
2. H	**SPINE Robotic Alignment SOFTWARE**
a)	Robotic alignment software for Spine provides visual guidance towards region of interest with real-time tracking of instruments including trocar for drilling preparation and drill guide. Automatic alignment to planned screw trajectory after arm positioning. The drill guide teeth designed for forceless anchoring on the bone and length suitable for various patient anatomies
b)	Seamless workflow with navigation-ready instruments including tissue protecting trocar for minimally-invasive spine surgery. It provides stable procedure support when locked in place after alignment and with sharp teeth anchoring on the bone. Vendor-neutral compatibility with multiple implant sets.
2. I	**SPINE INSTRUMENTS**
a)	Instruments such as drill guide tube and drill bit of sizes 2.4mm, 2.6mm, 3.2mm should be provided. (3 sets)
b)	Pre-calibrated marker geometry tracking array spine for spine robotics
c)	Preparation trocar 6mm with depth array for spine robotics
d)	Drill guide depth control setting of maximum drill depth
f)	Sterilization tray for safe, efficient sterilization (autoclaving) and storage of the spinal drilling accessories for robotics
2. J	**SPINE DISPOSABLES**

e)	Disposable kit with Robotic alignment module and a sterile drape (5 qty x 2) x 5 = 50 qty.
	Advanced Planning Software's (Optional)
3A	**STEREOTAXY SOFTWARE WITH LEAD LOCALISATION:**
a)	The System should allow Stereotactic localization of MR/CT images and Intuitive definition of AC, PC and mid-sagittal-plane for Stereotaxy planning.
b)	It should support Definition of the trajectory (Target and Entry) in AC/PC relative Coordinates (Distances and Angles)
c)	Target and Entry should be displayed in AC/PC and DICOM image coordinates
d)	Should have Automatic localization of the 3D object/shape of the implanted lead from the post- operative CT dataset
e)	It should allow automatic localization of the 3D object/shape of the implanted lead from the post-operative CT dataset. This localized lead can be linked to the 3D Basal Ganglia segmentation in the planning for visualization of the contact point by the user so that further neurological programming can be performed
f)	It should have Automatic Patient specific Multimodal 3D segmentation of Basal Ganglia and integration of the same with Stereotaxy planning is a must
g)	It should allow Multi-modal image based trajectory planning in stereotactically unlocalized images prior to surgery
h)	Should have Automatic calculation & PDF print out of specific arc settings
i)	It should have Flexible 3D shapes for case-specific trajectory visualization (e.g. DBS leads, sEEG electrodes, shunts,)
j)	Should overlay a model of microelectrodes and DBS leads onto surgical plans providing visualization of lead and contacts relative to the target and surgical plans
k)	Should have Manual editing of detected lead position
l)	Stereotactic software should be fully integrated with MR Cranial Distortion Correction software
m)	Stereotaxy software should have Combined visualization of supplemental information such as Fibertracks, Nuclei and Leads
n)	All Software for DBS and sEEG should be from the same brand which supplies the navigation system
o)	It should Support the below mentioned stereotactic frames, localizers, and ring and arc configurations to meet specific procedure needs:
	Integra® CRW® - CT and Luminant localizers/
	Elekta™ Leksell®- CT and MR localizers (G frame and Vantage)/
	Inomed® ZD - Rev R, and Rev U localizers
p)	Should Support various mounting orientations for supported frames (e.g. lateral-left, lateral-right,sagittal-anterior, sagittal-posterior)
q)	Should have adjustment of planned trajectory entry point in 3D skin reconstruction view of volumetric data
r)	It should have different viewing layouts to plan, verify the trajectories and then compare the preoperative and intraoperative imaging data (bimodal view)
s)	Should have software generated pre-defined margin for safe planning of trajectories
3B	**Automatic Patient Specific Multi-modal Segmentation of Cranial Objects**
a)	Automatic segmentation of patient specific anatomical brain structures on MR and CT- data sets
b)	Thorough Anatomical Mapping based on Synthetic Tissue Model
c)	Patient specific segmentation of Cranial objects
d)	Segmentation should be based on multiple types of MRI (T1, T2, FLAIR) images of the same patient
e)	Teaching tool for visualization and identification of patient's Brain anatomy in diagnostic images
f)	Customizable list of objects to be segmented depending on workflow and clinical protocol.
g)	The list of segmented objects should include Amygdala, Brainstem, Capsula Externa, Capsula Interna, Central Sulcus, Caudatus, Cerebellum, Cerebrum, Cochlea ,CSF, Chiasm, Corpus Callosum, Geniculate, body, Globus Pallidus, Gray Matter, Hippocampus, Hypothalamus, Left Amygdala, Left Capsula, Externa, Left Capsula Interna, Left Caudatus, Left Globus Pallidus, Left Hippocampus, Left Lens, Left Optic Nerve, Left Optic Tract, Left Putamen, Left Thalamus, Optic Nerve and tract, Pineal Gland, Pituitary Gland, Putamen, Right Amygdala, Right Capsula Externa, Right Capsula Interna, Right Caudatus, Right Globus Pallidus, Right Hippocampus, Right Lens, Right Optic Nerve and Tract, Right Putamen, Right Thalamus, Temporal lobe, Thalamus, Ventricles, Vessel, White Matter, whole Brain, Facial Nerve, Precentral Gyrus, Postcentral Gyrus, Skin, Trigeminal Nerve, Vestibulocochlear Nerve, Eyes
h)	It should offer Immediate data processing upon patient selection
3C	**Automatic 3D Basal Ganglia Segmentation**
a)	It should be Automatic MR-based multimodal segmentation of 3D structures in the basal ganglia region
b)	It should be based on Anatomical Mapping based on Synthetic Tissue Model and it should do Immediate data processing upon patient selection

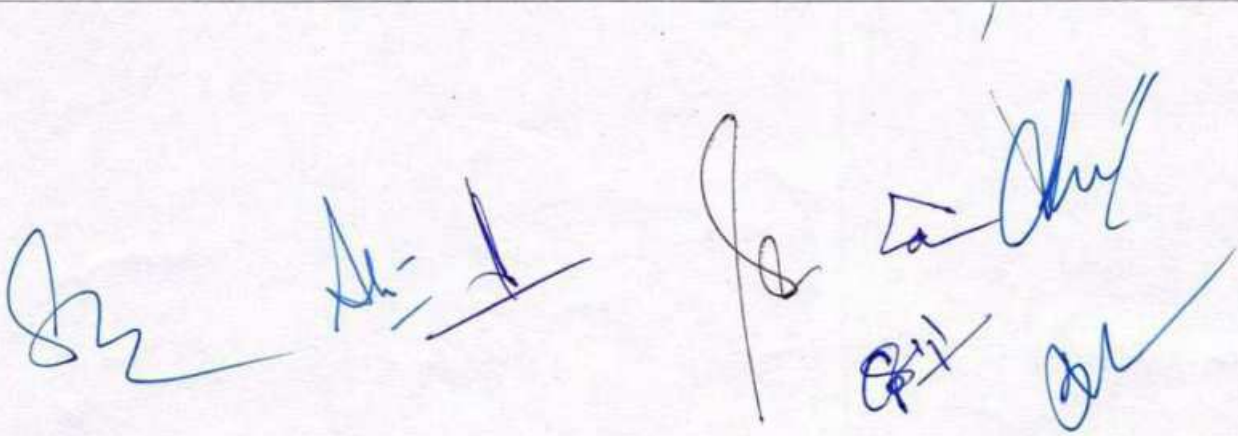
c)	The list of segmented objects should include Globus pallidus internal &external, Nucleus ruber, Substantia Nigra compacta & Reticulata, Subthalamic Nucleus, Ventral Tegmental Area, Ventral Intermediate Nucleus, Zona Incerta
3D	**Software for Surgical AVM planning & Navigation (if applicable)**
a)	Software should provide AVM resection planning in Frameless workflow
b)	It should provide view layouts with 2D-DSA angiographies fused to 3D angiographies, combining vascular flow information with anatomical information
c)	It should provide "Angio + ACS" view and "Angio + MIP" view for very clear AVM outlining & planning
d)	It should have Frameless co-registration of 2D angiography data and 3D vascular image sets
e)	It should provide support of multiple 2D DSA acquisitions: frontal, lateral and oblique angles to support the outlining from different perspectives
f)	It should have manual selection of 2D and 3D fusion pairs enabled
g)	It should have selection of ROI (Left/Right, Basilar Artery) to support the co-registration
h)	It should have colored visualization of blood contrast flow for better recognition of early and late contrast phase
i)	It should provide further usage of co-registration in navigation workflow.
j)	It should have quick and easy interactive 3D contouring tool for outlining of cranial vascular structures
k)	It should have side-by-side outlining on 2D DSA images and fused 3D image series
l)	It should provide delineation of clinical target under consideration of dynamic contrast flow
m)	It should provide visualization of 2D DSA projection as Color Intensity Projections
n)	It should have proposal of nidus object
o)	It should have capability for seamless outlining and fine-tuning of objects with SmartBrush, 2D and 3D Brush in 3D image data and in DSA projections
p)	It should have dedicated view layouts with selection of various fused 2D DSA pairs
q)	It should have capability for creation of multiple nidus objects for staging and follow-up
r)	It should have further usage of vascular object in navigation
O	**Spine & Trauma Navigation:**
a)	System should be provided with Sterile-wireless user interface communication device or a sterile remote for acquiring the points independently
b)	System should offer a simple patient registration with few defined anatomical landmarks on an operating bone and rest all registration landmarks should be randomly acquired
c)	System should support the patient registration based on pre-planned anatomical landmarks on 3D model of patient CT images and guide the surgeon to acquire the same during registration for small bony anatomies like cervical spine. Also, software should be able to identify that planned landmarks are on the bone for acquired registration.
d)	System should also guide the surgeon on deviation from the planned trajectory of the screw. Real-time information on angle and distance to target should be provided by the system
e)	Software should be offer Simultaneous navigation on multiple fused datasets
f)	Software should be able to co-register the CT and MR imaging data and navigable with MRI images during spine tumor navigation procedures
g)	Software should be able to detect left-right lamina swap if laminas are swapped accidentally during registration process .it should open an onscreen dialog box to correct the orientation.
g)	Software should be able to view the planned trajectory of the screw at various depths.
h)	Real-time tracking and 2D/3D visualization of a pointer and of up to 4 instruments simultaneously in various views.
i)	System should be implant independent wherein screws from any implant company can be used for navigation.
j)	System should be an open platform allowing the use of instruments from any implant company. The instrument calibration should use a calibration matrix to calibrate any rigid instrument for its length, diameter and vector and 3D simulation or the instrument or the screw should be displayed on the navigation screen while navigating with the calibrated instrument or screw.
k)	Software should offer reference array movement detection feature to avoid potential inaccuracy caused
	due to the movement of reference array
m)	Software should offer auto pilot view for the Screw navigation
n)	Software should offer cine view which plays through the slices on which planned screws perpendicularly intersects
o)	Software should provide a variety of navigation view options like Inline view, Probe's eye views, 3D view, DRR view, Cropped DRR view, Autopilot view, Spot View for planning and safe placement of the screws

p)	Planning Software to automatically labels vertebrae for 2D and 3D datasets (CT, CBCT, MR), and alternatively manual labeling and correction of labeling, suggests measurements on 2D images (AP /LAT), e.g. kyphosis angle and proposes screws from cervical to sacrum incl. Pedicle and Lateral Mass screws on CT, CBCT and MR. Also support of anatomical variations within the Spine e.g., L6, T13. Automatic rod visualization and rod length estimation, Different screw visualization options, Automatic report for planned screws & measurements
q)	It should have Digital Recording capabilities inbuilt into the navigation system without requiring any other devices thus keeping the OT clutter free.
r)	It should be able to locally record the procedure in digital HD quality of any display content (e.g. navigation software, microscope or endoscope video).
4B	**Automated Screw Planning Software:**
a)	Software should be capable of Manual planning of any type of screws on CT, XT and MR imaging modalities
b)	Automatic Screw planning of thoracic and lumbar pedicle screws on CT in which software proposes, plans and places the screw diameter, length automatically based on anatomy
c)	Software should be able to visualize rods and rod length estimation automatically for proposed pedicle screws
d)	Software should be capable of showing different screw visualization options i.e. detailed shapes or standard trajectories screws
e)	Planning Software to automatically labels vertebrae for 2D and 3D datasets (CT, CBCT, MR), and
	alternatively manual labeling and correction of labeling, suggests measurements on 2D images (AP /
	LAT), e.g. kyphosis angle and proposes screws from cervical to sacrum incl. Pedicle and Lateral Mass
	screws on CT, CBCT and MR. Also support of anatomical variations within the Spine e.g., L6, T13.
	Automatic rod visualization and rod length estimation, Different screw visualization options, Automatic
	report for planned screws & measurements
4C	**Software of Segmentation Spine**
a)	Automatic segmentation of anatomical vertebrae, spinal cord and spinal canal on CT data sets
b)	Objects are created for each anatomical structure, which can be visualized in spine planning, navigation and augmented reality applications
c)	Thorough Anatomical Mapping based on Synthetic Tissue Model
d)	Automatic body part detection like :Spinal Canal, Spinal Cord, Vertebra C01, Vertebra C02, Vertebra C03, Vertebra C04, Vertebra C05, Vertebra C06, Vertebra C07, Vertebra L01, Vertebra L02, Vertebra L03, Vertebra L04, Vertebra L05, Vertebra S, Vertebra T01, Vertebra T02, Vertebra T03, Vertebra T04, Vertebra T05, Vertebra T06, Vertebra T07, Vertebra T08, Vertebra T09, Vertebra T10, Vertebra T11, Vertebra T12
e)	Customizable list of objects to be segmented depending on workflow and clinical protocol
f)	Immediate data processing upon patient selection configurable
5	**Instrument for Spine Optical Navigation:**
a)	Basic spine referencing set
b)	Precaliberated awl, pedicle probes -lumber and thoracic.
c)	Accessory Package for Minimal Invasive Spine Surgeries
d)	90 Glions/Marker spheres
6	**Video Documentation Software**
7	**MICROSCOPE INTEGRATION:**
a)	Navigation System should be capable of Integration with Navigation Ready latest Microscope from Leica / Zeiss / Haag Streit. These features should be available with the vendor currently and the vendor should provide an authorization from the manufacturer confirming that these features are of currently released and available, however the department can decide to purchase these features at a later date
b)	The system should have Multicolor HUD which allows to allocate different colors to different organs in contouring.
c)	Microscope integration to provide Compensation for anatomy shift by matching vessels (Maximum Intensity Projection) or planned objects with anatomy seen. This integration should have the capability for the Microscope to Autotrack pointer & autofocus accordingly. These Augmented structures include anatomical objects like vessels, fiber tracts, trajectories and points. Visualization of these augmented planned structures injected as semi-transparent volumes into ocular
d)	Should allow to Tag region of interest with 'Set Pin' / 'Delete Pin' and help Move to stored Pin in six degrees of freedom. It should help to stay on Pin in six degrees of freedom and follow navigated instrument tip. It should also Align with navigated instrument's axis in six degrees of freedom
e)	The Navigation system should have the software that allows microscope Automatic follow and focus to navigated instruments' tip (i.e. tool tracking with smart autofocus)
f)	The Navigation software should have the Augmented Reality feature with Robotic Movement (6DOF) functionality for the Robotic Visualization System with available microscope model at department (ZEISS KINEVO 900)

	OTHER TERMS & CONDITIONS
1	The Original Equipment Manufacturer (OEM) provide an undertaking affirming their responsibility to ensure continuous service delivery throughout the warranty and CAMC periods, even in the event of a change in the authorized distributor /vendor for any season.
2	Accessories & Consumable:
	The price list of all spares parts, accessories, consumable items (required to use on machine) should be quoted separately in the financial bid section (PDF) and the quoted rates will be valid till the warranty & CAMC period (i.e. 10 years) from the date of installation of equipment. If, the price of any spares, consumables/accessories/parts not quoted by the firm in the price bid and will be required in future to run the system, the same has to be supplied by the firm at free of cost without any further term & conditions.
3	3. **Buy-back offer:** The existing S7 Navigation Machine (Sr. No. N01056088) Model- Stealth Station S7, make: Medtronic Trading NL BV, Netherland installed in 2012 is to be sold under buy-back basis. The reserve price of this equipment's isRs.4,25,000/-. The vendors are advised to see this equipment's with prior permission of HOD, Neurosurgery and must quote their buy-back price (must not be less than Reserve price) in the price bid section & BOQ. The buy-back price will be considered (minus) for ranking purpose.
4	a. The product or its earlier model should have been marketed in India during last for at least 2 years.
	b. The parent company should certify that the quoted product is not going to be out of assembly line for at least 10 years from date of quotation.
	c. The parent company should give an undertaking to provide the spares/accessories/consumables, required to run the equipment, during the warranty & CAMC period, as and when required basis.
	d. If the equipment is software based and new software is introduced within five years, all the updates will be provided by the OEM/Supplier at free of cost
5	Compliance Statement: The vendor must provide, in tabular form a comparative chart of the required technical specification and technical specification of the quoted product. The vendor must give the relevant page number and paragraph number, in their literature regarding that technical information in the technical bid. Merely stating "complies" or meets requirement" will lead to assumption that the quoted product does not have the required feature.
6	Important Conditions:
	The bidder must quote rates of equipment with **02 (two) years onsite Comprehensive warranty (Including all spares, all accessories, batteries, all 3rd party items and labor)** from the date of Installation of equipment. Further bidder must quote **rates of Comprehensive Annual Maintenance Contract (CAMC) Including all spares, all accessories, batteries, all 3rd party items and labor, for 3rdto 10th years,** after expiry of two years comprehensive warranty. In case, bidder not quoted rates for CAMC, it will be treated included and must be provide 10 years comprehensive warranty within quoted rates of equipment. No CAMC proposal will be considered later on.
	Note: - **The cost of equipment and Software for the mandatory requirement + Cost of 100 fiducials/glions/markers + 10 biopsy needles + CAMC (NPV) – buyback value (inclusive of GST), will be considered for ranking (L-1) purpose.**
	The L-1 bidder must submit copies of previous supply order placed by AIIMS, New Delhi or any other Govt./reputed Pvt. Hospitals/Organizations within one week of receiving the information for ascertaining the price reasonability of quoted equipment/instruments.
7	The principal firm has to certify that spares, consumables, accessories & support shall be available for next 10 years.
8	It will be responsibility of the vendor to submit proposal of CAMC at least 6 months before expiry of warranty period and previous CAMC.
9	If desired by the TSEC, Demonstration of quoted product would be mandatory at AIIMS, New Delhi premises. Only seven days' period will be given for preparation of
	demo unit and not further extension will be provided. All bidders are advised to keep ready their quoted product for demonstration. None attending demo meeting/non- demonstration of quoted product, the bid will be summarily rejected. Machine must be provided for 15 days or more so that it can be evaluated by all the faculty members, failing which your bid will be disqualify/rejected.
10	Proper training to Technical/related officials for the proper use of the equipment, must be provided by the company/vendor at free of cost
Server-Based Treatment Planning Software for Contouring and Data Enrichment with two Concurrent Session for Gamma Knife and Neurosurgery Planning	
1	**The software should be:-**
	User friendly and intuitive
	Server based planning can be done via any PC/Laptop within the network. A Dedicated Workstation should also be provided to access all the license.
	It should have the facility for remote workstation planning which will allow multiple user accounts and at least 2 concurrent users to work on the data and planning.
	Includes session showing & team planning functionality for simultaneous access to any of the concurrent active treatment plans by 2 different user accounts, supporting, collaborative, remote plan review & team discussion.
	System should be able to display 3-D image of patient anatomy with volumetric information.
1.1	**Advanced 3D Contouring Software (two Concurrent Session)**
	Should be a Quick and easy interactive 3D contouring tool for outlining of pathologies and anatomical structures in medical images



	Software should offer an Instant volume generation by outlining on just two orthogonal slices using multi-modal "Side by Side" or axial, coronal and sagittal view configurations
	It should offer Intelligent contour propagation with ambient edge detection supporting various CT, MR or PET sequence
	Should also have Slice-by-slice contour review using Gallery View layout
	Should have Automatic creation of "Volumetric Report" PDF files per object with representative screenshots and details on geometrical measurements like volume, RECIST and Macdonald criteria
	It should have fast contour adaptation and should have Intuitive user interface with both mouse and touch control compatibility
1.2	**Advanced Image Fusion Software (two Concurrent Session)**
	Software should offer fast and precise fusion based on mutual information algorithm and helps enables to exploit all anatomical & functional data sets simultaneously
	Software should offer fusion of numerous modalities including CT, MRI (T1, T2, FLAIR, MRA), PET, SPECT)
	It should have automatic pair selection with instantaneous pre-alignment and fusion. A possibility of manual fine-adjustments in all dimensions should also be provided
	It should have definition of a "Region of Interest" in all dimensions to exclude areas from fusion
	Software should offer Color overlay in amber-blue and Spyglass functionality for reviews
	It should have ability to fuse a series of image datasets from different modalities and points of time
1.3	**DTI SOFTWARE (two Concurrent Session)**
	DTI software for visualization of all information together with planning procedures
	Software should support multiples views like Brain Projection View, 3D-view, ACS-view, Interactive Tracking, ROI Templates. The Brain projection views should be available while visualization of fiber tracts. Should have both Deterministic DTI- and probabilistic CSD-based tractography.
	Software should have Fiber tracking ROI templates for specific cranial white matter tracts, based on universal atlas. Default templates to be included: Arcuate Fasciculus Left, Arcuate Fasciculus Right, CST Motor Left, CST Motor Right, DRT Crossed Left, DRT Crossed Right, DRT Uncrossed Left, DRT Uncrossed Right, Hand Motor Left, Hand Motor Right, IFOF Left, IFOF Right, ILF Left, ILF Right, Optic Radiation Left, Optic Radiation Right, Tumor-Adjacent Tract. It should also have feature of user defined Fiber templates
	It should have Fully automated DICOM DTI Data Preprocessing including De-noising, Motion- and Eddy Current Correction
	It should have Region-of-interest based tracking of DTI data
	Software should have capability for conversion of results into 3D objects for use and export to Navigation.
	It should have intuitive user interface for manual adjustment of tracking parameters and instant update of fiber tracking results
	It should have Automatic calculation of colored fractional anisotropy (FA) and anisotropic diffusion coefficient (ADC) maps
	It should support of DICOM DTI data from Siemens, Philips, GE and other manufacturers using standard DICOM MR diffusion information (at least 16 and up to 256 directions)
	Software should provide multicolor output to Fiber tracts according to their diffusion direction, i.e. separate fiber color for each tracts from (1) "Left-Right", (2) "Anterior-Posterior", (3) "Head-Foot".
	The software should include a parameters menu that lets you choose between two tracking methods: CSD (Probabilistic) and DTI (Deterministic). If CSD (Probabilistic) is selected, the available parameters will be Minimum Amplitude, Maximum Angulation. If DTI (Deterministic) is chosen, the available parameters will be Minimum FA and Maximum Angulation.
	Software should be provided with live fiber tracking functions for more interactive and real time.
1.4	**Automatic Patient Specific Multi-modal Segmentation of Cranial Objects (two Concurrent Session)**
	Automatic segmentation of patient specific anatomical brain structures on MR data sets
	Thorough Anatomical Mapping based on Synthetic Tissue Model
	Patient specific segmentation of Cranial objects
	Segmentation should be based on multiple types of MRI(T1,T2,FLAIR) images of the same patient
	Teaching tool for visualization and identification of patient's Brain anatomy in diagnostic images
	Customizable list of objects to be segmented depending on workflow and clinical protocol.



	The list of segmented objects should include Amygdala, Brainstem, Capsula Externa, Capsula Interna, Central Sulcus, Caudatus, Cerebellum, Cerebrum, Cochlea, CSF, Chiasm, Corpus Callosum, Geniculate body, Globus Pallidus, Gray Matter, Hippocampus, Hypothalamus, Left Amygdala, Left Capsula Externa, Left Capsula Interna, Left Caudatus, Left Globus Pallidus, Left Hippocampus, Left Lens, Left Optic Nerve, Left Optic Tract, Left Putamen, Left Thalamus, Optic Nerve and tract, Pineal Gland, Pituitary Gland, Putamen, Right Amygdala, Right Capsula Externa, Right Capsula Interna, Right Caudatus, Right Globus Pallidus, Right Hippocampus, Right Lens, Right Optic Nerve and Tract, Right Putamen, Right Thalamus, Temporal lobe, Thalamus, Ventricles, Vessel, White Matter, whole Brain, Facial Nerve, Precentral Gyrus, Postcentral Gyrus, Skin, Trigeminal Nerve, Vestibucochlear Nerve, Eyes
	It should offer Immediate data processing upon patient selection
1.5	**Software for Distortion Correction in Cranial (two Concurrent Session)**
	Software should offer Image Fusion with distortion correction possibilities for cranial MR data sets
	Should offer anatomical co-registrations through local deformations based on multi-ROI rigid fusions
	Should have Adaptation of distorted MR against reference MR (e.g. DTI to T1) as well as MR to CT
	Should support Generation of an adapted, artificial DICOM data set co-registered to the reference data set
	It should have Automatic content update like objects and landmarks according to the new registration field
	Should Supports automatic and interactive segmentation on new data sets
	It should have Direct comparison of distortion corrected with conventional results through toggling
	It should have Colored deformation grid highlights local deformations for detailed inspection
	Software should have Amber-blue color overlay and spyglass functionality complement the verification tools
1.6	**Software for Contour Export (two Concurrent Session)**
	Enables the Export of 3D objects
1.7	**Vessel segment based unlocalized 2D DSA Angio contouring (two Concurrent Session)**
	Software should be capable of fast and comprehensive intracranial nidus definition exploiting a fusion between a 3D data set and an unlocalized 2D dynamic angiography
	Should enable automatic vessel segmentation in contrast-enhanced volumetric data sets
	Should enable vascular co-registration of volumetric images to an unlocalized 2D dynamic angiographic image sequence
	Should enable Color-coded blood flow in angiography providing temporal flow information to differentiate effluent and affluent vessels from nidus
	Should enable automatic segmentation of a volumetric nidus object within a region-of-interest that has been defined on the angiography
	Should enable seamless nidus object refinement on co-registered planar and volumetric data sets with a smart contouring tool
	Should enable the possibility to register and exploit unlocalized diagnostic 2D dynamic angiographies
	Should enable optimized views bring time and spatial information from angiographic and volumetric data set into relation
	Should enable Intuitive user interface with both mouse and touch control compatibility
	Should enable CTA, MRA or 3D rotational angiography as volumetric data set
	Software should enable 2D antero-posterior and lateral projections as dynamic angiographic image sequence
1.8	**3D Viewer software should have below features (two Concurrent Session)**
	Intuitive image viewing, manipulation and data enrichment software for high-quality 3D visualization
	3D volume rendering of CT, MR, PET, SPECT datasets, with presets for visualization of skin, bone, vessel, DRR and MIP
	Manual or automatical alignment of ACS and 3D views along the Frankfurter horizontal plane
	3D multi-planar reconstructions in multiple planes (axial, coronal, sagittal, oblique)
	Concurrent display of multiple medical image series with flexible hanging protocols
	Image annotations and measurement functions for distance, angles and circles
	Selection of region of interest to cut and zoom onto the relevant anatomical volume
	Crop functionality to cut viewing plane into 3D visualization along any freely definable direction

1.9	Software for Retreatment review (two Concurrent Session)
	Software to give overview of all treatments as well as the current patient status. This software to support the follow-up and decision-making process for multiple brain metastases patients and easily facilitate retreatment planning
	It should have easy import of treatment plans from various third party treatment planning stations
	It should have automatic workflow from import via image fusion to retreatment review
	It should have special views with color coded display of treated and new lesions according to the treatment they belong to
	It should have automatic selection of the latest organ at risk available to prevent overcrowded views
	It should have Dose summation including weighting option for all imported treatment plans
	It should have Automatic calculation of max dose to OARs including weighting factor
	It should have DVH display of summed doses taking the weighting into account
	It should have Automatic conversion of previous treated PTVs in avoidance structures for new treatment plan

1.10	Software for Tumor segmentation (two Concurrent Session)
	Semi-automatic segmentation of diagnosed cranial tumors (metastases, meningiomas, cranial and paraspinal nerve tumors, gliomas, glioneuronal and neuronal tumors) on 3D Contrast Enhanced T1-weighted MR images
	It should support whole brain 3D contrast enhanced T1 weighted MRI with one or multiple contrast enhanced primary brain tumors
	It sould have quantitative analysis of segmented tumors, including volume, shape, and growth rate metrics provided by 3D contouring tool

1.11	Software for Contrast clearance analysis for separating regions of contrast clearance from contrast accumulation over time (two Concurrent Session)
	It should have High resolution, volumetric maps separating regions of contrast clearance from contrast accumulation
	It should supports assessment and clinical decision making before, during and after Cranial treatments
	It should have Color-coded visualization of accumulation and clearance regions without overlap
	It should be Calculated from delayed contrast MRIs which are acquired with a delay of more than one hour
	It should have cranial, delayed contrast MRIs

1.12	Software for Trajectory Planning (two Concurrent Session)
	It should provide planning of multiple trajectories for neurosurgical approaches
	It should have Flexible 3D shapes for case-specific trajectory visualization
	It should apply safety margin around trajectories
	It should have verification of trajectories in Axial, Coronal, Sagittal, Probe's Eye and Inline reconstructions
	It should have precise multiline, point, and angle measurement tools
	It should have multiple view layouts for optimal interactive target, entry and trajectory planning

1.13	Automatic Patient Specific Multi-modal Segmentation of Basal Ganglia Objects (two Concurrent Session)
	It should have automatic MR-based segmentation of structures in the basal ganglia region
	It should have anatomical Mapping based on Synthetic Tissue Model
	It should have automatic body part detection
	It should have customizable list of objects to be segmented depending on workflow and clinical protocol
	The list of segmented objects should include Amygdala, Capsula Externa, Capsula Interna, Caudatus, Cerebellum, Dentate Nucleus, Fornix, Globus Pallidus, Hypothalamus, Lateral Habenula, Nucleus Accumbens, Nucleus Basalis Of Meynert, Nucleus Ruber, Optic Nerve, Pedunculopontine Nucleus, Periaqueductal Gray, Periventricular Gray, Putamen, Substantia Nigra, Substantia Nigra Compacta, Substantia Nigra Reticulata, Subthalamic Nucleus, Thalamic Anterior Nucleus, Thalamic Reticular Nucleus, Thalamus, Ventral Intermediate Nucleus, Ventral Posterior Lateral Nucleus, Ventral Posterior Medial Nucleus, Ventral Tegmental Area, Ventricles, Zona Incerta

2.1	Basic Dicom functionality
	Software should have full control with support of touch gesture interaction, as well as mouse and keyboard support
	Should have advanced data import & export features (PACS, USB, CD/DVD, Quentry and network folder)
	Support of various modalities including CT, MR, PET/SPECT, X-ray
	PACS access via DICOM "Query/Retrieve" and "Push" (compatible to all standard conform PACS systems)
	Software should have receipt of data via DICOM "Push" and support of DICOM worklists
	Should have automatic content configuration of OR displays based on user pre-defined setups
	Optional HIS integration via HL7 interface (message types: SIU, ADT, ORM - requires Origin Integration of HIS)
	Should have intelligent export of screenshots (.png or DICOM) and video recordings (.mp4 or DICOM) via DICOM "C-Store"
	Should have advanced patient data management tools including new patient creation, merging and editing
	Should have HIPAA-compliant feature set including authentication, accountability log and automatic log-off

2.2	Planning software for Motion disorders: (two Concurrent Session)
	The system should enable precise localization of MR/CT images and provide intuitive tools for the definition of anatomical landmarks such as the anterior commissure (AC), posterior commissure (PC), and the mid-sagittal plane, to support advanced neurosurgical planning
	It should support Definition of the trajectory (Target and Entry) in AC/PC relative Coordinates (Distances and Angles)
	Target and Entry should be displayed in AC/PC and DICOM image coordinates
	Should have Automatic localization of the 3D object/shape of the implanted lead from the post-operative CT dataset
	It should allow automatic localization of the 3D object/shape of the implanted lead from the post-operative CT dataset. This localized lead can be linked to the 3D Basal Ganglia segmentation in the planning for visualization of the contact point by the user so that further neurological programming can be performed
	It should have Automatic Patient specific Multimodal 3D segmentation of Basal Ganglia and integration of the same with advanced Neurosurgical planning is a must.
	The system should support multimodal image-based trajectory planning on non-localized images prior to surgery, facilitating advanced applications such as Frame based procedure
	Should have Automatic calculation & PDF print out of specific arc settings
	It should have Flexible 3D shapes for case-specific trajectory visualization (e.g. Implantable Stimulation Electrodes, Depth Electrodes, shunts.)
	Should overlay a model of microelectrodes and implanted leads onto surgical plans providing visualization of lead and contacts relative to the target and surgical plans
	Should have Manual editing of detected lead position
	Planning software should be fully integrated with MR Cranial Distortion Correction software
	Advanced planning software should have Combined visualization of supplemental information such as Fibertracks, Nuclei and Leads
	All Planning Software for motion disorders, tremors etc. should be from the same brand which supplies the navigation system
	It should Support the below mentioned stereotactic frames, localizers, and ring and arc configurations to meet specific procedure needs (any 1 set compatibility should be provided at the time of order):
	Integra® CRW® - CT and Luminant localizers
	Elekta™ Leksell®- CT and MR localizers (G frame and Vantage)
	Inomed® ZD - Rev R, and Rev U localizers
	Should Support various mounting orientations for supported frames (e.g. lateral-left, lateral-right, sagittal-anterior, sagittal-posterior)
	Should have adjustment of planned trajectory entry point in 3D skin reconstruction view of volumetric data
	It should have different viewing layouts to plan, verify the trajectories and then compare the preoperative and intraoperative imaging data (bimodal view)
	Should have software generated pre-defined margin for safe planning of trajectories

2.3	Server Premium Configuration for server-based treatment planning for 2 Concurrent license
	ProLiant DL360 Gen11 server hardware (HPE – Hewlett Packard Enterprise) or any other with all the below mentioned capabilities
	Intel® Xeon® Gold 6448H, 32 cores (up to 4.1 GHz)

	Nvidia RTX 4000 Ada Generation Graphics Card
	256 GB RAM
	1.92 TB NVMe SSD, RAID 1: 2x 1.92 TB
	Network Interface Card: 2x 10Gbit/s copper SFP module - build in by default
	Optional, on demand: 2x 1Gbit/s copper SFP module
	Optional, on demand: 2x 10Gbit/s fiber SFP module
	Inclusive Licenses:
	Microsoft Windows Server 2022 Standard LTSC - English-US OS language (license pre-activated)
	5x CAL & 5x per User RDS CAL license on paper
	1x iLO Advanced License license on paper
	19" Rack mount kit with telescopic rails and cable management arm (rack is not included)

OTHER TERMS & CONDITIONS

1. The cost of all Consumables/Accessories/spares/parts should be quoted upfront and should be valid for 10 years. Cost of any Consumables/Accessories/spares parts not quoted will be considered **FREE OF COST**.
2. Warranty: **02 years onsite comprehensive** (including labour/accessories/spares parts) **+ 08 years CMC** (including labour/accessories/spare parts).
3. In no case the instrument should remain in non-working condition for more than 7 days, beyond which a penalty as the per the rules of the institute will be levied.
4. The vendor should have a good service and application back up along with instruments to provide an effective trouble shooting and support. (response time < 24 hours).
5. All technical bids comparative statement to the tender specifications must be enclosed along with reference no., paragraph no. from original catalogue of the equipment.
6. Original Manufacturer or their subsidiary or authorized dealer who is quoting should be present in India having selling experience of more than 5 years with at least 5 installations in government institutes/hospitals.
7. **Demonstration is Mandatory, failing which your bid will be disqualify/rejected.**
8. There are no consumables required for this equipment.

1.	**Prof. Sachin Borkar, Professor, Neurosurgery, AIIMS, Delhi**	**Chairman**	
2.	Dr. Satyashiva Munjal, Professor, Neurosurgery, RML Hospital, Delhi	**External Expert**	Consent given by email.
3.	Dr. Pragyan Sarma, Professor, Neurosurgery, VMMC & Safdarjung Hospital, Delhi	**External Expert**	Consent given on email
4.	Dr. Sujata Chaudhary, Additional DGHS, Dte.GHS	**DGHS Nominee**	Consent given on email
5.	**Prof. Shashwat Mishra, Officer in-charge, Neurosurgery Store, AIIMS, Delhi**	**Member Secretary**	

BRAINLAB

Brainlab SE
Olof-Palme-Straße 9
81829 Munich · Germany
phone: +49 89 99 15 68 0
fax: +49 89 99 15 68 5033

To Whom so ever it may concern

Munich, 18 December, 2025
Subject : Proprietary Certificate

We, Brainlab SE, Olof-Palme-Strasse 9, 81829, Munich Germany hereby certify that below mentioned features for Advanced Image Guided Navigation System for Cranial Application is proprietary to Brainlab SE, Germany.

1. **Advanced Cranial Navigation System:**

a) Curve Navigation system has large 32" capacitive touch display with 4K resolution (3840 x 2160 pixels) for brilliant visualization of clinical data. Curve has motorized joints for remote-controlled camera alignment.

b) High-performance computer with Intel® Core™ i9-10900X, 32 GB RAM memory and 960 GB SSD.

c) Navigation System has a smart home button to ensure interchangeability between multiple windows at any given point of time as per surgeon discretion. Any changes made on attached window gets automatically updated into navigation window.

2. **Advanced and Unique Patient Registration for Cranial :**

- Soft Touch Pointer & Surface Matching – Provides skin sensitive registration technique which allows patient registration in both supine & prone positions. Selective acquisition of registration points by touching the patients' skin with the Softouch registration pointer. Unique skin sensing tool tip works through the hairline and even for dry skin conditions. Surface point collection without skin shift and in areas not visible to navigation camera.

- Z touch Laser Pointer - Battery powered wireless laser pointer for quick and accurate patient registration without fiducials. Cost-efficient registration using existing diagnostic CT or MR data sets without the need for delicate disposables and extra scans. Touch-free surface point collection causing no skin shift distortions. Pilot laser beam with control LED for selective acquisition of optimal anatomical features at the patient's surface. Only system to acquire projected 3D laser points directly in the patient coordinate system, maximizing accuracy.

3. **Advanced Navigation Applications:**

- **Elements Viewer :**
Elements Viewer is an intuitive image review and data visualization application that enables clinicians to interactively explore and analyze medical imaging data. The software offers instant, high-quality 3D volume rendering with pre-configured visualization presets tailored to clinical needs, facilitating efficient interpretation and case review. It supports multi-modal image navigation, manipulation, and enrichment, and seamlessly integrates with other Brainlab Elements applications for treatment planning, segmentation, and documentation.
Validation studies have demonstrated the Viewer's effectiveness in improving visual clarity of anatomical structures and enhancing interdisciplinary communication during preoperative planning.

- **Elements Segmentation Cranial :**
Brainlab's automatic image segmentation applications are designed to accurately identify anatomical and pathological structures within medical imaging datasets. Unlike traditional atlas-based approaches that use

BRAINLAB

a fixed anatomical model elastically registered to a patient scan—which often fail to fully capture individual anatomical variations or image contrasts—Brainlab Elements Segmentation leverages a Synthetic Tissue Model to simulate patient-specific anatomy. All anatomical objects such as Amygdala, Brainstem, Capsula Externa, Capsula Interna, Central Sulcus, Caudatus, Cerebellum, Cerebrum, Cochlea, CSF, Chiasm, Corpus Callosum, Geniculate body, Globus Pallidus ,Gray Matter, Hippocampus, Hypothalamus, Left Amygdala, Left Capsula Externa, Left Capsula Interna, Left Caudates, Left Globus Pallidus, Left Hippocampus, Left Lens, Left Optic Nerve, Left Optic Tract, Left Putamen, Left Thalamus, Optic Nerve and tract, Pineal Gland, Pituitary Gland, Putamen, Right Amygdala, Right Capsula Externa, Right Capsula Interna, Right Caudatus, Right Globus Pallidus, Right Hippocampus, Right Lens, Right Optic Nerve and Tract, Right Putamen, Right Thalamus, Temporal lobe, Thalamus, Ventricles, Vessel, White Matter, whole Brain, Facial Nerve, Precentral Gyrus, Postcentral Gyrus, Skin, Trigeminal Nerve, Vestibulocochlear Nerve and Eyes are automatically contoured by the software. Teaching tool for visualization and identification of patient anatomy in diagnostic images.

- **Elements Object Management :**
  Elements Object Management is an integrated application within Brainlab Elements that enables the triggering, review, and management of segmented anatomical structures across multiple clinical workflows. It supports the contouring of organs-at-risk (OARs) for radiotherapy and radiosurgery planning, as well as structure definition for image-guided and frame-based neurosurgical procedures. The application ensures consistent object handling and facilitates efficient, standardized treatment planning.

- **Elements Distortion Correction :**
  Brainlab's Elements Distortion Correction is designed to correct patient-specific geometric distortions in cranial MRI datasets by applying a deformable registration that aligns images while preserving anatomical accuracy. The algorithm selectively corrects distortions within brain tissue, ensuring alignment with the true anatomical structures—without compromising the anatomical ground truth. This enhances the precision of downstream tasks such as contouring, image fusion, and navigation, particularly in stereotactic procedures where sub millimetric accuracy is critical.

- **Elements Fibertracking**
  Elements Fibertracking empowers clinicians with advanced visualization and analysis of patient-specific white matter pathways using both deterministic diffusion tensor imaging (DTI) and probabilistic Constrained Spherical Deconvolution (CSD)-based tractography. This dual approach allows for improved accuracy in identifying critical fiber structures—especially in regions of complex fiber crossing or deformation—where traditional methods may fall short.

  The incorporation of CSD-based tractography offers enhanced resolution and anatomical fidelity, enabling more precise planning for neurosurgical procedures such as tumor resections, epilepsy surgery, or functional interventions. It helps define safe surgical corridors and supports decision-making aimed at preserving essential motor, sensory, and cognitive functions.

- **Elements BOLD MRI Mapping:**
  The Elements BOLD (Blood Oxygen Level Dependent) MRI Mapping planning software enhances anatomical images for visualizing eloquent areas within cortical brain structures. This application offers two distinct analysis types: Resting state (Correlation Map) and Task-based (Activation Map) analyses. Utilizing these maps, the software facilitates the creation of objects for further treatment planning. Detecting BOLD responses stemming from patient tasks during MRI scanning or stimuli, and generating correlation maps to identify functionally connected brain areas, assists surgeons in determining the shortest and safest path to the pathology of interest. The combination of BOLD analysis and Fiber Tractography holds the potential for more precise functional pre-planning.

4. **VarioGuide® Alignment System** is a Frameless Biopsy System and universal instrument holder that bridges the gap between head frame and free hand procedures to systematically align tools to pre-planned trajectories. Clinical use cases includes biopsies, intracranial endoscopy and catheter placement. VarioGuide supports frameless stereotactic navigation procedures which reduce patient discomfort

BRAINLAB

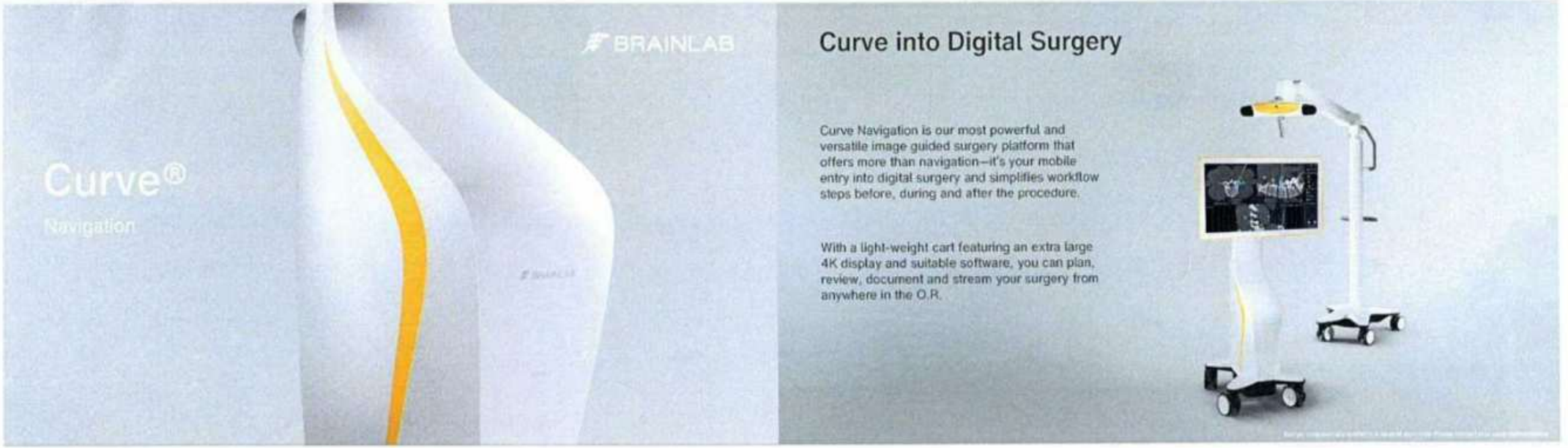
compared to frame-based surgical approaches. It eliminates the need for patients to undergo the unpleasant procedure of frame attachment and additional imaging, both while awake. VarioGuide supports instruments from Ø1.8–8mm and enables surgeons to take biopsies, place shunts or guide an endoscope.

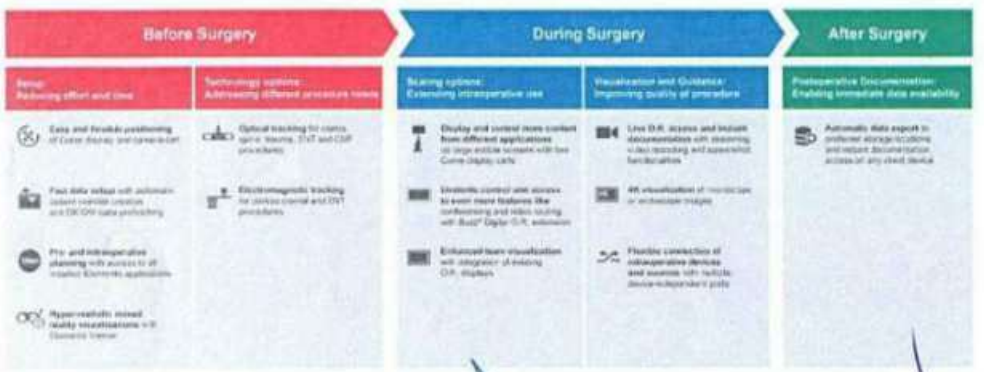
5. **Live 3D Ultrasound Integration with SNAP to MRI :** Navigation software has a facility to upgrade it to integrate 3D Ultrasound Integration. Acquisition of a series of 2D ultrasound images to assemble a new volumetric data set as 3D reconstruction data for navigation. It helps in visualization of the target region in all three planes of axial, coronal & sagittal compared to oblique ultrasound planes. This improves the ability to orient and interpret the ultrasound data, further enhanced by overlay to MR or CT data of the patient. Digital integration to ultrasound systems like the BK5000 further increases the ease of use and automation of using ultrasound in neurosurgery. With ULTRASOUND SNAP TO MRI (Image Fusion Ultrasound) we're enabling automated rigid fusion between the preop MRI image and the intraoperative 3D ultrasound image, allowing to update the registration and navigate on the most up-to-date patient anatomy.

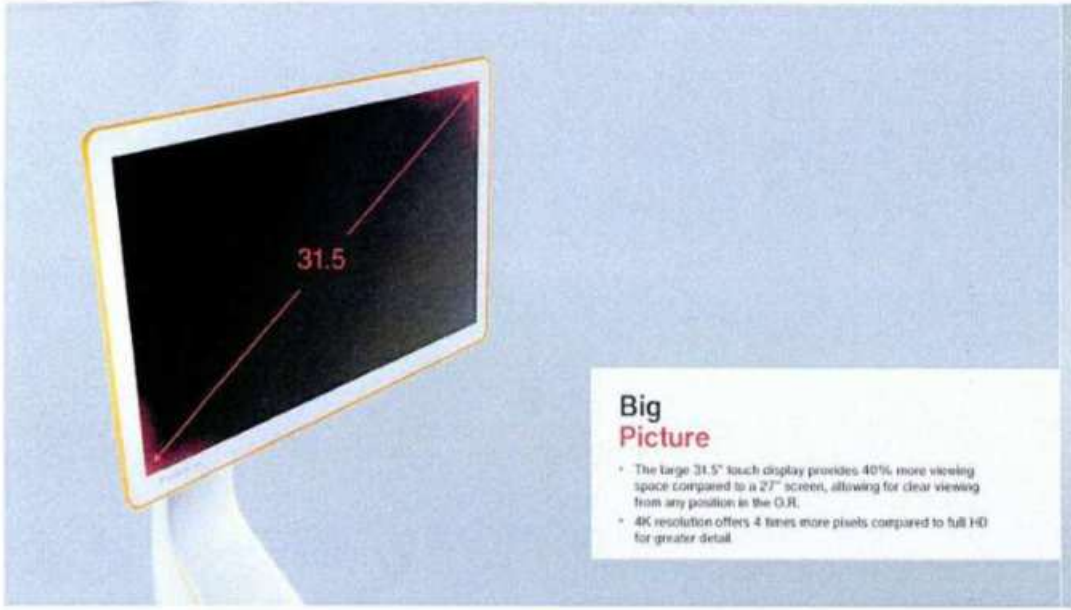
All the above mentioned platform and applications are proprietary technology of Brainlab SE. Although some applications on the list might be available by other systems, the overall solution and described combination of the product with software is unique and cannot be offered by any company worldwide. All information above is written to the best of my knowledge.

Thanking You
For Brainlab SE

Authorized Signatory
Florian Hoffmann
COO

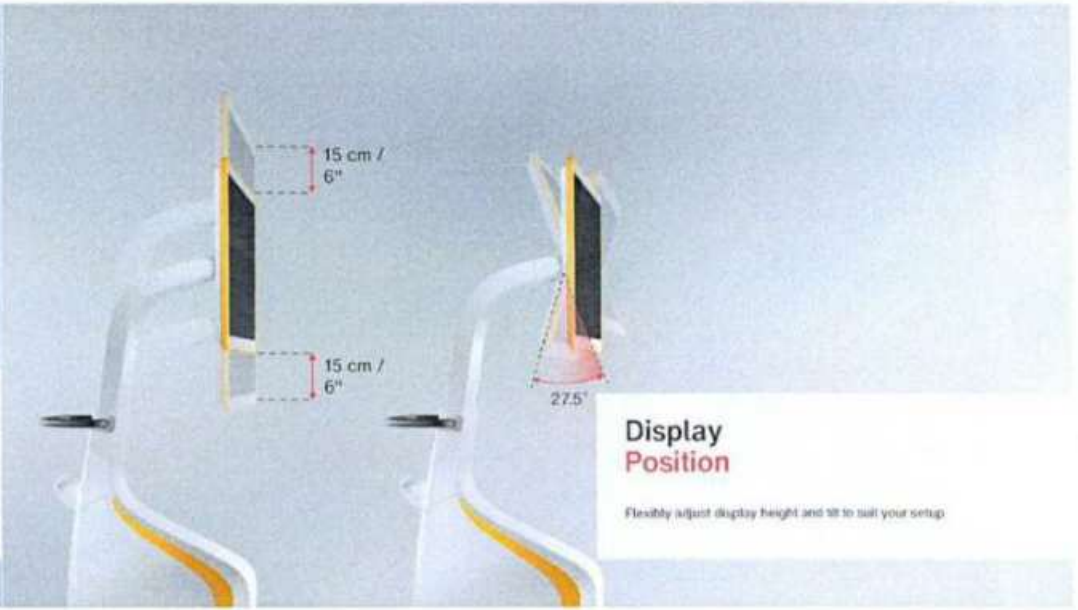






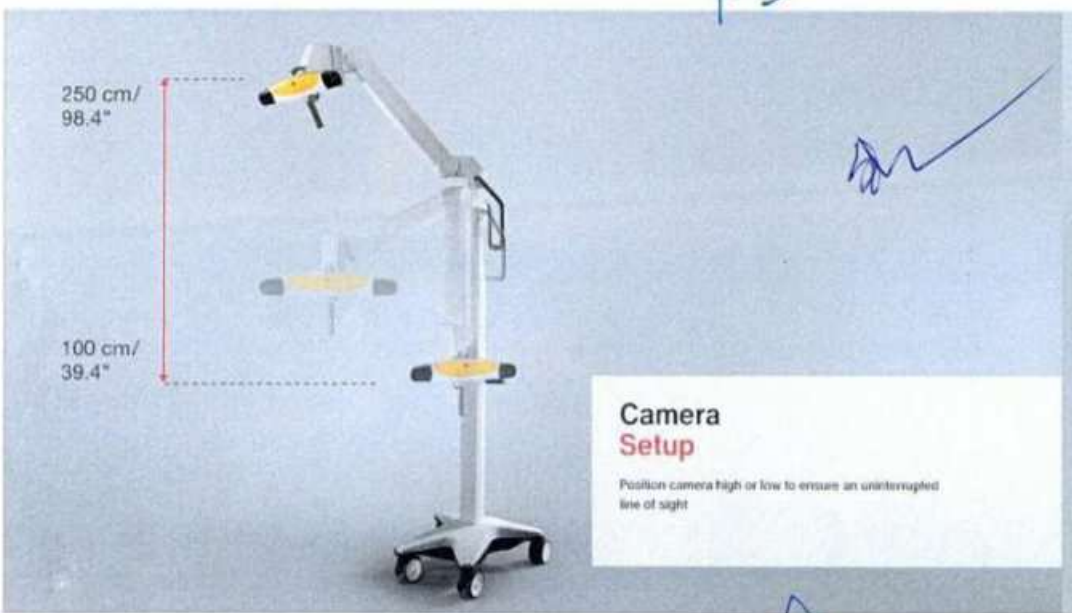
Big Picture

- The large 31.5" touch display provides 40% more viewing space compared to a 27" screen, allowing for clear viewing from any position in the O.R.
- 4K resolution offers 4 times more pixels compared to full HD for greater detail



Display Position

Flexibly adjust display height and tilt to suit your setup



Camera Setup

Position camera high or low to ensure an uninterrupted line of sight

Camera Alignment

- Remotely align the motorized tracking unit via touch display
- The built-in HD video camera provides a large field of view for fast and easy fine adjustment

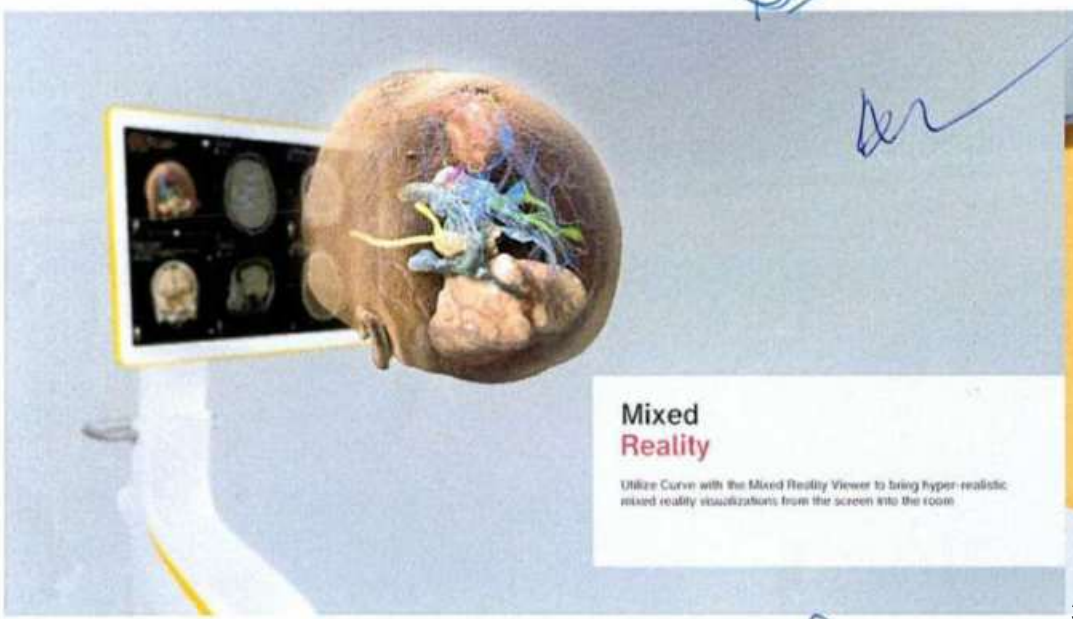
Data Pre-Loading

Automatic patient worklist creation and DICOM data-prefetching reduce wait times before surgery*

*Requires Origin Server Software

On-the-fly Planning

- Create and optimize plans right before or even during the procedure with O.R. access to any installed Brainlab Elements software
- Continue planning exactly where you left off using sleep mode, e.g. for system transport

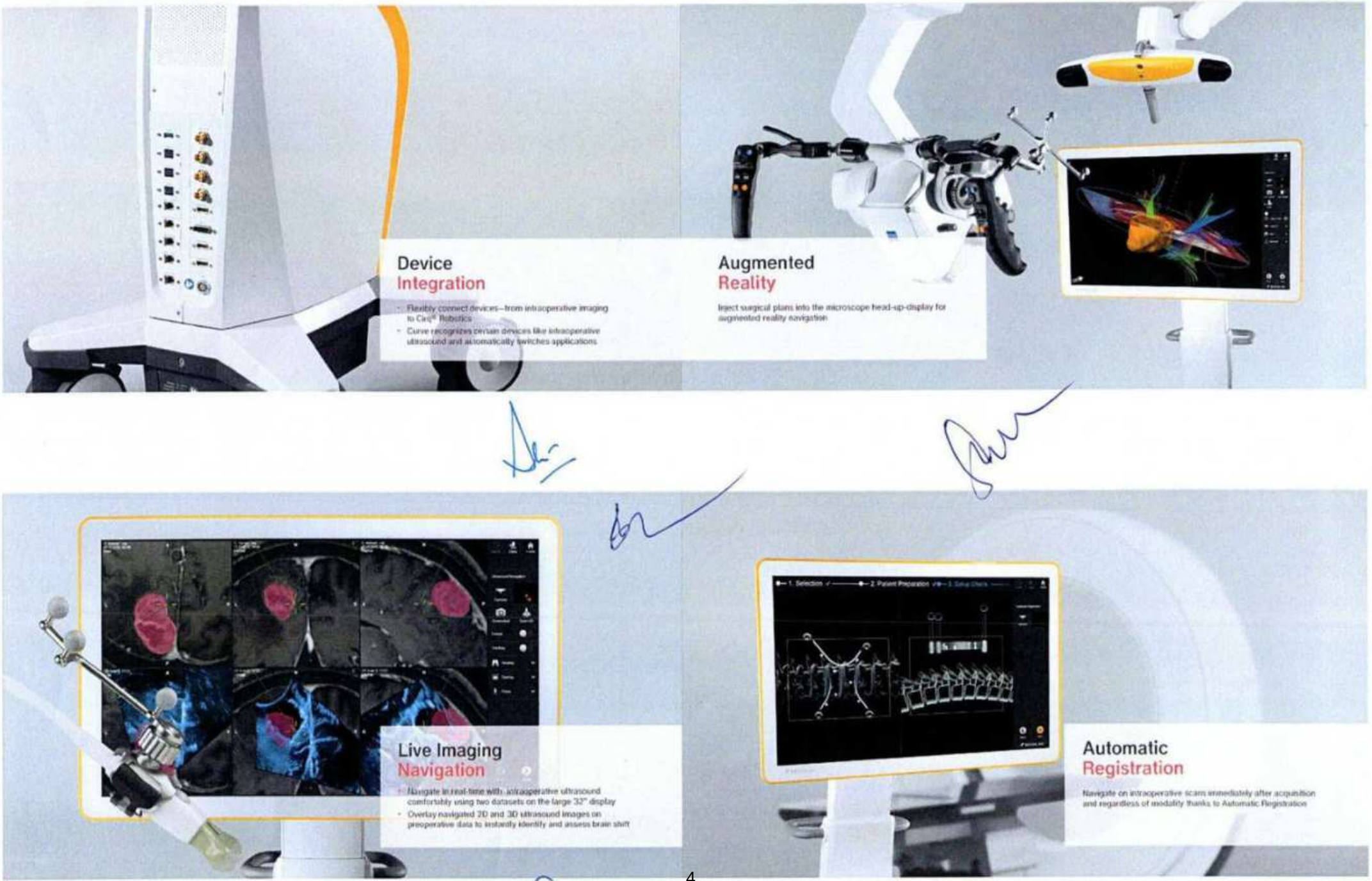


Mixed Reality

Utilize Curve with the Mixed Reality Viewer to bring hyper-realistic mixed reality visualizations from the screen into the room

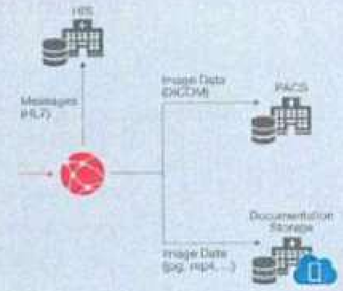
Live Streaming

Capture the surgical scene from high above and stream to colleagues or students outside the O.R.


Device
Integration
- Flexibly connect devices—from intraoperative imaging to Cirq® Robotics
- Curve recognizes certain devices like intraoperative ultrasound and automatically switches applications
Augmented
Reality
Inject surgical plans into the microscope head-up-display for augmented reality navigation
Live Imaging
Navigation
- Navigate in real-time with intraoperative ultrasound comfortably using two datasets on the large 32" display
- Overlay navigated 2D and 3D ultrasound images on preoperative data to instantly identify and assess brain shift
Automatic
Registration
Navigate on intraoperative scans immediately after acquisition and regardless of modality thanks to Automatic Registration

Mobile Robotic Imaging

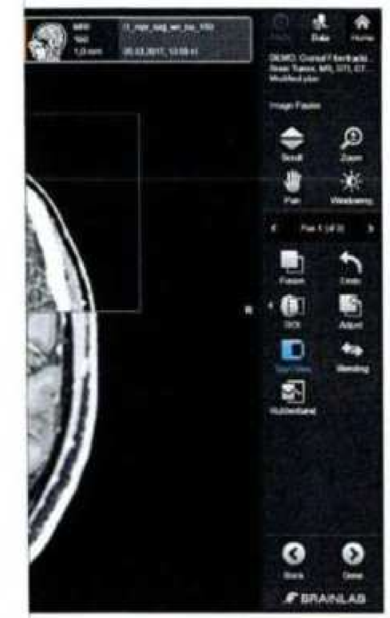
- Bring automation into system positioning, imaging and verification with Loop-X Mobile Imaging Robot
- Enhance spinal surgery workflows with extra-large, high quality intraoperative 2D and 3D scans



Postoperative Documentation

- Archive all data manually or automatically*
- Immediately access exported files on any client device for review or patient consultation

*Requires Origin Server Software



brainlab.com

PLF PP EN Cranial Navigation Nov25 Rev1

BRAINLAB

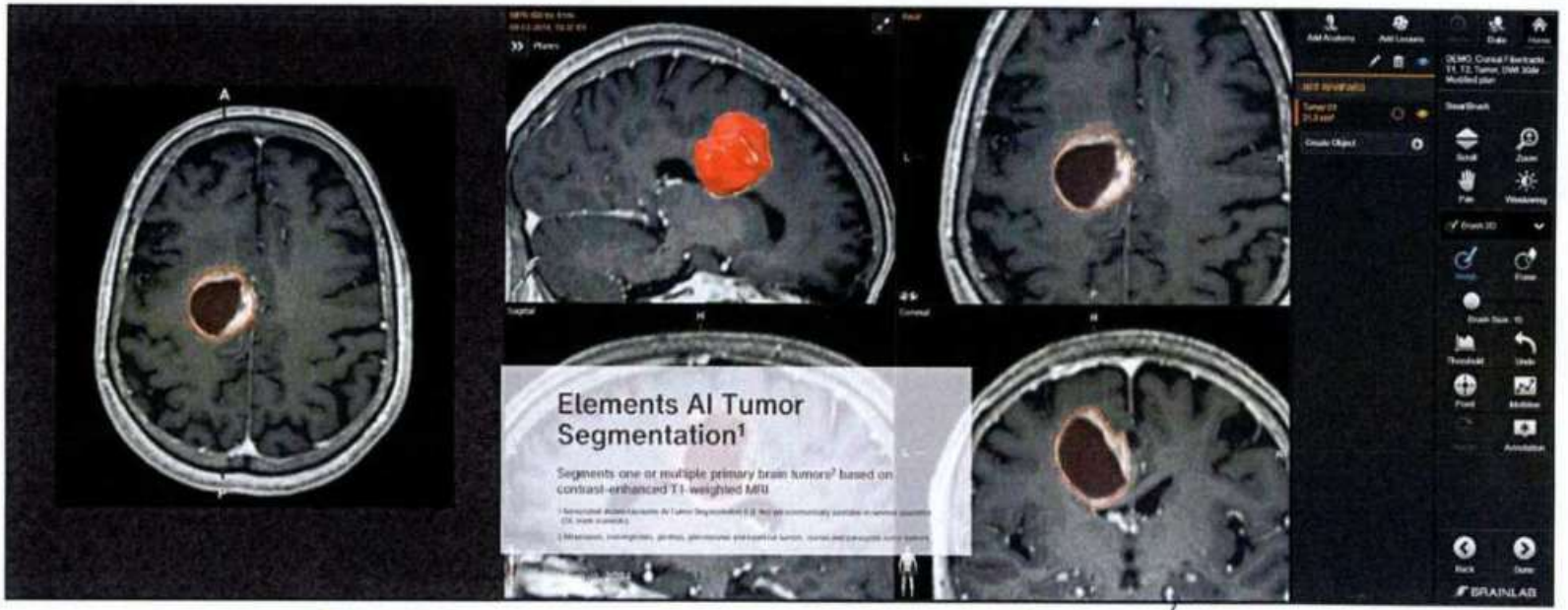
Elements

Cranial Planning

Semi-automatic tumor outlining

Elements AI Tumor Segmentation*

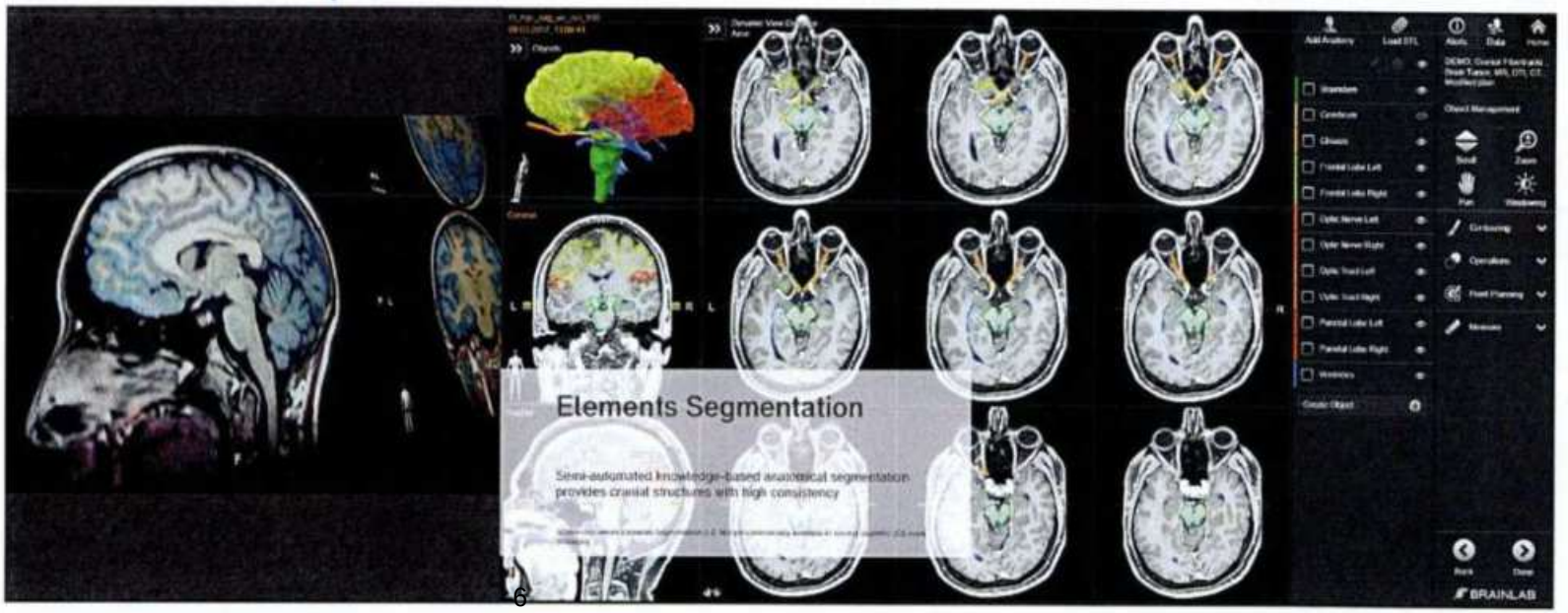
- Semi-automatic segmentation proposal of diagnosed cranial tumors: metastases, meningiomas, gliomas, glioneuronal and neuronal tumors, cranial and paraspinal nerve tumors
- Segmentation on contrast-enhanced T1-weighted MR images powered by the Anatomical Patient Model
- Artificial intelligence-based state-of-the-art U-net architecture software
- Registry-based annotated datasets used for training
- Detailed quantitative analysis of segmented tumors, including volume, shape, and growth rate metrics, provided by Elements SmartBrush

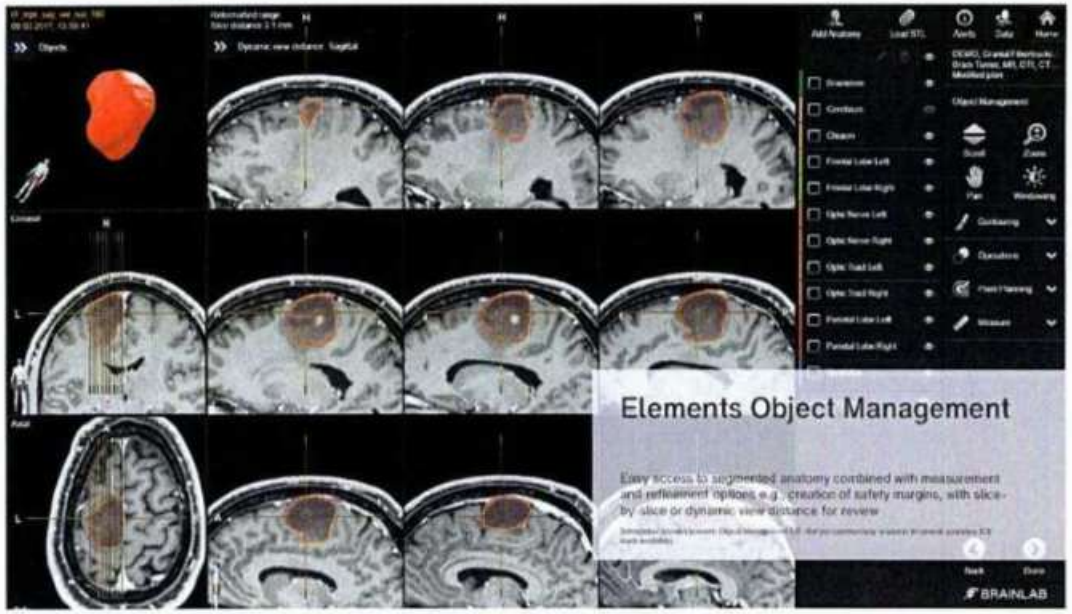


Anatomical Mapping

Elements Segmentation Cranial

- Semi-automatic MR- and CT-based segmentation of cranial structures
- Based on continuously refined patented Synthetic Tissue Model
- Synthetic Tissue Model flexibly adopts to patient anatomies and image modalities to provide structures with high consistency
- Efficient automation of time-consuming contouring process
- Intuitive, easy-to-use review and editing tools

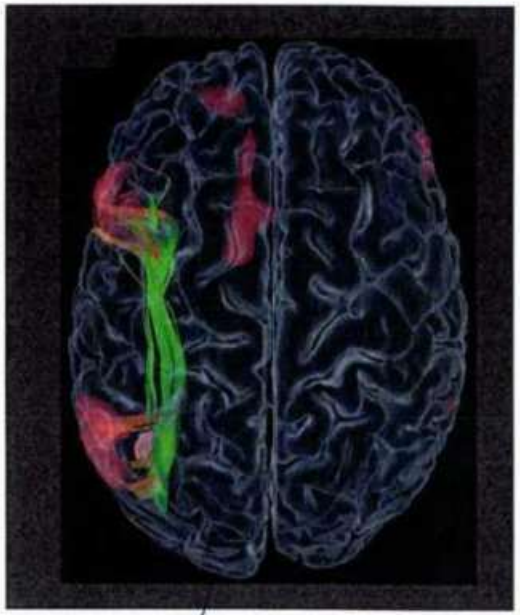


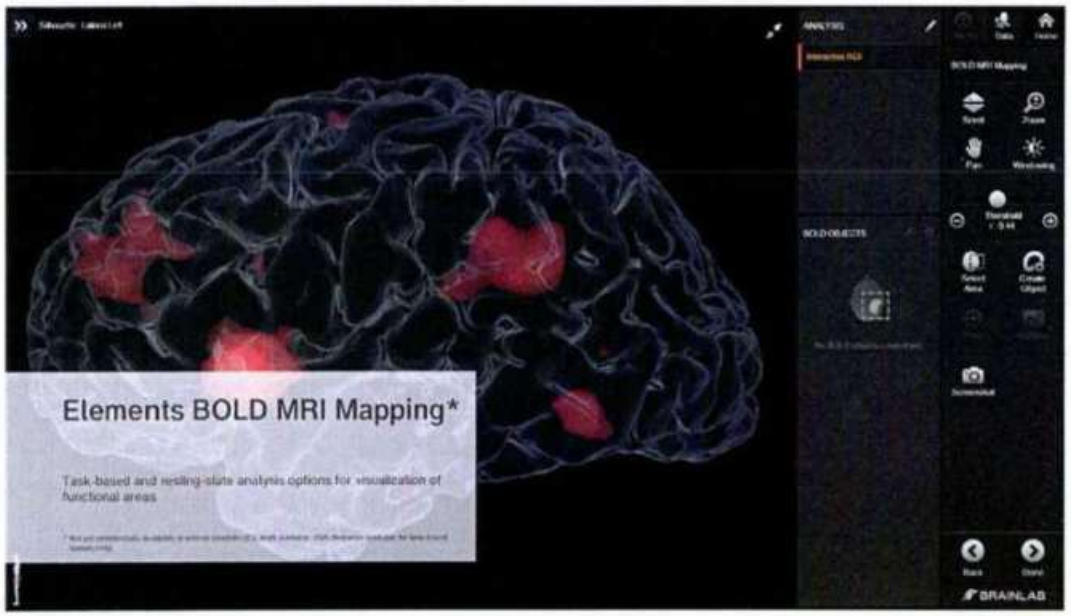


Refined functional planning

Elements BOLD MRI Mapping*

- Supports the localization of eloquent areas in cortical structures in the brain
- Resting-state (correlation map) and task-based (activation map) analysis options*
- May help identify a shorter and safer path to the pathology of interest
- Detection of BOLD responses from activity due to tasks performed by the patient during MR scanning or stimuli
- Creation of correlation maps to identify which plausible brain areas might be functionally connected to the seed region of interest (ROI)*
- Combination of BOLD analysis and fiber tractography creates potential for more precision in functional pre-planning

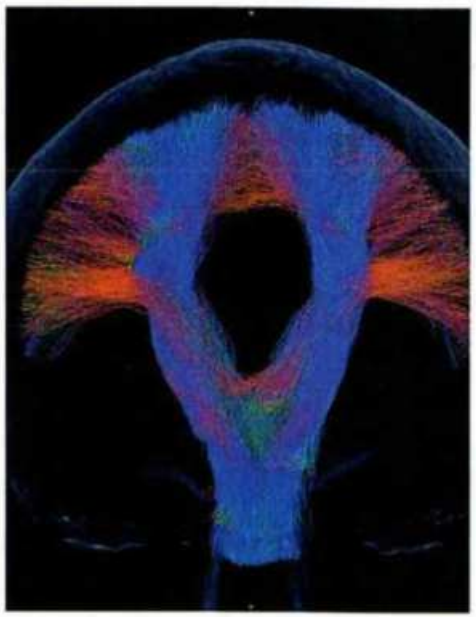




Advanced tractography

Elements Fibertracking

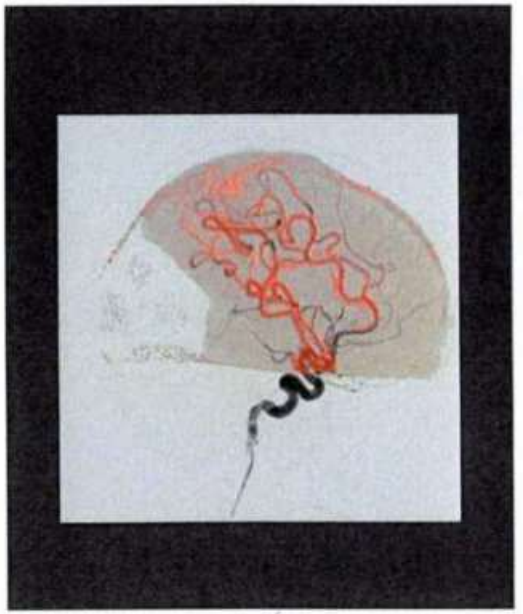
- Localization of eloquent areas by visualization of major white matter structures of the brain
- Deterministic DTI- and probabilistic CSD[2,3]-based tractography depending on specific use case
- Default templates (e.g., AF, CST, IFOF[3], ILF[3]) provide individual and reproducible fiber bundles
- Unique parameter combinations for each template
- Combination of region of interest-based and dynamic live tracking to refine results
- Brain projection view for direct review and planning on cortex
- Blending mode to overlay colored FA to structural images[1]
- Usage of BOLD MRI Mapping activations as ROIs
- Seamless data transfer to Cranial Navigation or other planning applications

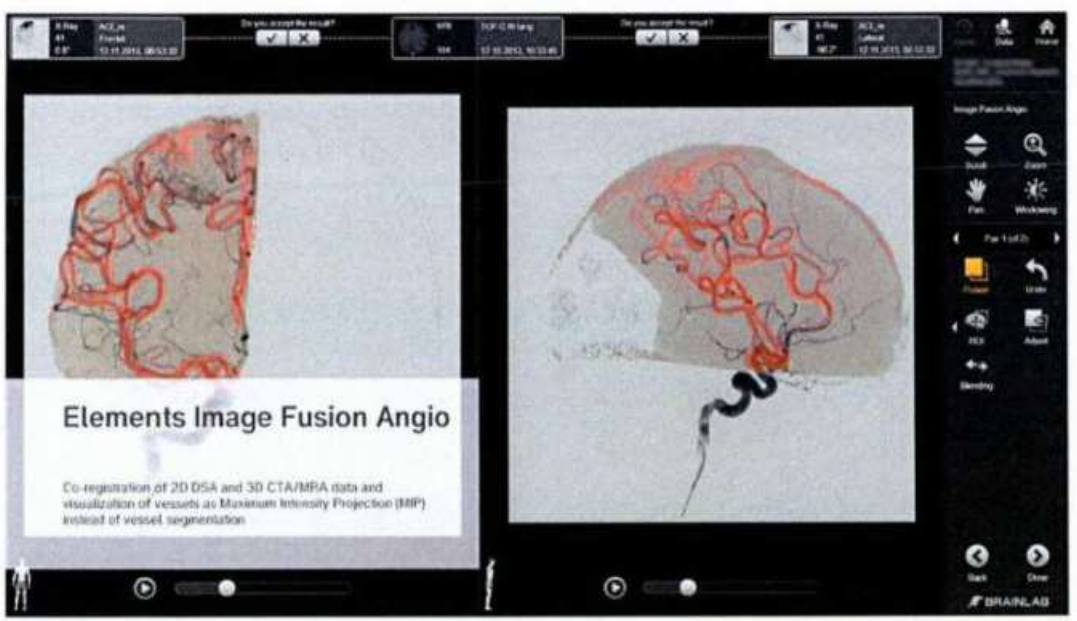


Neurovascular fusion

Elements Image Fusion Angio

- Co-registers 2D DSA and 3D CTA/MRA data with no need for a frame
- Use of diagnostic images saves extra scan with localizer frame, reducing radiation exposure and complexity
- Supports frontal, lateral and oblique 2D DSA data
- Supports 3D CT-Angio and 3D MR-Angio (with contrast or TOF) data
- Direct visualization of vessels as Maximum Intensity Projection (MIP) instead of vessel segmentation
- Colored visualization of blood flow for clear recognition of early and late contrast phases
- User-defined best DSA frame and region of interest contribute to robust fusion results

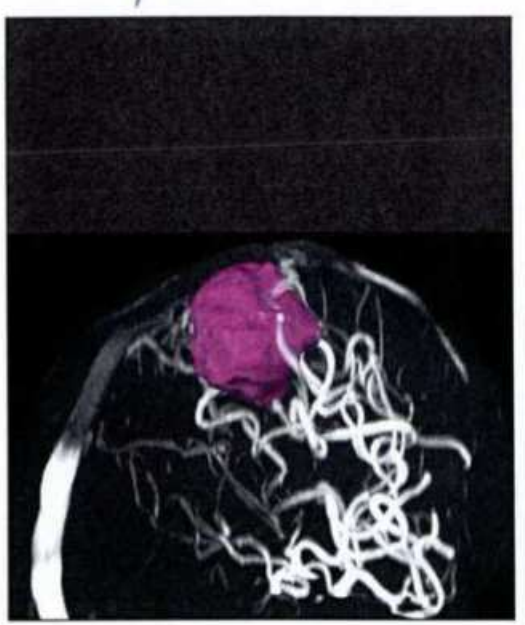


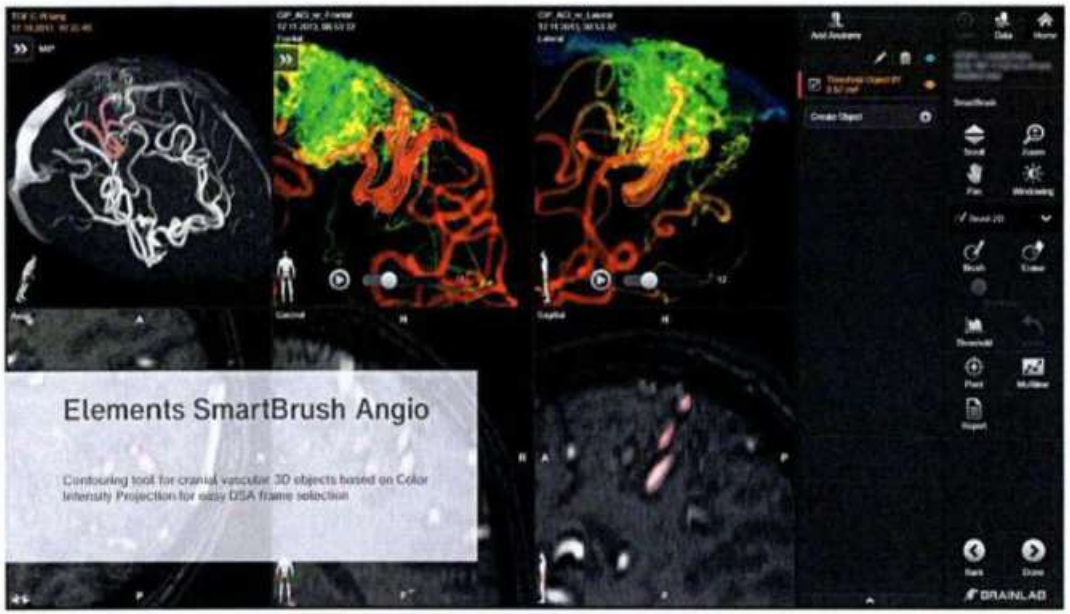


Neurovascular contouring

Elements SmartBrush Angio

- Generates a cranial vascular 3D object based on a user-defined region of interest and considering the dynamic contrast flow
- Color intensity projection for easy DSA frame selection and region of interest definition
- Side-by-side outlining on 2D DSA and fused 3D images helps differentiate feeding and draining vessels
- 3D nidus object refinement possibilities include SmartBrush, 2D Brush and 3D Brush
- Seamless export of Nidus object to Cranial Navigation or RT planning applications from Brainlab
- Enables consistent contouring and report generation over time

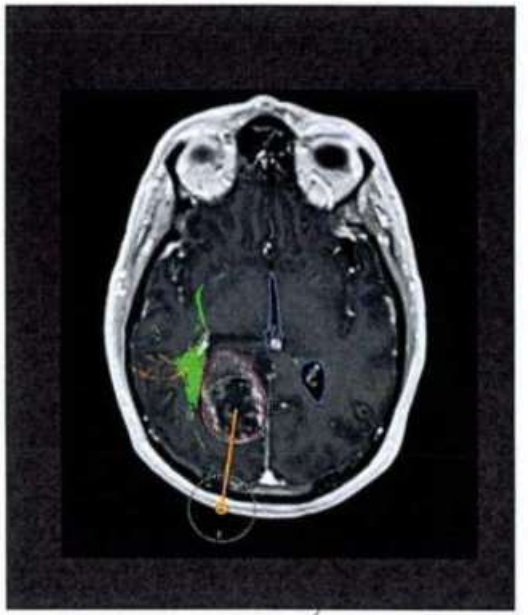


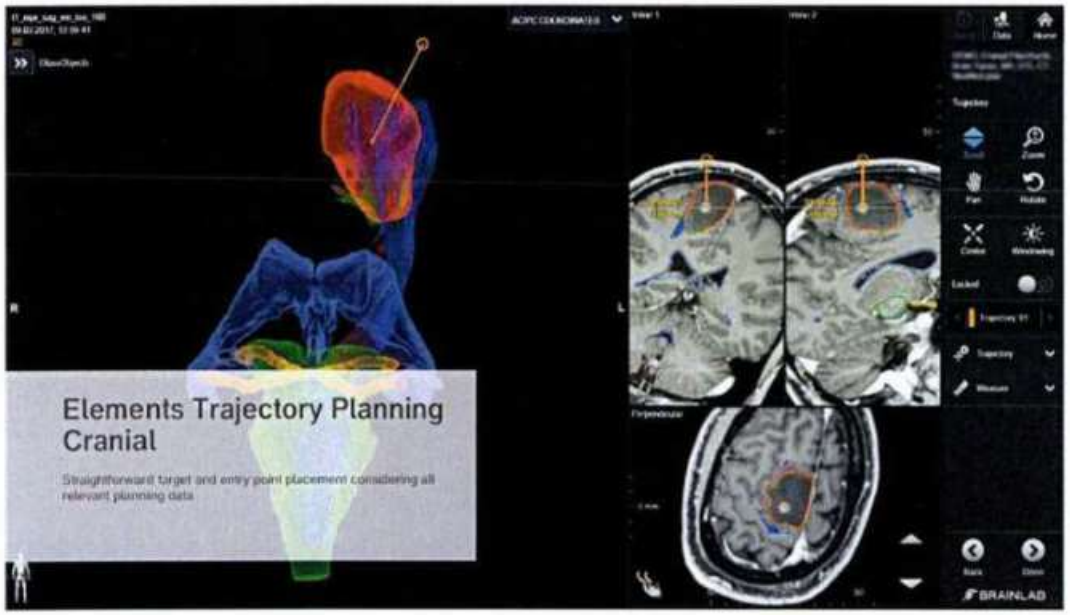


Approach definition

Elements Trajectory Planning Cranial

- Interactive target and entry point positioning
- Visualization of all surgical planning data
- Flexible definition of trajectories based on AC/PC-relative or DICOM coordinates
- Adjustable 3D trajectory shapes for case-specific visualization
- Axial, coronal, sagittal, probe's eye and inline views for trajectory verification

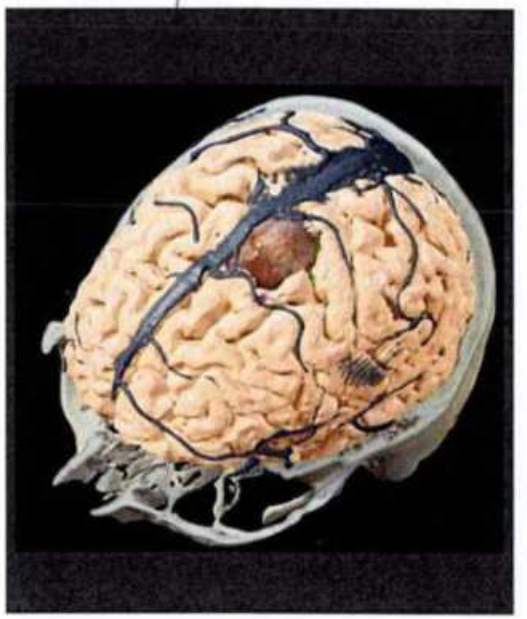




Data and plan review

Elements Viewer 3D

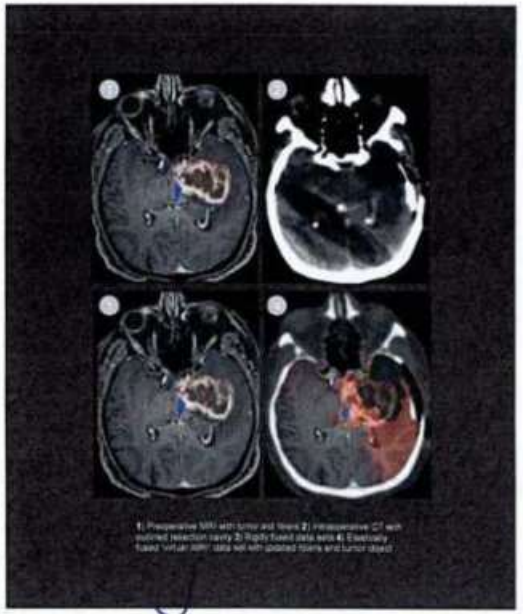
- Quick and direct interaction with DICOM data
- 3D multi-planar reconstructions in axial, coronal, sagittal and oblique
- 3D volume rendering of CT, MR, PET, SPECT
- Presets for skin, bone, vessel, DRR, MIP
- Superimposition of imaging and planning data
- Optional 'Smart Anatomy Cranial' provides high level of anatomic context and detail
- Stereoscopic visualization in combination with a 3D monitor improves spatial orientation
- Expandable with mixed reality software and hardware for data review



Intraoperative plan update

Elements Virtual iMRI Cranial

- Facilitates continued use of preoperative treatment plans
- Deforms a preoperative plan based on an intraoperative scan (MR or CT)
- Simulates anatomical changes caused by the intervention
- Updates pre-surgical plan including fiber tractography and segmentation
- Helps to quantify tissue deformation and estimate the extent of resection

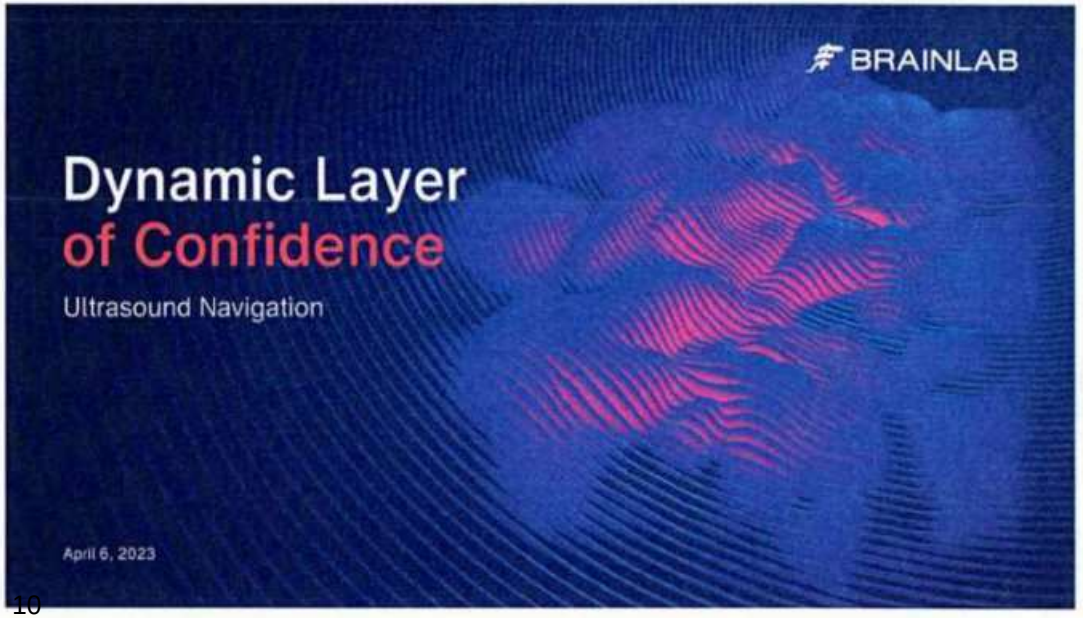


Pathways of significance

Up to 44%
of surgeons altered the surgical corridor
after the results of fiber tracking were taken into account.

10%
(21% -> 11%) reduction of pooled adverse event rate
of postsurgical permanent neurological deficits when preoperative fMRI mapping was performed in brain tumor resection.

20/23
studies agreed that resting-state fMRI is a suitable and useful
pre-operative mapping tool.



April 6, 2023

01. Executive Summary

April 6, 2023

Dynamic Layer of Confidence

Ultrasound Navigation

A whole new dimension. In real time. At any time.
We're delivering innovative, science-backed technology to help surgeons achieve their goal of maximum safe tumor or lesion resection, even if brain shift or other navigational inaccuracies occur. We're operationalizing ultrasound navigation in a new way, transforming tried-and-true intraoperative imaging technology to deliver an ultra beneficial and dynamic layer of confidence.

Main Benefits

Ultrasound Navigation

1 Ultrasound Unbound

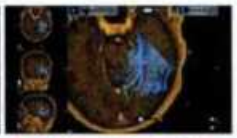
Real-Time Correlation of Intraop Ultrasound and Preop MRI

Forget everything you know about intraoperative ultrasound. Gain valuable real-time insights through the right orientation and instantaneous correlation between ultrasound and familiar preop MRI images.

2 Make the Shift

Precision and Confidence in Navigating Cranial Resection Challenges

Gain the navigational accuracy you need to address the greatest challenges in cranial resection: Visualization of and compensation for brain shift, achievement of maximum safe resection and identification of residual tumor.



New Ultrasound Snap to MRI®

Advanced Fusion for Navigation on the Most Up-to-Date Anatomy

Update patient registration and navigate on the most up-to-date anatomy with automated rigid fusion between the preop MRI image and the intraoperative ultrasound image using Brainlab Elements Image Fusion®.

3 On the Same Wavelength

Efficient Intraoperative Imaging Without Workflow Interruption

Take advantage of our cost-effective, fast and straightforward intraoperative imaging technology that will not interrupt your workflow.

April 6, 2023

100%
concordance to iMRI[1]

16.7%
less cerebellar mutism encountered, when used during resection of pediatric fourth ventricular tumors[2]

>80%
GTR[3] in pediatric and adult patients supra- and infratentorial intracranial tumors[3]

Maximum safe resection in LGGs[4] where only iMRI is helpful as visual resection tool[4]

Clinical Benefits

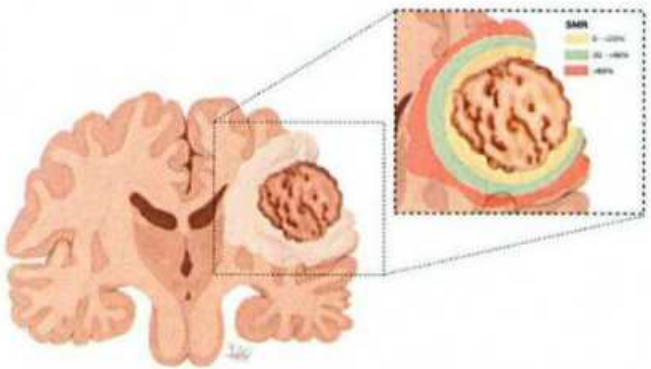
6 April 2023

02.
Surgical Goals and Challenges in Cranial Tumor Resection

April 6, 2023

Maximum Safe Resection

#1 Goal of Every Cranial Neurosurgeon

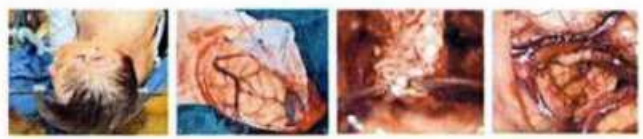


April 5, 2023

Standard Approach Today

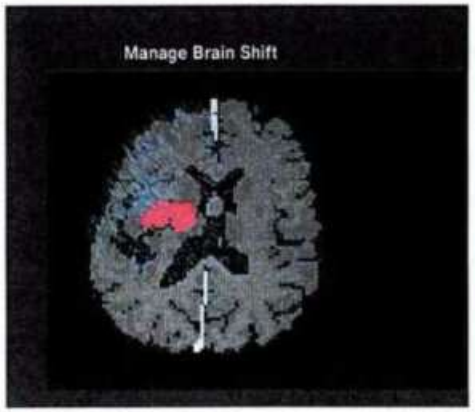
Cranial Neurosurgery – Tumor Resection

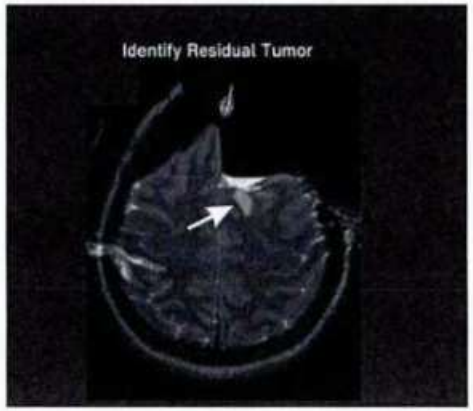
1 Craniotomy > 2 Tumor Approach > 3 Resection Control



Clinical Challenges in Neurosurgery

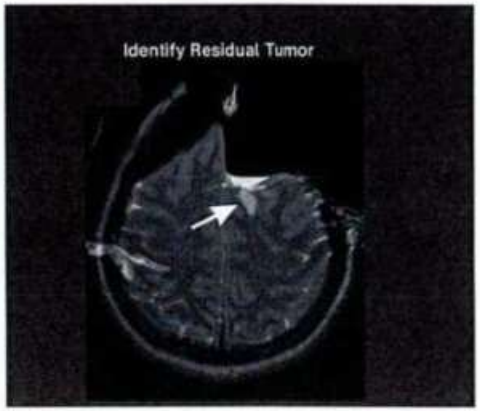
Cranial Neurosurgery





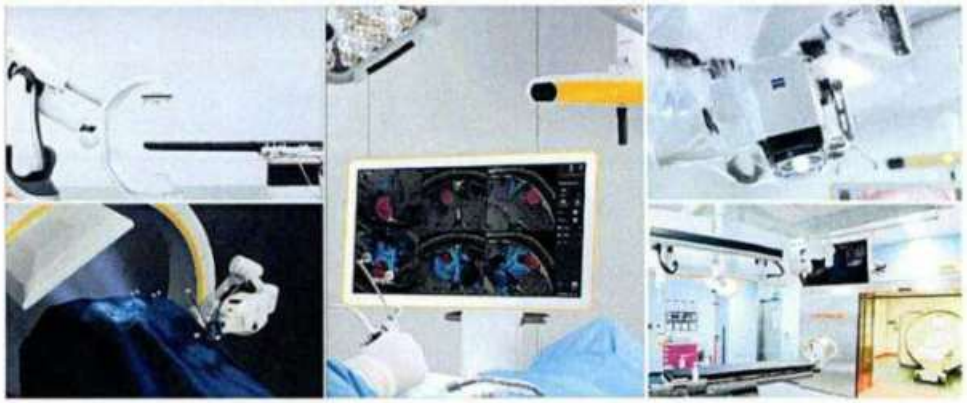
Clinical Challenges in Neurosurgery

Cranial Neurosurgery



03.
Introducing Intraoperative Imaging

April 6, 2023



Intraoperative Imaging

Updating Patient Scans in the O.R. for Cranial Surgery

April 6, 2023

Overview of Intraoperative Imaging Modalities

Cranial Tumor Resection

	iMRI	iCT	5ALA	iUS
High Grade Tumor Visualization	Excellent	Challenging	Very good	Very good
Low Grade Tumor Visualization	Excellent	Challenging	Not good	Very good
Time to Acquire One Image	~30-60 min	~15 min	~1 min	~1 min
Costs	$$$$	$$	$	$

April 6, 2023

04.
Ultrasound in Neurosurgery

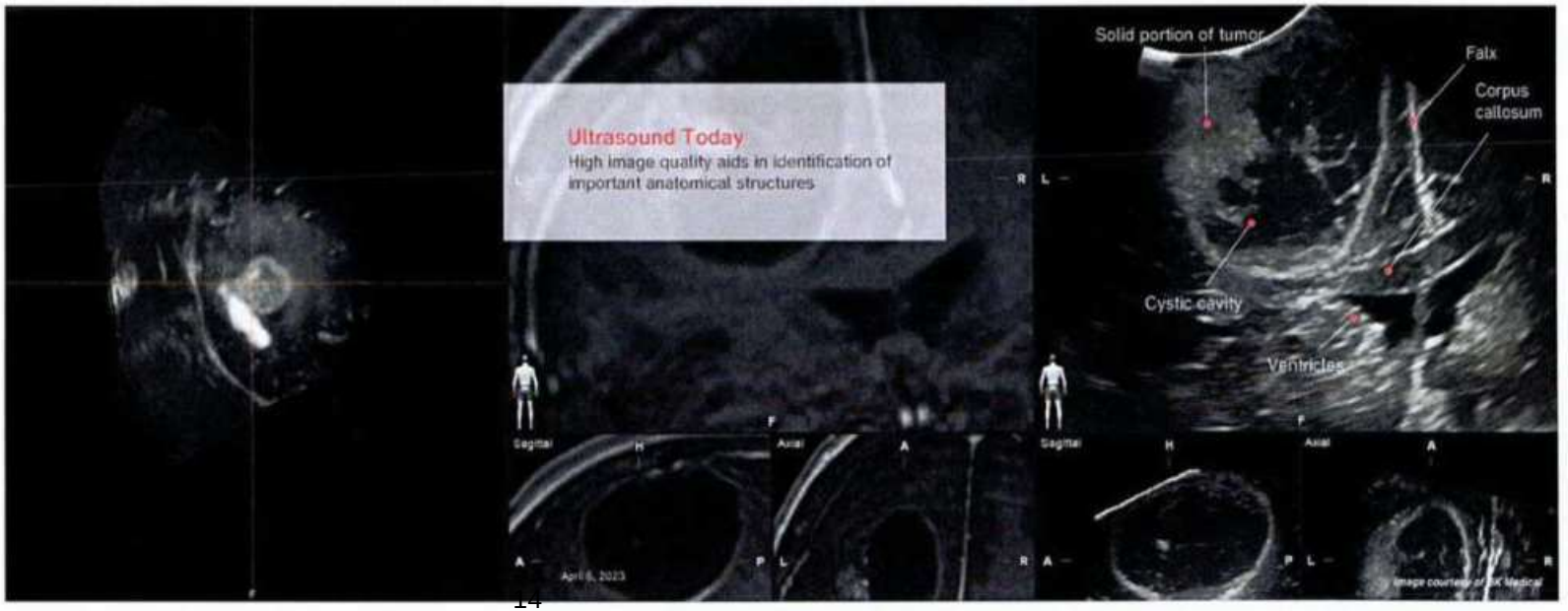
April 6, 2023

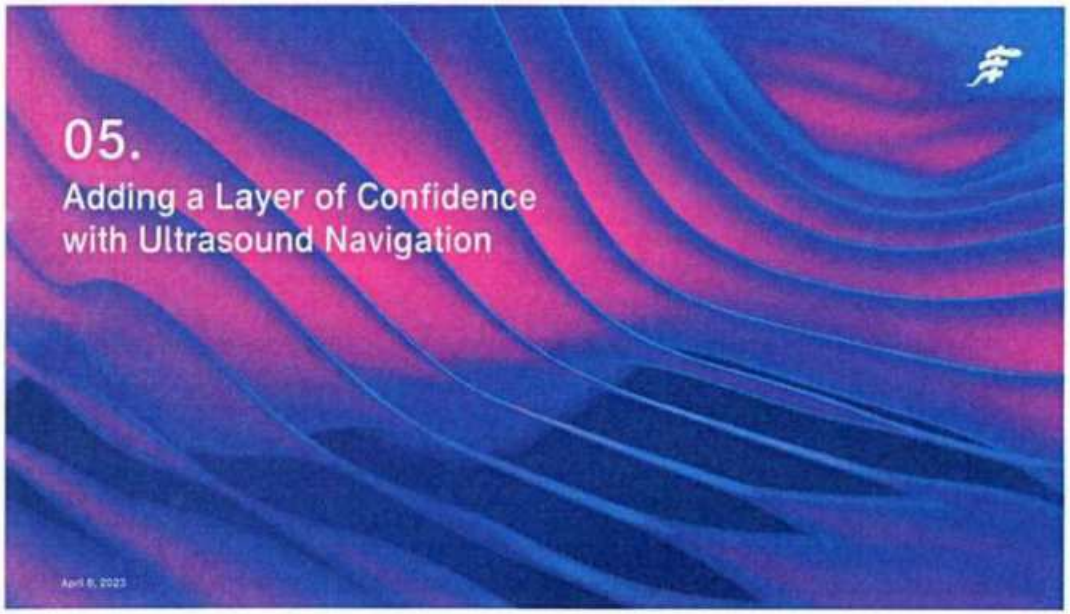
Traditional Pain Points

Stand-Alone Ultrasound Device Usage

1. **Image interpretation challenges**, small field of view and challenging anatomical orientation: is the image to the right axial, coronal or sagittal? Which landmarks can be seen here?
2. **Lack of training** in the neurosurgical community
3. **Solidified prejudices** that image quality is historically bad and that ultrasound tech usability is designed for radiologists not surgeons

April 6, 2023





Main Benefits

Ultrasound Navigation

1 Ultrasound Unbound

Real-Time Correlation of Intraop Ultrasound and Preop MRI

Forget everything you know about intraoperative ultrasound: Gain valuable real-time insights through the right orientation and instantaneous correlation between ultrasound and familiar preop MR images.

2 Make the Shift

Precision and Confidence in Navigating Cranial Resection Challenges

Gain the navigational accuracy you need to address the greatest challenges in cranial resection: Visualization of and compensation for brain shift, achievement of maximum safe resection and identification of residual tumor.

New Ultrasound Snap to MRI®

Advanced Fusion for Navigation on the Most Up-to-Date Anatomy

Update patient registration and navigate on the most up-to-date anatomy with automated rigid fusion between the preop MRI image and the intraoperative ultrasound image using BrainLab Elements Image Fusion.

3 On the Same Wavelength

Efficient Intraoperative Imaging Without Workflow Interruption

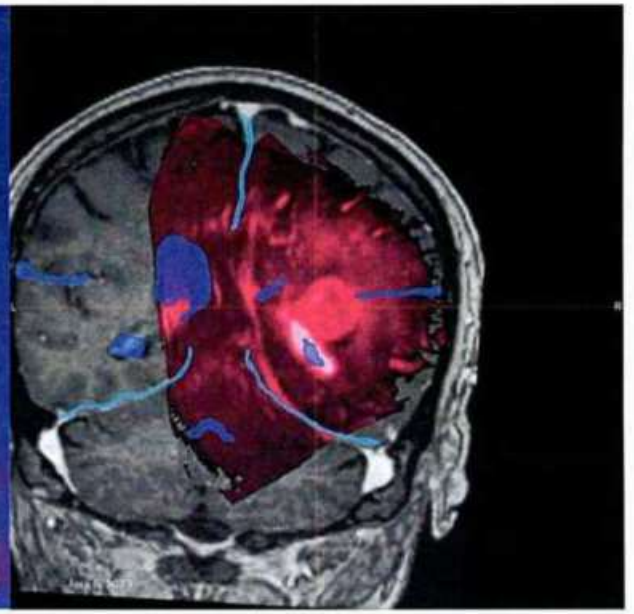
Take advantage of our cost-effective, fast and straightforward intraoperative imaging technology that will not interrupt your workflow.

April 6, 2023

1 Ultrasound Unbound

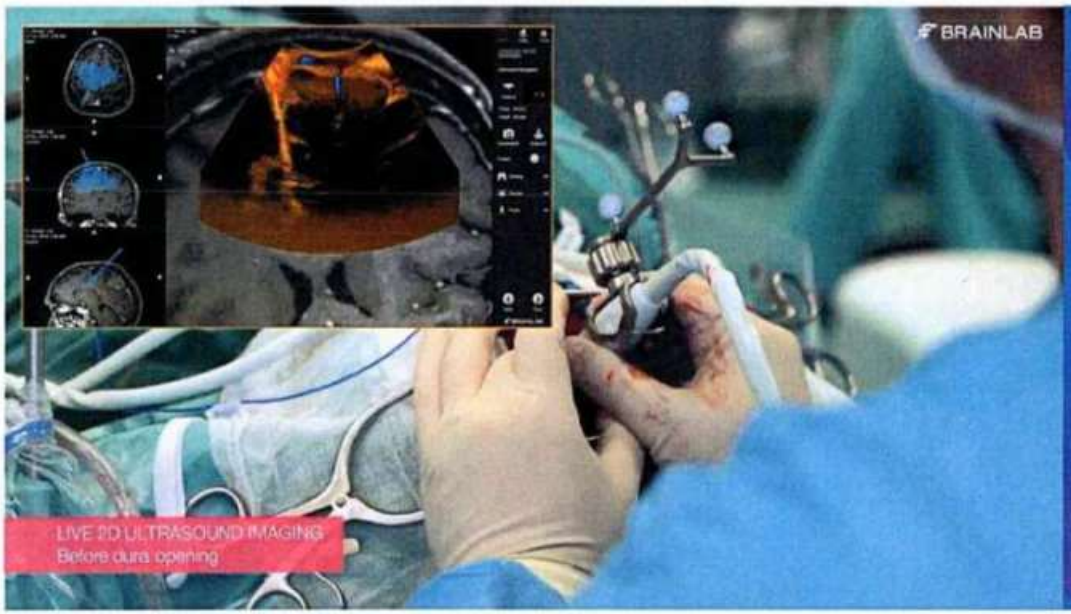
Real-Time Correlation of Intraoperative Ultrasound and Preop MRI

Forget everything you know about intraoperative ultrasound: Gain valuable real-time insights through the right orientation and instantaneous correlation between ultrasound and familiar preop MR images.



Superimpose live 2D ultrasound images onto preoperative patient data for direct comparison with intraoperative status in order to:

- Simplify the orientation
  Review correlated views between ultrasound and familiar preop MR images
- Visualize brain shift
  Instantly identify, assess and compensate for brain shift
- Link live ultrasound data to preop plan
  Add segmented anatomical landmarks to further help ultrasound data utilization



2 Make the Shift

Precision and Confidence in Navigating Cranial Resection Challenges

Gain the navigational accuracy you need to address the greatest challenges in cranial resection: Visualization of and compensation for brain shift; achievement of maximum safe resection and identification of residual tumor

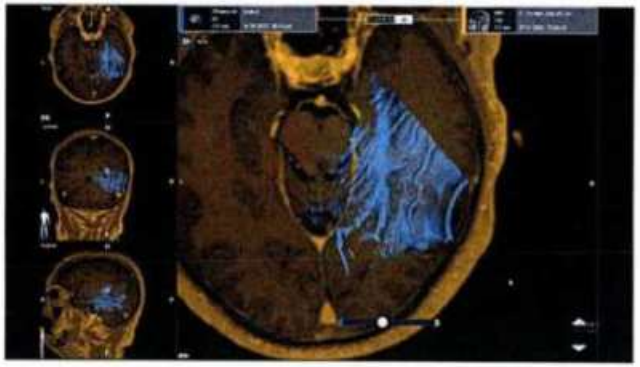
Ultrasound Snap to MRI

Brainlab Elements Image Fusion*

New

Advanced Fusion for Navigation on the Most Up-to-Date Anatomy

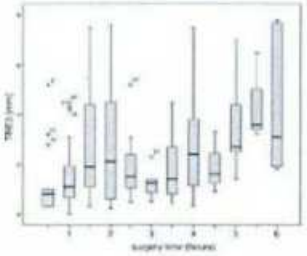
We're enabling automated rigid fusion between the preop MRI image and the intraoperative ultrasound image, allowing you to update the registration and navigate on the most up-to-date patient anatomy.



April 6, 2023

Challenge

The Silent Loss of Neuronavigation Accuracy[1]



The influence of time on the target registration error. CONCLUSION: "After registration, there is an ongoing loss of neuronavigation accuracy"... "Surgeons should be aware of this silent loss of accuracy when using neuronavigation."

Solution

Brainlab introduces **Ultrasound Snap to MRI*** to provide functionality for an automated rigid US-MR fusion with a sufficient accuracy to update the US-MR registration using Brainlab Elements Image Fusion*.

In essence, this rigid co-registration algorithm applies linear correlation of linear combination (LC2)-based similarity metric which exhibits local invariance to how much two channels of information contribute to an US image, i.e., correlation of the US image with both the MRI intensity values and its spatial gradient magnitude and allows for fully automatic US-MR registration in a matter of seconds (Wein et al. 2013, DOI: 10.1007/978-3-642-40811-3_5)

Clinical Study at Tata Memorial Hospital Mumbai

Validation of the benefit of Ultrasound Snap to MRI in supratentorial resection cases

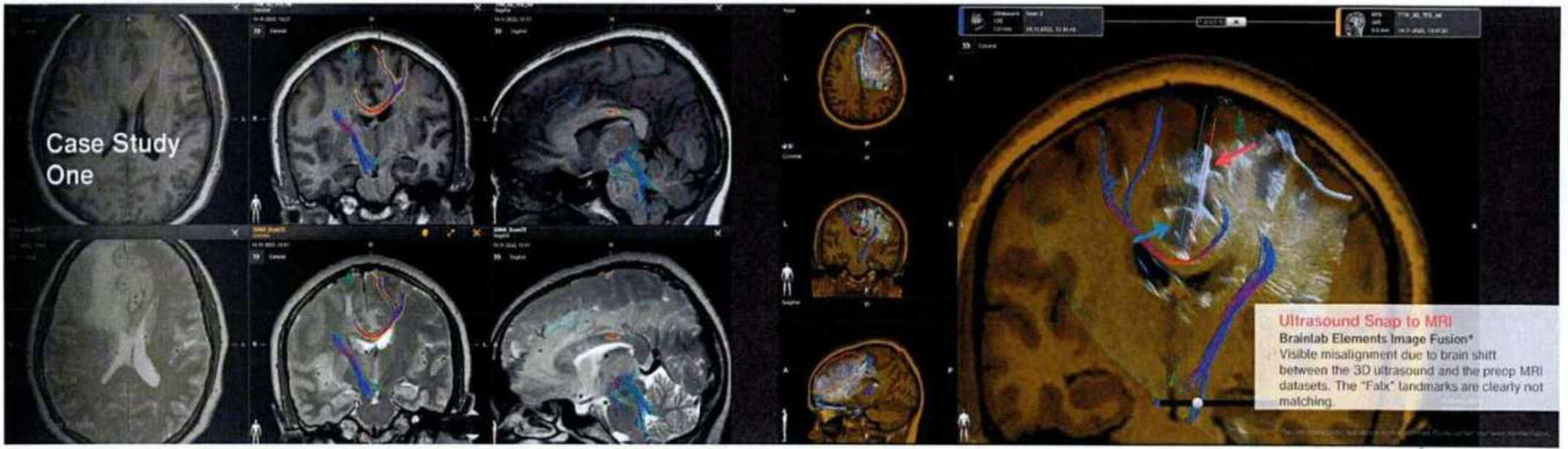
Timeframe:
August 2022 – April 2023

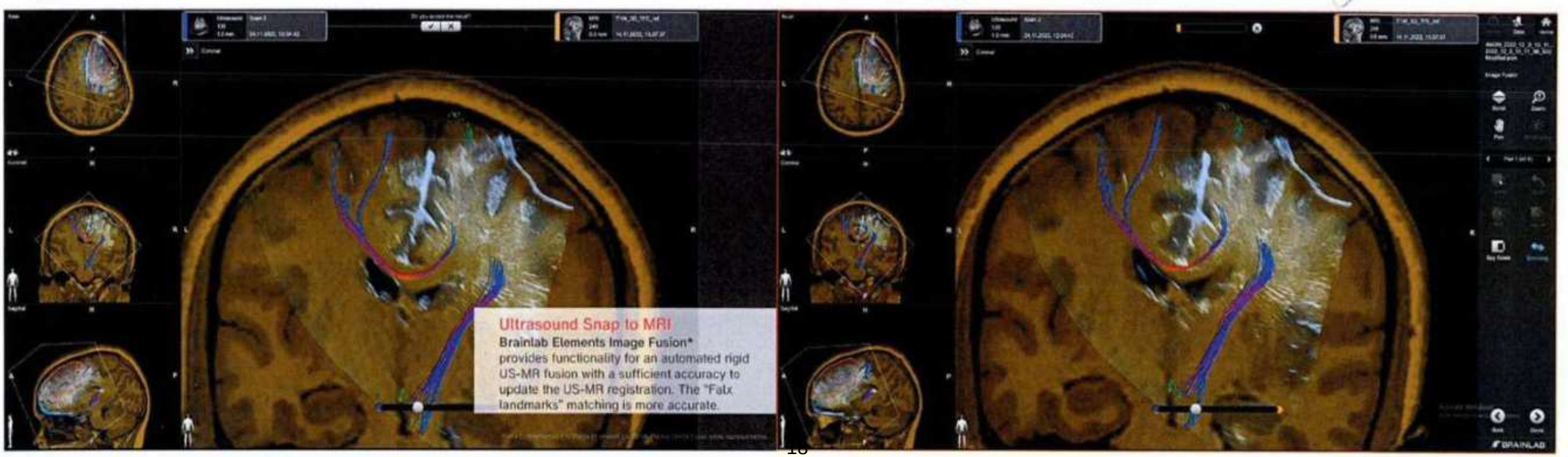
Study Goal:
Quantitative and qualitative validation of the benefit of **Ultrasound Snap to MRI** (Brainlab Elements Image Fusion software) in supratentorial gliomas:

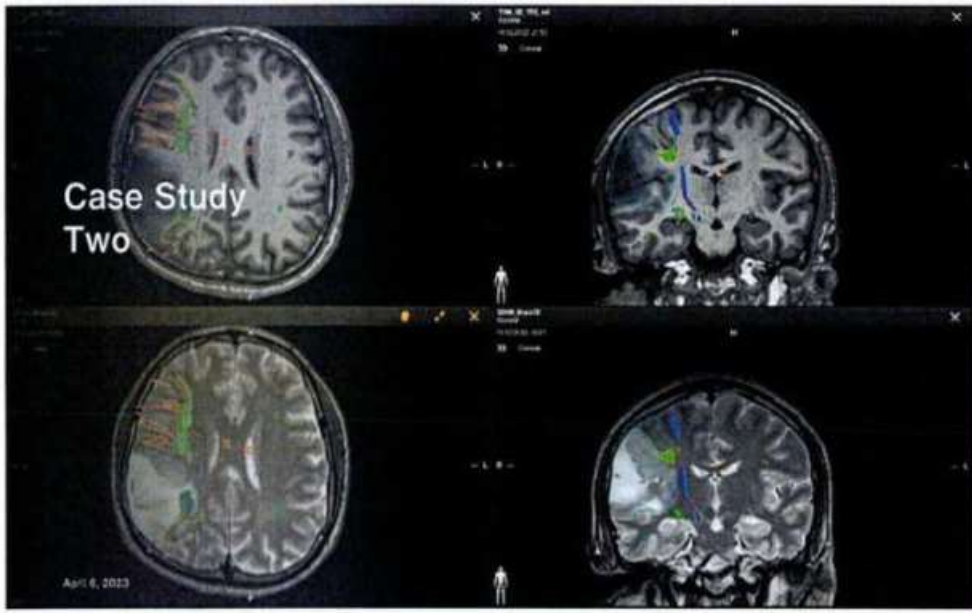
- Registration and navigation accuracy using defined landmarks by comparing the accuracy before using the Ultrasound Snap to MRI functionality and after using it.
- Comparing potential patient related factors influencing the benefit of Ultrasound Snap to MRI such as extent of the lesion, edema and location of the lesion.

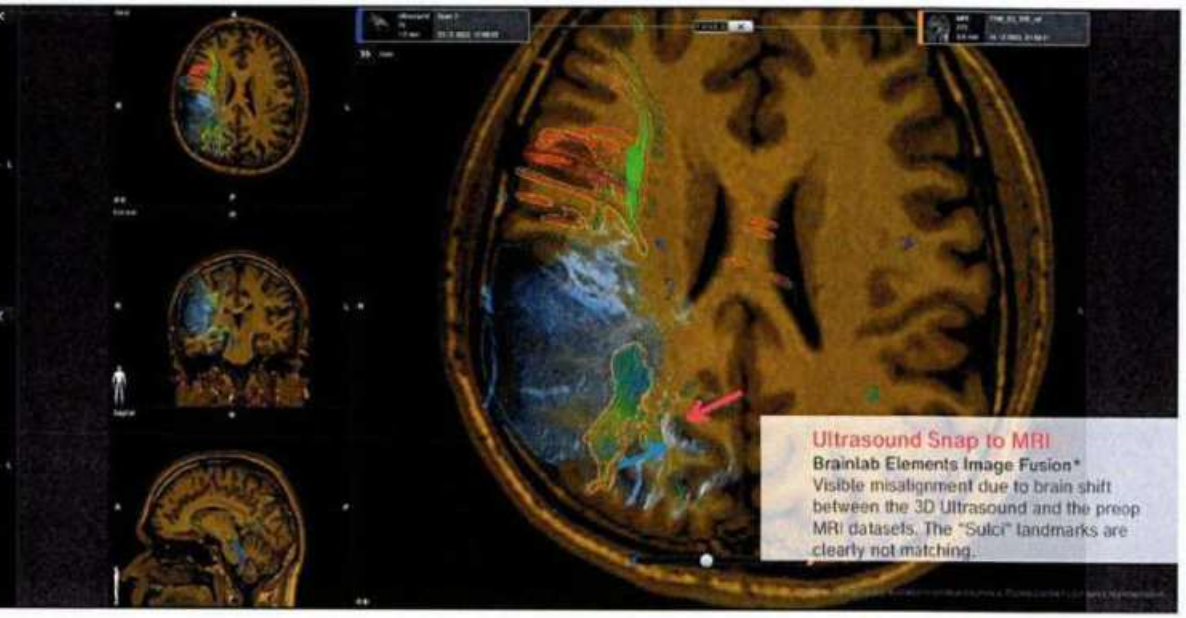
N = 25 adult patients with supratentorial glioma patients

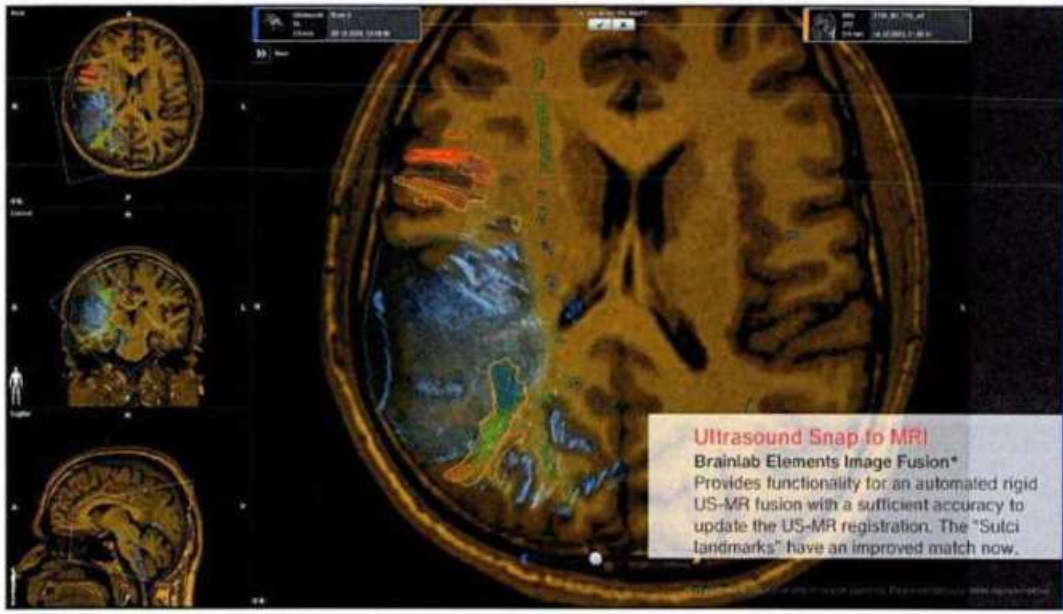
April 6, 2023


Case Study
One
Ultrasound Snap to MRI
Brainlab Elements Image Fusion*
Visible misalignment due to brain shift between the 3D ultrasound and the preop MRI datasets. The "Falx" landmarks are clearly not matching.


Ultrasound Snap to MRI
Brainlab Elements Image Fusion*
provides functionality for an automated rigid US-MR fusion with a sufficient accuracy to update the US-MR registration. The "Falx landmarks" matching is more accurate.
BRAINLAB


Case Study
Two
April 6, 2023


Ultrasound Snap to MRI
Brainlab Elements Image Fusion*
Visible misalignment due to brain shift between the 3D Ultrasound and the preop MRI datasets. The "Sulci" landmarks are clearly not matching.


Ultrasound Snap to MRI
Brainlab Elements Image Fusion*
Provides functionality for an automated rigid US-MR fusion with a sufficient accuracy to update the US-MR registration. The "Sulci landmarks" have an improved match now.


3 On the Same Wavelength
Efficient Intraoperative Imaging Without Workflow Interruption
Take advantage of our cost-effective, fast and straightforward intraoperative imaging technology that will not interrupt your workflow

Digital Integration

Ultrasound Navigation

Transmit valuable information instantly with our digital ultrasound integration

We're operating via a digital connection rather than conventional analog transmission, helping to reduce loss of image quality. Digital integration allows for:

- instant transmission of additional, valuable information, such as the probe's scan depth and image settings, without the need to calibrate separately.
- Streamlined system setup for cranial imaging with our dedicated neurosurgery configuration and full compatibility with BK Medical ultrasound devices.

April 6, 2023

Brainlab vs. Competition

Product Feature Overview

	Live 2D Ultrasound Navigation	3D Ultrasound Navigation	Digital Ultrasound Integration	Ultrasound Snap to MRI
				
Brainlab	YES	YES	YES	YES
Medtronic	YES	NO	NO	NO
Stryker	NO	NO	NO	NO
Masmec Biomed	YES	NO	NO	NO
Sonowand / Esaote	YES	NO	NO	NO

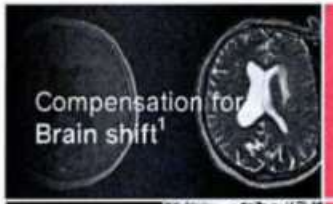
April 6, 2023

06.

Science That Is Making Waves in the Industry

April 6, 2023

Brainlab Ultrasound Navigation is designed to optimize safety, outcomes and responsible use of technology while reducing the costs and hurdles of ultrasound adoption. Here's the real-world evidence you need to make the shift.



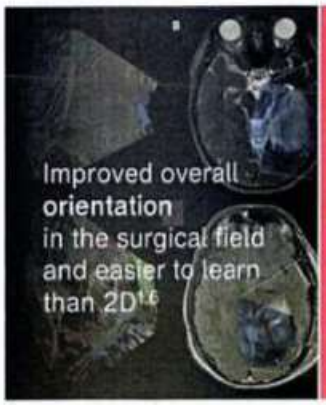
100%
concordance to iMRI[1]

16.7%
less cerebellar mutism encountered, when used during resection of pediatric fourth ventricular tumors[2]

>80%
GTR* in pediatric and adult patients supra- and infratentorial intracranial tumors[3]

Maximum safe resection in LGGs* where only iMRI is helpful as visual resection tool[4]

Clinical Benefits



42%
shorter length of surgery compared to intraoperative MRI, thus reducing the likelihood for postoperative complications[3]

No workflow interruption **with only minimal added time**[2]

Operational Benefits

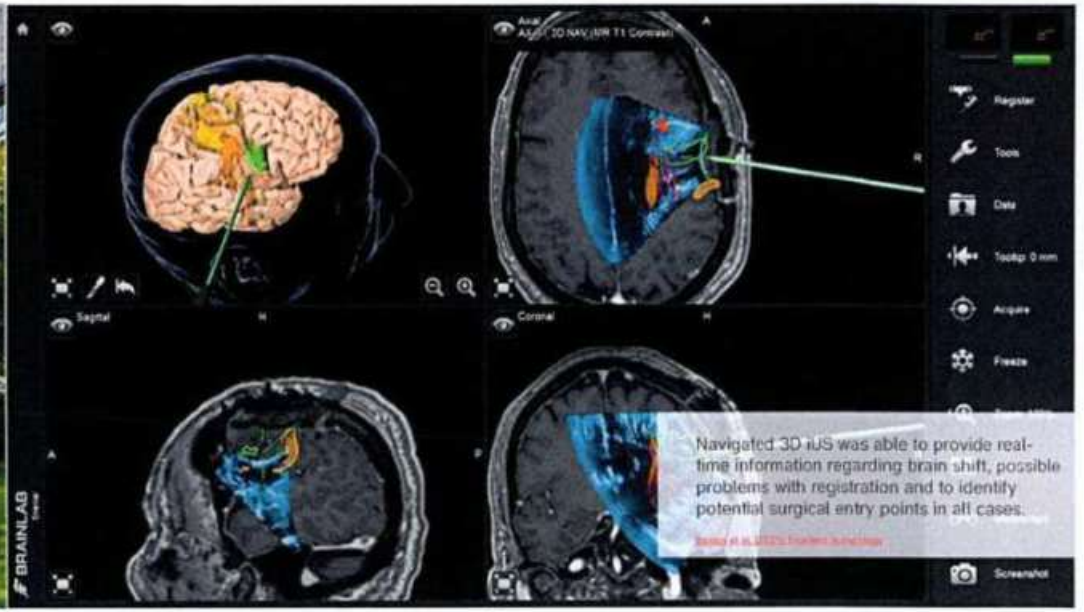
> 2 Mio. € iMRI investment cost compared to ~ € 50k Ultrasound Navigation + ultrasound device

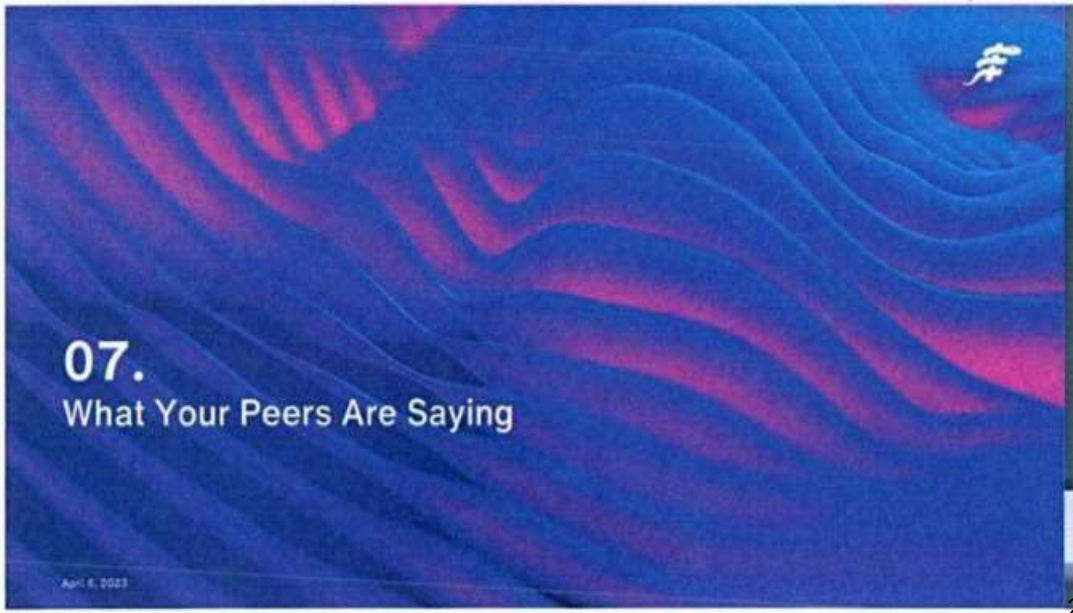
↓ 43% O.R. time[1]

↓ ≅ 78.6 minutes in O.R.[1]

Therefore, no personnel resources for the iMRI (radiology support)

Financial Benefits





The Nec Plus Ultra in Intraop Imaging

With Ultrasound Navigation you can make a substantial and positive impact for your practice, your facility and most importantly, your patients.

With its potential to become the standard of care for maximum safe resection and brain shift management, ultrasound navigation provides you with real-time feedback during surgery, layering in confidence and precision.

And the best part? It's relatively easy to learn, with plenty of training programs available globally. Whether you choose to attend courses organized by neurosurgeons or industry sponsors like Brainlab or BK Medical, there are ample opportunities to build in our re-engineered intraoperative imaging technology.

Brainlab Ultrasound Navigation is the **'nec plus ultra'** in intraoperative imaging technology - there is nothing further beyond to address your surgical challenges.

brainlab.com

Digital vs analog integration

Ultrasound 1.0 is more than just new features

Ultrasound 1.0 software is based on a digital connection rather than analog transmission

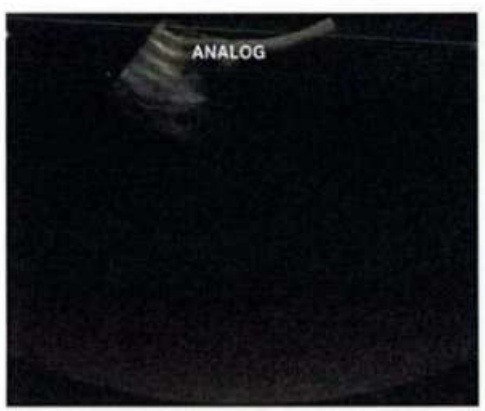
Analog

- Analog often results in loss of image quality
- Analog requires changing depth settings on both Nav and ULS for accuracy – error prone
- Each individual probe must be calibrated at each individual depth – extremely time consuming

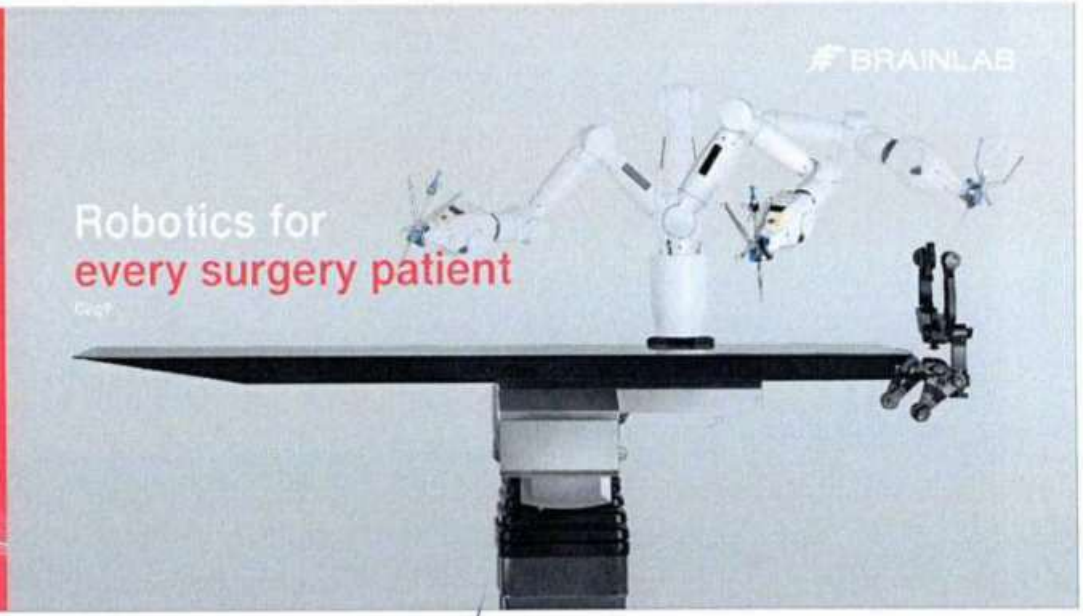
Digital

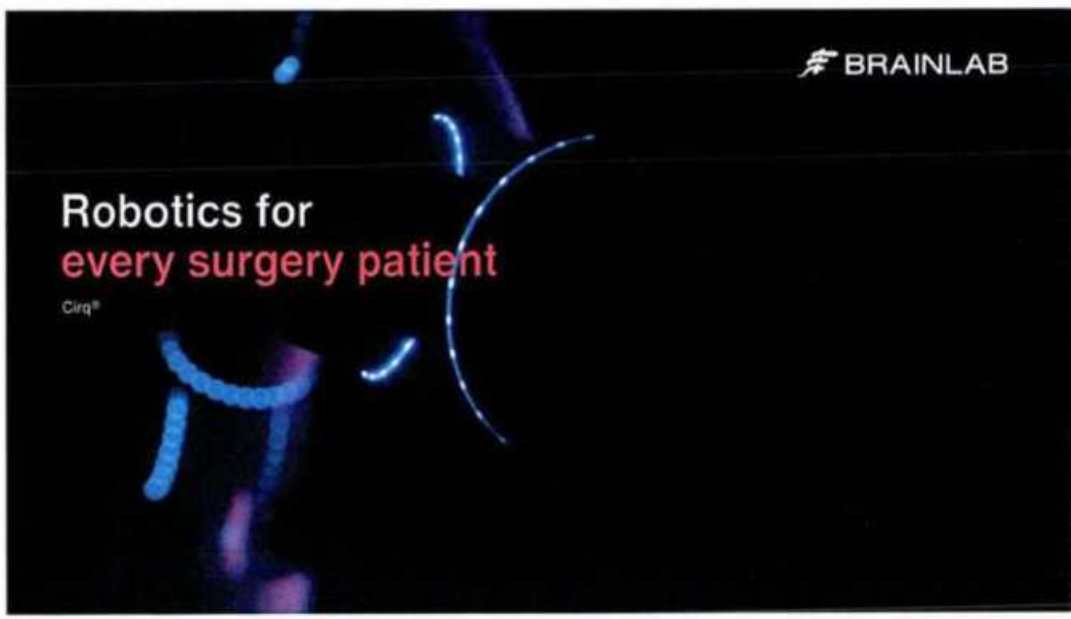
- Instant transmission of probe's scan depth and image settings
- One-step control both Nav and ULS using BK system
- Workflow improvements – less effort for more clinical impact
- No need for separate user calibration
- Significantly better image quality

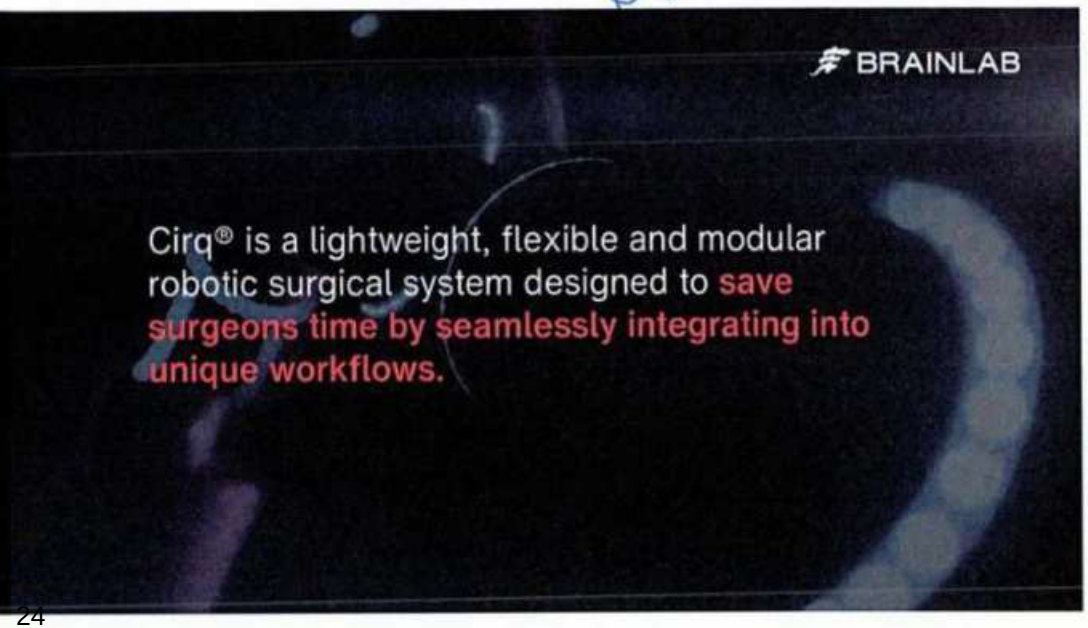
Digital vs. Analog



April 6, 2023

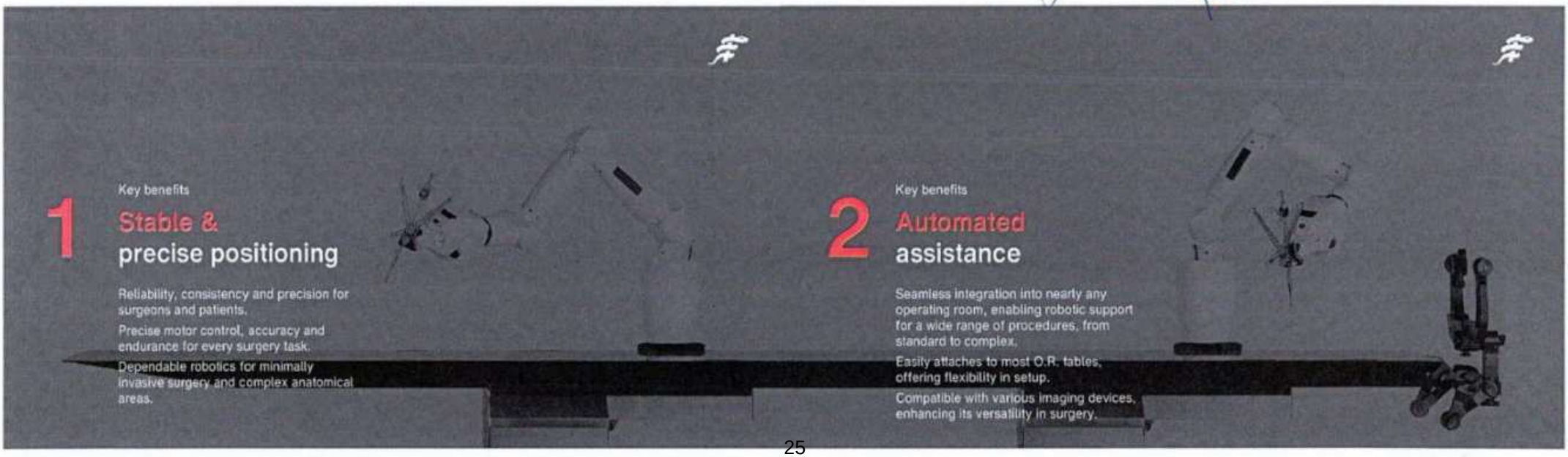


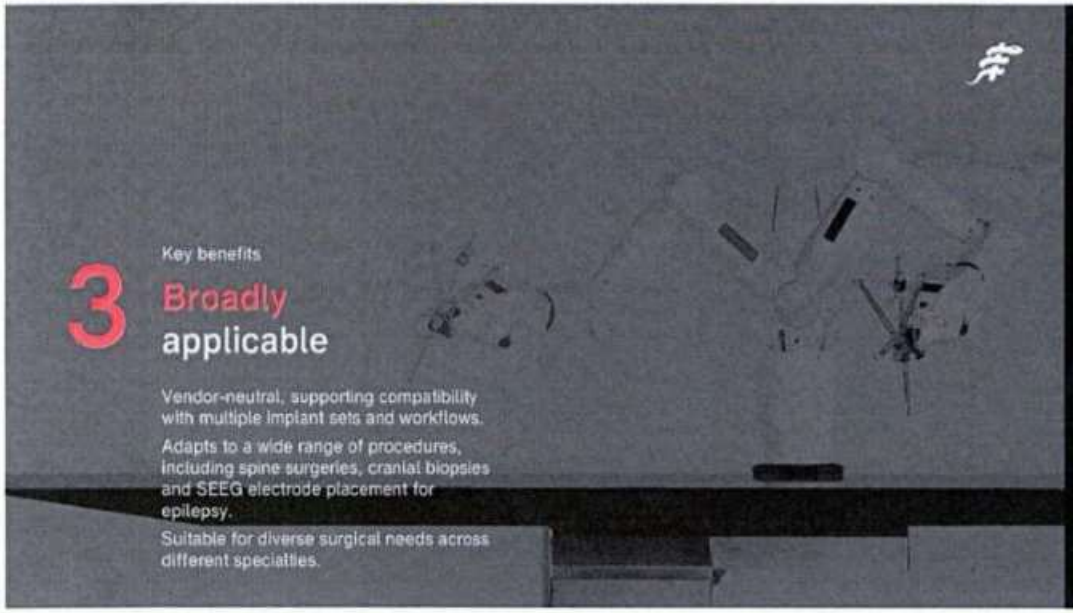


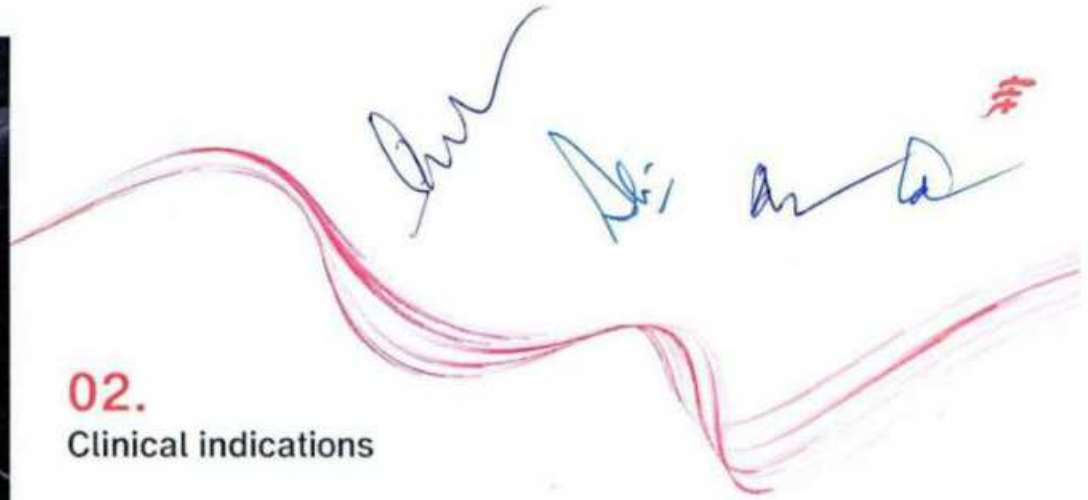


1. Benefits
2. Clinical indications
3. User feedback & scientific evidence
4. Hardware
5. Backup

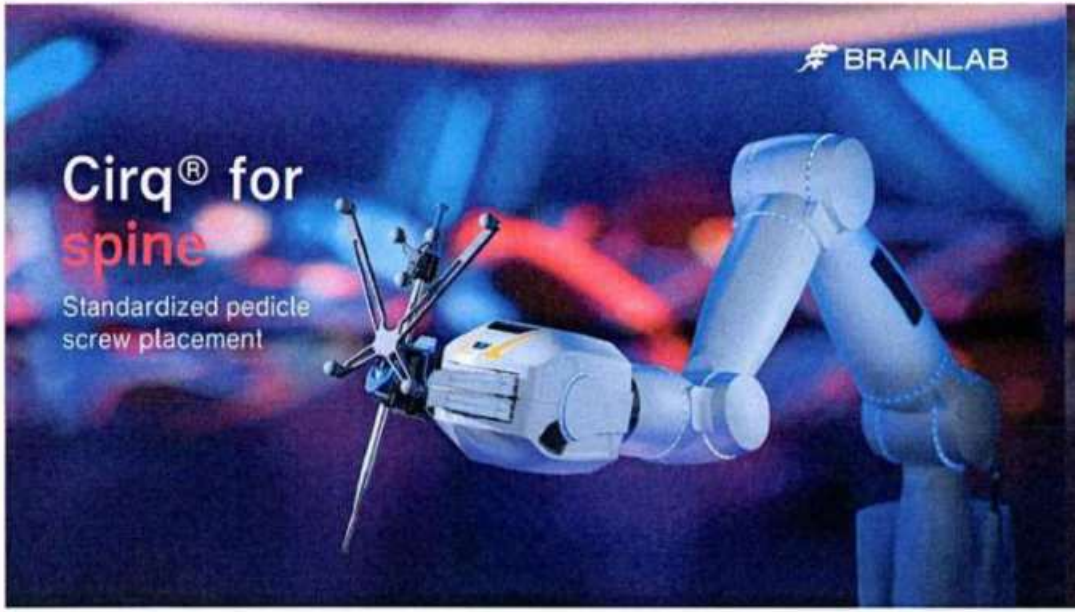
01.
Benefits

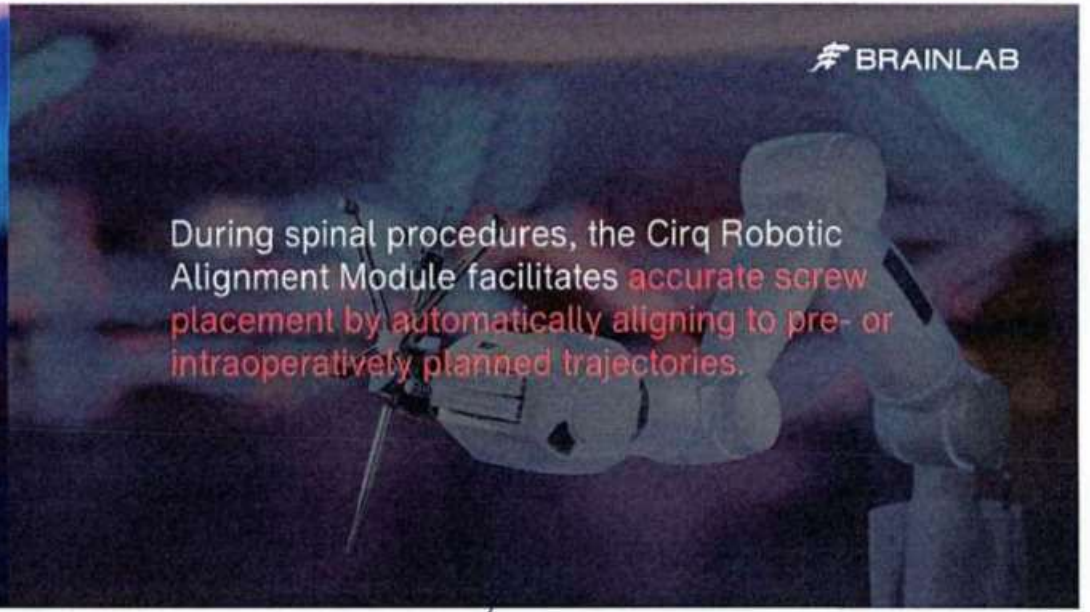






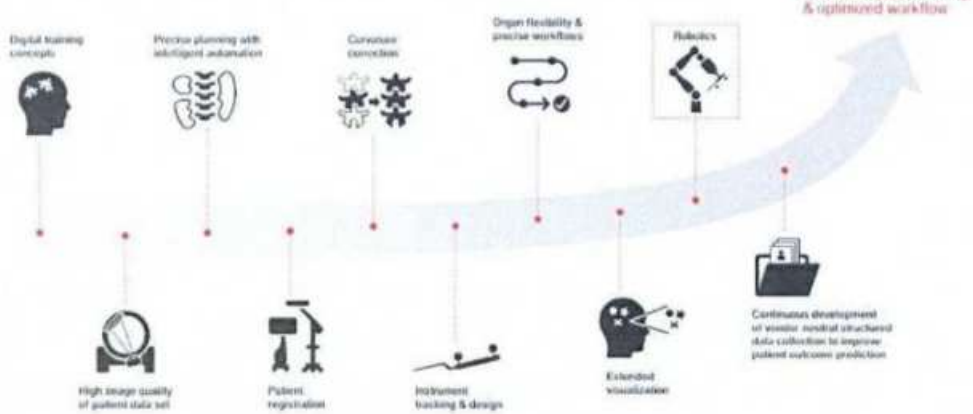
02.
Clinical indications





Taking care of every step in the accuracy chain

Advancing healthcare through aggregation of marginal gains



Key benefits

2 Automated alignment

Accuracy and precision take the lead.

Rely on the robotic alignment of the instruments without losing familiar haptic feedback.

Keep control of the workflow and react to the spine's flexibility.

Key benefits

3 Simplify and save

Benefit from simplified, reliable support and assistance.

The lightweight robotic system isn't the center of the workflow, so it has been designed to save space in the operating room.

High utilization through modularity, flexibility and mainly-reusable system components.

Efficient alignment → Instrumentation → Deviation monitoring → Repeat

Efficient alignment

Take control by quickly moving Cirq® to the vicinity of the trajectory.

The Cirq Robotic Alignment Module takes care of the precise, automatic alignment.

Efficient alignment → Instrumentation → Deviation monitoring → Repeat

Instrumentation

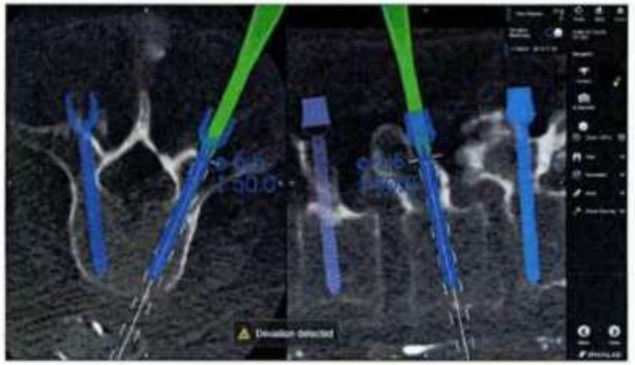
Confirm navigation accuracy with haptic feedback provided by the Cirq® instruments.

Prevent skiving by docking the Drillguide on the bone and create pilot holes using a highspeed drill.

Efficient alignment → Initialization → Deviation monitoring → Repeat

Deviation monitoring

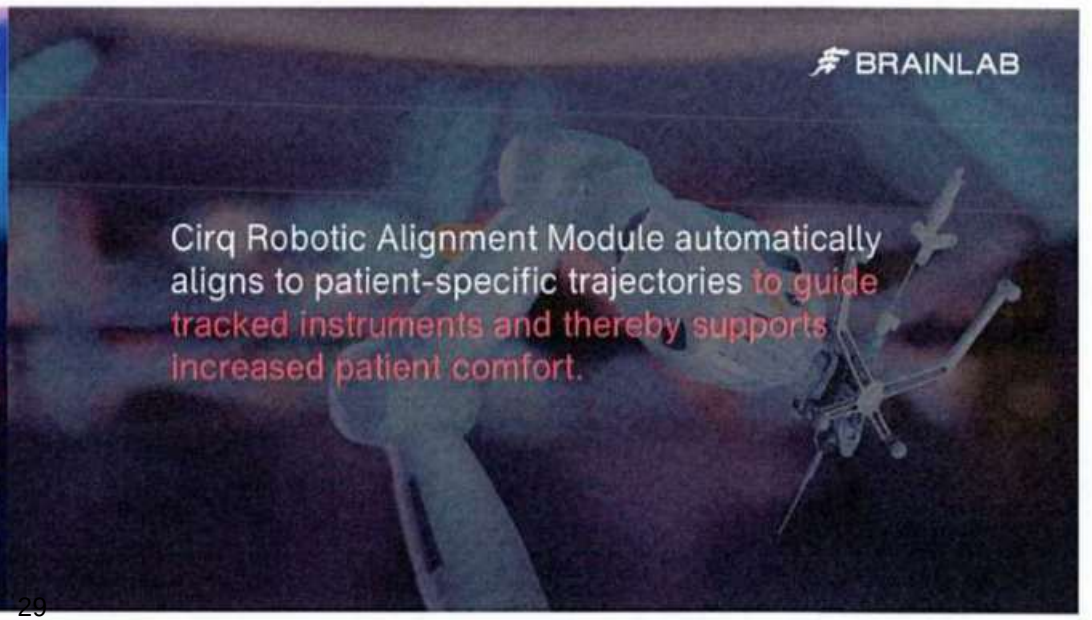
Drill with confidence using the visual and auditory feedback provided by Cirq®.



Efficient alignment → Initialization → Deviation monitoring → Repeat

Repeat

Select the next trajectory with the integrated buttons and repeat the previous steps to prepare all planned pilot holes.



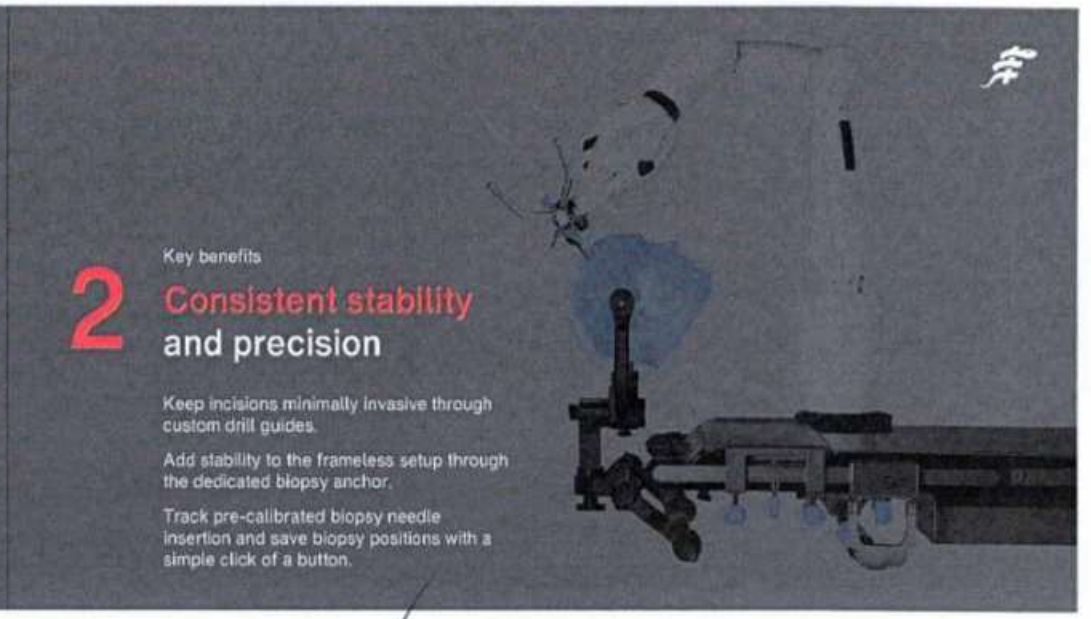
Key benefits

1 Accurate alignment to the right trajectories

Boost alignment accuracy through the visual guide toward the region of interest.

Brainlab Elements - Trajectory Planning supports in defining the right trajectories.

Real-time visualization of the biopsy window guides toward the predefined biopsy target.



Key benefits

2 Consistent stability and precision

Keep incisions minimally invasive through custom drill guides.

Add stability to the frameless setup through the dedicated biopsy anchor.

Track pre-calibrated biopsy needle insertion and save biopsy positions with a simple click of a button.

Key benefits

3 Seamless integration with navigation-ready instruments

With navigation-ready instruments, Cirq® is designed to seamlessly integrate into Brainlab planning and cranial navigation solutions as well as new and existing workflows.

These features maximize its utility during biopsy workflows and beyond.

Efficient alignment → Instrumentation → Smart pre-interventions → Repeat

Efficient alignment

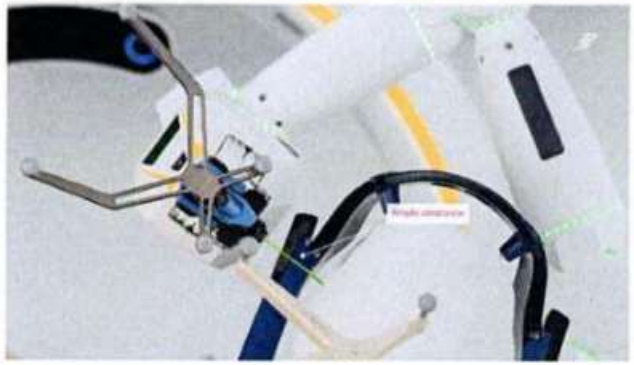
Take control by quickly moving Cirq® to the vicinity of the trajectory.

The Robotic Alignment Module takes care of the precise, automatic alignment.

Instrumentation

Indication specific stereotactic instruments enable minimal invasive approaches.

Take control over the accuracy with real time feedback of the instrument's position.

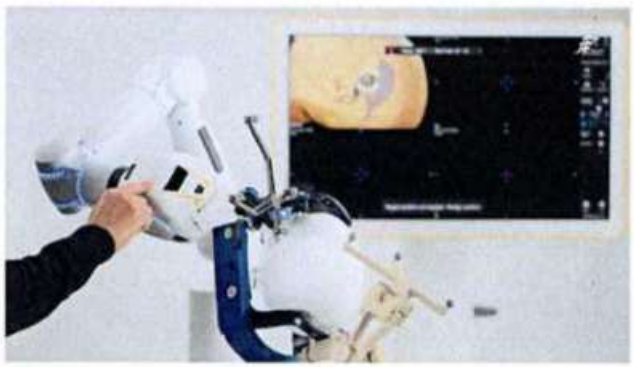


Smart measurements

Measure anatomical distances and relative instrument positions on the fly using accurate optical navigation and integrated software tools.

Repeat

Select the next trajectory with the integrated buttons and repeat the previous steps.



03.
User feedback & scientific evidence

Cirq® in numbers

As of December 2024

Overall installed base

- Cirq Robotic Alignment Modules: 113
- 34 Countries
- 87 Instrument Holder Modules
- 69 Cirq Arm System 1.4
- 73 Cirq Arm System 2.0
- 76% of our users utilize Cirq® for spine and cranial

Use cases

- 2530 Cranial uses
- 5820 Spinal uses
- >8300 Cases with Cirq®
- 3800 Uses with Cirq® passive
- 4550 Uses with Cirq® active

"Cirq® acts as the surgeon's 'third hand', eliminating the need to hold the drill guide steady on the bone. This allows the surgeon to focus entirely on drilling and sensing the drill's feedback, making procedures faster and more efficient, especially for complex cases."

PD Dr. med. Markus Bruder
Chief Physician Neurosurgery, Director Spinesurgery Kantonspital Aarau, Switzerland

Experience with Robotic-Assisted Pedicle Screw Placement Using Cirq®: Evaluation of 70 Screws

Pojskić et al. (2021)*

Study goal

The aim of the study was to analyze initial clinical data on the use of Cirq® and compare it with existing data on competitor products based on completed studies and existing literature.

Go to paper →

Summary

- With a high number of complex indications, Cirq® has proven to be a safe and effective device for accurate pedicle screw placement
- Significantly decreased mean time per screw throughout the course of the surgeries indicates an easy learning curve
- Results are comparable to the state of the art in robotic assisted spine surgery

Hybrid-3D robotic suite in spine and trauma surgery - experiences in 210 patients

Haida et al. 2024

Study goal

The study aimed to evaluate the potential benefits and clinical outcomes of using the Robotic Suite in trauma, orthopedic, and spine surgeries. It focused on assessing the precision, safety, and complication rates of surgeries performed with advanced navigation and robotic technologies.

Go to paper →

Summary

- Cirq® was used in 72.4% of cases, contributing to a spinal screw accuracy rate of 98.7% and an overall screw accuracy rate of 98.8%.
- Cirq® facilitated MIS in 66.2% of surgeries, which helped reduce trauma and infection rates.
- The use of Cirq® resulted in no revisions, indicating high precision and successful outcomes in surgeries.

04.
Hardware

Cirq Arm System 2.0

Robotic platform in a sleek design

1. Port for different modules
2. LEDs indicate system status
3. Integrated grip sensors unlock individual joints
4. 7 degrees of freedom for highest flexibility
5. Stable attachment to standard O.R. table side rails
6. Fully integrated design without external computing unit
7. Portable, light-weight design, no footprint

Sterile setup

Ensure sterility with one swift movement

1. After **draping** the patient and the arm, drape around the bottom of the arm to cover all unsterile parts.
2. Attach the **Cirq Instrument Holder** and instruments
3. Move the system with the **Cirq Robotic Alignment Module** attached

Technical Specifications

Physical Specifications	
Dimensions Cirq Arm System 2.0, L x W x D	1272 x 179 x 146 mm (50.1 x 7.0 x 5.7 in)
Reach (segment 2 – 4)	792 mm (31.2 in)
Weight	16 kg (35.3 lb.)
Payload	3 kg (6.6 lb.)
Power requirement	100 – 240 V, 50 / 60 Hz AC input voltage
Power consumption	max. 175 W (incl. power allocated to end effector)
Dimensions Cirq® Stabilization Brace, L x W x D	622-683 x 199 x 147 mm (21.4 – 25.6 x 7.7 x 5.7 in)

Interfaces	
Network Connection	Data socket (RJ45) (for connection to the navigation system, hospital network)
Power Connection	For medical grade 24 V power supply
Mechatronic Interface	Connection of application modules, power supply via arm max. 100 W (24 V at 2 A)
Mechanical Interfaces	Clamping jaw for attachment to O.R. table rail Cirq® Stabilization Brace interface

Technical Specifications

Environmental Conditions (Operation)	
Temperature range	10 - 30 °C (50 - 86 °F)
Relative humidity	30 - 75 % non-condensing
Air pressure	700 - 1060 hPa

Compatibilities	
Application module	Cirq Robotic Alignment Module (requires additional software) Cirq® Instrument Holder Module
Navigation system	Brainlab Buzz Navigation (Ceiling-Mounted) Brainlab Curve 1.1, Curve 1.2 and Curve Navigation 17700 Brainlab Kick 2.0 Navigation Station (Kick 2.0 and Kick 2.1)
O.R. table rail dimensions* , H x W	Europe: 25 x 10 mm (1.0 x 0.4 in) Swiss: 30 x 10 mm (1.2 x 0.4 in) USA: 28.6 x 9.3 mm (1.1 x 0.4 in) Japan: 32 x 9 mm (1.3 x 0.4 in) UK: 31.9 x 6.2 mm (1.3 x 0.2 in) Australia (Denyer): 38.3 x 6.2 mm (1.5 x 0.2 in)

Want to learn more?

Check our Webinar on Cirq Instrument Holder and Cirq Robotic Alignment Module

Go to webinar →

braintab.com

BRAINLAB

Brainlab AG
Olof-Palme-Straße 9
81829 Munich • Germany

phone: +49 89 99 15 68 0
fax: +49 89 99 15 68 33

EU-KONFORMITÄTSERKLÄRUNG

Hersteller	Brainlab AG
Herstellungsort (e)	Olof-Palme-Straße 9, 81829 Munich, Germany
SRN	DE-MF-000006183
Medizinprodukt	Ultrasound Navigation
Handelsname(n)	Navigation Software Ultrasound
Zweckbestimmung	The device enables image guided surgery
Basic-UDI-DI	4056481UltrasoundNavi53
Verordnung/Richtlinie	EU 2017/745 EU 2021/2226 80/181/EEC
Risikoklasse	Class IIb
Regel gemäß Anhang VIII	Rule 11, 1st paragraph + 2nd indent (a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb)
Normen/ gemeinsame Spezifikationen	See Annex I
Poduktcode(s)	MDA 0315- Software MDS 1010- Devices with a measuring function MDT 2010- Devices manufactured using electronic components including communication devices MDT 2011- Devices which require packaging, including labelling MDT 2012- Devices which require installation, refurbishment
GMDN code	62783- Electromagnetic/optical surgical navigation device tracking system
EMDN code	Z12011482 - SURGICAL NAVIGATION INSTRUMENTS - SOFTWARE ACCESSORIES
Benannte Stelle:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 Munich, Germany
Benannte Stelle Nr	0123
EU Bescheinigung	G10 037489 0059, valid until 2025-09-13

BRAINLAB

Wir, Brainlab AG, erklären in alleiniger Verantwortung, dass:

MDR

- das oben angegebene Produkt ein Medizinprodukt gemäß Artikel 2 der Richtlinie 2017/745 des Rates ist und den einschlägigen Bestimmungen dieser Richtlinie entspricht.
- das Medizinprodukt die grundlegenden Sicherheits- und Leistungsanforderungen gemäß Anhang I der Richtlinie 2017/745 des Rates erfüllt.
- das Verfahren gemäß Anhang IX der Richtlinie eingehalten wurde.

Reg. 2021/2226

- das oben genannte Medizinprodukt der Verordnung 2021/2226 über elektronische Gebrauchsanweisungen für Medizinprodukte entspricht und die Bestimmungen dieser Richtlinie erfüllt.

Directive 80/181/EEC

- das oben genannte Medizinprodukt der Richtlinie 80/181/EEC zur Angleichung der Rechtsvorschriften der Mitgliedstaaten über die Einheiten im Meßwesen entspricht und die Bestimmungen dieser Richtlinie erfüllt.

Diese Konformitätserklärung ist signiert in München und gültig ab Datum der Unterschrift.

Name	Funktion	Datum, Unterschrift
Wolfgang Steinle	Vice President R&D	24 May 2024

BRAINLAB

ANHANG I

ULTRASOUND NAVIGATION 1.2

NORMEN / GEMEINSAME SPEZIFIKATIONEN

Norm	Titel
EN ISO 13485:2016+AC:2018+A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019+ A11:2021	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
IEC 62366-1:2015 + AMD1:2020	Medical devices - Application of usability engineering to medical devices
IEC 80001-1:2010	Application of risk management for IT-networks incorporating medical devices - Part 1: Roles, responsibilities and activities
IEC 62304:2006 + AMD1:2015	Medical device software - Software life-cycle processes
MDCG 2018-5	UDI Assignment to Medical Device Software
MDCG 2019-11	Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR
MDCG 2019-16	Guidance on cybersecurity for medical devices
MDCG 2020-1	Guidance on clinical evaluation (MDR) / Performance evaluation (IVDR) of medical device software
MDCG 2020-5	Guidance on clinical evaluation - Equivalence
MDCG 2021-19	Guidance note integration of the UDI within an organisation's quality management system
DICOM	Digital Imaging and Communications in Medicine (DICOM)

BRAINLAB

ANHANG II

ULTRASOUND NAVIGATION 1.2

PRODUKTKENNUNG ENTHALTEN

UDI-DI	Name, Version
04056481144630	Ultrasound Navigation, 1.2

BRAINLAB

Brainlab AG
Olof-Palme-Straße 9
81829 Munich • Germany

phone: +49 89 99 15 68 0
fax: +49 89 99 15 68 33

EU-DECLARATION OF CONFORMITY

Manufacturer	Brainlab AG
Manufacturing site (s)	Olof-Palme-Straße 9, 81829 Munich, Germany
SRN number	DE-MF-000006183
Medical device	Curve Navigation 17700
Trade name(s)	Curve® Navigation, Curve Navigation System, Curve Navigation System EM, Curve Navigation – Extension Display Cart
Intended Purpose	The device enables image guided surgery
Basic UDI-DI	4056481PlatformsMR
Regulation/Directive	EU 2017/745 EC 1907/2006, REACH EU 2019/1021, POP 2011/65/EU, RoHS 2019/19/EU, WEEE 2015/863/EU , RoHS3
Risk class	Class IIb
Rule according to Annex VIII	Rule 9, No Indent
Standards/common specification	See Annex I
Product codes	MDA 0312 MDS 1009 MDT 2001, MDT 2002, MDT 2010, MDT 2011, MDT2012
GMDN code	62783
EMDN code	Z12011480
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 Munich, Germany
Notified Body Identification number	0123
EU Certificate	G10 037489 0059, valid until 2025-09-13

BRAINLAB

We, Brainlab AG, declare under our sole responsibility that:

MDR

- the device specified above is a medical device according to Regulation 2017/745 Article 2 and meets the provisions of this regulation.
- the device complies with the General Safety and Performance Requirements stated in Annex I of Regulation 2017/745.
- the procedure referred to in Annex IX of Regulation 2017/745 has been followed.

REACH

- the device specified above, including parts, components and packaging fulfills the requirements of the REACH regulation 1907/2006.

POP

- the device specified above, including parts, components and packaging fulfills the requirements according to the Art 3(1)(a), 3(1)(b) and 5 of the Stockholm Convention (Art. 3(1), 3(2) and 6(1) of regulation EU 2019/1021) and contains none of the POP (persistent organic pollutants) substances listed in Annexes A, B and C of the Stockholm Convention (Annexes I, II and III of Regulation (EU) 2019/1021) - apart from the exemptions expressly listed in the Stockholm Convention Annexes (Art. 4 of the Regulation (EU) 2019/1021).

ROHS

- the device specified above is in conformity with Directive 2011/65/EU (Restriction of Hazardous Substances, RoHS) and delegated Directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU as regards the list of restricted substances ("RoHS3")

WEEE

- the device specified above is compliant with Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) and meets the provisions of this Directive.

This declaration is signed in Munich and valid from the date of signature.

Name	Function	Date, Signature
Florian Hoffmann	Vice President R&D	Apr. 20, 2023

BRAINLAB

ANNEX I

CURVE NAVIGATION 17700

STANDARDS / COMMON SPECIFICATIONS

Standard	Title
IEC 63000:2016 + AMD1:2022	Technical Documentation For The Assessment Of Electrical And Electronic Products With Respect To The Restriction Of Hazardous Substances
EN ISO 13485:2016+AC:2018	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN 62304:2006 + Cor.:2008 + A1:2015	Medical device software - Software life-cycle processes
ISO 20417:2021	Medical device - Information to be supplied by the manufacturer
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
IEC 62366-1:2015 + A1:2020	Medical devices – Application of usability engineering to medical devices
EN 60601-1:2006 + Cor.:2010 + A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010 + A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
IEC 80001-1:2010	Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities
MDCG 2020-5	Guidance on clinical evaluation – Equivalence

BRAINLAB

ANNEX II

CURVE NAVIGATION 17700

DEVICE IDENTIFIERS INCLUDED

UDI-DI	Article Number	Name, Version	Tradename(s)
04056481142520	17700	Curve Navigation 17700	Curve® Navigation Curve Navigation System Curve Navigation System EM Curve Navigation – Extension Display Cart

BRAINLAB

Brainlab SE
Olof-Palme-Straße 9
81829 Munich • Germany
phone: +49 89 99 15 68 0
fax: +49 89 99 15 68 5033

The "Director"
All India Institute of Medical Sciences
Ansari Nagar, New Delhi-110029 India

Munich, March, 2026
Subject : Manufacturer's Authorization Form

We, **Brainlab SE**, are an established and globally recognized manufacturer of **server-based Gamma Knife treatment planning software and advanced surgical navigation systems**, which include **Brainlab Elements for Gamma Knife Planning (2 concurrent licenses)** and the **Curve Navigation System with USG Integration**, designed for high-precision radiosurgery and neurosurgical applications having factories at Olof-Palme-Strasse 9, 81829, Munich, Germany, hereby authorize Messrs. Brainlab India Pvt. Ltd., having registered office at B-26, Somdutt Chambers-II, 9, Bhikaji Cama Place, New Delhi -110066, India and Corporate office at #901-B, Time Tower, Mehrauli-Gurugram Road, Haryana-122022, India to submit a bid, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.

We also state that we are not participating directly in this bid for the following reason(s): Brainlab SE and its subsidiaries are duly represented by our local subsidiary M/s Brainlab India Pvt. Ltd., who has been fully authorized by us to act as our representative in whole of India to deal, undertake, participate in the business proceedings, quote rate for supply, installation, testing and commissioning, after sales services of our products/equipment and their spare parts together with consumables and procure purchase orders to pass to us on such rates and conditions as may be negotiated by them for and on behalf of us.

We further confirm that no supplier or firm or individual other than Messrs. Brainlab India Pvt. Ltd. , #901-B, Time Tower, Mehrauli-Gurugram Road, Haryana-122022, India on behalf of Brainlab SE, Olof-Palme-Strasse 9, 81829, Munich, Germany is authorized to submit a bid, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.

We also hereby extend our full warranty, CAMC as applicable as per clause 15 of the General Conditions of Contract, read with modification, if any, in the Special Conditions of Contract for the goods and services offered for supply by the above firm against this TE document.

We also hereby confirm that we would be responsible for the satisfactory execution of contract placed on the authorized subsidiary and the spares for the equipment shall be available for at least 10 years from the date of supply of equipment.

We also confirm that the price quoted by our subsidiary shall not exceed the price which we would have quoted directly".

Yours faithfully,
For Brainlab SE

Florian Hoffmann
COO

BRAINLAB

Brainlab Sales GmbH
Olof-Palme-Straße 9 · 81829 Munich · Germany

phone: +49 89 99 15 68 - 0
fax: +49 89 99 15 68 - 5033

All India Institute of Medical Sciences-Delhi
Ansari Nagar
110029 New Delhi
India

München, March 9, 2026
Quotation QN-AIIMSN-DDP-253

Subject : Optional Add-On Items for Future Upgrade: Ref: Server Based Gamma Knife Planning (2 Concurrent License) and Surgical Navigation System (on buy back basis 01) with USG Integration(1)

Delivery: CIP (Incoterms 2020)
Payment terms: Letter of credit 0% Order Confirmation, 75% Delivery, 25% Acceptance - within 30 days of the date on the respective invoice

The prices and conditions set forth in this quotation are valid for a period of 90 days from the date of its issue. The attached terms with the title 'Standard Terms and Conditions' are hereby incorporated and form an integral part of this quotation.

Cirq - Platform (Optional Future Upgrade)

Pos.	Art.No.	Description	Qty.	Period in months
		CIRQ		
1	22876	CIRQ ROBOTIC BASE SOFTWARE	1	
2	56500	CIRQ ARM SYSTEM 2.0	1	
3	56100	CIRQ ROBOTIC ALIGNMENT MODULE	1	
		LICENSE SUPPORT IMAGE GUIDED SURGERY		
4	87011-38	LICENSE SUPPORT CIRQ ALIGNMENT SOFTWARE BASE starts after 12 months	1	108
		SERVICE AGREEMENT SURGERY		
5	81995-07	LOANER PROGRAM CIRQ ARM SYSTEM (12 MONTHS) starts after 12 months	5	12
6	81995-08	LOANER PROGRAM CIRQ ROBOTIC ALIGNMENT MODULE (12 MONTHS) starts after 12 months	5	12
		IMPLEMENTATION SERVICES SURGERY		
7	B14281	INSTALLATION AND TRAINING CIRQ	1	

BRAINLAB

Pos.	Art.No.	Description	Qty.	Period in months
		FREIGHT, INSURANCE AND FEES		
8	50780	FREIGHT, INSURANCE AND FEES	1	

Cirq - Stereotaxy (Optional Future Upgrade)

Pos.	Art.No.	Description	Qty.	Period in months
		NAVIGATION CRANIAL		
9	22884	CIRQ ALIGNMENT SOFTWARE CRANIAL BIOPSY	1	
10	22892	CIRQ ALIGNMENT SOFTWARE CRANIAL SEEG	1	
		LICENSE SUPPORT IMAGE GUIDED SURGERY		
11	87011-40	LICENSE SUPPORT CIRQ ALIGNMENT SOFTWARE CRANIAL BIOPSY starts after 12 months	1	108
12	87011-42	LICENSE SUPPORT CIRQ ALIGNMENT SOFTWARE CRANIAL SEEG starts after 12 months	1	108
		ACCESSORIES CRANIAL		
13	B15207	CIRQ ROBOTIC SEEG ACCESSORY PACKAGE	1	
14	B15206	CIRQ ROBOTIC BIOPSY ACCESSORY PACKAGE	1	
15	56424	ALIGNMENT BONE ANCHOR CRANIAL 2.1 MM / 3.8 MM	10	
		DISPOSABLES IMAGE GUIDED SURGERY		
16	B15210	CRANIAL BIOPSY DRILL KIT (10 CASES)	2	
17	56102	CIRQ ROBOTICS DISPOSABLE KINEMATIC UNIT (5 PCS)	2	
18	56103	DISPOSABLE CIRQ ROBOTIC ALIGNMENT DRAPE (5 PCS)	4	
19	B15211	SEEG DRILL KIT PMT 2.1 MM (10 CASES)	2	
		ONE-TIME SERVICES SURGERY		
20	82093-01	CLINICAL CONSULTATION IMAGE GUIDED SURGERY (1 CASE)	2	
		FREIGHT, INSURANCE AND FEES		
21	50780	FREIGHT, INSURANCE AND FEES	1	

Cirq - Spine (Optional Future Upgrade)

Pos.	Art.No.	Description	Qty.	Period in months
		NAVIGATION SPINE & TRAUMA		
22	22880	CIRQ ALIGNMENT SOFTWARE SPINE	1	
		LICENSE SUPPORT IMAGE GUIDED SURGERY		
23	87011-39	LICENSE SUPPORT CIRQ ALIGNMENT SOFTWARE SPINE starts after 12 months	1	108

BRAINLAB

Pos.	Art.No.	Description	Qty.	Period in months
		ACCESSORIES SPINE & TRAUMA		
24	B15200	ACCESSORY PACKAGE SPINE DRILLING FOR CIRQ PASSIVE	1	
		DISPOSABLES IMAGE GUIDED SURGERY		
25	56102	CIRQ ROBOTICS DISPOSABLE KINEMATIC UNIT (5 PCS)	10	
26	56103	DISPOSABLE CIRQ ROBOTIC ALIGNMENT DRAPE (5 PCS)	10	
		ONE-TIME SERVICES SURGERY		
27	82093-01	CLINICAL CONSULTATION IMAGE GUIDED SURGERY (1 CASE)	2	
		FREIGHT, INSURANCE AND FEES		
28	50780	FREIGHT, INSURANCE AND FEES	1	

Cirq - Service Contract (Optional Future Upgrade)

Pos.	Art.No.	Description	Qty.	Period in months
		SERVICE AGREEMENT SURGERY		
29	81024-85	TECHNICAL SUPPORT PACKAGE CIRQ ARM SYSTEM 2.0 starts after 12 months	1	12
30	81025-28	TECHNICAL SUPPORT PACKAGE CIRQ ROBOTIC ALIGNMENT MODULE starts after 12 months	1	12

Curve - Navigation System for Spine (Future Optional Upgrade)

Pos.	Art.No.	Description	Qty.	Period in months
		ELEMENTS PERPETUAL		
31	26239	ELEMENTS SEGMENTATION SPINE	1	
32	26334	ELEMENTS CURVATURE CORRECTION SPINE	1	
33	26710	ELEMENTS SPINE PLANNING	1	
		NAVIGATION SPINE & TRAUMA		
34	22268	NAVIGATION SOFTWARE SPINE & TRAUMA 3D	1	
35	26780	REGISTRATION SOFTWARE SPINE	1	
36	22263	REGISTRATION SOFTWARE - EXTENSION SURFACE MATCHING SPINE	1	
37	22269	INSTRUMENT SETUP SOFTWARE SPINE	1	
		ELEMENTS LICENSE SUPPORT		
38	87010-15	LICENSE SUPPORT ELEMENTS CURVATURE CORRECTION SPINE starts after 12 months	1	108
39	87030-08	LICENSE SUPPORT ELEMENTS SPINE PLANNING starts after 12 months	1	108
40	87010-05	LICENSE SUPPORT ELEMENTS SEGMENTATION SPINE starts after 12 months	1	108

BRAINLAB

Pos.	Art.No.	Description	Qty.	Period in months
		LICENSE SUPPORT IMAGE GUIDED SURGERY		
41	87011-28	LICENSE SUPPORT NAVIGATION SOFTWARE SPINE & TRAUMA 3D starts after 12 months	1	108
42	87011-26	LICENSE SUPPORT INSTRUMENT SETUP SOFTWARE SPINE starts after 12 months	1	108
43	87011-25	LICENSE SUPPORT REGISTRATION SOFTWARE SPINE starts after 12 months	1	108
44	87010-29	LICENSE SUPPORT REGISTRATION SOFTWARE SURFACE MATCHING SPINE starts after 12 months	1	108
		ACCESSORIES SPINE & TRAUMA		
45	B23507	ACCESSORY PACKAGE SPINE FOR UNIVERSAL INSTRUMENT INTEGRATION	1	
46	B23527	REFERENCE PACKAGE SPINE UNIVERSAL	1	
47	41874	INSTRUMENT CALIBRATION MATRIX	1	
48	B23915	AWLS & PROBES	1	
49	B23916	CHISELS SHORT & LONG	1	
50	B23919	DRILL GUIDE (2.0 MM)	1	
51	B23918	DRILL GUIDE (2.4 MM)	1	
52	B23917	DRILL GUIDE (2.6 & 3.2 MM)	1	
53	B23920	DRILL GUIDE (4.5 MM)	1	
54	B23921	DRILL GUIDE HANDLE WITH 4 MARKER ARRAY	1	
55	52321	STERILIZATION TRAY DRILL GUIDE	1	
56	52307	STERILIZATION TRAY INSTRUMENTS SPINE	1	
57	55830-10	HANDLE GEARSHIFT FOR OPEN SURGERY	1	
		DISPOSABLES IMAGE GUIDED SURGERY		
58	53153	DISPOSABLE CLIP-ON REMOTE CONTROL (20 PCS)	1	
59	54929	DISPOSABLE FIXATION PIN 4.0 MM X 125 MM (10 PCS)	1	
60	55846	DISPOSABLE TROCAR INSERT FOR PEDICLE ACCESS NEEDLE (5 PCS)	1	
		FREIGHT, INSURANCE AND FEES		
61	50780	FREIGHT, INSURANCE AND FEES	1	

Intraoperative 3rd Party Scanners Integration Kit (Optional Future Upgrade)

3D C-ARM/O-ARM/CT SCANNER Integration Hardware and Software Kit.

Pos.	Art.No.	Description	Qty.	Period in months
		AUTOMATIC PATIENT REGISTRATION		
62	B13313	AUTO-REGISTRATION HARDWARE PACKAGE UNIVERSAL AIR	1	
63	26735	AUTO-REGISTRATION SOFTWARE UNIVERSAL AIR SPINE	1	

BRAINLAB

Pos.	Art.No.	Description	Qty.	Period in months
		LICENSE SUPPORT IMAGE GUIDED SURGERY		
64	87010-41	LICENSE SUPPORT AUTO-REGISTRATION SOFTWARE UNIVERSAL AIR SPINE starts after 12 months	1	108
		DISPOSABLES IMAGE GUIDED SURGERY		
65	22182	DISPOSABLE PATIENT SCAN DRAPE (10 PCS)	1	
		ONE-TIME SERVICES SURGERY		
66	81001-06	INTEGRATION AND VERIFICATION OF THIRD PARTY DEVICES (1 VISIT)	1	
		FREIGHT, INSURANCE AND FEES		
67	50780	FREIGHT, INSURANCE AND FEES	1	

Microscope Integration (Optional Future Upgrade)

Pos.	Art.No.	Description	Qty.	Period in months
		NAVIGATED MICROSCOPE		
68	23511	NAVIGATION SOFTWARE MICROSCOPE	1	
69	23512	NAVIGATION SOFTWARE MICROSCOPE - EXTENSION HEAD-UP DISPLAY	1	
70	23513	NAVIGATION SOFTWARE MICROSCOPE - EXTENSION AUGMENTED REALITY	1	
71	23514	NAVIGATION SOFTWARE MICROSCOPE - EXTENSION ROBOTIC MOVEMENT (ZEISS KINEVO 900 / KINEVO 900 S)	1	
72	15241-02	MICROSCOPE INTERFACE CABLE 4.0 (ZEISS KINEVO 900 / TIVATO 700)	1	
73	B11501	MICROSCOPE ADAPTER AND TRACKING ARRAY (ZEISS KINEVO 900)	1	
		LICENSE SUPPORT IMAGE GUIDED SURGERY		
74	87030-03	LICENSE SUPPORT NAVIGATION SOFTWARE MICROSCOPE - EXTENSION AUGMENTED REALITY starts after 12 months	1	108
75	87030-02	LICENSE SUPPORT NAVIGATION SOFTWARE MICROSCOPE - EXTENSION HEAD-UP DISPLAY starts after 12 months	1	108
76	87030-01	LICENSE SUPPORT NAVIGATION SOFTWARE MICROSCOPE starts after 12 months	1	108
77	87030-06	LICENSE SUPPORT NAVIGATION SOFTWARE MICROSCOPE - EXTENSION ROBOTIC MOVEMENT (ZEISS KINEVO 900) starts after 12 months	1	108
		IMPLEMENTATION SERVICES SURGERY		
78	89109-04	INSTALLATION AND CONFIGURATION BRAINLAB CONNECTED CARE	1	
79	81001-11	INSTALLATION CURVE NAVIGATION SYSTEM	1	

BRAINLAB

Pos.	Art.No.	Description	Qty.	Period in months
		ONE-TIME SERVICES SURGERY		
80	81001-06	INTEGRATION AND VERIFICATION OF THIRD PARTY DEVICES (1 VISIT)	1	
		FREIGHT, INSURANCE AND FEES		
81	50780	FREIGHT, INSURANCE AND FEES	1	

Cirq - Platform (Optional Future Upgrade)

	USD
TOTAL EXCL. TAX	**374,148.00**
5.57% Blended Discounts	-18,821.03
7.34% Blended Discounts	-2,670.99
DISCOUNTED PRICE (EXCL. TAX)	**352,655.98**

Cirq - Stereotaxy (Optional Future Upgrade)

	USD
TOTAL EXCL. TAX	**137,409.20**
5.57% Blended Discounts	-6,468.07
7.34% Blended Discounts	-1,565.62
DISCOUNTED PRICE (EXCL. TAX)	**129,375.51**

Cirq - Spine (Optional Future Upgrade)

	USD
TOTAL EXCL. TAX	**84,937.00**
5.57% Blended Discounts	-4,015.83
7.34% Blended Discounts	-944.44
DISCOUNTED PRICE (EXCL. TAX)	**79,976.72**

Cirq - Service Contract (Optional Future Upgrade)

	USD
TOTAL EXCL. TAX	**37,133.06**
7.34% Blended Discounts	-2,724.18
DISCOUNTED PRICE (EXCL. TAX)	**34,408.87**

Curve - Navigation System for Spine (Future Optional Upgrade)

	USD
TOTAL EXCL. TAX	**287,432.20**
5.57% Blended Discounts	-12,416.12
7.34% Blended Discounts	-4,741.23

BRAINLAB

DISCOUNTED PRICE (EXCL. TAX)	**270,274.85**

Intraoperative 3rd Party Scanners Integration Kit (Optional Future Upgrade)

	USD
TOTAL EXCL. TAX	**197,064.00**
5.57% Blended Discounts	-7,394.67
7.34% Blended Discounts	-4,722.22
DISCOUNTED PRICE (EXCL. TAX)	**184,947.12**

Microscope Integration (Optional Future Upgrade)

	USD
TOTAL EXCL. TAX	**243,631.00**
5.57% Blended Discounts	-8,713.77
7.34% Blended Discounts	-6,401.93
DISCOUNTED PRICE (EXCL. TAX)	**228,515.30**

	USD
Cirq - Platform (Optional Future Upgrade)	352,655.98
Cirq - Stereotaxy (Optional Future Upgrade)	129,375.51
Cirq - Spine (Optional Future Upgrade)	79,976.72
Cirq - Service Contract (Optional Future Upgrade)	34,408.87
Curve - Navigation System for Spine (Future Optional Upgrade)	270,274.85
Intraoperative 3rd Party Scanners Integration Kit (Optional Future Upgrade)	184,947.12
Microscope Integration (Optional Future Upgrade)	228,515.30

BRAINLAB

The Trade-in Credit is contingent upon provision of a handover protocol for the below items; it will be revoked if such handover protocol is not provided before or at the time of installation of the new equipment.

A Trade-In Credit will not be paid out in cash, even if it exceeds the value of the Quotation.

Subscription contracts enabled through a Trade-In Credits will enter into force upon Acceptance (as defined above) and may not be cancelled by the customer.

Existing Service Contracts that cover the product which was traded in will automatically transfer to cover the new equipment.

Curve - Navigation System

Trade-in credit for: stealth station s7

Technical Quote Review done by

Deepshikha Sharma
Technical Sales-Northern India
deepshika@brainlab.com

Thomas Kroenung
Technical Quote Review Specialist

BRAINLAB

Medical devices included

Please see below a table showing the relation between quoted articles and medical devices (UDI-DI).

UDI-DI is the medical device Unique Device Identifier – Device Identifier.

Pos.	Art.No.	Quoted Item Name	UDI-DI	EU Declaration of Conformity Name
1	22876	CIRQ ROBOTIC BASE SOFTWARE		EU-Alignment Software Cranial 2.0
2	56500	CIRQ ARM SYSTEM 2.0	04056481143961	EU-Cirq Arm System 2.0
3	56100	CIRQ ROBOTIC ALIGNMENT MODULE	04056481141646	EU-Cirq Robotic Alignment Module (MDR)
9	22884A	CIRQ ALIGNMENT SOFTWARE CRANIAL BIOPSY	TBD	EU-Alignment Software Cranial 2.1
10	22892A	CIRQ ALIGNMENT SOFTWARE CRANIAL SEEG		EU-Alignment Software Cranial 2.1
13	B15207	CIRQ ROBOTIC SEEG ACCESSORY PACKAGE		
	52336	STERILIZATION TRAY CIRQ ROBOTIC ALIGNMENT SEEG	04056481144340	EU-Sterilization Tray
	55758-30	HEX SCREWDRIVER BALL-END 2.5 MM	04056481139285	EU-Hex Screwdriver
	56401	CIRQ ROBOTIC INSTRUMENT HOLDER CRANIAL	04056481141578	EU-Cirq Robotic Instrument Holder
	56402	CIRQ ROBOTIC TRACKING ARRAY CRANIAL	04056481141561	EU-Cirq Robotic Tracking Array
14	B15206	CIRQ ROBOTIC BIOPSY ACCESSORY PACKAGE		
	52335	STERILIZATION TRAY CIRQ ROBOTIC ALIGNMENT BIOPSY	04056481144333	EU-Sterilization Tray
	55758-30	HEX SCREWDRIVER BALL-END 2.5 MM	04056481139285	EU-Hex Screwdriver
	56401	CIRQ ROBOTIC INSTRUMENT HOLDER CRANIAL	04056481141578	EU-Cirq Robotic Instrument Holder
	56402	CIRQ ROBOTIC TRACKING ARRAY CRANIAL	04056481141561	EU-Cirq Robotic Tracking Array
	56406-38	DRILL DEPTH STOP CRANIAL 3.8 MM	04056481144388	EU-Drill Depth Stop
15	56424	ALIGNMENT BONE ANCHOR CRANIAL 2.1 MM / 3.8 MM	04056481143817	EU-Alignment Bone Anchor
16	B15210	CRANIAL BIOPSY DRILL KIT (10 CASES)		
	56405-01A	DRILL BIT CRANIAL 3.4 MM / 3.8 MM	04056481143701	EU-Drill Bit Cranial
	56423	ALIGNMENT GUIDE TUBE CRANIAL 3.8 MM / 7.5 MM	04056481144418	EU-Alignment Guide Tube
	56424	ALIGNMENT BONE ANCHOR CRANIAL 2.1 MM / 3.8 MM	04056481143817	EU-Alignment Bone Anchor
17	56102	CIRQ ROBOTICS DISPOSABLE KINEMATIC UNIT (5 PCS)	04056481141677	EU-Cirq Robotic Disposable Kinematic Unit
18	56103	DISPOSABLE CIRQ ROBOTIC ALIGNMENT DRAPE (5 PCS)	04250676737984	EU-DISPOSABLE CIRQ ROBOTIC ALIGNMENT DRAPE (3rd party)

BRAINLAB

Pos.	Art.No.	Quoted Item Name	UDI-DI	EU Declaration of Conformity Name
19	B15211	SEEG DRILL KIT PMT 2.1 MM (10 CASES)		
	56405-04	DRILL BIT CRANIAL 2.1 MM / 4.0 MM	04056481143145	EU-Drill Bit Cranial
	56406-40	DRILL DEPTH STOP CRANIAL 4.0 MM	04056481143268	EU-Drill Depth Stop
	56411	ALIGNMENT GUIDE TUBE CRANIAL 4.0 MM / 7.5 MM	04056481144401	EU-Alignment Guide Tube
22	22880A	CIRQ ALIGNMENT SOFTWARE SPINE		EU-Alignment Software Spine 2.1
24	B15200	ACCESSORY PACKAGE SPINE DRILLING FOR CIRQ PASSIVE		
	41839-27A	DRILL GUIDE TUBE 2.4 MM X 150 MM	04056481139568	EU-Spine and Trauma Instruments
	41839-28A	DRILL BIT 2.4 MM AO SHANK (SUPPORTS DEPTH CONTROL)	04056481143244	EU-Drill Bit
	41839-29A	DRILL BIT 2.4 MM AO SHANK	04056481143237	EU-Drill Bit
	41839-30B	DRILL GUIDE TUBE 3.2 MM X 150 MM	04056481139520	EU-Spine and Trauma Instruments
	41839-35B	DRILL BIT 3.2 MM AO SHANK	04056481143220	EU-Drill Bit
	41839-36A	DRILL BIT 3.2 MM AO SHANK (SUPPORTS DEPTH CONTROL)	04056481143213	EU-Drill Bit
	41839-51	DRILL GUIDE DEPTH CONTROL INSERTABLE	04056481139612	EU-Spine and Trauma Instruments
	41839-60A	DRILL GUIDE TUBE 2.6 MM X 150 MM	04056481139537	EU-Spine and Trauma Instruments
	41839-65A	DRILL BIT 2.6 MM AO SHANK (SUPPORTS DEPTH CONTROL)	04056481143114	EU-Drill Bit
	41839-69A	DRILL BIT 2.6 MM AO SHANK	04056481143176	EU-Drill Bit
	52331	STERILIZATION TRAY CIRQ INSTRUMENT HOLDER SPINE	04056481139094	EU-Sterilization Tray
	55839-62	TROCAR SHARP TIP 3.2 MM	04056481139599	EU-Spine and Trauma Instruments
	55839-64	TROCAR SHARP TIP 2.4 MM	04056481139582	EU-Spine and Trauma Instruments
	55839-66	TROCAR SHARP TIP 2.6 MM	04056481139575	EU-Spine and Trauma Instruments
	56202	CIRQ INSTRUMENT HOLDER SPINAL DRILLING	04056481139087	EU-Cirq Instrument Holder for Spinal Drilling
	56203	DRILL GUIDE COMPACT HANDLE WITH 4 MARKER SPHERES	04056481139605	EU-Spine and Trauma Instruments
31	26239E	ELEMENTS SEGMENTATION SPINE	04056481145880	EU-Brainlab Elements Contouring 5.0
32	26334C	ELEMENTS CURVATURE CORRECTION SPINE	04056481145873	EU-Brainlab Elements Image Fusion 5.0
33	26710B	ELEMENTS SPINE PLANNING		EU-Spine Planning 3.0
34	22268G	NAVIGATION SOFTWARE SPINE & TRAUMA 3D	04056481144906	EU-Spine & Trauma Navigation 3.0
35	26780A	REGISTRATION SOFTWARE SPINE		EU-Spine & Trauma Navigation 2.0
36	22263C	REGISTRATION SOFTWARE - EXTENSION SURFACE MATCHING SPINE		EU-Spine & Trauma Navigation 3.0

BRAINLAB

Pos.	Art.No.	Quoted Item Name	UDI-DI	EU Declaration of Conformity Name
37	22269C	INSTRUMENT SETUP SOFTWARE SPINE		EU-Spine & Trauma Navigation 3.0
45	B23507	ACCESSORY PACKAGE SPINE FOR UNIVERSAL INSTRUMENT INTEGRATION		
	41796-27A	HEX SCREWDRIVER T-HANDLE 2.5 MM	04056481145606	EU-Hex Screwdriver
	41798	INSTRUMENT TRACKING ARRAY STARLINK SIZE M	04056481006242	EU-Instrument Tracking Array
	41799	INSTRUMENT TRACKING ARRAY STARLINK SIZE ML	04056481006235	EU-Instrument Tracking Array
	41801	INSTRUMENT TRACKING ARRAY STARLINK SIZE L	04056481006228	EU-Instrument Tracking Array
	55016	INSTRUMENT ADAPTER STARLINK EXTENSION 50 MM	04056481142209	EU-Instrument Adapter
	55101	INSTRUMENT ADAPTER CLAMP STARLINK SIZE S	04056481005351	EU-Instrument Adapter
	55102	INSTRUMENT ADAPTER CLAMP STARLINK SIZE M	04056481005344	EU-Instrument Adapter
	55113	INSTRUMENT ADAPTER CLAMP STARLINK SOFTGRIP SIZE L	04056481141202	EU-Instrument Adapter
	55114	INSTRUMENT ADAPTER CLAMP STARLINK SOFTGRIP SIZE XL	04056481141219	EU-Instrument Adapter
46	B23527	REFERENCE PACKAGE SPINE UNIVERSAL		
	52419A	ADAPTER X-PRESS FOR PATIENT REFERENCE ARRAY	04056481146610	EU-Patient Reference Array Adapter X-Press
	52424	DOUBLE OPEN-END WRENCH 10 X 14 MM	04056481005979	EU-Wrench
	52429	BONE FIXATOR 2-PIN X-PRESS	04056481005955	EU-Spine and Trauma Instruments
	55758	SPINE REFERENCE CLAMP CARBON WITH SLIDER	04056481139278	EU-Spine and Trauma Instruments
	55758-30	HEX SCREWDRIVER BALL-END 2.5 MM	04056481139285	EU-Hex Screwdriver
	55761-02A	ADAPTER LONG FOR PATIENT REFERENCE CLAMP	04056481142742	EU-Spine and Trauma Instruments
	55761A	SPINE REFERENCE ARRAY FOR REFERENCE CLAMP CARBON (4-SPHERE GEOMETRY)	04056481142728	EU-Spine and Trauma Instruments
47	41874B	INSTRUMENT CALIBRATION MATRIX	04056481002725	EU-Instrument Calibration Matrix

BRAINLAB

Pos.	Art.No.	Quoted Item Name	UDI-DI	EU Declaration of Conformity Name
48	B23915	AWLS & PROBES		
	55830-10B	HANDLE GEARSHIFT FOR OPEN SURGERY	04056481001292	EU-Handle for Open Surgery
	55830-20A	INSTRUMENT TRACKING ARRAY SPINE & TRAUMA 3-MARKER	04056481001261	EU-Instrument Tracking Array S&T
	55830-25A	INSTRUMENT TRACKING ARRAY SPINE & TRAUMA (SIZE ML)	04056481001254	EU-Instrument Tracking Array S&T
	55830-27	INSTRUMENT TRACKING ARRAY SPINE & TRAUMA 4-MARKER	04056481001247	EU-Instrument Tracking Array S&T
	55830-30A	AWL (4.0 MM) FOR OPEN SURGERY	04056481001223	EU-Chisel, Awl, Probe for Open Surgery
	55830-35A	AWL (3.0 MM) FOR OPEN SURGERY	04056481001216	EU-Chisel, Awl, Probe for Open Surgery
	55830-40	PROBE STRAIGHT (4.5 MM) FOR OPEN SURGERY	04056481001209	EU-Chisel, Awl, Probe for Open Surgery
	55830-43	PROBE STRAIGHT (3.5 MM) FOR OPEN SURGERY	04056481001193	EU-Chisel, Awl, Probe for Open Surgery
	55830-45	PROBE CURVED (4.5 MM) FOR OPEN SURGERY	04056481001186	EU-Chisel, Awl, Probe for Open Surgery
49	B23916	CHISELS SHORT & LONG		
	55830-15A	HANDLE UNIVERSAL FOR OPEN SURGERY	04056481001278	EU-Handle for Open Surgery
	55830-25A	INSTRUMENT TRACKING ARRAY SPINE & TRAUMA (SIZE ML)	04056481001254	EU-Instrument Tracking Array S&T
	55830-29	INSTRUMENT TRACKING ARRAY SPINE & TRAUMA (SIZE L)	04056481001230	EU-Instrument Tracking Array S&T
	55830-50	CHISEL LONG FOR OPEN SURGERY	04056481001179	EU-Chisel, Awl, Probe for Open Surgery
	55830-55	CHISEL SHORT FOR OPEN SURGERY	04056481001162	EU-Chisel, Awl, Probe for Open Surgery
50	B23919	DRILL GUIDE (2.0 MM)		
	41839-38	DRILL BIT 2.0 MM AO SHANK DEPTH CONTROL 0 - 60 MM FOR DRILL GUIDE	04056481145835	EU-Drill Bit
	51839-20	DRILL GUIDE TUBE (2.0 MM)	04056481144821	EU-Drill Guide - Guide Tube, Trocar Insert
	51839-93	DRILL GUIDE TROCAR INSERT (2.0 MM)	04056481145057	EU-Drill Guide - Guide Tube, Trocar Insert
51	B23918	DRILL GUIDE (2.4 MM)		
	41839-28A	DRILL BIT 2.4 MM AO SHANK (SUPPORTS DEPTH CONTROL)	04056481143244	EU-Drill Bit
	51839-24	DRILL GUIDE TUBE (2.4 MM)	04056481144814	EU-Drill Guide - Guide Tube, Trocar Insert
	51839-94	DRILL GUIDE TROCAR INSERT (2.4 MM)	04056481145064	EU-Drill Guide - Guide Tube, Trocar Insert

BRAINLAB

Pos.	Art.No.	Quoted Item Name	UDI-DI	EU Declaration of Conformity Name
52	B23917	DRILL GUIDE (2.6 & 3.2 MM)		
	41839-36A	DRILL BIT 3.2 MM AO SHANK (SUPPORTS DEPTH CONTROL)	04056481143213	EU-Drill Bit
	41839-62	DRILL BIT 3.2 MM AO SHANK DEPTH CONTROL 60 - 100 MM FOR DRILL GUIDE	04056481145859	EU-Drill Bit
	41839-65A	DRILL BIT 2.6 MM AO SHANK (SUPPORTS DEPTH CONTROL)	04056481143114	EU-Drill Bit
	51839-26	DRILL GUIDE TUBE (2.6 MM)	04056481144807	EU-Drill Guide - Guide Tube, Trocar Insert
	51839-32	DRILL GUIDE TUBE (3.2 MM)	04056481144791	EU-Drill Guide - Guide Tube, Trocar Insert
	51839-95	DRILL GUIDE TROCAR INSERT (2.6 MM)	04056481145071	EU-Drill Guide - Guide Tube, Trocar Insert
	51839-96	DRILL GUIDE TROCAR INSERT (3.2 MM)	04056481145088	EU-Drill Guide - Guide Tube, Trocar Insert
53	B23920	DRILL GUIDE (4.5 MM)		
	41839-39	DRILL BIT 4.5 MM AO SHANK DEPTH CONTROL 0 - 60 MM FOR DRILL GUIDE	04056481145842	EU-Drill Bit
	41839-64	DRILL BIT 4.5 MM AO SHANK DEPTH CONTROL 60 - 100 MM FOR DRILL GUIDE	04056481145866	EU-Drill Bit
	51839-45	DRILL GUIDE TUBE (4.5 MM)	04056481144784	EU-Drill Guide - Guide Tube, Trocar Insert
	51839-97	DRILL GUIDE TROCAR INSERT (4.5 MM)	04056481145095	EU-Drill Guide - Guide Tube, Trocar Insert
54	B23921	DRILL GUIDE HANDLE WITH 4 MARKER ARRAY		
	51839	DRILL GUIDE HANDLE	04056481144838	EU-Drill Guide - Handle, Array, Depth Control
	51839-01	DRILL GUIDE DEPTH CONTROL (0 – 60 MM)	04056481144777	EU-Drill Guide - Handle, Array, Depth Control
	51839-02	DRILL GUIDE DEPTH CONTROL (60 – 100 MM)	04056481144760	EU-Drill Guide - Handle, Array, Depth Control
	51839-03	DRILL GUIDE ARRAY	04056481144753	EU-Drill Guide - Handle, Array, Depth Control
55	52321	STERILIZATION TRAY DRILL GUIDE	04056481145491	EU-Sterilization Tray
56	52307	STERILIZATION TRAY INSTRUMENTS SPINE	04056481122836	EU-Sterilization Tray
57	55830-10B	HANDLE GEARSHIFT FOR OPEN SURGERY	04056481001292	EU-Handle for Open Surgery
58	53153	DISPOSABLE CLIP-ON REMOTE CONTROL (20 PCS)	04056481005634	EU-Disposable Clip-on remote Control
59	54929	DISPOSABLE FIXATION PIN 4.0 MM X 125 MM (10 PCS)	04056481145200	EU-Fixation Pin
60	55846	DISPOSABLE TROCAR INSERT FOR PEDICLE ACCESS NEEDLE (5 PCS)	04056481005108	EU-Disposable Trocar Insert Pedicle Access Needle

BRAINLAB

Pos.	Art.No.	Quoted Item Name	UDI-DI	EU Declaration of Conformity Name
62	B13313	AUTO-REGISTRATION HARDWARE PACKAGE UNIVERSAL AIR		
	19142-06	RADIOLUCENT DRAPELINK INTERFACE FOR CALIBRATION PHANTOM INTRAOPERATIVE CT	04056481004637	EU-Calibration Phantom Intraoperative CT
	19148-01A	CALIBRATION PHANTOM INTRAOPERATIVE CT	04056481004569	EU-Calibration Phantom Intraoperative CT
	19148-02A	STORAGE CASE FOR CALIBRATION PHANTOM INTRAOPERATIVE CT		EU-Calibration Phantom Intraoperative CT
	19152-02	RADIOLUCENT DRAPELINK PATIENT REFERENCE ARRAY	04056481004545	EU-Radiolucent DrapeLink Array
	52324	STERILIZATION TRAY REGISTRATION UNIVERSAL AIR	04056481139353	EU-Sterilization Tray
	55749-01	REGISTRATION MATRIX CT SPINE (OPEN SURGERY)	04056481140052	EU-Automatic Registration 2.5
	55749-02	REGISTRATION MATRIX CT SPINE (SMALL INCISION)	04056481140076	EU-Registration Matrix CT
	55749-03	REGISTRATION MATRIX CT CRANIAL AND SPINE (MINIMALLY INVASIVE)	04056481140069	EU-Automatic Registration 2.5
63	26735B	AUTO-REGISTRATION SOFTWARE UNIVERSAL AIR SPINE	04056481145101	EU-Automatic Registration 2.7
65	22182	DISPOSABLE PATIENT SCAN DRAPE (10 PCS)	00748426115891	EU-Patient Scan Drape (3rd party)
68	23511B	NAVIGATION SOFTWARE MICROSCOPE	04056481145828	EU-Microscope Navigation 1.7
69	23512	NAVIGATION SOFTWARE MICROSCOPE - EXTENSION HEAD-UP DISPLAY	04056481145828	EU-Microscope Navigation 1.7
70	23513	NAVIGATION SOFTWARE MICROSCOPE - EXTENSION AUGMENTED REALITY	04056481145828	EU-Microscope Navigation 1.7
71	23514	NAVIGATION SOFTWARE MICROSCOPE - EXTENSION ROBOTIC MOVEMENT (ZEISS KINEVO 900 / KINEVO 900 S)	04056481145828	EU-Microscope Navigation 1.7
72	15241-02	MICROSCOPE INTERFACE CABLE 4.0 (ZEISS KINEVO 900 / TIVATO 700)		EU-Curve Navigation
73	B11501	MICROSCOPE ADAPTER AND TRACKING ARRAY (ZEISS KINEVO 900)		
	41767-19A	MICROSCOPE TRACKING ARRAY	04056481141899	EU-Microscope Tracking Array
	41767-55B	MICROSCOPE ADAPTER FOR TRACKING ARRAY (ZEISS)	04056481003777	EU-Microscope Adapter