1. **General Specifications**
   1. The navigation system shall support:
      1. Trans-cranial tumor resection
      2. Frameless stereotactic biopsy procedures
      3. Trans-nasal endoscopic FESS (Functional Endoscopic Sinus Surgery) and Skull base surgeries
   2. Shall provide full instruments set for:
      1. **Brain Tumor resection** (i.e. Articulated arm, two patient frames, straight probe, registration probe, calibrator, sterilization tray)
      2. **Biopsy procedures** (i.e. Articulated arm, dual adaptor, biopsy aiming device, biopsy probe, reducing tube, sterilization tray)
      3. **Trans-nasal procedures** (i.e. Bayonet probe, registration probe, maxillary and frontal seekers, forehead patient reference, universal tracker, calibrator, sterilization tray).
   3. The navigation cart shall be:
      1. Stand-alone with only one power cable (No cable running to the patient table).
      2. A mobile touch display cart and a separate infrared camera cart for flexible positioning in the O.R.)
      3. Motorized joints for remote-controlled camera alignment with integrated laser pointer for fast and intuitive camera alignment.
      4. Camera Height: Range from 1000 mm to 2485 mm.
      5. Easily accessible connection panel for integration of intraoperative devices.
      6. 100-V – 240V, 50-60Hz.
   4. Shall satisfy the minimum requirements for the navigation computer:
      1. Screen: Large >= 27 " capacitive touch display for clear viewing and easy control 4K resolution (3840 x 2160 pixels) for brilliant visualization of clinical data).
      2. Processor: Intel Core i7 11th CPU or newer with 32GB RAM and 1TB SSD, and NVidia RTX 3070 GPU
      3. Peripherals: DVD Drive and USB 3.2
      4. Glass front for easy cleaning and disinfection and metal back for durability.
   5. The registration process shall take no longer than 2 minutes, and shall preferably include contactless acquisition of surface registration points on patients’ skin.
   6. Shall provide options to mount patient reference frame on:
      1. The skull holder
      2. The patient forehead
   7. Shall support CT & MRI images with image fusion capability, with ultrasound digital integration capability.
   8. Import DICOM images from DVD, USB and PACS.
   9. Shall support anatomical landmark registration and trace/surface registration.
   10. Shall provide planning features for segmentation of tumor and 3D modeling.
   11. Shall provide planning features for virtual craniotomy and visualizing brain tissues and fiber tracking capabilities.
   12. Shall provide features for compensation for distortions in MR datasets with deformable co-registration enabling contouring and tractography across modalities.
   13. Shall support virtual tip extension.
   14. Shall provide Navigation layouts to display anatomical, trajectory and probe eye views.
   15. Shall support automatic registration using intra-op CT and C-arm.
   16. Shall have video documentation of the entire navigation procedure.

# Tracking Device

* 1. Tracking system shall use the optical technology with accuracy of 0.2mm or better.
  2. The Tracking system shall provide reliable accuracy and will not be interfered in presence of any metallic surgical instrument or under OR light.
  3. Instruments reflective markers designed to be disposable.
  4. Instruments will be pre-calibrated and will not require re-calibration before each case.
  5. Shall provide a minimum of Two (2) expandable universal trackers to transform any surgical instruments to navigation enabled instruments.
  6. Shall provide visual feedback of the accuracy of the instruments tips and shall calibrate them if they are out of calibration.
  7. Shall provide live video from the working field for intuitive positioning of the tracking device and avoiding line of sight issues.

# Consumables

* 1. Shall provide free supply of 15 disposable biopsy needles.

# Regulatory, Warranty and Support

* 1. Shall be CE approved.
  2. Shall provide 2 years’ comprehensive warranty from the date of installation **and applied use.**
  3. Shall provide on-site training of the system to the OR staff.
  4. Shall provide free software upgrades during the product’s lifetime **according to the contrast.**
  5. Shall provide free online and remote support during the product’s lifetime.

**Optional:**

* **The navigation system supports spine procedures.**
* Provide full instruments set for Spine Procedures (i.e. navigated awl, registration probe, patient reference frame, spinous clamp, Percutaneous Surgery Unit, Universal trackers, calibrator, automatic registration solution for intra-op 3D CT, sterilization tray) C-Arm Registration.
* Shall provide options to mount patient reference frame on attachment for Open or MIS Spine surgery
* Shall provide free supply of disposable parts for spine surgeries for up to 100 procedures.
* Shall support pre-op and intra-op pedicle screw planning.