

## APPENDIX 3s

### LOT 19 SPECIFICATION

#### SURGICAL NAVIGATION SYSTEMS, ACCESSORIES, ASSOCIATED OPTIONS AND RELATED SERVICES

##### 1. Introduction

1.1. This Lot is for the supply of surgical navigation systems for use in surgeries including neurosurgery, spinal surgery, ear, nose and throat (ENT) surgery, orthopaedic surgery and trauma surgery. This lot also includes the supply of accessories, associated options and related services including biopsy guides/systems/needles, probes, probe adaptors, universal tool adaptors, calibration equipment, registration systems, frames, stereotactic frame integration, markers, instruments and instrumentation sets, screens, workstations, software, licences, upgrades, applications, head frames, lasers, tracers, reference stars, printers, 3D printers, microscope reference arrays, electromagnetic disposables, spare parts, case coverage, training and extended warranties.

1.2. The core product lines within this Lot are as follows:

Line Number	
1	Cranial /Neurosurgery/Spinal Surgical Navigation System
2	Ear, Nose and Throat (ENT) Surgical Navigation System
3	Orthopaedic/Trauma Surgical Navigation System

1.3. All product line(s) must be supplied with a minimum 6 year expected lifecycle under proper use and maintenance.

1.4. All navigations systems are expected to comprise of three key elements

- 1.4.1. Workstation and planning system or server based planning system.
- 1.4.2. Tracking and localisation system.
- 1.4.3. Ancillary equipment.

1.5. All workstation and planning systems/sever based planning systems must enable the user to reconstruct the patient's anatomy in 3-D and tri-planar two-dimensional images, provide imaging tools and, where required, quantitative calculations for surgical planning.

1.6. All tracking and localisation systems must have:

- 1.6.1. Optical and/or electromagnetic tracking options.
- 1.6.2. The capability for automatic and/or manual registration, in which the digital images of the patient's anatomy in the system are linked with the

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patient's physical position and the surgical instrument or implant to be tracked.

- 1.6.3. The ability to allow intraoperative re-registration.
- 1.6.4. The ability to provide a real-time image of the actual probe used by the surgeon and a navigational guide, showing the exact position of the probe relative to the patient's anatomy.
  
- 1.7. Any reusable instrumentation provided with a system must be suitable for sterilisation and reprocessing.
  
- 1.8. Project management must be available to the customer as an option to purchase.
  
- 1.9. Initial end user training (including training on software applications) must be provided free of charge upon installation, or at a time requested by the customer.
  
- 1.10. Installation is required (excluding any interface) and this must be free of charge and undertaken at a location specified by the customer

## **2. Line 1 – Cranial/Neurosurgery/Spinal Surgical Navigation System**

- 2.1. This is the core technical specification for the supply, delivery, installation and commissioning of a surgical navigation system for cranial/neuro/spinal surgeries, including surgical resection of brain tumours, epilepsy surgery, image guided biopsies of brain tissue, insertion of catheters and electrodes, and spinal surgery.
  
- 2.2. A Workstation and planning system or server based planning system for Cranial, Neurosurgery and Spinal Surgical Navigation must be capable of the following:
  - 2.2.1. Integrating with the Picture Archiving and Communication System (PACS) and import any DICOM images from Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Fluoroscopy and Ultrasonography systems.
  - 2.2.2. Identifying incision location, trajectories from the incision to the target on the patient's images, and, where required, provide distance and volumetric measurements, and segmentation of target lesions.
  - 2.2.3. Patient registration using either fiducial markers/anatomical points and/or surface matching registration.
  - 2.2.4. A position-sensing localisation method with an accuracy of better than 2mm.
  - 2.2.5. The system shall utilise navigation sensors/adaptors that allow for tip tracking of rigid, flexible and malleable surgical instruments, including but not limited to stylets, endoscopes and biopsy needles.
  
- 2.3. Additional capability is required depending on specification required for the customer – recognising that some will need only cranial neurosurgery

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specification, some will need only spinal surgery specification and some will require both.

- 2.3.1. Cranial planning with image fusion, fibre tracking, BOLD MRI mapping, Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), and also spine planning.
- 2.3.2. Providing neuro-navigation for biopsy, tumour resection, cerebrospinal fluid (CSF) management, and stereotactic planning procedures; ability to incorporate intra-operative imaging acquisitions.
- 2.3.3. Integrating with surgical microscopes to enable the user to visualise the workstation images through microscope oculars and navigate the microscope's focal point as a virtual probe.
- 2.3.4. Spinal Planning – Multimodality data-set fusion; Trajectory planning for screw placement.
- 2.3.5. Spinal – Intra-operative guidance for spinal fixation with ability to incorporate intra-operative imaging acquisitions.

### **3. Line 2 – Ear, Nose and Throat (ENT) Surgical Navigation System**

- 3.1. This is the core technical specification for the supply, delivery, installation, and commissioning of a surgical navigation system for ENT procedures, including skull-based surgeries and functional endoscopic sinus surgery.
- 3.2. A workstation and planning system or server based planning system for ENT surgical navigation must be capable of the following:
  - 3.2.1. Integrating with the PACS and import any DICOM images from CT and MRI.
  - 3.2.2. Provide distance and volumetric measurements, and segmentation of target lesions.
  - 3.2.3. Allowing the user to pre-plan the entire ENT procedure and then perform an image-guided realisation.
- 3.3. A tracking and localisation system for ENT surgical navigation must be capable of the following:
  - 3.3.1. Integrating with an endoscope system.
  - 3.3.2. Integrating with suction system instrumentation.
  - 3.3.3. Patient registration using either fiducial markers/anatomical points and/or surface matching registration.
  - 3.3.4. A position-sensing localisation method with an accuracy of better than 2mm.

### **4. Line 3 – Orthopaedic/Trauma Surgical Navigation System**

- 4.1. This is the core technical specification for the supply, delivery, installation and commissioning of a surgical navigation system for orthopaedic and/or trauma surgery, including hip surgery, knee surgery, and spinal surgeries.

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- 4.2. A workstation and planning system or server based planning system for orthopaedic/trauma surgical navigation must be capable of the following:
  - 4.2.1. Integrating with the PACS and import any DICOM images from CT, fluoroscopy, and ultrasonography systems.
  - 4.2.2. Identify incision location, trajectories from the incision to the target on the patient's images and provide distance and volumetric measurements.
  - 4.2.3. Creating a digital template for a total knee or hip replacement and trauma procedures.
  - 4.2.4. A network-based option for remote planning flexibility away from the operating theatre must be available for purchase.
  - 4.2.5. Being compatible with any templates for orthopaedic implants from third parties.
  - 4.2.6. Providing surgical navigation and producing patient-specific 3-D models, using information obtained in the operating room (non-image-based information may be acquired by a camera from specific anatomical reference points).
  - 4.2.7. Providing drill guides for use during an orthopaedic procedure.
  - 4.2.8. Registering and displaying images acquired during the procedure.
  
- 4.3. A tracking and localisation system for orthopaedic/trauma surgical navigation must be capable of the following:
  - 4.3.1. Being supplied with position sensors including adhesive-backed, implantable fiducial markers and pins or externally mounted fiducials that are compatible with imaging systems including CT and fluoroscopy systems.
  - 4.3.2. Performing image-less tracking.
  - 4.3.3. A position-sensing localisation method with an accuracy of better than 2mm and 1.7 degrees RMS (Root Mean Square).
  - 4.3.4. An anatomy-specific percutaneous referencing system.

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