**Standard Operating Procedure (SOP) for the Use of Robotic Scalpel in Hand Surgery**

**1. Purpose**

This SOP provides clear guidelines on the safe ordering, access, operation, infection control, and disposal of a robotic scalpel used in hand surgery. The procedure ensures compliance with hospital standards, regulatory requirements, and patient safety protocols.

**2. Scope**

This SOP applies to all clinical and non-clinical personnel involved in ordering, accessing, using, and maintaining the robotic scalpel in the operating theatre, including procurement staff, surgeons, surgical assistants, scrub nurses, and infection control teams.

**3. Responsibilities**

* **Procurement Team**: Responsible for ordering and receiving the robotic scalpel and ensuring it meets hospital requirements.
* **Operating Theatre Manager**: Manages access to the device and ensures that it is available and operational for scheduled surgeries.
* **Surgeons**: Operate the robotic scalpel during hand surgeries, following this SOP.
* **Scrub Nurse/Technician**: Assists the surgeon with the setup and handling of the robotic scalpel in the operating room.
* **Infection Control Team**: Ensures compliance with infection prevention standards.
* **Disposal Officer/Technician**: Manages the safe and regulated disposal of single-use components or equipment at the end of their life cycle.

**4. Procedure**

**4.1. Ordering and Delivery of the Robotic Scalpel**

1. **Request and Approval**:
   * The surgeon or operating theatre manager submits a request for a robotic scalpel to the procurement team.
   * The procurement team ensures the product is compliant with hospital standards and regulatory guidelines (e.g., MHRA approval in the UK).
   * A purchase order is generated and approved by the relevant department.
2. **Vendor Coordination**:
   * The procurement team coordinates with the manufacturer to confirm product specifications, delivery date, and any required training or installation services.
   * A designated contact person from the hospital receives the delivery.
3. **Receiving the Device**:
   * On arrival, the robotic scalpel is inspected by the biomedical engineering team to ensure it is fully functional.
   * The device is logged into the hospital’s asset management system, including serial numbers, software versions, and service history.

**4.2. Accessing the Robotic Scalpel in the Operating Theatre**

1. **Scheduling and Preparation**:
   * The robotic scalpel must be scheduled for use in the hospital’s surgical scheduling system at least 48 hours before the planned surgery.
   * Ensure all necessary disposable instruments and accessories (e.g., scalpels, trocars, sutures) are available.
   * Verify that the robotic system software is up to date before the procedure.
2. **Device Preparation**:
   * The operating theatre technician is responsible for setting up the robotic scalpel at least 30 minutes before surgery.
   * Conduct a pre-operation systems check to ensure:
     + All robotic arms and control units are functioning.
     + Instruments are correctly attached.
     + Calibration is complete.
3. **Surgeon Setup**:
   * The surgeon verifies that the system is properly configured, performs any last-minute adjustments, and familiarizes themselves with patient-specific preoperative planning.

**4.3. Infection Control Requirements**

1. **Sterilization of the Robotic Scalpel**:
   * All reusable components (e.g., robotic arms) must be sterilized before and after every surgical procedure, following standard hospital sterilization protocols.
   * Disposable components such as scalpel blades must be replaced for every surgery.
2. **Surgical Instruments**:
   * Instruments attached to the robotic system (e.g., scissors, needle holders) must be handled as per standard sterile procedures.
   * Sterile barriers or drapes should be used on the robotic arms to prevent contamination during surgery.
3. **Preoperative and Postoperative Infection Control**:
   * All personnel involved in the operation (surgeons, nurses, technicians) must follow hand hygiene and gowning protocols.
   * The operating theatre must undergo thorough cleaning and sterilization after each surgery, including all surfaces and any components of the robotic system that may have been exposed.

**4.4. Operation of the Robotic Scalpel**

1. **Patient Positioning and Setup**:
   * Ensure the patient is correctly positioned to facilitate robotic-assisted hand surgery. Proper positioning minimizes complications and ensures optimal access to the surgical site.
2. **Robotic Console Operation**:
   * The surgeon controls the robotic scalpel from the console, with real-time monitoring and adjustments. Key steps:
     + Navigate through the controls to ensure precision in movements.
     + Perform the surgery in line with pre-surgery planning and using the robotic scalpel for dissection, suturing, or bone repair.
     + Communicate with the surgical team throughout the procedure.
3. **Intraoperative Adjustments**:
   * The robotic arms and instruments may need repositioning or recalibration during the surgery, which should be handled by the operating theatre technician under the guidance of the surgeon.
   * Any issues or malfunctions with the robotic system must be reported and addressed immediately.

**4.5. Postoperative Actions**

1. **Shutdown and Cleaning**:
   * Once the surgery is completed, power down the robotic system according to manufacturer guidelines.
   * Clean and sterilize the device thoroughly, especially any parts that were directly involved in the procedure.
   * Single-use components should be safely removed and disposed of as per the hospital’s infection control protocols.
2. **Maintenance Logs**:
   * The operating theatre technician must log any maintenance activities, including system updates, repairs, or component replacements.
   * Submit an entry into the maintenance log after every surgery to track system use and performance.

**4.6. Disposal of Single-Use Equipment and End-of-Life Components**

1. **Single-Use Components**:
   * Scalpel blades, sutures, and any other disposable items used during the procedure should be disposed of in accordance with hospital biohazard waste disposal policies.
   * Sharps (e.g., blades) must be placed in designated sharps containers.
2. **End-of-Life Components**:
   * For reusable robotic parts that reach their end of life, the hospital’s biomedical engineering team should evaluate them for safe disposal.
   * Follow manufacturer guidelines and local regulations for the recycling or disposal of electronic equipment or surgical instruments.
3. **Regulatory Compliance**:
   * Ensure that all disposals comply with hospital regulations as well as environmental health standards for medical devices.
   * A disposal certificate must be issued and stored for any high-value or regulated components.

**5. Record-Keeping and Reporting**

1. **Device Usage Logs**:
   * Record the use of the robotic scalpel in the hospital’s asset management system, including details of the surgery, surgeons involved, and any technical issues encountered.
2. **Incident Reporting**:
   * Any malfunctions, errors, or complications with the robotic scalpel during surgery must be reported to the operating theatre manager and documented in the incident reporting system.
3. **Annual Review**:
   * The surgical team and hospital administration should conduct an annual review of the robotic scalpel’s use, including performance, maintenance, and clinical outcomes.

**6. Review and Updates to SOP**

* This SOP should be reviewed and updated annually or whenever new updates regarding the robotic scalpel are issued by the manufacturer or regulatory authorities.

**7. Key Contacts**

* **Procurement Team Lead**: [Name and Contact Info]
* **Biomedical Engineering**: [Name and Contact Info]
* **Operating Theatre Manager**: [Name and Contact Info]
* **Infection Control Officer**: [Name and Contact Info]
* **Disposal Officer**: [Name and Contact Info]