Trust Standard Operating Procedure

University Hospitals Plymouth NHS Trust

SOP for management and verification of Implants during invasive procedures.

Issue Date	Review Date	Version
May 2021	May 2026	4

Purpose

To provide a local standard for the management of prosthesis/implants used as part of invasive procedures.

Who should read this document?

All staff working in operating theatres in University Hospitals Plymouth NHS Trust and Tavistock Hospital

Key Messages

Robust processes for the management and verification of implants are essential to ensure the correct surgical placement of the appropriate implant. Failure to have a safe system for management and verification of implants could lead to patient harm, poor surgical outcomes and financial consequences for individuals and organisations.

Core accountabilities	
Owner	Cindy McConnachie – Senior Matron Theatres and Anaesthetics, Quality, Governance and Strategy. Jenny Pitt – Matron Theatres
Review	Theatre Clinical Governance Committee
Ratification	Surgical Clinical Governance Lead Theatres
Dissemination	Cindy McConnachie – Senior Matron Theatres and Anaesthetics, Quality, Governance and Strategy
Compliance	Theatre Matrons.

Links to other policies and procedures

Version History

1	April 2015	New policy, incorporating National Standards for management of prosthesis in invasive procedures
2	April 2016	Amended policy following clinical incident. Interim awaiting outcome of RCA
3	April 2018	Revised in to new template and minor amendments
3.1	September 2020	Minor Amendments

4	May 2021	Minor Amendments

The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available in the Document Library. Larger text, Braille and Audio versions can be made available upon request.

Standard Operating Procedures are designed to promote consistency in delivery, to the required quality standards, across the Trust. They should be regarded as a key element of the training provision for staff to help them to deliver their roles and responsibilities.

Standard Operating Procedure (SOP)

For the management and verification of implants during invasive procedures.

1 Introduction

Introduction

A prosthesis or implant is defined as an internal or external medical device for artificial replacement of an absent or impaired structure. Verification is essential for the correct surgical placement of the appropriate prosthesis.

The effects arising from incorrect prosthesis selection may include patient factors, e.g. mortality, morbidity and further procedures; surgical factors, e.g. substandard clinical outcome and financial costs, e.g. discarded prosthesis, medicolegal repercussions, cancelled cases due to lack of prosthesis availability.

Sterile implants are used in many specialities within theatres throughout the trust. This Standard Operating Procedure will define the local standard for management of implants during the following phases:

- Pre procedure.
- During the procedure
- After the procedure.

The aim is to ensure that the correct implant is supplied, selected and opened for the correct patient, therefore minimising the risk of harm. Failure to adhere to the process may impact on patient safety in the event the wrong prosthesis being implanted.

2 Definitions

Prosthesis/implant is defined as an internal or structural medical device for artificial replacement of an absent or impaired structure

The terms prosthesis and implant are synonymous in this Standard Operating Procedure (SOP).

3 Regulatory Background

In 2015, NHS England issued a patient safety alert, which supported the introduction of the National Safety Standards for Invasive Procedures (NatSSIP's)

All NHS funded organisations are required to develop local safety standards for invasive procedures (LocSSIP's) that include the key steps outlined within the National standards and to harmonise practice across the organisation.

NHS Organisations are accountable to their Clinical Commissioning Group and to the CQC for implementing local standards. Trust boards are responsible for ensuring local standards are created and harmonised with NatSSIP's.

4 Key Duties

- Theatre Policy Group - The body responsible for writing the Policies and Procedures used in Theatres
- Theatre Governance Board - The committee responsible for ensuring that the Theatre Policies and Procedures are followed
- Senior Matron, Theatres and Anaesthetics – Senior Nurse in overall charge of the day to day running of Theatres, responsible for safety, quality and efficiency
- Theatre Team Leaders – responsible for conducting regular audit of practice and ensuring their teams are practicing according to the policy and undertake annual review of practice
- Stores Manager – Responsible for ordering and maintaining stock items
- Consultant/Surgeon – responsible for identifying the specifications of the implant required for the individual patient and requesting implants when not stock items
- Service Line Manager – responsible for requesting non stock implants via Senior Team Leader
- Senior Team Leader- responsible for ensuring none stock implants are ordered and received prior to the date of the scheduled procedure
- Theatre Team Leader - responsible for the checking of stocks, ordering and ensuring that expiry dates are checked regularly, for implants kept outside of areas managed by the stores team.

- Organisation - responsible for the development of systems and processes to ensure implants can be tracked/traced to individual patients (enabling the recall of patients should a particular implant need monitoring or replacing).

5 Procedure to Follow

Pre-procedure management:

5.1. The correct type of prosthesis for a procedure can be communicated in the following ways:

- Via the surgeons kardex – if the prosthesis is a standard make, material and size routinely used for a procedure
- Stock items synonymous with the procedure eg osiclaur implants, variax plates and screws
- Non-stock or non-standard implants – surgeon to communicate requirements to the Theatre Team Leader, with sufficient time for the implants to be ordered and received. This must also be annotated on the operating list.

5.2 Permanent stocks of prostheses must have named individual(s) responsible for the checking of stock levels, expiry dates and ordering Out of date stock must be removed from circulation. This can be done by the Theatre team leader or Stores team.

5.3 The surgeon/operator or Service Line Manager must take responsibility for ensuring that the requirement for a non-standard/non stock implant is annotated on the operating list and where possible, specific information to include type, make and size or range of sizes.

5.4 The surgeon is responsible for ensuring device compatibility and specifying any defining characteristics eg size, strength, laterality.

5.4 Non-stock items must be ordered and received by a named individual in good time for the procedure, including any patient specific details. The name of the responsible person **must** be available to the theatre team.

5.5 The surgeon **must** confirm the prosthesis, or range of implants, required for the entirety of the operating list at the Safety Briefing at the start of the list.

5.6 The Theatre team must confirm that the correct implant for the patients is available prior to collecting the patient.

5.7 All required implants must be available near to the operating theatre but not inside the operating theatre, unless the implants are stored in the theatre, with no laterality or size variation for the procedure e.g. osicular implants, variax plates and screws.

During the procedure:

5.8 The surgeon/operator **must** request the required implant stating 'type', size, side and manufacturer where applicable

5.11. The scrub practitioner **must** confirm audibly the required implant/s to the circulating practitioner. The circulating practitioner must write this information on the transfer pad and on the swab board, before collecting the required implant/s. Only the implants identified for definite implantation are to be brought inside the operating theatre.

- Exceptions reference storage/annotation on swab board include those implants where laterality is not involved, there is no size variation or the implant size is chosen during the procedure e.g. osicular implants, variax plates and screws, IM nails and associated implants for orthopaedic/trauma surgery. These implants may be kept within scrub or prep room and do not need to be written on the swab board.

5.12. Before implants are opened, the scrub practitioner **must** request a ***'silent cockpit'*** in order to confirm the implant.

5.13. The Circulating practitioner **mus**t then check the implant with **BOTH** the scrub practitioner and the surgeon/operator, verbalising the following prosthesis characteristics;

- Type, design, style or material
- Size
- Laterality
- Manufacturer
- Expiry date
- Sterility
- Dioptre for lens implants
- Compatibility of multi-component prosthesis
- Any other required characteristics
- Programmable Shunt state pressure setting
- Fixed pressure Shunt state pressure required
- Bactiseal or not for ventricle/Peritoneal catheters

5.14. Where more than one implant is being used the surgeon **must** confirm implant compatibility

5.15. In areas where scan for safety is in use the implant should then be scanned

5.16. The outer packaging of the implant is then opened by the circulating practitioner. The surgeon and scrub practitioner then check the inner packaging to confirm the correct implant

5.17. The silent cockpit **must** remain in place for the duration of the time it takes to confirm all required implants prior to implantation taking place

After the procedure:

5.18. A record of the specific implant used for a patient must be made within the patient record. Also the National Joint Registry and the UK Shunt Registry (Orion database) where necessary. Where a manufacturer's label is available, this **must** be placed in the notes. When this is not available, the following information **must** be recorded.

- Manufacturer
- Style
- Size
- Manufacturer's unique identifier for the implant, e.g. serial number
- Shunt pressure setting

5.19. Compliance with local, national and international implant registries is a requirement

Failed Prosthesis verification:

5.20. Should any of the following occur:

- Failed prosthesis verification
- Wrong prosthesis insertion
- Near miss

There should be immediate escalation of the concern to the team leader, Matron for the area and the operating Surgeon. The Surgeon will determine if there is any action to take at this point to ensure the safety and wellbeing of the patient. This must be a clinical decision and **must** be documented in the patient's notes.

5.21. In the event of confirmed wrong prosthesis insertion, the following should be completed:

- Inform Surgical Care Group Clinical Director/Manager or Head of Nursing
- Inform Theatre Central Cluster Manager and Matrons
- Inform Risk and Incident Team
- Completion of Trust Electronic Incident Report
- Record of actions **must** be made within the patient record.
- Patient **must** be informed, apology issued and full duty of candour applied. The patient **must** be informed that an investigation will be undertaken and that they will be kept informed of the progress and outcome of this.

6 Document Ratification Process

The design and process of review and revision of this procedural document will comply with The Development and Management of Formal Documents.

The review period for this document is set as default of five years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be reviewed by the Theatre Policy & standard committee and ratified Clinical Governance Lead.

Non-significant amendments to this document may be made, under delegated authority from the Clinical Governance Lead by the nominated author. These must be ratified by the Clinical Governance Lead and should be reported, retrospectively, to the Theatre Policy & standard committee

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes.

7 Dissemination and Implementation

Following approval and ratification, this procedural document will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process.

Document control arrangements will be in accordance with The Development and Management of Formal Documents.

The document author(s) will be responsible for agreeing the training requirements associated with the newly ratified document with the Clinical Director / Clinical Governance Lead.and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

8 Monitoring and Assurance

- Datix incidents specific to management of implants/prosthesis will be monitored continuously.

  This information will be reported via the Theatre Clinical Governance Committee which meets monthly and speciality specific information will be communicated to the specific area for further

9 Reference Material

NHS England (2015) National Safety Standards for Invasive Procedures (NatSSIPs) September 2015

NHS England (2015) Patient safety alert*:* Supporting the introduction of the National Safety Standards for Invasive Procedures. September 2015