

Standard Operating Procedure for management and verification of Implants during invasive procedures.

Issue Date	Review Date	Version
July 2019	July 2020	3

Purpose

To provide a local standard for the management of prosthesis/implants used in 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 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	Service Line Director for Theatres
Dissemination	Cindy McConnachie – Senior Matron Theatres and Anaesthetics, Quality, Governance and Strategy
Compliance	Theatre Matrons.

Links to other policies and procedures

Version History

V1	April 2015	New policy, incorporating National Standards for management of prosthesis in invasive procedures
V2	April 2016	Amended policy following clinical incident. Interim awaiting outcome of RCA
V3	July 2019	Revised in to new template and 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.

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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.

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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 to patients. Should the process not be adhered to the implication for the patient is that patient safety is compromised and/or the wrong implant could be 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

4.1 A nominated individual(s) is responsible managing the procurement process and management of permanent or specialist orders.

4.2 Theatre staff (nominated person) – must check availability of required implants

4.3 The Circulating practitioner selects required implant when requested

4.4 Peri-operative team – must engage in silent cockpit during the checking process.

4.5 Surgeon - must specify the size and side of implant plus any defining characteristics e.g.: in cases where specific size or strength is required. In addition the surgeon must check implant and confirms implant compatibility.

4.6 A record of the specific implant used for a patient must be made within the patient record and National Joint Registry where applicable

4.7 The specific implant must be scanned in line with scan for safety in all participating areas

4.8 Organisations are required to develop systems and processes to ensure they can track and trace an implant to a specific patient. This will enable identification of any product issues and for recall of patients should implants need monitoring or replacement.

5 Pre-procedure management:

5.1. The surgeon or operator **must** ensure that the requirement for any individualised prosthesis is annotated on the operating list. Where possible, specific information to include type, make and size or range of sizes should be listed.

5.2 When a prosthesis is non-standard or is not included in an agreed permanent prosthesis/implant stock, i.e. a “non-stock” implant, the surgeon **must** ensure that the prosthesis requirements are communicated effectively to the procedural team in sufficient time for the implants to be ordered and received. Or follow any speciality specific SOP’s/Policies

If the prosthesis is a standard make, material and size then it may be listed within the surgeons kardex rather than annotated on the operating list e.g. inguinal hernia mesh.

5.3 A named team member **must** be responsible for the ordering and for checking that the correct implant has been delivered before the procedure. The name of the responsible person **must** be available to the team – unless another agreed stores/procurement process is in place.

5.4 When permanent stocks of prostheses are maintained in the organisation, named individual(s) **must** be responsible for the checking of stocks, ordering and ensuring that expiry dates are checked regularly. Out of date stock must not be used and must be removed - unless stock is managed by a stores/procurement team who then undertake this responsibility.

5.5 Prior to the list team brief, a nominated member of the theatre team **must** ensure ALL implants for the list are checked. Implants and all equipment required to ensure implant placement is then confirmed by the scrub practitioner during team brief.

5.6 The surgeon **must** use the safety briefing before the start of a procedural list to confirm with the procedural team that the required prosthesis, or range of implantable material is present near to the procedural area (eg a prep room) but **not** in the actual operating theatre. * NB Cath labs

5.7 The operator **must** inspect the available prosthesis and confirm that the correct prosthesis or ranges of implantable material is available before arranging for the patient to be brought to the procedural area. The most appropriate time to undertake the inspection is considered the team brief.

During the procedure:

- 5.8 The Surgeon **must** request the required implant stating 'type', size and side
- 5.9 The scrub practitioner **must** confirm out loud, to the circulating practitioner, the required implant/s. The circulating practitioner writes this information on the transfer pad (if implants are to be collected from outside of the theatre) and on the swab board before collecting the required implant/s – only the implants identified for definite implantation are to be brought into the actual operating theatre. **(Other sizes within a range that may or may not be required are to be kept outside of the theatre for example in the prep room)**
- 5.10 Before implants are opened, the scrub practitioner **must** request '**silent cockpit**' in order to confirm implant.
- 5.11 The Circulating practitioner **must** then check the implant with **BOTH** the scrub practitioner and the lead surgeon, reading out loud 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.
- 5.12 Where more than one implant is being used the surgeon **must** confirm implant compatibility
- 5.13 In areas where scan for safety is in use the implant should then be scanned
- 5.14 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
- 5.15 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
- 5.16 Any implants not to be used for that patient **must** be kept outside of the operating theatre to reduce the potential for confusion and an error to occur at the time of implantation.

After the procedure:

5.17 After the procedure a record of implants used **must** be made in the patient's notes. 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

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

Failed Prosthesis verification

5.19 Should an incident occur where there has been any of the following:

- Failed prosthesis verification
- Wrong prosthesis insertion
- Near miss

There should be immediate escalation of 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.

5.20 In the event of confirmed wrong prosthesis insertion, the following should be informed:

- Surgical Care Group Clinical Director/Manager or Head of Nursing
- Theatre Central Cluster Manager and Matrons
- Risk and Incident Team

5.21 Trust Electronic Incident reports

- A Trust electronic incident report **must** be completed for instances of failed prosthesis verification, wrong prosthesis insertion or instances of near miss
- 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 one year 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 Governance Committee / Theatre Policy & standard committee and ratified by the Clinical Director / Clinical Governance Lead.

Non-significant amendments to this document may be made, under delegated authority from the Clinical Director / Clinical Governance Lead by the nominated author. These must be ratified by the Clinical Director / Clinical Governance Lead and should be reported, retrospectively, to the Theatre Governance Committee / 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, currently the 'Vital Signs' electronic newsletter.

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.

- Audit of prosthesis verification process and data will be conducted monthly by process of observation of practice.
- 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

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