

Policy for management of Sharps in Operating Theatres and Procedural rooms

Issue Date	Review Date	Version
April 2018	April 2023	V5

Purpose

This policy identifies the correct procedure for counting sharps in the operating theatre and procedural rooms for invasive procedures.

Who should read this document?

This policy applies to personnel employed by University Hospitals Plymouth Trust (UHPHNT) and to personnel working in satellite facilities under the remit of UPHT

Key Messages

This policy will ensure that there is a system in place for the safe handling and management of instrument and sharps used in clinically invasive procedures and that they are accounted for at all times to prevent foreign body retention and subsequent injury to the patient.

Core accountabilities

Owner	Elton Trevor – Senior ODP Cindy McConnachie Senior Matron Theatres and Anaesthetics Michelle Smith – Theatre Matron Jenny Pitt – Theatre Matron
Review	Theatre Governance Committee
Ratification	Theatres Director Lead
Dissemination	Senior Matron – Theatres and Anaesthetics
Compliance	Theatre Policy Committee

Links to other policies and procedures

Throat Pack Use in Theatre

Standard operating procedure: Quarantine of surgical instruments used for 'High Risk' surgical procedures (2012)

Policy for Swab counts in the Operating theatre (Dec 2015)

Version History

V1	2.09.08	Final review by the Theatre Policy, Practice and Procedure Group, for signing through the Theatre Management Board
V1.2	28.01.09	Reviewed following several serious incidents
V2.0	May 2013	Policy reviewed and changed to stand alone Sharps policy.
V3	December 2015	Policy reviewed and changes approved
V4	September 2017	Reviewed to consider special cause variation where microscopes utilised and National Safety Standards for Invasive Procedures (NatSSIP's, 2015)
V5	April 2018	To be reviewed

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 on Trust Documents on StaffNET. Larger text, Braille and Audio versions can be made available upon request.

DRAFT

Contents

Section	Description	Page
1	Introduction	4
2	Purpose, including legal or regulatory background	4
3	Definitions	4
4	Duties	5
5	Sharps Counting in Perioperative Environment	5 - 9
6	Overall Responsibility for document	10
7	Consultation and ratification	10
8	Dissemination and Implementation	10
9	Monitoring compliance and effectiveness	10
10	References and associated documents	11
Appendix 1	List of Minor Procedures	11
Appendix 2	Examples of miscellaneous items to be counted	12
Appendix 3	Change of scrub practitioner	13
Appendix 4	Competency	14 - 15
Appendix 5	Dissemination plan	15
Appendix 6	Review and approvals checklist	16 - 17

1 Introduction

The Theatre Policy and Standards Group is committed to ensuring the safety of patients undergoing surgical procedures and recognises the need for a standardised procedure for management of Sharps in the Operating Theatre and procedural rooms. A clear policy enables the implementation of standard practice and reinforces the principle of consistency.

All staff has a responsibility to themselves, their colleagues and patients to safely handle, monitor and dispose of sharps and medical devices. As Health Care Practitioners the law is clear that they have a duty of care and are accountable for the care that is delivered. Health Care Practitioners must ensure that no harm is caused by leaving foreign objects in cavities during invasive procedures or disregard this policy; The risk exists for accidentally unplanned retention of surgical items and a standardised strategy accounting for items opened during a surgical procedure must be complied to as the risk cannot always be predicted;. All actions **must be** in compliance with European Directive 2010/32/EU.

2 Purpose

- 2.1 To provide a safe system for the counting, handling and managing sharps for invasive surgical procedures, that is in accordance with NatSSIP's (2015)
- 2.2 To eliminate the likelihood of a "Never Event" and promote engagement in the Surgical Safety Checklist process.
- 2.3 To identify responsibilities of staff for counting and recording.
- 2.4 To provide a standardised counting and recording system.
- 2.5 To provide a safe system to be followed when discrepancies occur.

3 Definitions

Sharps are designed to perform a specific function, for example

- Puncture, cut, saw
- Haemostatic electrode blades
- Guide wires

NB: For the purpose of this Policy the term sharp will refer to all single use and re-usable instruments/medical devices.

All sharps have the potential to become a foreign body if left in a wound and **must** be included in the general counts for all invasive procedures, including minimally invasive procedures.

Miscellaneous disposable bio-medical devices are classed as clinical waste following use.

Countable items may include, **but are not limited to**

- Scalpel Blades
- Suture needles
- Hypodermic needles
- Guidewires with connectors

- Endoscopic equipment including disposable items
- Miscellaneous small items that have the potential to be retained in a surgical wound (see Appendix 1)

4 Duties

Theatre Policy and Standards Group - The body responsible for writing the Policies and Procedures used in Theatres.

Theatre Governance Committee - The committee responsible for validating and ensuring that the Theatre Policies and Procedures are adhered to

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 Matrons and Team leaders – responsible for monitoring of local standards and reporting compliance

5 Sharps Counting in the perioperative Environment

Inclusion Criteria

5.1 Invasive Procedures

Each count for invasive procedures must be performed by two members of staff, one of whom must be a Registered Nurse (RN) or Operating Department Practitioner (ODP), Assistant Practitioner who has been assessed competent in the management of surgical counts..

Whenever possible, the same two perioperative staff should perform all the counts that are done during the surgical procedure.

5.2 Minimally Invasive Procedures (Definition – Appendix 2)

For minimally invasive procedures, such as excisions of lesions and biopsies carried out within a minor operations list performed under a local anaesthetic, the count must be performed by two practitioner's, one of whom must be a Registered Nurse (RN), Operating Department Practitioner (ODP) or Assistant Practitioner, who has been assessed competent in the management of surgical counts.

5.3 Preparation

All sharps are counted prior to the commencement of the procedure and before the team undertake the Surgical Safety check: "Time Out".

5.4 Packaging

The sharps packaging must be inspected to confirm that it is intact, dry and sterility is not compromised.

The expiry date must be checked prior to the commencement of the procedure and whenever any additional sharps are requested by the scrub practitioner.

5.5 Times of the Count

Counts of sharps must be performed

- Just before the start of the operation
- At the start of closure of a cavity
- On completion of wound closure
- At any other time it is deemed necessary and this includes on changeover of practitioner and/or surgeon during the case.

NB When additional sharps are added to sterile field this is added to the running total.

5.6 Change of Scrub Practitioner

In the event it is deemed necessary to change scrub practitioners, the first scrub practitioner will remain scrubbed until they have completed handover, unless there is a significant reason to not perform full handover (See appendix 3).

- A **full** count must be performed by both practitioners simultaneously and with another circulating person who will remain until the end of the surgical procedure when possible. The off going scrub practitioner will record handover of the count in the Integrated Care Pathway.

NB: Full count includes all instruments and bio-medical devices opened for the procedure.

5.7 The Counting Environment

Counts will be carried out in 'Silent Cockpit'

During counts the 'count time out' is established. Music must be turned off, phones/pagers are left unanswered and all unnecessary conversation ceases until the count is finished and is reported as correct. If necessary, the operating surgeon will enforce the 'Silent Cockpit' principle.

At the end of the final count the Surgical Safety Checklist "sign out" should immediately be performed to finalise the end of the procedure.

5.7.1 Method

Using a logical sequence to count and check sharps the Scrub Practitioner and circulator **must** -

- Count out loud and together confirm sharps present.

Scrub Practitioner **must** -

- Confirm sharps that have individual elements are present and safely stored on sterile field until required.

Circulator following count **must**-

- Record on the *first count transfer pad* and on completion of initial count transfer information on to the Dry Wipe Board located in Theatre

5.7.2 Identified miscellaneous sharps (see Appendix 1) that have potential to be retained items **must** be recorded as part of count on dry whiteboard.

5.7.3 When additional sharps are added to the sterile field steps 7.1 **must** be performed and circulator records additional items on dry wipe board.

NB Visual verification when atraumatic packets are opened assists an accurate count. Empty atraumatic packets should not be used to rectify a discrepancy in a closing count; although it can assist in reducing count discrepancy.

5.7.4 In the event that a sharp is inadvertently dropped from the sterile field, the circulator must safely retrieve the item. This sharp **must** be shown to the scrub practitioner before placing it in a sharps bin. In order to record that the sharp has been disposed of; the circulator **must** amend the count on the whiteboard by crossing through the total and subtract the amount of sharps removed from the count. The new count will reflect the number of sharps in circulation on the sterile field. The circulator will record in a separate area:

- sharp disposed of
- time of event
- record of their name

5.7.5 No sharps will be removed from the operating theatre until the operation is complete and the Scrub Practitioner is satisfied that the final count is correct and the Surgical Safety Check List “sign out” has been completed.

5.8 Waived Counts

In some circumstances e.g. a life-threatening emergency, it is recognised that it is not always possible to perform a count before surgery starts. In these circumstances all packaging must be retained to allow a count to be performed as soon as possible. Rationale for non-compliance to follow policy must be documented in the patient’s Perioperative Integrated Care Pathway (PICP).

5.9 Documents

The counts will be recorded in the patient's PICP.

At the end of a procedure, the Scrub Practitioner **must** check that the record of intra-operative counts has been signed in the PICP document and the Surgical Safety Checklist has been completed.

5.10 Discrepancies

5.10.1 If the count is incorrect, the operating surgeon must be informed at once

A second count **must** then be performed under 'Silent Cockpit' conditions

If the item is still unaccounted for:

- The Scrub Practitioner **must** perform a visual inspection of the area around the sterile field
- Circulating staff in theatre **must** carry out a thorough search for the missing item
- The Surgeon may decide to perform a methodical wound examination until the item is located and retrieved, and should delay further wound closure until located and retrieved
- When a missing item is found, the count **must** be repeated and the surgeon informed that it is now correct.

5.10.2 If the item is still missing, there should be a pause, during which time a verbal discussion must take place with the team. This is to risk assess the need for a diagnostic intervention and to consider the course of action which is in the 'best interest' of the patient. Evidence suggests that 10/10, 9/10 and 8/10 sutures will not be visible on x-ray, therefore diagnostic intervention is not appropriate. Plain x-ray is recommended (MHRA, 2005), fluoroscopy/image intensifier in such circumstances as they fail to locate radiopaque swabs/items.

If the patient's condition does not allow for diagnostic intervention, the senior practitioner on duty **must** be called, ie Band 6 or 7 or Theatre Matron. If x-ray intervention is not performed and the item still remains missing, the Senior Matron Theatres and Anaesthetics, Theatre Service line manager or Trust On-Call Duty Manager (out of hours) must be informed and the event discussed with the patient, their next of kin or significant other. If a missing item is not found, the Scrub Practitioner **must** complete a Trust Electronic Incident Report.

The patient's clinical condition must continue to be monitored until the earliest opportunity that allows for diagnostic intervention, if appropriate, to take place to confirm that the missing sharp has been identified and located. If appropriate, at the earliest opportunity, the patient should be returned to theatre for removal of

missing retained item. The Surgeon, Scrub Practitioner and Senior Practitioner must be informed of the result.

5.10.3 In the event that a sharp is broken inter-operatively the Scrub Practitioner **must** inform the Surgeon immediately and ideally retrieve all elements. The sharp is removed from the surgical field and Scrub Practitioner **must** check that all the broken elements are present.

At the end of the procedure an electronic Incident (Near Miss) report is completed by the Scrub Practitioner.

5.10.4 A risk assessment **must** be made by the Surgeon in the event of lost/ un-retrieved sharp/sharp fragments. In the event that the Surgeon decides that the sharp/sharp fragment remains in situ, a Trust Incident report must be completed. The Surgeon **must** record the risk associated with not retrieving the fragments in the patient's notes and the patient or their family must be informed.

5.10.5 Trust Electronic Incident Reports

A Trust Electronic Incident Report **must** be completed:

- If the sharp is found prior to the patient leaving theatre, the incident is classed as a "near miss".
- A Trust Electronic Incident report **must** be completed if a diagnostic intervention is performed to locate a missing sharp
- If the Surgeon has not completed the incident form, then it is incumbent upon the scrub practitioner to do so.
- A record of the incident **must** be made in the patient's PICP.
- Patients must be provided a full explanation and apology in line with Duty of candour. This must be documented within the patient record and on the Trust Electronic Incident report.

5.10.6 General Points

- Staff and learners **must** not be involved with counting procedures until assessed and signed off as competent (See Appendix 4).
- A formative assessment is a stage in developing competency in this process and is not sufficient to allow the learner to act as second checker, without supervision from a competent practitioner who will countersign the instrument count documentation.

- In the event that 2 surgical procedures are occurring simultaneously, with 2 different scrub practitioners and sharps counts, each scrub practitioner is responsible for their sharps count. In this event the 2 different counts are recorded independently in the PICP document.

DRAFT

6 Overall Responsibility for the Document

Senior Matron Theatres and Anaesthetics – Quality, Governance and Strategy
Project Lead NatSSIP's – Cindy McConnachie

7 Consultation and Ratification

The design and process of review and revision of this policy 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 Governance Committee and ratified by the Director Lead.

Non-significant amendments to this document may be made, under delegated authority from the Director, by the nominated owner. These must be ratified by the Director lead.

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.

8 Dissemination and Implementation

Following approval and ratification, this policy 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 owner will be responsible for agreeing the training requirements associated with the newly ratified document with the named Director and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

9 Monitoring Compliance and Effectiveness

Monitoring will be undertaken by the Theatre Governance Committee who will audit compliance of the policy.

Theatre Matrons and Team leaders are responsible for auditing practice against this policy monthly and reporting compliance at the monthly Performance Standards review.

In addition they will be responsible for investigating any incidents reported via the Trusts Electronic Reporting system.

10 References and Associated Documentation

Association for Perioperative Practice (July, 2017) Accountable items swab, instrument and Sharps count SOP Swab Counts

SOP for Instrument Counts

Westonburg and Parkinson - The small last suture needle – is x-ray worthwhile (2001)

BJU International

MHRA 2005

DIRECTIVES

COUNCIL DIRECTIVE 2010/32/EU

of 10 May 2010

implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EP

Examples of Miscellaneous Countable Items but not limited to-

Appendix 1

Atraumatics (suture needle)
Hypodermic Needle
Saw blades
Guide wires
Finger switch long and short blades-
Multilock retractor

- Skin tags / Skin biopsy
- Incision & drainage of an abscess
- Warts
- Mole removal
- Biopsy of skin growths
- Verrucae
- Benign skin naevi
- Hairy moles
- Penile & vaginal warts
- Spider veins
- Haemorrhoids excision treatment
- In-growing toenails
- Lipomas / Fatty tumours
- Laceration / Incision / repair of skin & soft tissue
- Leg vein treatment
- Joint injections
- Triggerpoint injections
- Dorsal slit for phimosis
- Breast biopsy / Endometrial biopsy sample
- Bartholins cyst / abscess
- Vulval biopsy / Cervical polyps
- Cervical loop excision biopsy
- Fine needle aspiration cytology & biopsy
- Foreign body removal from skin & soft tissue
- Insertion of contraceptive coils
- Epidural injections

The change of Scrub Practitioners should be kept to a minimum.

A discussion within the team, should take place before a practitioner scrubs for a long procedure, to assess their suitability and their shift times.

If it is necessary to change Scrub Practitioners (through illness or very long procedures) the first practitioner will remain scrubbed until they have completed their handover, unless they are unable due to illness.

A complete count should be performed by both practitioners.

The change of scrub practitioner will be recorded in the patient care pathway. If any discrepancies occur, please refer to Section 11.

DRAFT

Assessor Print Name		Date commenced
Staff Print Name		Date to be completed by

The purpose of this document is to record the assessment /competence process for correct Instrument counts. Staff should not be involved with counting procedures until assessed as competent to do so.

The learning process will require Self assessment, Formative assessment and Summative assessment. Benner’s Model Skill level 1-5 indicator will be used to indicate your knowledge and skill at of the process.

A time frame will be determined by the assessor for you to achieve minimum level 3 competences.

Self-verification is undertaken against each statement prior to formative assessment this will indicate the training required as part of the learning process, where there is an identified deficit in your knowledge/skill it is your responsibility to ensure that you seek further training.

Essential pre-reading: Policy for management of Sharps in Operating Theatres and Procedural rooms

Competency	Evidence	Self - assessment level 1-5	Formative	Summative
1.1 Demonstrates knowledge of the trust policy for counting sharps	Discuss			
1.2 Demonstrates a working knowledge of accountability when designated role as counter with scrubbed person	Discuss Demonstrate s			
1.3. Demonstrates recording count on “first count” transfer pad	Demonstrate s			
1.4 Demonstrates transferring record of count from transfer pad correctly on the whiteboard	Demonstrate s			
1.5 Intraoperatively demonstrates safe handling of sharps when dropped or counted off sterile field	Demonstrate s			
1.6 Can discuss rationale for counting additional sharps on to sterile field	Demonstrate s			
1.7 Can discuss rationale for all sharps to remain in theatre until all counts completed and Scrub practitioner confirms to Surgeon	Discuss			

1.8 Can discuss procedure for managing broken sharps	Discuss			
1.9 Can discuss process in the event of discrepancy of counts				
Print Name of Assessor	Assessor Signature		Date completed	
Print Name of Staff	Staff signature			

Association for Perioperative Practice (2007) AfPP Standards and Recommendations for Safe Perioperative Practice, Harrogate, Association for Perioperative Practice

Association of Perioperative Registered Nurses (AORN) (2011) *Perioperative Standards and Recommended Practices* AORN Inc

WHO Surgical Safety Checklist (2009) National Patient Safety Agency SOP for Swab Counts

On completion photocopy and send copy to Perioperative Clinical Educators

Dissemination Plan

Appendix 5

Core Information				
Document Title	Policy for management of Sharps in Operating Theatres and Procedural rooms			
Date Finalised	September 2013			
Dissemination Lead	Senior Matron Cindy McConnachie			
Previous Documents				
Previous document in use?	Yes			
Action to retrieve old copies.	Yes – archived by the Theatre Policy Group and Trust Document Controller			
Dissemination Plan				
Recipient(s)	When	How	Responsibility	Progress update
Theatre Band 7				
Local Induction				
All Trust wide theatre teams				
All Surgeons & Anaesthetists				

Review and Approvals Checklist		
Title	Is the title clear and unambiguous?	Yes
	Is it clear whether the document is a policy, procedure, protocol, framework, APN or SOP?	Yes
	Does the style & format comply?	Yes
Rationale	Are reasons for development of the document stated?	Yes
Development Process	Is the method described in brief?	Yes
	Are people involved in the development identified?	Yes
	Has a reasonable attempt has been made to ensure relevant expertise has been used?	Yes
	Is there evidence of consultation with stakeholders and users?	Yes
Content	Is the objective of the document clear?	Yes
	Is the target population clear and unambiguous?	Yes
	Are the intended outcomes described?	Yes
	Are the statements clear and unambiguous?	Yes
Evidence Base	Is the type of evidence to support the document identified explicitly?	Yes
	Are key references cited and in full?	Yes
	Are supporting documents referenced?	Yes
Approval	Does the document identify which committee/group will review it?	Yes
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	N/A
	Does the document identify which Executive Director will ratify it?	Yes
Dissemination & Implementation	Is there an outline/plan to identify how this will be done?	Yes
	Does the plan include the necessary training/support to ensure compliance?	Yes
Document Control	Does the document identify where it will be held?	Yes
	Have archiving arrangements for superseded documents been addressed?	Yes
Monitoring Compliance & Effectiveness	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Yes
	Is there a plan to review or audit compliance with the document?	Yes
Review Date	Is the review date identified?	Yes
	Is the frequency of review identified? If so is it acceptable?	Yes
Overall Responsibility	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes

Core Information	
Manager	Amanda Worley – Service Line Manager Jemma Edge – Service Line Cluster Manager
Directorate	Theatre Central
Date	April 2018
Title	Policy for management of Sharps in Operating Theatres and Procedural rooms
What are the aims, objectives & projected outcomes?	These guidelines have taken into consideration the cultural/religious and gender needs of patients. There is no impact on equality groups and no further action is required.

DRAFT