University Hospitals of Morecambe Bay
NHS Foundation Trust

Document Type: **Procedure**	**Unique Identifier:** ENDO/LOCSSIP/003
Document Title: **Local Safety Standards for Invasive Procedures (LocSSIP) for:** **The verification and opening of devices for endoscopic implantation**	**Version Number:** 3 **Status:** Ratified
Scope: Endoscopists (The Operator) Clinical unit Managers All nurses and support staff working in the endoscopy unit.	**Classification:** Departmental
Author / Title: Lindsey Kelsall, Advanced Nurse	**Responsibility:** Endoscopy
Replaces: Version 2, UHMB LocSSIPs Patient Safety Standards Procedural Document for: The verification and opening of devices for endoscopic implantation, Endo/LocSSIP/003	**Head of Department:** Jackie Pennington, Matron Endoscopy FGH & WGH Lindsey Kelsall, Advanced Nurse Practitioner Gastroenterology
Does this document refer to and account for the prescribing, supply, storage or administration of medication (especially via electronic media)? **N/A**	
Validated By: Medicine Procedural Document Group	**Date:** 04/08/2022
Ratified By: Medicine Governance and Assurance Group	**Date:** 31/08/2022
Review dates may alter if any significant changes are made	**Review Date:** 01/08/2025
• Does this document meet the requirements under the Equality Act 2010 in relation to age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation? **Yes** • Does this document meet our additional commitment as a Trust to extend our public sector duty to carers, veterans, people from a low socioeconomic background, and people with diverse gender identities? **Yes**	
Document for Public Display: No	

CONTENTS

1. SUMMARY

In the endoscopic unit a high volume of care, tailored to individual patient needs, is delivered by differently trained staff working with specialised technology in a busy and sometimes challenging environment.

Despite a genuine commitment to safe practice and a high degree of technical competence, there is ample scope for error.

Implantation of the wrong endoscopic device where the implant/device is fixed in the patient other than that specified in the procedural plan, either prior to or during the procedure, whereby the incident is detected at any time after the implant/device is placed in the patient is a 'Never Event'[1] .

A 'Never Event' has the potential to cause serious patient harm and can often, in cases of wrong device implantation cause disablement to the patient and instigate the need for a further interventional procedure. An error of this type is both devastating to patient and staff and not without further risk to the patient.

2. PURPOSE

The UHMB LocSSIPs for Endoscopic Device Verification Safety Standards are congruent with the NHS NatSSIPs (National Safety Standards for Invasive Procedures directive)[2] . The standards in this LocSSIP form an incremental checking process, when all the steps in the checking process are followed; they facilitate both assurance of the correct device and traceability standards for the correct device to be implanted into the correct patient.

The steps are simple and systematic; the Operator performing the endoscopic procedure and the procedural support team must ensure that the safety standards occur at the critical points prior to and during the invasive procedure.

These standards do not work in isolation but work in collaboration with the safety standards outlined in 'The Safe Endoscopy Standards' (see Section 6 for link) which is embraced at UHMB for all patients undergoing endoscopic procedures in the unit.

3. SCOPE

The standards within this procedural document will be applicable to those endoscopic patients and practiced without deviation by the endoscopist (the Operator) and the procedural team when a device is to be implanted.

- The Endoscopist will retain the overall responsibility for ensuring that the correct type and size of device is implanted in the patient.
- The Endoscopist has overall responsibility for ensuring that no non retainable parts of the device are retained at implantation.
- The Endoscopist has accountability that any manufacturer's instructions and literature is fully understood and followed.
- The lead nurse in the procedural support team has overall responsibility to ensure that tracking, traceability and re ordering occurs.

4. PROCEDURE

Local Safety Standards for device selection and verification
Device and Implant stock should be safely stored as close to the procedural room as possible, If practicable they can be stored on a moveable stock retaining trolley. This can then be move in and out of procedural rooms as required.

4.1 STEP 1: Prior to the commencement of the endoscopic list

- Stock reconciliation must be undertaken on a regular basis by the team and a record or log kept to demonstrate it has occurred..
- Discussion regarding device availability must occur on the day of scheduled lists and prior to the list start at the list Safety Briefing.
- It is the responsibility of the Operator to confirm that the implants present are suitable for the patients scheduled on the list.

4.2 STEP 2: Device size confirmation and initial verification during the endoscopic procedure

The following must be verbally stated in a clear auditable tone by the operator:
- The device name
- The device size
- The site if relevant
- implant/device that they have requested before they are selected
- Expiry date

4.3 STEP 3: Final device Verification prior to implantation

The Operator must confirm that the boxed implant before it is opened is the required device/implant.

This verification check must also include integrity of the prosthesis packaging for:
- Sterility including the Expiry date of sterility
- Size, type and site if applicable

4.4 CHECK 4: Traceability, Record Keeping & Reordering of Prosthesis implanted

- In each procedural room where devices are implanted, a traceability implant book must be maintained.
- 1 set of stickers from the device must be secured in the procedural room implant traceability book, along with a patient identification label – from which the re-ordering of the used implant can cross referenced as a check for the re-order process if required.
- Scan the device label onto the designated section on the electronic I.C.P. (Integrated Care Pathway).
- The device size/s will also be logged into patients electronic care record where systems allow.

4.5 Endoscopic Devices List

The manufacturer or device may change; the standards for implantation remain the same.

- Oesophageal stents - CareFusion
- Rectal stents - Boston Scientific
- Biliary stents - Cook
- Endoclips - Boston Scientific
- Polyloops – Olympus
- PEG

4.6 Errors, Discrepancies, untoward events

- Errors, discrepancies or near misses are untoward incidents.
- Detection of a wrongly implanted device is not exclusively limited to the time of insertion. It can be after or at clinic follow up upon realising any device implanted is incorrect; firstly ensure any immediate appropriate actions have been taken.
- The incident must be escalated and reported on the Trusts Patient Safety Module (Safeguard) by the raising of a Clinical Incident Report (CIR).
- The incident will be then be managed and investigated in line with the Trust's Policy for the management of incidents (see Section 6 for link).
- Always ensure that Duty of Candour if to be applied is followed according to policy (see Section 6 for link to 'Being Open' policy).

5. ATTACHMENTS	
Number	**Title**
1	Description of NatSSIP
2	Monitoring
3	Behavioural Standards Framework
4	Equality & Diversity Impact Assessment tool

6. OTHER RELEVANT / ASSOCIATED DOCUMENTS The latest version of the documents listed below can all be found via the Trust Procedural Document Library intranet homepage.	
Unique Identifier	**Title and web links from the document library**
Endo/LocSSIP/002	LocSSIP for: 4 Steps for Patient Safety (Endoscopy)
Corp/Proc/022	Reporting and Investigation of Incidents including Serious Incidents
Corp/Pol/023	Being Open

7. SUPPORTING REFERENCES / EVIDENCE BASED DOCUMENTS	
Every effort been made to review/consider the latest evidence to support this document?	Yes
If 'Yes', full references are shown below:	
Number	**References**
1	NHS England (2018) Revised Never Events Policy and Framework. Available at: Revised-Never-Events-policy-and-framework-FINAL.pdf (england.nhs.uk) (link checked and amended 03/08/2022)
2	NHS England (2015) National Safety Standards for Invasive Procedures (NatSSIPs) Available at: NHS England » National safety standards for invasive procedures (NatSSIPS) (link checked and amended 03/08/2022)

8. DEFINITIONS / GLOSSARY OF TERMS	
Abbreviation or Term	**Definition**
CIR	Clinical Incident Report
ICP	Integrated Care Pathway
UHMB	University Hospitals Morecambe Bay
MBHT	Morecambe Bay Hospital Trust
PEG	Percutaneous Endoscopic Gastrostomy

9. CONSULTATION WITH STAFF AND PATIENTS Enter the names and job titles of staff and stakeholders that have contributed to the document		
Name/Meeting	**Job Title**	**Date Consulted**
Sarah Marshall	WGH Endoscopy Unit Manager	12/07/2022
Suzanne Langley	FGH Endoscopy Unit Manager	12/07/2022
Kelly Langley	RLI Endoscopy Unit Manager	12/07/2022
Zoe Sayles	Endoscopy Service Manager	03/08/2022

10. DISTRIBUTION & COMMUNICATION PLAN	
Dissemination lead:	Lindsay Kelsall
Previous document already being used?	Yes
If yes, in what format and where?	Trust Procedural Document Library
Proposed action to retrieve out-of-date copies of the document:	Contact Policy Coordinator
To be disseminated to:	
Document Library	
Proposed actions to communicate the document contents to staff:	Include in the UHMB Weekly News – New documents uploaded to the Document Library

11. TRAINING		
Is training required to be given due to the introduction of this procedural document? **No** **If 'Yes', training is shown below:**		
Action by	**Action required**	**To be completed (date)**

12. AMENDMENT HISTORY				
Version No.	**Date of Issue**	**Page/Selection Changed**	**Description of Change**	**Review Date**
2	3.10.19		Whole document review	01/10/2022
3	31/08/2022		Reviewed. No changes	01/08/2025

Appendix 1: Description of NatSSIP

Description of NatSSIP which are mandatory inclusion in this LocSSIP. The mandatory standards in this document are not all the standards required for prosthesis verification, the only inclusion is what is relevant to this particular standard	By Whom	Where identified	Inclusion achieved
The operator must use the safety briefing before the start of the procedural list to confirm the range/type prostheses required		Standard 4 4.1 check 1 bullet points 1 to 4.	Yes
The operator must visually inspect and confirm the prosthesis with the team prior to the patient being sent to the operating area.		Standard 4 4.1 check 1 bullet point 5	Yes
A record of implants must be made		Standard 4.4 Traceability & Recording – all bullet points	Yes
The organisation must have in place a process for recording which prosthesis are used for which patients.		As above	Yes
Reconciliation of item used during invasive procedure		4.4 Reordering	Yes

Appendix 2: Monitoring

Section to be monitored	Methodology (incl. data source)	Frequency	Reviewed by	Group / Committee to be escalated to (if applicable)

Appendix 3: Behavioural Standards Framework

To help create a great place to work and a great place to be cared for, it is essential that our Trust policies, procedures and processes support our values and behaviours. This document, when used effectively, can help promote a workplace culture that values the contribution of everyone, shows support for staff as well as patients, recognises and celebrates the diversity of our staff, shows respect for everyone and ensures all our actions contribute to safe care and a safe working environment - all of which are principles of our Behavioural Standards Framework.

Behavioural Standards Framework – Expectations 'at a glance'

Appendix 4: Equality & Diversity Impact Assessment Tool

University Hospitals of Morecambe Bay NHS Foundation Trust

Equality Impact Assessment Form

Department/Function	Endoscopy	
Lead Assessor	Lindsey Kelsall	
What is being assessed?	LocSSIP for: The verification and opening of devices for endoscopic implantation	
Date of assessment	July 2022	
What groups have you consulted with? Include details of involvement in the Equality Impact Assessment process.	Network for Inclusive Healthcare?	NO
	Staff Side Colleague?	NO
	Service Users?	NO
	Staff Inclusion Network(s)?	NO
	Personal Fair Diverse Champions?	NO
	Other (including external organisations): YES – Endoscopy User Group	

1) **What is the impact on the following equality groups?**

Positive:	**Negative:**	**Neutral:**
➢ Advance Equality of opportunity ➢ Foster good relations between different groups ➢ Address explicit needs of Equality target groups	➢ Unlawful discrimination / harassment / victimisation ➢ Failure to address explicit needs of Equality target groups	➢ It is quite acceptable for the assessment to come out as Neutral Impact. ➢ Be sure you can justify this decision with clear reasons and evidence if you are challenged

Equality Groups	**Impact** (Positive / Negative / Neutral)	**Comments** ➢ Provide brief description of the positive / negative impact identified benefits to the equality group. ➢ Is any impact identified intended or legal?
Race (All ethnic groups)	Neutral	
Disability (Including physical and mental impairments)	Neutral	
Sex	Neutral	
Gender reassignment	Neutral	
Religion or Belief	Neutral	
Sexual orientation	Neutral	
Age	Positive	16 years and above
Marriage and Civil Partnership	Neutral	
Pregnancy and maternity	Neutral	
Other (e.g. carers, veterans, people from a low	Neutral	

socioeconomic background, people with diverse gender identities, human rights)		

2) In what ways does any impact identified contribute to or hinder promoting equality and diversity across the organisation?	
3) If your assessment identifies a negative impact on Equality Groups you must develop an action plan **to avoid discrimination and ensure opportunities for promoting equality diversity and inclusion are maximised.** ➢ This should include where it has been identified that further work will be undertaken to further explore the impact on equality groups ➢ This should be reviewed annually.	

Action Plan Summary

Action	**Lead**	**Timescale**

This form will be automatically submitted for review for Policies and Procedures once approved by Policy Group. For all other assessments, please return an electronic copy to EIA.forms@mbht.nhs.uk once completed.