Ministry of Health Malaysia

*Guideline on*

# The Management of Unintended Retained Surgical Item (URSI)

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Medical Care Quality Section
Medical Development Division
Ministry of Health Malaysia

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**GUIDELINE ON THE MANAGEMENT OF UNINTENDED RETAINED SURGICAL ITEM (URSI)**

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Medical Care Quality Section
Medical Development Division
Ministry of Health Malaysia
Level 4, Block E01, Complex E
Federal Government Administrative Centre
62590 Putrajaya.

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# Foreword by the Director General of Health Malaysia

Surgical item unintentionally left in patient following surgery may cause physical and emotional harm to patient. Despite the meticulous effort by healthcare practitioners to prevent this incident from occurring, the Ministry of Health Incident Reporting System still receive reporting of unintentionally retained surgical item nationwide. Thus, preventive strategies such as understanding and compliance to the Safe Surgery Saves Lives Programme, adherence to SOP of intra-op swab and instrument count strictly by the operating room nurses, effective communication and proper documentation are essential in preventing such incidents.

"Unintended retained surgical item (URSI)" was previously known as "unintended retained foreign body". This terminology is updated consistent with the international terminology. URSI has also been included as part of the Malaysian Patient Safety Goals 2.0.

In order to help in managing URSI, it is further sub-categorised into three groups depending on the mechanism of the incident; Category 2 and 3 of URSI are considered a "never event" and Ministry of Health is targeting zero case nationally.

- Category 1 - The surgical team was aware of the RSI, however, the surgeon determined the risk of retrieval is more than the risk of retention and thus leaves the item in the patient (e.g. broken drill bit in the bone).
- Category 2 - The surgical team was aware of the count discrepancy or broken surgical item(s) but unable to locate after thorough search according to the standard of practice.
- Category 3 - The surgical team was not aware at all of the RSI at the end of surgery. The RSI was discovered after the patient presented with symptoms or was accidentally detected.

The timely arrival of this "Guideline on The Management of Unintended Retained Surgical Item" aims to provide a practical guide to the healthcare practitioners, necessary appropriate steps to be taken should the incident occurred; in order to prevent or reduce further patient harm. This guideline needs to be used together with the "Ministry of Health Malaysia Guidelines on Safe Surgery Saves Lives Programme, 2nd Edition".

On behalf of the Ministry of Health, I would like to extend my gratitude and congratulations to each and every one who contributed their knowledge, experience and time in formulating this guideline spearheaded by the Medical Care Quality Section, Medical Development Division, Ministry of Health Malaysia and Safe Surgery Saves Lives Steering Committee, Ministry of Health. My appreciation also goes to every individual who has been working tirelessly in ensuring patient safety and safe surgery in our healthcare facilities.

**Tan Sri Dato' Seri Dr. Noor Hisham Abdullah**
Director-General of Health Malaysia
Chairman of Patient Safety Council Malaysia

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# *Acknowledgement*

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- **Dato' Dr. Mohammad Anwar Hau Abdullah, MoH Head of Orthopaedic Service, Chairman of MoH Safe Surgery Saves Lives Steering Commitee.**
- **Members of MoH Safe Surgery Saves Lives Steering Commitee.**
- **All the contributors.**
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- **My team from Medical Care Quality Section, Medical Development Division, Ministry of Health Malaysia especially Patient Safety Unit.**

I also would like to thank each individuals who have been part of the big team in championing Patient Safety and Safe Surgery. Let us make patient safety our priority and work together for patient safety.

Best regards,

**Dr. Nor'Aishah Abu Bakar**
Deputy Director
Medical Care Quality Section
Medical Development Division
Ministry of Health Malaysia

18 October 2021

## ADVISORS

**YBhg. Tan Sri Dato' Seri Dr. Noor Hisham Abdullah**
Director General of Health Malaysia

**YBhg. Dato' Dr. Asmayani Khalib**
Deputy Director General of Health (Medical)
Ministry of Health Malaysia

**Dr. Mohd Fikri Ujang**
Director of Medical Development Division
Ministry of Health Malaysia

## CONTRIBUTORS

**YBhg. Dato' Dr. Mohammad Anwar Hau Abdullah**
MoH Head of Orthopaedic Service
Senior Consultant Orthopaedic Surgeon
Raja Perempuan Zainab II Hospital, MoH

**Dr. Nor'Aishah Abu Bakar**
Public Health Physician
Deputy Director of Medical Care Quality Section
Medical Development Division, MoH

**Dr. Nor Fariza Ngah**
MoH Head of Opthalmology Service
Consultant Opthalmologist
Shah Alam Hospital, MoH

**Dr. Melor Mohd Mansur**
Previous MoH Head of Anaesthesiology & Intensive Care Service
Senior Consultant Anesthesiologist
Kuala Lumpur Hospital, MoH

**Dr. Azmi Alias**
Consultant Neurosurgeon
Kuala Lumpur Hospital, MoH

**Dr. Siti Hawa Tahir**
Consultant Orthopaedic Surgeon
Kuala Lumpur Hospital, MoH

**Datuk Dr. Hj. Abd. Razak Hj. Ahmad**
Consultant Otorhinolaryngologist
Head of Department
Melaka Hospital

**Dr. Shahila Tayib**
Consultant Obstetrician & Gynaecologist
Pulau Pinang Hospital, MoH

**Dr. Rashide Yaacob**
Consultant General Surgeon
Sultan Abdul Halim Hospital, MoH

**Dr. Zaleha Md Nor**
Public Health Physician
Head of Patient Safety Unit
Medical Care Quality Section, MoH

**Dr. Ahmad Muzammil Abu Bakar**
Senior Principle Assistant Director
Patient Safety Unit
Medical Care Quality Section, MoH

**Dr. Sharifah Balqis Sayed Abdul Hamid**
Senior Principle Assistant Director
Patient Safety Unit
Medical Care Quality Section, MoH

**Mrs. Norlela Jalil**
Nursing Matron
Women and Children Hospital Likas, MoH

**Mrs. Che Saniati Che Ali**
Nursing Sister
Selayang Hospital, MoH

**Mrs. Aidaliani Ghazali**
Nursing Sister
Patient Safety Unit
Medical Care Quality Section, MoH

## 1. INTRODUCTION

Unintended Retained Surgical Item (URSI)[1] is an incident that should be prevented. This may cause emotional and physical harm to patient and lead to medicolegal implications. Prevention of URSI is one of the Malaysian Patient Safety Goals and also need to be reported via MoH Incident Reporting System.

## 2. SCOPE

This guideline only covers all procedures performed in the operating theatre.

## 3. OBJECTIVE

To provide a practical guide for healthcare practitioner in the event of URSI.

## 4. DEFINITION OF TERMS

### 4.1 Retained surgical items (RSI)[1]:

Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.[2]

### 4.2 Surgical items:

Surgical items are defined as materials, instruments or devices that are used in performing surgical procedure. The items can be further classified as:

i. Soft goods:
   - Surgical Sponge
   - Surgical Towels
   - Dressing sponges, drape towels, packs, prep swabs, gauze, wound vac sponges

*[1] For the purpose of this SOP, the term URSI and RSI will be used for any item or foreign object retained after a surgical procedure regardless of when the object was discovered.*

*[2] California's Health and Safety Code 1279.1*

ii. Sharps/Needles
iii. Instruments
iv. Small Miscellaneous Items (SMI); e.g. vessel loop, Bulldog clamp
v. Devices such as guide wires or catheters:
   - Inadvertently left in body or
   - Un-retrieved broken device Fragments (UDF)
   - Un-retrieved Unrecognized device Fragments

### 4.3 Unintended Retained Surgical Item (URSI)

Unintended retention of a surgical item can be classified into 3 sub-categories:

- **CATEGORY 1**: The surgical team is aware of the RSI; however, the surgeon determines the risk of retrieval is more than the risk of retention and thus leaving the item in the patient (e.g. broken drill bit in the bone).

- **CATEGORY 2**: The surgical team is aware of the count discrepancy or broken surgical item(s), but unable to locate the item even after thorough search according to SOP[3].

- **CATEGORY 3**: The surgical team is not aware at all of the retained surgical item (RSI) at the end of surgery. The RSI is only discovered after the patient presents with symptoms or accidentally detected.

*Any material that is left intentionally for therapeutic/safety reasons is not considered as unintended retained surgical item.

## 5. MANAGEMENT OF URSI

### 5.1 CATEGORY 2

A. When there is any count discrepancy detected at any stage of the operation, the first step would be informing the surgeon and anaesthetist.

*[3]Refer to SOP for Managing Count Discrepancy in Guidelines on SSSL Programme Second Edition 2018; pg. 39.*

B. If the surgery is at a critical time (conditions where it is not feasible to stop the surgery either due to patient or practical issues), the surgeon shall proceed with the surgery until the condition permits.

C. If the surgery is not at critical time, surgeon shall stop the surgery and initiate the search.

D. Scrub nurse and circulating nurse will initiate recount and if discrepancy persist, to initiate parameter (thorough) search which include searching in the surgical field and Operating Room.

E. If the item was found, reconfirm the count, end search and continue with the surgery.

F. (i) Radio-opaque item:
   - If the missing item was not found after thorough search, use Image Intensifier (II) and/or portable X-ray for radio-opaque item.
   - If the item was not found through II and/or X-ray, consult radiologist/another senior colleague to review the x-ray and reconfirm (where applicable).

   (ii) Non radio-opaque item:
   - If it was not radio-opaque, continue thorough search.

G. In the meantime, surgeon and surgical team shall inform superior for advice while the search continues.

H. If the missing item was found, reconfirm the count, end search and continue with the surgery.

I. Activate damage control:
   - Inform top management
   - Explain to next of kin.

J. After extensive and thorough search with/without imaging, superior will have to decide whether to complete the surgery or to stop the surgery and close the operation site depending on the following scenarios and of course after informing and discussing with next of kin of the patient. (*For details, refer to Flow Chart of Management for Category 2 URSI* )

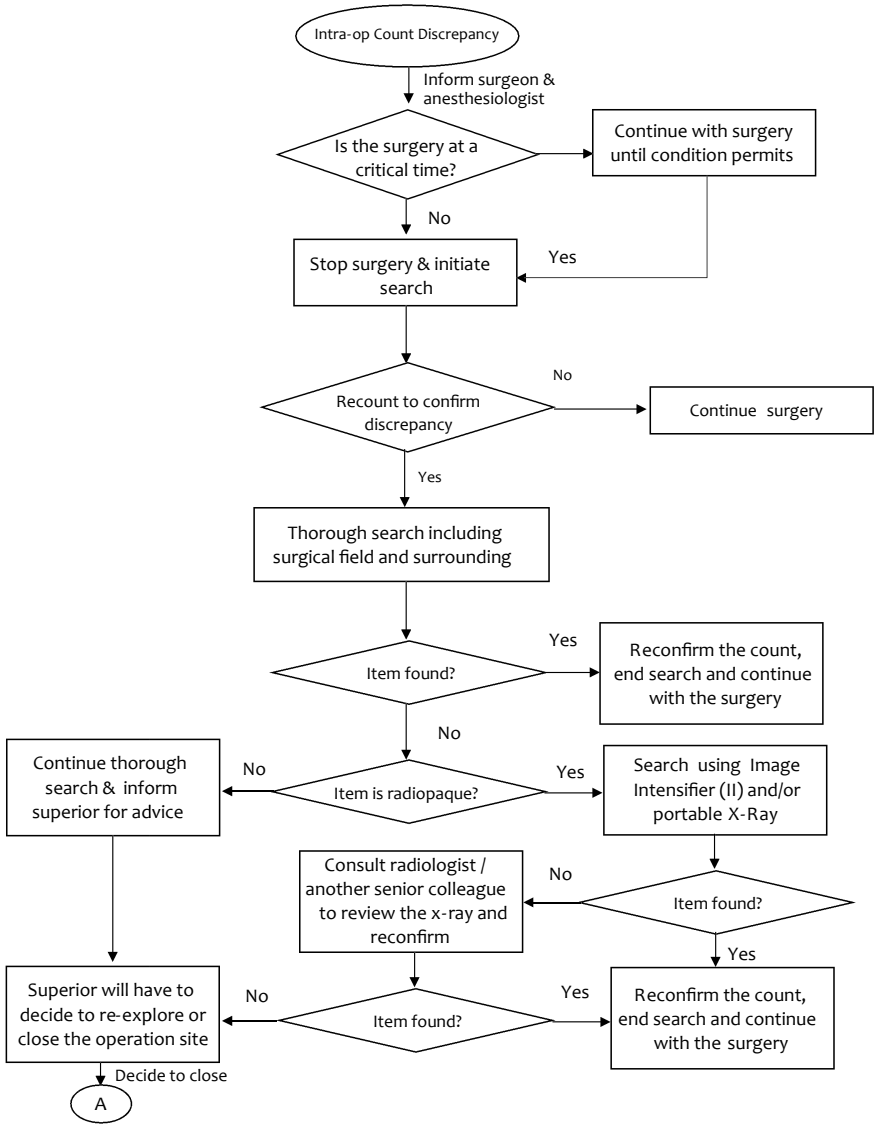
- If most appropriate, further imaging modality (e.g. CT scan / MRI / Ultrasound) is available immediately; send the patient for the said imaging without reversal.
- If further imaging modality is not immediately available; patient shall be reversed.
- If the facility does not have resources (most appropriate imaging modality) for further search process; reverse patient, arrange and transfer patient to the nearest facilities

K. If item was found through further imaging modalities, re-explore and retrieve item**.
***If item was detected but retrieving the item back may cause more harm to the patient, we may need to retain it.*

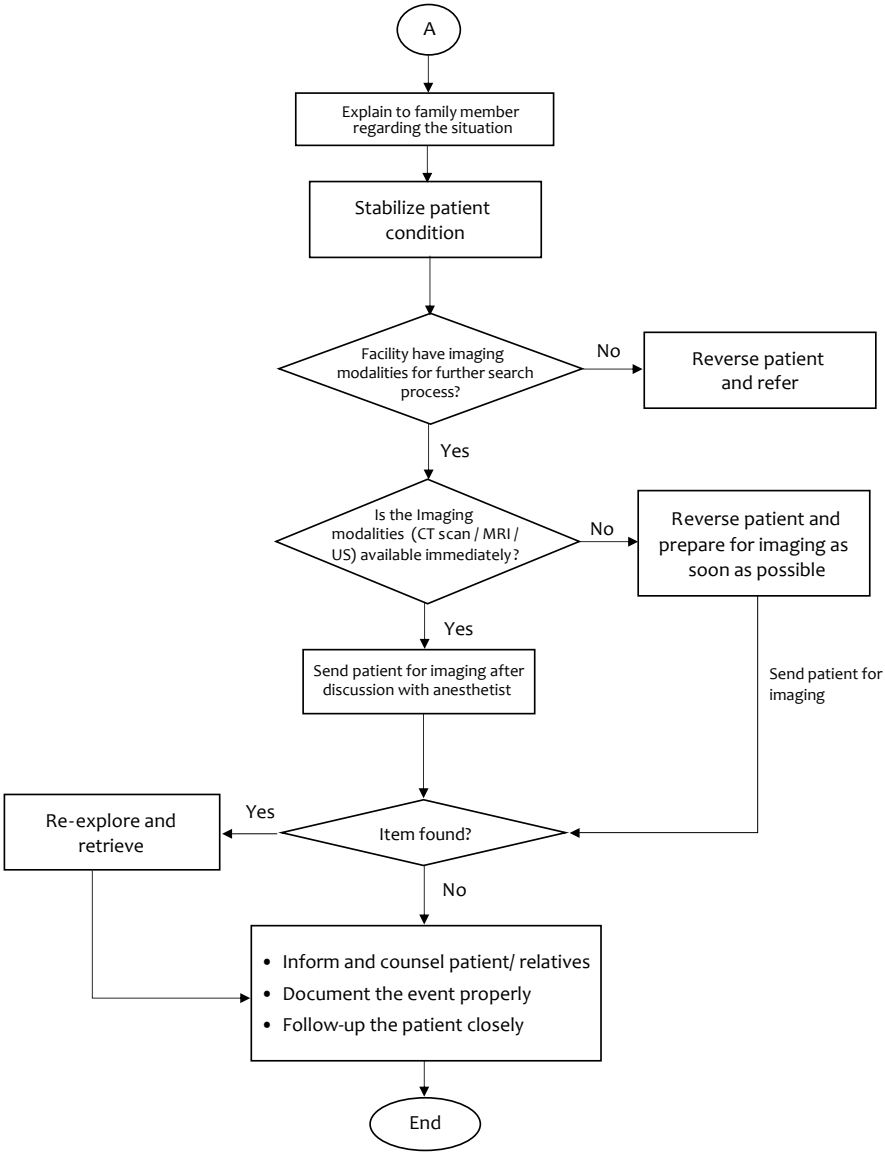
L. If item was not found through further imaging modalities, inform and counsel patient, and ensure proper documentation of the event as well as follow-up the patient closely.

M. Report the incident using the MoH Incident Reporting Form, conduct investigation to identify contributing factors and risk reduction strategies to prevent similar incident.

## FLOW CHART OF MANAGEMENT FOR CATEGORY 2 URSI (PAGE 1 OUT OF 2)



## FLOW CHART OF MANAGEMENT FOR CATEGORY 2 URSI (PAGE 2 OUT OF 2)



### 5.2 CATEGORY 1

A. Advice from superior should be taken before deciding the item falls into this group.

B. Decision is to leave the item in-situ with close monitoring and follow up.

C. Properly document the incident (in BHT, SSSL Checklist, Incident Report and RCA)

### 5.3 CATEGORY 3

A. Manage the case accordingly.

B. Proper damage control should be in place.

C. Document the incident properly and do close follow up.

D. Perform thorough case audit – look for weakness and remedial measures (i.e close the loop)

## 6. ADDITIONAL INFORMATION RELATED TO URSI INCIDENT

### 6.1 Damage control:

i. Inform the incident to superior or supervisor, head of department and depending on the situation, the hospital director.

ii. Soft skill & communication: explaining the incident, the risk and further action plan to patient/next of kin.

iii. Proper documentation of the incident. This includes documentation of the incident in the BHT, Safe Surgery Saves Lives Check List, make Incident Report and conduct Root Cause Analysis.

iv. Close follow up of the patient and further management of the incident would depends on the severity.

### 6.2 Good practice to prevent URSI

A. **Safe Surgery Saves Lives programme (SSSL)**: Implement SSSL programme in your facility and use the perioperative checklist. Ensure training and CME is done to give awareness on the importance of SSSL programme and train relevant staff on the implementation of SSSL programme.

B. **Effective Communication**: Leadership and good teamwork is essential in improving communication skills in operating team. Encourage staff to speak up for patient safety and voice out if there is any patient safety concern during surgical process.

C. **Documentation & Reporting**: Ensure proper documentation of surgical process and if any patient safety incidents occur, do incident report.

D. **Use of Technologies**: Use of technologies with safety feature can further reduce patient safety incidents.

E. **Minimize Distraction & Noise**: It is good practice to have operating theatre with minimal distraction and noise especially during crucial steps such as time-out, swab count and instrument count.

F. **Don't Disturb Scrub Nurse Table**: Avoid disturbing the scrub nurse table as it could lead to incorrect count of swab and instrument.

G. **Familiarity of Equipment, Proper Use of Equipment and Checking of Equipment**: Having proper knowledge on equipment and familiarity on equipment to be used in the procedure/surgery is necessary to prevent patient safety incidents. Do check your instrument before proceeding with the procedure or surgery.

H. **Credentialing and Privileging (C&P)**: It is best practice for healthcare practitioner to have C&P before conducting any procedure or surgery.

I. **Cavity Packing**:

   i. Use raytex gauze/abdominal pack/roller gauze

   ii. Use appropriate size gauze for packing

iii. Always inform the scrub nurse if you are packing

iv. Preferably, mention the side/location of the packing

v. In extremities packing, if the wound is not intended to be closed, make sure the end of the packing is easily visible

vi. Reconfirm with the scrub nurse and the circulating nurse the number of packed gauzes used before the outer dressing is applied

vii. Document clearly the number of packed gauzes in the Safe Surgery Checklist form and also in the operating notes.

## 6.3 Frequently Asked Questions:

### Throat pack removal

Removal of throat pack should be done by the person inserting the throat pack. The insertion and removal of throat pack should be notified to the scrub nurse and need to be documented in the swab count & instrument count checklist. Marking or indicator can be place on the patient to indicate the throat packing was inserted and not to be forgotten.

### Use of cut roller gauze

To use cut roller gauze should be avoided. In the event that it is required, the number of segmented roller gauze should be documented in the swab count & instrument count checklist and the end part of segmented roller gauze is hold by an arterial clamp (if applicable).

### Broken part of a stent/implant during removal

In situation where parts of stent/implant broken off during removal, steps in Group B URSI shall be used. Decision to remove the broken parts can be made by getting expert opinion from relevant speciality.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