

Instrument Counts during Invasive Procedures

Issue Date	Review Date	Version
June 2017	June 2022	V6.1

Purpose

This policy identifies the correct procedure for counting instruments and bio-medical devices during invasive procedures in operating theatres and procedural rooms

Who should read this document?

This policy applies to personnel participating in the care of patients undergoing invasive procedures working within the remit of UHP surgical services

Key Messages

This policy will ensure that there is a system in place for the safe handling and management of instruments and bio-medical devices 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	Michelle-Jane Smith – Matron Theatres Dy Taylor – Theatre Practitioner, Cindy McConnachie – Senior Matron Theatres and Anaesthetics
Review	Theatre Governance Committee
Ratification	Theatre Central Clinical Director
Dissemination	Senior Matron Theatres and Anaesthetics
Compliance	Theatre Board

Links to other policies and procedures

CLI.THE.POL.371.5 Swab Counts in the Operating Theatre Policy V5

CLI.THE.POL.797.4 Management of Sharps in Operating Theatres and Procedural Rooms Policy V4

CLI.THE.POL.???1 Planned Retained Wound Management Products in Theatre V1

CLI.INF.SOP.814.1 The use of Surgical instruments for neurosurgical patients born after 1st January 1997. SOP Decontamination 4

NHS England (2015) *National Safety standards for invasive procedures (NatSSIPS)*, London

Version History

V1	02/09/2008	Final review by the Theatre Policy, Practice and Procedure Group, for signing through the Theatre Management Board
V1.2	28/01/2009	Reviewed following several serious incidents
V1.3	31/01/2009	Additional comments incorporated following risk management meeting
V1.4	Jan 2011	Policy reviewed and change approved
V2	Jun 2012	Policy reviewed and changed to stand alone instrument policy
V3	Jun 2013	Policy reviewed and changes approved
V4	Apr 2014	Policy reviewed and changes approved

V5	Dec 2015	Policy reviewed and changes approved
V6	Jun 2017	Policy reviewed to ensure Natssips compliant and to incorporate learning from recent never event.
V6.1	Jun 2019	Policy reviewed and changes

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 Document Library.
Larger text, Braille and Audio versions can be made available upon request.**

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1 Introduction

The UHP Theatre Governance Committee is committed to ensuring the safety of patients undergoing surgical procedures and recognises the need for a standardised procedure for counting instruments during invasive procedures. Clear policies enable the implementation of standard practice and helps reinforce the principle of consistency

All staff participating in invasive procedures have a responsibility to themselves, their colleagues and patients to safely handle, monitor and dispose of instruments 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 and must not disregard this policy. The risks exist for accidental retention of surgical items, the outcome of which can be catastrophic. A standardised strategy accounting for items opened during a surgical procedure must be complied with as the risk cannot always be predicted.

2 Purpose

The purpose of this policy is therefore:

- To provide a safe system for the counting, handling and managing instruments for invasive surgical procedures
- 1.2 To eliminate the likelihood of a “Never Event” and promote engagement in the Surgical Safety Checklist process
- 1.3 To identify responsibilities of staff for counting and recording
- 1.4 To provide a standardised counting and recording system
- 1.5 To provide a safe system to be followed when discrepancies occur

3 Definitions

Surgical instruments or bio-medical devices are designed to perform a specific function, for example:

- cutting, grinding, and dissecting
- clamping
- grasping and holding
- probing
- dilating or enlarging
- retracting
- suctioning
- haemostasis

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

A single use disposable medical device is also performing a similar function but is classed as clinical waste following use.

All instruments 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 by:

- Verifying the presence of instruments against an instrument set list or individual instrument ‘ticket’
- Confirming the number of instruments within an instrument set
- Ensuring instruments are intact and all screws and bolts etc. are present

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

- Sterile Surgical instruments
- Endoscopic equipment including disposable items

- Miscellaneous small items that have the potential to be retained in the surgical wound

Examples of miscellaneous countable items (bio-medical devices)

- Retrieval Bag
- Vascular clamps
- Bowel clamps
- Cautery scratch pads
- Corneal shields
- Dura Hooks
- Lens cleaner pads
- Ligaclip cartridges
- Mouth gag inserts
- Additional Diathermy blades/needles
- Raney clips

This list is not exhaustive and will remain under constant review

4 Duties

Theatre Policy Group - The body responsible for writing the Policies and Procedures used in Theatres. This group comprises the Senior Theatre Matron, operational managers and clinical educators who co-ordinate the development and review of policies. Clinical experts will be used to develop the policies

Theatre Governance Committee - The committee responsible for approving theatre policies and procedures and ensuring they 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 Matron / Senior nurse jointly responsible for monitoring compliance with policy

Senior Team Leader – responsible for ensuring staff involved with care of the patient during a surgical event has been assessed and competent to perform instrument counts and ongoing monitoring of compliance with staff for performing the instrument counts

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Inclusion Criteria:

Instrument counts are part of the swab, instrument and sharps counting procedure

5.1.1 Invasive Procedures

- Each count for invasive procedures must be performed by two members of staff, one of which must be a Registered Nurse (RN) or Operating Department Practitioner (ODP) or Assistant Practitioner (AP) or Assistant Surgical Practitioner (ASP). This is the scrub practitioner. The second member of staff (the circulator) can be any of the aforementioned roles or a Health Care Assistant (HCA) who has achieved competence in Swab, Sharp and Instruments counting.
- Instrument tracking documentation must be available and form part of the count checking process
- Whenever possible, the same two perioperative staff should perform all the counts that are done during the surgical procedure

5.1.2 Minimally Invasive Procedures

- Any Anaesthetist/Anaesthetic Practitioner performing a minimally invasive procedure must manage safety and account for all bio-medical devices and instruments used during the procedure
- Be aware that although it is highly unlikely to accidentally retain an instrument in a minor procedure, all counts must proceed as per policy so that any subsequent instrument losses, e.g. in SDU, can be identified as not from the theatre environment

5.2 Counting Principles:

5.2.1 Assessment

- Scrub Practitioner staff and learners must not be involved with counting procedures until assessed and signed off as competent.
- 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

5.2.2 Packaging

- The sterility of instrument and single item packaging **must** be within the expiry date and the steriliser indicator must confirm that the pack has been subjected to an appropriate sterilisation process. Prior to the procedure, the outside packaging **must also be** inspected to ensure it is intact and dry and that the sterility has not been compromised
- An Instrument Tracking document **must** accompany reusable instrument(s) as this forms part of the count to check that all of the instruments are correct and present

5.2.3 Preparation

- All instruments are counted prior to the Surgical Safety Checklist “Time Out” utilising the instrument tracking sheet. During the Surgical Safety Checklist “Time Out” there must be verbal confirmation that all instrument sets/trays and biomedical devices pertaining to case on the list are present and checked

5.2.4 Times of the Count

Counts of instruments **must** be performed:-

- Directly before the start of the operation/procedure
- At wound closure
- At any other time it is deemed necessary

NB: When additional instruments are added to the sterile field, the instruments are counted by the scrub practitioner and circulator. Additional instruments without tracking documents **must be** recorded on the dry wipe board and included in the count e.g. retrieval bag.

5.2.5 The Counting Environment

- Counts will be carried out using the ‘silent cockpit’ principle
- During counts the ‘count time out’ is established. Music is turned off, phones/pagers are left unanswered and all unnecessary conversation ceases until the count is finished and is reported as correct. **All** members of the multi-disciplinary team are responsible for adhering to and enforcing the “Silent Cockpit” principle
- At the end of the final count the Surgical Safety Checklist “sign out” should be performed as soon as possible to finalise the end of the procedure

5.3 Method:

5.3.1 Scrub and Circulator roles:

- Using a logical sequence to count and check instruments, the circulator must read aloud from the set list/tracking document and visibly check the tray and confirm with the scrub practitioner the instruments and the number of them are correct
- All miscellaneous instruments/items without a tracking list that have the potential to be retained are counted and **must** be recorded as part of count on the dry whiteboard e.g. sloops
- This sequence also includes any sets or additional instruments added to the sterile field during the procedure
- If an instrument is inadvertently dropped off the sterile field, the circulator **must** safely retrieve the item and show the item to the scrub practitioner before placing it in an agreed place that is accounted for in the instrument final count

The Scrub Practitioner **must**:

- Check in view of the circulator that instruments with removable parts are present and secure e.g. screws and wing nuts
- Confirm that instruments which have individual pieces requiring assembling can be assembled

The Circulator **must**:

- Record consumable instruments on the first count transfer pad if counted in the prep room and transfer the information onto the dry wipe board
- Input the information required on the re-usable Instrument Tracking document and retain this document for final count

5.3.2 Multiple Scrub Practitioners

- In the event that different surgical procedures are occurring simultaneously, with 2 different scrub practitioners, each scrub practitioner is responsible for their instrument count as part of the swab, instrument and sharps count. The individual Scrub Practitioner and circulator performing the final count must indicate and record which surgical procedure they participated in and that the final count for each surgical intervention is recorded as separate count events in the PICP

5.3.3 Final Instrument Checks

- **No** instruments will be removed from the operating theatre/procedure room 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

NB: In exceptional circumstances, when instruments are required for quick turn around and have to be removed from theatre prior to the final instrument check, the Scrub Practitioner and Circulator **must**, using the instrument tracking document, check and verify that all the instrument(s) are correct and intact before releasing from sterile field

- The final instrument check should be performed at skin closure and never before a cavity is closed (including the subcutaneous fat layer)
- All re-usable instruments and sets opened during the procedure **must** be placed into a clear waste bag/container with the Instrument Tracking document completed, and identified with a bar coded patient ID label in compliance with IPG 196 (vCJD)
- The instrument check will be recorded in the patients’ Perioperative Integrated Care Pathway (PICP) or equivalent medical record. At the end of a procedure, the Scrub Practitioner **must** check that the record of intra-operative counts has been signed in the PICP/medical record and the Surgical Safety Checklist has been completed.

5.3.4 Change of Scrub Practitioner

- Change of scrub practitioners should be kept to a minimum

- A discussion within the team must take place before a practitioner scrubs for a long procedure to assess their suitability and their shift times to reduce requirement for change of Scrub Practitioner
- In the event that it is necessary to change Scrub Practitioners (through illness or prolonged procedures) the first scrub practitioner will remain scrubbed until they have completed a full count and handover; unless there is a significant reason to not perform a full handover e.g. through illness
- 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
- The change of scrub practitioner and handover must be recorded in the PICP

5.4 Waived Counts:

- In some circumstances e.g. a life-threatening emergency, 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 PICP or equivalent medical records

5.5 Discrepancies / Failed Reconciliation:

5.5.1 Incorrect counts:

- In the event of any discrepancy or fault when checking instruments prior to surgery, a non-conformance document needs to be completed. For single use medical devices, details of the lot number and batch information **must** be retained and then communicated to the Matron who will decide on the appropriate course of action. If the Matron is not available, contact the Senior Duty Practitioner
- If the count is incorrect during surgery the Scrub Practitioner **must** perform a visual inspection of the area around the sterile field and inform the operating surgeon immediately
- The Surgeon may decide to delay further wound closure and perform a methodical wound examination until the item is located and retrieved
- Circulating staff in theatre **must** also perform a methodical search for the missing item
- If the missing item is found, the count **must** be repeated and the surgeon informed that it is now correct

5.5.2 Failed Reconciliation

- When the count remains incorrect, a second count **must** be performed. If the item is still missing an x-ray **must be taken** before skin closure unless a clinical indication to do so would present a greater risk to the patient
- If a Raney clip cannot be found the patient will require an ultrasound as Raney clips cannot be seen under a plain film x-ray.
- In the event that the patient's condition does not allow for an on table x-ray:
 - **Escalation** to the senior practitioner on duty i.e. Band 7 or Theatre Matron **must** occur.
 - A verbal discussion **must** take place with the multi-disciplinary team to risk assess the agreed immediate actions, taking into consideration the 'best interest' of the patient
- When an x-ray is not performed, and an instrument remains missing, the On Call Duty Manager and the Patient Safety Team **must** be informed so that the event can be discussed with the patients' next of kin or significant other
- If the patient's condition does not allow for immediate x-ray, it is still essential to confirm if the missing instrument has been retained:

- Their clinical condition must continue to be monitored until it has improved sufficiently enough to allow for x-rays to be taken
- The Surgeon, Scrub Practitioner and Senior Nurse must be informed of the x-ray result
- If retention has occurred, the earliest opportunity for the patient to return to theatre for removal of the missing retained instrument must be established

5.5.3 Damaged Instruments

- In the event that an instrument is broken or fails inter-operatively, the Scrub Practitioner must inform the Surgeon immediately and retrieve all pieces. The instrument must be removed from the surgical field and checked that all the broken pieces are present and removed from the sterile field
- The circulator **must** complete a non-conformity document. At the end of the procedure, an Electronic Clinical Incident report **must** be completed and a Near Miss Incident recorded
- A risk assessment **must** be made by the Surgeon in the event that instrument/ bio-medical device fragments that have separated unintentionally are not retrieved. The requirement for an on-table x- ray should be considered. If the Surgeon takes the decision that the fragment(s) should remain in situ, a Trust Electronic Incident report must be completed and the Surgeon **must** document the risk associated with retrieving the fragment(s) in the patient records

5.6 Trust Electronic Incident Reports:

- If a missing instrument/fragment is not found, the incident must be brought to the attention of the Senior Matron Theatres and Anaesthetics, Service Line Manager or On Call Manager and the Patient Safety Team must be informed at the earliest opportunity. The Scrub Practitioner must complete a Trust Electronic Incident Report
NB Ultimately, the responsibility to ensure the incident is reported remains with the surgeon who is accountable for the patient and who **must** also complete a Trust Electronic Incident Report. It is the responsibility of theatre team leads to ensure an incident report is completed
- If the instrument is found prior to the patient leaving theatre, the incident is classed as a “**near miss**” and reported as such by the Scrub Practitioner
- A Trust Electronic Incident Report **must** be completed if an x-ray is performed to locate a missing or damaged instrument/biomedical device
- A record of any incident **must** be made in the patient’s PICP and in the Patients’ notes if ongoing care is required

NB An *unplanned* retention of foreign material in a patient is a Never Event; it is vital that all healthcare professionals remain vigilant in their practice and adhere to policies and guidelines set out to reduce such incidences. When a Never Event occurs, e.g. retained instrument, the patient will need to be informed, an apology issued and full duty of candour applied. This should be documented in the PICP and via the Trust Electronic Incident Report

6.1 Deliberately / Planned Retained Instruments:

In some surgical procedures, the surgeon may make the decision to leave an instrument/bio-medical device inside the patient

- Instruments remaining in the patient **must** be recorded by type and number in the designated section of the PICP or equivalent medical record
- This **must** then be signed and dated by the Scrub Practitioner and Circulating Practitioner

- The PICP or equivalent medical record **must** be signed and have an alert sticker attached at the front indicating that 'Instrument(s) Remain in situ'. A second visual alert must be attached to the exterior cover of the patient record/notes.
- At handover, a verbal report **must** be given to the receiving practitioner

6.2 Process for managing a patient returning to theatre for removal of retained instrument(s):

- At "Time Out" check the patient PICP or equivalent medical record from the previous surgical event to confirm location and number of retained instruments
- On the whiteboard the procedure **must** be identified as "Removal of Instrument"
- The Circulator **must** record on the whiteboard the retained instrument documented in the previous PICP
- When the retained instrument(s) is retrieved, the Scrub Practitioner must check for integrity, ensure it is complete and locate the instrument in a designated place on the sterile field. The Scrub Practitioner can then count the retrieved instrument(s) with the Circulator into a clear bag. If the instrument is not intact, normal escalation process to the surgeon and team leaders is to be taken
- The Circulator records on the clear bag '*retained instrument*' which is accompanied by a non-conformance document as no identification label will be present
- The Circulator confirms and records on the whiteboard all '*Retained instruments removed and accounted for*'
- The clear bag containing the "*Retained Instrument*" remains in theatre until the end of the surgical procedure when the final count is performed
- The Scrub Practitioner must acknowledge at final count that a "*Retained Instrument*" has been removed, accounted for and confirmation given to the Surgeon
- On completion of the surgical event, the Scrub Practitioner documents "*Instrument removed*" on the alert sticker located in the PICP of the previous surgical event and on the patient record

6.2.1 Accidentally Retained Instrument

In the event of a "Never Event" and a patient having to return to theatre for the removal of an accidentally retained instrument, follow the process as above but document "*Instrument removed*" in the PICP as there will be no alert sticker present

6.3 Temporary Retained Instruments:

Occasionally, instruments will be retained in the patient temporarily and removed before the end of the case or in the recovery room

- Any item left in the patient, even for a short space of time, must be documented on the whiteboard in the section marked 'Inside' and crossed off on removal
- Instruments that remain in the patient until the recovery room e.g. a sponge holder on the cervix **must** be documented in the PICP and full instructions for the removal given on handover
- The Scrub Practitioner will ensure that the documentation and set/tray remains in the sluice until complete. The recovery staff **must** document that the instrument has been removed and ensure its return to the appropriate theatre for processing

6 Overall Responsibility for the Document

Theatre Team leaders are responsible for auditing practice against this policy quarterly and reporting to the Theatre Governance Committee

Non-compliance will be addressed by the Theatre Team leaders in conjunction with Clinical Educators and Theatre Matrons. Non-compliance must be reported to the Senior Matron Theatres and Anaesthetics

Team Leaders will be responsible for investigating any incidents reported via the Trust's Electronic Reporting system.

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 Theatre Central Clinical Director / Clinical Lead

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

What are we monitoring?	Compliance with the Instrument Counts during Invasive Procedures Policy
How is it monitored?	Monthly auditing of instrument counting practice must be undertaken
Lead	Theatre Matron

Validation	Data results validated by Theatre Matrons and Lead Nurses Recorded incidents on Datix
Frequency	Monthly
Reporting Arrangements	The Theatre Governance Committee will be responsible for investigating any incidents reported via the Trusts Electronic Reporting system
Sharing the Learning	Lessons learned to be shared using appropriate communication pathways and training

10 | References and Associated Documentation

Association for Perioperative Practice (2011) AfPP Standards and Recommendations for Safe Perioperative practice pp323 - 329

NHS England (2015) *National Safety standards for invasive procedures (NatSSIPS)*, London (<https://www.england.nhs.uk/2015/09/natssips/>)

Policy for Planned Retained Wound Management Products in Theatre

NHS England (2014) *Surgical never events taskforce reports* (<https://www.england.nhs.uk/patientsafety/never-events/surgical/>)

Procedural documents

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 Perioperative Matron and for working with the Trust's training function, if required, to arrange for the required training to be delivered

Dissemination Plan			
Document Title	Instrument Counts during Invasive Procedures		
Date Finalised	June 2017		
Previous Documents			
Action to retrieve old copies	Archived by the Theatre Governance Committee and Trust Document Controller		
Dissemination Plan			
Recipient(s)	When	How	Responsibility
All Trust staff		Vital Signs	Information Governance Team

Review 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?	Yes
	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

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Core Information	
Date	June 2017
Title	Instrument Counts during Invasive Procedures Policy
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.
Scope of the assessment	
Collecting data	
Race	
Religion	
Disability	
Sex	
Gender Identity	
Sexual Orientation	
Age	
Socio-Economic	
Human Rights	
What are the overall trends/patterns in the above data?	
Specific issues and data gaps that may need to be addressed through consultation or further research	

Involving and consulting stakeholders				
Internal involvement and consultation				
External involvement and consultation				
Impact Assessment				
Overall assessment and analysis of the evidence				
Action Plan				
Action	Owner	Risks	Completion Date	Progress update

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