



POLICY ON SINGLE USE DEVICE

1.0 Purpose: To define a set of guidelines for the reprocessing of single use or disposable devices. (SUD)

2.0 Definition:

A device that is marketed or labeled for single patient use or single procedure use. It cannot be used on another patient. The label has no instructions for reprocessing.

2.1 Open but unused:

Is a device whose sterility has been breached. Also includes devices whose packaging has expired.

2.2 Reuse:

Is the repeated use of any device on multiple patients with applicable reprocessing.






2.3 Reprocessing:

Includes all operations to make a used device clean, sterile and functional.

3.0 Policy:

Sri Ramachandra Medical Centre is committed to reprocess SUD in a manner as to ensure patient safety with stringent quality controls.

SUDs that may be reprocessed are listed and the number of times they can be reused is specified after consultation with the primary users and the CSSD with priority for patient safety.

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SUDs not listed cannot be reprocessed and are to be discarded after single use.

For Reuse of SUD's following shall be noted:

- The maximum number of reuses specific for each device and material that is reused.
- The types of wear and cracking, among others, that indicate the device cannot be reused.
- The cleaning process for each device that starts immediately after use and follows a clear protocol.
- Identification of patients on whom reusable medical devices have been used and
- The process for the collection, analysis, and use of infection prevention and control data related to reused devices and materials, to identify risks and implement actions to reduce risks and improve processes. This shall also include a proactive evaluation of the safety of reusing single use items.

4.0 Authority:

Is vested with the infection control committee

5.0 PROCESS:

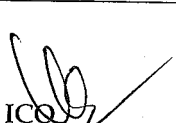
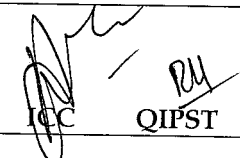
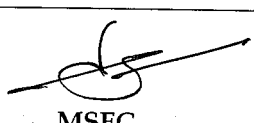

Sorting- Done initially to eliminate rejects and unapproved products

Cleaning- Done initially in running water under pressure and then with enzymatic detergents. Then thoroughly rinsed with water and left to dry.

Testing - Done to verify that they can perform the intended use.

Packaging - Packed sealed and labeled in approved pouches. The label will indicate the number of times it has been reprocessed.

Sterilization - All devices are appropriately sterilized with stringent quality control of the sterilizing equipment.

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SUD Recall- any SUD found to be unsafe shall be immediately recalled and disposed off.

Disposal - All SUD s that have been reused as per policy shall be mutilated and disposal as per hospital waste policy after the defined period of reuse is over or if the SUD is found to be dysfunctional at any point of time.

6.0 TRACK ON SUD

Every time a SUD is used for a patient, it shall be documented in the individual Department register with patient details.


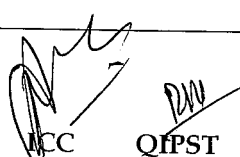


OR / Labour room/Radiology/ Pulmonology/ Urology Nurses shall check the number of times the device can be used according to the policy. They shall verify the number of times that particular device has been used on that day. Then the concerned departments nurse documented in the SUD register.

The appropriate number and a label to signal the last time it is used, is indicated by a red sticker that is applied on to the pouch under the supervision of CSSD personnel.

Each department register entry shall be checked by the shift incharge and counter checked and signed by the incharge nurse before it is sent for reprocessing.

In the CSSD, a similar register is maintained. The SUD shall be verified again by the CSSD personnel before accepting for sterilization. If the device is found to be unsatisfactory, it is recalled and documented on the SUD register.

The bar code label contains the product name, product code number, serial

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number of the item and the number of time it is being used.

One bar code label will be stuck over the outer pouch and three similar bar code free labels will be put inside the outer pack.

The outer pouch with the bar code label is preserved till that item is repacked and labeled. The used item is put back into it and taken to CSSD for reprocessing.

Three bar code labels will be stuck one each, on the concerned department register, SUD note book and in the CSSD

If CSSD identifies any other non-functioning of SUD the same has to be discussed in ICC meeting and to be updated.

6.DISTRIBUTION AND DOCUMENTATION CONTROL

6.1 Distribution List


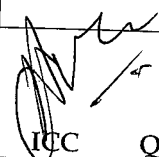


Chief Operating Officer, Medical Director, Assistant Medical Director, Chairman-QIPST, General Manager-HR, Chief Hospital Administrator, Chief Quality Officer, Nursing Superintendent, All Nursing Leaders & Concerned HOD's.
All Medical Staff. Emergency Room. Diagnostic Areas.

6.2 Mode of Distribution

Sri Ramachandra Medical Centre Intranet & Emails.

6.3 Mode of Training

Through SREE & In-service education trainings.

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6.4 Number of Copies

Nil

6.5 Documentation Control

Quality Office

6.6 Amendments

TRACK CHANGES					
If any changes made	Yes / No	Date	Reason	Section	Remarks
	No	10/10/18	Standard Updating	-	Nil
	No	11/01/21		-	Nil

1. REFERENCE

Joint Commission International Accreditation Standards for Hospitals 7th Edition. USA: Joint Commission Resources; Published on Apr'2020; Effective on Oct'2020.


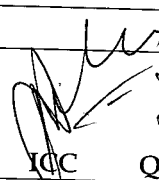



National Accreditation Board for Hospitals and Healthcare Providers (NABH), 5th Edition, Apr'2020

2. SPECIAL INSTRUCTIONS

Nil

3. APPENDIX

Nil

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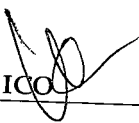
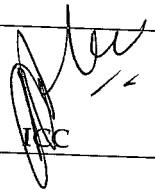





SRI RAMACHANDRA HOSPITAL - UNIT I
SRI RAMACHANDRA MEDICAL CENTRE

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Last reviewed: 11.01.2021
Issue: H
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POLICY ON SINGLE USE DEVICE - LIST OF ITEMS WHICH ARE NEVER REUSED

1. Endo Tracheal tube
2. Airway
3. Suction catheter
4. Suction tube
5. Syringes
6. Peripheral IV Catheters
7. IV Set
8. Blood set
9. Arterial Cannula
10. Humidvent
11. Urinary catheter
12. Urobag
13. Multilumen catheters
14. Pressure monitoring line
15. IV Extension Lines
16. IV 3way Stopcocks
17. Hudson mask
18. Needles
19. Ryles tube
20. Pressure Transducer
21. P.V.C Tubing (all sizes)
22. Oxygenators
23. Connectors
24. Filters
25. Cardio plegia reservoir
26. Intra Aortic Balloon catheter

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