Policy on Reprocessing Devices

1. **Purpose:**

   To define a set of guidelines for the reprocessing of single-use, or disposable medical devices (SUD)

   Note: This policy does not address the reprocessing of devices that are marketed or labeled as reusable or multi-use devices.

2. **Definitions:**

Single-Use or Disposable Device: A device that is marketed or labelled for single patient use or single procedure use. It is **not** marketed or labelled with the intent of reusing the device on another patient. The labelling identifies the device as single-use, or disposable and does not include instructions for reprocessing.

Note: Some SUDs are marketed and labelled as non-sterile and include appropriate pre-use sterilization or processing instructions to make the device patient ready. This is not considered "reprocessing".

Open but Unused: An "Open but Unused" product is a SUD whose sterility has been breached or whose sterile package was opened but the device has not been used on a patient. This also includes a device whose packaging has expired as identified by the label on the package.

Reuse: The repeated use or multiple use of any medical device on the same patient or different patients, with applicable reprocessing (cleaning, functionality verification, and/or disinfecting /sterilization) between uses.

Reprocessing: Includes all operations performed to assure that a previously used SUD is clean, sterile and will function as intended by the original equipment manufacturer (OEM). The process includes, but is not limited to, disinfection, cleaning, functional verification, packaging and possible sterilization.

Re-sterilization: The repeated application of a terminal process designed to remove or destroy all viable forms of microbial life, including bacterial spores, to an acceptable sterility level.

3.0 Policy:

3.1 INODAYA Hospital, Kakinada is committed to reprocess SUD's in a manner so as to ensure patient safety and stringent quality controls.

3.2 Items or devices that cannot be cleaned and sterilized or disinfected without altering their physical integrity and function should not be reprocessed. SUD's that may be reprocessed are those listed below. SUD's not listed cannot be reprocessed and shall be discarded after single use.

S.no	Single Use Device	Department	No. of times reprocessing allowed	Discard criteria
1	Octopus	CT-OT	15	• Loss of durability • Plastic breakage • When connectors become loose.
2	Dialyzer	Nephrology	5 (Renolin residual test maximum 10)	Renolin residual test maximum 10
3	Diagnostic Catheter, Guiding catheter	Cath lab	5	• Loss of durability
4	Y Connector	Cathlab	5	• Loss of durability
5	PTCA guide wires	Cathlab	5	• Loss of durability
6	Balloons	Cathlab	5	• Loss of durability
7	Sheath	Cathlab	5	• Loss of durability
8	TPI lead 6"f	Cathlab	5	• Loss of durability
9	Turmo and regular guide wires	Cathlab	5	• Loss of durability

10	2 port manifolder	Cathlab	5	• Loss of durability
11	Inflation Device	Cathlab	5	• Loss of durability

3.3 Authority:

Authority for the program is vested with the Infection Control Committee.

4.0 Procedure:

4.1 Re-Use Policy for Blood Dialyzers

Cleaning and sterilization.

1. Dialyzers' should be washed immediately after use in running water with pressure so that it is cleaned thoroughly to eliminate any blood or other body residue.

2. Fill 1% (renalin) in both the dialyzer compartments.

Labeling requirement

1. All reprocessed dialysers shall be labelled with patients name, date of first use of Dialyzer.
2. All reprocessed dialyzer shall be kept in closed container.

Disposal:

All devices that have been re-used for 10 times shall be disposed as per the hospital policy for waste management. But Reuse criteria depends on bundle volume which needs to be min 80%

4.2: Reuse Policy for Octopus:

I. **Sorting:**

An initial sort of SUD shall take place to eliminate obvious rejects or unapproved products.

II. **Cleaning:**
An initial clean with multi-enzyme cleaner will be done in O.T after use and later dipped in Cidex. After that it is washed under running water

III. **Testing:**
Verifying that devices perform as intended shall be an integral component of the reprocessing cycle.

IV. Packaging:
All devices shall be packaged, sealed and labeled in Hospital approved pouches for ETO purposes. Prior to packing, a dot with a permanent marker shall be placed on the device, indicating the number of times it has been reused.

V. Sterilization:
Sterilization shall be performed in state-of-the-art ETO gas sterilizer. Every load shall contain chemical and biological indicators that shall be sent to the Microbiology laboratory for testing once a week. All load shall pass PCD before sending it out of CSSD.

VI. Labeling requirements:

Reprocessed Octopus shall be labelled with number of times the device has been used and date of reprocessing. In addition, a non-repeatable number shall be allocated to the device in order to facilitate recall of the device. Look for indicator changes once received from CSSD, Check Doco Label strip for expiry date before use 6 months from the date of sterilization

VII. SUD Recall:

Any SUD found to be unsafe due to repetitive incidents or due to a report by Microbiology Department or from manufacturers, shall be immediately recalled and disposed off as per hospital policy for waste management

VIII. Disposal:

Octopus devices that have been reused for 15 times shall be mutilated and disposed off as per hospital policy for waste management.

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