



## INODAYA Hospitals - Kakinada

Documentation code:

INH/MOM.Doc.No:28

### Policy On Implantable Prosthesis & Medical Devices

Prepared date: 11/11/2025

Reference: MOM.1Ob.NABH Standards – 6<sup>th</sup> Edition

Issue Date: 11/11/2025

Issue no: 01

Review No: 0

Review date: 10/11/2026

#### 1.0 Purpose:

To establish a standard for effective procurement, storage, handling, distribution and dispensing of implantable prosthesis & medical devices across the hospital To ensure safe selection, storage, use, traceability, and disposal of implantable prostheses and medical devices in compliance with regulatory, infection control, and patient safety standards.

#### 2.0 Policy:

The pharmacy ensures a systematic process for procuring, storage, handling for prostheses & medical devices

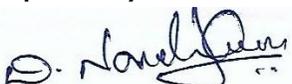
- Titanium
- Stainless steel
- Cobalt chromium
- Polymers
- Bio absorbable Polymers

**3.0 Responsibility:** Pharmacy stores team, Physicians, nurses & clinical support staff

#### 4.0 Definitions

##### Implantable Prosthesis:

A medical device intended to be permanently or long-term placed inside the human body (e.g., orthopedic implants, stents, pacemakers, mesh, valves).

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## 5.0 Responsibilities

Role	Responsibility
Consultant/Surgeon	Selection and clinical justification of implant
Nursing Staff	Verification, documentation, and handling during procedure
OT Technician	Ensures correct implant availability and sterility
Stores/Materials Dept	Procurement from approved vendors
CSSD	Sterilization of reusable devices
Biomedical Engineer	Maintenance of equipment/devices
Quality Department	Monitoring traceability and compliance

## 6.0 Procedure

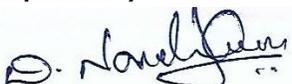
6.1 Implantable Prosthesis shall be used based on scientific criteria and required approvals.

6.2 The process protocol for proper procurement of prosthesis & medical devices are followed strictly according to the manufacturers recommendations

6.3 The information should be given 1 day prior to procedure for approved items and 2 days prior for new items.

6.4 They are further issued to user department after proper checking by the Pharmacy

6.5 They are received in the operation theatres by the respective nurses.

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6.6 Before the initiation of procedure, the availability of the required type and size of prosthesis / implants are verified through a “Time – out” procedure.

6.7 After the procedure the scrub / circulating nurse ensure that the label of the used prosthesis / implant is affixed in the patient record at the designated spaces.

6.8 One label each of the used prosthesis / implant is affixed in the master log Book.

6.9 The Pharmacy at various intervals would verify for the international certification & FDA approval of the specified brands.

6.10 Patient and his/her family are counseled for the usage of implantable prosthesis including precautions if any.

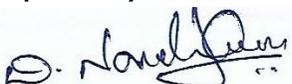
6.11 After using implant sticker should be placed on Discharge summary and in the case sheet and also in the Register.

#### 7.0 TRACEBILITY

7.1 The batch and serial number of the implantable prosthesis and medical devices are recorded in the patient’s medical record, master log and the discharge summary

**8.0 Reprocessing:** All single use devices shall be inspected for the feasibility of reuse and the authority for such control shall be the treating physician / Surgeon depending on the advice, if reuse is feasible, it shall be sent for appropriate re-sterilization.

**9.0 Storage:** All the implants will be stored according to the manufacturer’s recommendations and the storing facilities will be equipped with necessary temperature

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controls and storing conditions in operation theatre. In the operation theatre the implants whose clinical criteria and selection criteria, were already analyzed earlier will be ordered just in time for use.

#### 10. Discarding / Disposal

##### A. Implantable Prosthesis (Unused but Expired/Damaged)

Unused implantable prostheses that are expired or damaged shall be returned to the vendor wherever applicable. If return is not possible, the items shall be disposed of in accordance with Biomedical Waste Management Rules under the appropriate category (Yellow/Red as applicable).

##### B. Used Implants Removed from Patient

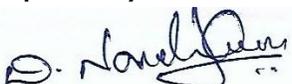
Implants removed from a patient shall be treated as biomedical waste. These items must be disposed of in the designated biomedical waste container as per category guidelines and must not be handed over to patients or attendants.

##### C. Single-Use Devices

Single-use medical devices shall be discarded immediately after use in the appropriate biomedical waste bins. All sharps shall be disposed of in puncture-proof, leak-proof, and tamper-proof sharps containers.

##### D. Electronic Implants (e.g., Pacemakers)

Electronic implants removed from patients, where applicable, shall be managed as

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electronic waste in accordance with e-waste management guidelines. Disposal shall be carried out in coordination with the Biomedical Engineering Department.

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