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|  QuXAT | QuXAT Quality Management System | | Document No: | QUXAT/SOP/37 |
| | Title | Procurement and Usage of Implantable Prostheses | Page No: | Page 1 of 4 |

1. PURPOSE

- 1.1. To outline the procedure for Procurement and Usage of Implantable Prostheses in the hospital

2. SCOPE

- 2.1. The procedure is relevant to all areas of the hospital that are involved in storage and administration of medications

3. RESPONSIBILITY

- 3.1. Nursing Incharge
- 3.2. Pharmacy Incharge
- 3.3. Stores Incharge
- 3.4. Operations Manager
- 3.5. Quality Manager
- 3.6. Doctors
- 3.7. Management

4. PROCEDURE

- 4.1. All the prosthetics/implants are procured as per the prevalent laws and regulations:
 - 4.1.1. Pharmacy Act
 - 4.1.2. Narcotics and Psychotropic substances Act
 - 4.1.3. Drugs and cosmetics Act
 - 4.1.4. Food and Drugs Act
 - 4.1.5. Drugs and magical remedies Act
- 4.2. Implants are purchased with relevant administrative approvals and stored as per the storage requirement specified by the manufacturers pertaining to temperature, light and ventilation
- 4.3. Pharmacy has process to prevent entry of pests / rodents and vermin at all location of implants storage such as stores and pharmacy
- 4.4. The storage of implants is done for easy identified of relevant implants
- 4.5. Implants are stored in a clean, well lit, and ventilated environment
- 4.6. Implants related stock registers and the same are cross checked on a daily basis to ensure that implants are protected from loss and theft
- 4.7. Expiry date of implants are checked constantly and near expiry medications (3 months before expiry) are identified and stored separately/returned to the supplier
- 4.8. Beyond Expiry Date implants are not stored/used in the hospital
- 4.9. Implants are replenished in a timely manner when they are used
- 4.10. First In and First Out - Inventory practice is followed while maintaining the implant inventory
- 4.11. Pharmacy Audits are conducted by the Quality Manager every 3 months
- 4.12. Purchase of implants/prosthetics is carried out after prior approval of the Medical Superintendent

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5. PROCUREMENT OF PROSTHESIS / IMPLANTS

- 5.1. Hospital uses only those implants which are approved by the Pharmacy Therapeutic Committee
- 5.2. Final approval is done after consultation with respective doctors
- 5.3. All the approved implants are listed in the approved formulary
- 5.4. These implants are of different types, manufactured by different companies
- 5.5. The implants to be used in particular patient are selected by the concerned surgeon in discussion with the patients and family after explaining the benefits and side effects of the same
- 5.6. All purchases of the implants and devices follow the purchase policies of the pharmacy
- 5.7. The commonly used implants can be kept in hospital stores
- 5.8. The doctors concerned can give the list of implants required
- 5.9. Orders can be placed through the stores for commonly used prosthesis
- 5.10. Selection of implantable prosthesis will be based on scientific criteria and internationally recognized approvals

6. CRITERIA FOR SELECTION OF IMPLANTS / PROSTHESIS:

- 6.1. Technology, safety, effectiveness and clinical uses of devices
- 6.2. Current national and international policy and regulation regarding the same
- 6.3. Medical profession's opinion
- 6.4. The regulatory status of the device, both nationally and internationally
- 6.5. Medical literature review
- 6.6. Economic Issues

7. STOCKING

- 7.1. Almost all the implants used are readily available in the hospital
- 7.2. Some specific implants need to be ordered before surgery
- 7.3. Order for the implants are given to the purchase and stores in-charge by the OT in-charge after consulting with the surgeon

8. DOCUMENTATION

- 8.1. The identification (Serial Number & Batch Number) and relevant traceability details of each implants used is maintained by pasting/mentioning the respective bar-coded identification stickers/above mentioned identification details in the OT register, respective patient case sheets (OT records, Procedure records) and in the discharge summary of the patient
- 8.2. It is important to write both the serial number, batch number, bar code sticker details in the register and case sheets (OT records, Procedure records, Discharge summary

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records) so that the serial numbers/other identification details are available even if the barcode stickers become illegible in future

- 8.3. In case of a recall notice, the recall procedure will be followed
- 8.4. Patient and his / her family are counselled for the usage of implantable prosthesis and medical device including precautions, if any, by the treating doctor. The brochure of the implant/ device is available is shared with the patient and family
- 8.5. Complete identification and traceability with respect to batch and serial number of implantable prostheses are maintained and recorded in the patient's case sheet

9. RECORDS

| S. No | Record | Responsibility | Retention Period |
|-------|--|-------------------|-------------------|
| 1 | Pharmacy Statutory Documents File | Pharmacy Incharge | 1 Year |
| 2 | OP Prescription Form | Doctor | As per MRD Policy |
| 3 | Pharmacy & Therapeutic Committee Register | Quality Manager | 1 Year |
| 4 | OP Pharmacy – Stock Register | Pharmacy Incharge | 1 Year |
| 5 | Fridge Temperature Monitoring Register | Pharmacy Incharge | 1 Year |
| 6 | Drug Formulary | Pharmacy Incharge | 1 Year |
| 7 | Look Alike and Sound Alike (LASA) List | Pharmacy Incharge | 1 Year |
| 8 | Emergency Medications List | Pharmacy Incharge | 1 Year |
| 9 | Pharmacy Audit Register | Quality Manager | 1 Year |
| 10 | Look Alike and Sound Alike (LASA) Register | Pharmacy Incharge | 1 Year |

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|----|----------------------------------|-------------------|--------|
| 11 | Emergency Medications Register | Pharmacy Incharge | 1 Year |
| 12 | Near Expiry Medications Register | Pharmacy Incharge | 1 Year |
| 13 | Expired Medications Register | Pharmacy Incharge | 1 Year |

10. REFERENCE

- 10.1. MOM. 2: Pre-Accreditation Entry Level standards for Healthcare Organizations
- First Edition

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