

IMPLANTABLE PROSTHESIS

Group 3

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Chapter, Standard


- CHAPTER- Management of Medications
- Standard- MOM 12a,12b,12c,12d

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- ✓ Medical Implants
- ✓ Role of Pharmacy Department
 - Who can select the implants?
- ✓ Storage of medical implants
- ✓ Family and patient education
- ✓ Sterilization
- ✓ Documentation

MEDICAL IMPLANTS

- Implant



Man made
medical devices



Replace a missing biological structure



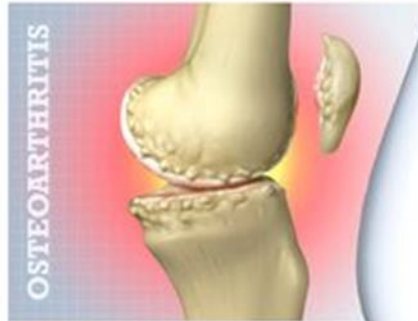
Support a damaged biological structure



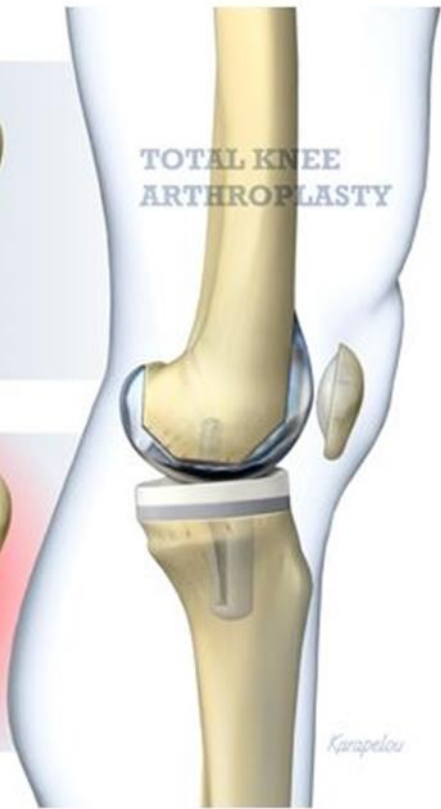
Enhance a existing biological structure



NORMAL



OSTEOARTHRITIS



TOTAL KNEE
ARTHROPLASTY

Karapetou



MEDICAL IMPLANTS

- Devices/tissues that are placed inside the body or under the surface of the body.
- Implants can be prosthetics that are intended to replace missing body parts or to deliver medication, monitor body function or support organs and tissues.
- Implants are made from bone, skin or tissues and can also be made with metal, plastic etc.
- Implants can be placed permanently or they can be removed once they are no longer needed.

Role of Pharmacy Department

- The Pharmacy department in the hospital needs to have a list of all the medical implants that is being used as per the scope of services
- This list shall include medical implants which will be selected and approved by the “Multidisciplinary Committee” of the hospital
- Implants needs to be purchased through pharmacy requests.
- The selection of implants shall be based on national / international approval or Good manufacturing Practices (GMP) certificates
- Reference – International notification from US-FDA, National notification from CDSCO (Central Drugs Standard Control Organization)

Storage of Medical Implant

- Documented procedures are necessary for procurement, storage, issuing and recording and are generally carried out by the operating room staff
- This shall all be done as per the manufacture's recommendations
- This document will be available in the OT along with the current stock indication /OT log book
- Hospital must list of doctors privileged to use them

Family and Patient Education

- Patient and family should be counseled about the implants
 - About the risks and complications – include bruising at the surgical site, pain, swelling and redness while removing and inserting the implants, infection and implant failures
 - Infections are common. If you get infection you may need to have a drain inserted near the implant, take medication or even have implant removed
 - Over time implant could move, break or stop working properly. If this happens one may require additional surgery to repair or replace the implant
- They need to be educated about the type and material of implant and possible allergies
- They need to be briefed on non-usage of specific drug
- When to report to hospital if a particular symptom occurs
- Benefits of the device and how it will affect their quality of life

Sterilisation of Medical Implants

- Implants can be either presterilized (joints) or sterilized in the hospital(screws ,plates).
- Steam, Ethylene oxide gas and gamma sterilization are the common forms of sterilization used for medical implants
- Two most common packages for medical implant devices are pouches and trays.
- Sealed packages must undergo packaging validation and sterilization validation to maintain the shelf life of the product.

Documentation

- Implant details such as

- Name of patient

- UHID number

- DOB/age/sex

- Patient address

- Procedure carried out

- Date of admission of implant

- Date of removal (if the implant is to be removed)

- Manufacturer

- Type of implant

- Size of implant use

- Batch number

- Serial number

➤ Details shall be documented in the implant register in OT, patient record and discharge summary along with the stickers

Thank

you

