IMPLANTABLE PROSTHESIS

by GROUP 4, CPOIH training, GNRC dispur

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- **Word ‘Prosthesis’ from Ancient Greek *prosthesis*, "addition, application, attachment“. medical device manufactured to replace a missing biological structure, support a damaged biological structure, or enhance an existing biological structure. Medical implants are man-made devices, in contrast to a transplant, which is a transplanted biomedical tissue. The surface of implants that contact the body might be made of a biomedical material such as titanium, silicone, apatite, acrylics, carbon fibres etc, depending on what is the most functional.[1] In some cases implants contain electronics e.g. artificial pacemaker and cochlear implants. Some implants are bioactive, such as subcutaneous drug delivery devices in the form of implantable pills or drug-eluting stents.**
- **Medical implants are devices or tissues that are placed inside or on the surface of the body. Many implants are prosthetics, intended to replace missing body parts. Other implants deliver medication, monitor body functions, or provide support to organs and tissues.**

Target Personnel's

- Surgeons (Ctvs, orthpedics, ENT etc)
- Prosthetists
- Psychiatrists
- OT staff
- Pharmacy
- Medical superintendant
- Occupational therapists
- Physiotherapists

Training schedules

- Twice a year training and audit of pharmacy purchase for implants
- Training once a year of the respective surgeons doing the implantations
- Twice a year training of OT staff
- Once a year training for Physiotherapists, psychiatrist, medical superintendants, regarding follow up of patients of implants procedures
- Twice a year meeting of concerned multi disciplinary committee, regarding vendor preference, quality of products, audit of stores and failure and complication rates if any

Labelling requirements for medical devices in India

- CDSCO is Indian FDA, on 25th September 2014, issued amendments to Drug & Cosmetic Rules, 1945. Rule 109A – amendment for labelling requirements.
  - ✓ Device should have proper name & details.
  - ✓ Manufacturing name & address. Date of manufacture, expiry, date of sterlization.
  - ✓ Distinctive batch number, correct statement of net quantity, required special storage, relevant precautions.
  - ✓ May bear symbols recognized by Bureau of Indian Standards or International Organization for Standardization.

Prosthetic amputee rehabilitation is primarily coordinated by a prosthetist and an inter-disciplinary team of health care professionals including psychiatrists, surgeons, physical therapists, and occupational therapists. Prosthetics are commonly created with CAD (Computer-Aided Design), a software interface that helps creators visualize the creation in a 3D form or can also be man made.

Types :

Craniofacial prostheses include intra-oral and extra-oral prostheses. Extra-oral prostheses are further divided into hemifacial, auricular (ear), nasal, orbital and ocular. Intra-oral prostheses include dental prostheses such as dentures, obturators and dental implants.

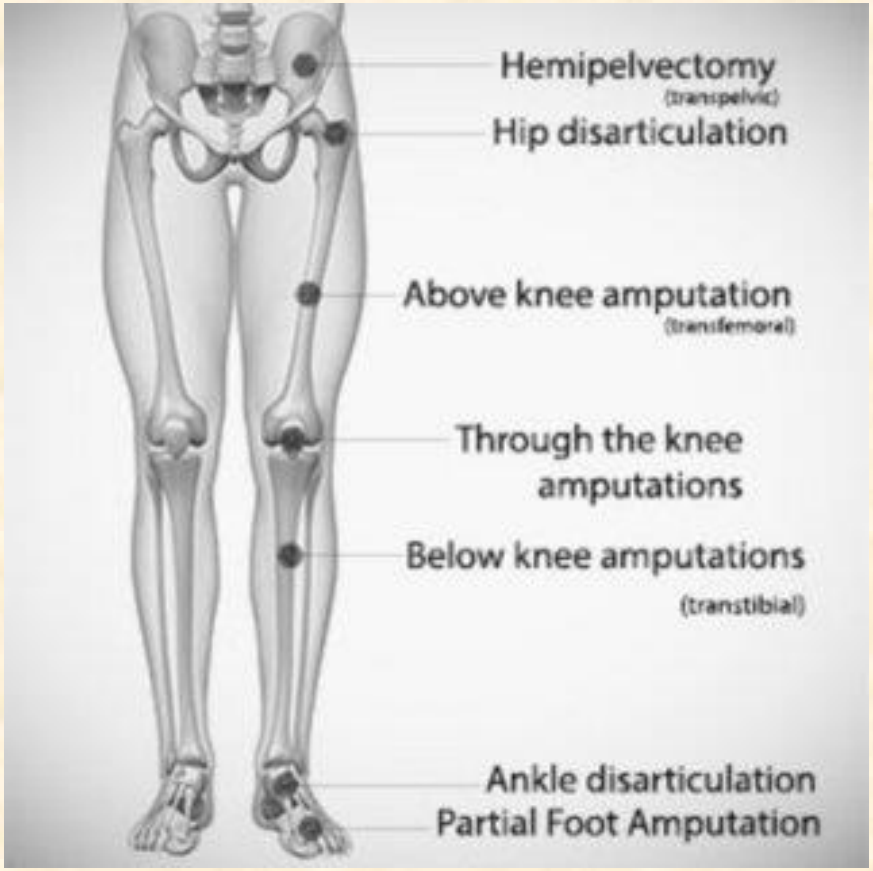
Prostheses of the neck include larynx, substitutes, trachea and upper oesophageal replacements,

Somato prostheses of the torso include breast prostheses which may be either single or bilateral, full breast devices or nipple prostheses.

Penile prostheses are used to treat erectile dysfunction.

Limb prosthesis.

- **Upper-extremity prostheses** are used at varying levels of amputation: forequarter, shoulder disarticulation, transhumeral prosthesis, elbow disarticulation, transradial prosthesis, wrist disarticulation, full hand, partial hand, finger, partial finger. A transradial prosthesis is an artificial limb that replaces an arm missing below the elbow.
- Upper limb prostheses can be categorized in three main categories: Passive devices, Body Powered devices, Externally Powered (myoelectric) devices.
- Passive – Absence of active grasping. Useful for bi manual tasks or in gesticulation in social interactions. According to scientific data, a third of upper limb amuptees world wide use a prosthetic passive hand.
- Body powered are basically cable operated.
- Myoelectric : Based on sensors via electrodes, picks up impulses from the connected muscles. Eg. When the muscles of the upper arm move, they cause an artificial hand to open or close.



Lisfranc : tarso metatarsal. Chopart : calcaneo cuboid. Syme amputation : ankle disarticulation.

FDA patient related questionnaire

- Will my implant be permanent or removable? If the device is permanent, find out how long it should last. If the device is removable, find out how long it will be implanted in you and what factors will determine when it can come out.
- What material will the implant be made from? Make sure you are not allergic to any of the components in the implant.
- How many of these procedures have you done? The more experience a doctor has with inserting implants, the better the outcome may be.
- What are the complication rates from the procedure? Make sure you understand the risks of the surgery, infection, and device failure.
- What are the benefits of the procedure? Make sure you understand how the device will benefit you and if it will affect your quality of life.

Medical devices under drugs and Cosmetic act, under CDSCO

- Disposable hypodermic needles
- Disposable hypodermic syringes
- Disposable perfusion sets
- IV diagnostic devices for HIV HCV HBSAG
- Cardiac stents
- Drug eluting stents
- Bone cement
- Heart valves
- Internal prosthetic replacements
- Ablation devices


Dzieki
Ačiū
TACK!
Þakka þér fyrir
Takk
Danke!
Teşekkürler
Salamat
Mahalo
Cảm ơn bạn
谢谢您
dhanayawad
Grazie
Хвала
Kiitos
Bedankt
mulțumesc!
¡gracias!
Спасибо
Σε ευχαριστώ
감사합니다
obrigado!
Hvala
Go raibh maith agat
THANK YOU!
ありがとうございました
Domo
merci!
Благодаря
a danke!
Paldies
תודות
Toda
TANAN
vďaka!
Asante