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HACKETTSTOWN COMMUNITY HOSPITAL

Division of Nursing

Index: 7420.000
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IMPLANTATION OF MEDICAL DEVICES

TITLE:

I.   Definition (Food and Drug Administration): A medical device is any health care product that does not achieve any of its purpose by chemical action or on the body or by being metabolized.

II.   Care & Handling of Implants

   A. In-Hospital Sterilization and Guidelines

       1. In-hospital sterilized implants are processed in Central Supply and held pending spore test results except for emergencies or when a one-of-a-kind implant is contaminated.

       2. In the event that it becomes necessary to use the implantable before the spore test is incubated, the following procedure will be used.

           a. A release form will be signed in Central Supply by the attending physician.
           b. An incident report will be made in the OR reflecting the reasons for the emergency and the parameters of the sterilization cycle.
           c. The attending physician and infection control practitioner will be notified of a positive biological indicator by Central Supply.

       3. In the event that an implantable must be processed in the OR, the following procedure will be used.

           a. The item will be cleaned to remove bioburdens according to C.S. standards/
           b. The item will be wrapped in one layer of cloth to prevent contamination when removed from the autoclave.
           c. A biological indicator will be included in the sterilization cycle and then labeled and incubated.
           d. The express pre-vac cycle will be used to sterilize the item. (4 min sterilize and 3 min dry).
           e. An incident report will be made reflecting the reasons for the emergency and the parameters of the sterilization cycle.
           f. The attending physician and infection control practitioner will be notified of a positive biological indicator.

   B. Resterilization of Implants

       1. Only those implants recommended by the manufacturer may be resterilized.

       2. Resterilization of used or damaged implant items in inappropriate.