HARDIN COUNTY GENERAL HOSPITAL
HOSPITAL-WIDE POLICY

Title: SAFE MEDICAL DEVICES ACT **Effective Date: 8/6/2006**
Policy Number: 146 **Med Staff:**
Regulation: Safe Medical Device Act of 1990 **Admin:**

I. POLICY

To promote the safety of patients, visitors and staff and comply with Safe Medical Device Act of 1990.

Appropriate corrective action will be taken to protect the safety of all patients, visitors and staff of Hardin County General Hospital whenever information on a product related hazard or potential hazard is brought to the attention of this facility.

The Safe Medical Device Act of 1990 requires that medical device users report to the manufacturer and/or the F.D.A. incidents that reasonably suggest that there is a probability that a medical device has caused or contributed to the death of a patient, serious injury or illness or a patient.

In accordance with Safe Medical Device Act of 1990, Hardin County General Hospital has established methods for reporting these events as described in this procedure. **In cases involving medical devices where patients are injured or become seriously ill, a report must be filed within 10 working days to the manufacturer or the FDA if the manufacturer is unknown.**

II. DEFINITIONS

Serious illness or injury as defined by the Act is an illness or injury that is life threatening or that either results in permanent impairment of bodily function or permanent damage to a bodily structure or necessitates immediate medical or surgical intervention to preclude permanent impairment of a bodily function or permanent damage to a bodily structure.

A medical device includes but is not limited to ventilators, monitors, and any other electronic equipment, implants, thermometers, patient restraints, syringes, catheters, in vitro diagnostic test kits and reagents, disposables, components, parts, accessories and related software.

Basically, anything that is not a drug is considered a device under the Act. Other examples include, but are not limited to, a(n): anesthesia machine, pacemaker, heart valve, suture, surgical sponge, wheelchair, hospital bed or gurney, catheter, infusion pump, dialysis machine and artificial joint.

III. RESPONSIBILITY

All employees who are involved with patient care, review patient care, repair devices or provide device preventative maintenance have a duty under the Act to report device-related incidents (*e.g.*, device failure, device malfunction, inadequate design or labeling and user error). This duty extends to physicians, nurses, allied health professionals, students, volunteers and all other persons affiliated with the facility.

IV. EQUIPMENT

V. PROCEDURES
INFECTION CONTROL: N/A

When a device-related incident occurs, employees should:

- Save the device, packaging and all related parts, and note the devices clinical engineering number or serial number.
- Place a "Defective . . . Do Not Use" tag on the device and remove it from use.
- Notify the patients physician or refer the visitor or employee to the Emergency Department.
- Notify the department most appropriate to handle the device (*e.g.*, Maintenance Department Pharmacy, etc.).
- Telephone Risk Management, Hospital Administrator, and/or Administrative Duty Representative immediately.
- Complete an incident report and deliver it to Risk Management within twenty-four hours following the occurrence.

The Risk Management office will file the report(s) with the manufacturer of the device and/or the FDA. Since these reports must be filed within ***ten working days*** of the date of the incident, ***prompt*** reporting to Risk Management is essential.

MEDICAL DEVICE IMPLANT TRACKING

The Act requires that hospitals report and track certain information regarding medical devices specified by the FDA. These devices are primarily medical devices that are permanently implanted in a patient or certain life-sustaining or life-supporting devices used outside of the hospital. The designated devices include, for example, vascular grafts, ventricular bypass devices, pacemakers, implantable infusion pumps, apnea monitors and certain silicone gel-filled prosthesis.

The Act requires that receipt of tracked devices be reported to the manufacturer and that **patient demographic and medical information be reported to the manufacturer upon implanting or use of the device within *five working days***. This enables the manufacturer to trace specified medical devices to patients and to facilitate patient notification and/or device recall.

VI. DOCUMENTATION