U.S. FOOD & DRUG ADMINISTRATION

Information about the Use of Forced Air Thermal Regulating Systems - Letter to Health Care Providers

August 30, 2017

Dear Health Care Provider,

The FDA is reminding health care providers that using thermoregulation devices during surgery, including forced air thermoregulating systems, have been demonstrated to result in less bleeding, faster recovery times, and decreased risk of infection for patients.

The FDA recently became aware that some health care providers and patients may be avoiding the use of forced air thermal regulating systems during surgical procedures due to concerns of a potential increased risk of surgical site infection (e.g., following joint replacement surgery). After a thorough review of available data, the FDA has been unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection.

Therefore, the FDA continues to recommend the use of thermoregulating devices (including forced air thermal regulating systems) for surgical procedures when clinically warranted. Surgical procedures performed without the use of a thermoregulation system may cause adverse health consequences for patients during the postoperative and recovery process.

Forced air thermal regulating systems, also called forced air warmers or forced air warming systems, are devices used to regulate a patient's temperature during surgical procedures. Forced air thermal regulating systems use an electrical blower to circulate filtered, temperature controlled air through a hose into a blanket placed over or under a patient.

To determine if there is an increased risk of surgical site infection when forced air thermal regulating systems are used during surgery, the FDA collected and analyzed data available to date from several sources, including medical device reports received by the agency, information from manufacturers and hospitals, publically available medical literature, operating room guidelines, and ventilation requirements.

As always, please follow the manufacturer's instructions for use in the operating room/and or the postoperative environment.

FDA ACTIONS

The FDA will continue to actively monitor this situation and will update this communication if significant new information becomes available.

CONTACT US

If you have questions about this communication, please contact CDRH's Division of Industry Communication and Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV), 800-638-2041, or 301-796-7100.

Sincerely,
/s/
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Center for Devices and Radiological Health
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