DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
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APR 25 2007

MEMORANDUM FOR COMMANDER, NAVY MEDICINE EAST
COMMANDER, NAVY MEDICINE WEST
COMMANDER, NAVY MEDICINE NATIONAL CAPITOL AREA
COMMANDER, NAVY MEDICINE SUPPORT COMMAND

SUBJECT: Policy on Reprocessing of Medical Single-Use Devices (SUD)

Ref: (a) Department of the Defense, Office of the Inspector General Report on Reprocessing Medical Single-Use Devices in DoD, September 30, 2002
(b) Assistant Secretary of Defense for Health Affairs (OASD/HA) Policy on Reprocessing Medical Single-Use Devices
(c) Department of Defense Directives 5136.1 "Assistant Secretary of Defense for Health Affairs," May 27, 1994
(d) Food and Drug Administration Guidance Document, "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals." August 14, 2000
(e) Department of Defense Policy Memorandum "Reprocessing of Medical Single-Use Devices" July 7, 2006
(f) Food and Drug Administration Medical Devices; Reprocessed Single-Devices 2003, FR Doc 03-10413
(g) Joint Commission on Accreditation of Health Care Organizations: Hospital Accreditation Standards; Surveillance, Prevention, and Control of Infection
(h) Joint Commission on Accreditation of Health Care Organizations: Standards for Ambulatory Care; Surveillance, Prevention, and Control of Infection
(i) BUMEDINST 622.09A. Nosocomial Infection Control Program
(j) Centers for Disease Control and Prevention Guidelines on Disinfection and Sterilization of Patient Care Equipment, 1985

This memorandum establishes policy and updated guidance for the reuse of single use devices based upon FDA and DoD guidance.

References (a) through (j) detail current Department of Defense, Food and Drug Administration (FDA) and CDC guidance for the reprocessing of medical SUDs. The FDA is the regulating authority for this process and the reprocessors. Reference (i) provides the current equipment disinfection and sterilization guidance applicable to Navy Infection Control Programs.

The FDA requires that all SUDs, as well as multiple use devices, be clearly labeled and differentiated. Medical devices that are not designated by original manufacturer labeling or instructions for multiple use are to be considered single-use devices. Military Treatment Facilities (MTFs) are not obligated to use reprocessed SUDs, but are authorized to reuse reprocessed SUDs approved for reuse by the FDA. MTFs will not reprocess SUDs internally. MTFs choosing to use reprocessed SUDs will utilize a third-party FDA approved reprocessor. Medical device reprocessor

organizations are required by the FDA to undergo the same inspection and regulatory scrutiny as the original manufacturer of the device. SUDs in Device Classes I-III will be considered for reprocessing if they have been approved for reprocessing by the FDA. Information on the most current device classification and on reuse can be found at www.fda.gov/cdrh/devadvice/3132.html and www.fda.gov/cdrh/reuse/index.shtml.

The reuse of SUDs should never compromise patient safety. SUDs are intended by the manufacturer to be used on a specific patient during a specific procedure. Prior to the decision to reuse SUDs, the MTF must address the following factors in policy guidance and operational procedures they develop:

1. A robust quality control program that monitors the SUDs received from the third party processors; a process for making staff aware of the reprocessing program and requirements;
2. Training on handling of the SUDs for designated staff;
3. Reporting mechanisms for all adverse events involving reprocessed SUDs to the command risk managers/patient safety staff, Region and Bureau of Medicine and Surgery.
4. Bureau of Medicine and Surgery will report the event to the FDA.

The decision to reprocess devices will be supported by command leadership and documented. Oversight will be delegated to an appropriate internal command authority (e.g., the infection control program) to ensure compliance with the most current CDC and FDA guidance. The program will be reviewed on a periodic basis to assess its efficacy.

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