THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C 20301-1200

HEALTH AFFAIRS

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MEMORANDUM FOR SURGEON GENERAL OF THE ARMY
SURGEON GENERAL OF THE NAVY
SURGEON GENERAL OF THE AIR FORCE

SUBJECT: Policy on Reprocessing Medical Single-Use Devices

References: (a) Department of Defense Directive 5136.1, "Assistant Secretary of Defense for Health Affairs," May 27, 1994

(b) Food and Drug Administration Guidance Document, "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals," August 14, 2000

(c) Department of Defense Inspector General Final Report, "Reprocessed Medical Single-Use Devices in DoD," September 30, 2002

(d) Department of Defense Policy Memorandum, "Reprocessing of Medical Single-Use Devices," October 18, 2002

(e) Food and Drug Administration Guidance Document, "Medical Device User Fee and Modernization Act of 2002, Validation Act in Premarket Notification Submissions (520(k) s) for Reprocessed Single-Use Medical Devices," June 1, 2004

This policy memorandum, issued under the authority of reference (a), provides guidance consistent with references (b)–(e) for the reprocessing of medical single-use devices (SUD). This memorandum based on current Food and Drug Administration (FDA) guidance updates a previous policy memorandum (reference (d)). The FDA is the regulating authority for this process and the reprocessors.

Military treatment facilities (MTFs) shall not be obligated to use reprocessed SUDs. Further, MTFs shall not reprocess SUDs internally for their own use, or any other facility. However, MTFs shall have the option of utilizing FDA-approved reprocessed SUDs. This document provides guidance if an MTF decides to pursue reprocessing SUDs.

Regardless of whether an MTF chooses to reprocess devices, the FDA requires that all SUDs, as well as multiple-use devices, be clearly labeled and differentiated. MTFs shall have procedures in place to determine how a SUD shall be handled after its use. Medical devices that are not noted by original manufacturer labeling or instructions for multiple use are to be considered single-use devices and treated accordingly. These procedures shall ensure that SUDs are properly identified before use, safely collected after initial use and appropriately disposed of, or transferred to a reprocessing service.

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MTFs are authorized to reprocess and reuse SUDs that are approved for reprocessing by the FDA. MTFs choosing to use reprocessed SUDs shall 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 shall be considered for reprocessing if they have been approved for reprocessing by the FDA. Information on the most current device classification can be found at *www.fda.gov/cdrh/devadvice/3132.html*.

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. An MTF should consider several factors before making a decision to reprocess. Along with an assessment of cost savings, etc., reprocessing may affect negotiations with medical device manufacturers and prime vendors possibly impacting prices, regional standardization initiatives and other incentives for MTFs. SUDs that have been reprocessed according to FDA standards have an excellent safety record. However, adverse events related to their use may occur. Per federal law, the event shall be reported to the FDA. These events shall also be reported per local policy to the MTF commander, the respective Service headquarters, and the DoD Patient Safety Center.

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

Facilities either considering having SUDS reprocessed, or that have questions about the reuse of certain devices should consult the FDA Web site, *www.fda.gov/cdrh/reuse/index.shtml*.

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This policy is effective immediately This memorandum supercedes previous memoranda on this subject.

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