THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D C 20301-1200

HEALTH AFFAIRS

OCT 18 2002

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

SUBJECT: Department of Defense Policy on Reprocessing of Medical Single Use Devices

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

(b) DoD Inspector General Draft Report, "Reprocessed Medical Single-Use Devices in DoD," June 28, 2002

(c) Food and Drug Administration (FDA) Guidance Document, "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals," August 14, 2002

This policy memorandum, issued under the authority of reference (a), provides guidance consistent with references (b) through (c) for the reprocessing of single use devices.

Medical single-use devices (SUDs) are intended by the manufacturer to be used on one patient during one procedure. Some of these devices can be reprocessed for further use. The FDA regulates the reprocessing of SUDs. Equipment reprocessors are required to undergo the same scrutiny as original medical device manufacturers. Meeting those requirements is difficult. There are no facilities in the Military Health System that are certified as reprocessors.

Reprocessing selected SUDs can provide significant savings for military treatment facilities (MTFs). Reuse of SUDs should never compromise patient safety. MTFs that choose to reuse single use devices must use a reprocessor who has been approved by the FDA for the reprocessing of that device. The Department of Veterans Affairs has a contract for the reprocessing of many types of devices that can be used by the MTFs MTFs may also use other contracts or local purchase agreements with FDA approved third-party reprocessors. Several factors should be considered by MTFs in making decisions about the reprocessing of single use devices. Facilities vary greatly in the number and types of SUDs they use. Different types of devices vary in their potential for cost savings with reprocessing. Reprocessing by third parties may affect negotiations with medical device manufacturers and prime vendors and could impact

prices and incentives for MTFs. Reprocessing may also affect regional standardization initiatives.

Facilities that are considering having SUDs reprocessed or who have questions about the reuse of certain devices should consult the FDA web site at http://www.fda.gov/cdrh/reuse/index.shtml for additional information

This policy is effective immediately.

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