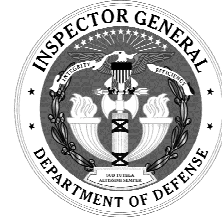


September 30, 2002



Health Care

Reprocessed Medical Single-Use Devices in DoD (D-2002-153)

Department of Defense
Office of the Inspector General

Quality

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Acronyms

AMC	Army Medical Center
ASD(HA)	Assistant Secretary of Defense (Health Affairs)
FDA	Food and Drug Administration
MC	Medical Center
MTF	Military Treatment Facility
NMC	Naval Medical Center
SCD	Sequential Compression Device
SUD	Single-Use Device



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September 30, 2002

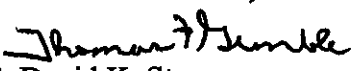
MEMORANDUM FOR ASSISTANT SECRETARY OF DEFENSE (HEALTH
AFFAIRS)
ASSISTANT SECRETARY OF THE AIR FORCE
(FINANCIAL MANAGEMENT AND COMPTROLLER)
NAVAL INSPECTOR GENERAL
AUDITOR GENERAL, DEPARTMENT OF THE ARMY

SUBJECT: Report on Reprocessed Medical Single-Use Devices in DoD
(Report No. D-2002-153)

We are providing this report for review and comment. The Assistant Secretary of Defense (Health Affairs) and the Army and Air Force Surgeons General did not respond to the draft report. However, we considered comments from the Navy when preparing the final report.

DoD Directive 7650.3 requires that all recommendations be resolved promptly. Therefore, we request that the Assistant Secretary of Defense (Health Affairs) provide comments on Recommendation 1. and the management controls over the reprocessing of single-use devices. We also request that the Army and Air Force Surgeons General provide comments on Recommendation 2. If possible, please provide management comments in electronic format (Adobe Acrobat file only). Send electronic transmission to the e-mail addresses cited in the last paragraph of this memorandum. Copies of the management comments must contain the actual signature of the authorizing official. We cannot accept the / Signed / symbol in place of the actual signature. If you arrange to send classified comments electronically, they must be sent over the Secret Internet Protocol Router Network (SIPRNET). We request that management provide comments on the report by November 29, 2002.

We appreciate the courtesies extended to the staff. For additional information on this report, please contact Mr. Michael A. Joseph (mjoseph@dodig.osd.mil) or Mr. Timothy J. Tonkovic at (ttonkovic@dodig.osd.mil) at (757) 872-4801. The audit team members are listed inside the back cover.


David K. Steensma
Deputy Assistant Inspector General
for Auditing

Office of the Inspector General of the Department of Defense

Report No. D-2002-153

September 30, 2002

(Project No. D2001LF-0177)

Reprocessed Medical Single-Use Devices in DoD

Executive Summary

Who Should Read This Report and Why? Assistant Secretary of Defense (Health Affairs) personnel responsible for military health system policy, Military Department Surgeon General personnel, and military treatment facility management and operational personnel should read this report. The report discusses the potential for significant cost avoidance that may be achieved through the use of reprocessed medical single-use devices.

Background. Medical single-use devices are manufactured to be used on one patient during one medical procedure. Multiple-use devices are intended to be used more than one time and include instructions for decontamination and resterilization.

The emergence of new materials and sterilization methods, and the increasing costs of health care, resulted in the development of medical single-use devices and the practice of reprocessing the devices. The practice of reprocessing medical single-use devices increased when hospitals realized that reuse produced up to a 50 percent savings compared with purchasing new single-use devices. Over time, the complexity of medical single-use devices increased and third-party reproducers evolved to meet the increased demand of making used single-use devices patient-ready.

The DoD worldwide military health system operates an extensive system of military treatment facilities (medical centers, hospitals, and clinics). As of September 2002, there were 27 Army, 25 Navy, and 22 Air Force medical centers and hospitals and approximately 460 clinics in the United States and overseas.

The Food and Drug Administration regulates medical single-use device reproducers. On August 14, 2000, the Food and Drug Administration issued regulatory guidance for third-party and hospital reproducers regarding their responsibility as manufacturers engaged in reprocessing devices labeled for single use. Under the Food and Drug Administration guidance, third-party and hospital reproducers are required to undergo the same scrutiny as original medical device manufacturers.

Results. The military health system used reprocessed single-use devices on a very limited basis during FY 2001. Additionally, three of the six military treatment facilities we visited were reusing single-use devices that had not been reprocessed in accordance with Food and Drug Administration guidance, partly because the devices were not identified as single-use devices. After considering patient safety and operational issues, the Assistant Secretary should issue policy regarding the reuse of medical single-use devices in the military health system. The Assistant Secretary should also initiate discussions with the Food and Drug Administration with the intent of clarifying single-use device labeling requirements. Also, the Military Department Surgeons General should issue policy consistent with the guidance from the Office of the Assistant

Secretary of Defense (Health Affairs) and ensure military treatment facility personnel are aware of and trained in the reuse of single-use devices. We recognize that cutting costs without compromising the safety and standards of patient care is a continuous challenge for military health system personnel. If the Assistant Secretary determines that reprocessing is in the best interest of DoD, reprocessing initiatives can result in procurement cost avoidances for military treatment facilities. We determined that the six DoD military treatment facilities could have avoided procurement costs of about \$605,000 during FY 2001 by reprocessing the limited number of devices we sampled. The full extent of potential monetary benefits will be quantifiable after military treatment facilities obtain complete single-use device procurement and usage information, DoD determines its level of participation in reprocessing initiatives, and the Food and Drug Administration finalizes its approval process. Policy and guidance issued by the Assistant Secretary concerning the reprocessing of medical single-use devices should alleviate the material management control weakness identified by this audit. (See the Finding section of the report for the detailed recommendations.)

Management Comments and Audit Response. A draft of this report was issued on June 28, 2002. The Navy concurred with the report and recommendations. The Assistant Secretary of Defense (Health Affairs) and the Army and Air Force Surgeons General did not respond to the draft report. We request that the Assistant Secretary and the Army and Air Force Surgeons General provide comments on the report by November 29, 2002.

See the Finding section of the report for a discussion of the management comments and the Management Comments section of the report for a complete text of the Navy comments.

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Background

Medical single-use devices (SUDs) are intended by the original manufacturer to be used on one patient during one medical procedure. A SUD is not intended for reuse on another patient or on the same patient at another time. Multiple-use devices are intended to be used more than one time and include instructions for decontamination and resterilization.

Manufacturers began to sell SUDs because of the development of new materials, the increased demand for disposable devices, and because of the development of new sterilization methods. The practice of reusing devices labeled as single use began in hospitals in the late 1970s. Since then, demand for reprocessing services steadily increased and third-party reprocessors evolved to satisfy the cleaning, functional testing, packaging, and sterilization necessary to make used SUDs patient-ready.

The Office of the Assistant Secretary of Defense (Health Affairs) (ASD[HA]) establishes policy that allows the military health system to provide health support for military deployments and to sustain the health of active duty Service members, their families, and other eligible beneficiaries. The Offices of the Military Department Surgeons General support the medical readiness of the Services and develop, maintain, and operate a comprehensive and cost-effective health care system.

The Food and Drug Administration (FDA) regulates SUD reprocessors. On August 14, 2000, the FDA issued regulatory guidance for third-party and hospital reprocessors regarding their responsibility as manufacturers engaged in reprocessing devices labeled for single use. Under the FDA guidance, third-party and hospital reprocessors are subject to the same FDA guidelines and scrutiny as original medical device manufacturers.

The FDA has categorized SUDs into three risk categories. Class I devices are devices with low patient risk, such as orthopedic surgical drills. Class II devices are considered to have moderate patient risk, such as a cardiac mapping catheter used to map electrical activity of the heart. Unless exempt by the FDA, Class I and II devices require a premarket notification submission to the FDA. A premarket notification informs the FDA of a reprocessor's intent to reprocess a device and includes information comparing the unique characteristics of a newly manufactured device with a reprocessed device. The FDA uses that information to determine the safety and effectiveness of the reprocessed SUDs.

Class III devices have a high patient risk and are the most regulated. An example of a Class III device is a cardiac ablation catheter, which is used to treat irregular heartbeats. Class III devices require a third-party or hospital reprocessor to submit a premarket approval application or a premarket notification, depending on the category and unique characteristics of devices within the category. A premarket approval application must include valid scientific evidence demonstrating the safety and effectiveness of the reprocessed device. Before approving a premarket application, the FDA requires a satisfactory inspection of a reprocessing facility.

SUD Reprocessing. Reprocessing includes all operations performed to make a used SUD patient-ready or to make an opened, but unused SUD patient-ready. When used SUDs arrive at a third-party reprocessor, they are inspected, sorted by type of device, and decontaminated. After decontamination and sorting, SUDs are individually examined for irreversible damage, then soaked, cleaned, and disinfected. After cleaning, SUDs are coded to ensure that they are returned to their originating hospital and are entered in a computerized logging system that tracks the SUD through the various reprocessing cycles. If a SUD is found to have defects or irreversible damage, the device is rejected and destroyed.

The next step in the reprocessing cycle includes placement of a nondestructive laser etching on most SUDs to allow instant retrieval of detailed information about the device, including the number of times the device has been reprocessed. Some SUDs, such as blades or saws, may require restoration. Other types of SUDs may require functional testing to ensure the device performs as intended by the original manufacturer. Any device that does not meet the standards and specifications of the original manufacturer is rejected and destroyed. After reprocessing, a “final clean” operation is performed that requires the SUDs to be processed with heated, reverse osmosis/deionized water.

Packaging and reesterilization is the final phase prior to shipment. Devices are placed in Mylar pouches with a chemical indicator strip on each pouch. Separate biological indicators are included during the reesterilization process to confirm sterility. After the reesterilization is complete, the reprocessed SUDs are quarantined and the biological indicators are removed and sent to an independent laboratory for testing. If the independent test results of the biological indicators are negative, the reprocessed SUDs are shipped to their originating hospital.

Objectives

The overall audit objective was to evaluate the use and handling of reprocessed SUDs in DoD. Specifically, we evaluated the extent of reuse that occurs in the military health system, determined whether reprocessing was performed in compliance with FDA guidance, and determined whether the reuse of SUDs could result in monetary benefits. We also evaluated the management control program as it related to the audit objectives. See Appendix A for a discussion of the audit scope and methodology, our review of the management control program, and prior coverage.

Reprocessing of Medical Single-Use Devices

The military health system used reprocessed SUDs on a very limited basis during FY 2001. Additionally, three of the six military treatment facilities (MTFs) we visited were reusing SUDs that had not been reprocessed in accordance with FDA guidance. Limited SUD reuse and reprocessing noncompliance occurred because DoD did not have a policy on the use of reprocessed SUDs. Also, some SUDs that had not been reprocessed in accordance with FDA guidance were not labeled for single use by the manufacturer. As a result, DoD did not take full advantage of opportunities available from the use of reprocessed SUDs and may be impacting patient safety by not complying with FDA guidance. Based on procurement data for a limited number of devices sampled, we calculated that the six DoD MTFs could have avoided procurement costs of about \$605,000 during FY 2001 by using reprocessed SUDs. The full extent of potential monetary benefits will be quantifiable after MTFs obtain complete SUD procurement and usage information, DoD determines its level of participation in reprocessing initiatives, and the FDA finalizes its approval process.

FDA Reprocessing Guidance on SUDs

On August 14, 2000, the FDA issued “Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals.” The guidance states that the FDA will regulate hospitals and third-party reproducers engaged in reprocessing SUDs the same way the FDA now regulates original medical device manufacturers. The FDA could not specify the exact number of regulated third-party reproducers, but estimated that there were about 17 in the United States.

The FDA guidance for third-party and hospital reproducers outlines the responsibility of manufacturers engaged in reprocessing medical devices labeled for single use under the Federal Food, Drug, and Cosmetic Act. The guidance requires third-party reproducers and hospital reproducers to meet the same basic requirements that are imposed on original medical device manufacturers. The FDA guidance states that third-party and hospital reproducers must:

- register their establishment with the FDA and provide a list of SUDs that are reprocessed or resterilized;
- establish SUD reporting systems of adverse events that may have involved a medical device;
- establish a SUD tracking system that will enable third-party reproducers and hospital reproducers to locate SUDs in the event corrective actions or modifications are necessary;

-
- report to the FDA any SUD corrections or removals undertaken to reduce a risk to health posed by a device;
 - establish good manufacturing practices that govern the controls, facilities, and methods used for the design, manufacture, packaging, labeling, storage, and servicing of all finished SUDs;
 - implement a labeling requirement regarding the name and place of manufacture and include adequate directions for the device's intended use or qualify for an exemption; and
 - submit either a premarket notification or premarket approval application to the FDA prior to reprocessing a SUD.

As of August 14, 2000, the FDA had identified more than 200 categories of medical SUDs that were known to be reprocessed by third-party reprocessors or hospital reprocessors. After August 14, 2000, third-party reprocessors were required to submit applications to permit them to continue reprocessing specific SUDs. Those applications permitted them to continue, on an interim basis, reprocessing SUDs pending FDA approval or rejection of the application. Upon approval of premarket applications, the FDA issues an "order" finding that devices included in the application are substantially equivalent to when they were originally manufactured and clears them for reprocessing and reuse. When the FDA rejects an application, the devices included in the submission cannot be reprocessed for reuse by the submitting reprocessor.

The term "category" used in this report refers to a group of similar devices, such as external fixation devices. The term "type" refers to individual devices with unique characteristics within a category, such as carbon fiber rods.

The types of SUDs reprocessed by third-party reprocessors can vary over time. For example, devices may be added when reprocessors determine that a new model SUD submitted from an MTF can be reprocessed under an existing application. Devices are removed from reprocessing lists when the SUDs are no longer economical to reprocess or when the FDA rejects an application. Additionally, not all reprocessors reprocess all categories or types of SUDs. Reprocessors tailor their operations to categories and types of SUDs that are economical and profitable to reprocess.

DoD Use of Reprocessed SUDs

The military health system used reprocessed SUDs on a very limited basis during FY 2001. Additionally, three of the six MTFs that we visited were reusing SUDs that had not been reprocessed in accordance with FDA guidance.

Awareness and Use of Reprocessed SUDs by DoD. Personnel from the Office of the ASD(HA) and the Offices of the Military Department Surgeons General were unsure of the extent of reprocessing in the military health system. Personnel at the Office of the Army Surgeon General stated that only 3 of 27 Army MTFs

were using a third-party reprocessing contractor. Office of the Navy Surgeon General personnel stated that none of the 25 Navy MTFs were using a third-party reprocessor. Personnel at the Office of the Air Force Surgeon General stated that only 2 of 22 Air Force MTFs were using a third-party reprocessor.

We visited two of the three Army MTFs and the two Air Force MTFs identified by the Offices of the Army and the Air Force Surgeons General as using third-party reprocessors. We also selected two Navy MTFs to visit. The two Army and two Air Force MTFs had used the services of third-party SUD reprocessors on a very limited basis during FY 2001. The two Navy MTFs had not used the services of a third-party reprocessor during FY 2001. None of the six MTFs we visited had applied to the FDA for approval to reprocess SUDs within the MTF.

Participation in Reprocessing Initiatives. Brooke Army Medical Center (AMC) and Keesler Air Force Medical Center (MC) were using the contract negotiated by the Department of Veterans Affairs to reprocess SUDs. Wilford Hall Air Force MC used a locally awarded contract to reprocess SUDs, while Madigan AMC used a local purchase agreement. The extent of reprocessing services used by the four MTFs during FY 2001 is shown in Table 1.

<u>MTF</u>	<u>Types of SUDs Reprocessed</u>	<u>Quantity Reprocessed</u>	<u>Cost to Reprocess SUDs</u>
Brooke AMC	22	1,964	\$ 48,321
Madigan AMC	2	4,332	51,548
Keesler MC	21	658	8,834
Wilford Hall MC	93	641	26,445
Total		7,595	\$135,148

In general, MTF personnel stated that most of the SUDs reprocessed for reuse in MTFs had slight or no impact on patient safety. For example, eight types of SUDs reprocessed for reuse at three MTFs were sequential compression devices (SCDs) that accounted for 6,817 (90 percent) of the 7,595 devices reprocessed. SCDs are noninvasive FDA Class II SUDs (inflatable sleeves to improve blood circulation) that are used on arms and legs. According to MTF personnel, SCDs are minimal risk devices and easily replaced if failure occurs. The remaining SUDs consisted of FDA Class I and II surgical instruments (such as burs, bits, and blades) and one category of Class III device (ablation catheters).

Compliance With FDA Guidance. Three of the six MTFs visited were reusing SUDs that had not been reprocessed in accordance with FDA guidance. At one MTF, personnel identified six types of ophthalmology devices that were resterilized within the MTF. The devices were marked for single use when

delivered new, but personnel were unaware of the FDA guidelines regarding the reprocessing of SUDs. At another MTF, personnel identified about 21 SUDs that had been resterilized at the MTF. MTF personnel responsible for resterilization were not aware that the devices were manufactured for single use or that the devices required reprocessing at an FDA-approved third-party or hospital reprocessor.

The three MTFs had medical kits containing used external fixation SUDs that had been resterilized but had not undergone FDA-approved reprocessing. The medical kits contained external fixation SUDs and other items that are typically used to keep fractured bones stabilized and in alignment. The external fixation SUDs in the kits included pins, clamps, carbon rods, and other items that may be used internally or externally. External fixation SUDs are delivered clean but not sterile by the original manufacturer. The devices normally include sterilizing instructions for first-time use. Some external fixation SUDs included in our review were not labeled as SUDs and we had to confirm with original medical device manufacturers that the devices stocked at the MTFs were intended for single use. Command personnel at the three MTFs stated they would discontinue the practice of resterilizing used SUDs within the MTF.

SUD Reuse Policy and Identification of SUDs

The limited use of reprocessed SUDs and the reuse of SUDs that had not been reprocessed in accordance with FDA guidance occurred because DoD had not developed a policy on the use of reprocessed SUDs. In addition, some of the SUDs were not labeled for single use by the manufacturer and were reused by the MTFs without proper reprocessing. We believe that a DoD policy on SUD reprocessing would provide increased oversight for the military health system and would result in the increased use of reprocessed SUDs by the MTFs and compliance with FDA reprocessing guidance. In developing such a policy, the ASD(HA) should consider patient safety and operational considerations as well as economic issues.

DoD-Wide Guidance. Although the Army and the Air Force had issued limited guidance on the reuse of SUDs, there was no consistent and comprehensive DoD policy. In addition, the Navy had not issued Service-wide guidance to its MTFs outlining its policy on the reuse of SUDs.

Army Policy. The Army Medical Command issued Operations Management Bulletin No. 7-01 on September 7, 2001. The Bulletin states that reuse of SUDs is an alternative that should be considered, but that use of reprocessed SUDs must conform to FDA guidance. The Bulletin's general guidance is that Army MTFs should use third-party reproducers. The two Army MTFs visited had also issued guidance on SUDs.

Brooke AMC. Pamphlet Number 40-2, "Infection Control Manual," September 2001, reiterates Bulletin No. 7-01 and allows reprocessing services to be performed by third-party reproducers. The Pamphlet prohibits reprocessing within the MTF.

Madigan AMC. Madigan AMC Memorandum 40-70, “Reuse of Disposable Medical Equipment and Supplies,” August 14, 2001, reiterates Bulletin No. 7-01 and permits contractual third-party reprocessing while prohibiting reprocessing within the MTF.

Navy Policy. The Navy had not issued guidance or policy regarding the reuse of SUDs in its MTFs. However, the two Navy MTFs we visited had issued limited reprocessing guidance.

Naval Medical Center Portsmouth. Naval Medical Center (NMC) Portsmouth’s Infection Control Manual (undated) states that SUDs are to be used as much as possible. The Manual states that SUDs should not be reused.

NMC San Diego. NMC San Diego’s Infection Control Manual, June 2001, states that “generally,” reprocessing of SUDs will not occur at the MTF.

Air Force Policy. Air Force Instruction 44-108, “Infection Control Program,” July 1, 2000, states that reprocessing of disposable supplies and equipment items labeled as “single patient use only” will not occur in the MTF. The Instruction further states that the reuse of SUDs is an alternative and that MTFs may use a third-party reprocessing company that complies with FDA good manufacturing practice guidelines. The two Air Force MTFs we visited also had internal guidance in place.

81st Medical Group, Keesler MC. Medical Group Instruction 44-172, “Infection Control Program,” February 20, 2001, permits contracted commercial reprocessing of SUDs. In-house reprocessing is not authorized.

59th Medical Wing, Wilford Hall MC. Medical Wing Instruction 44-9, “Infection Control Manual,” April 26, 2000, allows contracted commercial reprocessing with approval of the Infection Control Committee and the Regional Product Evaluation and Standardization Committee. In-house reprocessing is not authorized.

Implementation of reprocessing initiatives in DoD was limited and inconsistent among the Services. The Service policies are relatively new and DoD did not have a position on the use of reprocessed devices. As a result, MTFs were tentative about establishing or expanding a reprocessing initiative. For example, the Army and the Air Force had similar Service-wide policies, but the Navy had none. Additionally, the two Army MTFs we visited implemented Army guidance differently. None of the Service policies discussed how to handle devices without single-use or multiple-use designations, how MTFs could determine the economic viability of SUDs reprocessing, or oversight responsibilities for compliance with FDA guidance. The lack of a comprehensive SUD reprocessing policy and the inconsistent application of reprocessing initiatives shows that comprehensive DoD policy and oversight, that implements FDA guidance, is warranted.

SUD Designations on Device Packages. In addition to the lack of policy, manufacturer labeling issues were another reason why MTFs reused SUDs

without reprocessing the devices in accordance with FDA guidance. At the three MTFs that were reusing SUDs that had not been appropriately reprocessed, personnel were not always able to identify some devices as SUDs because the device labeling did not always indicate that the device was intended for single use.

Personnel at the three MTFs stated they resterilized external fixation devices because they were not invasive. They stated that used external fixation devices could be resterilized using the same sterilization procedures that accompanied the external fixation device when it was new. They also pointed out that labels on new external fixation devices did not identify the devices as SUDs. The FDA stated that following manufacturer specifications for sterilization of new SUDs makes the SUD ready for first-time use only.

FDA representatives were aware of the confusion regarding SUD labeling on external fixation and other medical devices. We believe that the ASD(HA) should work with the FDA to address the SUD labeling issue. In addition, we will forward information on the labeling issue to the Inspector General of the Department of Health and Human Services to assist in that effort.

Potential Benefits From Increased Use of SUDs

Our analysis at six MTFs showed that significant procurement costs could have been avoided by using reprocessed SUDs. We determined that the six MTFs we visited could have avoided about \$605,000 in procurement costs during FY 2001. If the ASD(HA) determines that DoD policy should be to pursue using reprocessed SUDs, the military health system could avoid costs by implementing reprocessing initiatives.

Cost Avoidance From Reprocessed SUDs. At the six MTFs, we judgmentally selected various types of SUDs that were candidates for reprocessing and were known to have been used at the MTF during FY 2001. However, our analysis was based on FY 2001 procurement information, not actual usage. We adjusted FY 2001 procurement information for each device to determine the number of new SUDs that would have been needed had the MTF fully implemented the use of reprocessed SUDs. Our methodology included an approximate device rejection rate of 20 percent and a predetermined number of times, by category, that the SUD could be reprocessed. See Appendix A for details on our methodology for determining the factors used in our calculation of procurement costs that could have been avoided. Table 2 shows, by MTF, the \$605,475 of procurement costs that we calculated could have been avoided for the SUDs we sampled. Additionally, the four sites that had reprocessing initiatives in place during FY 2001 had avoided costs of about \$163,000 through the reuse of SUDs reprocessed by third-party contractors.

Table 2. Costs That Could Have Been Avoided

<u>MTF</u>	<u>Types of SUDs Selected for Analysis</u>	<u>Calculations of FY 2001 Potential Cost Avoidances</u>
Brooke AMC	31	\$140,765
Keesler MC	28	61,964
Madigan AMC	29	53,621
NMC Portsmouth	37	93,687
NMC San Diego	39	155,837
Wilford Hall MC	14	<u>99,601</u>
Total		\$605,475

Our calculations were limited to the SUDs we judgmentally selected for review and do not include other SUDs that may be potential candidates for reprocessing. Additionally, our calculations include the cost to reprocess SUDs but do not include any other costs associated with reprocessing, such as contracting or logistical costs.

In our sample of devices, cost avoidances would have been greatest for SCDs and electrophysiology catheters. For example, Brooke AMC procured a substantial number of SCDs during FY 2001. The center could have avoided costs of \$76,000 if it had used reprocessed SCDs. Similarly, NMC San Diego could have avoided costs of about \$73,000 by reprocessing electrophysiology catheters during FY 2001. Table 3 shows our calculations of costs that could have been avoided, by category of SUD, at the six MTFs we visited.

<u>MTF</u>	<u>External Fixation</u>	<u>Burs, Bits, and Blades</u>	<u>Laparoscopic</u>	<u>Other</u>	<u>SCDs</u>	<u>EP¹ Catheter</u>
Brooke AMC	\$5,481	\$ 22,538	\$12,670	\$12,954	\$ 75,989	\$11,133
Keesler MC	0 ²	12,415	1,905	25,761	21,883	0 ³
Madigan AMC	— ⁴	14,547	12,528	10,990	15,556	0 ³
NMC						
Portsmouth	— ⁴	35,850	9,088	32,865	15,884	0 ³
NMC San Diego	— ⁴	21,499	11,316	0 ²	49,935	73,087
Wilford Hall MC	— ⁴	1,201	13,616	7,891	62,057	14,836
Total	\$5,481	\$108,050	\$61,123	\$90,461	\$241,304	\$99,056

¹Electrophysiology.
²No items selected from this category.
³Electrophysiology catheters not used at MTF.
⁴Procurement information was undeterminable.

The SUDS available for reprocessing will vary at each MTF depending on the product lines used, the type of patient care rendered, and the number and types of procedures performed. Also, the capability of reprocessors and the cost of specific SUDs to be reprocessed could be a factor to consider in regional standardization initiatives. For example, late in 2001, one third-party reprocessor discontinued reprocessing Aircast SCDs while other third-party reprocessors continued to reprocess that brand. Additionally, in February 2002, the FDA issued guidance that the reprocessing of cardiac ablation catheters would no longer be permitted. We did not exclude those SUDs from our calculations for the four MTFs that used them during FY 2001.

Our calculations of costs that could have been avoided by using reprocessed SUDs was not based on a statistical sample and cannot be projected to all procurements of SUDs within an MTF or the military health system. This report includes calculations of potential cost avoidances as a way of demonstrating the potential for significant benefits within the military health system. The amounts may be either overstated or understated because data concerning the use of SUDs at MTFs and MTF inventory balances were not available. However, when the ASD(HA) develops a standard policy for reusing SUDs, and the FDA completes its premarket application approvals, the military health system should be able to realize and quantify potential monetary benefits.

Economic Viability of Reprocessing. In developing a DoD reprocessing policy and when determining the economic viability of reprocessing at individual MTFs,

several issues must be considered. For example, the potential cost impacts on prime vendor Distribution and Pricing Agreements and manufacturer incentives need to be evaluated.

The competitive reprocessing pricing offered by third-party reprocessors may affect negotiations between original medical device manufacturers, prime vendors, and MTFs and could impact prices for the MTFs. A prime vendor is a single distributor of brand-specific medical supplies and provides MTFs the majority of their pharmaceutical and medical/surgical needs. The negotiated Distribution and Pricing Agreements and Federal Supply Schedule are used to identify prices for specific medical supplies.

In addition, original medical device manufacturers may offer incentives or lower prices for the use of their devices. For example, three TRICARE regions had negotiated and signed a regional incentive agreement to purchase one brand of SCD for their MTFs. As part of the agreement, the manufacturer provided and maintained for free the arthrombic pumps that accompanied the SCDs, a value of approximately \$975,000 for the 2-year term of the agreement.

Original medical device manufacturers have also independently offered more favorable pricing than the prices negotiated through Distribution and Pricing Agreements. For example, in exchange for using a major manufacturer's suture products, five MTFs received endoscopic equipment. The agreement allowed DoD to put approximately \$420,000 to better use from January 2001 through November 2001.

Potential Reduction of Medical Waste. In addition to the economic benefits, medical waste may be reduced through the reprocessing of SUDs. Increased emphasis on reprocessing initiatives would result in the procurement of fewer SUDs, therefore resulting in fewer SUDs that are discarded. We were unable to determine the extent of potential benefits available to the MTFs through reduced medical waste.

Patient Safety. The FDA is responsible for ensuring the safety and effectiveness of medical devices sold in the United States and decided to regulate the reprocessing of SUDs to ensure patient safety was not compromised. As a result, reprocessors and reprocessed SUDs undergo the same review processes that apply to new devices coming from the original manufacturer. Complying with FDA guidance on SUDs will help the military health system ensure patient safety.

Conclusion

Health care trends reflect both cost saving initiatives and demands for quality care and patient safety. Third-party reprocessing of used SUDs may be a viable alternative to procuring only new SUDs. Reprocessing in accordance with FDA guidance has the potential to provide MTFs with operational benefits. The inconsistent reprocessing and noncompliance with FDA guidance discussed in this report show the need for a clear and definitive DoD policy regarding the reuse

of SUDs. The Office of the ASD(HA) should determine whether reusing SUDs is in the best interest of the military health system. Any policy on the reuse of SUDs must consider patient safety.

Recently, the President and the Office of Management and Budget issued “The President’s Management Agenda” for FY 2002. The agenda provides strategies for improving the management and performance of the Federal Government. One of the program initiatives in the Agenda is to improve coordination of health care by sharing data on areas of concern between the Department of Veterans Affairs and DoD. As part of a strategy to coordinate Department of Veterans Affairs and DoD programs and systems, a Veteran Affairs/DoD Health Executive Council was established. One of the goals of the Council is to provide the best service through new initiatives and increased efficiency for the benefit of Service members, veterans, and the taxpayer. We believe that using reprocessed SUDs, when reprocessed in compliance with applicable FDA guidelines, is a viable consideration for the military health system. We also believe that the use of reprocessed SUDs corresponds with the Council’s efforts to coordinate health care services. To assist in those efforts, we will provide a copy of our final report to the Veteran Affairs/DoD Health Executive Council.

Recommendations, Management Comments, and Audit Response

1. We recommend that the Assistant Secretary of Defense (Health Affairs):

a. Issue policy and guidance that states the DoD position on the reuse of single-use devices. If the Assistant Secretary determines that reprocessing is in the best interest of the military health system, the policy should, at a minimum:

(1) Require that the program be consistent with Food and Drug Administration guidance.

(2) Provide guidance on how to handle medical devices without a single-use or multiple-use designation.

(3) Provide guidance for military treatment facilities to use in determining the economic viability of single-use device reprocessing, including consideration of the impacts of reprocessing on other initiatives, such as the Prime Vendor program, manufacturer incentives, and regional standardization efforts.

(4) Assign oversight responsibilities to ensure that military treatment facilities comply with Food and Drug Administration guidance.

b. Initiate discussions with the Food and Drug Administration and work toward clarifying single-use device labeling requirements with that agency.

Management Comments Required. The Assistant Secretary of Defense (Health Affairs) did not comment on the recommendation. We request that the Assistant Secretary provide comments in response to the final report.

2. We recommend that the Military Department Surgeons General:

a. Issue implementing guidance consistent with policy issued by the Office of the Assistant Secretary (Health Affairs).

b. Ensure adequate awareness and training for military treatment facility personnel regarding the reuse of single-use devices.

Management Comments. The Navy concurred and stated that a policy to reuse SUDs should include a thorough risk assessment, a legal assessment of the impact on liability risk and on informed consent procedures, a robust quality control system, and an assessment of and plan for potential adverse publicity.

Audit Response. The Navy comments are fully responsive and additional comments are not required. We agree that a decision to establish a policy to reuse SUDs in the military health system should include consideration of numerous issues. We expect that the ASD(HA) will consider patient safety and other issues such as those stated in the Navy response when establishing the DoD position.

The Army and Air Force Surgeons General did not provide comments on Recommendation 2. We request that the Army and Air Force Surgeons General provide comments on the recommendation in response to the final report.

Appendix A. Scope and Methodology

Our review focused on the reuse of medical SUDs in the military health system that occurred during FY 2001. We also reviewed reprocessing guidance issued by the FDA from August 2000 through February 2002 and obtained Service and MTF-specific guidance that discussed reprocessing and reuse of SUDs in MTFs. The Service guidance was issued from April 2000 through September 2001.

Neither the Office of the ASD(HA) nor the Offices of the Surgeons General actively managed reprocessing programs in DoD or the MTFs. We queried personnel from the Office of the ASD(HA) and the Offices of the Military Department Surgeons General to determine the extent of reprocessing, if any, in the military health system.

Personnel from the Office of the Army Surgeon General stated that only 3 of 27 Army MTFs were using a third-party reprocessing contractor. Personnel from the Office of the Navy Surgeon General stated that none of the 25 Navy MTFs were using a third-party reprocessor. Personnel at the Office of the Air Force Surgeon General stated that 2 of 22 Air Force MTFs were using a third-party reprocessor.

We visited four of the five MTFs identified by personnel in the Offices of the Army and Air Force Surgeons General as using a third-party reprocessing contractor and also visited two Navy medical centers. At those locations, we determined the extent of ongoing reprocessing initiatives, if any; identified SUD procurement information to determine costs that could have been avoided; and evaluated MTF compliance with FDA guidelines.

Two of the four MTFs reprocessed SUDs through orders placed against a Government-wide reprocessing contract awarded by the Department of Veterans Affairs. We discussed the contract with personnel from that Department and obtained FY 2001 and FY 2002 reprocessing fee schedules.

The Department of Veterans Affairs had awarded a reprocessing services contract to Alliance Medical Corporation in Phoenix, Arizona. We visited Alliance Medical Corporation where we observed their reprocessing operation. We obtained a master list of items that Alliance reprocessed during FY 2001. We also obtained limited information on SUD reprocessing from various Internet sites.

We performed the audit from August 2001 through June 2002 in accordance with generally accepted government auditing standards, except that the results discussed in this report were based on SUD procurement information that we obtained from six MTFs; actual usage information was not available. We recognize that true monetary benefits can only be calculated from usage data. Because we used the procurement data to demonstrate that the potential exists for significant cost avoidance, rather than to project potential monetary benefits, that limitation does not materially impact the audit results.

Neither the FDA nor DoD maintains lists of SUDs that are candidates for reuse. Therefore, to determine the relative extent that MTFs could use reprocessed SUDs and to demonstrate the significance of potential cost avoidances, we obtained a master list of items that one reprocessor (Alliance Medical Corporation) had processed during FY 2001. We used six categories of SUDs that Alliance Medical Corporation identified as commonly generating savings for hospitals. The categories consisted of burrs, bits, and blades; cardiac catheter devices; external fixation devices; laparoscopic devices; sequential compression devices; and other miscellaneous devices. We adjusted the master list to include only SUDs that were candidates for the complete reprocessing cycle, excluding open but unused SUDs because they were candidates only for reesterilization, not for reprocessing.

We compared SUDs procured at each of the six MTFs during FY 2001 with the adjusted master list of SUDs from the third-party reprocessor. From those SUDs identified, we judgmentally selected a small sample of SUDs at each MTF. For those devices, we obtained SUD nomenclatures, units of issue, number purchased, original manufacturer serial numbers, and unit prices. We also interviewed and obtained information from MTF risk managers; central sterile supply, infection control, and logistics personnel; and original medical device manufacturers.

Reprocessing Model. We developed a model to determine the quantity of new SUDs that would have to be procured when an MTF begins reprocessing. The model calculates the number of SUDs that would be reprocessed based on three, five, and six reprocessing cycles, depending on the type of device. The model generates a separate result for each annual demand, incorporating a 20 percent rejection rate and the reprocessing cycles.

The model employs continuous approximations for the demand and use of SUDs. It does not attempt to account for the many variables inherent to the use of particular devices, such as procurement cycles, demand histories, or minimum stockage levels. The model divides FY 2001 into 24 equal calculation periods (semi-monthly periods) and includes units that are returned from reprocessing. The following bullets list and discuss conditions and assumptions in our model.

- The model treats FY 2001 as the first reprocessing year and includes some start-up periods during which no items are returned from reprocessing.
- The model assumes that no “pre-loaded” units were available to be sent to reprocessing at the start of the year.
- The model divides annual demand equally into the semi-monthly periods, often resulting in fractional units.
- The model assumes smooth, continuous consumption of units within each semi-month period.
- The model assumes reprocessed items are used before any purchased items in the periods.

-
- The model assumes new devices are received and available for use on the first day of a semi-monthly period.
 - The model assumes that used devices are packaged and sent to an FDA-approved third-party reprocessor on the last day of the semi-monthly period during which they were used.
 - The model assumes that reprocessing turnaround time is three semi-monthly periods.
 - The model does not address emergency stock levels.
 - The model uses a predetermined number of times a SUD could be reasonably expected to be reprocessed, depending on the category of the device. (That number was based on Alliance Medical Corporation information on the average number of times a SUD could be reprocessed. The number of times a SUD could be reprocessed varied by category: six times for cardiac ablation catheters and five times for SCDs. All other SUDs typically could be reprocessed three times.)
 - The model uses a 20 percent rejection rate for each reprocessing cycle. The rate was applied to devices sent for reprocessing and represents those items that could not be reprocessed due to damage or some other imperfection. (The rejection rate was developed based on input from Alliance Medical Corporation.)

Calculation of Potential Cost Avoidances. SUD usage information and beginning inventory balances were not available from the six MTFs we visited; therefore, we used FY 2001 procurement costs and quantities for our calculations. We excluded from our costing calculations those SUDs with a procurement cost of less than \$10 per unit or a procurement quantity of less than 12. We used a fee schedule from the Government-wide reprocessing contract to determine revised reprocessing costs. The following figure illustrates the methodology used to determine cost avoidances from reprocessing initiatives for those devices selected for review.

Calculation of Potential Cost Avoidance

<u>Annual Procurement Cost Without Reprocessing</u>						
Annual Procurement Quantity	X	Cost Per Device	=	Annual Procurement Cost Without Reprocessing		
<u>Revised Annual Procurement Cost With Reprocessing</u>						
NEW DEVICES			+	REPROCESSED DEVICES		
Revised Annual Procurement Requirement ¹	X	Cost Per Device	=	Annual Reprocessing Requirement ²	X	Reprocessing Cost Per Device ³
Potential Cost Avoidance Using Reprocessing:⁴						\$XXX,XXX
¹ Number of new units required (based on the reprocessing model). ² Difference between annual procurement quantity and revised annual procurement requirement (based on the reprocessing model). ³ From Government contract fee schedule. ⁴ Difference between annual procurement cost without reprocessing and revised annual procurement cost with reprocessing.						

The cost that could have been avoided is the difference between annual procurement costs without reprocessing and a revised annual procurement cost with reprocessing. Those amounts may be high or low, depending on the differences between usage and procurement.

Use of Technical Assistance. Personnel from the Quantitative Methods Division, Office of the Inspector General of the Department of Defense reviewed the methodology we used to determine potential cost avoidances discussed in this report.

Use of Computer-Processed Data. We relied on various computer-processed procurement and pricing data from the MTFs without performing tests of general and application system controls to confirm the reliability of the data. We did not establish the reliability of the data because the data were used only to determine the relative extent of SUDs procured by the MTFs we visited and the relative significance of potential cost avoidances. Not establishing the reliability of the data did not materially affect the results of our audit.

General Accounting Office High-Risk Area. The General Accounting Office has identified several high-risk areas in DoD. This report provides coverage of the DoD Inventory Management high-risk area.

Management Control Program Review

DoD Directive 5010.38, "Management Control (MC) Program," August 26, 1996, and DoD Instruction 5010.40, "Management Control (MC) Program Procedures," August 28, 1996, require DoD organizations to implement a comprehensive system of management controls that provides reasonable assurance that programs are operating as intended and to evaluate the adequacy of the controls.

Scope of the Review of the Management Control Program. We reviewed the adequacy of the controls over the reuse of SUDs in the MTFs and the Military Department controls over in-house SUD reprocessing. We also reviewed the adequacy of management's self-evaluation of those controls.

Adequacy of Management Controls. We identified a material management control weakness involving SUD reprocessing in DoD. DoD management controls for SUD reprocessing had not been developed because the Office of the ASD(HA) did not have an established policy regarding SUD reprocessing. Recommendation 1., if implemented, will provide guidance and improve the oversight of SUD reprocessing programs in DoD. A copy of the report will be provided to the senior official responsible for management controls in the Office of the ASD(HA).

Adequacy of Management's Self-Evaluation. MTF personnel did not identify SUD reprocessing as an assessable unit and, therefore, did not identify or report the material management control weakness identified by the audit.

Prior Coverage

During the last 5 years, the General Accounting Office has issued one report discussing reprocessing of SUDs. Unrestricted General Accounting Office reports can be accessed over the Internet at <http://www.gao.gov>. Unrestricted Inspector General of the Department of Defense reports can be accessed at <http://www.dodig.osd.mil/audit/reports>.

General Accounting Office

General Accounting Office Report No. HEHS-00-123, "Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted," June 20, 2000

Appendix B. Report Distribution

Office of the Secretary of Defense

Under Secretary of Defense (Comptroller)/Chief Financial Officer
Deputy Chief Financial Officer
Deputy Comptroller (Program/Budget)
Under Secretary of Defense (Personnel and Readiness)
DoD-Veteran Affairs Executive and Health Benefits Council
Assistant Secretary of Defense (Health Affairs)

Department of the Army

Assistant Secretary of the Army (Financial Management and Comptroller)
Surgeon General of the Army
Auditor General, Department of the Army

Department of the Navy

Assistant Secretary of the Navy (Manpower and Reserve Affairs)
Naval Inspector General
Surgeon General of the Navy
Auditor General, Department of the Navy

Department of the Air Force

Assistant Secretary of the Air Force (Financial Management and Comptroller)
Surgeon General of the Air Force
Auditor General, Department of the Air Force

Non-Defense Federal Organizations and Individuals

Office of Management and Budget
Inspector General, Department of Health and Human Services

Congressional Committees and Subcommittees, Chairman and Ranking Minority Member

Senate Committee on Appropriations
Senate Subcommittee on Defense, Committee on Appropriations
Senate Committee on Armed Services
Senate Committee on Governmental Affairs
House Committee on Appropriations
House Subcommittee on Defense, Committee on Appropriations
House Committee on Armed Services
House Committee on Government Reform
House Subcommittee on Government Efficiency, Financial Management, and Intergovernmental Relations, Committee on Government Reform
House Subcommittee on National Security, Veterans Affairs, and International Relations, Committee on Government Reform
House Subcommittee on Technology and Procurement Policy, Committee on Government Reform

Department of the Navy Comments



DEPARTMENT OF THE NAVY
OFFICE OF THE ASSISTANT SECRETARY
(MANPOWER AND RESERVE AFFAIRS)
1000 NAVY PENTAGON
WASHINGTON, DC 20350-1000

10 Sept 02

MEMORANDUM FOR INSPECTOR GENERAL, DEPARTMENT OF DEFENSE

SUBJECT: DRAFT REPORT NO. (D2001Lf-0177) of 28 Jun 02 ON
REPROCESSED MEDICAL SINGLE-USE DEVICES IN DOD

The Department of the Navy has reviewed the subject report and concurs as written. Please find attached (Attachment 1) the Bureau of Medicine and Surgery's (BUMED) concurrence with comments.

If additional information or assistance is needed, the DON point of contact is Commander C. A. Simpson, MSC, USN at (73)693-0238.

A handwritten signature in black ink, appearing to read "Anita K. Blair".

ANITA K. BLAIR
Assistant Secretary of the Navy
(Personnel Programs)

Attachment:

1. Chief, Bureau of Medicine and Surgery response
Ser M8/2002U114000902 dated 20 Aug 02



DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
2300 E STREET NW
WASHINGTON DC 20372-5300

IN REPLY REFER TO

5700
Ser M8/2002U114000902
20 Aug 02

From: Chief, Bureau of Medicine and Surgery
To: Department of Defense Inspector General
Via: Assistant Secretary of the Navy (Manpower and Reserve
Affairs)

Subj: REPROCESSED MEDICAL SINGLE-USE DEVICES IN DOD

Ref: (a) DoDIG Draft Report Project No.(D2001LF-0177) of 28 Jun 02
(b) NAVINSGEN email tasker of 10 Jul 02

1. For references (a) and (b), BUMED concurs with the draft report and recommendations as written. However, the decision to reuse single-use devices (SUDs) should include the following items for consideration as the policy, guidance and operational procedures are developed:

- a) A thorough risk assessment for reuse of SUDs entering body cavities or those used intravascularly.
- b) A legal assessment of impact on liability risk and on informed consent procedures.
- c) A robust quality control system even if a third party reprocessor is chosen.
- d) An assessment and plan for potential adverse publicity.

2. Should you have any administrative questions, please contact Mr. Rick Barnish at (202) 762-3336 or email: JRBarnish@us.med.navy.mil. Technical questions may be directed to Commander K. S. Yew, MC, USN, at (202) 762-3264.

P. M. BULL
By direction

Copy to:
M3M

Team Members

The Readiness and Logistics Support Directorate, Office of the Assistant Inspector General for Auditing of the Department of Defense prepared this report. Personnel of the Office of the Inspector General of the Department of Defense who contributed to the report are listed below.

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