



COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

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The Honorable
The Secretary of Defense

Dear Mr. Secretary:

During a survey of Department of Defense health programs, we noted that some military hospitals were reusing disposable guidewires and catheters in vascular studies. The manufacturers and users are concerned about the reuse of these devices, because complete cleaning is virtually impossible and because reuse weakens them. Therefore, the possibility of infections, allergenic reactions, and product breakage are increased when catheters and guidewires are reused.

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Three of the four military hospitals we visited were reusing disposable guidewires and catheters. Officials of the three hospitals said that they were using these devices more than one time because of cost savings but that, from a medical standpoint, they preferred to use them once. The fourth hospital did not reuse these disposable devices because of the possible adverse effects to the patient.

USE OF CATHETERS AND GUIDEWIRES

Both the radiology and cardiology departments of a hospital use catheters and guidewires in vascular studies. The guidewires are inserted through a blood vessel to the study site, such as in the aorta, heart, or brain. The catheter is placed over the wire which is used to guide the catheter to the study site. Once the catheter is in place, the guidewire is removed. The catheter is then filled with a contrast medium for use in active catheterization and filming. Guidewires in current use are stainless steel or stainless steel with a teflon coating. Catheters are plastic tubes which may be constructed in combination with various types of material, such as stainless steel or teflon.

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DEVICES REUSED DESPITE
MANUFACTURERS' CAUTIONS

Guidewires and certain catheters are manufactured as disposables, and the manufacturers label the products as such, or state on the packaging, the accompanying literature, or the catalog that they are recommended, or intended, for one-time use.

Following is a statement made by one manufacturer in its product catalog about the reuse of guidewires:

"EXPLANATION FOR PRECAUTION--USE ONCE AND DISCARD

"A wire guide is a delicate and fragile instrument. Any time that a wire guide is reused, the hazard of damage is increased.

"An acute bend or kink of the coil wire weakens the guide. Physiological saline may be of sufficient concentration to start stress corrosion, and rusting of the stainless steel wire at room or elevated temperature. Complete internal cleaning of the guide after use is nearly impossible even with an ultrasonic cleaner. Several users have become concerned with possible allergic reactions in patients which could be caused by blood left inside guides after cleaning."

Manufacturers also caution that catheters be used only once. One manufacturer in its product catalog states that:

"To avoid all risks of re-infection the catheter should be discarded after use."

Similar warnings and precautions are also stated by the manufacturers in their catalogs and in the product packaging.

A representative of a manufacturer of catheters and guidewires said that disposable guidewires and catheters should not be reused and emphasized the dangers as given in the manufacturer's literature. He stated that the president of the firm he represented was very concerned about dangers

in the reuse of these disposable devices and was considering a price reduction in the product as a way of discouraging reuse.

We also visited the radiology departments in two non-profit hospitals serving the private sector. Personnel of both hospitals said that (1) catheters and guidewires were used once and discarded and (2) they believed it was virtually impossible to get the devices clean. They said also that the vascular procedure was sufficiently complicated without adding additional risk. Although we were told that some hospitals in the private sector reused these devices, we do not know the extent to which reuse occurred.

SOME MILITARY HOSPITALS REUSED THE DEVICES
BECAUSE OF FUNDING CONSIDERATIONS

The four military hospitals visited were reusing disposable catheters and guidewires, as follows:

| <u>Hospital</u> | <u>Number (range) of times reused</u> | |
|---|---|-------------------|
| | <u>Catheters</u> | <u>Guidewires</u> |
| Letterman Army Medical Center (note a) | 1 to 2 | 5 to 6 |
| David Grant U.S. Air Force Medical Center | 1 to 2 | 1 to 2 |
| Malcolm Grow U.S. Air Force Medical Center | 2 to 3 | 2 to 3 |
| Oakland Naval Regional Medical Center | (b) | (b) |

^aOnly by the radiology branch.

^bNot reused.

Personnel of the Oakland Naval Medical Center told us that they had been reusing catheters and guidewires but had discontinued the practice because the possible adverse effects to the patients outweighed the cost advantages of reuse. Further their decision to discontinue reusing the devices was made after they had pulled a guidewire apart, after initial use and cleaning, and found debris.

Personnel at the hospitals that reused the devices said that they were aware of the dangers of reuse but that limited funds for supplies resulted in assuming the risks of reuse. Although some of the personnel stated that the medical profession had mixed opinions on the safety of reusing disposable catheters and guidewires and that adverse effects of reuse had not been shown, they all indicated that they would not reuse the devices if funding was not a factor.

Guidewires normally range in price from about \$3 to \$12 and catheters from about \$6 to \$12. We were told that the number of guidewires and catheters used in vascular studies varied, but two guidewires and two catheters on a single vascular study would not be unusual, and sometimes considerably more would be used. On the basis of information given us, we estimate that the three military hospitals which reused the devices perform about 2,500 studies a year.

We believe that there are sufficient questions concerning patient safety in reusing guidewires and catheters for DOD to establish overall guidelines on the use of these devices in vascular studies. Subsequent to our discussions, the Letterman Army Medical Center discontinued reusing disposable guidewires and catheters.

RECOMMENDATION TO SECRETARY OF DEFENSE

We recommend that overall guidelines be established on the appropriate use of disposable catheters and guidewires in vascular studies.

AGENCY COMMENTS

DOD told us that it agreed with our recommendation and that action would be taken to implement it.

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We appreciate the cooperation and assistance given by DOD personnel during our survey and shall appreciate being advised within 60 days of the date of this letter of actions taken or planned as a result of our observations. If you have any questions on these observations, we shall be glad to discuss them with you or your representatives.

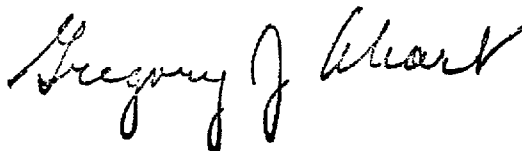
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We are sending copies of this report to the Chairmen,
House and Senate Committees on Appropriations, on Government
Operations, on Armed Services; and to the Director, Office
of Management and Budget.

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Sincerely yours,



Gregory J. Ahart
Director