

GUIDE TO INFECTION CONTROL IN THE HEALTHCARE SETTING

Reuse of Disposable Devices

Author

Samuel Ponce de León-R., MD, MSc

Chapter Editor

Gonzalo Bearman MD, MPH, FACP, FSHEA, FIDSA

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It seems to me that reusing disposable devices has an element of poetic justice ingrained, if one can become poetic about economics.

— V.W. Greene

KEY ISSUES

Reutilization of disposable devices is a common and growing practice but there are no well-founded standard guidelines to assure the quality and the safety of this practice.

KNOWN FACTS

- Disposable devices are expensive.
- Most disposable devices can be reused.
- Economic benefits can be obtained by reusing disposables.
- Sterilization is a well-known and common practice in hospitals.
- Infections and malfunction are higher risks if the device is damaged in the re-sterilization process.
- There are diverse studies showing the security of reprocessing a variety of cardiac and urinary catheters, balloon-tipped catheters, guide-wires, implants, needles, surgical instruments, hemodialysers, laparoscopic instruments, and pacemakers.
- There is evidence against the reuse of specific items with particular methods, such as transducer domes and esophageal stethoscopes with ethylene oxide sterilization.
- Risks associated with the reuse of disposable catheters include: infection, pyrogenic reaction, toxicity, particulate contamination,

breakage-catheter integrity, catheter biocompatibility, risk for personnel, and risk for the environment.

- Patients should know that a reused item is going to be utilized.
- The disposable devices industry is a high contributor to biomedical waste.

CONTROVERSIAL ISSUES

- The selection of patients on whom to use a resterilized device implies an ethical issue that should be resolved in every facility. Patients should know and accept the reuse of used disposables.
- There is a relationship between complexity of disposables and difficulties of sterilization. Single-use devices are not designed to allow decontamination.
- A clear limit should be established regarding the number of times an item can be reused.
- The burden of complications due to reutilization is not known.
- The US FDA considers reprocessing and reuse of disposable devices equivalent to manufacturing of those devices. Hospitals that reuse devices are subject to the same regulatory guidelines as the original device manufacturer.
- Reuse of disposable devices increases the risk of exposure of healthcare workers (HCW) to body fluids and chemicals used for sterilization.
- It is impossible for every facility to evaluate each item to be reused. In most cases decisions will be made based on published experience.
- Sterilization-specialized companies for reused devices should be an option.
- Ethical, regulatory, and legal implications should be considered.
- The reuse of disposable masks (N95 respirator) during epidemics or pandemics should be clearly regulated. The American Institute of

Medicine does not recommend their reuse, but in the case of a pandemic there will be a short supply.

- There are many questions and few answers (to many disposables and very few studies) and funding for this research is scarce.
- There are few reports of complications related to reutilized devices but disclosure of these events may be difficult.

SUGGESTED PRACTICE

- Reuse of disposables should not be an ad hoc practice or treated casually. A facility committed to the reuse of single-use devices should have an institution-specific policy and work with clear guidelines to ensure the safety of patients.
- Disposable devices should be classified according to the intrinsic risk of their reprocessing as: critical devices (contact with blood or normally sterile tissue); semi-critical devices (contact with mucous membranes); and non-critical devices (contact with unbroken skin).
- The American Society for Hospital Service Personnel has published the following guidelines:
 1. Review the package labeling and the manufacturer guidelines for use and reprocessing of the device.
 2. If the manufacturer has not determined reprocessing parameters, obtain information about the material properties (steel, rubber, latex, PVC, etc.). Ask the manufacturer if the product can be reprocessed and if so, ask for recommendations.
 3. Establish a list of form and function criteria, which the reprocessed device will be expected to meet. These include:
 - physical appearance (color, shape, size, etc.);
 - function (moving parts, tensile strength, flexibility, etc.).

4. Determine if you have the capability to demonstrate that the device can be adequately cleaned according to the material properties and cleaning methods available.
 5. Determine if you have the capability to demonstrate that the device can be adequately sterilized according to material properties and sterilizing methods available.
 6. Determine if reprocessing of this device is cost justified.
 7. For each device, establish a testing protocol that identifies:
 - the number of items which must be tested to get an adequate study sample;
 - the number of times the device can be reprocessed and still meet the form and function criteria;
 - employee safety considerations;
 - the procedures, chemicals, and equipment to be used in reprocessing;
 - process controls, quality assurance monitoring, and documentation;
 - testing of the reprocessed item in simulated use situations;
 - the necessity of destructive auditing to identify unacceptable changes to the material properties or the presence of residual toxicity;
 - documentation of testing results; and
 - a method for labeling the reprocessed device and marking for successive reprocessing episodes.
 8. Review testing protocols/results with appropriate review groups (administration, infections-control, ethics committee) and the manufacturer.
 9. Determine the need for policies for pricing, informed patient consent, and documentation of the use of reprocessed devices.
 10. Periodically review the use and methods.
- Other specific recommendations are:
 1. Have a procedure to ensure the destruction of pyrogens.

2. Start the cleaning and sterilization process as soon as possible.
3. For angioplasty catheters it is essential to inspect the balloon while inflated and deflated before using it.
4. In general, an institutional policy should be developed and should consider the use of a sterilization company specialized in reprocessing devices.

SUGGESTED PRACTICE IN UNDER-RESOURCED SETTINGS

- Reprocessing disposables is an unavoidable practice in low and middle-income countries (LMIC) as economical constraints are severe.
- Reprocessing procedures should be well planned, organized, and controlled.
- The number of times every item can be reprocessed should be limited and supervised.
- Be aware of complications related to reused items to prevent major complications and bigger expenses.
- Do not reprocess high-risk items (needles and syringes). These items are very high risk and actually their cost is low.

SUMMARY

Reutilization of disposable devices is a common and growing practice but can be associated with infections and/or device malfunction. A facility committed to the reuse of single-use devices should have an institution-specific policy and work with clear guidelines to ensure the safety of patients taking into consideration ethical, regulatory and legal implications.

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