The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

ACOG COMMITTEE OPINION

Number 769

(Replaces Committee Opinion No. 537, October 2012)

Committee on Gynecologic Practice

This Committee Opinion was developed by the American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice.

INTERIM UPDATE: The content on reporting adverse events has been updated as highlighted (or removed as necessary) to clarify language on reporting. Information has been added to direct the reader to the U.S. Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database.

Reprocessed Single-Use Devices

ABSTRACT: The reprocessing and reuse of single-use instruments has become increasingly common. Although there are limited data on reprocessed single-use devices, existing studies have found a significant rate of physical defects, performance issues, or improper decontamination. There are currently no data in the medical literature of studies evaluating the cost-effectiveness of reprocessed single-use devices in gynecologic surgery. The use of a reprocessed single-use device provides no direct benefit to an individual patient or her physician. It is the operating surgeon's ethical responsibility to make a good faith effort to know whether reprocessed single-use devices are to be used, and to not use instruments if he or she has concerns about the quality or safety of the instrument(s). Studies on the safety, quality, and cost-effectiveness of reprocessed single-use devices in gynecologic surgery are needed. Physicians should be informed whether the instruments used in surgery are original or reprocessed, and adverse events should be reported to improve the safety information about reprocessed single-use devices. Obstetrician–gynecologists are encouraged to report adverse events and outcomes associated with medical devices to the U.S. Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database.

Reprocessing single-use devices involves reusing instruments that were designed and sold for single-use only. Single-use instruments have been reprocessed and reused since the 1970s. Initially, hospitals widely accepted single-use devices in an effort to avoid product aging, overuse, and malfunction. Since the 1990s, efforts by hospitals to contain costs have created incentives to reprocess single-use devices. Today, the reprocessing market earns nearly $40 million annually. The reuse of single-use devices is a complex issue that requires consideration of patient safety, wise allocation of health care dollars, and informed consent. Due to the increase in the reprocessing of single-use devices, obstetrician–gynecologists should be educated about this practice. This document includes a discussion of the definition of reprocessed single-use devices, the regulation of these instruments, as well as issues of safety and quality, cost-effectiveness, and ethics.

Reprocessed Single-Use Devices

Because of the variety of single-use devices, from simple and inert to complex and electronic, it is challenging to critique the process. Single-use devices range from an external device designed to lie against the skin, such as the plastic boots used for venous thromboembolism prophylaxis (intermittent pneumatic compression), to more invasive and complex electrothermal equipment consisting of insulation, sharp blades, and crevices that may become filled with blood or human tissue.

Regulation

Current law requires that the institutions or companies that reprocess single-use devices for repeat use be held to the original manufacturing specifications for the single-use instrument. Testimony regarding the 1977 Compliance Policy Guide issued by the U.S. Food and Drug Administration (FDA) clarified that hospitals that reprocess single-use devices assume full liability and responsibility for their reprocessing actions (1). This policy did not provide for third-party reprocessors, so in 2000, the FDA issued a new guidance document that included descriptions of the regulations that the FDA would apply to third-party and hospital reprocessors of single-use devices (2). Under the Medical Device User Fee and

Modernization Act of 2002, a reprocessed medical device is considered a product of the reprocessing company and no longer a product of the original manufacturer; the name of the manufacturer of the reprocessed device is required to be placed in the space identifying the person responsible for reprocessing (3). This 2002 congressional act established new statutory requirements for reprocessed single-use devices, including labeling to identify the devices as reprocessed, submission of validation data for many reprocessed single-use devices, and submission of premarket notification (510[k]) with validation data (3, 4).

Safety and Quality

In a 2008 report to the U.S. Congress, the Government Accountability Office (GAO) stated that despite increased use of reprocessed single-use devices, there appears to be no increased health risk (5). However, this report may not reflect the full spectrum of important safety issues because it refers to all categories of devices and relies on voluntarily reported adverse events. The GAO also stated that because of the limited number of identified peer-reviewed studies related to reprocessing, there was insufficient evidence to support a comprehensive conclusion on the relative safety of reprocessed single-use devices compared with single-use devices on their initial use.

As with any surgical device, reprocessed or not, relying on voluntarily reported adverse events likely underrepresents associated health risks. Obstetrician–gynecologists are encouraged to report adverse events and outcomes associated with medical devices to the FDA's Manufacturer and User Facility Device Experience (MAUDE) database (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR%E2%80%93ElectronicMedicalDeviceReporting/default.htm). In the case of reprocessed single-use devices, particularly in products used for invasive procedures such as hysterectomy, it is unlikely that a postoperative surgical site infection would ever be linked to, or reported as related to, the use of a reprocessed single-use device. Furthermore, if an adverse event were to be reported, it may be attributed erroneously to the original manufacturer of the product. (For more information, MedWatch, the FDA safety information and adverse event reporting program can be accessed at http://www.fda.gov/Safety/MedWatch/default.htm.)

Publications exist in the medical literature on orthopedics and laparoscopic surgery that report on the quality of reprocessed single-use devices, such as arthroscopic shavers and harmonic scalpels (6–10). These studies have largely been funded by the original device manufacturers, and limited independent studies are available. However, all studies found a significant rate of physical defects, performance issues, or improper decontamination of reprocessed single-use devices.

Cost-Effectiveness

There are currently no data in the medical literature of studies evaluating the cost-effectiveness of reprocessed single-use devices in gynecologic surgery. Each reprocessed device costs less to purchase than the original, but no information is available regarding any change in operative time or the need to use more than one device if malfunction occurs. Reprocessed devices result in cost savings for the hospital, but it is not apparent that there is any financial benefit to the patient or third-party payers.

Existing Guidelines

The Association of periOperative Registered Nurses has issued a guidance statement regarding reprocessed single-use devices (11). This group's recommendations include that the sterility, integrity, and functionality of a reprocessed single-use device must be documented as safe for patient care and/or equal to the original device specifications.

Ethical Issues

The use of a reprocessed single-use device provides no direct benefit to an individual patient or her physician. Devices must be clearly labeled as manufactured by the reprocessor. Physicians should be informed that the instrument being used is a reprocessed single-use device. The right of the patient to be informed is also a consideration. It remains the operating surgeon's ethical responsibility to make a good faith effort to know whether reprocessed single use devices are to be used. If the surgeon has concerns about the quality or safety of the instrument(s), he or she has the ethical obligation to not use the instrument(s).

Conclusion

Studies on the safety, quality, and cost-effectiveness of reprocessed single-use devices in gynecologic surgery are needed. Physicians should be informed whether the instruments used in surgery are original or reprocessed. Adverse events should be reported to improve the safety information about reprocessed single-use devices.

References

1. Feigal DW. Reuse of medical devices labeled for single-use. Statement of David W. Feigal, M.D. before the Senate Committee on Health, Education, Labor, and Pensions, June 27, 2000. Silver Spring (MD): Food and Drug Administration; 2000. Available at: https://www.gpo.gov/fdsys/pkg/CHRG-106hhrg62970/html/CHRG-106hhrg62970.htm. Retrieved October 26, 2018.
2. Food and Drug Administration. Guidance for industry and for FDA staff: enforcement priorities for single-use devices reprocessed by third parties and hospitals. Silver Spring (MD): FDA; 2000. Available at: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107172.pdf. Retrieved April 30, 2012.

3. Medical device user fee and modernization act of 2002. Pub L No. 107-250, 116 Stat 216 (2002).

4. Food and Drug Administration. Summary of the Medical Device User Fee and Modernization Act of 2002: including changes made by the Medical Devices Technical Corrections Act. Silver Spring (MD): FDA; 2004. Available at: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109123.pdf. Retrieved April 30, 2012.

5. Government Accountability Office. Reprocessed single-use medical devices. Report to the Committee on Oversight and Government Reform, House of Representatives. Washington, DC: GAO; 2008. Available at: http://www.gao.gov/new.items/d08147.pdf. Retrieved April 30, 2012.

6. King JS, Pink MM, Jobe CM. Assessment of reprocessed arthroscopic shaver blades. Arthroscopy 2006;22:1046–52.

7. Weld KJ, Dryer S, Hruby G, Ames CD, Venkatesh R, Matthews BD, et al. Comparison of mechanical and in vivo performance of new and reprocessed harmonic scalpels. Urology 2006;67:898–903.

8. Roth K, Heeg P, Reichl R. Specific hygiene issues relating to reprocessing and reuse of single-use devices for laparoscopic surgery. Surg Endosc 2002;16:1091–7.

9. Granados DL, Jimenez A, Cuadrado TR. Assessment of parameters associated to the risk of PVC catheter reuse. J Biomed Mater Res 2001;58:505–10.

10. Hambrick D, 3rd. Reprocessing of single-use endoscopic biopsy forceps and snares. One hospital's study. Gastroenterol Nurs 2001;24:112–5.

11. Association of periOperative Registered Nurses. AORN Guidance Statement: reuse of single-use devices. In: Perioperative standards and recommended practices. Denver (CO): AORN; 2012:717–24.

Published online on February 21, 2019.

Copyright 2019 by the American College of Obstetricians and Gynecologists. All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, posted on the internet, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without prior written permission from the publisher.

Requests for authorization to make photocopies should be directed to Copyright Clearance Center, 222 Rosewood Drive, Danvers, MA 01923, (978) 750-8400.

American College of Obstetricians and Gynecologists
409 12th Street, SW, PO Box 96920, Washington, DC 20090-6920

Reprocessed single-use devices. ACOG Committee Opinion No. 769. American College of Obstetricians and Gynecologists. Obstet Gynecol 2019;133:e235–7.

This information is designed as an educational resource to aid clinicians in providing obstetric and gynecologic care, and use of this information is voluntary. This information should not be considered as inclusive of all proper treatments or methods of care or as a statement of the standard of care. It is not intended to substitute for the independent professional judgment of the treating clinician. Variations in practice may be warranted when, in the reasonable judgment of the treating clinician, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology. The American College of Obstetricians and Gynecologists reviews its publications regularly; however, its publications may not reflect the most recent evidence. Any updates to this document can be found on www.acog.org or by calling the ACOG Resource Center.

While ACOG makes every effort to present accurate and reliable information, this publication is provided "as is" without any warranty of accuracy, reliability, or otherwise, either express or implied. ACOG does not guarantee, warrant, or endorse the products or services of any firm, organization, or person. Neither ACOG nor its officers, directors, members, employees, or agents will be liable for any loss, damage, or claim with respect to any liabilities, including direct, special, indirect, or consequential damages, incurred in connection with this publication or reliance on the information presented.

All ACOG committee members and authors have submitted a conflict of interest disclosure statement related to this published product. Any potential conflicts have been considered and managed in accordance with ACOG's Conflict of Interest Disclosure Policy. The ACOG policies can be found on acog.org. For products jointly developed with other organizations, conflict of interest disclosures by representatives of the other organizations are addressed by those organizations. The American College of Obstetricians and Gynecologists has neither solicited nor accepted any commercial involvement in the development of the content of this published product.