REVIEW ARTICLE

How Accurate Are We When It Comes to the Reprocessing and Reuse of Gynecological Equipment?

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Abstract

Despite high per capita income and strong health insurance coverage, healthcare is expensive for a sizable section of the population. Reprocessing of devices began in the late 1970s in an effort to lower procedure costs. Reprocessing involves a number of steps, including appropriate cleaning, disinfection, and sterilization techniques. Reprocessing has the potential to compromise patient safety due to cross-contamination following insufficient sterilization because it is intended to save costs. During the sterilization/disinfection processes, there is also a chance that the reconditioned equipment would work differently. Therefore, it is necessary to provide appropriate criteria to choose reprocessing procedures for diverse gynecological equipment. Additionally, it is important to talk about and resolve the issues that gynecologists confront. In September 2022, a PubMed search was conducted using several search terms, including "recycling of medical devices", "Single Usage Devices", "methods of reprocessing of equipment in medical practice", "use of formalin chamber", "gynecological disposable disinfection", etc. All English articles were checked by title and abstract after duplicates were eliminated. After obtaining the whole contents of a few articles, we checked them against other connected articles to see if there were any. The articles were all examined. A product can be reused if it can be cheaply treated again using methods that have been proven effective while maintaining its functionality. After one use, it does not need to be thrown away. This procedure helps to limit the cost of a gynecological case and lessens the financial load. Food and Drug Administration regulations now in effect are rigorous. In medical practice, the contamination that is used to assess the sterilizing procedure is never truly present. New regulations that take the clinical research scenario into account are therefore preferred.

Keywords: Disinfection, Gynecology devices, Sterilizing.

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Introduction

Because of the expansion of diagnostic resources during the past two decades, there has been an increase in the number of gynecology endoscopic operations. The number of procedures carried out utilizing minimally invasive methods is also rising. The development of minimally invasive gynecology has led to the availability of a number of endoscopes and accessories. These instruments are pricey, though. While many of them are made for single use only, others are made for numerous uses after reprocessing. Due to the expense, it is not feasible to utilize one instrument on a patient before permanently discarding it. This upsets the surgical case's whole economics. In the late 1970s, the reusing of single-use medical equipment started.[1] As a cost-cutting approach, the reusing of single-use medical equipment (SUME) grew. About 30% of US hospitals reported reusing at least one kind of SUME.[2] Reusing SUME has been highly contentious for more than 25 years and includes regulatory, ethical, medical, legal, and economic challenges. The same legal specifications that applied to the device when it was first created must be met by a repurposed SUME.[3] Hospitals and gynecologists currently use indoor facilities in healthcare facilities to reprocess consumable medical items. Many of them also recycle single-use disposable medical gadgets that have been given the go-ahead by manufacturers in clinical settings. These devices are being used on additional patients more than once, frequently without informing the patients that the gadget may have previously been used. On the other hand, this procedure can jeopardize patient security. After insufficient disinfection of gynecological equipment, patient-to-patient infection transmission from cross-infection has been widely documented.[4] In a clinical or hospital setting, infectious organisms are frequently transmitted to other people. Due to the careless use of antibiotics, hospital-acquired infections with resistant viruses and bacteria are on the rise.[5,6] Reprocessing medical equipment that has been created, produced, and advised to single-use only by makers has been the subject of heated discussion. The use of reprocessed SUMEs has both benefits and drawbacks, according to studies.[7] Two patient safety issues are brought up by this approach. One is whether the SUMEs can be properly cleaned and sanitized before being used on other patients, and two is if cleaning and sterilizing these devices can impair their functionality or result in a defective product. Important factors to take into account with the reusing of refurbished devices include

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ensuring that all patients receive an equal level of protection from infections, calculating patient risks, the requirement for informed consent, regulatory integrity, and monitoring and evaluation of reprocessing units. Even industrialized nations with high per capita incomes and high health insurance coverage are reusing the equipment after processing due to the rising endoscopic workload. For underdeveloped nations with low health insurance coverage, where the finances of a surgical procedure become crucial, "guidelines for reprocessing" must be developed. The creation of guidelines for the selection of appropriate reprocessing techniques is also necessary. These guidelines should take into account the infection risks connected to a given procedure, the affordability and accessibility of the appropriate equipment, as well as the time needed for reprocessing. By delivering a written questionnaire, Ahuja and Tandon conducted research on single-use accessory reuse and disinfection practices. Only 39% of those who answered, they discovered, were reprocessing in accordance with the prescribed methods. Additionally, they discovered that following reprocessing, more than 89% of responders were prepared to reuse SUMEs.[8] As a result, it is essential to develop criteria to ensure that the tools used in gynecological practice are cleaned, disinfected, and sterilized to the highest level possible. It is crucial to sanitize instruments and equipment using the right procedures. Additionally, the personnel in charge of it should be diligent, skilled, and well-trained. This guarantees that every piece of equipment used on each patient has been effectively sterilized. These procedures must be continuously observed. We will give a quick overview of the sterilization and disinfection procedures used for single-use and multiple-use medical instruments and devices used in gynecological practice in this post. The difficulties that surgeons encounter on a daily basis in clinical practice will also be covered. We will talk about commercial and hospital standards with a focus on patient outcomes in underdeveloped nations.

Spaulding Classification Scheme

The classification system used to identify the products used in healthcare institutions is approved by the Food and Drug Administration (FDA) and is based on the potential risk of infection posed by the usage of the device. The things that penetrate sterile tissues or the circulatory system are considered critical items. Ureteric catheters and double-lumen ureteric stents fall under this category, which merely needs to be sterilized. The products that come into contact with mucous membranes or damaged skin are considered semicritical. Cystoscopes, laparoscopes, hysteroscopes, and RGCs fall under this category and need to be sterilized or thoroughly disinfected.[9]

Summary of the Process

A SUME is a piece of equipment that is designed to be used only once or on a single patient throughout a single treatment. A medical instrument that may be used again on the same or other patients with the proper cleaning and other reconditioning in between usage is referred to be reusable.[10] Reprocessing is the use of approved procedures to make a used or contaminated medical equipment suitable for a further single usage.[10] These procedures are intended to clean surfaces to eliminate soil and pollutants and to disinfect or sterilize objects to render germs inactive. It is usually better to plan for the worst-case situation during reprocessing, which involves device contamination during clinical usage by the most resistant bacteria.

Cleaning is the First and Most Crucial Stage in the Reprocessing Process

Cleaning is the process of removing visible filth (such as organic and inorganic debris) from items and surfaces. It is often carried either physically or mechanically utilizing water together with detergents or microbial treatments.[11] Prior to high-level disinfection and sterilization, the surfaces of the instruments must be thoroughly cleaned since organic and inorganic residue reduces the efficiency of these procedures. Cleaning has been demonstrated to lower microbiological contamination by 4–6-log 10.[12] Disinfectants' ability to fight microbes can be hindered by organic substance in the type of serum, blood, pus, or lubricant. This interference is caused by a complex that is less germicidal or nongermicidal as a result of a chemical interaction between the germicide and the organic material, which leaves less of the active germicide accessible for disinfection/sterilization. Second, organic material can serve as a physical barrier to defend bacteria from harm.[13,14] Since both organic and inorganic dirt are easily eliminated by washing, this stresses the significance of meticulously cleaning medical devices prior to any sterilization or disinfection operation. The devices' surface biofilms are also removed during the mechanical cleaning operation. Microbial colonies known as biofilms are firmly affixed to surfaces and are difficult to remove. When compared with the identical bacteria in suspension, microorganisms in biofilms are up to 1000-times more immune to antimicrobials.[15] Reprocessing thus begins with swift initial cleaning procedures to avoid drying out soil and pollutants within and on top of the device. The most crucial stage of the reprocessing process is immediate, thorough cleaning. Any reprocessing delay might make disinfection or sterilization more difficult.

Dismantling and Rearranging

Reprocessing for devices with detachable parts requires previous dismantling and reinstallation of the item to enable cleaning.[16] Depending on how the manufacturer specifies, reassembly should take place either before or after sterilization.

Techniques for Cleaning

Cleaning might be carried out either mechanically or manually. Where mechanical equipment is either unavailable or necessary for fragile instruments, manual cleaning is carried out. Friction and fluidics are the two key elements of manual cleaning. When the design prevents the passage of a brush through a channel, fluidics is used to remove soil and detritus from channel walls after brushing and from the contaminated region using friction. Water must flow quickly through all internal passages for at least 60s.[17] With the aid of a dishwasher, utensil dryer, ultrasonic cleaner, etc., automated/mechanical cleaning may be carried out. Automatic cleaning equipment may improve efficiency and production while lowering worker exposure.[18,19] By using more cleaning chemicals and enzymes, the cleaning process' efficacy can be improved. Cleaning chemicals that have been shown to be effective and compatible with the device (for example, detergents like quaternary ammonium complexes and enzymatic detergents) can be used.[20] The optimum material compatibility characteristic and dirt removal are provided by detergent solutions with a pH that is close to neutral. Cleaning chemicals can have enzymes (such as protease, lipase, and peptidases) added to them to help them remove organic matter as they target the proteins in blood and pus.[21] The only

way to determine if a gadget is "clean" at the moment is by visual inspection. A cleaning procedure should, at the very least, lessen natural bioburden and eliminate organic/inorganic pollutants. Devices will therefore have a satisfactory sterility assurance level (SAL 10–6) after sterilization.[22]

Storage, Drying, and Rinsing

Rinsing is necessary to get rid of chemical residues left over from cleaning and reprocessing so that they would not obstruct the next stage of processing.[13] According to published recommendations, tap water may be used for washing rather than sterile or filtered water exclusively.[23,24] Saline is not advised for final rinse since it might cause certain devices to corrode.[13] Device drying is advised since the devices will be damp after reprocessing. After sterilization/disinfection operations, moisture that remains on devices might jeopardize the quality of packages and the performance of seals. Drying lessens or completely prevents recontamination of unwrapped equipment that has undergone high-level disinfection or sterilization during reprocessing.[25] Never put a contaminated endoscope in the carrying case since the case itself might get infected. The transporting case used to keep and carry the instrument inside the healthcare institution should be different from the carrying case used it to transfer clean and reprocessed surgical instruments outside of the setting.[26]

Superior Disinfection

Disinfection is a term used to describe a technique that gets rid of most or all harmful germs on inanimate items, with the exception of bacterial spores.[11] In medical facilities, liquid chemicals are typically used to disinfect things. Disinfection is not sporicidal, in contrast to sterilization. Some disinfectants, referred to as chemical sterilants, will destroy spores with lengthy exposure durations (3–12 h). A sterilant is used in a deadly procedure called high-level disinfection that takes place in less-than-sterile circumstances. All microbial life is destroyed by the procedure, with the exception of a significant quantity of bacterial spores.[11] Bacterial spores, fungi, lipid and nonlipid viruses, bacteria, and mycobacteria are the microorganisms with the greatest resistance to germicide chemicals.

Glutaraldehyde and ortho-phthalaldehyde (OPA) are two often-utilized high-level disinfectants in gynecological practice. Disinfectants should be used with caution to avoid the emergence of resistant microorganisms.[27] Because of its lack of sporicidal effect, ethyl alcohol is not suitable for sterilizing medical and surgical materials. It is also incapable of penetrating protein-rich materials.[28] When employed as a liquid solution called formalin (37% formaldehyde by weight), formaldehyde acts as an antibacterial agent, tuberculocide, antifungal, virucide, and sporicide.[29,30] Paraformaldehyde is a formaldehyde solid polymer. It may be evaporated by heat and its laminar flow can be utilized to decontaminate biologic safety cabinets with gaseous decontamination. Despite this, its usage is restricted due to its unpleasant vapors and strong odor, even at extremely low levels (1 ppm). Additionally, it leads to respiratory issues like asthma as well as skin irritations like dermatitis and itching. It might play a part as a probable human carcinogen connected to lung and nasal cancer.[31] Because of its benefits, including good biocidal qualities, activity in the presence of organic matter, and noncorrosive action to endoscopic equipment, glutaraldehyde has acquired widespread recognition as a high-level disinfection for gynecological equipment. Plastics, rubber, and lens-equipped devices are not left with any lingering harm.[32] The solution successfully kills vegetative bacteria in about 2 minutes and *Mycobacterium tuberculosis*, fungus, and pathogens, including HIV, hepatitis B, and hepatitis C in about 10 minutes when it is "activated" by the application of alkalinating chemicals to pH 7.5–8.5. Glutaraldehyde kills Bacillus species spores quickly, however, it takes 3 hours to destroy bacteria and Clostridium species spores.[33] The minimal exposure period for successfully killing mycobacterium and other vegetative bacterium with >2% glutaraldehyde is thought to be 20 minutes at room temperature.[34] Most solutions have a minimum shelf life of 14 days after being activated. With the help of innovative glutaraldehyde formulations, the issue of fast activity loss has been solved, and they may now be used for up to 28–30 days while still retaining outstanding microbicidal activity.[35,36] Acute or long-term exposure to glutaraldehyde can cause dermatitis or skin irritation. Additionally, healthcare workers exposed to glutaraldehyde have been observed to develop nosebleeds, contact dermatitis, asthma, and rhinitis.[37–39] Ortho-phthalaldehyde, a powerful disinfectant, was given FDA approval in October 1999. With only a 12-minute exposure time need, it possesses superior mycobactericidal and outstanding microbicidal action. It does not cause known eye or nasal irritation, does not need exposure assessment, has a barely detectable odor, and needs no activation. It also has great stability across a broad pH range (pH 3–9).[40] Ortho-phthalaldehyde is not suggested for reprocessing gynecologic equipment, nevertheless, as incidences of anaphylaxis-like reactions following cystoscopy have been documented when the scope was done thus.[41]

Sterilization

In healthcare facilities, sterilization is a procedure that uses physical or chemical means to remove or eradicate all forms of microbial life.[11] Any microbial contamination might lead to disease transmission in medical equipment that comes into touch with sterile human fluids or tissues. Surgeons often utilize autoclave, ethylene oxide gas, ozone gas, liquid chemicals, and hydrogen peroxide gas plasma as their primary sterilizing agents in healthcare facilities. The likelihood of finding a single live bacterium on a product after sterilization is known as the SAL of the product. Normal SAL expression is 10–n. A SAL is, in essence, a calculation of the lethality of the whole sterilizing procedure. Reusable devices should have a SAL of 106 if they are meant to be used sterile.[42] The bioburden number and position of microorganisms, previous cleaning, the kind of pathogen, the existence of proteins and salt, biofilm buildup, lumen length and diameter, and other factors all impact how well a device is sterilized.[43,44] Steam sterilization is the suggested sterilizing method if the equipment is heat-resistant since it offers the widest safety margin due to its dependability, uniformity, and lethality. However, low-temperature sterilizing techniques (LTSTs) are necessary for reprocessing heat-sensitive goods.[45] The most popular and acceptable sterilizing technique is moist heat steam sterilization, which uses saturated steam under pressure. It is nontoxic, affordable, quickly sporicidal, microbicidal, and penetrative.[46,47] All heat- and moisture-resistant critical and semicritical goods can utilize it. In a gravitational displacement sterilizer, the minimum exposure times for sterilization are 30 minutes at 121°C, or 4 minutes at 134°C in a prevacuum sterilizer. Using "flash" steam sterilization, an object is sterilized at 132°C for 3 minutes at 27–28 pounds of pressure. When there is not enough time to sterilize an item using the recommended procedure, it can

also be utilized to process cleaned patient care items. For implanted devices, flash sterilization is not advised due to the risk of severe infections.[48]

Technologies for Low-temperature Sterilization

This covers the use of ETO gas sterilization (ETO–CFC, ETO–CO2, ETO–HCFC, and 100% ETO) as well as more recent LTSTs such as ozone sterilization and hydrogen peroxide gas plasma. Every LTST has its limits. They first show a large number of failures when serum or salt is present because these substances shield bacteria and spores from harm. Additionally, it has been demonstrated that the issue worsens exponentially as lumen length and diameter decrease. Microorganisms generate physical crystals that shield them when they are combined with bodily fluid. The protective function, however, is lost after 1 minute of contact with water because the salts disintegrate. This demonstrates the significance of thorough cleaning prior to sterilization.[49–51] All microorganisms and the majority of bacterial spores are rendered inactive by ETO sterilization, which has great microbicidal efficacy. It is frequently used in healthcare institutions to sterilize sensitive to moisture or heat, semicritical, and critical goods.[52] The key benefit is that it can sterilize medical equipment that is sensitive to heat or moisture without harming the materials used to make the devices. It also penetrates many plastics and medical packaging, is compatible with the majority of medical materials, and is simple to manage and monitor the cycle, among other benefits. The main drawbacks are the prolonged cycle and aeration times, the expense of each cycle, the potential for expensive equipment damage, and the possible risks to patients and employees.[49,50] Due to ETO's capacity to permeate, lengthy durations of aeration are necessary. Acute ETO exposure may cause central nervous system depression and irritation of the skin, cornea, gastrointestinal, or respiratory tracts. Cataract development, cognitive decline, neurologic dysfunction, and debilitating polyneuropathies have all been connected to chronic inhalation.[53–55]

Sterilization with Ozone

FDA approved ozone in August 2003 for use in treating reusable medical equipment. At the conclusion of the cycle, it transforms back into oxygen and water vapor before being vented into space. The sterilizing cycle lasts 4 hours and 15 minutes and takes place between 30°C and 35°C. It has demonstrated effective microbicidal properties against a range of bacteria. The sterilizing chamber's tiny size (4 ft) and the lack of data on its microbicidal efficiency due to its restricted application are drawbacks.[56]

Areas with Problem

Food and Drug Administration has high criteria. The FDA has established very strict standards for standardized sterilization and disinfection. To assess the effectiveness of disinfection and sterilization, the FDA mandates the presence of 5% fetal calf blood dried onto the devices infected with 106 colony-forming units of the most resistant test organisms. In the exhibition of sterilization effectiveness, cleaning is not permitted before sterilization.[57] Nearly, all sterilization techniques will fall short of successfully inactivating the microbial load in the presence of these conditions.[58] Such rigorous standards are never used in clinical settings. Used medical equipment often has a low bioburden of microbiological contamination. Medical devices used in general and gynecological surgery were examined by Nystrom.[59] He discovered that following usage, 60%, 80%, and 90% of the instruments were infected by pathogens less than 10^1, less than 10^2, and less than 10^3, respectively. More than 99% of the instruments had less than 10^1 organisms after being cleaned in an instrument washer, and none had more than 10^2 organisms. The bioburden on the inner and exterior surfaces of rigid-lumen medical devices varied from 10^1 to 10^4 organisms per device in a different investigation. About 80% of the gadgets still had 10^2 or less organisms after cleaning.[59,60]

Manufacturers' Role

Gynecological equipment manufacturers never advise reusing SUMEs. According to FDA guidelines, they can be used again if the product meets the manufacturers' sterilizing requirements after routine reprocessing processes. The FDA has established very strict standards for the standardization of reprocessing methods, as we have already mentioned. In actual clinical settings, such microbial loads hardly rarely occur to support reuse policies. However, it is nearly impossible for manufacturers to advise reprocessing and reuse given the strict standards required by the FDA for manufacturers. Because of this, the labeling lacks sufficient directions for appropriate dismantling, reassembly, washing, and reprocessing. According to manufacturer recommendations, using a new equipment for every new instance raises the total cost of operation and places a significant financial burden on the healthcare sector.

Medical–Legal Concerns and Surgeons's Fear of Psychosis

Due to linked medicolegal concerns and the lack of conventional rules addressing the reprocessing of SUMEs, gynecologists are at a high risk of acquiring dread psychosis. Devices having a long, thin lumen that should be sterilized or disinfected. Any narrow-lumen medical equipment used in patient care that requires immediate cleaning poses a significant obstacle to reprocessing.[61,62] Retro-flushing with the small lumen has been demonstrated to offer sufficient cleaning. Retro-flush cleaning lost its effectiveness if reprocessing was put off for longer than 24 hours. The cleaning and sterilizing procedures are impacted by the physical characteristics of the object, such as the existence of fissures, joints, and apertures in the devices.

Formalin-filled Rooms

The usage of formaldehyde vapor cabinets dates back to the late 19th century. Up to the end of 1988, it was often utilized in hospitals. According to Janet's theory, these cabinets sterilize objects using formaldehyde gas over a 24-hour period at room temperature and at the proper pressures.[63] However, the tablets of paraformaldehyde (located on the bottom tray) release gas slowly and with little partial pressure. There are no facilities for the proper flow and removal of formaldehyde gas, and the humidity and temperature inside the cabinet might not be regulated. Perforated drawers in the cabinet may stop gas diffusion, especially if they hold equipment. As a result, it is unknown if this method has microbicidal properties.[64] There are no reliable manufacturer's instructions for using these cabinets or for the efficient generation of gas inside of them. The FDA has not approved the use of the formaldehyde steam sterilization system, and it is not suggested that it be used as a high-level disinfectant.

Workload and Quick Procedures

Due to time constraints, it is not always possible to disinfect each and every piece of equipment in-between two gynecological cases at facilities with a large volume of cases per day and limited

sets of instruments. High-level disinfection is advised in such circumstances. For efficient high-level disinfection when using glutaraldehyde, there should be a minimum of 30 minutes between two instances.

Conclusion

Disinfection and sterilization can guarantee the proper reusing of recyclable devices and many single-use gynecological equipment if FDA criteria are rigorously adhered to.

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