Reprocessing medical devices : is this following evidence-based medicine?

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Introduction

The rising cost of healthcare is one of the main focuses in today's mainstream media. The costs present new problems to individuals, hospitals and healthcare systems. There are new innovative treatments, preventative measures, diagnostic techniques and technology that have not only advanced the health potential of the human race but also advanced the competition in the marketplace of medical care. Combining the business of healthcare with the reduction of insurance reimbursement, these costs have continued to rise. With the rising costs, healthcare administrators are placed in the unique position of attempting to cut the costs for each of their individual systems (Unger & Landis, 2016). One place that healthcare administrators have discovered the ability to cut costs is in the reuse of medical devices. The reprocessing of such medical devices has created a complex system itself inside of healthcare.

Healthcare is a system that has always and will always include trade-offs; these trade-offs are due to the limited resources that are available (R. C. Lee, Berzins, & Alfieri, 2007). These limited resources include materials, healthcare providers, medications and access to healthcare. One of the main incentives behind trade-offs in medicine is the potential financial benefit. However, the trade-off of reprocessed medical devices for new medical devices is much more complex than a way to benefit financially. Reprocessing medical devices has an impact on the lives of patients, healthcare providers, and hospitals every day.

As with any decision, there are risks and benefits that come along with choosing to use reprocessed medical devices. Perhaps the most discussed risk that accompanies reprocessing medical devices is the risk of disease transmission due to inadequate reprocessing. However, there are many other risks that also accompany reprocessing. Such risks include legal risks,

ethical risks, environmental effects and even financial risks that all may result from the system of reprocessing medical devices (R. C. Lee et al., 2007).

The reprocessing of medical devices is a business that generates millions of dollars annually for reprocessing companies and in return saves large amounts of money for healthcare systems across the United States. Due to the prevalence of reprocessing, over the years, the federal governing bodies, the Food and Drug Administration (FDA), have been put in a position to address the reprocessing. Over years, the FDA has published guidelines and recommendations regarding the safety and process for the sterilization and cleaning involved in the reprocessing of previously used medical devices. Such guidelines will be examined to more extent in this paper.

This paper will discuss many aspects that are involved within the complex system of reprocessing used medical devices. The purpose is to determine if the reprocessing of medical devices can be considered evidence based medicine. In order to further examine the reprocessing of medical devices, this paper will begin by looking through the history of medical devices and the decisions involved with reprocessing. From there, the literature review will include economic motivations and consequences, ethical implications, and risks that are involved with the reprocessing of medical devices.

Literature Review

The History of Reprocessing

For decades, medical devices have been sterilized and disinfected after use in order to be used again. When manufactured and designed, such devices are labeled as multiple-use devices. A multiple-use medical device is designed to be used on multiple patients over time (Shuman & Chenoweth, 2012). Such devices are said to withstand the cleaning process without any device damage or malfunction as a result of the process. In the 1970s and 1980s, synthetic materials such as plastic lead to a new market in medical devices. The use of synthetic materials allowed for products to be labeled as single-use devices (SUDs). With the label of SUD, these products were marketed for single use only. Under this label, the function and sterility of the device was guaranteed for one time only and was expected to be discarded properly after one use. (Jacobs, Polisena, Hailey, & Lafferty, 2008). The products that were manufactured with the synthetic-materials allowed buyers to purchase a product at initial lower cost and then dispose of the product (Unger & Landis, 2016).

The label of SUD also came with the implication that the device, whether due to materials or design, was unable to be used more than once and that reusing the device was unsafe (Hussain, Balsara, & Nagral, 2012). Above all else, labeling the device as single-use ensured function and sterility for one use only (Jacobs et al., 2008). SUDs include a large array of medical materials. SUDs range from basic supplies used in healthcare such as gloves, to more expensive and complex equipment (R. C. Lee et al., 2007).

Just as the financial benefit of using synthetic material was discovered, the benefit of reusing devices made of synthetic material was also discovered. The reprocessing of single-use devices became a way to save financially, not only on initial costs, but also avoiding the cost of a

new device by reprocessing these devices instead. By the time the FDA asserted regulations and guidelines involving the reprocessing of single-use devices, the system of reprocessing was already established. A list of single use devices, provided within the FDA document for enforcement of reprocessed single-use devices is provided in the appendix. This list of reprocessed medical devices in the appendix is not a list of devices approved to be reprocessed. Instead, this list is a list of medical devices that were known by the FDA to be reprocessed. There has been no list updated by the FDA since the publication of this list in 2005.

In 2000, the FDA released guidelines on the practice of reusing medical devices, including those that were originally manufactured for single use. These guidelines were to be implemented into a practice that was already well established. The goal of the policy put forward by the FDA was to keep the public health at the forefront of reprocessing. Alongside maintaining public health, the FDA also held firmly to their belief that their guidelines were based on and backed by scientific evidence ("FDA releases final guidance on the reprocessing and reuse of single-use devices," 2000). Although the FDA held firmly to keeping the public health as the main goal, they allowed the involved hospital systems and other involved parties to determine the risks involved with the reuse of every device (Shuman & Chenoweth, 2012). The decision to inform patients of any possible breaks in sterilization or the use of reprocessed devices is not required by a federal or governing body. This decision lies in the hands of the individual hospital system.

In 2015, the FDA created revised guidelines for reprocessing medical devices. These guidelines were intended to address the manufacturers that were creating and designing the medical devices. The FDA emphasized that during the design and creation phase, the manufacturers should consider how the device would be used, the level of contamination that it

would endure during use, and the ease of cleaning of each individual device. In addition, this guideline required the manufacturers of such devices to provide validation studies for the cleaning process. These validation studies were previously only required for sterilization of devices (Nania, 2015). With this guideline, the FDA was stressing the importance of medical device design and the ability of the device to be cleaned and reused without harm to the device or patient.

In addition to the guidelines put forward by the FDA, the Medical Device Directive (MDD) is a piece of legislation that focused on the design of the device. This directive states the importance of the initial design and manufacturing of every device. The MDD encourages manufactures to first analyze what the device is going to be used for along with the clinical conditions that it will encounter. Likewise, understanding and predicting any compromising qualities of the device, whether through use or cleaning, is important to consider as well. The use, condition and design affect the overall safety of the device. The MDD urges manufacturers to assess the risks accompanied with the use, design and conditions. These risks should be weighed against the potential adverse effects to human health (Hall., 2007).

The Science of Reprocessing

Sterilization of both single-use medical devices and multiple-use medical devices is a complex process that varies based on numerous factors, factors which are changing constantly. Reprocessing depends on the type of device, device design and material, the body cavity that it comes in contact with, and the number and type of microbes that it encounters. To understand reprocessing and the decisions that go along with sterilization and disinfection of individual devices, it is important to understand the science and terminology.

The FDA defines sterilization as a process that destroys or eliminates all forms of microbial life. Sterilization is carried out by either physical or chemical methods. In contrast, the definition of disinfection is a process that eliminates many or all microbes, besides spores, on an inanimate object. Disinfection and sterilization can be compared to cleaning which is defined as the removal of visible soil from an object which is done either manually or mechanically using water along with detergents or enzymatic products (Rutala et al., 2008).

Earle H. Spaulding created an approach to the cleaning, disinfection and sterilization of medical devices. This approach was, and still is, viewed by many as a clear, logical and rational approach. This scheme was created decades ago and is still implemented today. This method of rationalization is termed the Spaulding Scheme. Spaulding rationalized his approach by categorizing medical devices. There were three categories which include critical items, semi-critical items, and non-critical items.

Critical items are medical devices with the highest risk for causing infection in a patient if they are contaminated with microbes; these medical items come in contact with sterile tissue or the vascular system. Examples include surgical instruments and cardiac and urinary catheters. Semi-critical items are those items that only come in contact with mucous membranes and non-intact skin. Semi-critical items include anesthesia equipment, some endoscopes and endoscope blades. Finally, non-critical items are those that come in contact with intact skin only. Examples of non-critical items are encountered daily in the medical field. Such non-critical items include blood pressure cuffs and bed pans (Rutala et al., 2008). The categorization of medical devices builds the foundation of the Spaulding Scheme.

There are many critics of the effectiveness of the Spaulding Scheme. Many state that the rationalization for this approach over-simplifies the issue at hand. The critics argue that there are

many issues that the Spaulding Scheme ignores. The categorization of critical, semi-critical and non-critical ignores the individuality of medical devices. The devices may be composed of different materials, different design, and different ability to withstand cleaning techniques. Similarly, the Spaulding approach does not take into consideration the types of microbes encountered. Different microbes may be resistant to certain techniques that other microbes may be susceptible to. Another issue that critics argue is ignored, includes situations when critical items may come in contact or be combined with semi-critical items during certain medical procedures. By definition of the Spaulding Scheme, this would undermine the ability of the critical items to maintain their proper sterility (Rutala et al., 2008).

Compared to the simplicity of categorizing medical devices, as in the Spaulding Scheme, much evidence emphasizes that the reprocessing of a medical device depends on each individual device and the circumstances that surround that device and cannot be generalized. Viewing each device individually begins by examining the path that the device has taken. Each medical device, enters a specific body cavity. Individual body cavities have different microbes that are known to thrive in that specific area of the body. In addition, each individual patient has their own bioburden. Bioburden, by definition, is the number of microbes, or the microbial load, that is present. Sterilization and disinfection is greatly affected by the bioburden (Colonna & Thomas, 1999). As the bioburden increases, the more amount of germicide is needed to eliminate it (Rutala et al., 2008).

In addition to the patient's individual bioburden and the body cavity encountered, the type of microbe also greatly affects effective reprocessing. Individual microorganisms have mechanisms that help provide resistance. Prions have the highest resistance followed by bacterial spores. The following list of microorganisms are organized from most resistant to least resistant:

prions, bacterial spores, coccidian, mycobacteria, non-lipid or small viruses, fungi, vegetative bacteria, lipid or medium-size viruses (Rutala et al., 2008). Of newer concern are emerging pathogens; there is not sufficient research on emerging pathogens to know the proper technique required to destroy these new microbes. Similarly, there are microbes which little is known; viruses such as noroviruses cannot be grown in tissue culture and therefore little is known about them (Rutala et al.). In addition, there is also emerging resistance of microbes to the techniques that were once known to destroy all pathogens. Bioburden and the variability within microbial life all point to the need for individualizing the process of reprocessing.

Individualizing Reprocessing

There are many decisions that need to be made in regards to reprocessing for each individual medical device and the condition that it has encountered. One of the first decisions that is made during reprocessing is choosing a specific sterilant. When choosing a sterilant, it is important to not only think of the bacteria that it will encounter but also maintaining the integrity of the device (Colonna & Thomas, 1999). In addition to effective microbial destruction, it is vital that the device's mechanical integrity is not compromised by the use of any particular sterilization process. Reprocessing may also include manual scrubbing or cleaning right after use. Scrubbing can negatively affect the mechanical integrity of the instrument as well as the overall sterilization process. Likewise, the instrument is initially washed with sterile water right after use; saline water should not be used because salt corrodes the instrument which can produce new crevices and undermine the integrity of the instrument as well (Nania, 2015).

Along with choosing the proper sterilant and maintaining device integrity, it is vital that the sterilant comes into contact with the microbes. Device design has a large impact on the ease

of the sterilant coming into contact with the microbes. Crevices, lumen diameter and length, sharp bends and other aspects of device design all impact that ability of the sterilant to come into direct contact with the microbes. Similarly, biofilm accumulation can prevent contact with microbes. Biofilm is defined as a group of microbes which are tightly attached to a surface and are not easily removed. Biofilms act as a protective mechanism for the bacteria; bacteria within biofilms are up to 1,000 times more resistant to antimicrobials than the same bacteria when it is within a suspension (Rutala et al., 2008). Whether it is a biofilm, blood, protein, or device design that acts as an obstacle, the contact of the sterilant with the microbe is vital to the effectiveness of reprocessing and must be individualized for each medical device.

The device design must be taken into consideration when choosing individualized reprocessing techniques. In particular, many medical devices require assembly when being used and disassembly after use. Disassembly prior to sterilization and disinfection is vital to effective reprocessing of certain devices. Similarly, many devices include crevices, joints and channels that all pose unique difficulties. Crevices and joints provides spaces for bioburden to accumulate that are more difficult to eliminate than those on surfaces without crevices or joints. Other device designs that may impact the disinfection and sterilization include sharp bends, screws and hinges. Devices with lumens may require different amounts of forced flow through the lumen to have effective reprocessing. For instance, longer lumens may need increased forced flow to get the same effectiveness as those with shorter lumens. Blind lumens may also impact sterilization and disinfection (Rutala et al., 2008).

The Process of Reprocessing

The process of sterilization and disinfection starts from the moment the device is used. This is called point of use cleaning; point of use cleaning is cleaning that is performed right after the instrument is used. This cleaning of the instrument should use sterile water immediately which removes gross contamination and helps in the prevention of further biofilm build up. Similarly, this is when manual scrubbing is used to remove gross contamination (Nania, 2015). From there, many steps are performed before the device reaches another patient. The more steps that are encountered along the process, the more opportunity for sterilization to be negatively impacted. Each step requires careful correctness to achieve sterility. One study showed that it is common for staff not to perform the recommended process of sterilization correctly (Donskey et al., 2014). The sterility of the device still has the opportunity to be affected even after the sterilization process is completed. There is inspection of the device and packaging that are all required to complete the process of sterilization (O'Hara, Patel, Caldwell, Shone, & Bryce, 2015). From the moment the device leaves the first patient until the moment that same device is ready for use by another patient, the sterilization and disinfection of the device can be undermined.

With all of the variability involved, there is not one simple procedure for the most effective reprocessing. This process must be individualized to each medical device and every situation. Many factors can influence sterilization: cleaning, bioburden, lumen, design, material, staff, specific sterilant used, and many more. Biological indicator tests are used to see any remaining microbial organisms that have withstood the sterilization process (U. S. Department of Health and Human Service, Food and Drug Administration, 2015). However, this type of test is not guaranteed to identify all of the bacteria left on medical devices, especially surgical devices.

The bioburden that exists on surgical devices is known to be lower than the amount that is necessary for these biological indicators to indicate that there are microbial organisms present (Rutala et al., 2008). Overall, the process of sterilization and reprocessing includes many steps which must have the ability to be adhered to while still being flexible, and depend on many variable factors.

Failures in Reprocessing

Hospitals and other third-party reprocessors are able to voluntarily report lapses in the sterilization and disinfection to the FDA's Manufacturer and User Facility Device Experience (MAUDE). The lapses consist of adverse events that are reported voluntarily. Such adverse events include device malfunction and patient injury, or death. In the MAUDE database, it is shown that both infections and colitis have been attributed to reprocessing errors as well as defective equipment. Between January 1, 2007 and May 11, 2010 there were 80 reports of reprocessing errors. The errors that were attributed to reprocessing include errors in all parts of reprocessing. Errors include general non-adherence to protocols, skipped steps and improperly completed steps. The errors that were reported were reported multiple times. There was only one single occurrence. Through examining the MAUDE database, it can be understood that most of the errors in reprocessing that are admitted do not get fixed (Dirlam Langlay et al., 2013).

With limited studies, it is difficult to address the effects of failures of reprocessing directly. However, examining the techniques of reprocessing devices at individual systems and hospitals has given insight into reprocessing. In 2008, the U. S. Centers for Medicare and Medicaid Services did just that; they performed unannounced inspections for infection control practices. While examining 68 surgical centers the U .S. Centers for Medicare and Medicaid

Services concluded that 39 of these 68 surgical centers not only had deficiencies in infection control but 19 of these centers failed to properly reprocess medical instruments (Dirlam Langlay et al., 2013). Another observational study done in 2010 showed that only 48% of observed GI endoscopes were properly reprocessed. Of the 183 endoscopes that were observed, all of these locations stated that they followed protocol and guidelines given for reprocessing endoscopes. When manual methods were used to reprocess endoscopes, it was shown during this same observational study that as high as 99% did not adhere to protocol and guidelines (Dirlam Langlay et al.).

The Business of Reprocessing

One of the motives behind the start of reprocessing of medical devices, and especially the single-use medical devices, was an economic motivation. There is a two-fold cost savings with reprocessing of medical devices. One part of the savings comes from medical waste. U. S. hospitals are said to spend between $259 million to $401 million on waste annually. Decreasing waste production by reusing single-use medical devices is a way to save financially and environmentally for hospital systems (Unger & Landis, 2016). The other financial savings results from the decrease in purchasing of new medical devices. In addition to decreasing the amount of devices purchased, single-use devices have lower initial costs due to their inexpensive material (Colonna & Thomas, 1999). Reprocessed medical devices are said to be 50% less expensive than new medical devices. In 2000, health care facilities that were using reprocessed medical devices were saving on average between $200,000 to $1 million annually (Association of Medical Device Reprocessors [AMDR], 2011)

The reprocessing system has become a competitive business. Globally, in 2008 the reprocessing industry was said to be worth over $500 million and was estimated to grow 12-14% annually (Hussain et al., 2012). It is estimated that there are two third-party reprocessors in the United States that do 95% of the reprocessing: Stryker Sustainability Solutions and SteriMed Inc (Noble). With reprocessing being such a large financial incentive for hospitals, this has forced manufacturers of medical devices to lower their original prices. Lowering the prices of the new medical devices allows the manufacturers to compete with reprocessors. There is also evidence that manufacturers lowered prices as a part of agreement with medical facilities that would agree not to reprocess. Third-party reprocessors stated that medical facilities would stop using their services when this type of agreement was made (AMDR, 2011). Overall, the business of reprocessing has driven many costs down and savings up.

Although there is a large financial incentive to reprocess medical devices, there are still costs that come along with reprocessing. Such costs associated with reprocessing include: labor, testing the effectiveness of the sterilization, testing the integrity of the medical device, cleaning agents, education on reprocessing staff, development, liability insurance, disposal and increased inventory and storage (R. C. Lee et al., 2007).

In addition to the predicted costs of reprocessing there are also unforeseen costs that arise. There is a risk for infections from these reprocessed devices. With the risk of infections increases costs of the consequences of such infections. Costs can arise from increased morbidity and mortality (O'Hara et al., 2015). Similarly, there are costs to the patient that may result from the risk of infection. Costs that result from loss of productivity and decreased quality of life (Jacobs et al., 2008). Not only are there unforeseen costs to the patient but also unforeseen costs to the hospitals as well. Such costs can potentially offset the savings with liability insurance and

lawsuits (Colonna & Thomas, 1999). Reprocessing medical devices is a business for manufacturers, healthcare systems and third-party reprocessors. As with any business, financial gains must be weighed against financial costs.

The Ethical Aspects of Reprocessing

Despite all of the advancements in medicine there are specific aspects of medicine that transcend both time and technology. These aspects include the informed consent of patients, physician and provider liability, and providing the best care to each patient.

Informed consent is emphasized and prioritized in all aspects of clinical medicine. The emphasis on informed consent should therefore remain in regards to using reprocessed devices. However, are patients being informed that the devices being used during their procedures are reprocessed devices? According to Shuman and Chenoweth (2012), it is uncommon to inform patients that reprocessed devices may be used during their procedure. Patients should not only be informed of the devices being reprocessed but they should also have the choice between reprocessed devices and new medical devices.

Another aspect of informed consent that must also be considered is, if the contamination process was in any way altered or broken: should the patients be informed? Very few failures of the sterilization process have resulted in patients being informed of such breaks in protocol. The patients are not notified of these breaks in sterilization because the hospital finds the risks of infection due to the break in sterilization negligible (Hall, 2007). Overall, informed consent has always been a vital part of medicine. Informed consent should not stop for processes that are deemed as “negligible” by individuals other than the patient.

Another ethical aspect of reprocessing of medical devices includes the intent of the original device. As stated previously, single-use-devices are medical devices that are manufactured, designed, and distributed labeled and expected to be used one time (Jacobs et al., 2008). Reprocessing a SUD is using a device that is contrary to the original manufacturer's label (R. C. Lee et al., 2007). Examining the medical device's original manufactured purpose presents another ethical aspect of the reprocessing of medical devices.

Physicians and other medical providers have a unique ethical aspect that they must consider with the reprocessing of medical devices. Providers must consider their liability by choosing to use reprocessed medical devices. By using reprocessed devices, especially those that are labeled as single-use-devices, are making themselves liable legally. The liability of physicians and providers include those of malpractice, vicarious liability or failure to obtain informed consent (Rutala et al., 2008). The provider may be held liable in the situation if a patient was harmed or affected by using a reprocessed medical device. The healthcare provider may be held liable for failure to disclose the use of a reprocessed device or a known failure in the sterilization process for that device. Similarly, the single-use only label may be called into question legally; the use of reprocessed devices that aren't manufactured for reuse and without informed consent, can exemplify that the physician or provider violated the standards set forth of medical practice (Rutala et al.).

Within medicine, diminishing medical waste and diminishing the cost of medical waste is a large focus. With single-use-devices, after they are used once, and not reprocessed, it is important to properly and safely dispose of these devices. When medical devices are used only once, there is a large amount of medical waste which translates into additional costs and more importantly, public health concerns due to the disposal of these devices. When examining the

ethical aspect of reprocessing medical devices in regards to medical waste, using multiple-use devices should be implemented instead of single-use devices (R. C. Lee et al., 2007).

Situations that cause people to question whether it is right or wrong must always be discussed and researched extensively. The reprocessing of medical devices is no different. The lives and health of patients are affected by reprocessing of devices. Similarly, the practice and careers of many providers are affected by reprocessing of medical devices. Whether it is the patient, provider or hospital system, it is important for all parties to be informed.

Infections and Reprocessing

There are documented infections which resulted from transmission from multiple-use medical devices. The risk of such infections has been estimated and recorded as low. However, it is impossible to determine the number of transmitted infections because of limitations in the availability of studies (R. C. Lee et al., 2007). The number of recorded breaks in sterilization and reprocessing protocol are few. Additionally, the number of informed patients due to breaks in protocol and possible contamination is even lower (Hall, 2007). As stated previously, patients are often not informed of breaks in protocol because the risk seen to the patient is viewed as negligible. Despite the few number of reported infections, according to Wocher (2014), it is important to note that the risk for reprocessing devices is always greater than zero.

There are many infections that can be caused by the failure of reprocessing. In the United States, there was an outbreak of *C. perfrigens* due to surgical wound infection (Eickhoff, 1962). Similarly, one dialysis center was attributed with 15 deaths due to ineffective reprocessing of the hemodialyzers. The deaths were attributed to overdilution of chemicals that were used to sterilize the hemodialyzers (“Hazards in Reuse,” 1986). Not only are infections caused by the failure of

reprocessing, but they can also result when reprocessing was followed correctly. There are multi-drug resistant organisms, such as Carbapenem-resistant *Enterobacteriaceae*, that were reported throughout the United States even when the guidelines were followed (Nania, 2015).

Not only are infections caused by bacteria that withstand or elude the process of sterilization, but there are other impacts from the sterilization and reprocessing system itself. The chemicals used for reprocessing have a toxicity associated with them. These chemicals can leave residue on the devices that could cause adverse events with the patient that is exposed to the residue (R. C. Lee et al., 2007). Wash water has shown to be a problem to not only the patients but to the staff as well. There have been pyrogenic reactions to wash water, which is known to be a source of endotoxins (R. C. Lee et al.). Although the adverse events associated with reprocessing are few in record, there are not sufficient studies to examine the extent of infections caused by the system of reprocessing medical devices.

The Reprocessing of Endoscopes

Endoscopes are readily used worldwide. They are effective tools for the detection, diagnosis and treatment of many diseases, some of which are fatal, and have become a vital part in health maintenance. However, there have been more outbreaks in the healthcare setting due to contaminated endoscopes than any other medical device on record (Rutala et al., 2008). Each endoscope is typically reprocessed and reused for 5-10 years (D. H. Lee et al., 2015). The shelf-life for endoscopes is unknown. Not only is there little research about the shelf-life, but the research that does exist has differing recommendations on the shelf-life. The Association of Perioperative Registered Nurses states that the shelf-life for endoscopes is five days. Other research, however, states that endoscopes have a shelf-life of 21 days (Choi & Cho, 2015).

There are current guidelines and standards when it comes to reprocessing endoscopes. However, many sites that independently reprocess their endoscopes divulge from the guidelines (Choi & Cho, 2015). Many audits have shown that hospital employees do not adhere to guidelines consistently (Rutala et al., 2008). Automated endoscope reprocessors (AERs) are used during the reprocessing of endoscopes. The AERs are combined with manual handling. The manual cleaning is a critical step of the reprocessing and is a vulnerable part of the process due to human error. Possible errors in the manual portion of reprocessing include failure to clean channels, lack of education about the endoscopes or the process, failing to assess blocked or leaking channels and not flushing the endoscope adequately. These errors may lead to inadequate sterilization (Choi & Cho).

Endoscopes enter body cavities that contain a high amount of bioburden. Due to the high amount of bioburden that each endoscope encounters with each use, these medical devices are categorized as high risk devices (Rutala et al., 2008). In areas of high bioburden, endoscopes also encounter blood, body fluids and other infectious material (Choi & Cho, 2015).

Due to their purpose, endoscopes have a complex design. Endoscopes contain many channels, including a suction channel. They also contain water bottles, connectors and vacuum canisters. This complex design poses challenges to adequate and effective sterilization (Rutala et al., 2008). The highest levels of bacteria in the endoscope have been found in the suction channels. Endoscopes are subjected to high-level disinfection which is expected to destroy all microorganisms. However, with the high number of microorganisms that are present after each use of endoscopes, bacterial spores can survive (Rutala et al.). Due to the design of the endoscopes and the process of disinfection and sterilization, there are physical and chemical affects that are visible on the surface of the endoscope throughout the life of the endoscope (D.

H. Lee et al., 2015). Higher patient-to-patient contamination rates for reprocessed endoscopes are a result of multiple factors. The increased risk of infection is a result of the design of the endoscope, the design of the AER, human error, delay in reprocessing and failure to correctly select proper disinfectants and sterilants (Choi & Cho, 2015).

There is limited research in regards to replacements of the many parts of endoscopes. Proper replacement for water bottles, suction tubes and vacuum canisters is unknown due to the limited research. Currently, the proper replacement protocol is immediate replacement of each piece of the endoscope system (Choi & Cho, 2015). If reprocessing is delayed, this increases the risk for transmission of bacteria between patients. Delayed reprocessing allows the endoscopes to sit idle continue contamination before reprocessing (Choi & Cho).

Even with the high number of reported infection from endoscopes, it has been stated that there are many more infections from contaminated endoscopes than previously thought. It was reported that as many as 350 patients from 41 different medical facilities have been exposed between January 1, 2010 and October 31, 2015 (Perrone, 2016). There have been outbreaks of carbepenem-resistant *Enterobacteriaceae* (CRE) in patients who had an endoscopic retrograde cholangiopancreatography (ERCP) in the United States (Choi & Cho, 2015). The recent rise in infections being attributed to contaminated endoscopes has caused not only an increase in research but also has caused the federal government to address the possible contamination associated with reprocessing.

Discussion

Medical devices have evolved right alongside advancements in medicine and have become an intricate part of the healthcare field. They allow prevention, detection, diagnosis, and treatment of a variety of medical issues. They are used in every aspect of clinical medicine from the emergency room, in the surgery suite, to the outpatient clinic. The diverse use of medical devices has created multiple issues financially, increasing the amount of medical waste, as well as impacting the health of the patients that the medical devices are used on. The reprocessing system has become an intricate part of the realm of medical devices.

Due to the rapid pace medical devices have advanced, regulating medical devices has posed a complex issue for the federal government throughout their evolution. Reprocessing medical devices has advanced ahead of the governing bodies. The regulation of reprocessing has lagged behind, often seemingly responding to the system of reprocessing instead of anticipating what is to come. Most recently, the FDA has responded to the evidence that is showing that there are many more infections as a result of contaminated medical devices, specifically endoscopes, than previously thought. This new information has forced the FDA to publish a draft guidance for emerging signals. In other words, a draft that is addressing the need to tell the public of possible adverse events as a result of medical devices, before these adverse events occur.

The ability to anticipate adverse events as a result of reprocessed medical devices is difficult. This difficulty results in part from the lack of research that is available about infections or adverse events resulting from the use of reprocessed medical devices. There are few long-term studies including large numbers of patients. Similarly, limited data is also a result of the difficulty attributing adverse events to the reprocessed devices (Shuman & Chenoweth, 2012). Adverse events need to be reported in order to contribute to any data. Relying on voluntary

reporting makes it difficult to get proper data. In addition, very few reports of reprocessing errors that go on to cause infections or death are reported in the scientific community and journals. For example, out of a number of infections that were caused by contaminated endoscopes, only one of these was published in a peer-reviewed journal. The rest of the publications were seen in media reports and other sources, making it difficult not only to identify the true numbers but also making the access to the data difficult for the scientific community (Dirlam Langlay et al., 2013).

The healthcare community is driven by science, data, financial affordability and safety of patients. Medical devices, and the advancement that continues to occur, benefit the healthcare world as a whole. However, the data to back up the safety of reprocessing of medical devices is not currently at the level of standard to which most medical evidence is held.

In healthcare, the phrase practicing medicine is often used. In order to practice medicine, healthcare providers look to research to know which medications, treatments, surgeries, and lifestyle modifications are backed by the evidence. Practicing evidence-based medicine provides patients with the most effective healthcare. Evidence-based medicine is also a way for providers to defend themselves legally. In order to use reprocessed medical devices under the realm evidence based medicine, it is vital to collect data that will allow the healthcare community to confidently and effectively use medical devices.

Conclusion

The purpose of this literature review was to examine the safety of reprocessed medical devices to determine if using reprocessed medical devices is practicing under the realm of evidence based medicine. After reviewing the literature available, in my opinion, there is not enough research to qualify using reprocessed medical devices as evidenced based medicine. There is an insignificant amount of data available to prove the infallibility of reprocessing devices. As a physician assistant, this is vital to our practice. Reprocessed medical devices are used daily. As a provider, it is expected to uphold patient safety, informed consent and non-maleficence. In my opinion, without further research backed evidence, we are unable to do that while using reprocessed medical devices.

Appendix: List of Single-Use Devices Known to Be Reprocessed or Considered for Reprocessing

Risk categorization:
1= low risk
2=moderate risk
3= high risk
3*=high risk due to neurological use

	Medical Specialty	Device Type	Regulation Number	Class	Product Code	Risk	Critical/ Semicritical/ Noncritical	Pre-market Exempt
1	Cardio	Cardiopulmonary Bypass Marker	Unclassified		MAB	1	C	N
2	Cardio	Percutaneous & Operative Transluminal Coronary Angioplasty Catheter (PTCA)	Post-Amendment	3	LOX	3	C	N
3	Cardio	Percutaneous Ablation Electrode	Post-Amendment	3	LPB	3	C	N
4	Cardio	Peripheral Transluminal Angioplasty (PTA) Catheter	870.1250	2	LIT	3	C	N
5	Cardio	Blood-Pressure Cuff	870.1120	2	DXQ	1	N	N
6	Cardio	Angiography Catheter	870.1200	2	DQO	3	C	N
7	Cardio	Electrode Recording Catheter	870.1220	2	DRF	3	C	N
8	Cardio	High Density Array Catheter	870.1220	2	MTD	3	C	N
9	Cardio	Fibeoptic Oximeter Catheter	870.1230	2	DQE	3	C	N
10	Cardio	Steerable Catheter	870.1280	2	DRA	3	C	N
11	Cardio	Steerable Catheter Control System	870.1290	2	DXX	3	C	N
12	Cardio	Guide Wire	870.1330	2	DQX	3	C	N
13	Cardio	Angiographic Needle	870.1390	2	DRC	3	C	N
14	Cardio	Trocar	870.1390	2	DRC	3	C	N
15	Cardio	Syringes	870.1650	2	DXT	3	C	N
16	Cardio	Injector Type Syringe Actuator	870.1670	2	DQF	3	C	N
17	Cardio	Oximeter	870.2700	2	DQA	3	N	N
18	Cardio	Tissue Saturation Oximeter	870.2700	2	MUD	3	C	N
19	Cardio	Intra-Aortic Balloon System	870.3535	3	DSP	3	C	N
20	Cardio	Vascular Clamp	870.4450	2	DXC	3	C	N
21	Cardio	Heart Stabilizer	870.4500	1	MWS	2	C	Y
22	Cardio	Noncompression Heart Stabilizer	870.4500	1	MWS	3	C	Y
23	Cardio	External Vein Stripper	870.4885	2	DWQ	3	C	N
24	Cardio	Compressible Limb Sleeve	870.5800	2	JOW	1	N	N
25	Dental	Bur	872.3240	1	EJL	1	C	Y
26	Dental	Diamond Coated Bur	872.3240	1	EJL	3	C	Y
27	Dental	Diamond Instrument	872.4535	1	DZP	3	C	Y
28	Dental	AC-Powered Bone Saw	872.4120	2	DZH	2	C	N

	Medical Specialty	Device Type	Regulation Number	Class	Product Code	Risk	Critical/ Semicritical/ Noncritical	Pre-market Exempt
29	Dental	Manual Bone Drill and Wire Driver	872.4120	2	DZJ	2	C	N
30	Dental	Powered Bone Drill	872.4120	2	DZI	2	C	N
31	Dental	Intraoral Drill	872.4130	1	DZA	1	C	Y
32	Dental	Injection Needle	872.4730	1	DZM	3	C	Y
33	Dental	Metal Orthodontic Bracket	872.5410	1	EJF	3	S	Y
34	Dental	Plastic Orthodontic Bracket	872.5470	2	DYW	3	S	N
35	ENT	Bur	874.4140	1	EQJ	1	C	Y
36	ENT	Diamond Coated Bur	874.4140	1	EQJ	3	C	Y
37	ENT	Microdebrider	874.4140	1	EQJ	3	C	Y
38	ENT	Microsurgical Argon Fiber Optic Laser Cable, For Uses Other Than Otology, Including Laryngology & General Use In Otolaryngology	874.4490	2	LMS	1	S	N
39	ENT	Microsurgical Argon Fiber Optic Laser Cable, For Use In Otology	874.4490	2	LXR	1	S	N
40	ENT	Microsurgical Carbon-Dioxide Fiber Optic Laser Cable	874.4500	2	EWG	1	S	N
41	ENT	Bronchoscope Biopsy Forceps (Nonrigid)	874.4680	2	BWH	3	C	N
42	ENT	Bronchoscope Biopsy Forceps (Rigid)	874.4680	2	JEK	1	C	N
43	Gastro/ Urology	Biopsy Forceps Cover	876.1075	1	FFF	1	C	Y
44	Gastro/ Urology	Biopsy Instrument	876.1075	2	KNW	3	C	N
45	Gastro/ Urology	Biopsy Needle Set	876.1075	2	FCG	3	C	N
46	Gastro/ Urology	Biopsy Punch	876.1075	2	FCI	2	C	N
47	Gastro/ Urology	Mechanical Biopsy Instrument	876.1075	2	FCF	2	C	N
48	Gastro/ Urology	Nonelectric Biopsy Forceps	876.1075	1	FCL	3	C	Y
49	Gastro/ Urology	Cytology Brush For Endoscope	876.1500	2	FDX	2	S	N
50	Gastro/ Urology	Endoscope Accessories	876.1500	2	KOG	2	S	N
51	Gastro/ Urology	Extraction Balloons/Baskets	876.1500	2	KOG	2	S	N
52	Gastro/ Urology	Endoscopic Needle	876.1500	2	FBK	3	C	N
53	Gasro /Urology	Simple Pneumoperitoneum Needle	876.1500	2	FHP	3	C	N
54	Gastro /Urology	Spring Loaded Pneumoperitoneum Needle	876.1500	2	FHO	3	C	N
55	Gastro/ Urology	Active Electrosurgical Electrode	876.4300	2	FAS	3	S	N
56	Gastro/ Urology	Biliary Sphincterotomes	876.5010, 876.1500	2	FGE	3	C	N

	Medical Specialty	Device Type	Regulation Number	Class	Product Code	Risk	Critical/ Semicritical/ Noncritical	Pre-market Exempt
57	Gastro/ Urology	Electric Biopsy Forceps	876.4300	2	KGE	3	C	N
58	Gastro/ Urology	Electrosurgical Endoscopic Unit (with or without accessories)	876.4300	2	KNS	3	S	N
59	Gastro/ Urology	Flexible Snare	876.4300	2	FDI	3	S	N
60	Gastro/ Urology	Flexible Suction Coagulator Electrode	876.4300	2	FEH	3	S	N
61	Gastro/ Urology	Flexible Stone Dislodger	876.4680	2	FGO	3	S	Y
62	Gastro/ Urology	Metal Stone Dislodger	876.4680	2	FFL	3	S	Y
63	Gastro/ Urology	Needle Holder	876.4730	1	FHQ	1	C	Y
64	Gastro/ Urology	Nonelectrical Snare	876.4730	1	FGX	1	S	Y
65	Gastro/ Urology	Urological Catheter	876.5130	2	KOD	2	S	N
66	Gastro/ Urology	Single Needle Dialysiss Set	876.5540	2	LBW, FIE	3	C	N
67	Gastro /Urology	Hemodialysis Blood Circuit Accessories	876.5820	2	KOC	2	S	N
68	Gastro/ Urology	Single Needle Dialysis Set	876.5820	2	FIF	3	C	N
69	Gastro/ Urology	Hemorrhoidal Ligator	876.4400	2	FHN	2	C	N
70	General Hospital	Implanted Programmable Infusion Pump	Post Amendment	3	LKK	3	C	N
71	General Hospital	Needle Destruction Device	Post Amendment	3	MTV	1	N	N
72	General Hospital	Nonpowered Flotation Therapy Mattress	880.5150	1	IKY	2	N	Y
73	General Hospital	NonAC-Powered Patient Lift	880.5510	1	FSA	2	N	Y
74	General Hospital	Alternating Pressure Air Flotation Mattress	880.5550	2	FNM	1	N	Y
75	General Hospital	Temperature Regulated Water Mattress	880.5560	1	FOH	2	N	Y
76	General Hospital	Hypodermic Single Lumen Needle	880.5570	2	FMI	3	C	N
77	General Hospital	Piston Syringe	880.5860	2	FMF	3	C	N
78	General Hospital	Mattress Cover (Medical Purposes)	880.6190	1	FMW	2	N	Y
79	General Hospital	Disposable Medical Scissors	880.6820	1	JOK	1	N	Y
80	General Hospital	Irrigating Syringe	880.6960	1	KYZ, KYY	1	C	Y
81	Infection Control	Surgical Gowns	878.4040	2	FYA	1	C	N
82	Lab	Blood Lancet	878.4800	1	FMK	1	C	Y
83	Neurology	Clip Forming/Cutting Instrument	882.4190	1	HBS	3*	C	Y
84	Neurology	Drills, Burrs, Trephines & Accessories (Manual)	882.4300	2	HBG	3*	C	N

	Medical Specialty	Device Type	Regulation Number	Class	Product Code	Risk	Critical/ Semicritical/ Noncritical	Pre-market Exempt
85	Neurology	Drills, Burrs, Trephines & Accessories (Compound, Powered)	882.4305	2	HBF	3*	C	N
86	Neurology	Drills, Burrs, Trephines & Accessories (Simple, Powered)	882.4310	2	HBE	3*	C	N
87	OB/GYN	Oocyte Aspiration Needle		3	MHK	3	C	N
88	OB/GYN	Laparoscope Accessories	884.1720	1	HET	2	C	Y
89	OB/GYN	Laparoscope Accessories	884.1720	2	HET	3	C	N
90	OB/GYN	Laparoscopic Dissectors	884.1720	1	HET	2	C	Y
91	OB/GYN	Laparoscopic Graspers	884.1720	1	HET	2	C	Y
92	OB/GYN	Laparoscopic Scissors	884.1720	1	HET	2	C	Y
93	OB/GYN	Insufflator Accessories (Tubing, Verres Needle, Kits)	884.1730	2	HIF	3	C	Y
94	OB/GYN	Laparoscopic Insufflator	884.1730	2	HIF	2	N	N
95	OB/GYN	Endoscopic Electrocautery and Accessories	884.4100	2	HIM	2	N	N
96	OB/GYN	Gynecologic Electrocautery (and Accessories)	884.4120	2	HGI	2	N	N
97	OB/GYN	Endoscopic Bipolar Coagulator-Cutter (and Accessories)	884.4150	2	HIN	2	N	N
98	OB/GYN	Culdoscopic Coagulator (and Accessories)	884.4160	2	HFI	2	N	N
99	OB/GYN	Endoscopic Unipolar Coagulator-Cutter (and Accessories)	884.4160	2	KNF	2	N	N
100	OB/GYN	Hysteroscopic Coagulator (and Accessories)	884.4160	2	HFH	2	N	N
101	OB/GYN	Unipolar Laparoscopic Coagulator (and Accessories)	884.4160	2	HFG	2	N	N
102	OB/GYN	Episiotomy Scissors	884.4520	1	HDK	1	C	Y
103	OB/GYN	Umbilical Scissors	884.4520	1	HDJ	1	C	Y
104	OB/GYN	Biopsy Forceps	884.4530	1	HFB	3	C	Y
105	OB/GYN	Assisted Reproduction Needle	884.6100	2	MQE	3	C	N
106	Ophthalmic	Endoilluminator	876.1500	2	MPA	3*	C	N
107	Ophthalmic	Surgical Drapes	878.4370	2	KKX	2	C	N
108	Ophthalmic	Ophthalmic Knife	886.4350	1	HNN	3	C	Y
109	Ophthalmic	Keratome Blade	886.4370	1	HMY, HNO	3	C	N
110	Ophthalmic	Phacoemulsification Needle	886.4670	2	HQC	3	C	N
111	Ophthalmic	Phacoemulsification/ Phacofragmentation Fluidic	886.4670	2	MUS	2	C	N
112	Ophthalmic	Phacofragmentation Unit	886.4670	2	HQC	1	N	N
113	Orthopedic	Saw Blades	878.4820	1	GFA, DWH, GEY, GET	1	C	Y
114	Orthopedic	Surgical Drills	878.4820	1	GEY, GET	1	C	Y
115	Orthopedic	Arthroscope Accessories	888.1100	2	HRX	2	C	Y
116	Orthopedic	Bone Tap	888.4540	1	HWX	1	C	Y

	Medical Specialty	Device Type	Regulation Number	Class	Product Code	Risk	Critical/ Semicritical/ Noncritical	Pre-market Exempt
117	Orthopedic	Burr	888.4540	1	HTT	1	C	Y
118	Orthopedic	Carpal Tunnel Blade	888.4540	1	LXH	2	C	Y
119	Orthopedic	Countersink	888.4540	1	HWW	1	C	Y
120	Orthopedic	Drill Bit	888.4540	1	HTW	1	C	Y
121	Orthopedic	Knife	888.4540	1	HTS	1	C	Y
122	Orthopedic	Manual Surgical Instrument	888.4540	1	LXH	1	C	Y
123	Orthopedic	Needle Holder	888.4540	1	HXK	1	C	Y
124	Orthopedic	Reamer	888.4540	1	HTO	1	C	Y
125	Orthopedic	Rongeur	888.4540	1	HTX	1	C	Y
126	Orthopedic	Scissors	888.4540	1	HRR	1	C	Y
127	Orthopedic	Staple Driver	888.4540	1	HXJ	1	C	Y
128	Orthopedic	Trephine	888.4540	1	HWK	1	C	Y
129	Orthopedic	Flexible Reamers/Drills	886.4070/ 878.4820	1	GEY, HRG	1	C	Y
130	Orthopedic	External Fixation Frame	888.3040/ 888.3030	2	JEC, KTW, KTT	2	N	N
131	Physical Medicine	Nonheating Lamp for Adjunctive Use Inpatient Therapy	890.5500	2	NHN	1	N	N
132	Physical Medicine	Electrode Cable	890.1175	2	IKD	1	N	Y
133	Physical Medicine	External Limb Component, Hip Joint	890.3420	1	ISL	2	N	Y
134	Physical Medicine	External Limb Component, Knee Joint	890.3420	1	ISY	2	N	Y
135	Physical Medicine	External Limb Component, Mechanical Wrist	890.3420	1	ISZ	2	N	Y
136	Physical Medicine	External Limb Component, Shoulder Joint	890.3420	1	IQQ	2	N	Y
137	Plastic Surgery	Stapler	878.4800	1	GAG, GEF, FHM, HBT	2	C	Y
138	Radiology	Isotope Needle	892.5730	2	IWF	3	C	N
139	Respiratory	Endotracheal Tube Changer	Unclassified	3	LNZ	3	C	N
140	Respiratory	Anesthesia Conduction Needle	868.5150	2	BSP	3	C	N
141	Respiratory	Short Term Spinal Needle	868.5150	2	MIA	3	C	N
142	Respiratory	Respiratory Therapy and Anesthesia Breathing Circuits	868.5240	1	CAI	2	S	Y
143	Respiratory	Oral and Nasal Catheters	868.5350	1	BZB	1	C	Y
144	Respiratory	Gas Masks	868.5550	1	BSJ	1	S	Y
145	Respiratory	Breathing Mouthpiece	868.5620	1	BYP	1	N	Y
146	Respiratory	Tracheal Tube	868.5730	2	BTR	3	C	N
147	Respiratory	Airway Connector	868.5810	1	BZA	2	S	Y
148	Respiratory	CPAP Mask	868.5905	2	BZD	3	S	N
149	Respiratory	Emergency Manual Resuscitator	868.5915	2	BTM	2	S	N
150	Respiratory	Tracheobronchial Suction Catheter	868.6810	1	BSY	3	S	Y

	Medical Specialty	Device Type	Regulation Number	Class	Product Code	Risk	Critical/ Semicritical/ Noncritical	Pre-market Exempt
151	Surgery	AC-Powered Orthopedic Instrument and Accessories	878.4820	1	HWE	2	C	N
152	Surgery	Breast Implant Mammary Sizer	Unclassified		MRD	1	C	N
153	Surgery	Ultrasonic Surgical Instrument	Unclassified		LFL	3	C	N
154	Surgery	Trocar	874.4420	1	KAB, KBG, KCI	3	C	Y
155	Surgery	Endoscopic Blades	876.1500	2	GCP, GCR	2	C	N
156	Surgery	Endoscopic Guidewires	876.1500	2	GCP, GCR	1	C	N
157	Surgery	Inflatable External Extremity Splint	878.3900	1	FZF	1	N	Y
158	Surgery	Noninflatable External Extremity Splint	878.3910	1	FYH	1	N	Y
159	Surgery	Catheter Needle	878.4200	1	GCB	3	C	Y
160	Surgery	Implantable Clip	878.4300	2	FZP	3	C	N
161	Surgery	Electrosurgical and Coagulation Unit with Accessories	878.4400	2	BWA	2	C	N
162	Surgery	Electrosurgical Apparatus	878.4400	2	HAM	2	C	N
163	Surgery	Electrosurgical Cutting & Coagulation Device & Accessories	878.4400	2	GEI, NUJ	2 3	C	N
164	Surgery	Electrosurgical Device	878.4400	2	DWG	2	C	N
165	Surgery	Electrosurgical Electrode	878.4400	2	JOS	2	C	N
166	Surgery	Implantable Staple, Clamp, Clip for Suturing Apparatus	878.4750	2	GDW	3	C	N
167	Surgery	Percutaneous Biopsy Device	878.4800	1	MJG	3	C	Y
168	Surgery	Gastro-Urology Needle	878.4800	1	FHR	3	C	Y
169	Surgery	Aspiration and Injection Needle	878.4800	1	GAA	3	C	Y
170	Surgery	Biopsy Brush	878.4800	1	GEE	1	C	Y
171	Surgery	Blood Lancet	878.4800	1	FMK	1	C	Y
172	Surgery	Bone Hook	878.4800	1	KIK	1	C	Y
173	Surgery	Cardiovascular Biopsy Needle	878.4800	1	DWO	3	C	Y
174	Surgery	Clamp	878.4800	1	GDJ	1	C	Y
175	Surgery	Clamp	878.4800	1	HXD	1	C	Y
176	Surgery	Curette	878.4800	1	HTF	1	C	Y
177	Surgery	Disposable Surgical Instrument	878.4800	1	KDC	1	C	Y
178	Surgery	Disposable Vein Stripper	878.4800	1	GAJ	1	C	Y
179	Surgery	Dissector	878.4800	1	GDI	1	C	Y
180	Surgery	Forceps	878.4800	1	GEN	2	C	Y
181	Surgery	Forceps	878.4800	1	HTD	2	C	Y
182	Surgery	Gouge	878.4800	1	GDH	1	C	Y
183	Surgery	Hemostatic Clip Applier	878.4800	1	HBT	2	C	Y
184	Surgery	Hook	878.4800	1	GDG	1	C	Y
185	Surgery	Manual Instrument	878.4800	1	MDM, MDW	1	C	Y
186	Surgery	Manual Retractor	878.4800	1	GZW	1	C	Y

	Medical Specialty	Device Type	Regulation Number	Class	Product Code	Risk	Critical/ Semicritical/ Noncritical	Pre-market Exempt
187	Surgery	Manual Saw and Accessories	878.4800	1	GDR, HAC	1	C	Y
188	Surgery	Manual Saw and Accessories	878.4800	1	HAC	1	C	Y
189	Surgery	Manual Surgical Chisel	878.4800	1	FZO	1	C	Y
190	Surgery	Mastoid Chisel	878.4800	1	JYD	1	C	Y
191	Surgery	Orthopedic Cutting Instrument	878.4800	1	HTZ	1	C	Y
192	Surgery	Orthopedic Spatula	878.4800	1	HXR	1	C	Y
193	Surgery	Osteotome	878.4800	1	HWM	1	C	Y
194	Surgery	Rasp	878.4800	1	GAC	1	C	Y
195	Surgery	Rasp	878.4800	1	HTR	1	C	Y
196	Surgery	Retractor	878.4800	1	GAD	1	C	Y
197	Surgery	Retractor	878.4800	1	HXM	1	C	Y
198	Surgery	Saw	878.4800	1	HSO	1	C	Y
199	Surgery	Scalpel Blade	878.4800	1	GES	1	C	Y
200	Surgery	Scalpel Handle	878.4800	1	GDZ	1	C	Y
201	Surgery	Scissors	878.4800	1	LRW	1	C	Y
202	Surgery	Snare	878.4800	1	GAE	1	C	Y
203	Surgery	Spatula	878.4800	1	GAF	1	C	Y
204	Surgery	Staple Applier	878.4800	1	GEF	2	C	Y
205	Surgery	Stapler	878.4800	1	GAG	2	C	Y
206	Surgery	Stomach and Intestinal Suturing Apparatus	878.4800	1	FHM	2	C	Y
207	Surgery	Surgical Curette	878.4800	1	FZS	1	C	Y
208	Surgery	Surgical Cutter	878.4800	1	FZT	1	C	Y
209	Surgery	Surgical Knife	878.4800	1	EMF	1	S	Y
210	Surgery	Laser Powered Instrument	878.4810	2	GEX	2	C	N
211	Surgery	AC-Powered Motor	878.4820	1	GEY	2	C	Y
212	Surgery	Bit	878.4820	1	GFG	1	C	Y
213	Surgery	Bur	878.4820	1	GFF, GEY	1	C	Y
214	Surgery	Cardiovascular Surgical Saw Blade	878.4820	1	DWH	1	C	Y
215	Surgery	Chisel (Osteotome)	878.4820	1	KDG	1	C	Y
216	Surgery	Dermatome	878.4820	1	GFD	1	C	Y
217	Surgery	Electrically Powered Saw	878.4820	1	DWI	2	C	Y
218	Surgery	Pneumatic Powered Motor	878.4820	1	GET	2	C	Y
219	Surgery	Pneumatically Powered Saw	878.4820	1	KFK	2	C	Y
220	Surgery	Powered Saw & Accessories	878.4820	1	HAB	2	C	Y
221	Surgery	Saw Blade	878.4820	1	GFA	1	C	Y
222	Surgery	Nonpneumatic Tourniquet	878.5900	1	GAX	1	N	Y
223	Surgery	Pneumatic Tourniquet	878.5910	1	KCY	1	N	Y
224	Surgery	Endoscopic Staplers	888.4540	1	HXJ	2	C	Y
225	Surgery	Trocar	876.1500/ 870.1390	2	GCJ, DRC	3	C	N
226	Surgery	Surgical Cutting Accessories	878.4800/ 874.4420	1	GDZ, GDX, GES, KBQ, KAS	2	C	Y
227	Surgery	Electrosurgical Electrodes/Handles/ Pencils	876.4300/ 878.4400	2	HAM, GEI, GAS	2	C	N

	Medical Specialty	Device Type	Regulation Number	Class	Product Code	Risk	Critical/ Semicritical/ Noncritical	Pre-market Exempt
228	Surgery	Scissor Tips	878.4800/ 884.4520/ 874.4420	1	LRW, HDK, HDJ, JZB, KBD	2	C	Y
229	Surgery	Laser Fiber Delivery Systems	878.4810/ 874.4500/ 886.4390/ 884.4550	2	GEX, EWG, LLW, HQF, HHR, HQB	1	C	N

Note. Reprinted from "List of Single-Use Devices Known to be Reprocessed or Considered for Reprocessing," by U. S. Food and Drug Administration, 2005 September 29, Federal Register, 70(188): 56911-56925. Retrieved from http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm121218.htm

Glossary

Bioburden: number and types of viable microorganisms with which an item is contaminated; also called bioload or microbial load

Biofilm: accumulated mass of bacteria and extracellular material that is tightly adhered to a surface and cannot be easily removed

Biologic Indicator: device for monitoring the sterilization process

Blind lumen: closed-end lumen

Cleaning: removal, usually with detergent and water or enzyme cleaner and water, of adherent visible soil, blood, protein substances, microorganisms and other debris from the surfaces, crevices, serrations, joints and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination

Critical Items: confer a high risk for infection if they are contaminated with any microorganism. Thus, objects that enter sterile tissue or the vascular system must be sterile because any microbial contamination could transmit disease.

Endoscope: an instrument that allows examination and treatment of the interior of the body canals and hollow organs

Noncritical Items: those that come in contact with intact skin but not mucous membranes

Semicritical items: contact mucous membranes or non-intact skin

Shelf-life: length of time a sterilized product is expected to remain sterile

Spaulding Scheme: nature of disinfection could be understood readily if instruments and items for patient care were categorized as critical, semicritical, and noncritical according to the degree of risk for infection involved in use of the items

Sterilization: describes the process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods.

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Abstract

Objective: This literature review explores the reprocessing of medical devices. This review includes the science of reprocessing, economic incentives along with ethical implications. Consequences of reprocessing medical devices are also examined.

Method: The search engines utilized include PubMed, Google Scholar, and the FDA Database. Search terms included reprocessing, single-use device, medical device, infections, economics, and endoscopes.

Results: Each medical device must be treated on an individual basis due to the device design, conditions it encounters and the specific steps taken during reprocessing. The reports of infections as a result of failures of reprocessing are low. There is great financial incentive to reprocessing medical devices.

Conclusion: The reprocessing of medical devices has become engrained within the healthcare system. Despite guidelines for reprocessing, decisions lie in the hands of the individual reprocessing. There is insufficient research today, due to lack of reporting, to uphold the infallibility of the reprocessing medical devices.