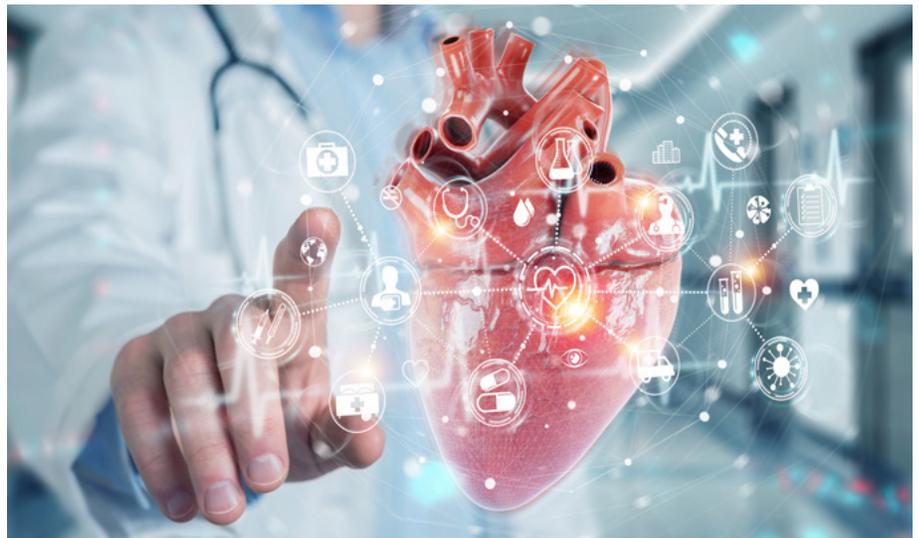


DESIGN AND MATERIALS CONSIDERATIONS AFFECTING REPROCESSING DURABILITY OF REUSABLE MEDICAL DEVICES



Introduction

Newer reprocessing technologies and higher rates of medical device use are resulting in significant changes to reprocessing practices. In light of these changes, manufacturers of reusable medical products that wish to remain competitive are advised to consider fresh approaches to design and the use of new materials to prevent premature product failure.

Design engineers, purchasing and sourcing analysts, quality managers, and other decision-makers at device manufacturing companies will need to create their reprocessing test plans accordingly, examining both the chemistries and the operating parameters of the reprocessing technologies and combining those with their knowledge of material science and the risks inherent to specific materials. In doing so, these individuals can draw up an optimized test plan for thoroughly evaluating any potential design issues induced by repeatedly processing a device.

Reprocessing 101

Processing a medical device for reuse must render it safe for use on the next patient and be nearly harmless to the device itself. Today's reprocessing technologies can be highly effective at making reusable devices sterile and safe for patients, but they can be harsh on the actual devices. Testing devices to determine their ability to withstand cleaning, disinfecting, and sterilizing is therefore of utmost importance, so test plans must be created thoughtfully.

How Reusable Medical Devices are Reprocessed

For some devices, including certain types of cable assemblies, reprocessing is relatively simple, involving a wipe-down between uses with such agents as detergent, disinfectant, bleach, alcohol, or glutaraldehyde. For more complex devices that are in contact with bodily fluids or compromised tissues, a two-step process is generally required: 1. Decontamination through washing with detergent (often enzymatic), followed by 2. Disinfection or sterilization.

For the first step, decontamination, the use of automated washers/disinfectors continues to gain popularity over manual washing. These systems employ enzymatic detergents of either neutral or high (caustic) pH and a very hot final rinse of up to 194 degrees Fahrenheit. The washed devices are dried before sterilization via a hot-air (up to 220-degrees-Fahrenheit) cycle. For the second step, disinfection/sterilization, both liquid- and gas-based processes are available. The former includes the use of such chemicals as quaternary-ammonium compounds, hydrogen-peroxide solutions, peracetic acid solutions, dialdehydes, phenols, and bleach solutions, and whether liquid-based processes disinfect or actually sterilize depends on the type of chemical used and its duration of contact with the device being reprocessed.

Devices requiring terminal sterilization (for which they remain sterile within their packaging during storage), such as those used in invasive surgical procedures, are now almost exclusively sterilized via gasbased processes, usually low-temperature hydrogen peroxide (H_2O_2) vapor or high-temperature autoclave/steam. (Historically, invasive surgical devices were either soaked in liquid glutaraldehyde or processed with ethylene oxide [EO] gas. The latter approach, in particular, has fallen out of favor due to its reputation as an environmentally unfriendly carcinogen and mutagen.)

Today's gas-based sterilization processes are much less toxic than their EO predecessor; however, they can be harder on materials because they rely on oxidation chemistry or high-temperature saturated steam. Cycle times run approximately 28 to 75 minutes, with 40-45-minute average cycles.



Fig.1. Mechanical stresses, like threaded mating components, can increase likelihood of cracking due to reprocessing.

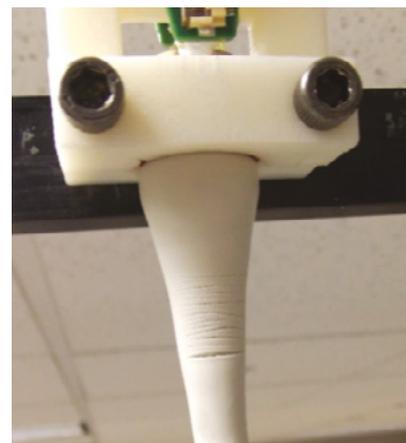


Fig.2. Cracking of a cable flex relief due to combination of cleaning + handling.



Fig.3. Blooming of Additives after repeated H_2O_2 Sterilization.

Sterilizing with Hydrogen Peroxide (H₂O₂) Vapor

Today, hydrogen peroxide vapor sterilizers, available from companies such as Advanced Sterilization Products, STERIS Corporation, and TSO3 Incorporated, are widely used for products requiring low temperature (<60°C) sterilization. When devices are sterilized with H₂O₂ vapor, the process runs as follows:

- Air is evacuated from the sterilizing chamber
- The H₂O₂ sterilant is introduced in vapor form. (Some processes also use plasma or ozone.)
- Multiple phases of pump-down injection of the sterilant occur, followed by venting and diffusion

For all H₂O₂-vapor sterilizers, cycle parameters are not programmable by the user; however, various cycles are available. For device compatibility (or durability) testing, the worst-case-scenario cycle is usually the longest.

Devices undergoing H₂O₂-vapor sterilization are exposed to multiple pressure gradients in each sterilization cycle. This method is an effective way of sterilizing, yet the pressure gradients, in combination with the strongly oxidizing H₂O₂ vapor, can present risks to device design and materials.

Sterilizing Via Autoclave/Steam

For high-temperature steam sterilizing, two main types of autoclaves exist. The first is gravity-displacement, in which steam is forced into the chamber from the top as air is pushed out the bottom. The second is pre-vacuum/dynamic air displacement, for which air is first pumped from the chamber prior to sterilizing. The latter type is more prevalent these days for sterilizing medical devices and is the type used by TE Connectivity's business unit TE Medical for its in-house testing.

The process for pre-vacuum autoclave sterilization is as follows:

- Air is evacuated from the chamber via pulses of steam and vacuum
- Sterilization begins. Duration and temperature are the key parameters for this phase, with a typical sterilization temperature being 135 degrees Celsius. (No heaters are present in the autoclave chamber. In this method of sterilization, temperature and pressure are not independent variables. Two atmospheres gage of steam pressure are effective in killing organisms but can drive steam into the device.)
- The chamber is evacuated via vacuum for the drying phase

In autoclave sterilization, the primary risks to the device materials and design are the pressure extremes and the high-temperature steam.



Fig.4. "Shar Pei" effect—stretching of cable jackets due to repeated manual cleaning

In contrast to the H₂O₂-vapor sterilization method, with autoclave sterilization the cycle parameters can be programmed by the user. (The ANSI/AAMI ST79 document, “Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities,” provides recommended cycle parameters for device manufacturers and hospitals.) TE Medical’s typical standard autoclave-sterilization times and temperatures, for instance, are 132 to 137 degrees Celsius for 4 minutes, based on ANSI/AAMI ST79, and 135 degrees Celsius for 18 minutes, per the 1999 World Health Organization recommendation for guarding against prion diseases. This second longer cycle is known as a TSE, BSE, or French cycle.

In Practice: Disinfection and Sterilization’s Effects on Device Design and Materials

Cleaning, disinfecting, and sterilizing reusable medical devices are, of course, crucial for maintaining patient safety within healthcare facilities. They can, however, take their toll on the devices themselves, resulting in discoloration, degradation, and even breakage. Fortunately, design and materials solutions exist for nearly every problem caused by cleaning and sterilization. Case studies highlighting a few common problems and solutions follow.

Liquid Solutions for Cleaning/Disinfecting

Problem: Detergent residue and build-up on wiped-down or soaked circular connectors are the result of an incomplete rinse and can lead to intermittent opens.

Solution: Use soak caps on connectors whenever they are cleaned; however, a better, longer-lasting solution is to design a planar connector rather than a circular one. A card edge featuring a printed circuit board can be cleaned with a wetted swab, thereby reducing the potential for residue and build-up.

Problem: Low-modulus (“bunching”) damage to silicone cable jackets, sometimes referred to as “the Shar-Pei effect,” results from repeated manual wipe-downs..

Solution: Design cables with reinforced silicone jackets to better withstand wiping. This design change can reduce the amount of stretching at a medium load by 10 to 15 times.

Problem: Discoloration of cables, which may seem like a trivial, cosmetic matter, can decrease patient confidence and increase patient anxiety in a clinical setting.

Solution: Consider an alternative resin for the cable, or simply choose a darker hue that won’t show the discoloration.

Loss of Additives in Polymers/Polyvinyl Chloride (PVC)

Problem: Alcohol-based cleaning agents and disinfectants, while quite effective at removing residues from devices and components, can also cause additives (such as plasticizers) to leach from PVC. This leaching can lead to cracking in cable jackets.

Solution: For PVC-based cable jackets, choose aqueous-based disinfectants and wipes. Additionally, designing cables with non-phthalate, high-molecular-weight plasticized resins will minimize leaching in both polar and non-polar solvents.

Problem: Low pressures encountered in gas-based sterilization processes can cause additives to bloom, or migrate to the surface of the polymer, particularly in PVC.

Solution: To mitigate additive blooming, consider choosing additives with lower vapor pressures. A higher molecular weight additive, for instance, could substantially reduce blooming. Alternately, select a polymer with fewer additives.

Absorption of H₂O₂ Vapor and Gas Permeability

Problem: Thermoplastic urethane (TPU) resins are hygroscopic and can absorb both water vapor and H₂O₂ vapor during sterilization, and they vary considerably in their levels of heat and chemical resistance.

Solution: Consider the heat and chemical resistance of TPU resins to mitigate the effects of automatic-washing and sterilization processes. The overall design of the cable assembly can also dramatically minimize TPU swelling and cracking.

Alternative resins have better heat and chemical resistance than TPU but lack some of its abrasion and cut resistance.

Design and Materials Considerations Affecting Reprocessing Durability of Reusable Medical Devices

Problem: Steam permeation of silicone in the autoclave can lead to leakage current at high voltages and condensation on optics, switches, and other components.

Solution: The drying phase of the sterilization cycle will help remove steam to minimize condensation that can compromise the device, but the device should still be designed with an eye toward preventing steam permeation.

Effects of Reprocessing on Metals and Rigid Plastics

Problem: Anodized metal components can discolor (or lose their anodization altogether) during reprocessing.

Solution: Adjust and test production anodization processes until they result in anodization that holds up during sterilization, with minimal discoloring. Processes that can withstand fading during H_2O_2 sterilization may not withstand autowash processes that use high-pH detergents.

Problem: Cracking of rigid plastic parts can result from residual stresses from the molding process, and the use of o-rings and screw threads can apply stresses to a part when those elements are mated with other components in the design.

Solution: Include those stresses in testing. For high-temperature (autoclave) sterilization, consider differentials in thermal coefficient of expansion between plastic and metal as well as the different rates at which they heat and cool.

Considerations for Effective Test-Plan Design

When designing a reprocessing-test plan, three key factors must be considered:

- Test samples must be sealed the same way the finished devices would be. Ignoring pressure differentials in gasbased sterilization processes can lead to unhappy surprises; in particular, the effects of the pressure fluctuations will not be included in the test—so test samples might pass, while actual assemblies will fail.
- All stresses must be represented in test samples: threaded components must be mated, o-rings must be sealed to mating surfaces, etc.
- Typical material failure mechanisms must be known and addressed. For example, additive losses in resins and softening of thermoplastics at high temperatures must be considered.

Reducing Qualification Test Times

Based on the risks identified in the test plan, and with customer approval, strategies can be employed to reduce test times.

Autoclave. For faster autoclave cycling, samples will not be wrapped in a pouch or Central Supply Room (CSR) wrap as is done in the clinical setting; instead, samples will be set directly on the rack. By doing so, air-evacuation and drying times are reduced.

Some test facilities use autoclaves with custom programming capabilities that allow around-the-clock, 24/7 cycling without operator intervention.

Trade-offs of these test strategies must always be discussed with customers before a final test plan is approved and include such risks as gas permeability leading to moisture accumulation and electrical issues. These risks can be mitigated by employing certain strategies, and, with these strategies in place, a 500-cycle autoclave test can be completed in about two weeks.

H_2O_2 Vapor. Reducing test times for H_2O_2 -vapor sterilization is a bit more complicated and offers less leeway. For instance, samples must be wrapped in a pouch or CSR wrap, and the number of samples in each load must be limited based on surface area. Additionally, H_2O_2 -vapor sterilizers will not auto-start the next cycle, and some test protocols call for samples to be removed from the chamber between cycles. A 500-cycle H_2O_2 -vapor test can be completed in 6 weeks when the test lab is staffed across multiple shifts.

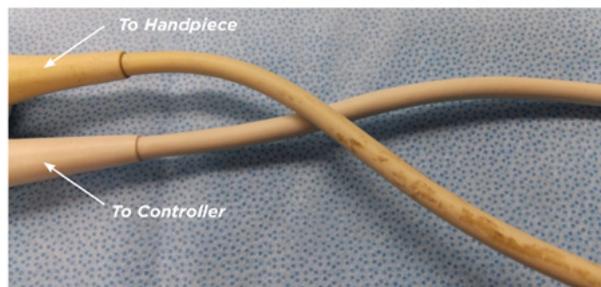


Fig.5. Cleaning/disinfection can lead to discoloration

Addressing Reprocessing Interactions in Test Plans

An approach being used with greater frequency is to design reprocessing test plans that can capture potential interactions between decontamination and sterilization processes and handling of a medical device. One method of achieving this, for example, is to run test iterations comprising 20 consecutive wash cycles followed by 20 consecutive sterilization cycles, followed by 10 to 15 hours of mechanical manipulation—typically flex cycling for cable assemblies. Then, the next iteration of the 20 washes, 20 sterilization cycles, and 10 to 15 hours of handling is undertaken, and this process is repeated until the total number of cycles specified in the test plan is reached. With this very thorough approach, about 16 weeks' time is required to complete a test consisting of 500 wash cycles, 500 sterilization cycles, and 350 hours of simulated handling. The lab must be staffed across multiple shifts, plenty of test technicians must be involved, and up-to-date service contractors need to be in place for the reprocessors. Sometimes previous test results can be leveraged in order to mitigate the long time required for this particular type of test. (As long as no confidentiality agreements are violated, the company can perform extensive internal evaluation of materials and design as part of its own qualification, and this data may be able to be shared with customers.)

Summary: Knowledge and Understanding Breed Better Testing

An understanding of sterilization and cleaning processes, failure mechanisms of materials, and designs and materials previously tested makes it possible to optimize reprocessing test plans. This optimization empowers test teams to subsequently identify possible interactions or design issues for any reusable medical device.

Parsing the Terminology: Cleaning, Disinfecting, and Sterilizing

To **clean** a medical device means to remove all visible soil from it.

To **disinfect** a medical device means to kill most of the organisms present on it, with the exception of some bacterial spores.

To **sterilize** a medical device means to kill all forms of microbial life present on the device. A Sterility Assurance Level (SAL) of 10^{-6} is frequently used for the terminal sterilization of medical devices (probability of 1 in 1,000,000 of finding a non-sterile unit).

These three terms are not interchangeable.

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med-device-sterilization-wp-en 04/23

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