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KEEP OR TOSS? LIMITED-USE SOLUTIONS FOR THE MEDICAL FIELD

CONTENT

ABSTRACT

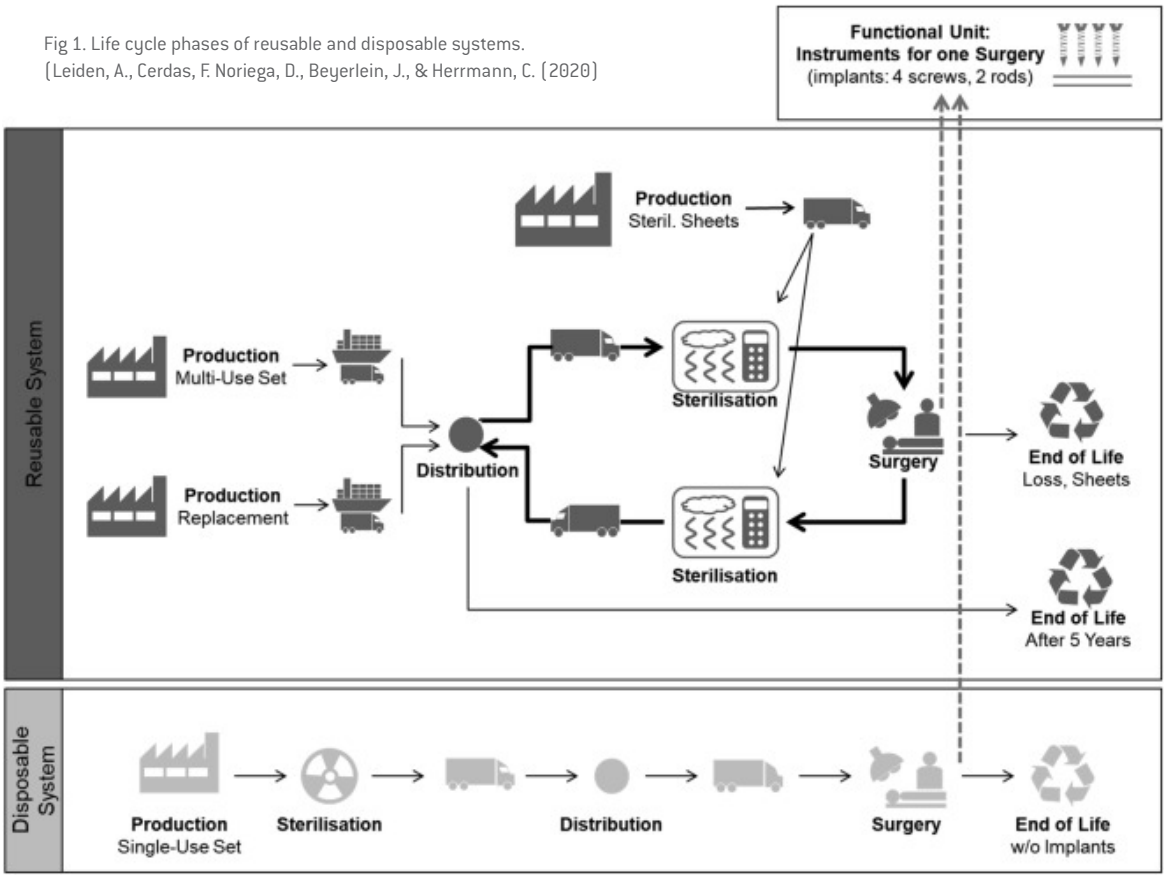
In modern surgical suites, the basic patient parameters are tracked and recorded including; heart rate (HR) or ECG parameter, blood pressure, SpO2 saturation for oxygen levels, respiration rate, SpO2 parameters, and temperature parameters. Cables and connectors associated with these devices or within the patient vicinity, must be either disposed of or sterilized after use. Initially, it may appear that single-use, disposable assemblies offer the better solution because they pose no contamination risk and have lower up-front costs. Compare to the costs of processing reusable equipment including labor, time, cost of operating room time, and sterilization supplies and equipment. There are certainly some applications in which true single-use cables and connectors are appropriate. However, some single use connectors can be low quality, unreliable, environmentally unfriendly or poorly designed for operation and reprocessing. Fortunately, ODU has developed high-quality connectors with up to 5,000 mating cycles and can be sterilized up to 200 times. In order to further drive out costs, the product can be fully assembled by ODU. Combining the best attributes of lower initial cost, but designed with the advantages to be used in either single use, high reliability applications or sterilized for repeated usage, all within reasonable price points.

ENVIRONMENTAL CONCERNS

Recent studies showed that surgical instruments are, beside the HVAC system, the main driver in the environmental impact of surgical procedures and account for up to 65 % of the GWP (Global Warming Potential) (Leiden, A., Cerdas, F., Noriega, D., Beyerlein, J., & Herrmann, C. ,2020). Therefore, selection of surgical instruments and implants with minimal environmental impact might contribute to the reduction of the environmental impact of the whole healthcare system.

Various studies have supported or refuted the advantages of disposable instead of re-usable with a variety of factors, including the sterilization techniques, equipment processed, transportation, and other various factors. However, while it is mostly beyond the scope of this paper when considering all costs and environmental impacts. A general consensus is not necessary to determine that the waste product in disposable product far exceeds a reusable product, especially over time. Refer to the Fig 1, which gives a short summary of the lifetime product that is either disposable or re-usable.

Fig 1. Life cycle phases of reusable and disposable systems. (Leiden, A., Cerdas, F. Noriega, D., Beyerlein, J., & Herrmann, C. (2020)



STERILIZATION

After each completed surgery, critical and semi-critical devices and accessories within the patient environment, must be either sterilized or replaced. Medical devices that have contact with sterile body tissues or fluids are considered critical items. If these items are heat resistant, the recommended sterilization process is steam sterilization, because it has the largest margin of safety due to its reliability, consistency, and lethality. This approach to disinfection and sterilization is commonly referred to as Spaulding's approach and summarized in table 1. However, this is not without problems due to "…oversimplification. For example, the scheme does not consider problems with reprocessing of complicated medical equipment that often is heat-sensitive or… processing of an instrument in the semi-critical(sic) category (e.g., endoscope) that would be used in conjunction with a critical instrument that contacts sterile body tissues." (Centers for Disease Control and Prevention, 2019).

Spaulding's Classification of Devices

Devise / Item	Definition	Risk of infection	Example	Reprocessing procedure
Critical	Medical device that is intended to enter a normally sterile environment, sterile tissue or the vasculature	High	Surgical instrument, cardiac catheter, implants, needle, ultrasound probes used in sterile body cavity	Sterilization by steam, plasma, or ethylene oxide
Semi-critical	Devices that are intended to come in contact wit the mucous membrane or non intact skin	High / intermediate	Flexible endoscope, respiratory therapy equipment, manometry probes, diaphragm-fitting rings, laryngoscope blades	Sterilization desirable, high-level disinfectants
Noncritical	Devises come in contact with the intact skin	Low	Blood pressure cuff, stethoscope	Intermediate or low-level disinfectant

Table 1. (Mohapatra, S., 2017)

When we evaluate methodologies, we recognize there are multiple methods used across different specialties, in dentistry for example, dry heat sterilization is more common than steam heat or autoclave. Equipment sensitivity, product designs with inaccessible areas or multiple layers may require the use of ETO.

As a simplification, the most commonly used methods are listed below:

1. Moist heat or steam (autoclave) or Dry Heat
2. Hydrogen Peroxide Gas Plasma (Sterrad®)
3. Gamma Irradiation
4. Ethylene Oxide (ETO)
5. Chemical cleaning base on phthalaldehyde, peracetic acid, glutaraldehyde etc.

MEDICAL EQUIPMENT INTERCONNECT

The consequence of so much equipment in the operating room leads to the necessity of interconnecting the equipment and the communications between devices and sensors/ actuators on the patient. The use of cables and connectors becomes more important than a simple accessory, but impacts safety and reliability of entire medical devices. Additionally, considerations for patient and operator safety are becoming increasingly more protective with regards to essential performance precautions against electrical hazards per IEC 60601-1. A third concern, is of course the human factors and experience of the operator. According to one study, operators " (24%) mentioned problems with cables. On one hand, problems with the technical aspects of cables, e.g., unplugged cables, bent or worn out plugs …" (Leiden, A., Cerdas, F., Noriega, D., Beyerlein, J., & Herrmann, C. ,2020).

It is the equipment manufacturers that design a medical device with the end use and sterilization in mind, including the connector and cable assemblies used with their product. The component selection should not only meet, but exceed a set of reprocessing standards. These are typically set into the instructions for use (IFU).

Decision Factor	Disposable Cable	Reusable Cable
Patient prep time	Shorter time	Longer – depends on cable sanitization time
Cost	Lower cost per cable assembly, but requires purchasing and stocking multiple assemblies – perhaps dozens.	Higher cost per cable assembly, plus the amortized cost of the autoclave machine and sanitizer fluid
Durability	Less durable, but only intended for single use.	More durable. The essential choice when connected to a costly, durable, and reusable end device such as an endoscope or robotic arm.
Eco-friendliness	Less friendly	More friendly

Table 2.

NEW REQUIREMENTS FOR 60601-1 MOP

The IEC 60601-1 states maximum requirements concerning the protection from electric shock for medical applications in which patients and operators can get into direct contact with electrical equipment and systems. In order to reduce risks to a minimum, manufacturers must integrate two means of protection in their products. For this purpose, they can either implement two separate measures or apply a single measure twice. Overall the specified protection level 2 MOPP (means of patient protection) or 2 MOOP (means of operator protection) must be obtained. In addition, manufacturers must introduce a management process in which they not only investigate all protection-relevant aspects, but also document the results in detail.

Due to these reasons the approval procedures for medical electrical equipment and systems have become recently even more complex than they already were prior to the effective release of the latest version of the IEC 60601-1. In order to simplify the risk management process and to save time and costs during the implementation of the protective measures from electric shock, manufacturers should involve the suppliers of electronic components in the development process of their products from the start. At best, those components would already be fully compliant with the IEC 60601-1. If the implemented components, such as connectors, fulfill 2 MOPP and 2 MOOP on their own, e.g. by means of mechanical measures, the costs of product development can be reduced to a minimum, and the necessary time for approval procedures can be substantially shortened.

DISPOSABLE VS. REUSABLE

A third category should also be considered besides disposable (single use) and reusable (sterilizable), due to cases of re-use of single-use devices or devices that are used a limited number of times. Another consideration when considering disposable and reusable connectors is the function of each connector half. In most instances there is a "permanent" or medical equipment (ME) side which is not considered disposable, but is in fact reusable 1,000's of times. This illustrates the wide range of system requirements from the capital side, to in-line, to the device side.

According to the CDC, "approximately 20 to 30% of U.S. hospitals reported that they reuse at least one type of single-use device. Reuse of single-use devices involves regulatory, ethical, medical, legal, and economic issues and has been extremely controversial for more than two decades. In August 2000, FDA released a guidance document on single-use devices reprocessed by third parties or hospitals. In this guidance document, FDA states that hospitals or third-party reprocessors will be considered "manufacturers" and regulated in the same manner. A reused single-use device will have to comply with the same regulatory requirements of the device when it was originally manufactured." (Centers for Disease Control and Prevention, 2016).

Table 2 lists the decision factors to be considered in making such a selection. In either case, the chosen product as component or cable assembly, must meet the safety and effectiveness regulations specified by the U.S. Food & Drug Administration (FDA). ANSI/AAMI/ISO 17664:2017 lists requirements for processing that consists of all or some of the following activities:

1. Preparation at the point of use
2. Preparation, cleaning, disinfection
3. Drying
4. Inspection, maintenance and testing
5. Packaging
6. Sterilization
7. Storage

DISPOSABLE SOLUTIONS – SINGLE USE VS. LIMITED USE

In recent years, there have been introduced a wide range of product categories in the category of disposable cable assemblies to be sub-divided into true single-use assemblies, single patient use, disposable, and limited use assemblies. A different category has also been developed for lower cost but with limited sterilization cycles and reusability informally as "re-sposable" cables. In the end, the OEM must make a risk assessment against the intended use,

Fig 2. ODU MEDI-SNAP® disposable connector and receptacle

actual use and the requirements for safety and quality in the selected interconnects. To achieve lower cost, the disposable connector and receptacle housings used in such cables are made of an alternative plastic such as Polysulfone (PSU) rather than metal or a higher cost, more durable plastic such as Polyetherimide (PEI) or Polyetheretherketone (PEEK). For example, the ODU MEDI-SNAP® Disposable connector and receptacle (Figure 2) are rated at 25 mating cycles, whereas the more durable and reusable members of the family are rated up to 5,000 mating cycles on the receptacle side. The importance of longevity when selecting connectors for the medical device should be included into any evaluation of lifetime mating cycles.

ODU's wide range of products also includes another family of disposable connectors and receptacles specifically designed for medical applications – the ODU MINI-MED® family of integrated cable/connector assemblies (Figure 3). The primary difference between the ODU MINI MED® and ODU MEDI-SNAP® disposable families lies in the number of contacts each can support: 2-6 for ODU MINI MED® and 2-8 for ODU MEDI-SNAP®. The ODU MEDI-SNAP® is compliant with the IEC 60601-1 standard for maximum protection of both patients and operators – 2 Methods Of Patient Protection (2 MOPP) and 2 Methods Of Operator Protection (2 MOOP).

Fig 3. ODU MINI-MED® disposable connector and receptacle

ODU MINI-MED® connectors are not available as stand-alone components, but as pre-terminated cable assemblies to reduce the overall costs. The company achieved further savings through use of the most cost-effective materials (Table 3). Nonetheless, these connectors are rated at more than 1,000 mating cycles, and in no way do they jeopardize the safety of the patient. In other words, ODU MINI-MED® products can be considered as either disposable or reusable. In the latter case, the cables can be sterilized between uses, using the Ethylene Oxide (ETO) gas sterilization method.

Component	Material
Outer housing	Polyamide (PA) [common name: Nylon]
Inner housing	Polycarbonate (PC)
Overmold	Thermoplastic Polyurethane (TPU)
Cable	Polyvinyl Chloride (PVC)

Table 3.

CONCLUSION

Equipment used in hospitals and at emergency sites must be extremely reliable and as close to sterile as possible. A patient's life may depend on it. Until a few years ago, that meant the cables and connectors used in medical systems had to fall into one of two categories – disposable or reusable. In order to be reusable, they had to be sterilizable and autoclavable between uses, and they had to be capable of many thousands of mating cycles. Those requirements made reusable cables and connectors substantially more expensive than their disposable counterparts.

Recently, a third category has been established - limited use – offering the cost advantages of disposable, but with a limited level of reusability. Cables and connectors in this category are sometimes referred to as "re-sposable". They are sterilizable and autoclavable using the less harsh methods; and their mating cycles are limited to dozens or hundreds – not thousands. ODU has pioneered the development of limited-use cables and connectors, and has partnered with numerous medical equipment companies as their supplier of interconnect solutions. ODU was chosen because of the renowned quality of their products, as well as their ability to manufacture complete custom cable solutions in high volume.

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