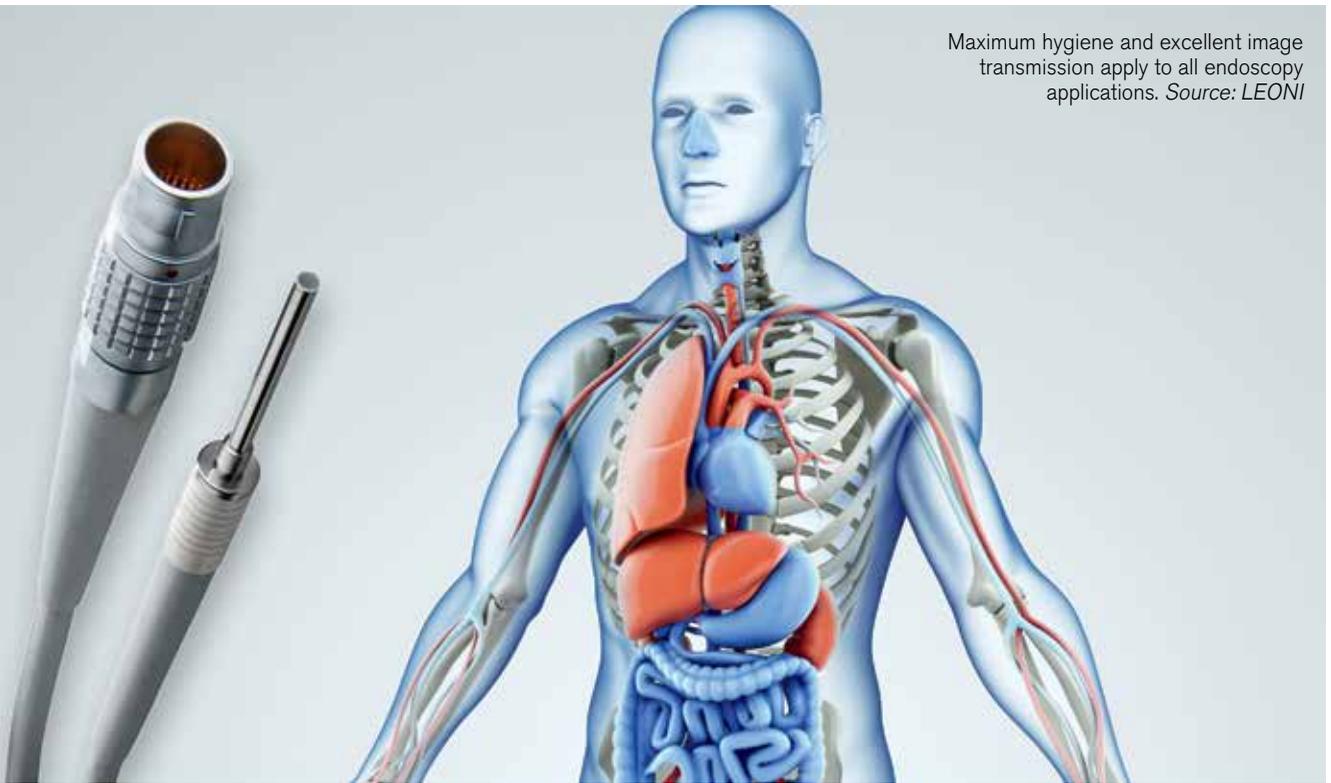


Maximum hygiene and excellent image transmission apply to all endoscopy applications. Source: LEONI



Hygienic Cable Solutions for Medical Applications

With antimicrobial cables and systems, connections can become even cleaner and help reduce the risk of infections in hospitals.

by **ken anderson** and **tobias höft**

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Strict regulations and standards imposed and set by such organizations as the Food and Drug Administration (FDA) or the American National Standards Institute (ANSI) as well as by original equipment manufacturers (OEMs) of medical devices, ensure among other things quality-assured preparation of medical cables for diagnostic, therapeutic or monitoring applications. Continued improvement in hygiene can be achieved and the risk of infection can be decreased through specific materials, design and structure of a modern cable system. Considerations during the development phase of a medical device, the early integration of tests, as well as antimicrobial agents integrated in a plastic surface can provide new options for safe connections in hygienically demanding applications.

Maximum patient safety is the primary directive for all products, services, institutions or people related to healthcare applications. The containment of hospital-

acquired infections (HAIs) has become not only a public health challenge, but also a concern for manufacturers and suppliers of medical devices and their components.

According to a study from 2002, the estimated number of HAIs in the U.S. is approximately 1.7 million, leading to almost 99,000 deaths per year (Klevens R.M., Edwards J.R., Richards C.L., Horan T.C., Gaynes R.P., Pollock D.A., Cardo D.M. "Estimating Health Care – Associated Infections and Deaths in U.S. Hospitals", 2002. CDC Public Health Reports (2007 Mar-Apr), vol 122:p.160-166).

In terms of HAIs being transferred from one patient to another, there is a special focus on patient monitoring cables. For example, ECG lead wires have been found to be a reservoir for multidrug resistant organisms in intensive care units. A study from 2004 stated that 77% of reusable ECG leads harbor one or more antibiotic-resistant pathogens after cleaning and reprocessing (Jancin B. "Antibiotic-resistant patho-



Maximum hygiene expertise is mandatory for all component manufacturers in minimally-invasive or non-invasive applications. *Source: LEONI*

gens found on 77% of ECG lead wires”, *Cardiology News* (2004 Mar)). With minimally-invasive diagnostic and therapeutic procedures, flexible endoscopes are often associated with infections in hospitals. The use of disposable lead wires is therefore already recommended in most monitoring applications, and single-use elements are also available for some endoscopic procedures.

But involving a cable and system supplier early in the design stage can help with finding reusable cable solutions. Aside from the cables specifications, the conditions in use and the cleaning and disinfection skills should also be considered and tested with the supplier in the development phase of a medical device.

Strict rules and standards govern the cleaning and disinfecting of medical devices and components. Transmission of bacteria, viruses and spores by reusable medical cables can result in serious infections that must be avoided under all circumstances. Effective disinfection and sterilization after every use is mandatory for all cables that come into contact with the human skin or mucous membrane. Such official organizations as the FDA and ANSI, as well as manufacturers have to uphold the highest hygiene requirements. Suppliers must develop and produce their components with a focus on efficient preparation for non-invasive or minimally-invasive devices.

Optimized contours for more hygiene

Due to their structure, medical cables may have grooves, crevices and gaps that

make straightforward cleaning more difficult. Furthermore, many of the individual components of reusable cable systems are difficult to clean. Some materials are resistant to either heat or chemicals, making them unsuitable for particular disinfection or sterilization processes. This allows for an increased risk that infections are transmitted during use.

Steam sterilization is a preferred method when reprocessing minimally-invasive instruments. While the main focus when sterilizing endoscopes is on the endoscope channels and instruments, the same strict preparation criteria also apply to connection hoses and all other leads. The endoscopy cables and connected components must last and withstand several hundred cycles using these methods of sterilization. Along with the materials utilized, the design and structure of a modern cable system can contribute to ensuring the lasting sterility of a flexible endoscope. Combining a silicone jacket and Liquid Silicone Rubber (LSR) molding, endoscopy systems can be

exposed to safe and durable sterilization for up to 1,000 cycles at 290 F in an autoclave while maintaining optimized gliding properties. Grooves, gaps and cavities can be avoided by overmolding the connection and thereby making the system nearly 100% sealed. If incorporated connectors are furthermore molded with such materials as epoxy resin, adhesive or silicon, the penetration of fluids can also be prevented at these points.

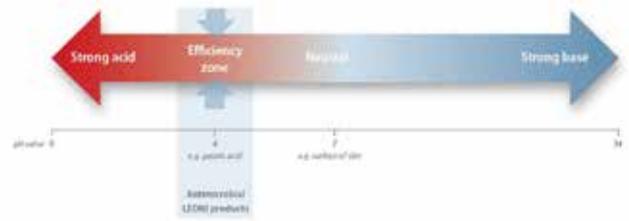
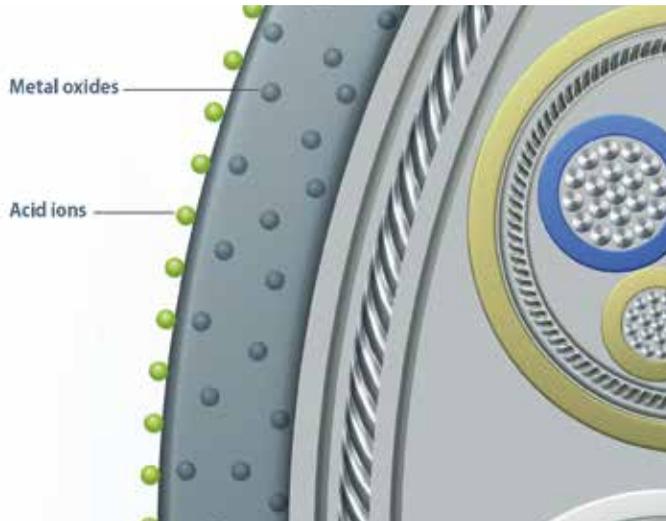
For ECG and other patient monitoring cables, chemical disinfection is the preferred preparation method. While electrodes are mostly single-use products, reusable ECG cables must resist repeated treatment with different disinfecting agents. Cable jackets and overmolds of thermoplastic polyurethane (TPU) are a good choice when also considering high cable flexibility. Equipping the ECG cable with an additional antimicrobial effect can help to close possible loopholes in hygiene procedures.

With respect to hygiene aspects in cable



Reduced risk of infection: The antimicrobial jacket of the Leoni ECG cables in Integral Process systems reduces the bacterial load under multiple-use conditions. *Source: Integral Process*

MEDICAL



The antimicrobial characteristic of cable surfaces can be achieved by releasing a special metal oxide in the sheath material. These ions cause a drop in pH on the cable's outer surface – similar to the protective acidic mantle on human skin.

system design generally, the connection between differing materials often leads to problems when connecting plugs or ferrules. For instance, when metal and plastic come into contact, a biofilm can form in cavities or recesses that provides fertile ground for microorganisms. Such gaps and holes at the connection points can best be prevented by applying the same material to the molding and the cable, as well as the appropriate overmolding technology.

Which processes and materials are deployed will depend on the application of the overmolded components. The preferred material for overmolded connectors, grommets and y-splitters for endoscopy systems is LSR. Combined with an LSR jacket, cable systems will most likely meet the user requirements concerning flexibility, gastightness and autoclavability of the system. Alongside silicone, such biocompatible materials as fluorinated ethylene propylene (FEP), ethylene tetrafluorethylene (ETFE) are the preferred materials used for non-invasive cables in near-patient applications.

In contrast, cables located outside or inside the device are overmolded with such technical plastics as thermoplastics or thermoplastic elastomers for mechanically demanding applications in device wiring, or electronic components are overmolded with (thermoplastic) thermal fusion adhesives. Further shields can be added and plastics that are up to 30% glass fiber-strengthened can be overmolded in high pressure processes.

Hygiene standards with lasting disinfection

and sterilization of reusable systems can thus be established by selecting the right material, design and overmolding procedure as early as the development of monitoring or medical devices and their connecting system. The early integration of electrical, mechanical and thermal testing will help in finding the best solution for a specific application.

Antimicrobial surfaces help in closing possible hygiene loopholes

Various cables are available for reusable ECG systems. The cables have an antimicrobial jacket that reduces the bacterial load under multiple use conditions. Many manufacturers of ECG system rely on disposable solutions to reduce hospital infections. Yet this can become very costly in the case of more complex cable structures.

There is a technology that gives plastic surfaces a bacteria-killing effect for reusable medical technology systems with more complex cable structures. It can close unwanted loopholes in the hygiene chain and is now deployed with reusable ECG systems.

A metal oxide is bonded into the cable jacket to give the ECG leads an antimicrobial property. Due to a larger grain size, this does not come under the controversial area of nanotechnology. Nor does this innovative technology use any silver or copper, meaning that the cables maintain their antimicrobial effect even when coming into contact with perspiration or proteins. The same applies to cleaning: the methods commonly used in hospitals do not exert any adverse impact on the effectiveness of the

antimicrobial surface.

Despite this additive, these cables remain skin compatible. The biocompatibility of these ECG leads is DIN EN ISO 10993 approved. Due to the use of special, silver-plated tinsel conductors, the cables are very flexible and lightweight. A special shield ensures their electromagnetic compatibility.

The color coding of the ECG leads and a picture with the instructions on correct positioning of the electrodes on the amplifier housing make it quick and easy to connect the ECG system to various patient monitoring devices.

Ultimately, early involvement of a cable system supplier in the development phase of a medical device can yield cost savings not only for OEMs by finding the right connection for their products; it can also help to reduce the consequent costs for hospitals, insurance companies and the public by helping to contain the risk of HAIs.

The expertise of system suppliers includes material and design knowledge, processes and technologies to implement design specifications, and comprehensive testing options.

With antimicrobial cables and systems, connections can become even cleaner and help reduce the risk of infections in hospitals. ■