HELIX™
MEDICAL

Tube with bonded molding

Bonding in Medical Technology

Bonding is still a developing method in medical technology, but it is becoming increasingly more important. Adhesives must not only be biocompatible, but also sterilizable.

Sometimes the combination of silicone tubing and extruded or injected silicone molding cannot be achieved without further action. The reason for this could be particularly complicated component geometry or the piece count may be too low, making the necessary tools too expensive. In such cases, manual bonding in a cleanroom may be the only solution. Some examples of medical devices that require a bond are cannulas, endoscopes, and surgical instruments. One challenge in medical technology is that materials used in the human body must be both biocompatible and sterile. With implantable devices such as insulin pumps, cochlear implants, and intraocular pressure sensors, adhesives must not only be biocompatible but also must exhibit the desired deformation and flow properties (rheological characteristics) and the corresponding mechanical property profile. For this reason, only adhesives with safety certificates are used in medical technology; some examples are certification for cytotoxicity (DIN EN ISO 10993-5), tests for in-vitro cytotoxicity, and USP Class VI biocompatibility requirements (U.S. Pharmacopeia).

The selection of adhesives for medical technology is indeed limited by biocompatibility, but a much greater challenge is adequate sterilization resistance. Especially in multi-use products, such as surgical instruments, it must be determined how adhesives change over several sterilization cycles. Hot steam sterilization produces high temperatures which are generally much higher than the glass transition temperature of the adhesives. Additionally, the pressurized humid environment can cause the physical and chemical properties of the adhesive bond to change significantly. In ethylene oxide sterilization, a change in the chemical structure, and consequently a change in the physical properties of the adhesive can occur. Only the use of Sterrad® (a low-temperature sterilizer) should not be detrimental to heat- and moisture-sensitive, bonded instruments. Adhesive manufacturers often do not provide information about sterilization resistance of their adhesives.

Additionally, component-dependent stresses can occur through sterilization. In endoscopes, for example, several different optical glasses are glued to a lens. If the endoscope is heated to 134°C during sterilization and then abruptly cooled to room temperature, these glasses expand to significantly different degrees, which the layers of adhesive must withstand.

It must also be determined to what extent the adhesive used will change as a result of stresses in the relevant application; whether they change and how they change under the influence of body fluids and cleaning agents. Bonded surgical instruments are used only for a short time in the body, and the stress on the adhesive by contamination with body fluids, microorganisms and the like can be neglected. Here, the stress is caused mainly by humidity and temperature during sterilization. Adhesive manufacturers usually make no claims regarding the aging behavior of adhesives in use.

Depending on the component, the field of application, and associated conditions, new and specific test equipment and model test specimens are needed to test adhesive compounds for their suitability for medical use. In order to create a system for the testing of medical devices, we have profiled the various requirements for bonds in the table below. Depending on the field of application, the chemical and thermo-mechanical stability, aging, and the influence of contamination; bonding can now be studied in a targeted and application-specific manner.

Field of Application	Requirements / Characteristics	Adhesive /Surface Treatment
Syringe systems, cannula systems	UV-transparent joining partner, short production times, high volumes, disposable items, hot steam sterilization, ethylene oxide sterilization	Joining partners: metal, glass, plastic Adhesives: UV curing Pre-treatment: cleaning, activation by plasma
Optical bonding: Endoscopes	Low bond gaps, precise positioning, no structural loads to be transmitted, compensation for different thermal expansions of the joining partners, hot steam sterilization, Sterrad®, cleaning devices	Joining partners: SiO2 and Al2O3-ased components (glass, sapphire, quartz), metal Adhesives: 2K Epoxy Pre-treatment: cleaning, precision cleaning glass using plasma
Bonding of instruments: scissors, forceps, tongs	Bonding differing materials: metal/metal, metal/plastic, metal/ceramic, structural bonds, disposable and reusable instruments, hot steam sterilization, cleaning devices	Joining partners: metal, glass, plastic Adhesives: 2K Epoxy Pre-treatment: cleaning, plasma, mechanical pre-treatment

Helix Medical is a global medical contract manufacturing leader specializing in the design, manufacture, assembly, and lifecycle management of silicone and thermoplastic components and extrusions. The company has served the needs of the medical device, pharmaceutical, bioprocessing, and IVD markets since 1984.

Freudenberg Research Services, with more than 220 associates in chemistry, physics, and engineering sciences, is a development partner to Helix Medical and their customers to provide research services and to support material, process, and component development.

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