



EP42HT-2Med: Utilized in Prosthetics and Fully Implantable Medical Devices

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Among the most challenging medical applications for an epoxy compound are prosthetics and fully implantable medical devices. Not only must the material be capable of withstanding sterilization procedures, it must also exhibit biocompatibility over an extended period of time. Prosthetics and implantable devices must be able to maintain performance levels even when in direct contact with tissue and bodily fluids, and must not introduce toxins or cause injury, a physiological reaction, or immunological rejection.

Master Bond EP42HT-2Med is a two-component epoxy that is designed specifically for use in medical applications. Capable of withstanding repeated sterilizations, including ethylene oxide (EtO), radiation, chemical sterilants, and autoclaving, EP42HT-2Med offers superior bonding, sealing, and coating performance, and is castable to thicknesses of up to 2-3 inches. It is highly resistant to many acids, bases, solvents, and fuels, offers excellent electrical insulation properties, and is serviceable from -60°F to 450°F. EP42HT-2Med cures at room temperature or more rapidly at elevated temperatures. Optimal performance and biocompatibility can be achieved by curing EP42HT-2Med overnight at room temperature and then for an additional 2-4 hours at 150-200°F.

EP42HT-2Med is commonly used in the manufacture and assembly of surgical instruments, catheters, endoscopes, and other medical devices. Available in both amber-clear and black as a USP Class VI system, EP42HT-2Med is well suited for use in prosthetics and implantable medical devices. In several research and development publications, scientists and engineers have singled out EP42HT-2Med for use in their applications. Following are brief descriptions of each application and its use of EP42HT-2Med.

Implantable Multi-panel Sensors

Application

Researchers at the Swiss Federal Institute of Technology (EPFL) in Lausanne, Switzerland, the Università degli Studi di Genova in Italy, and the Institute for Research in Biomedicine (IRB) in Bellinzona, Switzerland, have been studying ways to develop biocompatible packaging for implantable devices to be used for remote monitoring of metabolites, such as glucose and lactate, and drugs.^{1,2,3,4} They designed a fully implantable sensor device consisting of a microfabricated sensing platform, custom designed integrated circuits (ICs), and a coil for power and data transmission. The device is powered through an inductive link between an external power coil and the coil embedded within the device. Metabolic readings are captured by the sensors and transmitted from the device to an external receiver. The three subcomponents were to be assembled into an integrated device and then encased in a biocompatible package prior to implantation in mice.

Key Parameters and Requirements

The goal of the research team's latest study was to assess the biocompatibility of three different multi-panel sensor devices.¹ The three prototypes varied in their shape, size, and the structure and composition of the device packaging. Additionally, two of the devices were implanted in the backs of the mice while the third was implantable in the peritoneum.

In one of the prototypes, Master Bond EP42HT-2Med was used both in the assembly of the sensor device and in the formulation of a biocompatible outer membrane for the device. EP42HT-2Med was used as an adhesive to join the substrate containing the electronics (ICs and antenna) with the sensing platform and as a glob top to protect the aluminum wire

bonds that connect the electronics with the pads of the sensing platform. The outer membrane, which consisted of a mixture of EP42HT-2Med and polyurethane (PU), was applied by dip-coating the device three times at intervals of one hour. To ensure biocompatibility, the coated device was kept overnight at room temperature and then subjected to a temperature of 80°C for two hours to complete the cure process. After curing, the device was kept at room temperature overnight and then stored in phosphate-buffered saline (PBS) for an additional 24 hours.

Results

All three prototypes were implanted in cavities created in two-month old male mice. After 30 days, the implants were removed, the implant sites were rinsed with PBS, and the liquid collected from each site was centrifuged and examined. The percentage of neutrophils and concentration of adenosine triphosphate (ATP), both of which serve as indicators of local inflammation, collected in the liquid from each prototype were measured and compared to the levels of neutrophils and ATP produced by control conditions. Control conditions included a cavity absent an implant, a cavity implanted with a biocompatible commercial chip, and a cavity injected with bacterial lipopolysaccharides (LPS).

Research findings indicated that each of the two prototypes implanted in the back, including the one that used EP42HT-2Med, was tolerated by the host after 30 days of implantation, while the device implanted in the peritoneum was rejected. ATP and neutrophil levels for each of the accepted prototypes were comparable to those of the negative controls (i.e., the empty cavity and the commercial chip) and were well below those of the positive control (i.e., the LPS-filled cavity).

The researchers concluded that the PU membrane enhanced with Master Bond EP42HT-2Med presents the best solution because it provides effective biocompatible coverage and a more reliable, more reproducible deposition process than the method used to add the protective membrane to the sensing platform in the other biocompatible prototype.

Tibial Implant

Application

Total knee replacements generally consist of three major parts: a tibial component, which is connected to the shinbone, a femoral component, which is connected to the thighbone, and a meniscal bearing component, which is located between the other two components and allows them to slide over each other. The tibial and femoral components are usually made of metal or a metal alloy while the bearing component is made of a synthetic plastic, such as polyethylene. Early designs of prosthetic knees fixed the bearing component to the tibial component, but newer designs allow the bearing component to float to some extent, allowing increased freedom of movement within the knee. However, all knee prostheses incur some risk of dislocation or spinout, especially if the ligaments fail to provide adequate support. Ideally, a prosthetic knee should allow for some flexion and tension of the knee joint while lowering the risk of dislocation and bearing spinout.

Solution Design

An inventor at Howmedica Osteonics Corporation in Mahwah, NJ, was awarded a patent for his design of a limited motion tibial implant.⁵ The design calls for the addition of an elastic gasket between the tibial component and the bearing component of a prosthetic knee. Master Bond EP42HT-2Med is cited in the patent as a suitable adhesive for mounting the gasket on a plate. The gasket-plate combination is designed to fit (without affixing) into an undercut rim on the top surface, or baseplate, of the tibial component. A lip around the top perimeter of the gasket is designed to couple with a groove in the bearing component.

Results

When the three parts are sandwiched together, the gasket fills the space between the inner wall of the tibial component and the outer wall of the bearing component. The bearing component is free to move along the tibial baseplate, and as it moves, it compresses the gasket. The spring constant and thickness of the gasket restrict the movement of the bearing component along the tibial baseplate. Thus, the design provides for limited motion with enhanced stability over designs with floating bearing components.

Transradial Socket for Arm Prosthesis

Application

For individuals who are missing part of an arm, a prosthesis may be attached to the arm remnant via a socket. Many socket designs achieve the primary goal of attaching the prosthetic arm, but present issues to the amputee that result in reluctance to wear the prosthesis. Non-permeable full-contact sockets, for instance, tend to be uncomfortably hot and

humid, while open socket designs are more breathable, but are bulky and unaesthetic. Many close-fitting designs are difficult to put on and take off, while looser designs may not be sufficiently stiff to support the arm remnant. Ideally, the socket connecting the artificial arm to the arm remnant should be close-fitting, comfortable to wear, easy to put on and take off, adjustable, lightweight, and self-suspending, among other characteristics.

Key Parameters and Requirements

At Eindhoven University of Technology, a master's degree candidate was interested in developing a design for a transradial (that is, below the elbow) socket that improved on earlier designs while taking advantage of recent advances in materials.⁶ The thesis project explored several different options for socket design and material selection, ultimately narrowing down viable choices to three designs. The researcher examined how well each of the three designs met 13 different requirements gleaned from patient surveys, assigning each design a superscore.

Results

A stainless steel wire mesh socket was identified as the best of the three transradial socket designs, because stainless steel does not irritate the skin, the mesh design allows for breathability, the socket can be designed to be close-fitting and self-suspending, and the wire mesh prosthetic should be easy to put on and take off. The design calls for the wire mesh to be shaped by forming it around a wooden sphere. The edges of the wire mesh are joined together with adhesive and then covered with a polyurethane strip. In joining the edges of the mesh, the adhesive must fill all gaps in the overlapping edges. A standard prosthetic arm shell is attached to the spherical mesh via a polyurethane strip that is glued to the mesh. Master Bond EP42HT-2ND2Med Black was selected as the adhesive to join the stainless steel mesh edges together, to join the polyurethane strip to the stainless steel mesh, and to attach the closure to the mesh. EP42HT-2ND2Med Black met the requirements for joining the plastic and metal materials, filling the mesh gaps, and not irritating the skin.

Conclusion

Prosthetic and fully implantable devices face unique environmental challenges. All materials that come into contact with the patient must not harm the patient, and the device must operate flawlessly while subjected to motion and surrounded by physiological materials. Medical device manufacturers and researchers count on biocompatible Master Bond EP42HT-2Med and EP42HT-2ND2Med Black to assemble and protect medical devices while ensuring patient safety.

References

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