New Developments and Trends in Medical-grade Adhesives

a report by
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Immunisations for infants, flu shots, restorative dental fillings, blood transfusions, heart bypass surgery, urological surgery, anaesthesia administration, intravenous drug delivery – these and many other modern medical procedures would not be possible without the advanced adhesives used today to assemble thousands of medical devices on highly automated assembly lines around the globe. Add double-digit real volume annual growth and the market for adhesives used in the assembly of disposable medical devices is one of the most exciting segments in the specialty chemical industry. Some estimates even forecast growth as high as 24% annually for the next five years, but most participants peg annual real volume growth at about 13% to 15%, which, by most standards in the adhesives industry, is rather phenomenal in these times of challenged growth. Perhaps even more exciting are estimates that only about one-half of the applications that could be served by adhesives are actually using adhesives in assembly, leaving significant growth opportunity for the industry. By all measures, growth potential is very attractive and this market segment generates a lot of interest among adhesive suppliers.

Disposable Medical Devices

Generally, disposable medical devices are single-use non-implantable medical devices that are typically disposed of after use. Implantable devices such as orthopaedic implants, permanent stents and pacemakers, etc., are generally not considered in this market segment, although many of these do use adhesives in their manufacture or implantation. These implantable devices are not included in this discussion of adhesives used in medical devices. Other related applications not included in this discussion are wound coverings, bandages, non-woven products, orthopaedic grouts and dental adhesives and fillers.

Material trends are an important driver to the disposable medical devices market. As would be expected, thermoplastics find broad application in the medical devices market for their utility, low cost and biocompatibility. However, there is a clear trend to reduce the use of polyvinyl chloride (PVC) components, particularly in Europe. PVC usage is being reduced, but has not by any means been eliminated as it is such a versatile material, particularly in applications requiring high flexibility, low cost and, in some instances, clarity. As would be expected, trends towards more use of polyolefins will create new challenges to design and process engineers who wish to employ adhesives in assembly operations.

Other important plastics include polystyrene, polycarbonate, acrylics, silicone rubber, polyethylene, polypropylene and synthetic 'rubbers' such as polychlroroprene and polyisoprene, along with many others. Stainless steel finds use wherever durability is required, and, in some instances, titanium or titanium alloys find use, but metals are less commonly used substrates in disposable medical devices.

Industry Trends

Certainly in the US, cost cutting in the healthcare industry is a reality and likely here to stay. Hospitals and other large healthcare providers have formed very successful buying groups who are pressuring suppliers for lower prices and additional services, which, in turn, creates cost pressures on all suppliers throughout the value chain. In some instances, high-end devices that were manufactured for single use are being cleaned via sophisticated on-site processes to stretch the healthcare dollar even further. There has also been significant consolidation via merger and acquisition of participants at all levels of the value chain. In recent years, large distributors have emerged and everyone is aware of the consolidation of hospital and other large healthcare providers. As a result, the industry screams for lower total costs, and adhesives offer the potential for ever-increasing production speeds. "Cheaper and faster" is the mantra of the industry today. Miniaturisation is also an on-going trend that requires more micro-application of adhesives at very high production speeds.

Since thermoplastics find such utility in the design of disposable medical devices, adhesive-less thermal bonding is always a viable alternative to adhesive bonding and the industry must continually offer performance or process advantages over thermal assembly techniques that do not require any consumable material. From a pure materials play,

adhesives almost always result in higher cost, so performance or processing advantages must prevail for adhesives to compete successfully. However, there are many applications and bond configurations that do not lend themselves easily to thermal bonding techniques. Adhesives are almost always the assembly method of choice when one or more of the substrates are a thermoset material or when the bond line geometry presents a gap needing to be filled. The most common thermal bonding methods include ultrasonic welding, vibrational welding and hot air welding. Designers and process engineers must assess carefully the entire component to select the best joining method to meet the requirements of the device and the production process.

Diverse Adhesive Types

The disposable medical device assembly market makes use of a variety of adhesive types and formulative technologies. Formulative technologies employed include:

- solvent borne;
- one-part, 100% solids reactive systems;
- two-part, 100% solids reactive systems;
- hot melts; and
- water borne.

Several chemistry types dominate this market segment:

- acrylic;
- epoxy;
- silicone; and
- styrene block copolymers.

Minor adhesive types include:

- ethylene vinyl acetate;
- polyolefins (primarily polyethylene hot melts);
- polyamide;
- polyurethanes; and
- natural rubber.

Acrylic adhesives include the cyanoacrylate (CA) family, both traditional single component types curing primarily via reaction with atmospheric moisture, but also newer formulations employing ultraviolet and visible light cure mechanisms. Recently, the introduction of truly flexible CAs promises to open new opportunities for these versatile adhesives. Other acrylic chemistries finding niche use in medical device assembly include anaerobic types, which are used for locking threads and other tight metal assemblies, but are often used with surface primers to activate the relatively inert stainless steel surfaces frequently used in medical applications where metals are required as opposed to plastics. The need for quality control and non-destructive testing is driving more adhesives to contain fluorescent tracers, which, while not truly allowing for non-destructive testing, do offer the opportunity to examine assemblies visually to ensure that adhesive is present and placed properly.

The selection of the proper and best adhesive is an important consideration for the device designer as well as the process engineer who will need to manufacture the ultimate device efficiently, with near perfect quality and within ever-tightening overall cost targets. Each type of adhesive offers distinct advantages and disadvantages to the designer and process engineer.

CAs are chemically similar to the common 'superglues' familiar to industry and the consumer. These new medical grades of CAs are themselves thermoplastics when cured and cure from a single component liquid via reaction with moisture, radiation cure or a hybrid approach using both cure mechanisms. CAs are known for the ability to cure 'instantly', but can cause problems in some components due to bloom or frosting, which is caused by a volatile CA monomer curing on surfaces not intended to see adhesive. Recent advancement in 'low-bloom' CAs has reduced some of these problems. Until the recent introduction of truly flexible CAs, the brittleness of these cured adhesives has hindered their penetration into applications requiring very high degrees of flexibility.

Other acrylic-based chemistries employed in the assembly of medical devices include various acrylate terminated formulations, which cure via radiation cure, and, in some cases, hybrid cure systems, allowing shadow cure of cure behind opaque substrates. As mentioned, advances in curing equipment have opened new markets and applications for radiation-cured adhesives, especially the relatively safe visible light and light-emitting diode (LED) curing systems where formulators have responded rapidly with formulations to take advantage of these new technologies.

Silicones have found success in many specialised applications in this market due to their strong biocompatibility and very high flexibility. Radiation cure, two-component, heat cure and one-part moisture cure formulations exist. Silicone-based adhesives have been particularly successful in bonding flexible moulded silicone components.

Epoxy chemistry is probably the oldest adhesive type used in this market segment and remains an important category. Strong biocompatibility can be achieved by selecting the proper raw materials in the formulations. Single and multi-component epoxy systems can be used, although, in some applications, the presence of an exotherm in curing can be

troublesome, particularly when bonding to glass, a common substrate for epoxy adhesives. Epoxy adhesives can fill large gaps and are generally easy to use and apply.

Polyurethanes find limited use, but are expected to become more important in the medical device market. Polyurethanes offer very high strength, high flexibility and proven impact resistance, but biocompatibility must be considered carefully when formulating. Polyurethanes are found most often where actual skin or body contact is either not required or is minimal. The relatively new reactive polyurethane hot melt adhesives offer some obvious performance and processing advantages where near instant fixture can be achieved, with structural level bonds developing over time as the adhesive cures via atmospheric or incorporated moisture.

Some of the growth of adhesives in the disposable medical device market will result from improved processing methods and technology and not just new adhesive advancements. Application and curing equipment play a critical role in the design and manufacture of these devices. Today, we are seeing more sophisticated precision applicators and dispensing systems that can consistently deliver precise micro quantities of adhesive at very high production speeds and accuracy. Newer cure systems have forced adhesive formulators to advance in cure chemistries continually. Today, it is not uncommon to find visible light and even LED cure systems that are safer, more precise and offer higher processing throughput for adhesive end-users.

Regulatory standards are an important factor for adhesive suppliers to consider. While adhesives themselves do not have to meet particular biocompatibility standards, the manufactured devices do. Adhesive suppliers test almost universally to current standards to assure their customers of being able to meet biocompatibility requirements if their adhesives are incorporated into the device design. In the past, the US standard Class VI was accepted universally, but, in recent years, the more global International Organization for Standardization (ISO) Standard 10993 has been adopted. The older Class VI standard was more associated with materials than devices or adhesives.

Adhesive Market

ChemQuest estimates the US adhesives market for assembly of disposable medical devices to have been US$36 million in 2003 and will enjoy an 11% annual growth rate through 2008. The global market was estimated to be about US$70 million in 2003, with about 75% of the non-US volume being consumed in Europe, while the remaining 25% being accounted for in the Asia Pacific region. Growth in the Asia Pacific region is expected to outpace that of both the US and Europe. Asia Pacific growth is forecast to be about 22% during the period as more manufacturing is shifted to that region, although much of the finished product will be manufactured for US and European healthcare markets. Dental adhesives, used for restorative and for dental appliance fabrication, are estimated to account for an additional US$510 million in the US alone, but are generally used by dental practitioners in small unit dose dispensers and, due to the widespread use of fluoride treatments for recent generations, is not expected to show significant growth. Generally, these dental adhesives are not considered to be a part of the market for disposable medical devices, but need to be mentioned due to their large revenue component, albeit at relatively low volumes.

End-use Applications

Some of the specific end-use applications for adhesives in disposable medical devices include:

- syringe needle bonding – typically stainless steel to an olefinic thermoplastic cannula;
- catheter bands;
- catheter balloons;
- fistulas used on dialysis treatments – typically a CA adhesive bonding flexible PVC tubing thermoplastic elastomer;
- Stainless steel syringe cannulas to K-resin syringe bodies on newer safety syringes using light cure adhesives;
- silicone tips to flexible silicone tubing for wound drain devices – often dual cure silicones using both heat and atmospheric moisture cure;
- PVC inhalation mask assembly; and
- ostomy devices.

Adhesives continue to offer manufacturers of disposable medical devices efficient and high-quality means to assemble these critical healthcare products and deliver them to a very dynamic and increasingly cost-conscience marketplace. Many of these life-saving and quality-of-life-enhancing products would be impossible to deliver efficiently to the marketplace without the high-quality and innovative adhesives being supplied and developed today and into the future. Few segments within the adhesives industry can offer the level of growth expected within this very dynamic market. ■