Use of Adhesives in the Medical Device Industry

How to select the right adhesive for your application

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Introduction

Over the past few decades, adhesives in one form or another have been replacing many other fastening systems in the assembly of medical devices. And for good reasons! Adhesives come in many different forms, structural, non-structural and pressure sensitive adhesive, to meet different needs. When chosen judiciously, adhesives can offer significant benefits over other mechanical fastening systems.

Adhesive Categories

Adhesives are generally categorized as structural, non-structural and pressure sensitive. The right adhesive should bond well to the substrates and provide a strong enough bond for the application requirements.

Structural adhesives can be one or two part epoxies, acrylics or urethanes, that are used for load bearing applications. These are chemically curing compounds and typically offer the highest strength. They can be used to bond metals, plastics, rubbers and other difficult to bond materials, sometimes without much surface preparation.

Structural adhesives are used for a wide range of applications, from bonding surgical instruments together, to rubber bumpers on the bottom of crutches or walking canes, and plastic soles to the bottom of cast boots. Traditionally, these applications would have required the use of nails, screws or rivets.

Cyanoacrylates are fast curing and widely used in the medical device industry. Cyanoacrylates are liquids that are moisture cured. Some cyanoacrylates are formulated to be dual cure systems that include a moisture and a light cure (UV or visible) mechanism. These can be used in the manufacture of IV tube sets, needle bonding or attaching plastic tubing to a blood bag. Traditionally, strong solvents are used for making these bonds.

General benefits of using various adhesives over mechanical bonding techniques
Strong, uniform bond and improved durability
No holes to drill or leak through
Maintain material integrity and prevent potential corrosion, such as rusting
Uniform stress distribution over the bonded surface vs. stress risers at screws and rivets
Ability to disassemble if desired, depending on adhesive selection
Bond and seal simultaneously
Join dissimilar or hard to bond materials, sometimes without much surface preparation
Can be easier to automate process with potential for time saving.

Non-structural adhesives include hot melts, contact, aerosol and rubber & gasket adhesives, amongst others. These adhesives do not cure chemically but instead attach physically, such as hot melt adhesives that solidify on cooling, or solvent/water based contact adhesives that bond as they dry. These adhesives are generally used to join surfaces that do not see an excessive load under normal use, and maintain flexibility after bonding. Adhesives in a range of bond strengths are available to bond rubbers, plastics, fabric, foam, leather, metal, glass, etc.

Spray adhesive can be used in the construction of equipment carrying cases to attach foam to foam or to the carrying case. Hot melt or spray adhesives can be used to bond fabric to wood, plastic or metal for wheelchair seat cushions, thus avoiding stitching or riveting.

Pressure sensitive adhesives (PSA) are now commonly used in the assembly of medical devices. When first applied, these need pressure to form a good bond. PSAs function because of the viscoelastic properties of the adhesive. This means that the adhesive can flow into the surface because of the viscous nature and resist stress due to the elastic nature. For non-uniform surfaces, the adhesive can cold flow into the nooks and crannies of the substrate, thus increasing the contact area and also creating a mechanical bond.

PSAs are used in bonding any number of flexible and non-flexible materials and the bond strength can be moderated by selecting the appropriate adhesive family. PSAs offer a lot of flexibility, in that the adhesive properties can be formulated from being repositionable to ultra high bonds.

A common application of PSA is in the assembly of blood glucose monitoring strips or for attaching products to skin, such as a surgical drape, a first aid dressing for cuts and bruises or an insulin pump. PSAs offer a key advantage in that the two substrates do not need to be attached at the same time. The PSA can be applied to one surface at manufacturing and it can later be easily bonded to the second surface with the application of pressure.

The table below shows examples of materials and applications most commonly joined by the different adhesive categories.

Selecting the Right Adhesive for the Application

Before selecting an adhesive, it is critical to understand the design and application of the device, the materials being used in the construction and application of the device, the environment it will be exposed to from manufacturing to end use, the stresses it will see during the same period and the desired durability and shelf life, to name a few. When an adhesive is applied to a non-standard surface such as skin, it presents a whole different series of challenges and appropriate questions that need to be addressed for the application to be successful.

For applications to skin and certain In Vitro Diagnostic (IVD) devices, such as the glucose monitoring strips, it is also important to ensure appropriate compatibility of the adhesive being used, per applicable ISO guidelines.

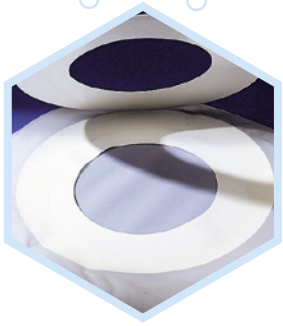
Common stresses seen on any bond are tensile, shear, peel or cleavage, depending on the joint design and the forces being applied to it. The right adhesive selection and testing needs to be done to test the adhesive bond during the development phase.

Some typical questions to address when selecting the adhesive and adhesion technique for your application:
Which materials are being joined? More specifically, what is the surface energy of the substrates involved?
What are the surface characteristics of the subtrates?
What is the strength of the desired joint?
How much surface area is available for adhesive application?
How and where will the device be used?
How much force/stress will be seen by the joint?
What environment will the device be exposed to? E.g. heat, humidity, chemicals, UV etc.
What is the desired method of adhesive application?
What are the limitations for the application techniques that can be used?
What are the storage conditions and the shelf life of the adhesive?

	Structural	Non-structural	Pressure Sensitive
Adhesive type	Epoxy Urethane Acrylic Cyanoacrylate	Hot melt Solvent/water based liquid Aerosol	Non-skin use Skin use
Bond materials	Low and high surface energy materials Metals, plastics, rubbers PTFE Silicone TPE (Thermoplastic Elastomers) Skin	Nonwovens Leather Foam Paper	Some low surface energy materials High surface energy materials Metals Some plastics Skin
Applications	Blood bag assembly Walking cane Cast boot sole attachment Hospital equipment IV tube set Respirators Skin sealant	Decorative laminates Respirators Surgical drapes construction Wheelchair cushion assembly	Electrodes First aid dressings Glucose test strips Insulin pump attachment Microplate cover tapes Monitor face plates Ostomy appliances Surgical drapes Toupee tapes Wound dressings

If the adhesive is to be applied to skin, which is a non-standard surface with properties varying from person to person and over time for the same person, special considerations have to be taken into account to allow for a successful attachment of the device to skin.

Additional questions for stick to skin applications:
To which part of the body is the device going to be applied?
Is the device meant for a special segment of the population, e.g. Geriatric, Neonatal, etc.?
Is it a onetime use (e.g. Surgical drape) or long term use (e.g. Ostomy appliance) application?
Is the device going to be sterilised and if so, what sterilisation method will be used?
What conditions will the device be subjected to during use?
Which chemicals, if any, will the device come in contact with during use?
What stress forces will the device see during use and removal?



Summary

Adhesives offer a number of advantages over other fastening systems. For a successful outcome, it is important to know and understand the properties of the substrates involved, define the bond requirements well, identify all the environmental conditions the bond will be exposed to, select the most appropriate adhesives and then test and narrow the choices to the optimal product for the application. A number of adhesive are available and there is no such thing as “one adhesive fits all”!

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