Ensuring the Reliability of Disposable Syringes with Light-Cure Adhesives: Simplified,Cost-Effective Needle-to-Hub Assembly

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DYMAX®

Perhaps one of the most challenging aspects of disposable medical syringe production involves permanently and safely attaching the stainless steel cannula to the plastic hub. This joint is critical to the safety of syringes found on hypodermic and biopsy needles, syringes, winged infusion sets, blood lancets, and a variety of other devices. In all these applications, poor hub-to-cannula assembly could result in leakage of bodily fluids and medication or catastrophic device failure, situations that could be dangerous to the patient and the medical professional. Mechanical failure of a syringe can cause painful insertion or extraction, seal failure during use, cancellation of a procedure, or other unsafe complications.

Most hub-to-cannula designs today use some form of adhesive to ensure a high strength, permanent bond. Historically, manufacturers have used complex and time consuming processes such as mechanical interlocking designs and insert molding, but these methods can not eliminate leakage or guarantee acceptable aesthetics for a device that will make direct contact with the body. In today's syringe manufacturing processes, adhesives including epoxies, cyanoacrylates, and light-cure technologies are commonly used for device assembly.

During assembly, the hollow tubular cannula or needle – most often made of stainless steel – must be inserted through a cylindrical channel in the hub that is slightly larger than the diameter of the cannula. This channel begins where the hub meets the barrel and passes through the hub's core, exiting into a well designed to hold adhesive. Joint design is critical for the hub-cannula assembly. The right design that incorporates the right adhesive delivers a well-sealed syringe assembly that will not allow fluids to leak or migrate and will safeguard the cannula from moving or releasing during use.

Finding the "Right" Adhesive Technology

A number of adhesive technologies can be used in manufacturing needle assemblies to deliver high-strength bonding and sealing, gap filling, and easy in-line processing. For low volume, manual assembly operations, two-part epoxies and cyanoacrylate adhesives will both permanently secure the hub-to-cannula assembly. Epoxies, however, require hours to set and cure, resulting in racked parts and work in process delays. While significantly faster, cyanoacrylates offer virtually no time to reposition parts and ensure that the cannula is fixed appropriately. Cyanoacrylates' tendency to experience "blooming", the formation of a hazy white discoloration on nearby surfaces, can also negatively impact the critical clean aesthetics of the syringe.

For high-volume, high-speed automated syringe assembly lines, UV/Visible light-cure adhesives cure in seconds to thermoset polymers that form lasting bonds with a variety of substrates including metals and plastics. These one-part adhesives eliminate work in process by curing rapidly on exposure to the right intensity and wavelength of light. They can be formulated with fluorescing properties to allow for easy bond-line inspections to detect adhesive coverage and volume. Some adhesives offer color-change technology that allows manufacturers to confirm cure.

Light-cure adhesive formulations are available from thin wicking (Newtonian) grades to thixotropic gels. Cure

can take from as little as two to 20 seconds depending upon the color of the substrate, the depth of the well, and any UV inhibitors present in the substrate. Deeper cures can be achieved from the top or sides of the hub assembly depending on the adhesive chemistry, cure equipment, and time requirements. Overall hub design also plays a part in cure time. Once cured, these adhesives can achieve a rigid state or remain soft and flexible depending upon the formulation. They also offer very good thermal and chemical resistance.

A wide range of light-cure adhesives are available on the market. The correct adhesive for a specific needle-bonding application will be determined based on variables such as the needle design itself and the manufacturing process. Adhesive viscosities, readings that communicate the adhesive's ability to flow around parts, are available to suit almost any manufacturing process. Easy-flow Newtonian materials are considered low viscosity and are measured in low cP readings (e.g. 100 cP). The higher the reading, the thicker or lower-flow the adhesive. For example, thicker Newtonian adhesives have viscosities near 5.000 cP while thixotropic gel formulations approach 20.000 cP. Parts geometry, process design, assembly method, and speed should be considered together to determine appropriate adhesive viscosity.

Substrate Selection is Critical

Any adhesive selected must effectively and permanently bond to both the stainless steel cannula and the hub substrate. But many of the plastics used to manufacture today's disposable medical syringes are hard-to-bond materials such as polyethylene, polypropylene, ABS, and acrylic – formulations that usually require surface treatment in order to deliver a permanent bond. Hard-to-bond plastics should be pretreated to change their surface characteristics in order to achieve strong permanent bonds.

Two methods of surface treatment can be performed on polyolefin plastics to improve their adhesion. Corona discharge is widely used in needle manufacturing as it can be incorporated directly into an automated production line. In this treatment, a gas such as oxygen, argon, helium, or air is excited at low pressure to produce free radicals that bombard the substrate surface, increasing reactivity and the ability of the adhesive to spread over a larger area rather than bead up. As corona discharge has a limited shelf life, parts must be assembled fairly quickly.

Plasma treatment is very similar to corona discharge but must be done offline as a batch process. Since this slows production time and the potential shelf life of the treatment is very short, corona treatment is typically preferred in light-cure processes. Either process will increase the needle assembly's pull strength by as much as five to ten times the original strength without treatment.

Substrate color can also affect adhesive performance. The color of the syringe's hub is typically used to denote cannula size, with pink, green, blue, purple, grey, yellow, and white denoting different gauges. Syringe manufacturers using light-cure adhesives should know that substrate opacity may vary depending upon the color of the plastic, and should look for colored plastics that are translucent to allow light to penetrate through the hub to the needle. Certain specialty adhesives are available on the market that are more compatible with colored or less translucent substrates.

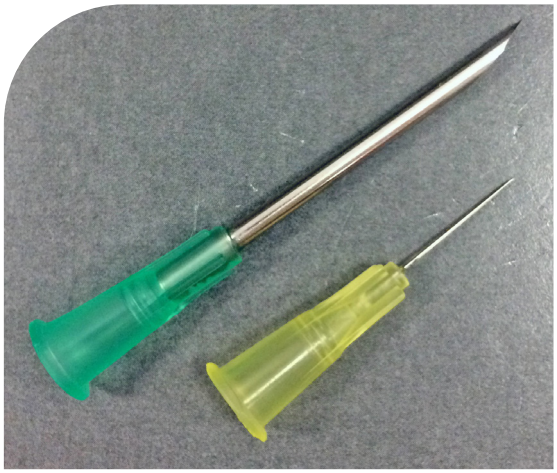


Figure 1. Colored Syringe Hub

The cannula can also be treated to enhance the strength of the adhesive bond. The most common cannula treatment is grit blasting or micro blasting. This extremely accurate technology cleans, roughens, and deburrs the surface of very small metal parts. For cannula surface treatment, micro blasting uses 50-µm aluminum oxide to deliver a roughened, high-adhesion finish. The adhesive can then be applied and has more surface area to wet, enhancing bond strength.

Joint Design Considerations

The mechanical strength of a hub-to-cannula joint assembled using adhesives is assessed through pull strength testing. This test of tensile strength can be done online during syringe production or offline on a random sample of devices pulled from the production batch. The test typically involves the steel needle being held by pneumatic grips that exert a pulling force on the needle and hub assembly. The test may pull the assembly to the force that it is designed to withstand or pull the assembly to the point of failure. Regardless of the exact methodology, the device either should not fail or adhesive strength should exceed substrate strength, with the adhesive bond outlasting the substrate's strength under stress.

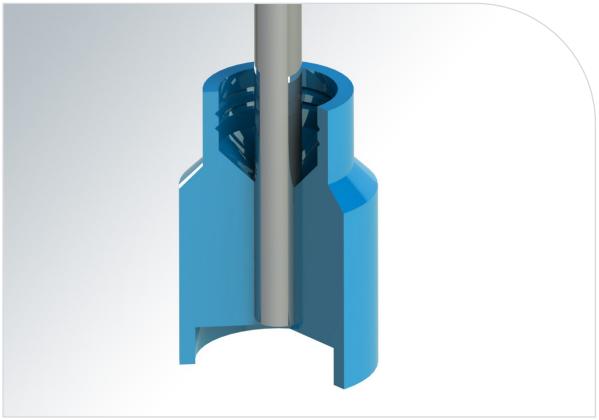


Figure 2. Hub/Cannula Assembly - Cutaway

Figure 2 shows a cutaway of a hub and cannula assembly. The stainless steel cannula typically extends from the base of the syringe barrel through the engagement length of the hub's core, and out through the well where adhesive secures the cannula in place. The longer the engagement length of the core, the higher the pull strength of the assembly.

The gauge size of the cannula also affects pull strength. As gauge size increases, circumference of the cannula decreases. This reduces the pull strength of the assembly because the surface area of the joint is smaller. So the smaller the gauge size, the higher the bond strength.

While cured adhesive in the well secures the needle in place, the design of the well area can also help increase pull strength. The best designs allow adhesive to easily wick around the cannula and bond to the needle and the hub substrate. The wider the well diameter, the larger the bond area and the easier it is for adhesive to fill the well completely. The deeper the well, the higher the pull strength. Figure 3a illustrates a typical well configuration where the hub is flared at the distal end. The well in this illustration is large enough to permit the use of mid-range viscosity adhesives.

Figure 3b shows a cylindrical well design where the diametrical gap between the cannula and the hub is small (less than 0,1 mm). A cylindrical hub that fits closely to the cannula requires a low viscosity, wicking grade adhesive with superior bond strength to both substrates to ensure a lasting bond. Typical diametrical gap is 0,002 to 0,006 inch. The smaller the diametrical gap, the greater the potential for joint failure.

Figure 3c illustrates a mechanical lock made with the adhesive to increase pull strength. In this design, annular rings or grooves are molded into the inner diameter of the well or core substrate. These grooves are typically 0,127 to 0,2 mm deep.

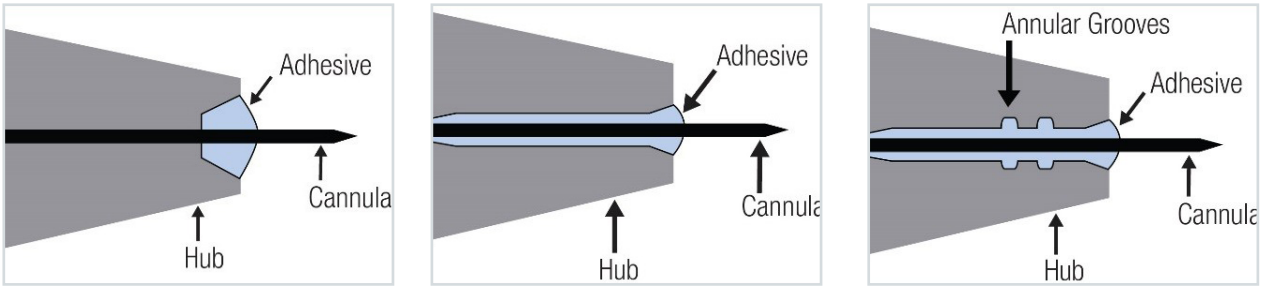
The low-to-medium viscosity adhesive wicks into the grooves and cures in place, forming a mechanical lock between the cannula and the inner wall of the hub substrate. This grooved design increases pull strength and dramatically reduces the potential for device failure.

Dispense, Dwell, and Cure Requirements

For needle bonding, adhesive may be applied before or after the cannula is inserted into the hub assembly. Dispensing adhesive onto the cannula before it is inserted into the hub guarantees adhesive coverage in the right places as the adhesive is forced into the well and the core during insertion of the cannula. By using a high-viscosity adhesive of 3.000 to 30.000 cP, adhesive will cling to the cannula and will not run off prior to insertion into the hub. Also, no wicking or flow time is required before cure.

When adhesive is dispensed after the needle is inserted, low-viscosity Newtonian adhesives of 20 to 3.000 cP achieve the best results as they will quickly wick into the hub-to-cannula joint. Generally, the lower the viscosity, the faster the adhesive will flow and fully cover

Figure 3. Hub-to-Cannula Joint Designs, Cross Section



A - Well Configuration

B - Cylindrical Well

C - Mechanical Lock

the diametrical gap and well. For example, in a syringe assembly with a diametrical gap of 0,002 inches, a 500 cP viscosity adhesive will take five to ten seconds to wick into the engagement length of the core, whereas a 9.000 cP adhesive will take up to four minutes to fill the same space. But flow time can be a double-edged sword since the adhesive must be cured very rapidly once dispensed or the material may leak out of the part before cure is completed.

For thixotropic adhesives, manufacturers can accelerate flow time by applying a slight vacuum to the area under the hub. The vacuum pulls the adhesive into the inner diameter of the well, significantly reducing flow time to just seconds. Heating the adhesive or the parts to be assembled will also accelerate flow time for higher-viscosity Newtonian adhesives. For example, the viscosity of an 850 cP Newtonian material, when heated to 50ºC, can drop to 150 cP, a viscosity that will considerably decrease flow time. As the adhesive cools and wicks into the well, it returns to its original viscosity and is less likely to leak out of the joint before curing.

Since adhesive flow times can be dramatically affected by the rheology of the adhesive and surface energy of the substrates, manufacturers should test the actual parts to determine real flow times rather than using the adhesive manufacturer's data for the material.

Once the adhesive is dispensed and has adequately filled the required gaps in the hub-to-cannula design, the adhesive can undergo cure. Light-cure adhesives must be exposed to light of the appropriate intensity and wavelength, emitted by a specialized light source, in order to cure fully. The amount of time an adhesive must be exposed to a condition – light, heat, etc. – is called the adhesive's cure speed. Typical cure speed of light-cure adhesives range from two to 20 seconds depending on the equipment/adhesive combination and the area and depth of cure.

An adhesive fillet that is exposed to air can sometimes remain tacky as oxygen can inhibit cure on that surface. To solve this issue, needle manufactures may cover the adhesive with a nitrogen blanket (or other inert gas) during cure, increase the irradiance of the light source or better match the wavelength of the light source to the absorbance of the photoinitiator in the adhesive.

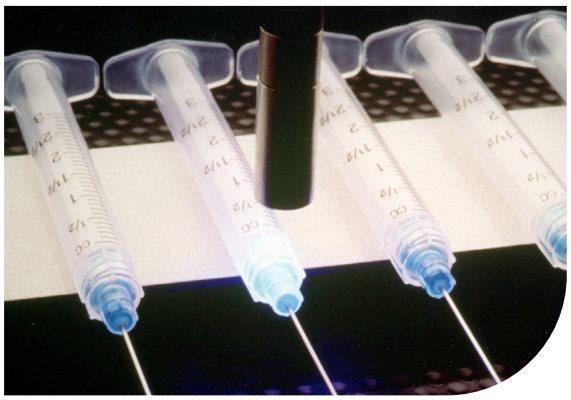


Figure 4. Adhesive Undergoing Cure

Parts Inspection/In-line Detection

Needle manufacturers often audit the adhesive dispense process before cure and inspect the component post-cure to make sure that the correct volume of adhesive has entered the bond line and that full cure has been achieved. These inspection processes can be used to detect missed dispense cycles, undersized beads of adhesive, oversized beads of

adhesive, air bubbles, and plugged or broken dispense tips.

Many of today's light-cure adhesive technologies are formulated to confirm adhesive placement, which can be observed either with the human eye or by automated vision systems. Some formulations offer color change technology where the adhesive changes from a bright color (e.g. blue) in its uncured state to lack of color in its cured state. The colored adhesive can easily be viewed to confirm that the correct volume of adhesive has filled gaps after dispensing occurs. By transitioning from blue to colorless, the adhesive allows manufacturers to confirm that cure is complete and the bond has been achieved.

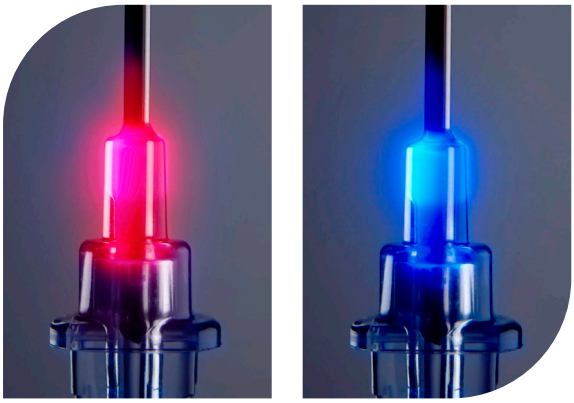


Figure 5. Red & Blue Fluorescing Technology

Certain adhesives are formulated with fluorescent dyes that remain colorless until they are exposed to a 365 nm black light, at which point they fluoresce red or blue. Adhesives that fluoresce red are particularly effective for use with plastic substrates that naturally fluoresce blue such as PVC and PET, allowing easy inspection of bond lines.

Sterilization

Once a disposable syringe is manufactured, it must be sterilized before it can be used. Typical sterilization methods include autoclave, ethylene oxide (EtO), and gamma exposure. Light-cure adhesives offer excellent resistance to both gamma and EtO sterilization. Autoclaving alone is too aggressive a procedure for most syringe assemblies.

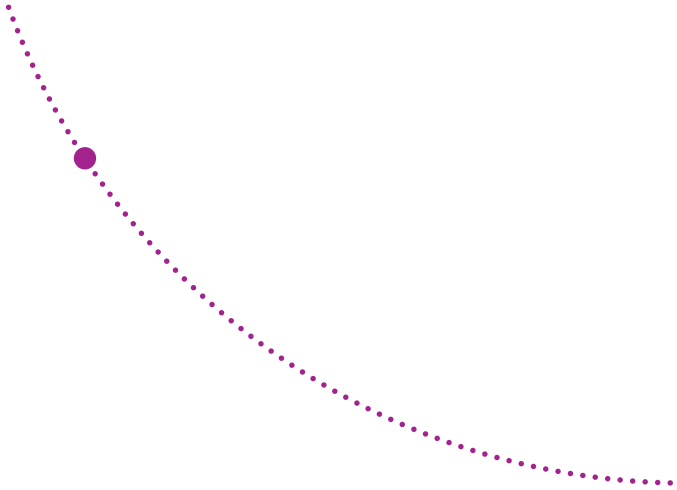
Many factors can affect a needle assembly's ability to withstand sterilization including the sterilization method itself, the adhesive formulation, selected substrates, joint designs, and cannula gauge sizes.

Accelerated aging tests, which involve exposing the syringe to elevated temperatures over time, can help manufacturers predict the life of needle assemblies exposed to sterilization procedures. According to industry research, the majority of light-cure adhesives maintain at least 85% of their strength after four weeks aging at 60ºC when a polycarbonate hub is bonded to a 22-gauge cannula. Pull strength may even increase slightly upon exposure to gamma and EtO.

Ensuring Reliability

There are many factors to consider in designing a needle bonding process. Validating the appropriate adhesive technology, substrate, joint design, process parameters (including the appropriate selection of cure equipment), inspection needs, and sterilization techniques are all critical in avoiding failures.

Medical design engineers can narrow their search for the most suitable adhesive by working closely in partnership with their adhesive suppliers' sales, engineering, R&D, and technical service groups to thoroughly test prototypes of syringes on a simulated production line before actual production has launched. This testing can include dispense/dwell times, cure validation (wavelength selection and cure time), and pull evaluations. By conducting research and testing up front during the design phase, device manufacturers can ensure the success of the assembly during high-volume manufacturing and over the life of the device.



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