

Swelling Agents: Accelerate Medical Device Assembly

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As medical devices become smaller and more complex, designers and manufacturers are utilizing new and more sophisticated components to incorporate into their device designs. Patients want smaller, more portable devices while providers want more functional and better performing alternatives. This includes items such as IV tubes and bags, drainage catheters, dialysis machine tubing and a host of other products using tubing and hoses.

These demands are pushing the development of state-of-the-art tubing designs. For instance, OEMs need tubing that meets tight tolerances including smaller inner and outer diameters and thinner wall thickness. In addition, many next-generation devices require multi-lumen tube construction that has multiple channels running inside the tubing to deliver fluids, gases, guide wires or other materials within a single tube. Therefore, it is critical that today's advanced tubing performs flawlessly with leak-free connections between the medical device and the tubing. However, connecting these tubes to fittings and devices can be slow and labor intensive. This is where swelling agents play a key role.

Making connections easier

For many medical device manufacturers, silicone elastomers are the preferred tubing material. The remarkable physical properties of silicone — durable, flexible, low cost, structural versatility, resistance to bacterial growth, low extractables and easy sterilization — make it a good choice for medical grade tubing and for fluid or gas transfer within the medical device.

However, mating complex silicone tubing onto parts made of harder materials can be problematic for two reasons. First, while silicone is flexible, it will not generally expand or stretch without assistance. Secondly, silicone has a high coefficient of friction, or tacky surface, that makes sliding a silicone tube onto a fitting difficult.

Fortunately, there are chemical formulations that make connecting silicone tubing quicker and easier. There are three common methods of joining silicone tubing or parts: lubricating with alcohol or oil, or swelling with elastomer swelling agents.

3 methods of joining tubing

Isopropyl Alcohol (IPA)

Ultra-pure isopropyl alcohol (IPA) can lubricate silicone tubes for assembly. IPA is easy to obtain, is relatively inexpensive and it evaporates without residue. But IPA dries slowly, which can increase assembly cycle time. Also, IPA is of little assistance when assembling thin-wall tubing because the tubing will collapse or fold, making it difficult to press or slide the tubing onto a fitting. In addition, if the assembly is not completely dry there may be problems with the device later on.

Silicone Oils

Another choice is to lubricate the tubing with silicone oils. It is effective, but messy. The oil will stay on a surface indefinitely. Also, silicone oil makes housekeeping difficult because the oil will migrate through the factory. Plus, the oil captures dirt from the environment and, medical grade silicone oils are expensive. As with IPA, thin wall tubing will collapse or fold making assembly a challenge.



A silicone swelling agent significantly improves assembly times.



Swelling fluid allows the tubing to easily slide over fittings or other connectors.

Swelling Fluids

A third option is swelling agents. Swelling allows the tubing to easily slide over a barbed fitting or other connector. The two most common swelling agents are either hexane or an engineered silicone swelling fluid. Hexane has a strong odor so proper ventilation or PPE (personal protective equipment) is essential. Hexane is also an extremely aggressive solvent so it might remove surface coatings or ink markings, damage plastic components or permanently change the physical properties of the tubing. Although effective at swelling silicone, hexane is a volatile organic compound (VOC) that contributes to poor air quality.

A better choice is to use an engineered silicone swelling fluid. When one end of a silicone tube is immersed and soaked in the swelling fluid, the tubing wall quickly swells uniformly. The fluid expands the elastomer like a sponge absorbing water. Exposure time determines how much the tube swells. Because tubing dimensions may only need to expand by 1-2% for assembly, the entire swelling process can often be accomplished in less than a minute.

The tubing swells in a highly predictable manner without changing the physical properties of the tubing. This makes assembly faster and easier when connecting thin wall tubing to barbed fittings.

Once the tube is in place, the swelling fluid evaporates quickly and completely from the tube. The tubing recovers to its original size, durometer, compression, color shape and strength. It forms a tight, leak-proof, secure grip over the fitting, no matter how complex the geometry. Since the swelling fluid's active ingredient is a methyl siloxane — a member of the silicone family — it doesn't affect the chemical structure of the tubing or the physical properties of the fitting.

In addition, an engineered swelling fluid has excellent materials compatibility. It works on thin wall and even softer, larger diameter tubing. The swelling fluid does not cause a long-term change to the mechanical properties with the tubing material. It will not weld or bond the tubing onto the fitting, so the tubing can be easily removed later if needed.

Swelling fluid benefits

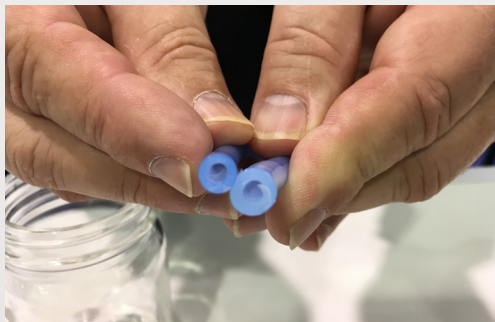
Better for workers:

Swelling fluid helps reduce the amount of force needed to insert a tube onto a barb or other type of connector. This is especially true with thin wall tubing that has minimal structural rigidity making it prone to folding over or collapsing during assembly operations. This helps workers avoid potential carpal tunnel, wrist problems and other workplace-related injuries. It also has slight skin and eye irritation, and has low toxicity making it a safer choice than hexane.

Less waste and scrapped parts: Swelling fluid helps prevent tubing damage including stress cracks during manufacturing. This helps eliminate scrapped parts and reduces waste.



Swelling fluid makes medical device assembly easier and faster.



When the end of a silicone tube is immersed and soaked in the swelling fluid, the tubing wall quickly swells uniformly.



Easier validation:

An engineered silicone swelling agent is selective in function, it readily swells silicone tubing without any impact on other polymers such as polycarbonate or polyurethane and has excellent compatibility with metal components. In addition, its use results in a much smaller weight gain due to solvent absorption, resulting in lower fluid use and faster recovery of tubing to its original state. Since heat, glue or other types of adhesives that can affect the integrity of the tube, fitting or device are not introduced into the assembly process, it is easier to qualify and validate. Plus, swelling fluids do not produce residue that could adversely impact clean room integrity and adversely affect the qualification of the manufacturing process.

Faster assembly:

It is time-consuming to manually insert silicone tubing over rigid plastic or barbed fittings when assembling medical devices. Adding a silicone swelling agent to the process can significantly improve assembly times.

Environmentally friendly:

Many swelling fluids are environmentally friendly and sustainable. They are not a hazardous air pollutant (HAP) and do not contribute to ground level air quality issues.

Excellent materials compatibility:

Swelling fluids are typically used on silicone, a go-to material for medical tubing. However, there are other swelling fluids available for other tubing materials, including polyethylene and polyimide. There are also swelling agents compatible with polyurethane and other molded thermoelastomer tubing and hoses. Look for a swelling fluid that is selective and does not impact other polymers that are part of the assembly.

Conclusion

Swelling fluids provide enhanced design flexibility and an effective, efficient, and environmentally superior way to join silicone, polyurethane or other thermoelastic tubing to fittings and molded parts. Using a swelling fluid helps simplify medical device assembly, therefore increasing throughput and boosting overall productivity. Many swelling fluids are an easy-to-handle and reliable alternative to aggressive solvents such as hexane. Plus, they are a sustainable choice since they have a low GWP (Global Warming Potential) and comply with most air quality regulations. When choosing a swelling fluid, it is best to consult with a company that specializes in medical lubricating and coating technology. They have the experience and expertise to help choose the best swelling fluid for each individual application.

About the Author:

Jay Tourigny is Senior Vice President at MicroCare which offers precision cleaning, lubricating and debinding solutions. He has been in the industry more than 30 years and holds a BS from The Massachusetts College of Liberal Arts. Tourigny holds numerous U.S. patents for cleaning-related products that are used on a daily basis in medical, fiber optic and precision cleaning applications. For more information, visit microcare.com.

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