

Novel multilayer tube design enables infusion of drug products suspended in DMSO

How TekniPlex Healthcare developed a tubing solution that both solved the problem and saved money.



Advancements in treatment for patients who require hormone, cellular or gene therapies have enabled these critical medications to be delivered through infusion. These therapies are typically suspended in strong solvents such as DMSO (dimethylsulphoxide) and NMP (n-methyl-2- pyrrolidone) to maintain their stability and enhance their effectiveness.

The medical tubing and assembled solution required for these applications must be rigorous enough to withstand the solvents' caustic effects to ensure the integrity of the infusion sets and systems used to deliver these sensitive therapies.

PROBLEM

A designer of a dual hormone infusion system needed to deliver both insulin and a suspension of glucagon which was carried in a DMSO solution. All commercially available multilayer tubing products previously tested for DMSO transfer in the application suffered severe chemical attack and eventually had catastrophic failures and leaked during use. Without a DMSO resistant fluid path, this infusion system could not be brought to market.

The design team also needed to ensure the luer fittings would be DMSO stable and that the tube solution could be solvent bonded using common bonding solvents.

A post tube manufacturing operation to apply fittings at the end of the tube was required to connect to the infusion pump. If the bond between the fitting and tube is insufficient, this could cause a dangerous situation for the patient and could add to the risk of hypoglycemia if glucagon infusion is interrupted.



SOLUTION

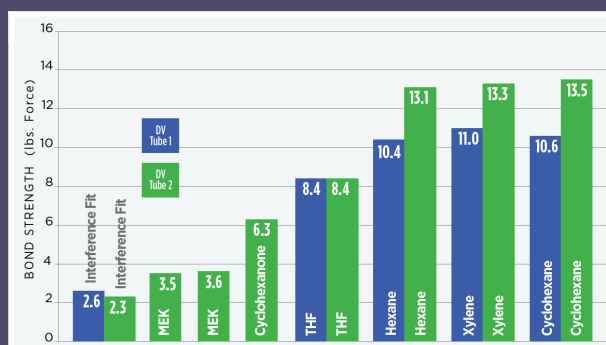
TekniPlex Healthcare developed a multilayer tube design where the layers are bonded securely to each other using tubing particularly well adapted for bonding to a fitting comprised of inert polypropylene. Polypropylene fittings are not impacted when exposed to DMSO, making it the ideal fitting choice for the application.

This patented new product eliminates the use of UV curable adhesives, which are expensive and require the additional step of exposure to UV light, causing a considerable cost increase in assembling the tubing and fitting.

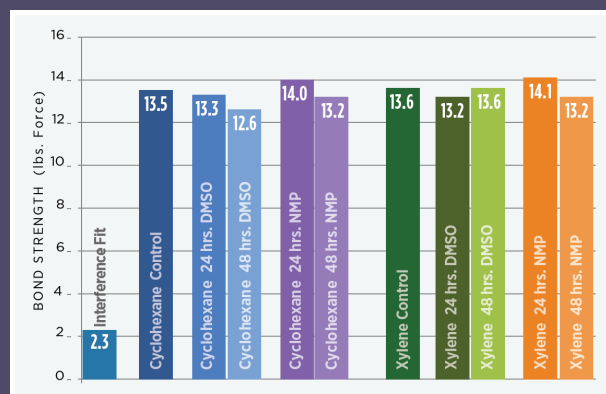
BENEFIT

- **Continuous Fluid Transfer** - The novel infusion system allowed for the safe and continuous transfer of the glucagon suspension that **improved the therapeutic effectiveness and reduced the overall risk to the patient**.
- **Easy Manufacturing and Scale Up** - The solution was fit for easy manufacturing and scale up by **utilizing commonly used chemicals for solvent bonding** (see chart).
- **Secure Treatment Device** - The final assembly had **sufficient tube-to-fitting bond strength** to reduce the risk of glucagon leakage and loss of flow to the person receiving the therapy.

BOND TEST RESULTS TO PP LUERS WITH VARIOUS SOLVENTS



BOND STRENGTH AFTER FILLING WITH DMSO AND NMP SOLVENT RESISTANCE



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