



An Eldon James Company

Eliminating Adhesives in Medical Tubing Assemblies

**A Case Study: Bonded Connector Assemblies Compared
With Single-Barb Fitting Assemblies**

Eliminating Adhesives in Medical Tubing Assemblies

Bonded Connector Assemblies Compared With Single-Barb Fitting Assemblies

A case study

The Challenge

To reduce the manufacturing time and cost for a customer designed medical assembly.

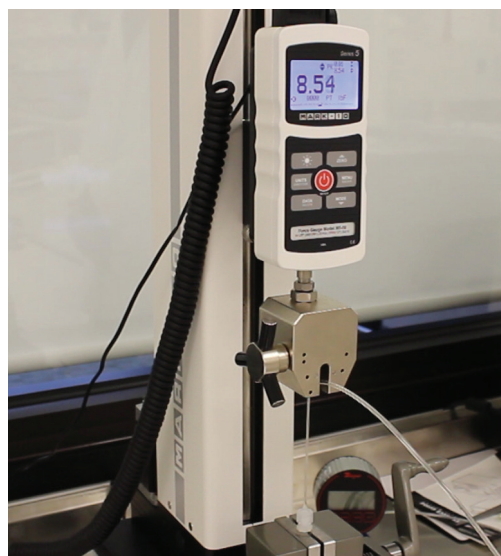
The assembly specified sections of tubing extruded from **Teknor Apex MD 585** TPE resin that were to be bonded to luer fittings made from a USP Class VI material. The completed assemblies were required to meet specific pull, flow and leak tests.

Initially, our Design Team considered manufacturing bondable (glue-in style) luers from TPE because similar materials tend to create more stable bonds. Although the TPE material met all of the regulatory requirements and was overall an excellent material choice, using a high durometer TPE material to produce the luer components would not contain manufacturing costs.

Eldon James Corp. already manufactured standard, single-barb luer sizes in a USP Class VI compliant polypropylene material (a lower cost alternative to TPE), but retooling to make glue-in style connectors would add time and expense to the project and there was a risk that the dissimilar components would not bond as well. The polypropylene material had been previously qualified by the customer for other projects so additional validation time and cost savings could be realized if the barbed luers could meet the project performance requirements.

reviewing several options, the Design Team at Eldon James developed a high level of confidence that standard, single-barbed luer fittings would meet or exceed the requirements established for bonded (glue-in) fittings. A proposal was presented to the customer and an agreement was reached to immediately begin performance validation trials. In order to maintain the aesthetic

integrity of the assembly, the customer required that no addition clamps or fastening devices would be used to secure the connection.



Pull test on a gas sample line assembly with no adhesives.

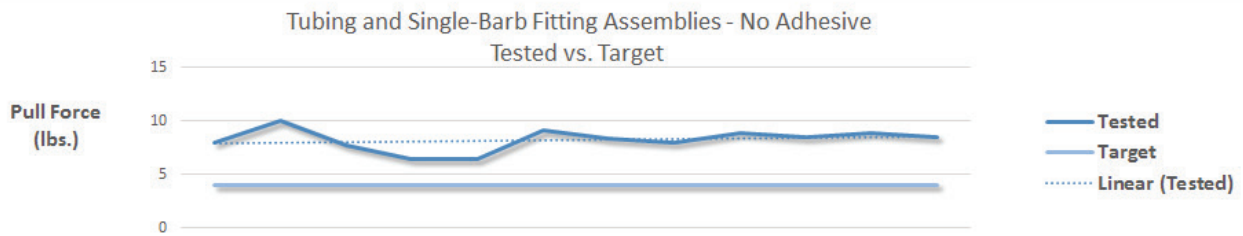
The Results

Performance acceptance criteria for the assembled device were as follows:

1. Fittings must withstand a pull-off force of 4 pounds or greater.
2. Flow test – minimum 200CC/minute flow @ 40 cm H₂O or less (small ID tubing and luer size)
3. Leak Test – less than .009 LPM leakage @ 60 ±1 cm H₂O

Single-barbed fittings consistently exceed the required pull force (see Figure 1), while also surpassing all other criteria originally established for bonded (glue-in) fittings. The table represents a typical example from 1000 tested assemblies.

Figure 1 - Barbed Fitting Validation Results



Top 8 Advantages

Several additional cost and time saving benefits related to the use of single-barb fittings came to light during the validation trials. Here are the top 8 advantages:

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ADVANTAGES TO SINGLE-BARB / NO ADHESIVE ASSEMBLIES

1. Single step process
2. No risks associated with using volatile organic compounds
3. Non-bondable or dissimilar materials compatibility is not an issue
4. Low risk for cross contamination
5. Cure time is not a factor
6. Additional ventilation systems or safety precautions are not required
7. Concerns related to aging, thermal cycling and chemicals affecting the connection are alleviated
8. Additional document maintenance that is required for tracking glue/solvent expiration and lot numbers is unnecessary

Conclusion

Where cost is a factor, the use of single-barb tube connectors provides a viable alternative to using bonded or glue-in fittings. Single-barb fittings exceeded the specification requirements established for bonded fittings, without any sacrifice in performance.



Test Equipment used in this study:

Pressure monitor: Dwyer model DP6-102 (0-15 psi)

Force gauge: Mark 10 model M5-50 (0-55 lb)

Flow meter: DUT model FMA-4308 0-500 sccm @70 °F

About EJ BioMed

EJ BioMed, an Eldon James company is an ISO Class 7 cleanroom production facility specializing in the manufacturing of PVC-free and BPA-free tubing, luers and hose connectors used in the medical and bioprocess applications. Autoclavable TPE tubing, bag ports, luers and connectors made with USP class VI resins are manufactured to the highest quality standards in an ISO 9001 and ISO 13485 certified environment. The company offers partnership manufacturing capabilities that include: extrusion, injection molding and single-use assembly.



ISO Class 7 Cleanroom Extrusion and Injection Molding



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