

WHITE PAPER 0138

Overmolded

Connection Performance
in Single-Use Systems



BIOPROCESS SOLUTIONS | LIFE SCIENCES



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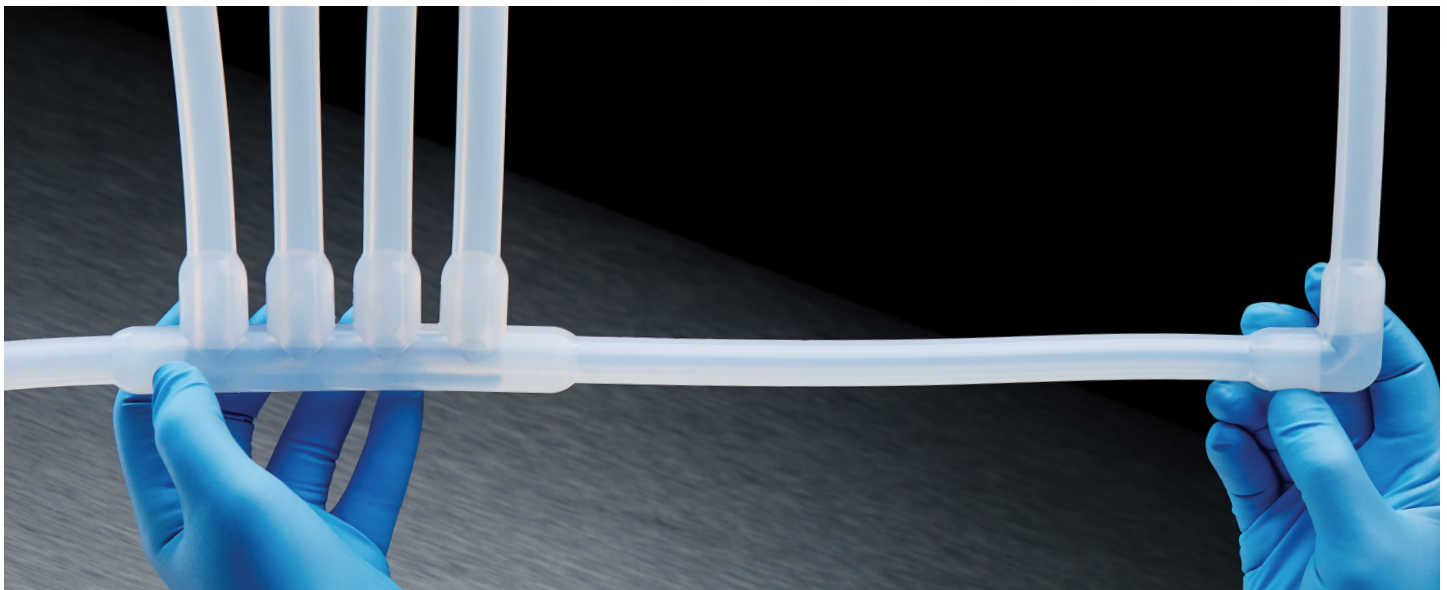
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Overmolded assemblies improve process integrity in single-use biopharmaceutical systems by reducing leak points, eliminating operator variability, and ensuring compliance with USP <788> and <85> standards.

TABLE OF CONTENTS

Abstract	3
Introduction	4
Performance Testing and Materials Selected for Evaluation	4
Tubing Selection	4
Overmold	4
Barbed Fittings as a Benchmark for Comparison	4
Retainers Used in Mechanical Assemblies	4
Sterilization	4
Demonstrating Robustness	5
Controlled Manufacturing for Reduced Risk and Variability	5
Engineered Connection Strength	5
Tensile Testing	5
Burst Testing	6
Streamlined Design Offering Functional Advantages	7
Reduction of Leak Points	7
Compact Assembly Footprint and Reduced Internal Volume	7
Simplified Extractable Profile – Avoidance of Validating Diverse Materials	7
Limited Dead Volume	8
Seamless Fluid Path	9
Additional Testing and Compliance .	11
USP <788> Sub-visible Particulate Matter Testing	11
USP <85> Endotoxin Testing	11
Integrity Testing	11
Conclusion	12



ABSTRACT

Saint-Gobain Life Sciences has recognized the advantages of overmolding over traditional mechanical connection methods and has pioneered the development of overmolded solutions in the field of single-use assemblies. This white paper presents experimental evidence and supporting data that demonstrates the superior performance of overmolded assemblies across multiple dimensions.

Overmolded assemblies are manufactured using a validated, controlled, and monitored injection molding process, reducing variability and risk compared to manual assembly. They are engineered for strength, exhibiting superior tensile and pull resistance while meeting the pressure specifications of the tubing. While minimizing leak risk is essential across all modalities, including mAbs, vaccines, and peptides such as GLP-1, it becomes particularly critical in applications involving highly potent active pharmaceutical ingredients (HPAPIs), both such as ADCs (Antibody Drug Conjugates), where safeguarding operator exposure and maintaining product integrity are paramount. By eliminating multiple manual connection points, overmolding significantly reduces leak risks and simplifies the extractables profile, as the molded material is similar to the tubing itself. This material compatibility reduces the need for disassembly prior to disposal, streamlining end-of-life handling and supporting more sustainable practices. Even if single-use assemblies are not recyclable at the end of their life because of their status, Saint-Gobain Life Sciences is committed to improve circularity for easier dismantling and better recycling.

Additional benefits include a reduced assembly footprint and internal volume, minimized dead space, and a seamless fluid path, all contributing to improved process integrity and product purity. Fluid extracts from overmolded assemblies successfully meet USP <788>, Particulate Mater in Injections and are below the 0.25EU/mL limit per USP <85> testing. Overmolding assemblies have also been subjected to pressure decay testing using both air and helium, further confirming the reliability and robustness of overmolding.

Overmolding features collectively support compliance with regulatory expectations, particularly those outlined in Annex 1, by promoting product-material compatibility, ensuring component integrity and mechanical robustness, reducing process complexity, and minimizing particulate contamination.



INTRODUCTION

In single-use biopharmaceutical assemblies, connection integrity plays a critical role in ensuring process reliability, product safety, and operational efficiency. Traditionally, mechanical connections such as barbed fittings and clamps have been widely used to join tubing and components. These connections, while effective when properly assembled, may present a higher sensitivity to operator technique, which can influence leak performance. Mechanical connections may also lead to greater hold-up volume and shear stress, factors that may compromise fluid continuity and overall system performance.

Overmolded connections offer a robust alternative, providing seamless, bonded interfaces that eliminate voids and dead legs. This design enhances fluid flow by minimizing shear and hold-up volume, while also delivering superior mechanical strength and leak resistance. Saint-Gobain Life Sciences' overmolded assemblies are engineered specifically for pharmaceutical, biotechnology, and laboratory applications, offering a high-performance solution that supports critical fluid transfer needs through improved strength, reliability, and flow continuity.

PERFORMANCE TESTING AND MATERIALS SELECTED FOR EVALUATION

To evaluate the performance and integrity of overmolded assemblies, testing was conducted using components representative of those commonly employed in biopharmaceutical manufacturing processes. These materials were selected because they reflect both the methods used in assembly and the types of products typically produced. Assemblies incorporating these components underwent a series of evaluations, including tensile strength, burst pressure, fluid flow modeling, particulate analysis, and overall integrity testing. The following components were included in the assemblies tested:

Tubing Selection:

- Sani-Tech® STHT®-C-250-4 (0.250" ID × 0.500" OD [6.35 mm × 12.7 mm]) was used in all assemblies tested

Overmold:

- Sani-Tech® LIM was used in the coupler overmolded connections
- Injection overmolded coupler connection #IM00209

Barbed Fittings as a Benchmark for Comparison:

- Two different polypropylene barbed coupler fittings were used:
 - Pure-Fit® Coupler Fitting– PFC250PPAF
 - Competitor Coupler Fitting

Retainers Used in Mechanical Assemblies:

- Cable Ties

Sterilization:

- Assemblies were exposed to gamma irradiation @ 25 - 40kGy

DEMONSTRATING ROBUSTNESS

Controlled Manufacturing for Reduced Risk and Variability

Overmolded assemblies offer additional assurance by eliminating manual assembly steps and mechanical interfaces that are prone to human error, wear, and installation variability over time. By replacing these with a validated process, overmolding ensures consistent performance and long-term sealing integrity. Validation data confirms that the overmolding process is both reliable and repeatable – demonstrating robust machine capability and process control across multiple production runs and harmonized performance across our global manufacturing sites. This proven consistency reduces the risk of failure during handling, sterilization, and dynamic operation, offering greater assurance in life sciences applications.

Engineered Connection Strength

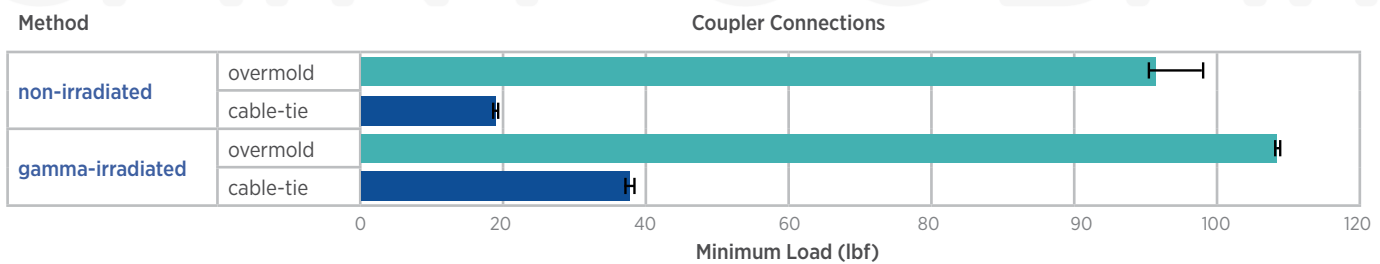
Tensile Testing

The mechanical integrity of coupler assemblies (overmold vs mechanical) was evaluated using standardized tensile testing performed on an Instron universal testing system. Test specimens were subjected to uniaxial tensile loading at a controlled crosshead speed of 20"/minute (50.8 cm/min) until mechanical failure occurred. The maximum load at failure (reported in pounds-force, lbf) was recorded as a measure of ultimate tensile strength at the coupler interface.

Overmolded assemblies exhibited superior performance, demonstrating a 3-4x increase in tensile strength compared to conventional mechanical connections utilizing barbed fittings with cable ties. This enhanced mechanical robustness is particularly important during routine installation and handling, where assemblies may be subjected to tensile stresses, such as those encountered during pump set-up, tubing routing, or extraction and installation in isolator environments, (for example, when withdrawing in assemblies from a DPTE-BetaBag).

While the maximum tensile loads measured in testing may exceed the forces typically seen during normal operation, the increased tensile strength of overmolded connections can, in rare cases, help prevent unintended disconnection when tubing is placed under temporary load or stretching during set-up. The increased tensile load capacity of overmolded assemblies mitigates the risk of disconnection or leakage due to inadvertent pulling or snagging, thereby improving system reliability and process safety.

Figure 1: Maximum load for assemblies



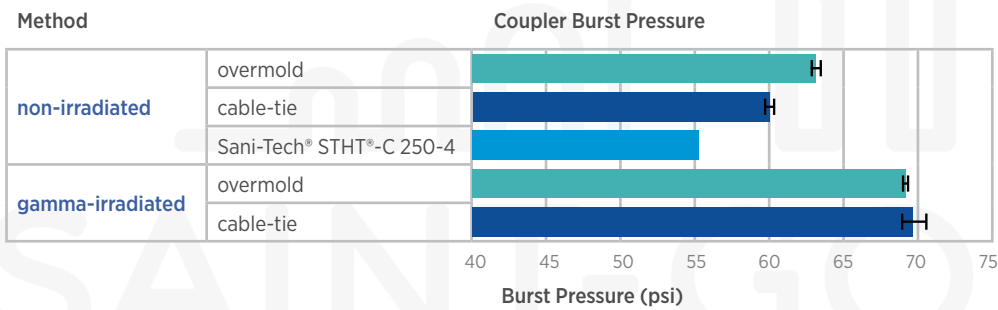
Burst Testing

Burst pressure refers to the maximum internal hydraulic pressure that a tubing or assembly can withstand before failure, serving as a critical indicator of mechanical integrity and safety under pressurized conditions. Burst pressure testing was conducted in accordance with ASTM D1599 for plastic pipe, tubing, and fittings. All tests were performed at ambient room temperature (approximately 23 ± 2°C).

For this study, both overmolded and mechanically connected assemblies were evaluated using Sani-Tech® STHT®-C-250-4 silicone tubing (0.25" ID × 0.50" OD). Assemblies were tested in both non-irradiated and gamma-irradiated states, with irradiation doses ranging from 25 to 40 kGy.

Pre-irradiation, overmolded assemblies demonstrated slightly higher burst pressure compared to mechanically connected assemblies, with both exceeding the STHT®-C tubing datasheet reference value (56 psi). Post-irradiation, both overmolded and mechanically connected assemblies showed improved burst pressure performance, and the results demonstrated no statistically significant difference between the two connection methods in the gamma-irradiated condition. In every tested configuration, failure occurred in the tubing rather than at the connection, indicating that both connection methods provide sufficient mechanical robustness under hydraulic loading.

Figure 2: ASTM D 1599 Burst Testing Results

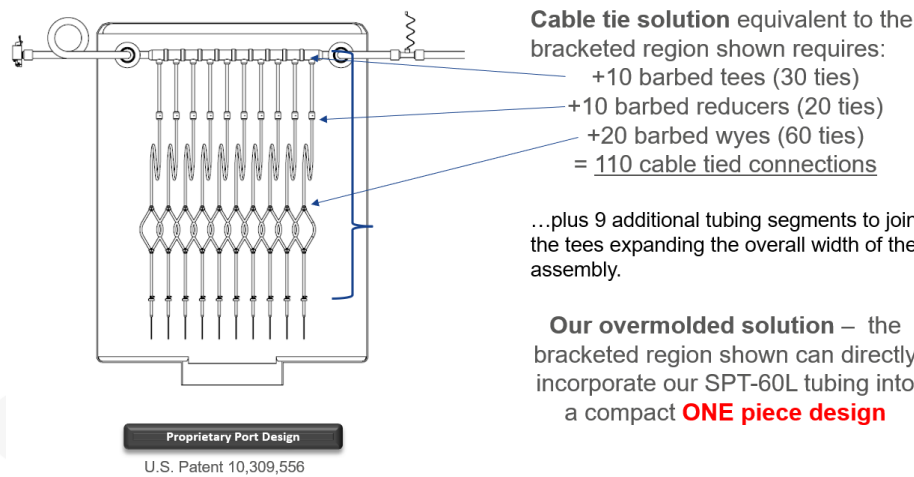


STREAMLINED DESIGN OFFERING FUNCTIONAL ADVANTAGES

Reduction of Leak Points

As illustrated in Figure 3, overmolding streamlines assembly design by consolidating multiple components into a single, integrated structure. In this example, a traditional mechanical joining approach requires 110 individual connections and several tubing segments, increasing complexity and the potential for leaks. In contrast, the overmolded design significantly reduces connection points, simplifying the assembly and enhancing reliability.

Figure 3: Overmolded Fill Finish Assembly



Compact Assembly Footprint and Reduced Internal Volume

Overmolding offers a distinct advantage in minimizing both the physical footprint and internal volume of fluid assemblies. By integrating connection points into a single molded joint, overmolding eliminates the need for bulky mechanical components such as clamps, cable ties, and fittings. A streamlined overmolded design not only conserves valuable space within the assembly but also reduces the internal volume where fluid may stagnate or become trapped. The result is a more compact, efficient system that supports better fluid dynamics, simplifies installation, and enhances overall process cleanliness, particularly critical in high-purity applications.

Simplified Extractable Profile – Avoidance of Validating Diverse Materials

Overmolded assemblies help streamline the validation process by minimizing the number of fluid contact materials. In conventional mechanical assemblies, barbed fittings introduce additional polymers that require separate extractables testing, adding complexity and time to qualification efforts. Overmolding eliminates these components by forming a single, continuous connection using a polymer material typically matched to the tubing. This approach simplifies extractables analysis, reduces regulatory overhead, and supports consistent material compatibility across applications.

Limited Dead Volume

Fluid hold-up is a critical parameter in the design of a tube assembly. In the biopharmaceutical industry, minimizing fluid hold-up in tubing assemblies ensures higher product recovery, better process control, lower contamination risk, and overall improved process economics. It's a critical parameter in single-use system design. This is shown below with a visual representation of a colored liquid and with computational fluid dynamics (CFD) modeling in the next section.

Colored liquid was passed vertically through assemblies for a visual representation of hold-up volume. An uninterrupted fluid path is observed for the overmolded connection (Figure 4) compared to the mechanical connection with a barbed fitting that shows the interruption of the fluid path and the blue liquid that remains after emptying the line (Figure 5).

Figure 4: Overmolded Coupler showing uninterrupted flow through the assembly and when emptied no hold-up volume



Figure 5: Barb fitting B showing restriction of fluid and hold-up volume at the barb when emptied



Seamless Fluid Path

Computational fluid dynamics (CFD) modeling was used to evaluate pressure drop (ΔP) and shear stress across various tubing and connector configurations commonly used in biopharmaceutical systems. Shear sensitivity is a critical consideration in bioprocessing, particularly when handling shear-sensitive fluids such as cell proteins, or other biologics.

A laminar flow (Navier-Stokes equations for fluid flow) was used for the model. It was assumed that the inlet rate was 18mL/s (0.285 gal/min) with zero backpressure.

Material Properties:

- Fluid with density 998.6 kg/m³ and viscosity 1 cP to simulate aqueous-based protein solution at low end of viscosity range
- Fluid with density 998.6 kg/m³ and viscosity 30 cP to simulate protein-based solution at high end of viscosity range

A straight overmolded connection with tubing of 0.250 in x 0.375 in (6.35 mm x 9.53 mm) was compared to two different polypropylene barbed fittings that are used for tubing of the same size (Figures 6 and 7).

Figure 6: Pure-Fit® fitting used in the model

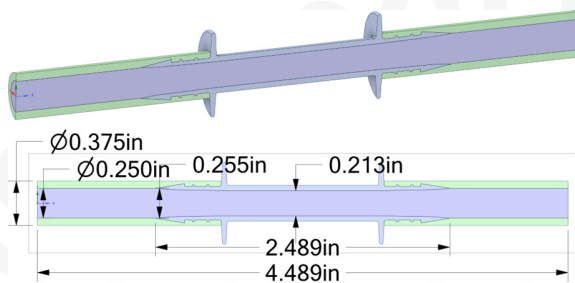


Figure 7: Competitor fitting used in the model

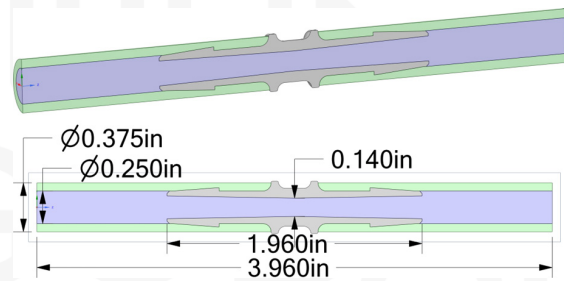
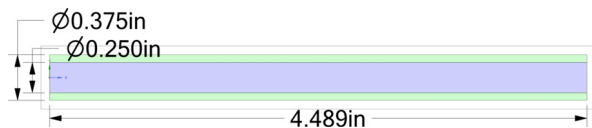


Figure 8: Straight coupler overmolded connection IM00209 for 1/4" ID (6.35 mm ID)



The overmolded coupler has an advantage in handling shear-sensitive fluids thanks to its seamless flow path, which eliminates the transitions typically present in mechanically assembled connections using barbed inserts. This smooth geometry is key to reducing both pressure drop (ΔP) and maximum shear stress, two critical performance metrics for fluid integrity. While barbed fittings induce high levels of shear stress as fluid flows through constrictions at the connection, the unique Saint-Gobain Life Sciences' Pure-Fit® design shows a reduction compared to the competitor's fitting. Among the connections tested, the "straight coupler overmolded connection IM00209" demonstrated the best performance, with the lowest ΔP and lowest maximum shear stress (Figures 9 and 10 on next page).

Figure 9 (next page) shows pressure drop (ΔP) results from the CFD calculations. There are two important results shown in Figure 9. First, ΔP increases with viscosity for each coupler. Second, the ΔP is much higher for the competitor barbed fitting ("1/4 in Barbed Fitting B"); the reason is that the competitor barbed fitting has blunt edges and reduced cross-section that slow down the fluid flow through the fitting. At 1cP, competitor ΔP is 15x higher (1397 vs. 91 Pa), and at 30 cP competitor ΔP is 4x higher (6318 vs 1624 Pa).

Figure 10 below shows shear stress results from the CFD calculations. In this figure, notice that shear stress increases with viscosity for each coupler. Also note that the shear stress is much higher for the competitor barbed fitting (1/4 in Barbed Fitting B); the reason is that the competitor barbed fitting contains blunt edges and reduced cross-section that resist the flow and causes shear in the fluid. At 1cP, competitor max shear stress is 40x higher (48 Pa vs 1.2 Pa), and at 30 cP competitor max shear stress is 13x higher (297 Pa vs. 24 Pa).

This performance advantage for the overmolded coupler is beneficial in applications where shear-induced degradation, phase separation, or viscosity loss can critically impact product quality and process efficiency. Importantly, the ranking of performance, Overmolded Coupler > Saint-Gobain Life Sciences' Pure-Fit® > Competitor, holds true across the entire viscosity range tested (1-30 cP), confirming the robustness of the overmolded design under varying fluid conditions. The competitor fitting, with its blunt barbed geometry and reduced cross-sectional area, consistently showed the highest ΔP and shear stress (Figure 9 and 10 below), underscoring the importance of flow-optimized design in maintaining fluid integrity.

Figure 9: Comparing Pressure Drop

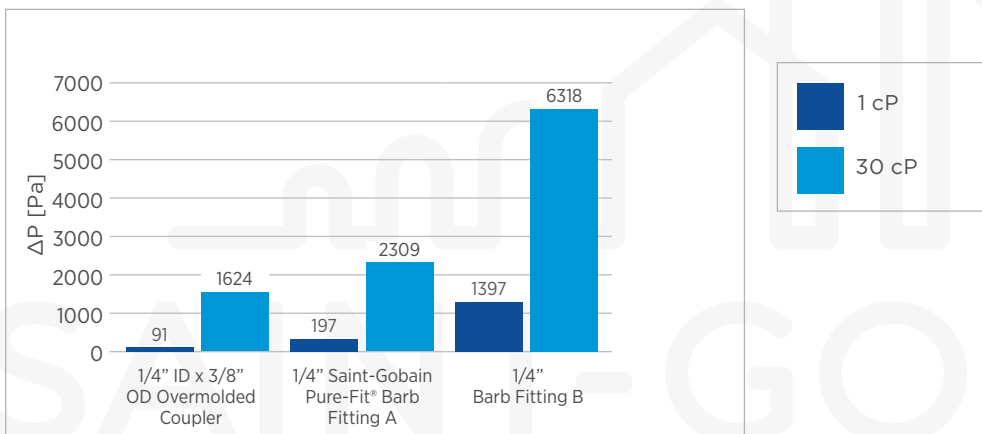
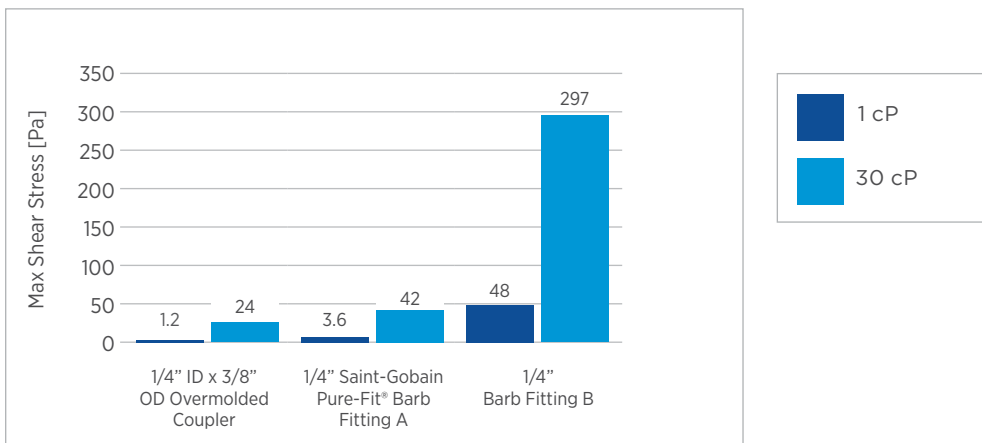


Figure 10: Comparing Shear Stress



ADDITIONAL TESTING AND COMPLIANCE

To further validate the reliability and safety of Saint-Gobain Life Sciences' overmolded assemblies, a series of compliance and performance tests were conducted. These tests were selected to reflect industry standards and address critical concerns in pharmaceutical and bioprocessing environments.

USP <788> Sub-visible Particulate Matter Testing

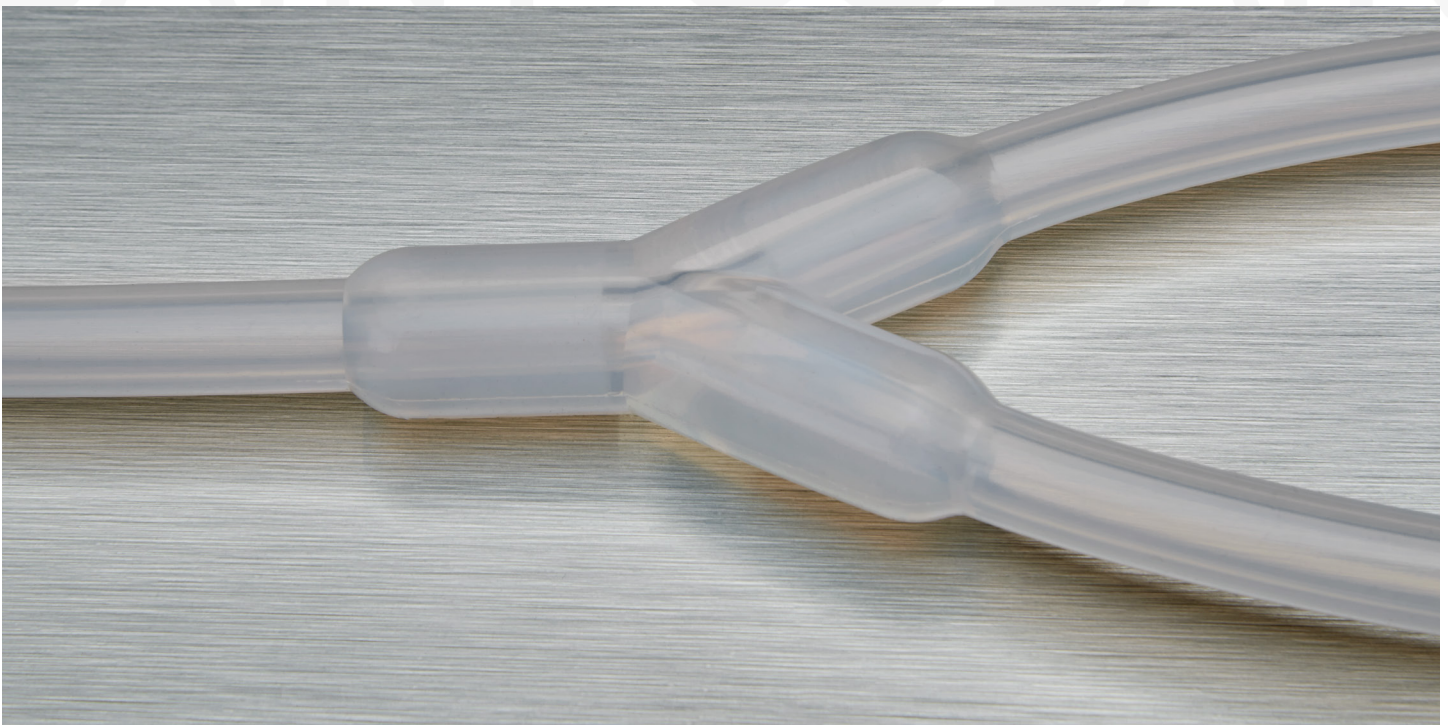
Testing in accordance with USP <788>, particulate matter in injections, revealed no significant differences between overmolded assemblies and traditional mechanical connections, indicating that both connection types pass the stringent particulate cleanliness requirements for biopharmaceutical applications. This finding supports the suitability of overmolded assemblies in critical applications requiring high particulate cleanliness.

USP <85> Endotoxin Testing

Routinely tested products representative of overmolded assemblies have consistently met Saint-Gobain Life Sciences' strict limit of <0.25 EU/mL when tested in accordance with USP <85> Bacterial Endotoxins. These routine tests confirm compliance with endotoxin requirements, ensuring the safety and suitability of overmolded assemblies for use in biopharmaceutical applications. This approach supports confidence in environments where strict contamination control is essential. Compliance with USP <85> reinforces the reliability of overmolded components in maintaining product integrity and protecting patient safety.

Integrity Testing

Assemblies were initially subjected to pressure decay testing using air to verify their ability to maintain pressure integrity. Both overmolded and mechanically connected assemblies successfully passed this test. To further evaluate sealing performance under more stringent conditions, additional assemblies were submitted to a third-party laboratory for helium leak testing. These assemblies also passed, confirming that both connection types can maintain a seal suitable for use in critical biopharmaceutical applications. While helium leak performance was comparable, overmolded assemblies offer additional assurance by eliminating manual assembly steps and mechanical interfaces that are more susceptible to human error, wear, or installation variability over time. The inherent consistency of the overmolding process contributes to long-term sealing reliability and reduced risk of process failure during handling, sterilization, or dynamic operation.



CONCLUSION

As single-use technologies continue to evolve in biopharmaceutical manufacturing, the need for reliable, efficient, and low-risk fluid handling solutions has become increasingly critical. Overmolded assemblies directly address this need by simplifying system architecture, reducing manual assembly steps, and enhancing overall process integrity. The design eliminates the complexity of multiple mechanical connections, each a potential failure point, and replaces them with a single molded interface that improves both performance and safety.

Manufactured through a validated, controlled, and monitored injection molding process, overmolded assemblies eliminate operator-dependent variability, ensuring consistent dimensional accuracy and sealing integrity across production batches. This precision translates into superior tensile and pull strength, (up to 4 times vs. mechanical connections), with assemblies engineered to meet the pressure specifications of the tubing being overmolded. This increased tensile load capacity allows for more robustness during installation of single-use solutions in constrained environments like isolators and it improves system reliability and process safety.

Leak prevention is especially vital in bioprocessing environments, where exposure across all modalities - from monoclonal antibodies (mAbs) and vaccines to drug substances, peptide therapeutics such as GLP-1, and highly potent active pharmaceutical ingredients (HPAPIs), including antibody-drug conjugates (ADCs) - can pose serious safety risks. Additionally, preventing leaks helps protect against the loss of valuable product, as leakage can result in significant financial impacts and operational setbacks.

Overmolding delivers a compact, integrated connection that reduces assembly footprint and internal volume, improving fluid dynamics and minimizing dead space. This design supports better system ergonomics while enhancing cleanliness and reducing contamination risk. Additionally, the seamless fluid path helps preserve fluid integrity by minimizing shear forces and pressure drop, reducing the likelihood of shear-induced degradation, phase separation, or changes in fluid viscosity.

From a regulatory and validation standpoint, overmolding simplifies the extractables profile by using a single polymeric material system, similar to the tubing itself. This reduces the need for complex material compatibility assessments and supports compliance with industry standards. Additionally, the use of a unified material system supports more sustainable end-of-life handling by reducing the need for disassembly prior to disposal, aligning with broader efforts to improve circularity in single-use bioprocessing. Fluid extracts from overmolded assemblies successfully meet USP <788>, Particulate Matter in Injections, and are below the 0.25EU25 EU/mL limit per as defined by USP <85> endotoxin testing. Overmolded assemblies have also been subjected to rigorous pressure-decay testing using both air and helium, confirming their reliability under demanding processing conditions. From a sustainability perspective, overmolding offers several advantages. Using the same polymer, or a closely compatible polymer family, for both the tubing and the overmold creates a unified material system that reduces complexity and supports future circularity efforts as recycling pathways evolve. This material alignment also simplifies end-of-life handling by avoiding the need to disassemble or sort different polymers. Additionally, the elimination of manual connection components such as barbed fittings, cable ties, and clamps reduces resource consumption, minimizes the number of small parts discarded after use, and results in a more compact, integrated assembly.

In summary, overmolded assemblies offer a validated, high-performance alternative to traditional mechanical connections, enhancing safety and reliability in biopharmaceutical manufacturing and meeting the most stringent requirements from Annex 1. Adoption of overmolded assemblies aligns with the industry's ongoing shift towards automation, standardization, and risk mitigation and sustainability in single-use system design.

About

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Saint-Gobain Life Sciences

The Bioprocess Solutions business of Saint-Gobain Life Sciences is an industry-leading provider of materials science-based solutions for single-use fluid management, including TPE and silicone tubing, connection and flow control components, bioprocess and cell culture bags, filtration products, sensors, and over-molded technology, all available in customized assemblies that are produced in 19 manufacturing facilities located around the world. To find out more about Saint-Gobain Life Sciences and to learn how we can assist you with your application needs, [visit our website](#).