

Final Fill (C-Flex®)

The Challenge

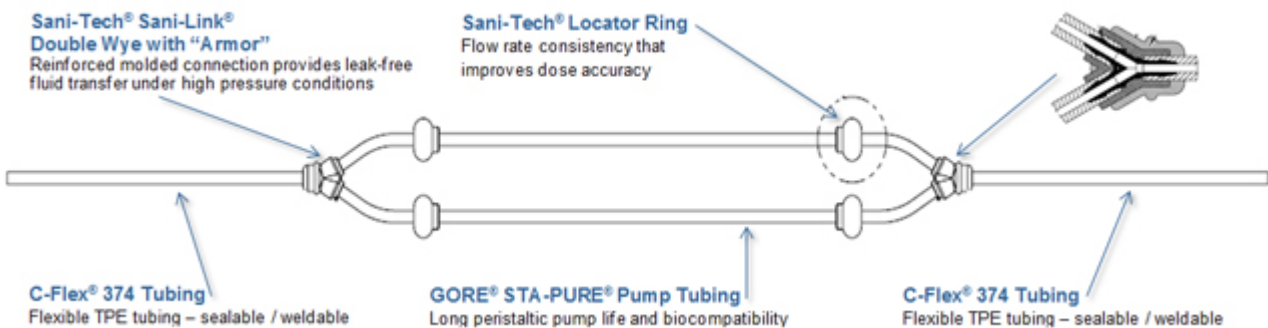
Cancer drug manufacturer experienced repeated air/fluid leakage and variable volume dose delivery during their final fill operation. This failure resulted from a mechanical tubing assembly with barbed fittings that was provided by their current supplier. It was critical that the new single-use assembly replacement could endure prolonged peristaltic pump stress and achieve the desired small volume dose delivery. The implied risk was very high during this final fill operation as two production batches had been previously lost due to original mechanical assembly failure. Further batch lost was not an option.

The Saint-Gobain Collaborative Design Services' Solution

The manufacturer's original mechanical assembly had included GORE® STA-PURE® Pump Tubing but delivered flow rate inconsistency and fluid leakage at wye-connections during final fill operations due to product performance limitations. Saint-Gobain applied design innovation to create a new Sani-Tech® Sani-Link® overmold technology that would securely bond the platinum-cured silicone to GORE STA-PURE Pump Tubing and polypropylene to C-Flex® 374 assembly segments. Also, a locator ring was incorporated into the double wye segment to improve dose accuracy. The end result was a robust final fill single-use system.

Customer Experience

Customer's final fill operation delivered improved dose control resulting in greater process repeatability. This product development generated new customer interest in forming a global strategic relationship with Saint-Gobain for customized bioprocess solutions.



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