



ONE FLEX

Biopharmaceutical Grade TPE Tubing

BIOPROCESS SOLUTIONS



WELDING TPE TUBING

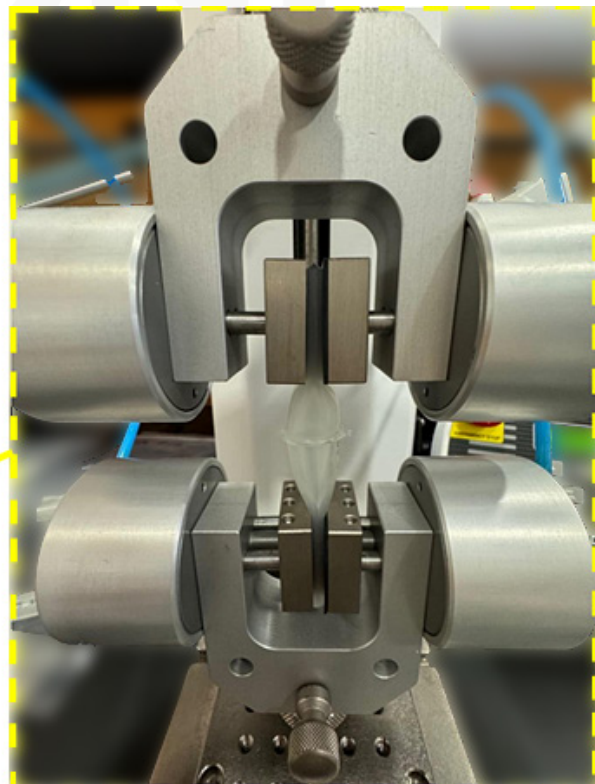
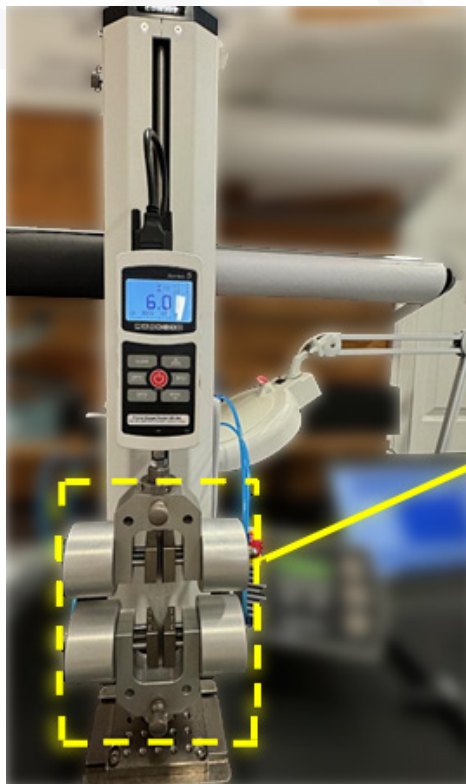
Thermoplastic elastomer (TPE) tubing is often chosen in the biopharmaceutical industry for applications requiring tube welding due to its unique physical properties. In assessing the suitability of tubing used in those applications, important performance parameters, such as hydraulic integrity testing and tensile strength, are used to evaluate product performance.

Combinations of gamma-irradiated Purity One™ OneFlex, AdvantaPure AdvantaFlex®, and Saint-Gobain C-Flex® 374 3/8" x 5/8" tubing were welded with a Sartorius BioWelder®, and testing was conducted to evaluate performance of dry welds utilizing pre-programmed settings. The goal was to qualify BioWelder® program settings that provide a robust weld using Purity One™ OneFlex tubing welded to itself, and co-welded to AdvantaPure AdvantaFlex®, and Saint-Gobain C-Flex® 374 tubing.

TEST METHODS

The tests to evaluate the different combinations of tubing and the robustness of the welds included:

1. **Hydraulic Integrity Testing** to maximize pressure, ballooning, or burst (leakage).
2. **Tensile Strength Testing** to maximize tensile load (force) or break.



PERFORMANCE EVALUATION METHODS

Hydraulic Integrity Testing

Performance testing for hydraulic integrity was performed via:

- Samples were visually inspected after the completion of the welding operation.
- Both Ends of the tubing sample were assembled with stainless steel hose barbs attached and secured using stainless steel band clamps.
- Tubing samples were attached to the hydraulic pressure source outfitted with a pressure gauge.
- Tubing was filled with deionized water and all entrained air verified for removal via pumping in a recirculation loop. Thereafter, the outlet valve downstream of the test tubing was closed.
- Pressure was then slowly increased in the sample unit until it began to balloon or leak (burst). Maximum pressure was recorded over a one-minute period until 1 bar (14.5 psig) was attained and then the pressure was increased to 75 psig or ballooning, whichever came first.

Tensile Strength Testing

Performance testing for tensile strength was performed via:

- Samples were visually inspected after the completion of the welding operation.
- The test tubing was secured and aligned in the tensile test machine using pneumatic grips.
- The tensile test was conducted at a crosshead speed of 10 inch/minute
- The maximum tensile force, elongation at break, and failure mode was recorded after the weld or tube failed.

ACCEPTANCE CRITERIA

Attribute	Acceptable	Unacceptable
Hydraulic Integrity	No leakage during test to 1 bar (14.5 psig)	Leakage during test to 1 bar (14.5 psig)
Maximum Hydraulic Pressure Attained	≥ 1 bar (14.5 psig)	< 1 bar (14.5 psig)
Maximum Tensile Load Attained	≥ 50% of C-Flex® tensile Strength noted in BioWelder® Validation Guide	< 50% of C-Flex® tensile Strength noted in BioWelder® Validation Guide
Visual Condition of Weld	Continuous, no gaps present in the weld	Gaps are present in the weld
Visual Condition of Weld during Hydraulic Test	No Ballooning, tube rupture at the weld during hydraulic test to 1 bar (14.5 psig).	Ballooning, tube rupture at the weld during hydraulic test to 1 bar (14.5 psig).

RESULTS

Hydraulic Integrity Testing

Hydraulic integrity tests performed post-welding demonstrated the thermal welds were robust and capable of maintaining greater than 1 bar (14.5 psig) for one minute without any discernible change deformation, integrity issues, or leakage for all tubing.

As the pressure was increased, the tubing became elongated, increased in outer diameter, and in some instances, formed a bulge along the tubing or at the weld. When ballooning or the bulge formed, the pressure was no longer able to be increased, resulting in an average maximum hydraulic pressure at approximately five times the acceptance criteria.

The average maximum hydraulic pressure attained for the test samples is shown in the chart below.

Tubing Type Welded to Tubing Type	Welding Parameter Name	Hydraulic Integrity at > 14.5 psig	Visual Condition of Weld at > 14.5 psig	Average Maximum Hydraulic Pressure (psig)
OneFlex to OneFlex	AdvantaFlex®	Acceptable	Acceptable	75.0
	C-Flex® 374	Acceptable	Acceptable	75.0
	TuFLux®	Acceptable	Acceptable	85.6
OneFlex to C-Flex®	C-Flex® 374	Acceptable	Acceptable	63.0
OneFlex to AdvantaFlex®	AdvantaFlex®	Acceptable	Acceptable	73.0
	C-Flex® 374	Acceptable	Acceptable	78.0
C-Flex® to C-Flex®	C-Flex® 374	Acceptable	Acceptable	57.5
AdvantaFlex® to AdvantaFlex®	AdvantaFlex®	Acceptable	Acceptable	73.0
C-Flex® to AdvantaFlex®	AdvantaFlex®	Acceptable	Acceptable	61.5
	C-Flex® 374	Acceptable	Acceptable	61.0

Controls:

- PurityOne OneFlex, unwelded, control tubing was 80 psig
- AdvantaFlex® unwelded, control tubing was 77 psig
- C-Flex® unwelded, control tubing was 65 psig

RESULTS

Tensile Strength Testing

Tensile strength tests performed post-welding demonstrated the thermal welds were robust and capable of exceeding 50% of the maximum tensile load for C-Flex® (gamma irradiated) noted in the BioWelder® Valdiaton guide (84.3 lbf for 3/8" x 5/8" C-Flex®). Due to the limitations of the tensile testing machine, the control, non-welded samples did not break at tensile forces of 98-123 lbf.

The average maximum tensile load for the test samples is shown in the chart below.

Tubing Type Welded to Tubing Type	Welding Parameter Name	Maximum Tensile Force Attained ≥ 42 lb _f	Visual Condition of Weld at >14.5 psig	Average Maximum Tensile Force (lb _f)
OneFlex to OneFlex	AdvantaFlex®	Acceptable	Acceptable	64.5
	C-Flex® 374	Acceptable	Acceptable	85.8
	TuFLux®	Acceptable	Acceptable	84.6
OneFlex to C-Flex®	C-Flex® 374	Acceptable	Acceptable	69.8
OneFlex to AdvantaFlex®	AdvantaFlex®	Acceptable	Acceptable	75.2
	C-Flex® 374	Acceptable	Acceptable	91.7
C-Flex® to C-Flex®	C-Flex® 374	Acceptable	Acceptable	64.5
AdvantaFlex® to AdvantaFlex®	AdvantaFlex®	Acceptable	Acceptable	78.7
C-Flex® to AdvantaFlex®	AdvantaFlex®	Acceptable	Acceptable	61.5
	C-Flex® 374	Acceptable	Acceptable	72.7

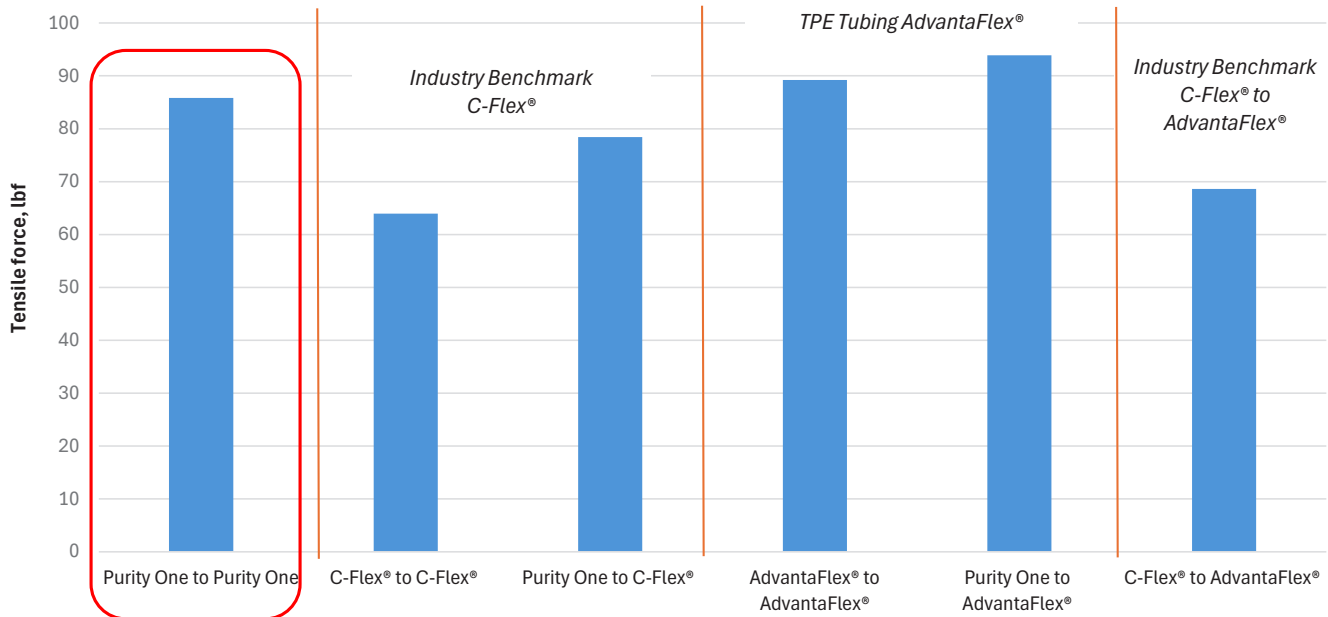
The average maximum elongation for the test samples is shown in the chart below.

Tubing Type Welded to Tubing Type	Welding Parameter Name	Maximum Tensile Force Attained ≥ 42 lb _f	Visual Condition of Weld at >14.5 psig	Average Maximum Elongation, inch
OneFlex to OneFlex	AdvantaFlex®	Acceptable	Acceptable	5.2
	C-Flex® 374	Acceptable	Acceptable	7.1
	TuFLux®	Acceptable	Acceptable	7.1
OneFlex to C-Flex®	C-Flex® 374	Acceptable	Acceptable	6.3
OneFlex to AdvantaFlex®	AdvantaFlex®	Acceptable	Acceptable	6.2
	C-Flex® 374	Acceptable	Acceptable	8.1
C-Flex® to C-Flex®	C-Flex® 374	Acceptable	Acceptable	6.4
AdvantaFlex® to AdvantaFlex®	AdvantaFlex®	Acceptable	Acceptable	6.6
C-Flex® to AdvantaFlex®	AdvantaFlex®	Acceptable	Acceptable	5.2
	C-Flex® 374	Acceptable	Acceptable	7.4

RESULTS

Tensile strength after co-welding 3/8" x 5/8" gamma-irradiated Purity One OneFlex Tubing:

Tensile Forces after Co-Welding: Gamma Irradiated, 3/8" x 5/8" Tubing
(with Purity One Tubing co-welded at the C-Flex Weld Setting)



CONCLUSION

Gamma-irradiated Purity One™ OneFlex TPE tubing in the 3/8" x 5/8" size is satisfactory for aseptic welding applications in biopharmaceutical processes with a Sartorius BioWelder®. Hydraulic integrity and tensile strength tests were acceptable for dry thermal welds across all combinations of Co-welded Purity One™ OneFlex, AdvantaPure AdvantaFlex®, and Saint-Gobain C-Flex® 374 tubing.

Hydraulic –All welded tubing easily attained the upper hydraulic pressure limit of >15 psig and on average reached a maximum pressure without any leakage or integrity issues, until ballooning occurred at greater than five times higher pressure. Overall, pressure ratings were comparable to other thermoplastic elastomer tubing in the industry.

Tensile – All welded tubing experienced tensile forces that exceeded 50% of the tensile strength specified for C-Flex® tubing in the Sartorius BioWelder® Validation Guide. The tests yielded the best results for Purity One™ OneFlex at the C-Flex® setting, in welding both to itself and to the other manufacturers' tubing.