





dvantaFlex TPE (thermoplastic elastomer) tubing addresses the need for a flexible, translucent, sterilizable, moldable, heat sealable, *and* weldable biopharmaceutical tubing for fluid processing. AdvantaFlex maintains its physical properties following sterilization processes, resists kinking, remains translucent for visible product flow, and does not become gummy.

Full BPOG standardized extractables test protocol has been performed by a fully-accredited, third-party test lab.

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# Key Features

- Sterile weldable and heat sealable
- Available as leak-proof molded connections and tubing
- Made from FDA-approved ingredients
- Certified free of silicone oils and animal-derived ingredients
- Sterilizable by autoclave or gamma radiation
- Available with validated sterility assurance of 10<sup>-6</sup> via gamma irradiation per ISO 11137 method VDmax 25
- Meets various ISO and USP standards, including Class VI
- Meets European Pharmacopoeia 3.2.2.1 standards
- REACH, RoHS and California Proposition 65 compliant
- Excellent low absorption and adsorption characteristics as compared to silicone
- Low permeability as compared to silicone
- Smooth interior for excellent flow and performance
- Translucent for fluid flow visibility
- Excellent tubing component for Single-Use systems
- Sizes from 1/8" (.125) through 1" (1.000) I.D.
- Custom sizes, lengths and packaging available
- Supplied double bagged; sealed in polybags at manufacture for cleanliness
- Documented lot traceable with identification on packaging
- Documented quality control per ISO 9001:2015
- Single resin validation no need to graft to other tubing materials like silicone for media filling and sampling that involves peristaltic pumps; helps eliminate operator errors
- "Extractables" test portfolio available upon request
- Included in our Rx-360 Joint Audit Program for Single-Use Systems

Full BPOG standardized extractables test results available on request



# better There is a alternative











#### SPECIFICATIONS

Product	I.D.		Wall (Ref.)		O.D.		Working Pressure		Standard Lengths	Standard Lengths
Number	(in.)	(mm.)	(in.)	( <b>mm.</b> )	(in.)	( <b>mm.</b> )		(21.1°C)	Coiled	on Spools
							(PSI)	(Bar)	(ft.)	(ft.)
APAF-BP-0125-0250	.125	3.18	.062	1.57	.250	6.35	30	2.1	50, 100	500
APAF-BP-0188-0313	.188	4.76	.062	1.57	.313	7.94	23	1.6	50, 100	
APAF-BP-0188-0375	.188	4.76	.094	2.38	.375	9.52	32	2.2	50, 100	-
APAF-BP-0250-0375	.250	6.35	.063	1.59	.375	9.52	20	1.4	50, 100	-
APAF-BP-0250-0438	.250	6.35	.094	2.38	.438	11.11	23	1.6	50, 100	300
APAF-BP-0250-0500	.250	6.35	.125	3.18	.500	12.70	30	2.1	50	_
APAF-BP-0313-0438	.313	7.94	.062	1.57	.438	11.11	21	1.4	50, 100	300
APAF-BP-0313-0500	.313	7.94	.094	2.38	.500	12.70	24	1.6	50	_
APAF-BP-0375-0500	.375	9.52	.062	1.57	.500	12.70	18	1.3	100	_
APAF-BP-0375-0563	.375	9.52	.094	2.39	.563	14.30	23	1.6	50	-
APAF-BP-0375-0625	.375	9.52	.125	3.18	.625	15.88	24	1.6	50, 100	150
APAF-BP-0500-0750	.500	12.70	.125	3.18	.750	19.05	22	1.5	50, 100	100
APAF-BP-0625-0875	.625	15.88	.125	3.18	.875	22.23	18	1.3	50	-
APAF-BP-0750-1000	.750	19.05	.125	3.18	1.000	25.40	17	1.2	50, 100	75
APAF-BP-0750-1125	.750	19.05	.188	4.76	1.125	28.58	18	1.3	100	_
APAF-BP-1000-1375	1.000	25.40	.188	4.76	1.375	34.93	18	1.3	25	-

Sold by standard lengths only. Add length suffix code to product number when ordering—see the Coil Length Legend at right for length suffix codes. Example: a 50 foot coil of .125 inch I.D. x .250 inch O.D. tubing is product number APAF-BP-0125-0250L. Add length and "S" to denote "spool" for products with lengths available on spools. Example: a 500 foot spool of .125 inch I.D. x .250 inch O.D. tubing is product number APAF-BP-0125-0250L. Working pressures are calculated from burst testing using a 3:1 safety factor. Coils and spools are supplied double bagged in heat-sealed polybags and bulk packed. Contact your AdvantaPure Sales Representative for other packaging options.

**Coil Length Legend:** 

P = 25 feet

L = 50 feet

K = 100 feet

#### **APPLICATIONS**

- Sterile filling
- Vaccine production
- Pharmaceutical sampling and delivery systems
- Single-Use systems
- Bioreactor processes
- Cell media, harvesting, and fermentation
- Pharmaceutical production and processing
- High purity water transfer
- Filtration

### Physical Properties

Specific Gravity	.89
Hardness, Shore A $\pm 5$	65
Ultimate Tensile Strength, PSI	1000
Ultimate Elongation, %	550
Tensile Modulus @ 100%, PSI	410
Tear Strength, Die B, PPI	240
Compression Set, % per ASTM D-395B	25
Maximum Operating Temperature, °F	275
Brittle Temperature, °F	-88

Values listed are typical for the material used in manufacture, except where noted, and are meant only as a guide to aid in design. Field testing should be performed to find the actual values for your application.

Phone: 215-526-2151 Toll Free Phone: 888-755-4370

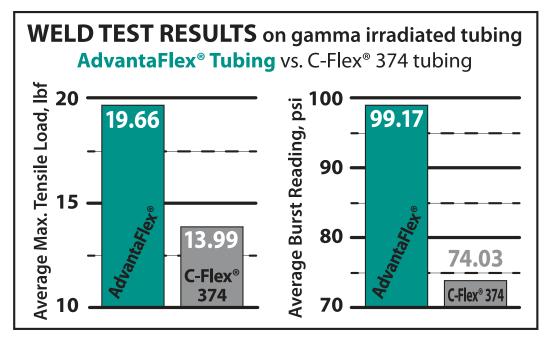
## GET BETTER WELD STRENGTH

#### Up to 40% stronger than C-Flex<sup>®</sup> 374

Increase your process security by reducing the risk of failure at the weld. AdvantaFlex welds hold stronger than C-Flex<sup>®</sup> 374 welds, providing a secure, sterile boundary to protect your investment.

Turn the page for more detailed test results, and visit **www.advantapure.com/advantaflex.htm** to view the tensile and burst test video.





C-Flex® is a registered trademark of Saint-Gobain Performance Plastics and is not endorsed, sponsored, affiliated or associated with NewAge® Industries, Inc.



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## WELD BURST AND TENSILE TESTING RESULTS

Test Type	Number of Lots Tested	Average Burst Reading - PSI	Average Max Tensile Load - Ibf						
Gamma Irradiated <sup>1</sup>									
AdvantaFlex to AdvantaFlex	3	99.17	19.66						
AdvantaFlex to C-Flex 374	3	80.73	15.24						
C-Flex 374 to C-Flex 374	3 74.03		13.99						
Combined Sterile Methods: Gamma Irradiated <sup>1</sup> to Autoclaved <sup>2</sup>									
AdvantaFlex to AdvantaFlex	3	103.43	21.18						
AdvantaFlex to C-Flex 374	3	90.17	18.15						
C-Flex 374 to AdvantaFlex	3	83.20	14.06						
C-Flex 374 to C-Flex 374	3	75.53	13.99						

<sup>&</sup>lt;sup>1</sup> Gamma irradiation exposure defined as a range with a minimum dose of 25 kGy and a maximum dose of 45 kGy.

 $^{\scriptscriptstyle 2}$  Steam autoclave, one cycle at 121°C for 1 hour.

Weld strength was derived by testing the weld site's ability to hold pressure (measured in pounds per square inch, psi) and the maximum tensile load (measured in pounds of force, lbf) it can take before failure.

All tubing welds were made on the Terumo SCD<sup>®</sup> IIB sterile tube welder. All tests were performed on 1/8" ID X 1/4" OD size tubing using the pre-programmed setting in the welder. A new welding blade was used for each individual test article. Ten samples were tested per lot, per the test method defined.

#### **Burst Test Procedure:**

Samples are visually inspected after the completion of the welding operation. Each sample is attached to a pressure source with a pressure gauge using a stainless steel mini Tri-Clamp<sup>®</sup> and secured with an Oetiker<sup>®</sup> one-ear stepless clamp. Tubing is filled with water and the open end closed off with a pinch clamp. Pressure is slowly increased in the sample until it begins to balloon or burst. Maximum pressure is recorded.

#### Tensile Weld Strength Test Procedure:

Samples are visually inspected after the completion of the welding operation. Plug gauges with rounded ends are inserted into each end of the sample to prevent crushing of the tubing by the grips during testing. The sample is secured and aligned in the tensile test machine using pneumatic grips with vee jaws. The tensile test is conducted at a crosshead speed of 20 in/min. The maximum force, elongation, and failure mode are recorded after the weld fails.

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#### AdvantaFlex Options

- Molded Single-Use Tubing Assemblies eliminate the need to splice silicone tubing sections into a process line
- Molded assemblies reduce the number of barbed fittings and cable ties needed *and* their potential for contamination.
  - leaks and a wasted batch of product
- Molded connections provide a smooth inner surface for even, unrestricted flow
- Choose from T's, Y's, crosses, reducers, mini and standard Tri-Clamps<sup>®</sup>, and BioClosure<sup>®</sup> container closures and inserts such as GL45's
- Available with validated sterility assurance of 10<sup>-6</sup> via gamma irradiation per ISO 11137 method VDmax 25
  - Sealed Tubing Ends for Single-Use applications
  - make it easy to maintain your sterile, closed system
  - Weld to bags or container closures for sampling and storage applications
  - Ideal for reducing operational costs, improving production efficiencies and decreasing cross contamination risks
  - Single-Use Sterile Bottle Assemblies provide a ready to use, cost effective solution for aseptic sampling, cell growth and filling applications
  - Robust molded closure design features a continuous flow path that reduces the risk of barbed fitting leaks and contamination





- Molded Tubing Ends are ideal for aseptic transfer and processing
- AdvantaFlex tubing is overmolded with a USP Class VI polypropylene mini Tri-Clamp to form a smooth fluid path
- The ends reduce leaks and cross contamination risks
- Available from stock in several tubing sizes and lengths





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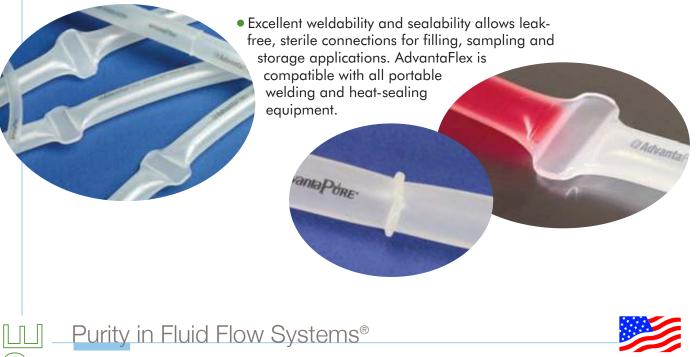




- Bioreactor Tubing Kits are built-to-order and clean room packaged
- Offer faster turnaround time, increasing your processing capacity
- Assembled from various components tubing, filters, connectors — for convenience and efficiency



#### Welding & Sealing AdvantaFlex





Advanta Pure®



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