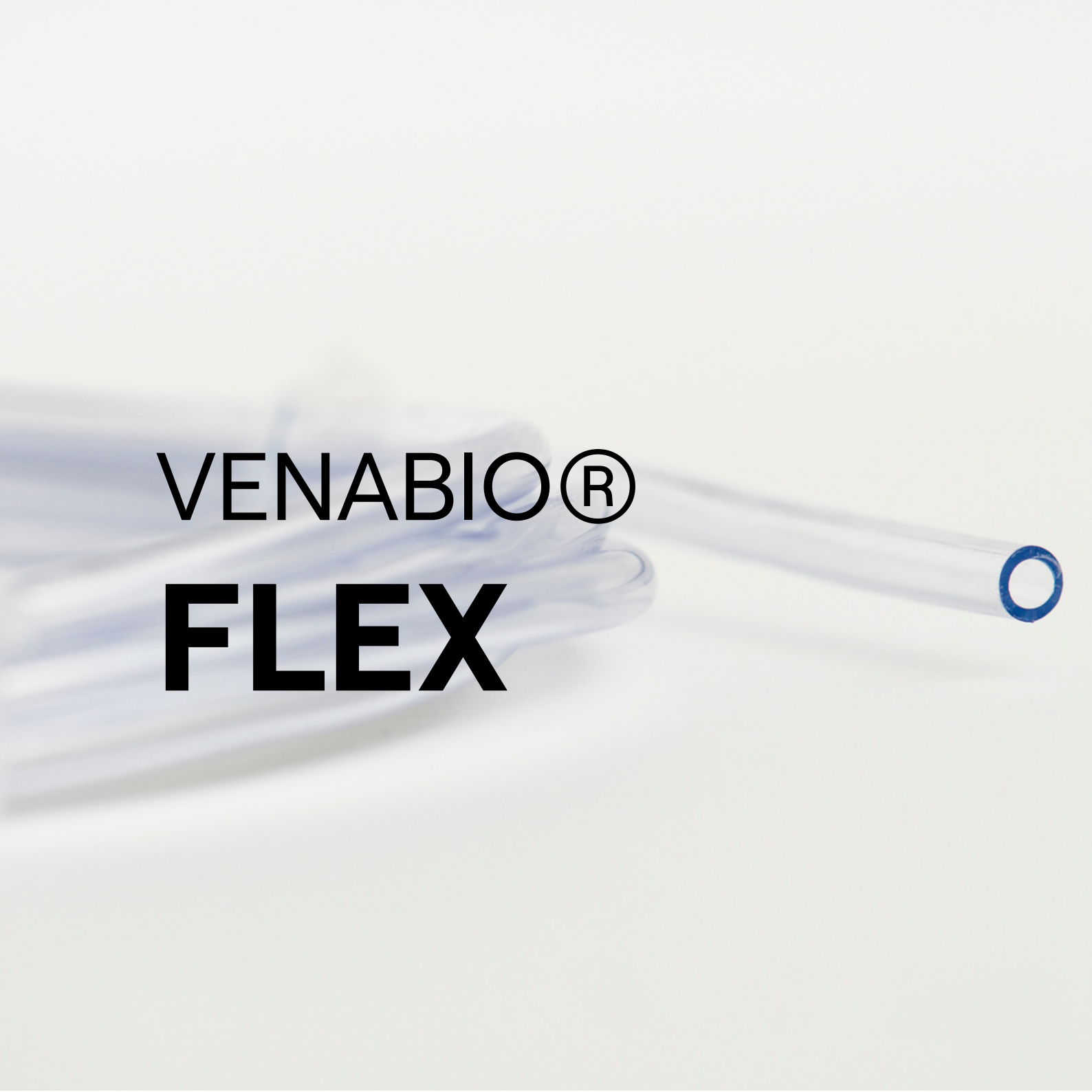


VENABIO® FLEX

Thermoplastic Elastomer tubing

This product satisfies the need for a heat sealable and weldable biopharmaceutical tubing. It provides disconnection and re-connection capabilities through a cuttable seal and aseptic welding.

venair
Fluid solutions. Solid performance.

SUMMARY

Introducing Venabio® flex, a cutting-edge thermoplastic elastomer designed to deliver exceptional mechanical performance in fluid transfer applications, while also enabling aseptic welding.

This advanced material meets the highest standards of certification essential for all biopharmaceutical applications. Our commitment to quality extends to the manufacturing, inspection, and packaging processes, all meticulously carried out in a state-of-the-art ISO-7 cleanroom environment.

Choose Venabio® flex for a seamless blend of superior functionality and exceptional biopharmaceutical standards.

- Excellent peristaltic pump life with low spallation rate
- Exceptional mechanical properties
- Weldable with competitor's TPE tubing with Sartorius Biowelder
- Double-bagged individually
- Transport validation based on ASTM D-4169-22
- Manufactured in Barcelona (Spain) in an ISO7 certified cleanroom
- Compatible with Gamma, e-Beam and X-Ray sterilization
- Excellent thermal resistance (-30°C to 120°C)
- Low extractable profile
- Optionally sterilized (SAL<10-6) according to ISO 1137-1
- Fully biocompatible, TSE/BSE and animal components derived free

PROPERTIES

The raw material used presents the following mechanical properties.

Property	Value
Hardness (shore A) ASTM D2240	70± 3
Tensile Strength (MPa) ASTN D412	>5
Elongation at break (%) ASTM D412	>300
Density (g/cm3) ASTM D412	0.90± 0.02

To ensure this product is suitable for its intended applications in weldable aseptic transfer lines, several tests and validations were performed in representative sizes of extruded tubing:

- **Weldability tests**

Venabio Flex weldability has been validated using a Biowelder® by Sartorius with the program Advantaflex. This validation ensures a 100% reopening ratio of the welded section, both pre and post gamma irradiation.

- **Burst pressure**

Burst pressure was analyzed post gamma irradiation before and after welding to ensure a proper resistance in its intended use. A comparison between both conditions with a 12.7 mm (ID) x 19.1 mm (OD) can be found below. A complete summary of working and burst pressures is available at the end of this document.

- **Tensile tests**

Tensile strength was also analyzed post gamma irradiation before and after welding with a 3.2 mm (ID) x 6.4 mm (OD) tubing.

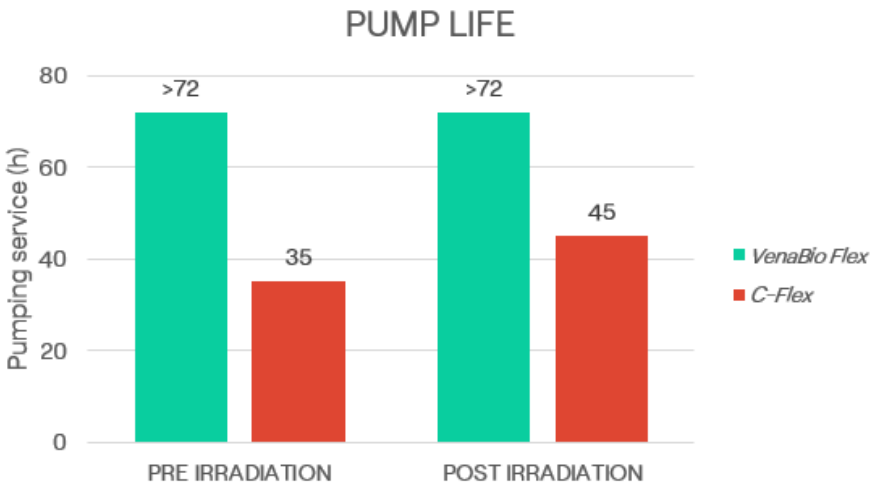
- **Bending radious test**

According to ISO 10619-Rubber and plastics hoses and tubing - Measurement of flexibility and stiffness - Part 1: Bending tests at ambient temperature), Venabio Flex presents the following resistance to bending in two representative diameters tested after gamma irradiation.

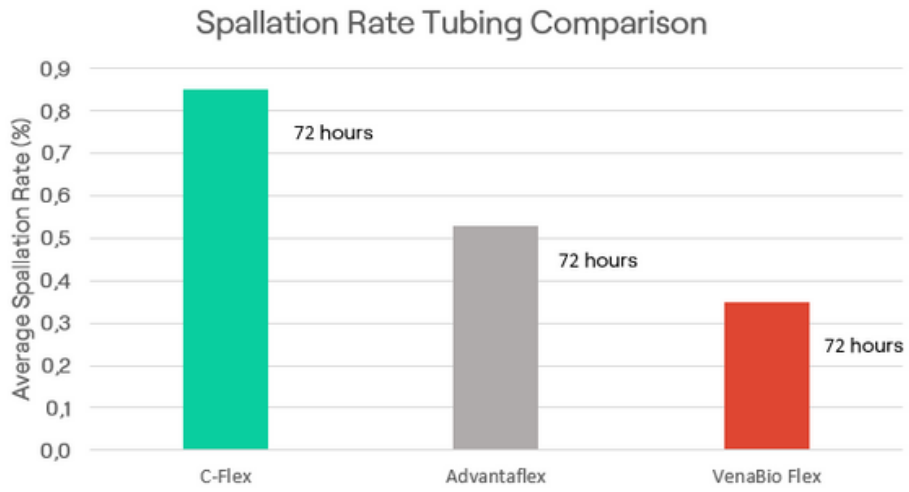
ID (mm)	OD (mm)	Min. B. Radius (mm)
3.2	6.4	24.1
12.7	19.1	106

- **Pumplife and spallation**

Pumplife tests in peristaltic pump were performed with 3.2 mm (ID) x 6.4 mm (OD) tubing after gamma irradiation. Results compared to a similar product in the market can be seen below.



Spallation tests were performed with 3.2 mm (ID) x 6.4 mm (OD) tubing. The loss of mass was measured after 72 h of continuous operation at a peristaltic pump at 300 rpm. Results compared to a similar product in the market can be seen below.



QUALITY AND COMPLIANCE

We uphold the highest standards of quality and regulatory compliance, ensuring your confidence in the safety and efficacy of our single-use bioprocess containers. ISO 13485 certification for medical device manufacturing and GMP (Good Manufacturing Practice) compliance for aseptic production demonstrate our unwavering commitment to excellence. Regular audits and inspections by independent bodies and big pharma end users are performed periodically.

- **Biocompatibility**

  ADCF
  BPA and Phthalate free
  BSE/TSE free
  EU 10/2011
  FDA 21CFR178.2010
  USP <87> Biological Reactivity Test in Vitro
  USP <88> Class VI Certificate
  USP <661>
  ISO 10993-4
  ISO 10993-5

- **Extractables**

  Extractable profile according to USP 665 "Plastic Components and Systems Used to Manufacture Pharmaceutical Drug Products and Biopharmaceutical Drug Substances and Products".

- **Documentation**

  COC
  COA per batch
  Full validation guide with extractable data
  Batch release with USP<85> Bacterial endotoxins and USP<788> Particulate matter available under demand

CONFIGURATIONS

Reference 9200871*	ID mm (inches)	OD mm (inches)	Wall mm (inches)	Working pressure Bar (PSI) at 20°C	Burst pressure Bar (PSI) at 20°C
920087100306	3,2 (1/8)	6,4 (1/4)	1,6 (1/16)	1.9(28)	5,7(84)
920087100508	4,8 (3/16)	7,9 (5/16)	1,6 (1/16)	1,5(22)	4,5 (66)
920087100610	6,4 (1/4)	9,5 (3/8)	1,6 (1/16)	1,1 (16)	3,3 (48)
920087100611	6,4 (1/4)	11,1 (7/16)	2,4 (3/32)	1,5(21)	4,5(63)
920087100613	6,4 (1/4)	12,7 (1/2)	3,2 (1/8)	2,3 (34)	6,9 (93)
920087100813	7,9 (5/16)	12,7 (1/2)	2,4 (3/32)	1,4(20)	4,2(60)
920087100914	9,5 (3/8)	14,3 (9/16)	2,4 (3/32)	1,2 (18)	3,6 (54)
920087101016	9,5 (3/8)	15,9 (5/8)	3,2 (1/8)	1,4(20)	4,2(60)
920087101319	12,7 (1/2)	19,1 (3/4)	3,2 (1/8)	1,4 (20)	4.2 (61)

CONTACT