

Innovaflex®



BIOPHARMACEUTICAL PUMP TUBING

A unique, specially formulated thermo-plastic elastomer tubing for the critical needs of the biopharmaceutical applications. Clear, flexible, weldable, sealable and applicable for use in peristaltic pump

USP VI



Innovaflex®

Innovaflex® complies with USP Class VI standards and is manufactured by Innovapure under strict GMP guideline. It is non-pyrogenic, non-cytotoxic and has excellent resistance to acids and alkalis as well as good performance on peristaltic pump. Unlike other products, Innovaflex is totally free of silicone and amide lubricants, more pure and less extractables. Its special formulation enables much stronger welding strength during aseptic welding process.

Features

- Long peristaltic pump life
- Free of silicone
- High welding strength
- Low permeation
- Low protein bonding
- Sterilization by EO, Gamma, autoclave
- ISO Class 7 manufacturing
- Full validation studies

Regulations

- ISO 10993
- USP 87/88 Class VI
- ADCF
- Drug Master File
- Extractables studies

Applications

- Cell culture media
- Cell fermentation
- Diagnostic equipment
- Pharmaceutical production
- Vaccine production
- Pinch valves
- Sterile filling and dispensing system



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Innovaflex® inventoried sizes

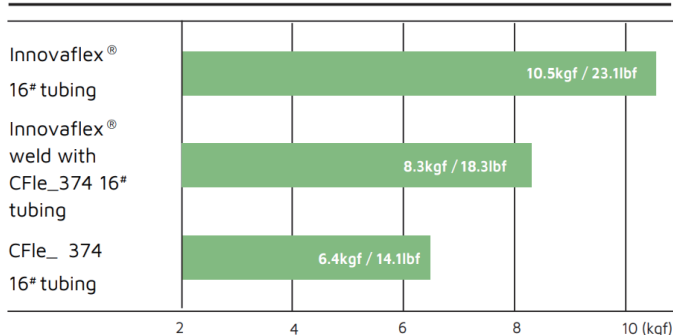
Model #	Tube #	I.D.		O.D.		Wall thickness		Length / Box*	
		(mm)	(Inch)	(mm)	(Inch)	(mm)	(Inch)	(M)	(Feet)
XP40-202-0159-0476	14#	1.59	1/16	4.76	3/16	1.59	1/16	15.2	50
XP40-202-0238-0556	19#	2.38	3/32	5.56	7/32	1.59	1/16	15.2	50
XP40-202-0318-0635	16#	3.18	1/8	6.35	1/4	1.59	1/16	15.2	50
XP40-202-0318-0794	120#	3.18	1/8	7.94	5/16	2.38	3/32	15.2	50
XP40-202-0476-0794	25#	4.76	3/16	7.94	5/16	1.59	1/16	15.2	50
XP40-202-0476-0953	15#	4.76	3/16	9.53	3/8	2.38	3/32	15.2	50
XP40-202-0635-0953	17#	6.35	1/4	9.53	3/8	1.59	1/16	15.2	50
XP40-202-0635-1111	24#	6.35	1/4	11.11	7/16	2.38	3/32	15.2	50
XP40-202-0794-1111	18#	7.94	5/16	11.11	7/16	1.59	1/16	15.2	50
XP40-202-0794-1270	35#	7.94	5/16	12.70	1/2	2.38	3/32	15.2	50
XP40-202-0953-1270	96#	9.53	3/8	12.70	1/2	1.59	1/16	15.2	50
XP40-202-0953-1429	36#	9.53	3/8	14.29	9/16	2.38	3/32	15.2	50
XP40-202-0953-1588	73#	9.53	3/8	15.88	5/8	3.18	1/8	15.2	50
XP40-202-1111-1429		11.11	7/16	14.29	9/16	1.59	1/16	15.2	50
XP40-202-1270-1905	82#	12.70	1/2	19.05	3/4	3.18	1/8	15.2	50

*Other sizes and length can be customized

Innovaflex® typical properties

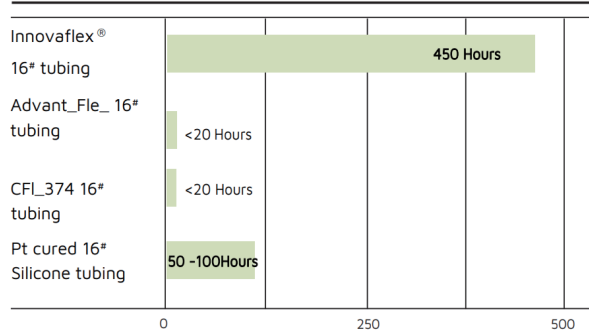
Physical Properties	Test Method	Unit	Typical Value
Color	-		Translucent
Shore A, 5 sec.	ISO 868		60
Specific gravity	ISO 2781	g/cm ³	0.89
Tensile strength	ASTM D 412	Mpa	6.45
Elongation at 100%	ASTM D 412	%	620
Compression set, 23C 168Hrs	ASTM D 395	%	19
Vicat softening point	ISO 306 (10N)	C	58

Innovaflex® welding strength comparison



Uses 5 standard 16# size tubings, sterilized under 25kGy Gamma radiation, measure tensile strength after tubing welding by using GE STF-IRc welder.

Innovaflex® peristaltic pump life



Tests above were conducted by using 16# standard size peristaltic pump tubings, under conditions of 1.5Bar pump head pressure, zero back pressure, water medium and room temperature. A 4 rollers peristaltic pump was used under 600rpm until tube leakage or 30% lower flow rate was observed.

Innovaflex® chemical compatibility chart, regulations and validation details are available on www.innovapure.com or call Innovapure sales representative.



Important

It is the user's responsibility to ensure the suitability and safety of Suzhou Innovapure Co., Ltd. products for all intended uses. Laboratory and clinical tests must be conducted in accordance with applicable regulatory requirements in order to determine the safety and effectiveness for use of tubing in any particular application.

Innovaflex[®] biopharmaceutical tubing



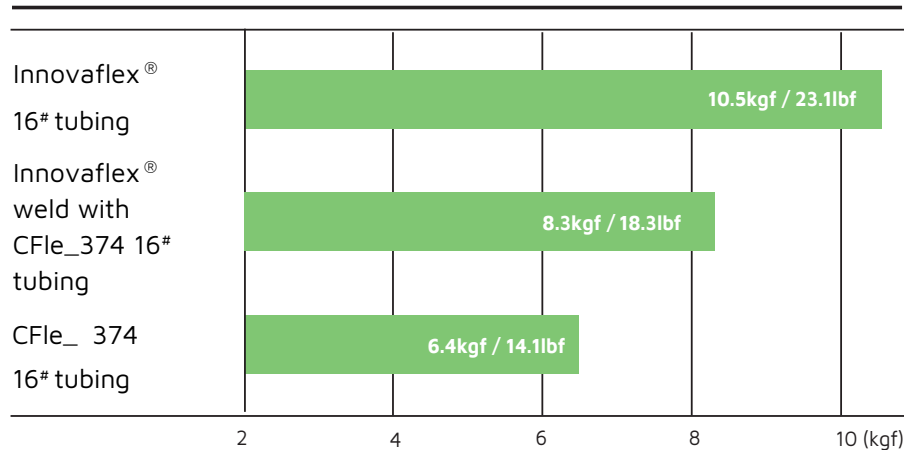
Properties

- Formulated for biopharmaceutical uses, and complies with USP Class VI and ISO 10993 standards
- Manufactured, assembled and packaged in ISO Class 7 clean room, where is well controlled with USP 788, USP85 and USP 61 guidelines.
- Weldable and sealable in aseptic environment, perfectly matches existing widely-used CFlex[®] series tubing.
- Applicable for peristaltic pump use with stable flow rate and ultra long life time
- Available at 60 and 70 Shore A durometers
- Low permeation, low protein binding, totally silicone and amide free
- Non-pyrogenic, non-cytotoxic, non-hemolytic
- Sterilizable by radiation, ETO, autoclave or chemicals



Properties	Regulations	Applications	Sterilization methods
Long pump life	USP Class VI	Pump use in biopharma applications	Autoclave
Stable flow rate variation	ISO 10993 Parts 3, 4, and 11	Single use fluid delivery	ETO
ISO14644-1 certified ISO Class 7 clean room	ADIF	Final filling	Gamma
Extractables and leachables studies	Drug Master File (in processing)	Vaccine manufacturing	
Aseptic weldable and sealable	Extractables and leachables studies	Buffer delivery	
Regulations compliance			
Available at 60 and 70 Shore A duro			
Available in various dimensional sizes			
Totally free of silicone and amide additives			

Innovaflex[®] welding strength comparison



Uses 5 standard 16# size tubings, sterilized under 25kGy Gamma radiation, measure tensile strength after tubing welding by using GE STF-IRc welder.

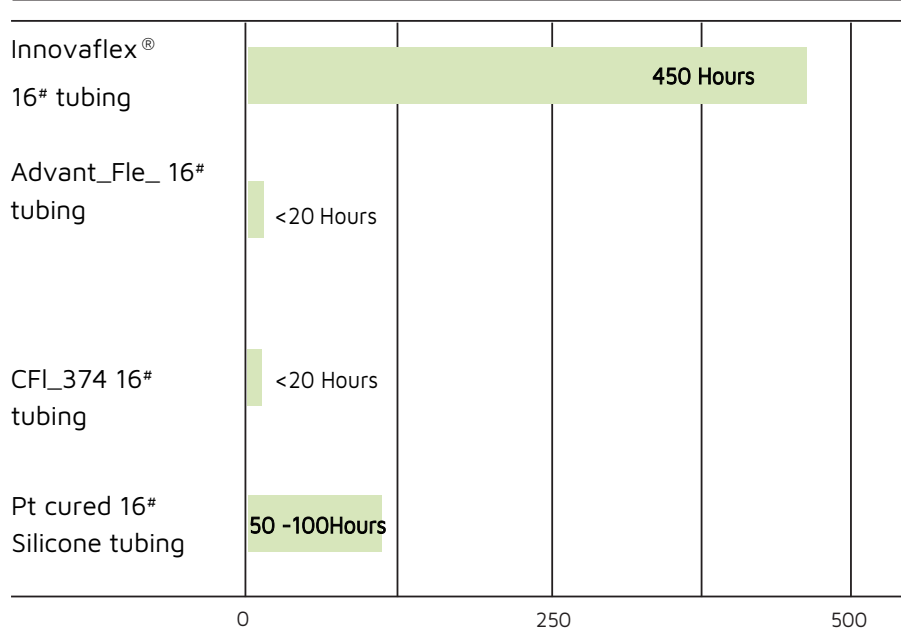


Innovaflex[®] is a translucent tubing, and complies with USP Class VI, ISO10993 standards, is animal derived ingredient free. Innovaflex[®] tubing is manufactured in ISO14644-1 certified ISO Class 7 clean room, and verified via ISO11137 VDMax 25 method to ensure 10⁻⁶ sterilization requirement under various sterilization methods. It is a perfect alternative tubing product to Advant_Fle[®], CFlex[®] and has wide uses in biopharmaceutical applications.



Innovaflex® physical properties	ASTM	SI	Methods
Specific gravity	0.89	0.89	ASTM D792
Shore A durometer(15 sec.)	61	61	ASTM D2240
Compression set(23C,168 hr.)	19%	19%	ASTM D395B
Tensile strength @ break: @STP	934psi	6.44MPa	ASTM D412
Elongation @ break : @STP	620%	620%	ASTM D412
Vica soft point VST	136F	58C	ISO 306 (10N)
Color	Transluscent		

Innovaflex® peristaltic pump life



Tests above were conducted by using 16# standard size peristaltic pump tubings, under conditions of 1.5Bar pump head pressure, zero back pressure, water medium and room temperature. A 4 rollers peristaltic pump was used under 600rpm until tube leakage or 30% lower flow rate was observed.

Innovaflex® series tubing is specially formulated to enable stronger welding strength, much longer peristaltic pump life against other similar products since its low compression set contributes to stable flow rate over pump life time. Innovaflex® is completely silicone and amide free and has much less extractables vs other elastomeric tubing, thus is ideal for biopharmaceutical uses.

Standard sizes

Part number	Tubing #	ID	OD	Wall
XPXX-XX2-0079-0397	#13	1/32"	5/32"	1/16"
XPXX-XX2-0159-0318		1/16"	1/8"	1/32"
XPXX-XX2-0159-0476	#14	1/16"	3/16"	1/16"
XPXX-XX2-0238-0556		3/32"	7/32"	1/16"
XPXX-XX2-0318-0476		1/8"	3/16"	1/32"
XPXX-XX2-0318-0635	#16	1/8"	1/4"	1/16"
XPXX-XX2-0476-0794	#25	3/16"	5/16"	1/16"
XPXX-XX2-0476-0953	#15	3/16"	3/8"	3/32"
XPXX-XX2-0635-0953	#17	1/4"	3/8"	1/16"
XPXX-XX2-0635-1111	#24	1/4"	7/16"	3/32"
XPXX-XX2-0635-1270	#26	1/4"	1/2"	1/8"
XPXX-XX2-0794-1111	#18	5/16"	7/16"	1/16"
XPXX-XX2-0794-1270	#35	5/16"	1/2"	3/32"
XPXX-XX2-0953-1270	#96	3/8"	1/2"	1/16"
XPXX-XX2-0953-1429	#36	3/8"	9/16"	3/32"
XPXX-XX2-0953-1588	#73	3/8"	5/8"	1/8"
XPXX-XX2-1270-1905	#82	1/2"	3/4"	1/8"
XPXX-XX2-1588-2223		5/8"	7/8"	1/8"
XPXX-XX0-1905-2540		3/4"	1"	1/8"

Innovaflex® is available at 15ft, 25ft and 50ft standard length, and can be customized with customer requirement



MADE IN CHINA

苏州英纳薇科技有限公司
SUZHOU INNOVAPURE CO., LTD.

中国制造

Visit www.innovapure.com for more details