

VENA[®]Bio PURE ISO7



Description

Vena[®]Bio Pure ISO7 is a platinum postcured tubing made of low volatile biopharm grade silicone. It has been optimized over the years to perform better than its main competitors in all key features.

Typical applications are media and buffer preparation, downstream processing, formulation, filling, drug delivery and peristaltic pumps.

Features

- High surface smoothness avoids protein binding and biofilm formation
- High resistance to ozone, radiation, moisture, compression set, chemical attack and weathering
- Unmatched operational temperature range starting from 220°C and going as low as -60°C
- Indelible traceability through laser etching: reference description and lot number

Delivery options

- Customized bores
- Sterilization prior shipment
- 50ShA, 60ShA or 70ShA
- Rolls of 15m and 30m. Reels of 50m and 100m
- Double bagged and delivered in a crushproof box
- Customized single use systems available
- Labels on bags and cardboard box for optimum traceability
- Free of animal-derived ingredients, phthalates and bisphenols
- Best in class biocompatibility
- Double bagged in clean room ISO 7 according ISO 14644-1
- Complete validation package under request

Sterilization Methods

- Autoclavable at 121°C for a maximum exposure of 90 minutes. Total recommended exposure is 150h
- Dry air sterilization at 200°C
- Beta radiation
- Gamma radiation up to 50 Kgy
- Ethylene oxide
- Hydrogen peroxide

Biocompatibility

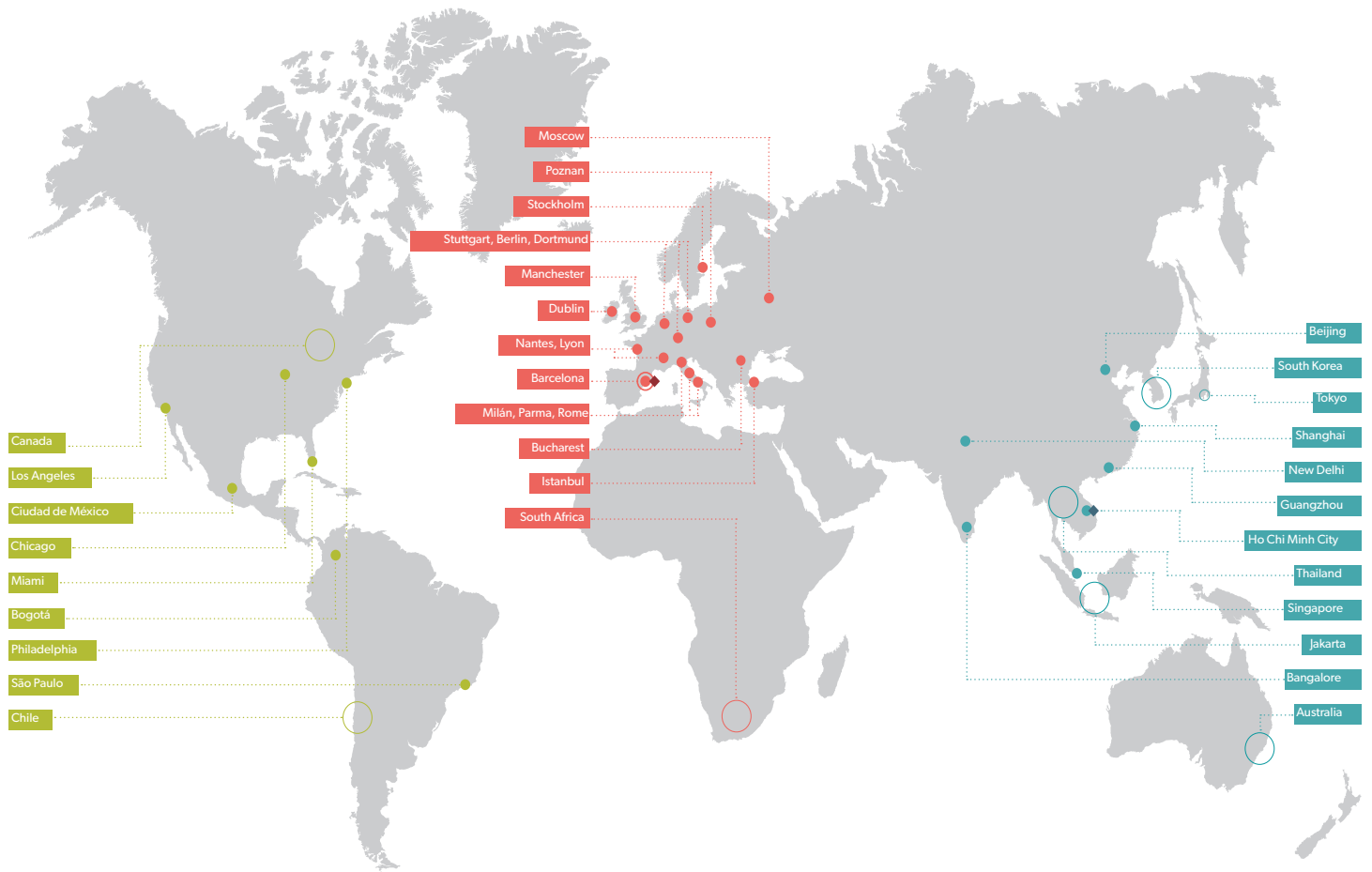
Vena® Bio Pure ISO7 is fully characterized and tested for complete validation package contact your sales representative.

Reference	Title	Result
(EU) No 10/2011 (EU) No 1935/2004	Plastic materials and articles intended to come into contact with food Simulant B (3% Acetic acid aqueous solution) and Simulant D1 (50% ethanol)	✓
FDA 21 CFR 177.2600	Rubber articles intended for repeated use, FDA ITEM 177.2600 (e)	✓
BfR recommendation XV	Recommendations on the health assessment of plastics and other high polymers	✓
United States Pharmacopoeia <88>	Biological reactivity tests, IN VIVO Class VI - 121°C	✓
ISO 10993-4	Biological evaluation of medical devices—Part 4: Selection of tests for interactions with blood	✓
ISO 10993-5 & USP <87>	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity	✓
ISO 10993-6	Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects After Implantation	✓
ISO 10993-10	Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization	✓
3A 18-03	Sanitary Standard Procedure N° 18-03 Class I	✓
European Pharmacopoeia 3.1.9.	Silicone elastomer for closures and tubing	✓
Extractables and Leachables study available for 70ShA silicone	Extraction experiment in organic solvent Extraction experiment in polar organic-aqueous solvent system Extraction experiment in aqueous solvent, alkaline conditions Extraction experiment in aqueous solvent, acidic conditions	✓

Dimensions

ID (inch)	OD (inch)	WALL (inch)	ID (mm)	OD (mm)	WALL (mm)
1/32	3/32	1/32	0,8	2,4	0,8
1/32	5/32	1/16	0,8	4,0	1,6
1/16	1/8	1/32	1,6	3,2	0,8
1/16	3/16	1/16	1,6	4,8	1,6
3/32	5/32	1/32	2,4	4,0	0,8
3/32	7/32	1/16	2,4	5,6	1,6
1/8	3/16	1/32	3,2	4,8	0,8
1/8	1/4	1/16	3,2	6,4	1,6
1/8	5/16	3/32	3,2	7,9	2,4
1/8	3/8	1/8	3,2	9,5	3,2
5/32	9/32	1/16	4,0	7,1	1,6
5/32	7/32	1/32	4,0	5,6	0,8
5/32	11/32	3/32	4,0	8,7	2,4
3/16	1/4	1/32	4,8	6,4	0,8
3/16	5/16	1/16	4,8	7,9	1,6
3/16	3/8	3/32	4,8	9,5	2,4
3/16	7/16	1/8	4,8	11,1	3,2
1/4	5/16	1/32	6,4	7,9	0,8
1/4	3/8	1/16	6,4	9,5	1,6
1/4	7/16	3/32	6,4	11,1	2,4
1/4	1/2	1/8	6,4	12,7	3,2
5/16	7/16	1/16	7,9	11,1	1,6
5/16	1/2	3/32	7,9	12,7	2,4
5/16	9/16	1/8	7,9	14,3	3,2
3/8	1/2	1/16	9,5	12,7	1,6
3/8	9/16	3/32	9,5	14,3	2,4
3/8	5/8	1/8	9,5	15,9	3,2
7/16	9/16	1/16	11,1	14,3	1,6
1/2	5/8	1/16	12,7	15,9	1,6
1/2	11/16	3/32	12,7	17,5	2,4
1/2	3/4	1/8	12,7	19,1	3,2
5/8	7/8	1/8	15,9	22,2	3,2
3/4	1	1/8	19,1	25,4	3,2
3/4	11/8	3/16	19,1	28,6	4,8
1	11/2	1/4	25,4	38,1	6,4

About Venair



Venair Group is an engineering company since 1986 specializing in design and manufacturing of hoses and special pieces in silicone. We are experts in the creation of high quality elastomers, offering solutions for several branches strategically distributed in America, Europe and Asia and working in the most demanding markets: food, pharmaceutical, biotechnological, military, nautical, aerospace and energy generation.

Vena® Bio overview

Vena® Bio comprises the range of extruded from VENAIR. It supplies the pharmaceutical and biotech-based markets with **outstanding quality** tubing of different materials. Other constructions from this range (please consult your sales representative):

Vena® Bio Weld: Heat weldable and sealable TPE tubing.

Vena® Bio Pump: Pump grade TPV tubing.

Vena® Bio Braided: Platinum postcured braided tubing.

Vena® Bio PVC: Medical grade DEHP free flexible tubing.

Vena® Bio PTFE, FEP, ETFE: Fluoropolymer tubing range for demanding chemical compatibility.



IMPORTANT:
 The Company reserves the right to change, amend, modify, suspend, continue or terminate all or any part of this Catalogue at any time without notice. It is the user's responsibility to ensure the suitability and safety of the VENAIR products for all intended uses. All the tests must be conducted in accordance with applicable regulatory requirements in order to determine the safety and effectiveness for use of the hoses in any particular application.
 Limited Warranty: For a period of 6 months from the date of sale, VENAIR warrants this product to be free from defects in materials and workmanship. Our only obligation will be to replace any portion proving defective, or at our option, to refund the purchase price thereof. User assumes all other risk, if any, including the risk of injury, loss or damage, direct or consequential, arising out of the use, misuse, or inability to use, this product. THIS WARRANTY IS IN LIEU OF THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, AND ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. No deviation is authorized. VENAIR assumes no obligations or liability for any advice furnished by it, or for results obtained with respect to those products. All such advice is given and accepted at the buyer's risk.
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