

# PCS Tubing and TPE Tubing

## BROCHURE

Flexible single use tubing is an essential part of fluid transfer in biopharmaceutical manufacturing.

Process owners of critical processes involving transfer of media, buffer, process intermediates, drug substances and drug products are not only concerned about safe and secure transfer of these process fluids, but also about particulate matter, endotoxins and leachables, which otherwise may impact drug product. Also, some highly critical applications such as final fill and finish require accurate dispensing and consistent flow rates over time.

**mdi** has developed Platinum Cured Silicone (PCS) tubing and Thermoplastic Elastomer (TPE) tubing. These tubing are manufactured in ISO clean rooms that offers less contamination and enhanced smooth fluid flow operation.

**mdi** offers different kind of tubing for various applications:

- PCS tubing:
  - AseptiFlo™ for fluid transfer
  - PresFlo™ High pressure tubing for fluid transfer applications
  - AcuFlo™ for accurate pumping applications
  - PumpFlo™ for pumping applications
- TPE Tubing:
  - AseptiFlex™ for fluid transfer



**BRC PCSTPEX2425C**

## Clean Room Manufacturing

**mdi** tubing are manufactured in clean rooms certified by external agencies and monitored in-house for viable and non viable particles. Employee hygiene, change rooms, gowning and de-gowning procedures and continuous monitoring of the areas is an essential part of these facilities. These facilities have been designed for unidirectional work flow with appropriate change rooms for personnel and air locks for material movement.

## Quality Management Systems

**mdi** tubing are well designed products with in-built quality assurance. ISO-9001:2015 Certified Quality Management System, careful selection of raw materials, validated production processes and testing procedures based on international standards and guidelines such as CFR, PDA, and ASTM, ensures manufacture of consistently high quality tubing.

## Regulatory Compliance

**mdi** tubing are deeply characterized and validated to meet international regulatory requirements with regards to bioburden, endotoxins, particulate matter and extracables.

## Biosafety

Passes Biological Reactivity test, In-Vivo, as per USP<88> for Class VI plastics.

Passes the Biological Reactivity Tests, In Vitro for Cytotoxicity as described in USP<87>.

## Bioburden Testing

Bioburden level is < 1000 cfu/device as per ISO 1737-1:2018.

## Sterilization

### PCS tubing

**By Gamma Irradiation:** up to 50 kGy

**By Autoclave:** at 125°C for 30 minutes, 1 cycle

### TPE tubing

**By Gamma Irradiation:** up to 50 kGy

**By Autoclave:** at 125°C for 30 minutes, 1 cycle

## Sterility Assurance

The gamma sterilization process for gamma sterilized tubing has been validated as per ISO 11137 to ensure a sterility assurance level (SAL) of  $10^{-6}$ .

## Endotoxin Testing

Aqueous extracts exhibit <0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>.

## Fiber Release

Passes test as per USP and comply with USFDA Title 21 CFR Part 210.3(b)(6) for fiber release.

## Particle Release

Complies with USP <788> test for particulate matter in injections.

## Non Animal Origin

The materials used for manufacture of **mdi** tubing do not contain substance of animal origin as per EMEA/410/01 Rev. 03.

## Indirect Food Additives

These PCS tubing meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520.

## Extractables

Extractable profiles for both PCS and TPE tubing are available **as per BioPhorum Best Practices Guide for Extractable Testing of Polymeric Single Use Components used in Biopharmaceutical Manufacturing.**

## Packaging Integrity

**mdi** tubing with 15 M roll length are packed in double polyethylene bags to ensure package integrity during transit as well as to prevent particulate contamination.

## Total Traceability

PCS and TPE tubing come with completely traceable lot numbers to facilitate easy and fast retrieval of manufacturing and quality control data. These unique lot numbers are printed on the labels of the packaging.

**mdi**  
Membrane Technologies

**Certificate of Quality**

**mdi AseptiFlo Platinum Cured Silicone (PCS) tube** has been manufactured in a cGMP compliant mdi facility. These are produced using validated production processes in classified clean rooms. The quality management system complies with ISO 9001 standards.

**AseptiFlo PCS Tube 9.5 mm X 15.9mm**

Cat. No. : AFST095159AXX01

Lot Number : STXXXX

Expiry Date : XX-XXXX

**LOT RELEASE CRITERIA:**

The above lot of AseptiFlo PCS tube was sampled, tested and released based on following criteria:


<b>Visual Inspection</b>	: Passes the Visual Inspection Criteria
<b>Dimensional Testing</b>	: Meets the specifications
<b>Burst strength</b>	: $\geq 45$ psi
<b>Hardness</b>	: 55-65 shore A*

**VALIDATED FOR**

<b>Microbial Ingress</b>	: Resistance to microbial ingress against a challenge of $10^7$ org/mL of <i>B. Diminuta</i>
<b>Bio burden Level</b>	: The bio burden level has been tested as per ISO 11737.
<b>Endotoxin Level</b>	: $< 0.25$ EU/ml as determined by Limulus Amebocyte Lysate (LAL) test as per USP <85>.
<b>Particle release</b>	: Passes test as per USP <788> Particulate matter in Injections.
<b>Biosafety</b>	: Passes Biological Reactivity tests, <i>In Vivo</i> for Class VI plastic as per USP <88>.
<b>Cytotoxicity</b>	: Passes Biological Reactivity tests, <i>In Vitro</i> for Class VI plastic as per USP <87>.
<b>TSE/BSE</b>	: Free from TSE/BSE causing agents

**CUSTOMER SUPPORT**

mdi offers its unique interdisciplinary skills to provide solutions to specific problems. Please contact our factory or the local application specialist.

  
Quality Assurance  
Issue Date: 13-Dec-2023

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**An ISO 9001 Company**

## Certificate of Quality

Each lot of mdi tubing is provided with certificate of quality.

## Shelf Life

Both mdi PCS and TPE tubing have a shelf life of 5 years.

## Description

**mdi** AseptiFlo™ Platinum Cured Silicone (PCS) tubing offers a reliable solution for fluid transfer and management in biopharmaceuticals processes.

## Applications

- Single use assemblies for fluid transfer
- Tube and bag manifolds for aseptic sampling

## Specifications

<b>Hardness</b>	55 Shore A
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Catalog No.	Inner Diameter	Outer Diameter	Wall Thickness	Working Pressure	Burst Pressure	Roll Length
AFST012044AXX01	1.2 mm	4.4 mm	1.60 mm	13 psi	40 psi	15 metre
AFST016031AXX01	1/16" (1.6 mm)	1/8" (3.1 mm)	0.75 mm	22 psi	65 psi	15 metre
AFST016034AXX01	1.6 mm	3.4 mm	0.90 mm	22 psi	65 psi	15 metre
AFST016048AXX01	1/16" (1.6 mm)	3/16" (4.8 mm)	1.59 mm	33 psi	100 psi	15 metre
AFST031063AXX01	1/8" (3.1 mm)	1/4" (6.3 mm)	1.59 mm	28 psi	85 psi	15 meter
AFST031079AXX01	1/8" (3.1 mm)	5/16" (7.9 mm)	2.38 mm	31 psi	94 psi	15 meter
AFST048079AXX01	3/16" (4.8 mm)	5/16" (7.9 mm)	1.55 mm	19 psi	57 psi	15 meter
AFST048095AXX01	3/16" (4.8 mm)	3/8" (9.5 mm)	2.35 mm	26 psi	78 psi	15 meter
AFST063095AXX01	1/4" (6.3 mm)	3/8" (9.5 mm)	1.58 mm	16 psi	48 psi	15 meter
AFST063111AXX01	1/4" (6.3 mm)	7/16" (11.1 mm)	2.38 mm	18 psi	55 psi	15 meter
AFST063127AXX01	1/4" (6.3 mm)	1/2" (12.7 mm)	3.20 mm	27 psi	80 psi	15 meter
AFST079111AXX01	5/16" (7.9 mm)	7/16" (11.1 mm)	3.18 mm	17 psi	50 psi	15 meter
AFST079127AXX01	5/16" (7.9 mm)	1/2" (12.7 mm)	2.40 mm	23 psi	70 psi	15 meter
AFST095143AXX01	3/8" (9.5 mm)	9/16" (14.3 mm)	2.40 mm	18 psi	54 psi	15 meter
AFST095159AXX01	3/8" (9.5 mm)	5/8" (15.8 mm)	3.18 mm	17 psi	50 psi	15 meter
AFST127190AXX01	1/2" (12.7 mm)	3/4" (19.0 mm)	3.18 mm	17 psi	50 psi	15 meter
AFST159222AXX01	5/8" (15.9 mm)	7/8" (22.2mm)	3.16 mm	17 psi	50 psi	15 meter
AFST254340AXX01	1" (25.4 mm)	1.33" (34.0mm)	4.30 mm	13 psi	40 psi	15 meter
AFST030053AXX01	3 mm	5.30 mm	1.15 mm	18 psi	55 psi	15 meter

## Ordering Information

To order, please specify the catalog number and quantity.

### Example

AFST012044AXX01, 2 rolls

# PresFlo™

## High Pressure PCS Tubing

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### Description

**mdi** PresFlo™ Platinum Cured Silicone (PCS) tubing offers a reliable solution for high pressure fluid transfer and management in biopharmaceutical processes.

### Applications

Processes requiring high pressure fluid transfer such as Pre-use Post Sterilization Integrity Testing (PUPSIT) tubing/ single use assemblies which should withstand air/gas pressure up to 5 bar

### Specifications

Hardness	77 Shore A
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Catalog No.	Inner Diameter (ID)	Outer Diameter (OD)	Wall Thickness	Working Pressure	Burst Pressure	Tube Length
AFSH063095AXX01	1/4 " (6.3 mm)	3/8" (9.5 mm)	1.60 mm	33 psi	100 psi	15 meter
AFSH095159AXX01	3/8" (9.5 mm)	5/8" (15.9 mm)	3.20 mm	50 psi	150 psi	15 meter
AFSH127190AXX01	1/2" (12.7 mm)	3/4" (19.0 mm)	3.15 mm	33 psi	100 psi	15 meter
AFSH190254AXX01	3/4" (19.0 mm)	1" (25.4 mm)	3.20 mm	32 psi	95 psi	15 meter
AFSH254349AXX01	1" (25.4 mm)	1 1/8" (34.9 mm)	4.75 mm	32 psi	95 psi	15 meter

### Customized tubing for Extreme Pressure Applications

Catalog No.	Inner Diameter (ID)	Outer Diameter (OD)	Wall Thickness	Working Pressure	Burst Pressure	Tube Length
AFSH063144AXX01	1/4 " (6.3 mm)	9/16" (14.4 mm)	4.05 mm	73 psi	220 psi	15 meter
AFSH090200AXX01	9.0 mm	20.0 mm	5.50 mm	77 psi	230 psi	15 meter

**These tubing are specially designed for extreme pressures applications such as PUPSIT assemblies.** Contact us for your customized tubing requirement.

### Ordering Information

To order, please specify the catalog number and quantity.

#### Example

AFSH063095AXX01, 2 rolls

### Description

AcuFlo™ accurate pump PCS Tubing is specially designed for biopharmaceutical applications where accurate dispensing and consistent flow rates are required.

AcuFlo™ tubing has well finished and extremely smooth fluid contact surface that helps in consistent flow rates without any particle generation.

### Application

Single use disposable filling lines for pumping and accurate fluid transfer from surge bags to filling needles

### Key Features

#### 1. Accurate Dispensing

AcuFlo™ accurate pump PCS tubing comply with USP <1151> PHARMACEUTICAL DOSAGE FORMS.

Fill Volume	Recommended Excess Volume	Percentage	Volume Variability
5 mL	0.30 mL	6 %	0.20 %
10 mL	0.50 mL	5 %	1.76 %
20 mL	0.60 mL	3 %	0.40 %
30 mL	0.80 mL	2.6 %	0.21 %
50 mL	–	2 %	0.97 %
80 mL	–	2 %	0.70 %
100 mL	–	2 %	0.30 %
200 mL	–	2 %	0.72 %

#### 2. No Drip Formation

AcuFlo™ accurate pump PCS Tubing do not show any drip formation at different fill volumes with a pause time of 30 seconds with water.

Fill Volume	Drip Formation
5 mL	No Drip Formation
10 mL	No Drip Formation
20 mL	No Drip Formation
30 mL	No Drip Formation
50 mL	No Drip Formation
80 mL	No Drip Formation
100 mL	No Drip Formation
200 mL	No Drip Formation

#### 3. No Spallation : No Particle Generation

AcuFlo™ accurate pump PCS Tubing comply with USP <788> for Particulate Matter in Injections and USP <790> for Visible Particulate in Injections over 4 hours of pumping.

#### 4. Consistent Flow Rates

AcuFlo™ accurate pump PCS Tubing offers consistent flow rates.



## Specifications

Catalog No.	Inner Diameter	Outer Diameter	Wall Thickness	Working Pressure	Burst Pressure	Roll Length
AFSA008040AXX01	0.8 mm	4.0 mm	1.60 mm	13 psi	40 psi	15 metre
AFSA012044AXX01	1.2 mm	4.4 mm	1.60 mm	13 psi	40 psi	15 meter
AFSA016048AXX01	1/16" (1.6 mm)	3/16" (4.8 mm)	1.59 mm	33 psi	100 psi	15 metre
AFSA031063AXX01	1/8" (3.1 mm)	1/4 " (6.3 mm)	1.59 mm	28 psi	85 psi	15 meter
AFSA063095AXX01	1/4 " (6.3 mm)	3/8" (9.5 mm)	1.58 mm	16 psi	48 psi	15 meter

## Ordering Information

To order, please specify the catalog number and quantity.

### Example

AFSA016048AXX01, 2 rolls

# PumpFlo™

## Pump PCS Tubing

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### Description

PumpFlo™ Pump PCS Tubing are designed to withstand rigours of prolonged usage in peristaltic pump. These tubing are validated to ensure no spallation and consistent flow rates.

### Key Features

#### No Spallation : No Particle Generation

PumpFlo™ pump PCS Tubing comply with USP <788> for Particulate Matter in Injections and USP <790> for Visible Particulate in Injections over 4 hours of pumping.

### Application

Use in peristaltic pumps for fluid transfer

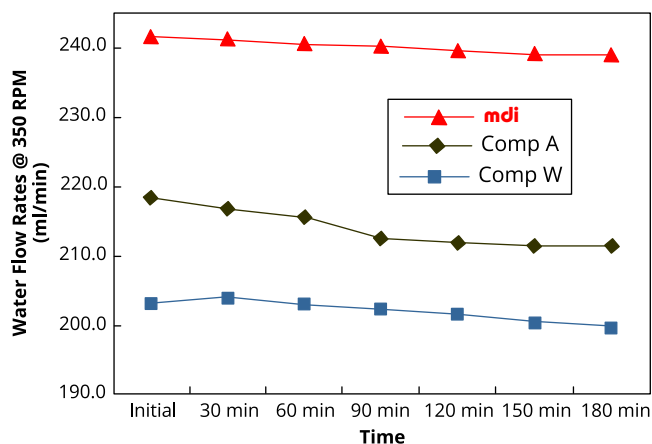
### Ordering Information

To order, please specify the catalog number and quantity.

### Example

AFSP012044AXX01, 2 rolls

### Consistent Flow Rates



### Specifications

Catalog No.	Inner Diameter	Outer Diameter	Wall Thickness	Working Pressure	Burst Pressure	Roll Length
AFSP012044AXX01	1.2 mm	4.4 mm	1.60 mm	13 psi	40 psi	15 metre
AFSP016048AXX01	1/16" (1.6 mm)	3/16" (4.8 mm)	1.59 mm	33 psi	100 psi	15 metre
AFSP031063AXX01	1/8" (3.1 mm)	1/4" (6.3 mm)	1.59 mm	28 psi	85 psi	15 meter
AFSP063095AXX01	1/4" (6.3 mm)	3/8" (9.5 mm)	1.58 mm	16 psi	48 psi	15 meter
AFSP095159AXX01	3/8" (9.5 mm)	5/8" (15.8 mm)	3.18 mm	17 psi	50 psi	15 meter
AFSP127190AXX01	1/2" (12.7 mm)	3/4" (19.0 mm)	3.18 mm	17 psi	50 psi	15 meter
AFSP254340AXX01	1" (25.4 mm)	1.33" (34.0mm)	4.30 mm	42 psi	125 psi	15 meter

# AseptiFlex™ TPE Tubing

BROCHURE

BRC PCSTPEX2425C

## Description

**mdi** AseptiFlex™ thermoplastic elastomer (TPE) tubing offers a reliable solution for process requiring fluid transfer and management.

AseptiFlex™ tubing are manufactured in certified clean rooms and have been validated to meet standard regulatory and functional requirements for critical applications ranging from aseptic sampling to sterile filling of drug products.

## Applications

- Tube welding for sterile fluid pathway connections
- Tube sealing for sterile fluid pathway disconnections
- Single use bag and tubing assemblies

## Physical Properties

Hardness	60 Shore A
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Catalog No.	Inner Diameter	Outer Diameter	Working Pressure	Burst Pressure	Wall Thickness	Roll Length
AFTT031063AXX01	1/8 " (3.2 mm)	1/4 " (6.3 mm)	30 psi	90 psi	1.5 mm	15 meter
AFTT063111AXX01	1/4 " (6.3 mm)	7/16" (11.1 mm)	27 psi	80 psi	2.4 mm	15 meter
AFTT063095AXX01	1/4" (6.3 mm)	3/8" (9.5 mm)	20 psi	60 psi	1.6 mm	15 meter
AFTT063127AXX01	1/4" (6.3 mm)	1/2" (12.7 mm)	40 psi	120 psi	3.2 mm	15 meter
AFTT079127AXX01	5/16" (7.9 mm)	1/2" (12.7 mm)	23 psi	70 psi	2.4 mm	15 meter
AFTT095127AXX01	3/8" (9.5 mm)	1/2" (12.7 mm)	17 psi	50 psi	1.6 mm	15 meter
AFTT095159AXX01	3/8" (9.5 mm)	5/8" (15.9 mm)	23 psi	70 psi	3.2 mm	15 meter
AFTT127190AXX01	1/2" (12.7 mm)	3/4" (19.0 mm)	20 psi	60 psi	3.2 mm	15 meter
AFTT190254AXX01	3/4" (19.0 mm)	1" (25.4 mm)	15 psi	45 psi	3.2 mm	15 meter



## Key Features

- Heat weldable
- Heat sealable
- Uniform, smooth inner bore for efficient fluid flow

## Weld Strength

**mdi** AseptiFlex™ thermoplastic elastomer tubing offers high weld strength and welds well with other TPE tubing such as C-Flex® and AdvantaFlex® with commercially available equipment under industry standard welding cycles.

Tubing	Burst Strength		
	1/8" (3.2 mm) ID - 1/4" (6.3 mm) OD	1/4" (6.3 mm) ID - 7/16" (11.1 mm) OD	3/8" (9.5 mm) ID - 5/8" (15.9 mm) OD
<b>mdi to mdi</b>	101 psi	80 psi	75 psi
<b>mdi</b> to AdvantaFlex	75 psi	65 psi	75 psi
<b>mdi</b> to C-Flex	77 psi	65 psi	52 psi
AdvantaFlex to AdvantaFlex	103 psi	55 psi	77 psi
C-Flex to C-Flex	75 psi	60 psi	52 psi
AdvantaFlex to C-Flex	78 psi	65 psi	52 psi

## Ordering Information

To order, please specify the catalog number and quantity.

### Example

AFTT031063AXX01, 2 rolls

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