CRT-PES Series PES Filter Cartridge

The CRT-PES Biological Grade Cartridges, designed for both pre and final filtration in biopharmaceutical processes, deliver product sterility with superior flow and chemical compatibility. These cartridges are engineered with a specialized hydrophilic PES membrane known for its low protein binding and wide pH compatibility, operating efficiently within a pH range of 1-14. This feature makes them versatile across various biopharmaceutical processes. The design is meticulously developed to eliminate the need for pre-wetting, avoiding potential contamination, and to provide exceptional flow rates and chemical compatibility. CRT-PES Biological Grade Cartridge is rigorously tested for integrity and pre-rinsed with pyrogen-free water, streamlining the setup process and minimizing downtime with a low extractable content. Crafted to be free from animal-derived substances, adhesives, binders, or surfactants, these cartridges satisfy the industry's stringent quality and performance standards, maintaining compliance with ISO 13485 & ISO 14001 certifications.

Application

- Buffers and Media
- LVP (Large Volume Parenteral)
- Vaccines
- Scale up processing

- Product Sterilization
- Fine Chemicals
- Biologics
- Ultrapure Water
- Fermentation Broths
- Pharmaceuticals
- Antibiotics
- > Serums

Part Number: CRT-PES-10-XXX-X6S / CRT-PES-10-XXX-X6S-5





Technical Data Sheet

Micron Rating:

- 0.10 µm
- 0.20 µm
- 0.45 µm
- 0.65 µm
- 0.80 µm
- 1.20 µm

Effective Filtration Area:

• 5-Inch; 3.75 ft² (0.35 m²)

• 10-Inch; 7.5 ft^2 (0.7 m^2)

• 20-Inch; 15.0 ft^2 (1.4 m^2)

• 30-Inch; 22.5 ft^2 (2.1 m^2)

Materials of Construction:

Membrane: PES (Polyethersulfone)

Membrane Feature: Hydrophilic, Broad Chemical Compatibility, High Flow Rate

Media Supports: Polypropylene

Shell, Cage, Core, End Caps: Polypropylene

O-Rings: Silicone (Standard)

Sealing: Thermally Bonded

Operating Conditions:

Maximum Forward Differential Pressure: Liquid: 5.5 bar (80psi) at 77°F/25°C

Gas: 4.1 bar (60psi) at 77°F/25°C

Minimum Burst Pressure: 8.3 bar (120psi) at 77°F/25°C

Maximum Reverse Differential Pressure: 3.0 bar (44psi) at 68°F/20°C

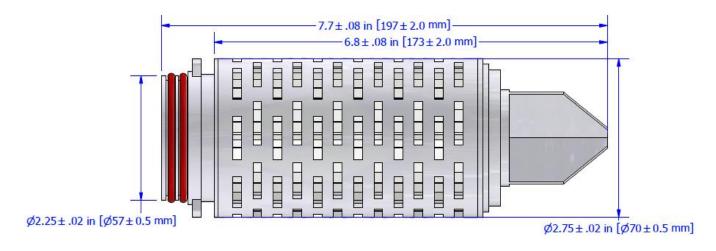
Maximum Operating Temperature: 176°F/80°C at 0.7 bar (10psi)

[Contact International Filter Products for high-temperature application above 122°F/50°C operating temperature]

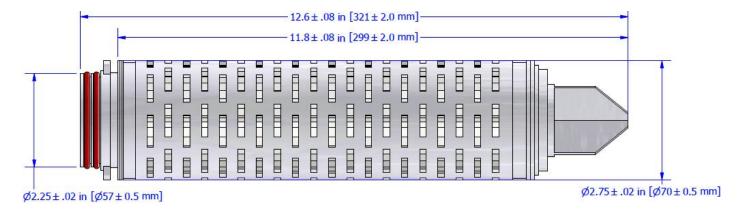


Nominal Dimension:

Part Number: CRT-PES-05-XXX-X6X / CRT-PES-05-XXX-X6X-5

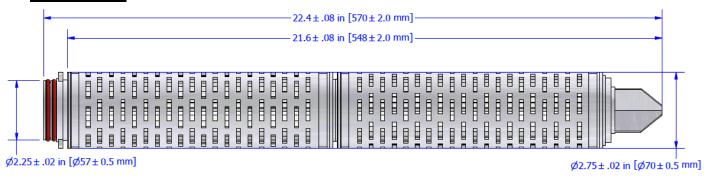


Part Number: CRT-PES-10-XXX-X6X / CRT-PES-10-XXX-X6X-5

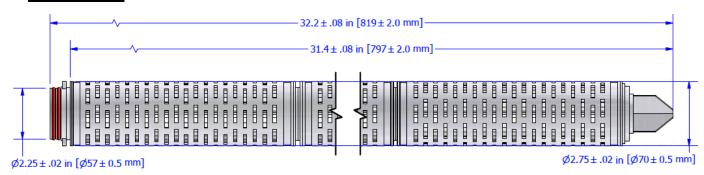




Part Number: CRT-PES-20-XXX-X6X / CRT-PES-20-XXX-X6X-5



Part Number: CRT-PES-30-XXX-X6X / CRT-PES-30-XXX-X6X-5



Typical Filtered Volume:

5-Inch; 25L- 200L

10-Inch; 50L- 400L

20-Inch; 100L- 800L

30-Inch; 150L-1,200L



Regulatory Compliance

Bacterial Retention:

Micron Rating	Challenge Organism	LRV
0.1 μm	B. diminuta	LRV 8
0.2 μm	B. diminuta	LRV 7
0.45 μm	S. marcescens	LRV 7
0.65 μm	L. brevis	LRV 7
0.8 μm	S. cerevisiae	LRV 7
1.2 μm	PSL Particle	

Filter Integrity:

Micron Rating	Minimum Bubble Point		
	Psi	bar	
0.1 μm	61 psi	4.2 bar	
0.2 µm	50 psi	3.4 bar	
0.45 µm	26 psi	1.8 bar	
0.65 µm	17.4 psi	1.2 bar	
0.8 µm	14.5 psi	1.0 bar	
1.2 µm	13 psi	0.9 bar	

Physiochemical:

- USP Oxidizable Substances
- USP <645> Conductivity
- USP <643> Non-Volatile Residue
- Total Organic Carbon (TOC) Analysis

Cleanliness:

- USP <85> Bacterial Endotoxin Test
- USP <788> Particulate Matter
- 21 CFR 210.72 and 2010.3 (b) (6) Fiber Shedding

Biocompatibility:

- ASTM F756-17 Hemolysis
- USP <88> (USP Class VI Plastics) Biological Reactivity Tests, In Vivo
- USP <87> / ISO 10993-5, In Vitro Cytotoxicity
- 21 CFR 177 FDA Indirect Food Additive



USP Bacterial Endotoxins:

A representative sample from the lot is tested to confirm that an aqueous extraction of the product contains <0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.

Sterilization:

- Autoclave: The filters can be autoclaved for up to 50 cycles at 125°C (257°F) for 30 minutes.
- Steam-in-place: The filters can be sterilized by steam-in-place procedure up to 30 cycles at 135°C (275°F) for 30 minutes at less than 0.3 bar differential pressure.
- <u>Sanitization:</u> The filters can be sanitized by hot water or common chemicals that are compatible with filter components.

Animal-derived Components:

No animal-derived material is intentionally added or used during the manufacture of IFP CRT-PES cartridges.

Human and Veterinarian Use:

The product is safe for Human and Veterinarian use. CGMP CFR part 210 & 211, additional requirement of 21 CFR part 600 and 21 CFR part 680 are applicable to the aseptic manufacturing process.

RoHS:

Restriction of Hazardous Substances (RoHS 3) Directive 2015/863

REACH:

REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) Article 57, Regulation No. 1907/2006)

Traceability:

For traceability and easy identification:

- A Certificate of Conformance is provided with each capsule.
- Each filter bag and box are labeled with the product part number, lot number, and identifying characteristics.

Each capsule is engraved and labeled with the product part number, lot number, and identifying characteristics.

Shelf Life:

The CRT-PES Biological Grade cartridges have a shelf life of 5 years from the date of manufacture.





CRT-PES Series PES Cartridge

(Biological Grade)

Ordering Guide

CRT PES [1] [2] A [3] [4] [5] [6]								
[1]	[2]	[3]	[4]	[5]	[6]			
Length	Micron Rating	End Modification	O-Ring / Gasket Material	Optional	Grade			
 10:10-Inch 20:20-Inch 30:30-Inch 40:40-Inch 05:5-Inch 	 001: 0.10 μm 002: 0.20 μm 004: 0.45 μm 006: 0.65 μm 008: 0.80 μm 010: 1.2 μm 	 2: 222 O-Ring Flat 6: 226 O-Ring Fin 7: 226 O-Ring Flat 0: DOE Flat Gasket 	 S: Silicone E: EPDM N: Buna-N PV: Teflon	• -5 : Stainless Steel Insert	• -B : Biological Grade			

Example:

CRTPES10002A6S-B

IFP CRT PES Cartridge (Biological Grade), 0.2µm PES hydrophilic membrane (Sterilizing Grade), 10.0-inch Long, Filtration Area 0.7 m², 226 O-Rings with Fin, Silicone Double O-Rings.

Part Number Description





Special Configuration:

Layer Option:

- Single Layer
- Dual Layer

End Modification Option:

- 2: 222 O-Ring Flat
- 6: 226 O-Ring Fin
- 7: 226 O-Ring Flat
- 0 : DOE Flat Gasket

Micron Rating Option:

- 0.04 Micron
- 0.1 Micron
- 0.2 Micron
- 0.45 Micron
- 0.65 Micron
- 0.8 Micron
- 1.2 Micron

O-Ring/Gasket Material Option:

- S: Silicone
- E : EPDM
- N : Buna-N
- PV : Teflon Encapsulated Viton
- PS: Teflon Encapsulated Silicone
- V : Viton

