



## Fluid Purification

## SPECIFICATIONS

## Microfiltration Products

# Zetapor® 045SP Pharmaceutical Grade Cartridge



Zetapor 045SP Pharmaceutical Grade Cartridges are designed for safe, reliable, and efficient operation. The SP cartridge has been validated for bacteria removal and has passed the USP XX Class VI Safety Test. The electropositive charge of the Zetapor membrane provides highly efficient filtration and pyrogen reduction.

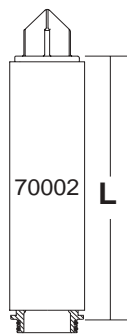
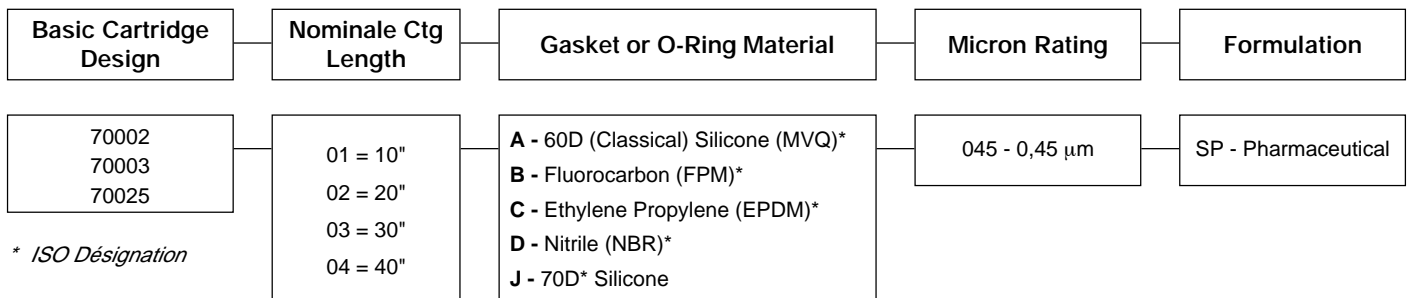
### APPLICATIONS

- Final filtration of LVP solutions.
- Prefilter to 0.20 µm final filters.
- Pyrogen removal filter
- Solvents
- Pharmaceutical solutions

### FEATURES AND BENEFITS

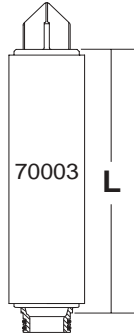
- Charge modified Nylon N<sub>66</sub>
- Validated by ASTM procedures for bacterial retention
- Double layer reinforced membrane
- Naturally hydrophilic membrane
- Integrity testable
- Biologically safe
- Non pyrogenic
- Drug Master File (DMF)
- Large compatibility chemical
- Cartridge style for all housing
- Electropositive charge of Zetapor provides enhanced particle removal
- Validation guide available
- Assures filtration performance
- Fast and complete wetting without use of surfactants
- Verify cartridge integrity and proper installation
- In accordance with USP XX Class VI test + 12 additional safety tests
- Assure safe use with parental products
- Provides added documentation for users
- Wide solvent compatibility
- Large housing compatibility

# ORDERING GUIDE



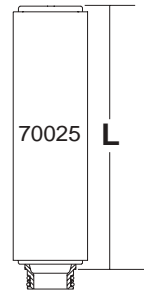
Single open end  
Code 7 (226) O-Ring  
Bayonet Lock

Nominal Ctg Length	70002 L (mm)
01	259
02	506
03	754
04	1002



Single open end  
Code 8 (222) O-Ring

Nominal Ctg Length	70003 L (mm)
01	260
02	507
03	755
04	1003



Single open end  
Code 3 (222) O-Ring

Nominal Ctg Length	70025 L (mm)
01	260
02	507
03	755
04	1003

## Cuno...A World Leader in Fluid Purification

Cuno is a U.S. based multinational, high technology company with over 1300 employees worldwide and manufacturing facilities in the United States, France, Japan, Australia and Brazil. Cuno filtration products offer safety, efficacy and superiority. With over 200 patents worldwide, Cuno offers the most advanced and innovative products available for pharmaceutical, biological and bioprocessing filtration.

Global manufacturing sites, combined with trained stocking distributors, assure a consistent supply of advanced filtration products to pharmaceutical and biological manufacturers worldwide.

Cuno's broad product offering for pharmaceutical manufacturing includes membrane-based sterile product and air filters, a broad range of pleated and depth prefilter systems, and sanitary design filter housings.



Visit our Web Site @ [www.cuno.com](http://www.cuno.com).

Your Local Distributor :

## APPLICATIONS SUPPORT - SASS

Cuno's Scientific Applications Support Services (SASS) is staffed by scientists and engineers, with state-of-the-art laboratory facilities.

The SASS staff, familiar with a wide range of filtration and separation applications, work closely with the customer to recommend the most effective and economical Cuno filtration systems.



## Service Worldwide

## Fluid Purification

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**CUNO GmbH** - Wilh-Th-Römheld - Str. 32 - 55130 Mainz - Germany  
Telefon 061 31 - 98 442-0 - Telefax 061 31 - 98 44222

**CUNO Srl** - Via Zara, 38 - 20032 Cormano (Mi) - Italy  
Tel : 02 615 516.1 - Fax : 02 615 516 30

**CUNO** - Z.I. de la Sablière - 94372 Sucy-en-Brie - France  
Tel. : 01 49 82 91 00 - Fax : 01 49 82 91 01

**CUNO Belux** - Nieuwe Weg 1 - Haven 1053 - 2070 Zwijndrecht (Antvers) - Belgium  
Tel. : 03 250 15 40 - Fax : 03 250 15 49

**CUNO Latina Ltda** - Rua Amf do Brasil 251A  
18120 Mairinque-SP - Brazil

**CUNO Pacific Pty. Ltd.** - 140 Sunnholt Road  
Blacktown, N.S.W. 2148 - Australia

**CUNO Filtration Asia** - Pte. Ltd.  
18 Tuas Link 1, (3<sup>rd</sup> Floor) - Singapore 638597

**CUNO K.K.** - Hodagaya Station - Building 6F  
1-7 Iwai-cho, Hodagaya-ku - Yokohama 240 Japan

**CUNO Incorporated**  
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This information contained in this document is accurate at time of print. Continuous product development may lead to specification changes and/or product replacement without notice. Please contact your nearest Cuno Office for most recent revision.

## PERFORMANCE VALIDATION

Zetapor 045SP Pharmaceutical Grade cartridges have passed a thorough validation program that documents product claims and safety.

### Bacterial Retention

Bacterial removal to levels in excess of  $10^6$  cells/cm<sup>2</sup> was verified using ASTM procedure with *Serratia marcescens*.

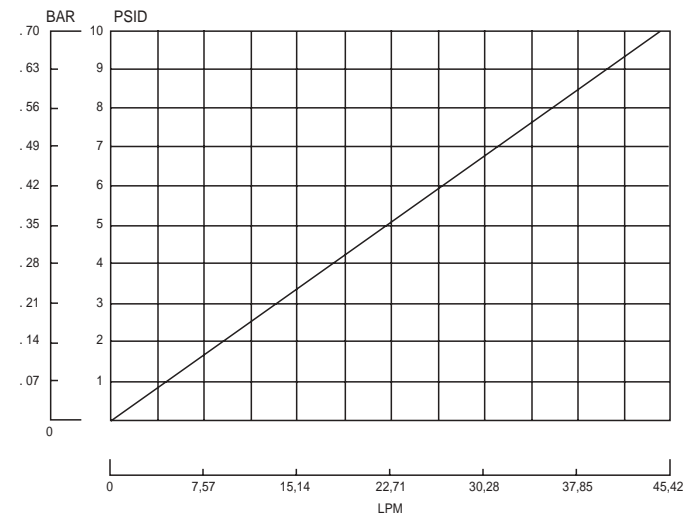
### Integrity Test

The integrity tests document the relationship between 100 % bacterial retention and provide the user with two nondestructive integrity tests.

### Water Flow Rate

The 045SP cartridges provide consistent water flow rates (see graph).

WATER FLOW AT 25°C



Defined flow rates provide a means for system sizing. The flow rate specification is 20 LPM per 10 in. elements at 25°C. Housing losses have been deducted.

### Sterilisation

The SP cartridge can be sterilised by steam or autoclaved for up to 10 hrs. at 145°C.

## BIOLOGICAL SAFETY

The Zetapor 045 SP cartridge is biologically safe as determined by the USP XX Class VI Safety Test and has been subjected to the following 12 additional safety tests, many of which are more specific and sensitive.

- Primary Skin Irritation Study
- Hemolysis Test
- Primary Eye Irritation Study
- Single Dose Oral Toxicity Test
- Kligman Maximization Test
- Agar Overlay Cytotoxicity Test
- Recalcified Whole Blood Clotting Time
- Lymphocompatibility Test
- Ames Bacterial Mutagenesis Test
- Neutral Red Uptake Test
- CHO Clonal Cytotoxicity
- WI-38 Cytotoxicity (MEM Elution)

The complete Biological Safety Report for Zetapor SP Cartridges is available upon request.

## EXTRACTABLES

### Oxidizable Substances and Pyrogenicity

Zetapor 045 SP cartridges are low in extractable oxidizable substances and are non-pyrogenic. However, it is recommended as a good manufacturing practice to rinse the cartridges with 750 ml of fluid (WFI or the product) per 10 in. element prior to use.

### Gravimetric Extractables

Zetapor SP cartridges were tested for total gravimetric extractables and chemical compatibility by a 4-hour soak test at temperatures noted in the compatibility chart. Extractable values for a number of these solvents are contained in the Validation Guide.

### Chemical Compatibility

Zetapor 045SP cartridges exhibit wide chemical compatibility. The compatibility data that follow are intended as a guide only. CUNO recommends that the compatibility of the chemical considered for use with the cartridge be established under actual filter process conditions since the operating parameters may affect the interaction between the cartridge and chemical. Consideration must also be given to the selection of suitable O-ring materials to ensure complete chemical compatibility.

## ZETAPOR CARTRIDGE CHEMICAL COMPATIBILITY

SOLUTION	TEMP. °C	COMPATIBILITY
Acetic Acid 25%	22	G
Acetic Acid 70%	22	L
Acetic Acide Glacial	22	L
Acetone	22	G
Amonia 10%	22	G
Acetonitrile	22	L
Acetonitrile	22	N
Ammonium Hydroxide 28%	22	G
Benzene	22	L
Benzyl Alcohol	22	G
n-Butanol	22	G
n-butyl Acetate	22	G
Butyl Carbitol	22	G
Carbon Tetrachloride	22	L
Carbon Tetrachloride	77	N
Cellosolve Acetate	22	G
Cellosolve Solvent	22	G
Chloroform	22	N
Cotton Sedd Oil	22	G
Cyclohexane	22	L
Cyclohexanone	22	L
Diethyl Acetamide	22	L
Diethyl Formamide	22	N
Dimethyl Formamide	22	N
Dimethyl Sulfoxide	22	L
Ethanol Absolute	22	G
Ethanol Absolute	78	L
Ethanol 50%	22	G
Ethyl Acetate	22	L
Ether, Diethyl	22	L
Ether, Diethyl	35	L
Ethylene Dichloride	22	G
Ethylene Glycol	22	G
Ethylene Oxide 12- 88%	22	L
Formaldehyde 37%	22	G
Glycerol	22	G
n. Heptane	22	L
Hexane	22	L
Hydrochloric Acid 3.7%	22	N
Isobutyl Alcohol	22	G
Isopropyl Alcohol	22	G
Methanol	22	G
Methylene Chloride	22	N
Methyl Isobutyl Ketone	22	G
Monethanolamine	22	L
n-Propanol	22	G
Propylene Glycol	22	G
Pyridine	22	L
Sodium Hydroxide 10%	22	G
Sodium Hypochlorite	22	G
Toluene	22	L
Trichlorotrifluoroethane (Freon)	22	G
Water	22	G
Water	82	G
Xylene	22	L

### Explanation of ratings

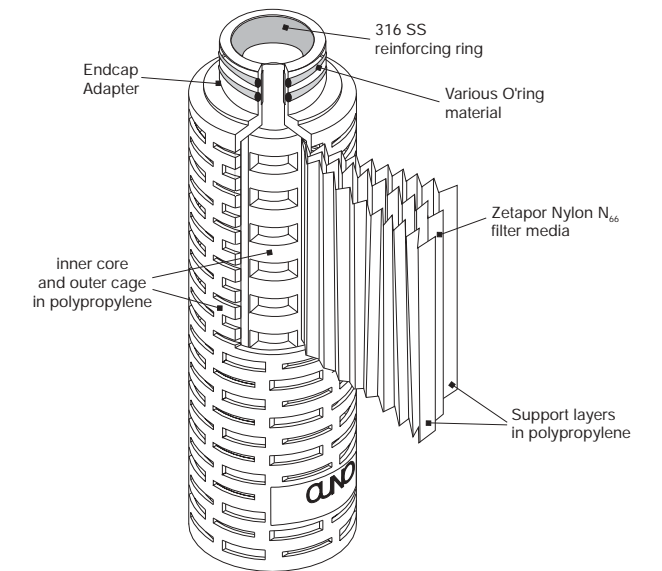
G = good compatibility to the temperatures indicated  
 L = limited compatibility - consult factory  
 N = not recommended  
 (Recommendations based on 4 hr. soak test)

## CONSTRUCTION

Zetapor 045SP cartridges are produced from a pleated filter composite containing a reinforced double layer charge modified Nylon 66 microporous membrane, with polypropylene upstream and downstream supports. Multiple lengths of various end cap styles are produced by thermoplastic welding to eliminate the need for adaptors. No adhesives or surfactants are used in the cartridge assembly.

## MATERIALS

All materials are listed by the FDA in the CFR 21 for food contact. Materials of construction are tested for biological safety (USP Class VI)



## QUALITY ASSURANCE

Zetapor 045SP cartridges are 100 % integrity tested prior to shipment by the diffusion flow method. Each cartridge batch is sample tested for flow, charge capacity, bacteria retention, pyrogenicity, total extractables, and oxidizable substances. In addition, each cartridge is engraved with a unique serial number that provides complete traceability from raw materials through to the finished product.

## CARTRIDGE SPECIFICATIONS

Removal Rating	0.45 µm
Bacterial Removal Efficiency	10 <sup>6</sup> cells <i>Serratia marcescens</i> /cm <sup>2</sup>
Diffusion Flow Rate*	≤ 10 cc/min 1.75 bar
Water Bubble Point	2 bar
Extractables*	< mg 25°C
Oxidizable Substances*	Neg after 500 ml flush
Pyrogenicity*	< 25 pg / ml for first 250 ml
Material of Construction	See Materials section
Water Flow Rate	See Graph
End Cap Styles	See ordering guide
Filter Area	0.5 m <sup>2</sup> / 10"
Dimensions (nominal)	2.8 in. OD, lengths to 40 in.

\* per 10"

## OPERATING CONDITIONS

Maximum Operating Temperature	80°C
Max. differential pressure (25°C)	4.5 bar forward 4.5 bar reverse
Sterilisation procedure	In-situ steam or autoclave to 145°C
Recommended rinse volume	750 ml minimum (per 10" length)

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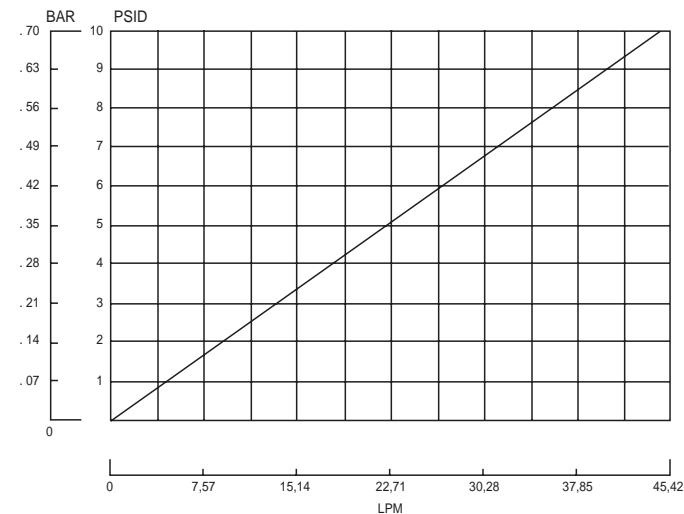
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Butyl Carbitol	22	L
Carbon Tetrachloride	22	G
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Cellosolve Acetate	22	G
Cellosolve Solvent	22	G
Chloroform	22	N
Cotton Sedd Oil	22	L
Cyclohexane	22	L
Cyclohexanone	22	L
Diethyl Acetamide	22	L
Diethyl Formamide	22	N
Dimethyl Formamide	22	N
Dimethyl Sulfoxide	22	L
Ethanol Absolute	22	G
Ethanol Absolute	78	L
Ethanol 50%	22	G
Ethyl Acetate	22	L
Ether, Diethyl	22	L
Ether, Diethyl	35	L
Ethylene Dichloride	22	G
Ethylene Glycol	22	G
Ethylene Oxide 12- 88%	22	L
Formaldehyde 37%	22	G
Glycerol	22	G
n. Heptane	22	L
Hexane	22	L
Hydrochloric Acid 3.7%	22	N
Isobutyl Alcohol	22	G
Isopropyl Alcohol	22	G
Methanol	22	G
Methylene Chloride	22	N
Methyl Isobutyl Ketone	22	G
Monethanolamine	22	L
n-Propanol	22	G
Propylene Glycol	22	G
Pyridine	22	L
Sodium Hydroxide 10%	22	G
Sodium Hypochlorite	22	G
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Trichlorotrifluoroethane (Freon)	22	G
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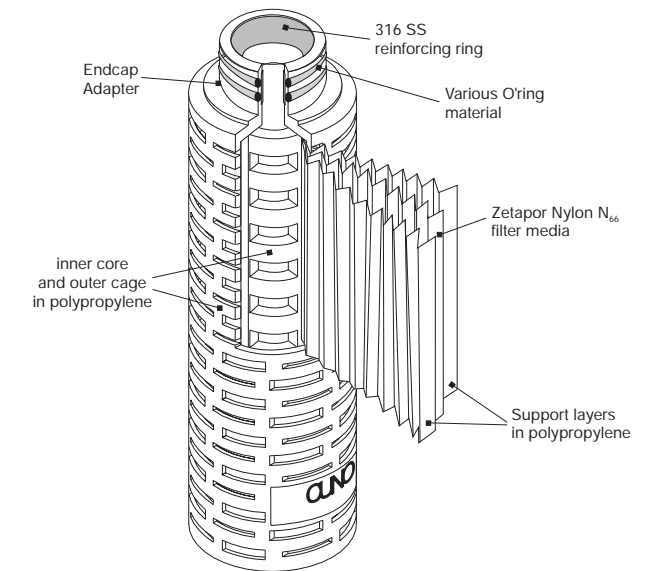
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