

LENNTECH

info@lennotech.com Tel. +31-152-610-900
www.lennotech.com Fax. +31-152-616-289

LifeASSURE™ 045SP Series

Nylon 6,6 membrane filters
for pharmaceutical applications

LifeASSURE™ 045SP pharmaceutical grade cartridges - formerly known as CUNO 045SP cartridges - are designed for safe, reliable and efficient operation. The LifeASSURE 045SP cartridge has been validated for bacteria removal and has passed USP Class VI Safety Test. The electropositive charge of the LifeASSURE 045SP membrane provides highly efficient filtration and pyrogen reduction.

Materials

All materials of construction are tested for biological safety (USP Class VI).

Quality assurance

LifeASSURE 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 oxidisable substances. In addition, each cartridge is engraved with a unique serial number that provides complete traceability from raw materials through to the finished product.

Features and benefits

Charge-modified Nylon 6,6

- Electropositive charge of LifeASSURE 045SP provides enhanced particle removal

Validated by ASTM procedures for bacterial retention

- Validation guide available

Double layer reinforced membrane

- Assures filtration performance

Naturally hydrophilic membrane

- Fast and complete wetting without use of surfactants

Integrity testable

- Verify cartridge integrity and proper installation

Biologically safe

- In accordance with USP Class VI test + 12 additional biological safety tests

Non-pyrogenic

- Assure safe use with parenteral products

Drug Master File (DMF)

- Provides added documentation for users

Large chemical compatibility

- Wide solvent compatibility

Cartridge style for all housing

- Large housing compatibility



Applications

Final filtration of LVP solutions

Prefilter to 0.20 µm final filters

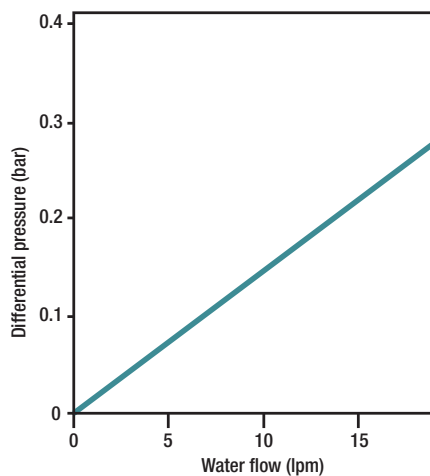
Pyrogen removal filter

Solvents

Pharmaceutical solutions

3M

Clean water flow per 10" cartridge at 25 °C



Performance validation

LifeASSURE 045SP pharmaceutical-grade filter 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/cm² 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 non-destructive integrity tests.

Water flow rate

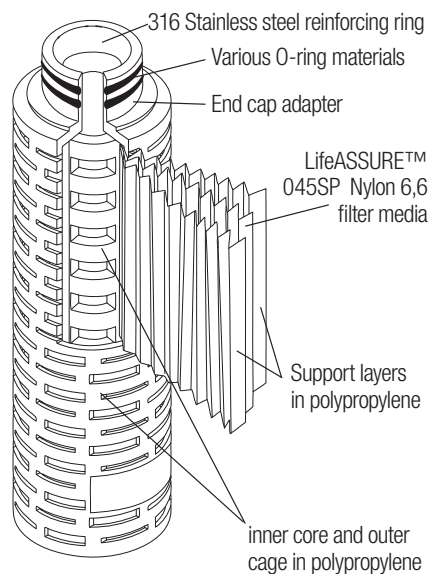
The LifeASSURE 045SP cartridges provide consistent water flow rates (see graph).

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

Sterilisation

The LifeASSURE 045SP cartridge can be sterilised by steam or autoclaved up to 145 °C up to ten 1 hour cycles.

Standard cartridge construction



Biological safety

The LifeASSURE 045SP filter cartridge is biologically safe as determined by the USP 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 maximisation 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)

A complete Biological Safety Report for LifeASSURE 045SP filter cartridges is available upon request.

Extractables

Oxidisable substances and pyrogenicity

LifeASSURE 045SP cartridges are low in extractable oxidisable 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" element prior to use.

Gravimetric extractables

LifeASSURE 045SP filter 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

LifeASSURE 045SP cartridges exhibit wide chemical compatibility. The compatibility data that follow are intended as a guide only. 3M Purification 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.

Construction

LifeASSURE 045SP cartridges are produced from a pleated filter composite containing a reinforced double layer charge-modified Nylon 6,6 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.

Cartridge specification

Removal rating	0.45 µm
Bacterial removal efficiency	10 ⁶ <i>Serratia marcescens</i> cells / cm ²
Diffusion flow rate*	≤ 10 cc/min 1.75 bar
Water bubble point	2 bar
Extractables*	< 20 mg 22 °C
Oxidisable 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 ² / 10"
Dimensions (nominal)	2.8 in. OD, lengths to 40"
* per 10"	

Operating conditions

Maximum operating temperature	80 °C
Maximum differential pressure (25 °C)	4.5 bar forward 4.5 bar reverse
Sterilisation procedure	<i>In situ</i> steam or autoclave to 145 °C
Recommended rinse volume	750 ml minimum (per 10" length)

Applications support - SASS

3M Purification'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 3M Purification filtration systems.

Cartridge chemical compatibility table

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 Seed 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

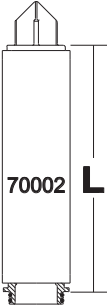
G = good compatibility to the temperatures indicated
L = limited compatibility - consult 3M Purification
N = not recommended
(Recommendations based on 4 hr. soak test)

LifeASSURE™ 045SP Series filter cartridges - Ordering guide

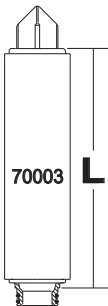
Basic cartridge design	Nominal cartridge length	Gasket or O-ring material	Micron rating	Formulation
70002 70003 70025	01 – 10" 02 – 20" 03 – 30" 04 – 40"	A – 60D (classical) silicone (MVQ)* B – Fluorocarbon (FPM)* C – Ethylene propylene (EPDM)* D – Nitrile (NBR)* J – 70D* silicone	045 – 0.45 µm	SP – Pharmaceutical

* ISO designation


Note: LifeASSURE 045SP is new name for CUNO Zetapor SP 045.



Single open end Code 7 (226) O-ring Bayonet lock	
Nominal cartridge length	70002 L (mm)
01	259
02	506
03	754
04	1002



Single open end Code 8 (222) O-ring	
Nominal cartridge length	70003 L (mm)
01	260
02	507
03	755
04	1003



Single open end Code 3 (222) O-ring	
Nominal cartridge Length	70025 L (mm)
01	260
02	507
03	755
04	1003

Important Notice

The information described in this literature is accurate to the best of our knowledge. A variety of factors, however, can affect the performance of the Product(s) in a particular application, some of which are uniquely within your knowledge and control. INFORMATION IS SUPPLIED UPON THE CONDITION THAT THE PERSONS RECEIVING THE SAME WILL MAKE THEIR OWN DETERMINATION AS TO ITS SUITABILITY FOR THEIR USE. IN NO EVENT WILL 3M PURIFICATION BE RESPONSIBLE FOR DAMAGES OF ANY NATURE WHATSOEVER RESULTING FROM THE USE OF OR RELIANCE UPON INFORMATION.

It is your responsibility to determine if additional testing or information is required and if this product is fit for a particular purpose and suitable in your specific application.

3M PURIFICATION MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER NATURE HEREUNDER WITH RESPECT TO INFORMATION OR THE PRODUCT TO WHICH INFORMATION REFERS.

Limitation of Liability

3M Purification will not be liable for any loss or damage arising from the use of the Product(s), whether direct, indirect, special, incidental, or consequential, regardless of the legal theory asserted, including warranty, contract, negligence or strict liability. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to you.

3M is a registered trademark of the 3M Company. LifeASSURE is a registered trademark of the 3M Company used under license.

LENNTECH

info@lennotech.com Tel. +31-152-610-900
www.lennotech.com Fax. +31-152-616-289



For more contact addresses visit our website www.3M.eu/filtration or www.3Mpurification.com/international.

Data may be subject to change without further notice.

© 3M 2012. All rights reserved.

v.2 - DOC10084
LITCTLA045SP1.EU - 0112

70002 01 A 045SP	70025 01 A 045SP
70002 01 B 045SP	70025 01 B 045SP
70002 01 C 045SP	70025 01 C 045SP
70002 01 D 045SP	70025 01 D 045SP
70002 01 J 045SP	70025 01 J 045SP
70002 02 A 045SP	70025 02 A 045SP
70002 02 B 045SP	70025 02 B 045SP
70002 02 C 045SP	70025 02 C 045SP
70002 02 D 045SP	70025 02 D 045SP
70002 02 J 045SP	70025 02 J 045SP
70002 03 A 045SP	70025 03 A 045SP
70002 03 B 045SP	70025 03 B 045SP
70002 03 C 045SP	70025 03 C 045SP
70002 03 D 045SP	70025 03 D 045SP
70002 03 J 045SP	70025 03 J 045SP
70002 04 A 045SP	70025 04 A 045SP
70002 04 B 045SP	70025 04 B 045SP
70002 04 C 045SP	70025 04 C 045SP
70002 04 D 045SP	70025 04 D 045SP
70002 04 J 045SP	70025 04 J 045SP
70003 01 A 045SP	
70003 01 B 045SP	
70003 01 C 045SP	
70003 01 D 045SP	
70003 01 J 045SP	
70003 02 A 045SP	
70003 02 B 045SP	
70003 02 C 045SP	
70003 02 D 045SP	
70003 02 J 045SP	
70003 03 A 045SP	
70003 03 B 045SP	
70003 03 C 045SP	
70003 03 D 045SP	
70003 03 J 045SP	
70003 04 A 045SP	
70003 04 B 045SP	
70003 04 C 045SP	
70003 04 D 045SP	
70003 04 J 045SP	