www.parker.com/dhDairy

ASEPT-X Filter Cartridges

A Technical Guide

Parker domnick hunter

ENGINEERING YOUR SUCCESS.

Parker domnick hunter specialise in filtration and separation technology for gas purification and sterilisation in critical applications within the food and pharmaceutical industries.

As a customer of Parker domnick hunter you have access to leading technologies to control specific contamination hazards to defined standards, protecting food quality at the lowest cost of ownership.

With technical experts represented within industry organisations worldwide and scientific, engineering and sales staff operating in 50 countries, we can support your global operations. We can provide technical support around system design and operation to ensure maximum protection and a high level of food safety in your process.

With over 50 years of experience supporting leading brands in critical industries, Parker domnick hunter is the perfect partner for gas purification and sterilisation solutions.

www.parker.com/dhDairy

Protecting aseptic processes with ASEPT-X sterile gas filters

The ASEPT-X range of sterilising grade gas filters provides increased microbial security and reduced costs for the aseptic processing of sensitive food and beverage products.

ASEPT-X sterilising grade filters have been validated to withstand reverse steam sterilisation processes without the need for condensate management. This unique feature allows a reduction in hardware and automation capability leading to reduced engineering costs per filter application. Maintaining filter integrity under these harsh conditions also safeguards the sterile gas process, reduces the risk of contamination and improves filter lifetime significantly over alternatives.

- Complete assurance of process sterility.
- Increased element lifetime and microbial security.
- Reduced hardware and automation costs for SIP processes.

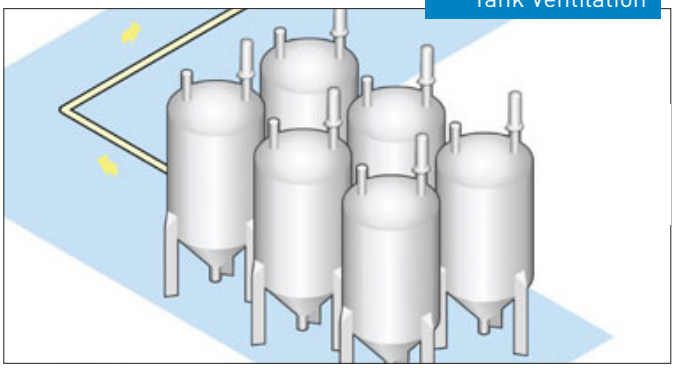
Application description

The ASEPT-X range of filters has been designed to provide sterile gas for critical processes within food and beverage production.

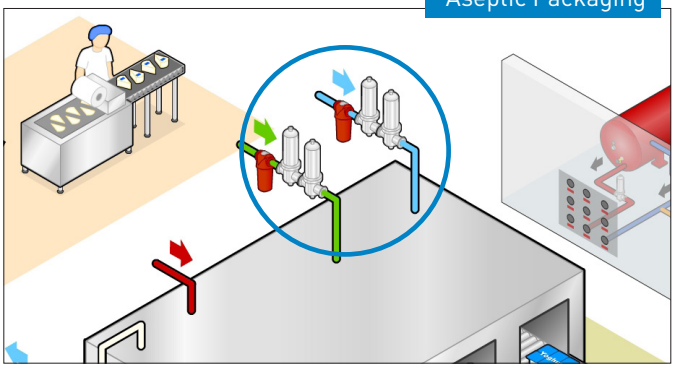
Most food manufacturing processes are warm, humid environments, offering perfect conditions for the proliferation of bacteria and bacteriophage organisms. In food production and packaging facilities microorganisms can be transmitted by aerosols consisting of particles dispersed in air. These liquid or solid particles may have microorganisms inside or on their surfaces.

It is for these reasons why careful control of microbial contamination is required in order to protect the products during processing and to deliver the required shelf-life once packaged. To maintain product quality any gas which comes into contact with the food, either in storage or in final packaging, is deemed critical and should be sterile filtered to prevent contamination.

Tank Ventilation



Aseptic Packaging



Microbial retention / validation

The retention efficiency of ASEPT-X filters has been determined through multiple bacterial challenge investigations in both aerosol and liquid phases.

Aerosol challenge testing was used to determine the microbial retention efficiency of the filters in their typical mode of operation when acting as sterile gas filters. Liquid bacterial challenge testing was used to determine the microbial retention efficiency when passing bulk liquid condensate which occurs during steam sterilisation.

In both challenge methodologies, ASEPT-X filters which returned pass results when tested with a calibrated Valairdata integrity test machine were used. The results therefore demonstrate the typical microbial retention characteristics of fully integral ASEPT-X filters in critical sterile gas filtration applications.

Aerosol challenge testing

Two microorganisms were used to determine the microbial retention efficiency of ASEPT-X filters in the aerosol phase:

- *Bacillus atrophaeus* NCTC 10073
- MS-2 Bacteriophage NCIMB 10108

Bacillus atrophaeus was chosen to challenge the filters as this is a non-pathogenic species capable of providing the highest possible challenge concentration of viable microorganisms to allow a fully quantitative assessment of the filters to be made. Spores of *Bacillus atrophaeus* were used as a bacterial model because they are known to survive the stresses caused by aerosolisation.

MS-2 bacteriophage is an unenveloped, single stranded, RNA coliphage, 23nm in diameter with a molecular weight of 3.6 x 10^6 Daltons. This organism was chosen to represent other typical coliphage species which can pose processing challenges to food and beverage manufacturers, particularly in the dairy industry.

The challenge apparatus (see figure 1 below) is designed to challenge filters with high concentrations of airborne microorganisms for relatively short times. A suspension of microorganisms in aqueous solution is nebulised by a collison spray forming a fine aerosol containing viable microorganisms. The aerosol was then drawn through connecting stainless steel pipe work leading to the filter housing containing the ASEPT-X test filters. The efficiencies of the filters are calculated by determining the airborne concentration of viable microorganisms upstream and downstream of the filter using suitable aerosol sampling techniques and microbial assay methods.

The retention efficiency of the filters is expressed in terms of log reduction value (LRV) where:

$$LRV = \log_{10} \frac{\text{number of organisms challenging the filter}}{\text{number of organisms recovered in filtrate}}$$

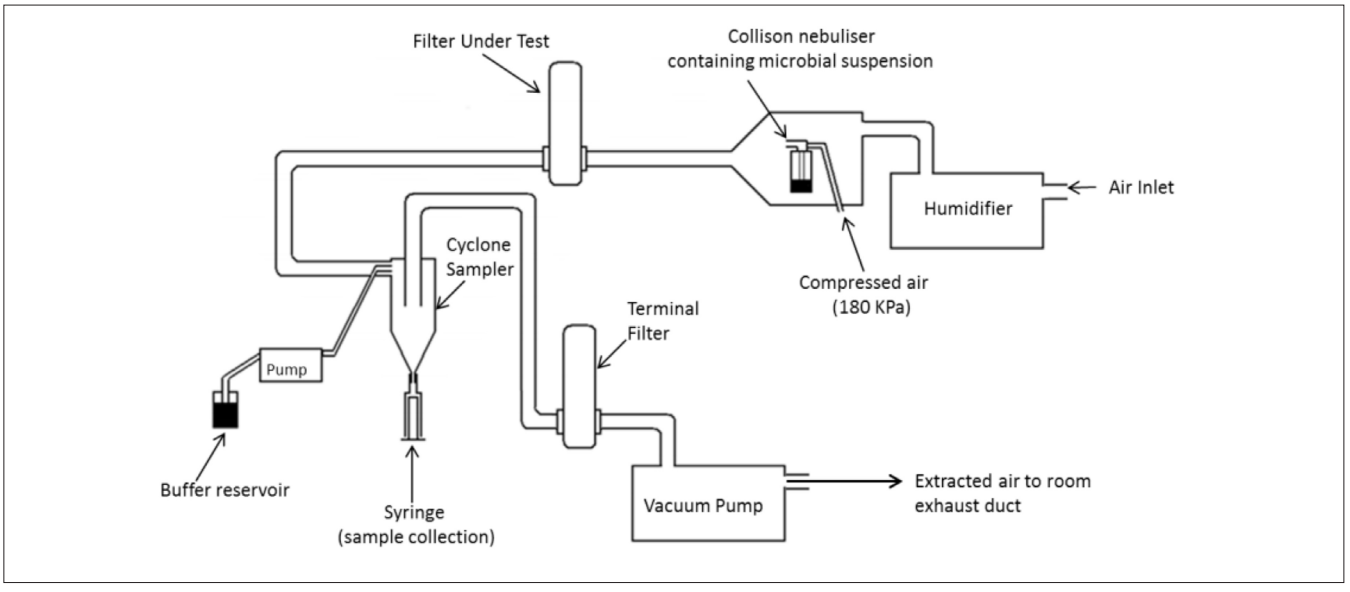


Figure 1. Schematic diagram of aerosol challenge testing apparatus.

Test organism	Total challenge level	Challenge level per cm²	Log reduction value (LRV)
Bacillus atrophaeus	2.38 x 10^{10} cfu	3.78 x 10^6 cfu	11.8
MS-2 Bacteriophage	2.06 x 10^{11} pfu	4.13 x 10^8 pfu	>11.3

Table 1. Summary of aerosol challenge testing results.

Liquid challenge testing

Liquid bacterial challenge testing of ASEPT-X filters was carried out based upon methodologies outlined in ASTM F838 'Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration". Under these test conditions, the test filter is challenged with a minimum of 10^7 viable *Brevundimonas diminuta* (ATCC 19146) per square centimetre of effective filtration area. Any organisms that pass through the test filter are collected and cultured on the surface of analytical discs. The filter retention is quantified by expressing the filter's efficiency to remove the challenge organism from the challenge suspension as a Log Reduction Value (LRV).

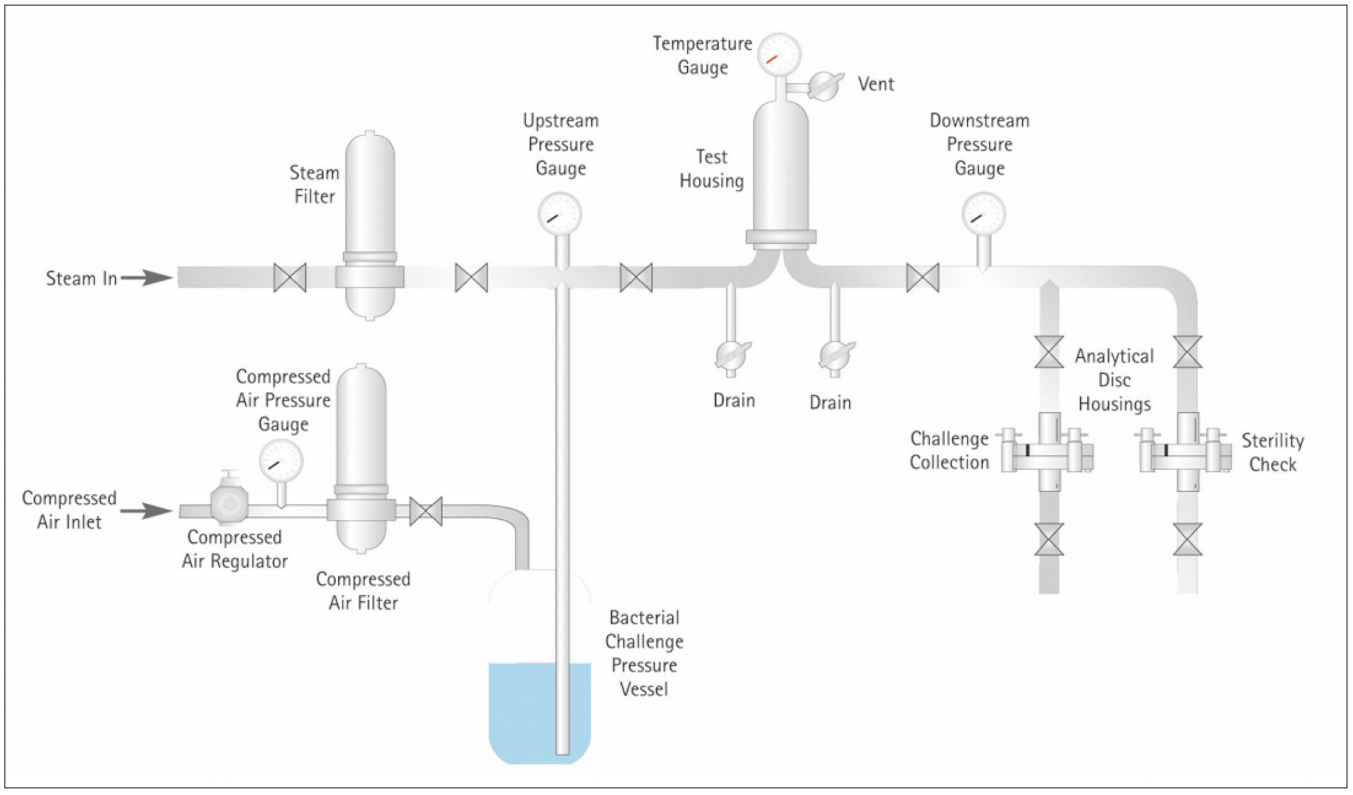


Figure 2. Schematic diagram of liquid bacterial challenge testing apparatus.

Test organism	Total challenge level	Challenge level per cm²	Log reduction value (LRV)
B. diminuta	1.66 x 10^{11} cfu	2.65 x 10^7 cfu	10.6

Table 2. Summary of aerosol challenge testing results.

Conclusions:

This test work demonstrates that ASEPT-X filters return high levels of retention of typical contaminating microorganisms in both the aerosol and liquid phases. This qualifies the suitability of ASEPT-X filters for use as sterilising grade gas filters for critical gas filtration applications in food and beverage production.

Integrity testing

The sterile filtration of gases which come into direct contact with product, product contact surfaces or packaging are deemed critical and therefore qualify as "critical control points" within the HACCP framework. As such a suitable monitoring programme is required to make sure the filter system is fit for purpose and is capable of delivering sterility during use. Non-destructive integrity testing is used to satisfy the monitoring requirements as part of the HACCP plan.

ASEPT-X filters can be routinely integrity tested during use by the aerosol challenge method to comply with the requirements of HACCP to demonstrate filter integrity and to ensure process security.

During the aerosol challenge the test filter is challenged with a high concentration of aerosolized challenge fluid (FDA approved for food use) within the 0.2µm - 0.3µm size range. This size is considered the most penetrating particle size for a sterilising grade gas filter. Along with size exclusion, retention mechanisms in gas are also influenced by electrostatic interactions, Brownian motion and inertial impaction. The test simulates an aerosolized bacterial challenge under high loading, worst-case conditions. Any aerosol which passes through the filter to the downstream, sterile side is directed through a laser particle counter which directly detects the presence of any penetration and calculates a percentage penetration value. On this basis a "pass" or "fail" result for the test filter is established.

Any test filter which returns a "pass" result will perform as validated, thus demonstrating the integrity of the process. Any test filter which returns a "fail" result is unlikely to perform as validated, which can potentially compromise the security of the process if used.

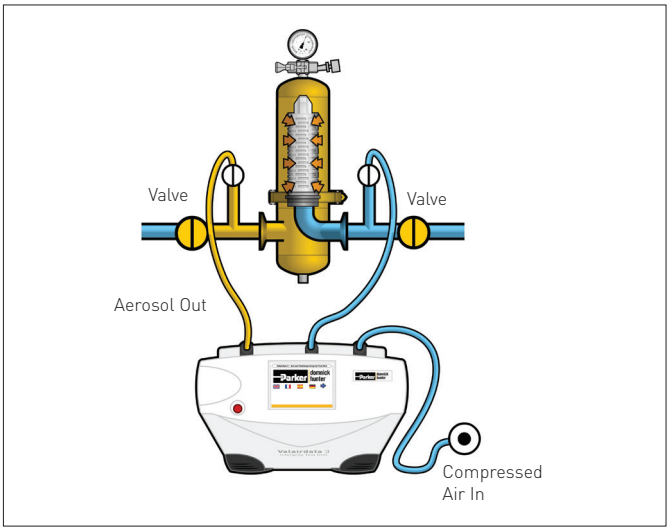
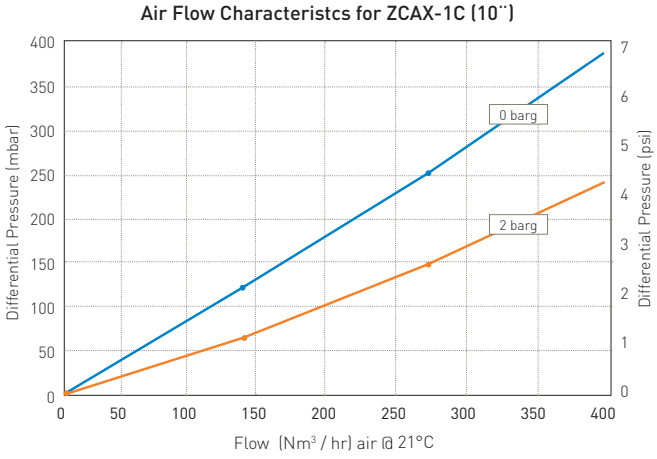
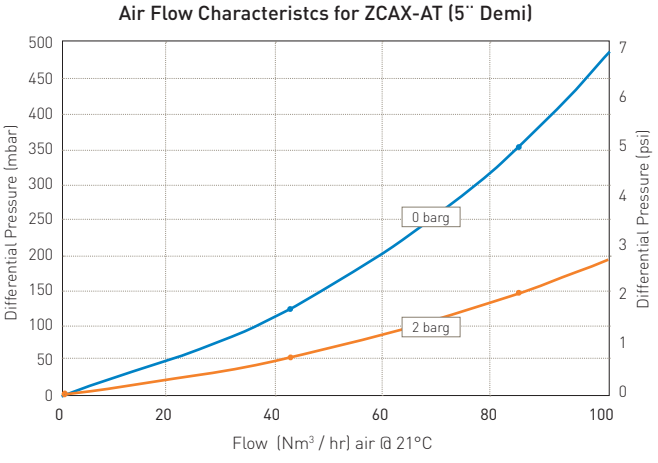


Figure 3. Aerosol challenge integrity testing setup.

Flow rate characteristics

High flow and low pressure resistance are important characteristics for sterilising grade gas filters in order to return economical operation. The typical flow rates for different formats of ASEPT-X filters are provided below. For accurate filter system sizing for any application, please contact your local Parker representative for more information.





Steam sterilisation

In order to maintain aseptic conditions when processing and packaging microbially sensitive foods, it is necessary to frequently sterilise the sterile gas filter system and delivery pipe-work. Steam in place (SIP) is the industry standard method for achieving full system sterility.

In some sterile gas applications, particularly where the steam is introduced to the filter in the reverse direction (e.g. from a sterile tank, or the aseptic zone in a filling machine) the requirement to drain away bulk liquid condensate is undesirable both from a process control perspective and with regards to maintaining downstream sterility.

ASEPT-X filters have therefore been designed to withstand frequent steam sterilisation cycles without the requirement to drain bulk liquid condensate which may damage other sterile gas filter cartridges unless this process is tightly controlled.

ASEPT-X filters have also been validated to withstand the aggressive temperature and pressure conditions which frequently occur in real world sterile gas applications.

To validate the ability of ASEPT-X filters to withstand aggressive SIP cycles without the need to drain condensate, multiple batches of ASEPT-X filters were exposed to multiple 30 minute SIP cycles in a specially designed test rig in both the forward and reverse directions with no condensate drainage across the filter system.

The integrity of the filters was determined before and after SIP testing by the aerosol challenge method using a calibrated Valairdata integrity test machine.

Forward steam sterilisation

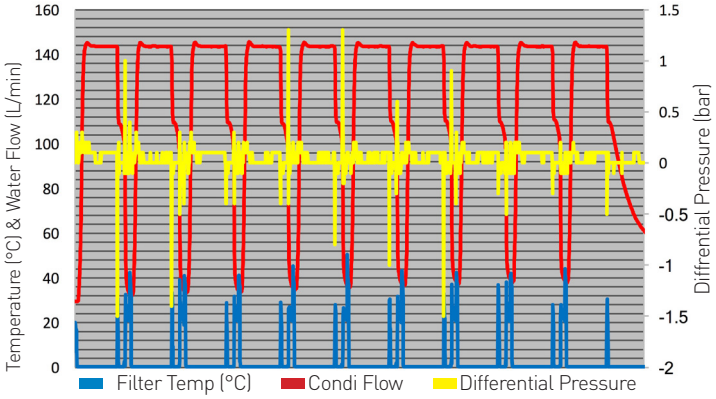


Figure 4. Summary of forward SIP telemetry.

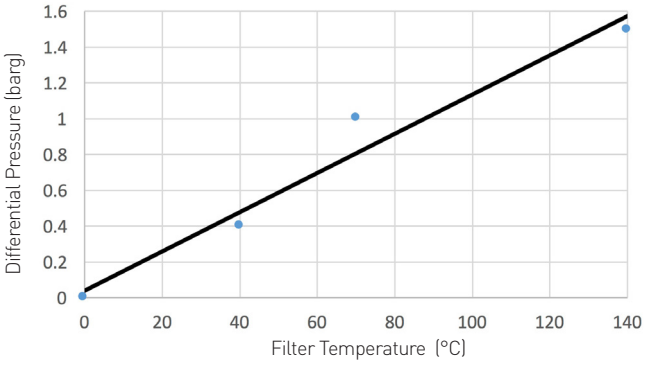


Figure 5. Summary of differential pressure and temperature exposures during forward SIP testing.

Conclusions:

- ASEPT-X filters are capable of withstanding 100 x SIP cycles in the forward direction without the requirement to drain bulk condensate.
- ASEPT-X filters are capable of withstanding aggressive differential pressures at steam temperatures in the forward direction – up to 1.5barg at 140°C.

Reverse steam sterilisation

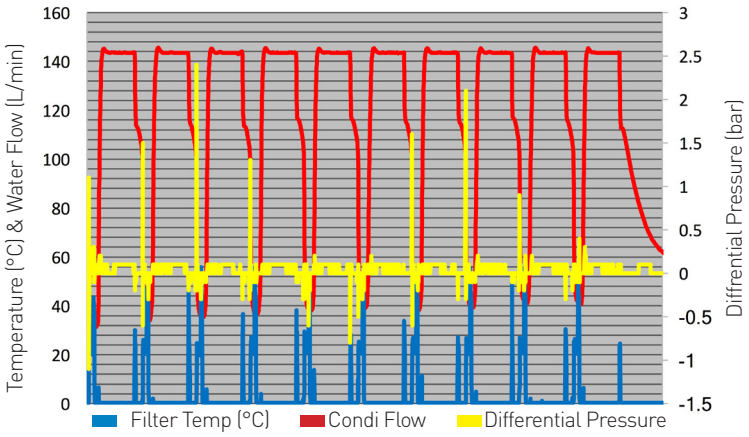


Figure 6. Summary of reverse SIP telemetry.

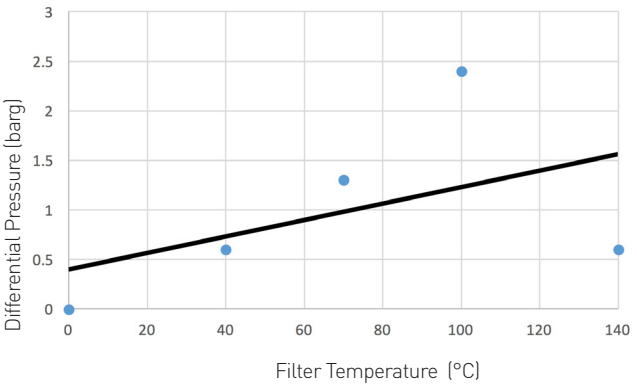


Figure 7. Summary of differential pressure and temperature exposures during reverse SIP testing.

Conclusions:

- ASEPT-X filters are capable of withstanding 100 x SIP cycles in the reverse direction without the requirement to drain bulk condensate.
- ASEPT-X filters are capable of withstanding aggressive differential pressures at steam temperatures in the reverse direction – up to 1.5barg at 140°C.

Recommended operating conditions

Maximum operating tempertaure	70°C
Maximum SIP temperature	145°C
System sizing	It is recommended to size the filter system in order to provide a low starting dP (<200mbar for compressed gas). For tank vent applications restrictions may apply, so please contact your Parker representative for guidance.
Gas velocity	For maximum operational efficiency, it is recommended that gas velocity does not exceed 40m/s.

Quality assurance

Product Release & Traceability

Introduction

Quality is built into all Parker domnick hunter filtration products through a rigorous product design process, careful selection of suppliers and materials, and manufacture within a highly controlled environment using validated production technologies in adherence to cGMP.

Manufacturing Facilities

ASEPT-X filters are manufactured at Parker Hannifin Manufacturing Ltd, domnick hunter, Process Filtration – Europe.

All personnel within the manufacturing operations are fully trained in cGMP and against competency frameworks to ensure their suitability to operate within specific manufacturing areas.

Parker domnick hunter is certified to current versions of the following quality standards by Lloyds Register Quality Assurance:

BS EN 9001 Quality Management Systems
BS EN 14001 Environmental Management Standard
BS EN 22000 Food Safety Management System Standard

Material Conformity

ASEPT-X filters are intended for the sterilisation of gas in food and beverage applications. In this context, Parker domnick hunter's range of ASEPT-X products meets the European Regulatory Requirements and guidelines under the scope of Regulation EC1935/2004.

Materials of Construction

Filtration membrane	Polytetrafluoroethylene (PTFE)
Prefiltration layer	Polypropylene
Upstream support	Polypropylene
Downstream support	Polypropylene
Inner support core	316L stainless steel
Outer protection cage	Polypropylene
End caps	Polypropylene
End caps insert	Polysulphone
O-rings	Silicone /EPDM

Product Release

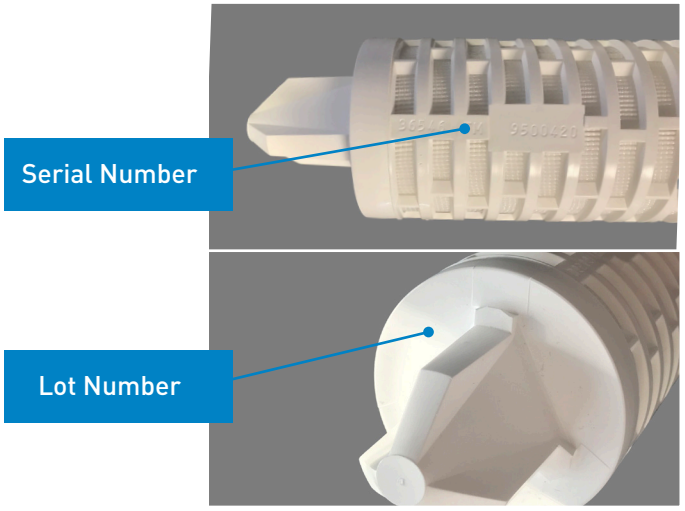
All ASEPT-X filter cartridges undergo final product quality control prior to shipment. This includes: an aerosol challenge integrity test to ensure product integrity prior to dispatch, final inspection and packaging sealed in a protective polyethylene bag within the controlled manufacturing environment.

Traceability

The product code, lot number and unique serial number are printed on all ASEPT-X products.

Additionally, the lot number is identified on the protective bag label and the box label within which the cartridge is packed.

The serial number provides complete traceability back to pleated materials used in the manufacture of each cartridge and the manufacturing processes through the module routing sheet.



Ordering information

ZCAX – [ ] [ ] – [ ]

Code	Length (Nominal)	
B*	2.5¨	(65mm)
A*	5¨	(125mm)
K	5¨	(125mm)
1	10¨	(250mm)
2	20¨	(500mm)
3	30¨	(750mm)
4	40¨	(1000mm)

* *Demi cartridges supplied in packs of 3*

Code	End cap 10¨
C	P-7
P	Bio-X Retrofit
H	UF Retrofit

Code	End cap Demi
H	UF Retrofit
T	TRUESEAL
Y	Demi MCY
Z	Demi A & B Std

Code	O-rings
E	EPDM
S	Silicone

Parker Worldwide

Europe, Middle East, Africa

AE – United Arab Emirates, Dubai
Tel: +971 4 8127100
parker.me@parker.com

AT – Austria, Wiener Neustadt
Tel: +43 (0)2622 23501-0
parker.austria@parker.com

AT – Eastern Europe, Wiener Neustadt
Tel: +43 (0)2622 23501 900
parker.easteurope@parker.com

AZ – Azerbaijan, Baku
Tel: +994 50 2233 458
parker.azerbaijan@parker.com

BE/LU – Belgium, Nivelles
Tel: +32 (0)67 280 900
parker.belgium@parker.com

BY – Belarus, Minsk
Tel: +375 17 209 9399
parker.belarus@parker.com

CH – Switzerland, Etoy
Tel: +41 (0)21 821 87 00
parker.switzerland@parker.com

CZ – Czech Republic, Klecany
Tel: +420 284 083 111
parker.czechrepublic@parker.com

DE – Germany, Kaarst
Tel: +49 (0)2131 4016 0
parker.germany@parker.com

DK – Denmark, Ballerup
Tel: +45 43 56 04 00
parker.denmark@parker.com

ES – Spain, Madrid
Tel: +34 902 330 001
parker.spain@parker.com

FI – Finland, Vantaa
Tel: +358 (0)20 753 2500
parker.finland@parker.com

FR – France, Contamine s/Arve
Tel: +33 (0)4 50 25 80 25
parker.france@parker.com

GR – Greece, Athens
Tel: +30 210 933 6450
parker.greece@parker.com

HU – Hungary, Budapest
Tel: +36 1 220 4155
parker.hungary@parker.com

IE – Ireland, Dublin
Tel: +353 (0)1 466 6370
parker.ireland@parker.com

IT – Italy, Corsico (MI)
Tel: +39 02 45 19 21
parker.italy@parker.com

KZ – Kazakhstan, Almaty
Tel: +7 7272 505 800
parker.easteurope@parker.com

NL – The Netherlands, Oldenzaal
Tel: +31 (0)541 585 000
parker.nl@parker.com

NO – Norway, Asker
Tel: +47 66 75 34 00
parker.norway@parker.com

PL – Poland, Warsaw
Tel: +48 (0)22 573 24 00
parker.poland@parker.com

PT – Portugal, Leca da Palmeira
Tel: +351 22 999 7360
parker.portugal@parker.com

RO – Romania, Bucharest
Tel: +40 21 252 1382
parker.romania@parker.com

RU – Russia, Moscow
Tel: +7 495 645-2156
parker.russia@parker.com

SE – Sweden, Spånga
Tel: +46 (0)8 59 79 50 00
parker.sweden@parker.com

SK – Slovakia, Banská Bystrica
Tel: +421 484 162 252
parker.slovakia@parker.com

SL – Slovenia, Novo Mesto
Tel: +386 7 337 6650
parker.slovenia@parker.com

TR – Turkey, Istanbul
Tel: +90 216 4997081
parker.turkey@parker.com

UA – Ukraine, Kiev
Tel +380 44 494 2731
parker.ukraine@parker.com

UK – United Kingdom, Warwick
Tel: +44 (0)1926 317 878
parker.uk@parker.com

ZA – South Africa, Kempton Park
Tel: +27 (0)11 961 0700
parker.southafrica@parker.com

North America

CA – Canada, Milton, Ontario
Tel: +1 905 693 3000

US – USA, Cleveland
Tel: +1 216 896 3000

Asia Pacific

AU – Australia, Castle Hill
Tel: +61 (0)2-9634 7777

CN – China, Shanghai
Tel: +86 21 2899 5000

HK – Hong Kong
Tel: +852 2428 8008

IN – India, Mumbai
Tel: +91 22 6513 7081-85

JP – Japan, Tokyo
Tel: +81 (0)3 6408 3901

KR – South Korea, Seoul
Tel: +82 2 559 0400

MY – Malaysia, Shah Alam
Tel: +60 3 7849 0800

NZ – New Zealand, Mt Wellington
Tel: +64 9 574 1744

SG – Singapore
Tel: +65 6887 6300

TH – Thailand, Bangkok
Tel: +662 717 8140

TW – Taiwan, Taipei
Tel: +886 2 2298 8987

South America

AR – Argentina, Buenos Aires
Tel: +54 3327 44 4129

BR – Brazil, Sao Jose dos Campos
Tel: +55 12 4009 3500

CL – Chile, Santiago
Tel: +56 2 623 1216

MX – Mexico, Apodaca
Tel: +52 81 8156 6000

VE – Venezuela, Caracas
Tel: +58 212 238 5422

Ed. 2010-09-29

TP_FB_03_10/17_REV2

Parker Hannifin Manufacturing Ltd
domnick hunter
Process Filtration - Europe
Durham Road
Birtley, Co. Durham
DH3 2SF, England
phone +44 (0)191 4105121
email: dhprocess@parker.com
www.parker.com/processfiltration

Parker Hannifin Corporation
domnick hunter
Process Filtration - North America
2340 Eastman Avenue
Oxnard, California, USA 93030
toll free: +1 877 784 2234
phone: +1 805 604 3400
fax: +1 805 604 3401
email: dhpsales.na@parker.com
www.parker.com/processfiltration