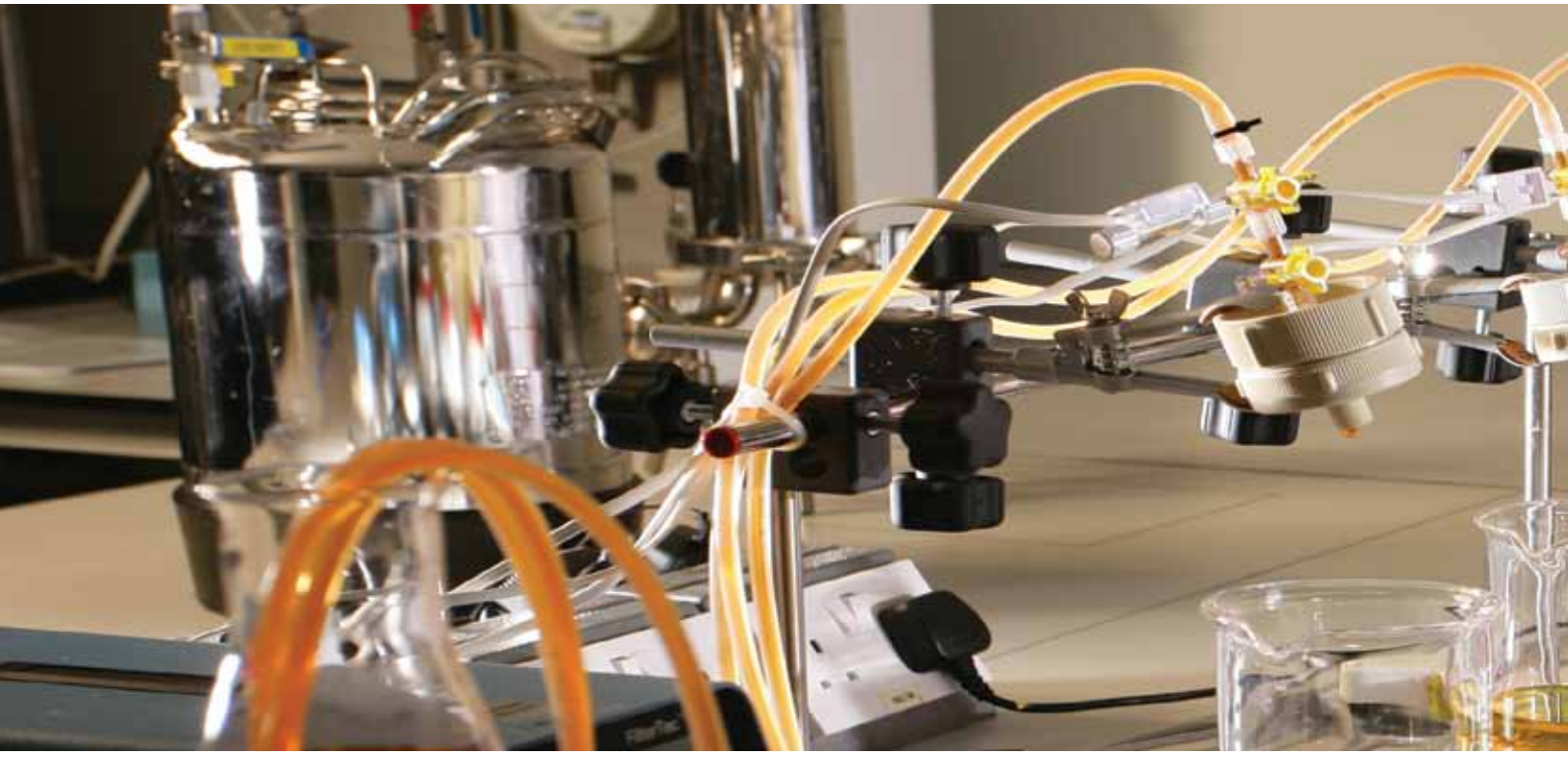
Your Partner in Chemically Synthesized Pharmaceutical Ingredients Filtration

Adding value to your business

aerospace
climate control
electromechanical
filtration
fluid & gas handling
hydraulics
pneumatics
process control
sealing & shielding

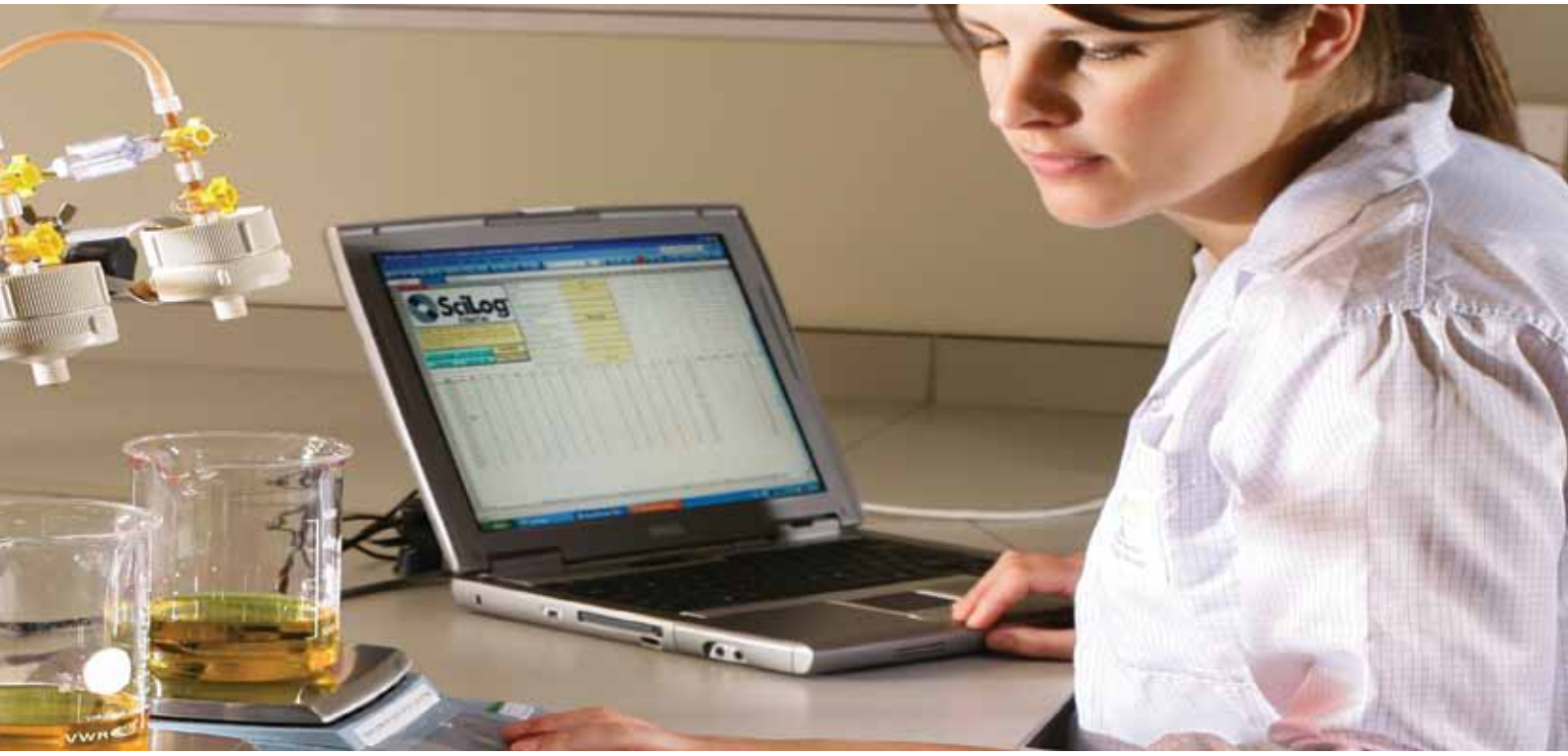
Parker | domnick hunter

ENGINEERING YOUR SUCCESS.



Clear thinking. Clear results.

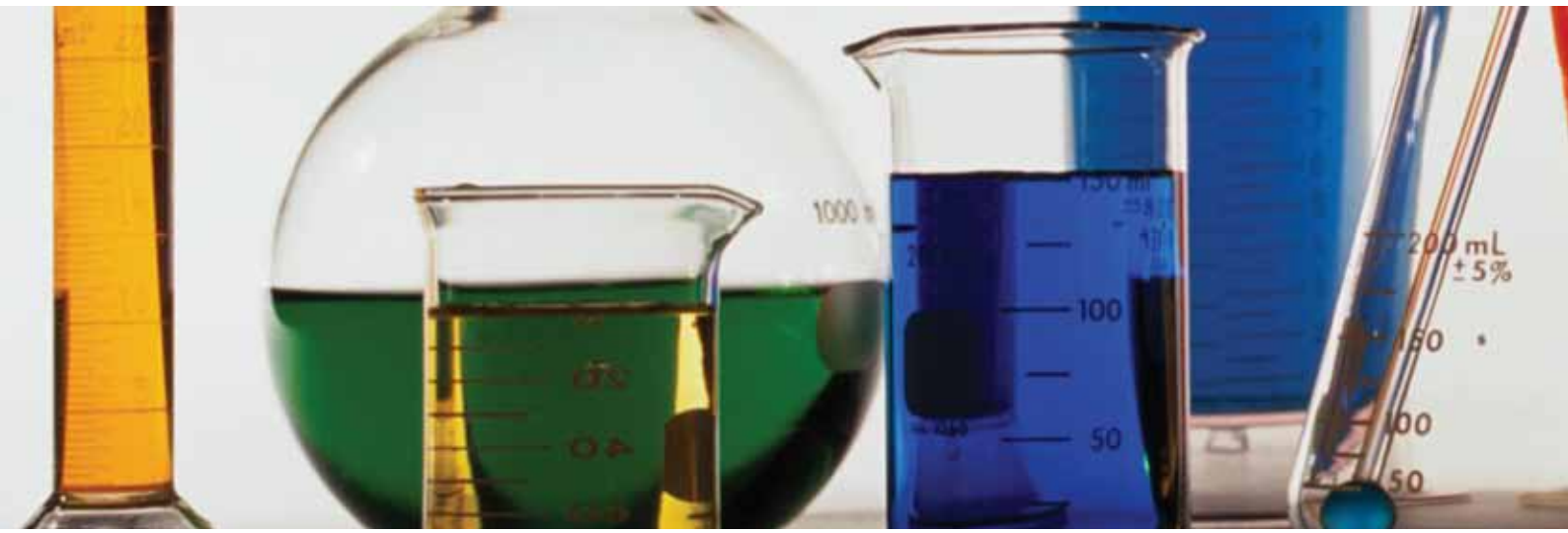
From initial filtration of raw solvents and chemicals through to particulate control and sterilization of the finished active pharmaceutical ingredient (API), Parker domnick hunter understands the problems faced by API manufacturers.
We are dedicated to providing processing solutions that are specially developed to reduce your processing costs, ensure product quality and patient safety.



Focused on adding value to your business

The foundations of process improvement

Supported by high quality products, state-of-the-art technical facilities and an international team of specialists, Parker domnick hunter understands and supports the specific needs of your process, from research & development through to full-scale production.



Commitment to quality

Parker domnick hunter understands that manufacturers of chemically synthesized active pharmaceutical ingredients (APIs) face ever more stringent regulatory requirements. Meanwhile, an increasingly competitive environment and pressure to drive down the price of generic drugs are leading manufacturers to minimize processing costs.

From utilities and raw ingredients to final fill & finish, Parker domnick hunter filtration solutions for the API industry are designed to meet your requirements for economy and reliability as well as reproducible quality throughout your process.

Specialized technical expertise

Parker domnick hunter's dedicated technical support team is available to assist you throughout your entire development process. From system sizing, scale-up and validation through to full-scale process design and optimization, our technical experts work with you to ensure smooth and fast transition between development stages for successful commercialization.

Global support

Wherever you are in the world, Parker domnick hunter is there to help you get the most out of your filtration and fluid management systems. With a dedicated international support team, multiple laboratory and manufacturing facilities, and a network of customer support centres operating in more than 50 countries worldwide, Parker offers you quality support locally.

Dedicated product range

Customer collaboration and a flexible approach to product development have delivered a dedicated, application based filtration and fluid handling product range for the chemically synthesized pharmaceutical ingredients industry. Our customers are an integral part of our product development team leading to focused solutions to meet your present and future business needs.

Solvent and chemical filtration

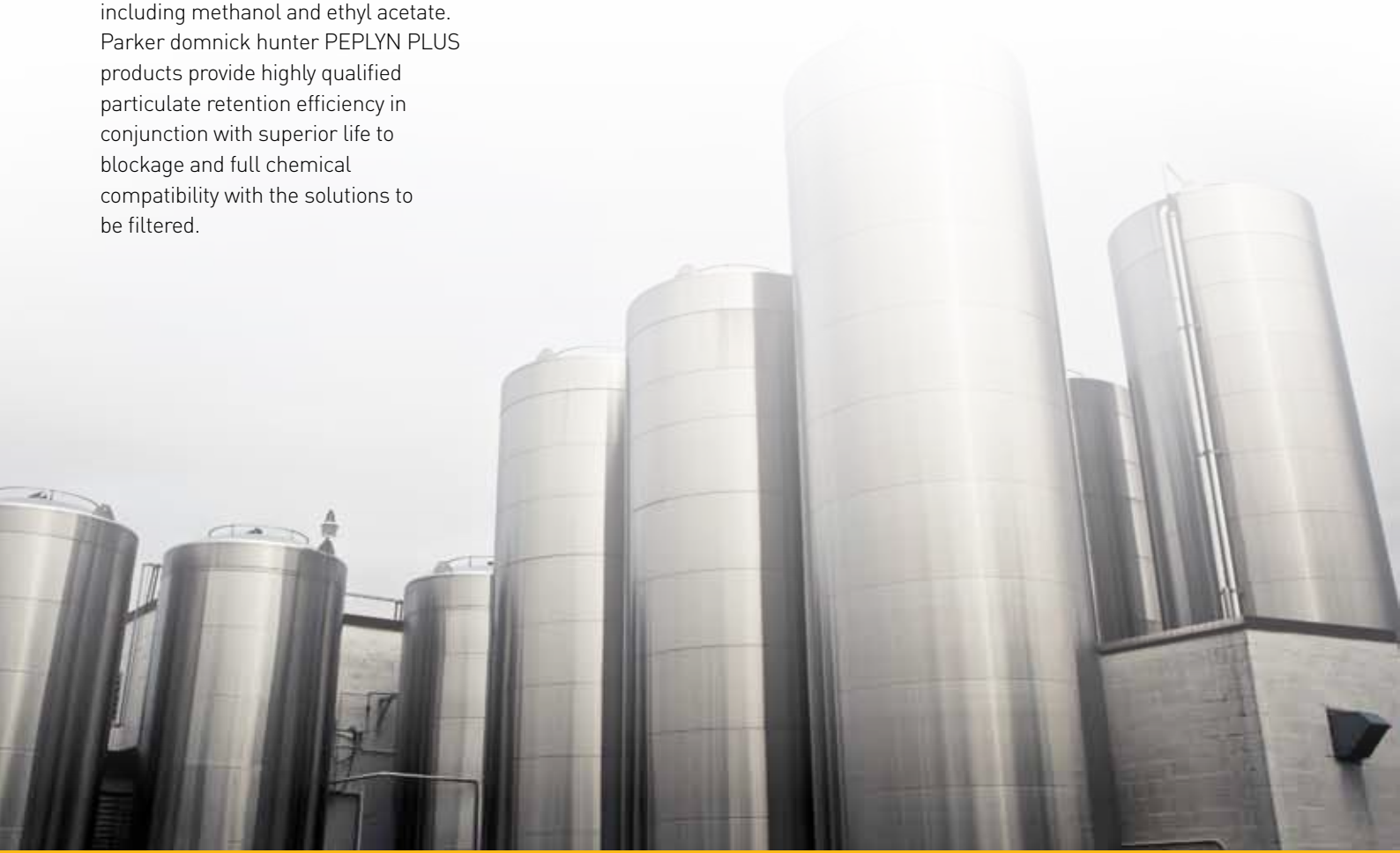
Ensuring quality and system performance

Parker domnick hunter provides filter elements compatible with the diverse range of chemicals and solvents used in the manufacture of chemically synthesized active pharmaceutical ingredients.

Parker domnick hunter offer a wide range of filter housings and elements to ensure compatibility combined with proven experience of providing successful solutions within a wide variety of applications.

Parker domnick hunter supplied a customer with PEPLYN PLUS products for solvent storage tank filling stages to provide filtration of six solvent types, including methanol and ethyl acetate. Parker domnick hunter PEPLYN PLUS products provide highly qualified particulate retention efficiency in conjunction with superior life to blockage and full chemical compatibility with the solutions to be filtered.

The qualified particulate retention and compatibility with the solution, combined with product benefits allowed the end-user to operate their process with confidence that the filtration system would provide the required level of protection to downstream operations, ensuring no risk of system downtime occurring as a result of filter blockage

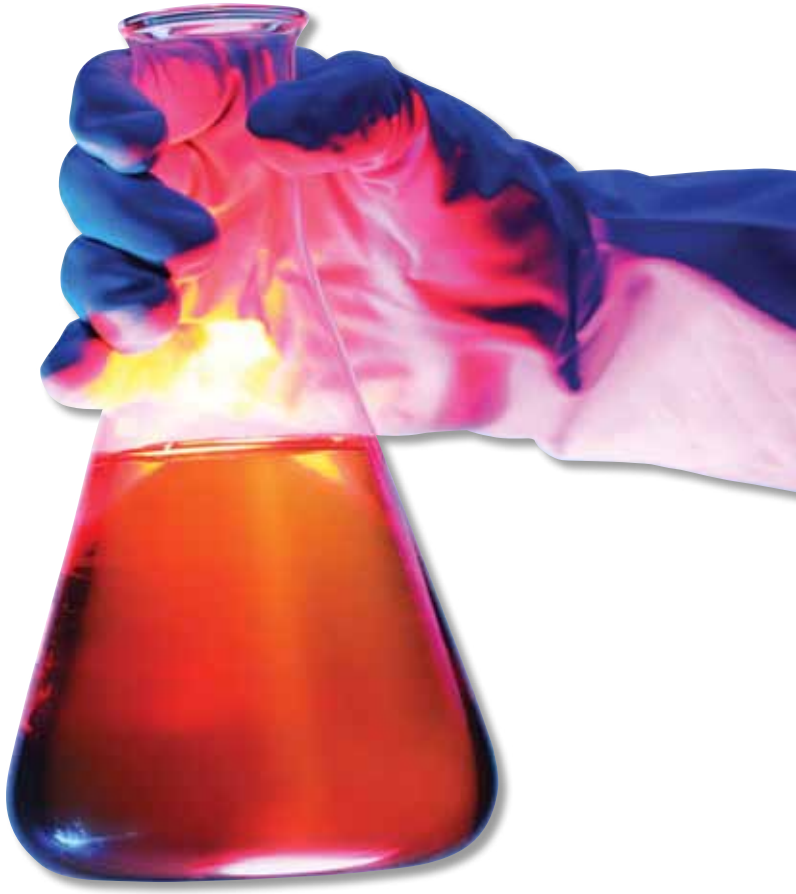


In addition to a wide range of filter products, Parker domnick hunter provides filter housings suitable for use with the diverse range of aggressive solvents and chemicals.

Parker domnick hunter supplied an active pharmaceutical ingredient manufacturer with filtration housings constructed using Alloy 22. As part of their production process, the customer was required to filter aggressive solvents and concentrated acids, chemicals which have a high potential to corrode standard 316L stainless steel hardware. Alloy 22 is principally composed of Nickel, Chromium, Molybdenum and Tungsten which in combination provide outstanding resistance to pitting, corrosion and chemical attack, properties which are highly beneficial in many active pharmaceutical ingredient production applications.

Paired with Parker domnick hunter's TETPOR PLUS filter product which is constructed entirely from fluoropolymer, this system provides compatibility with highly aggressive chemical filtration processes.

This assurance of compatibility allows the end-user to operate the filtration system with a high level of confidence that the product is filtered to the required quality and will not be contaminated by extracted compounds resulting from chemical attack of system components.



Sterile gas supply

Filtration of high-temperature sterile gas

Parker domnick hunter has an extensive range of air and gas filtration solutions to provide high quality sterile gas supply to a wide range of applications.

Parker domnick hunter provided HIGH FLOW TETPOR HT sterilizing grade gas filter cartridges and HIGH FLOW PREPOR GFA gas prefiltration cartridges to supply sterile nitrogen to a large spray dryer system.

Parker domnick hunter's HIGH FLOW TETPOR HT product was utilized as the nitrogen was supplied at a continuous temperature of 100 °C, intermittently up to 115 °C. HIGH FLOW TETPOR HT is constructed using heat stabilized componentry and temperature resistant support material allowing the product to resist degradation by oxidation which typically occurs at high operating temperatures.

HIGH FLOW PREPOR GFA gas prefilter cartridges (also constructed using temperature resistant componentry and supports) were provided to protect the sterilizing gas stage from powder ingress from the dryer system as this could potentially create false failures during system integrity testing.

The prefiltration stage trapped drug product on the cartridge surface which could then be removed to regenerate the filters by performing a post-campaign CIP process prescribed by Parker domnick hunter.

As a result of the highly robust and temperature resistant filter construction, use of this system provided the end-user with a high degree of assurance of quality and system sterility over an extended operating period.

Integrity testing

Aerosol integrity testing of multi-round sterile gas systems

Parker domnick hunter has extensive experience of integrity testing sterile gas filtration systems, providing solutions to ensure that filter integrity is maintained and thereby guarantee filtrate quality.

Parker domnick hunter provided a VALAIRDATA aerosol integrity test unit to an end-user operating a large multi-round sterile nitrogen system used to supply a spray dryer process.

The filter system had originally been water intrusion tested to ensure filter integrity, however, water intrusion testing can be difficult to perform *in-situ*, especially on large multi-round filter housings. Additionally, due to the averaging effect of this type of test which measures total water flow through the filter housing, it is possible that marginal failures occurring on individual cartridges can go undetected on large systems.

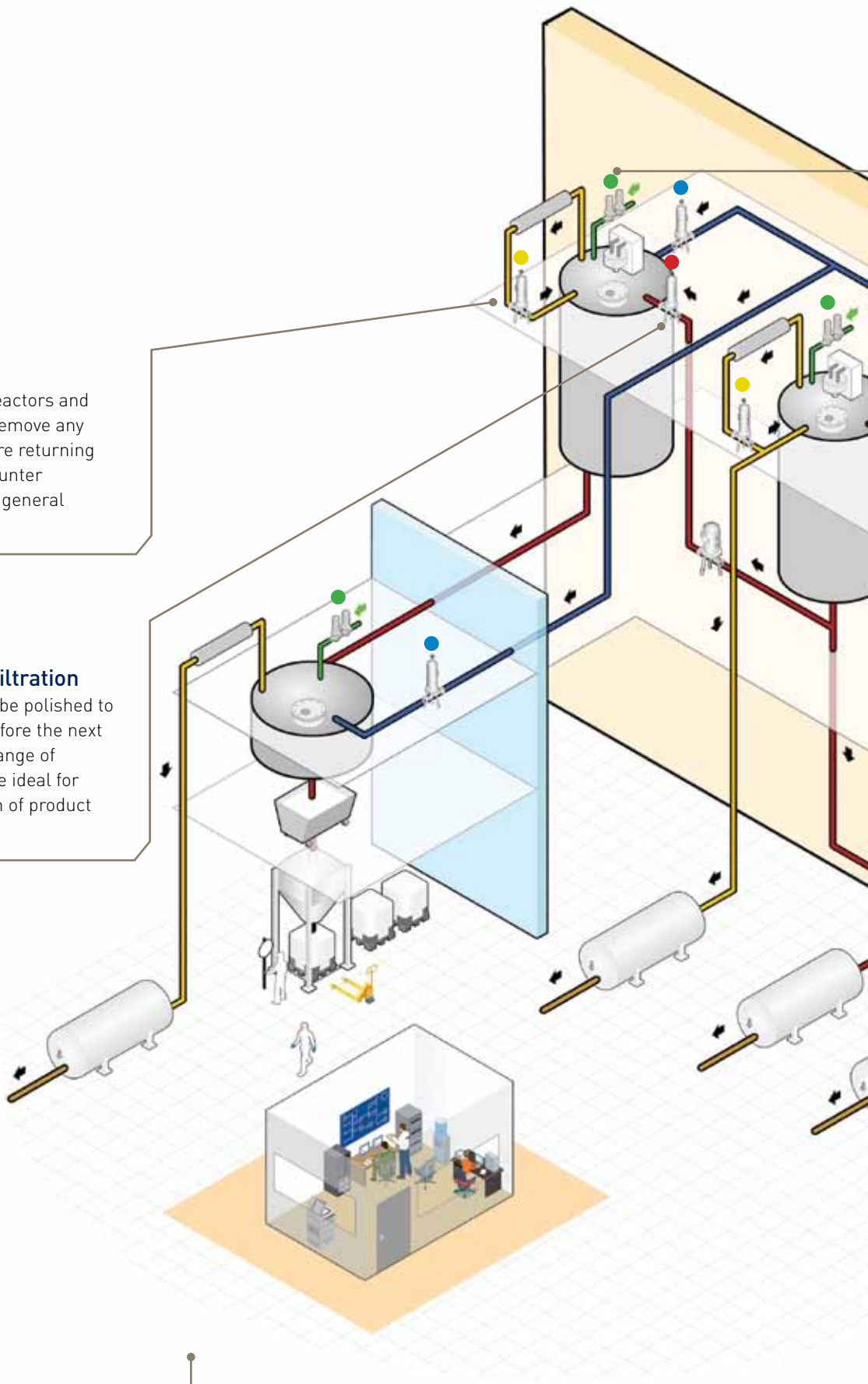
The VALAIRDATA integrity test unit overcomes this potential problem as it generates an aerosolized particulate which is fed into upstream side of the filter housing, the unit then measures any penetration of the aerosol into the downstream side of the filter system. By this method, any significant flaw in the filtration system can be detected.

The VALAIRDATA aerosol integrity test is also extremely quick to perform, typically lasting for around one minute, whereas a traditional water intrusion test on a similarly sized system is likely to take around 30 minutes from start to finish.

This system allowed the customer to perform rapid and convenient *in-situ* integrity tests on the sterile gas supply stage and provided a high level of assurance that process sterility was maintained.

Reflux clarification
Reflux return from condensers on reactors and crystallization vessels is filtered to remove any carbon and particulate present before returning to the vessel. The Parker domnick hunter polypropylene products are ideal for general clarifications of this type.

Intermediate and product filtration
Intermediate product streams must be polished to remove large levels of particulate before the next stage. The Parker domnick hunter range of polypropylene and PTFE products are ideal for clarification and bioburden reduction of product streams.

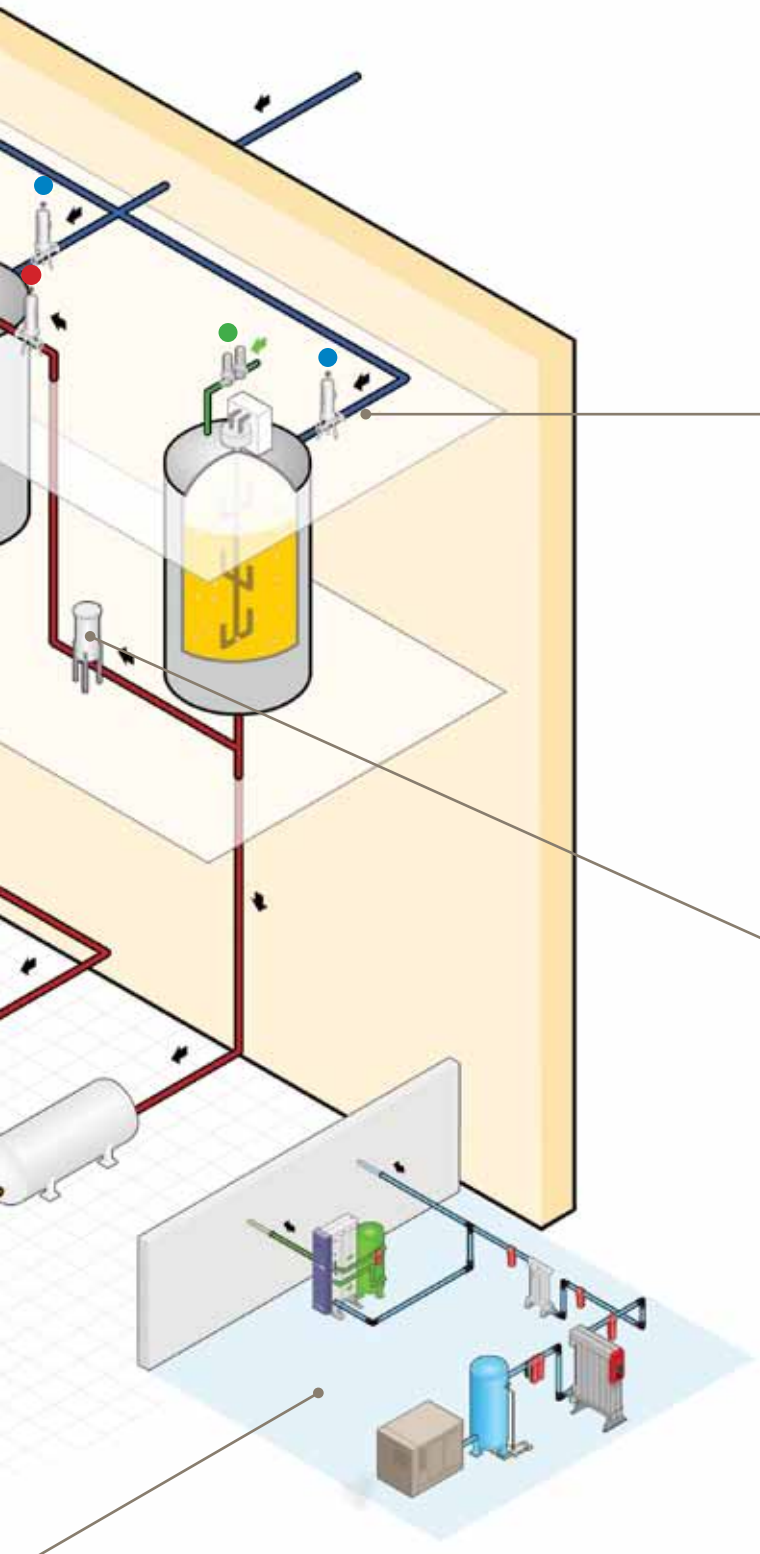


Formulation and final fill finish
Parker can offer a range of products in both cartridge and capsule format for secondary manufacturing processes. The Parker domnick hunter PROCLEAR and PROPOR product ranges have been specifically designed for the clarification, bioburden reduction and sterilization of pharmaceutical solutions.

Compressed gas utilities
Parker domnick hunter is the market leader in compressed gas purification and nitrogen generation solutions with a range of technologies and services to guarantee the efficient and trouble free operation of your compressed gas utilities.

Nitrogen filtration

To ensure the quality of nitrogen entering reactor, crystallization and drying vessels for blanketing, the gas is first processed through a sterilizing grade filter. The Parker domnick hunter class-leading range of gas filters ensures fast and effective sterilization of nitrogen throughout the process.



Solvent and chemical filtration

Parker have the widest range of filter housings and elements to ensure compatibility with a variety of process chemicals and solvents. The Parker domnick hunter housing range includes Alloy 22, PTFE and lined vessels as well as stainless steel. Meanwhile, the availability of elements in polypropylene, fluoropolymer and stainless steel offers a broad choice for system compatibility.

Catalyst and carbon removal

Catalysts and carbon added to reactors during various stages of the synthesis must be removed at the end of each step. Parker offers a range of economical solutions for the removal of catalysts and carbon from product streams including traditional and pleated bag filters.

Complete quality assurance

Delivered throughout your process

Parker domnick hunter's controlled approach to quality ensures your process is supplied with clean reliable filtration and fluid handing solutions. Our processes, from raw material selection through to final product release, are designed to guarantee reproducible product quality.

Meeting quality standards

All Parker domnick hunter pharmaceutical grade filtration products are manufactured by trained operators using the latest cleanroom technologies in facilities which meet the current ISO 9001 Quality Management System Standard as well as ISO 13485 Medical Device Standard. In addition, we are leading the way through compliance with PS 9100, the application of ISO 9001 GMP guide to pharmaceutical excipients.

Ensuring repeatable quality

Our focus on raw material selection and our extensive supplier quality assurance programme ensures our base materials conform to current regulations such as FDA, CFR's and cGMP guidelines as well as specifications from our scientists, engineers and validation experts. This, together with the use of validated manufacturing and test methodologies, gives high batch-to-batch reproducibility in our products.

A controlled approach

Parker domnick hunter pharmaceutical grade filtration products carry both a lot number and serial number providing full traceability back to base materials. In addition, our products must pass strict lot release criteria before leaving the factory. Regular process audits by trained auditors across the business, as well as extensive customer audits, are performed on a regular basis ensuring the reliability of our quality management systems.

Products

Clarification filters

BAG filters

1 - 1000 micron

- Cost-effective filtration
- Available in a wide range of material types and retention efficiencies
- High dirt holding capacity

Parker domnick hunter bag filters provide cost-effective filtration, suitable for a wide range of applications requiring high dirt-holding capacity, high flow rates and broad spectrum chemical compatibility.

PB SERIES pleated bags

- All polypropylene construction provides broad-spectrum compatibility
- Pleated construction provides high surface area with very high dirt holding capacity
- Available in a wide range of micron ratings and efficiencies

Parker domnick hunter PB SERIES pleated bag filters offer significant performance benefits over traditional filter bag formats; providing increased dirt holding capacity and higher particulate removal efficiencies.

PROSPUN A

0.5 - 70 micron — Polypropylene

- Consistent absolute retention under a wide range of operating conditions
- High dirt holding capacity
- All polypropylene construction providing broad spectrum chemical compatibility

Closely controlled fibre diameter and density in a multiple layered construction serve to maximize service life of PROSPUN A whilst delivering absolute particle retention.

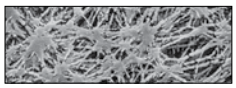
PROSTEEL

3 - 10 micron - 316L Stainless Steel

- Absolute rated stainless steel liquid filters
- Ideal for aggressive solvents, viscous and hot solutions
- High dirt holding capacity and excellent flow rates

PROSTEEL filters provide the ideal solution in applications where traditional polymer based filters are limited by compatibility, exposure time or a combination of high temperature and viscosity.

TETPOR LIQUID

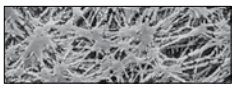


0.1 - 1.0 micron — PTFE

- Superior chemical resistance of PTFE membrane combined with polypropylene hardware
- Integrity tested prior to despatch
- Validated to ASTM 838-05 methodology
- Comprehensive range of end cap configurations for retrofitting

TETPOR LIQUID filters are particularly suitable for sterilization of particulate removal from aggressive chemicals (including acids, bases and solvents) within a wide range of critical processing industries

TETPOR PLUS



0.1 - 1.0 micron — Polytetrafluoroethylene PTFE

- PTFE membrane and PFA hardware providing exceptional resistance to solvents and oxidative environments
- Sterilizing grade validated to ASTM F838-05 methodology
- Available in a wide range of micron ratings to suit all applications

TETPOR PLUS filters are manufactured entirely from fluoropolymers making them extremely resistant to a wide range of aggressive chemicals.

PEPLYN PLUS

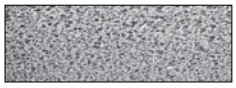
0.6 - 100 micron — Polypropylene

- Pleated media for high flow rates and long life
- Graded density for excellent particle retention
- Wide range of end caps to provide retrofitting of existing systems
- All polypropylene construction

PEPLYN AIR liquid filter cartridges are utilized for the clarification and prefiltration of a wide range of products in the pharmaceutical, beverage, ultrapure water and fine chemical industries.

Final fill & finish

PROPOR SG

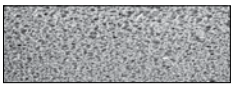


0.1 - 0.45 micron — Polyethersulphone

- Up to 3.5 times higher flow rates than competitive sterilizing grade filters
- Fully validated and integrity testable membrane for assurance of sterility
- Low binding for minimal product loss

PROPOR SG sterilizing grade filters feature a microbially retentive polyethersulphone membrane for fast, reliable and cost-effective sterile filtration of pharmaceutical fluids.

PROPOR BR



0.2 micron — Polyethersulphone

- *Brevundimonas diminuta* retention of LRV >5 for efficient bioburden reduction
- Additional prefilter layer gives excellent throughput to blockage
- Low binding for minimal product loss

PROPOR BR filters have been specifically designed for the fast and cost-effective bioburden reduction of pharmaceutical solutions.

PROCLEAR PP

0.6 - 100 micron — Polypropylene

- Dual layer media or increased capacity and assurance
- Maximizes retention for protection of downstream membranes
- Ideal for difficult to filter solutions

PROCLEAR PP filters are designed for a wide range of prefiltration duties within the production of pharmaceuticals and are particularly suited to applications where chemical compatibility is an issue.

Air and gas filters

HIGH FLOW PREPOR GFA

1.0 micron — Glass Microfibre

- High surface area and voids volume filter media
- Exceptionally high flow rates with low pressure drops
- Reliable efficient protection of final sterilization filters
- Heat stabilized componentry to allow operation at elevated temperatures

HIGH FLOW PREPOR GFA is a high capacity glass fibre prefilter specifically designed for the removal of bulk particulate from compressed air and gases. It is used extensively for prefiltration duties in dry compressed air systems and provides excellent protection of final sterile filters.

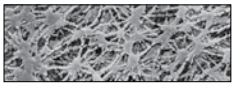
PEPLYN AIR

1.0 - 25 micron — Polypropylene

- Cost-effective prefiltration
- High flow rates and long life
- Steam sterilizable
- Graded density for excellent particle retention
- No release of particles even during system pressure fluctuations

PEPLYN AIR filter cartridges have been specifically designed to guarantee removal of particulate from gas streams.

TETPOR AIR

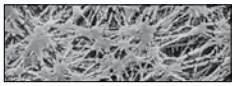


0.2 micron — Expanded PTFE

- Assured biosecurity with absolute rated filtration
- High flow rates with low pressure drops
- High voids volume PTFE membrane
- Steam sterilizable to 142 °C (287.6 °F)
- Unique prefilter layer

TETPOR AIR sterilization filter cartridges offer exceptional filtration performance whilst providing the highest levels of biosecurity throughout the process industry.

HIGH FLOW TETPOR II

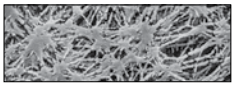


0.2 micron — PTFE

- Steam sterilizable up to 225 cycles at 142 °C (287.6 °F)
- Unrivalled flow rates combined with low pressure drops
- Fully validated to ASTM 838-05 for liquid bacterial challenge
- Fully validated to aerosol and viral challenge

HIGH FLOW TETPOR II gas sterilization filters have been developed to benefit from technological advances within the manufacture of PTFE membranes. This new generation of filter sets the standard with an unrivalled combination of efficiency, flow rate and strength.

HIGH FLOW TETPOR HT



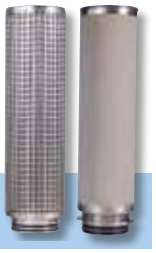
0.2 micron — PTFE

- Long service life even at elevated temperatures 100 °C (212 °F)
- Assured biosecurity with absolute rated filtration
- Exceptionally high flow rates and low pressure drops
- Steam sterilizable up to 142 °C (287 °F)

HIGH FLOW TETPOR HT gas sterilization filter cartridges provide unrivalled performance in process industry applications where continuous cartridge operation of up to 100 °C (212 °F) is a requirement.

Other Parker products

Steam Filters



- 316L stainless steel filter cartridges
- Exceptionally high flow rates
- Available in culinary grade 1 micron
- High dirt holding capacity
- 'JUMBO' filter configuration ensures maximum utilization of pipework capacity

Parker domnick hunter steam filters are designed to provide high quality steam whilst maintaining optimal system performance via low pressure drops / high flow rates and high dirt holding capacity.

VALAIRDATA

- 30 second test time for a single 10¨ (250mm) cartridge challenge
- Results correlated to aerosol bacterial and viral challenge
- Fully validated secure option design to GAMP 4 Guidelines and meets the FDA's 21 CFR Part 11 requirements

Aerosol challenge testing of sterile gas filters. The VALAIRDATA combines the sound principles of aerosol testing with a compact, portable and ergonomic design reducing test times and improving multi-cartridge system sensitivity.

PORECHECK IV

- Designed to 21 CFR Part II and Annex II compliant environments
- Configurable to automatically flush and drain filters
- 100 storable test programs defined in blocks

The PORECHECK IV is configured for water intrusion testing, pressure decay and bubble point testing.

Filter housings

- Biopharmaceutical industry standard
- 316L and Alloy 22 materials
- Designed in accordance with international design and sanitary standards

Demi, single and multi-round liquid and gas housings designed specifically for pharmaceutical applications.

Gas utilities

- Compressed air treatment in accordance with ISO 8573.1
- Filtration, drying and condensate management
- Tailored on-site nitrogen generation solutions

A comprehensive range of compressed air purification solutions guaranteeing the removal of a potential 10 contaminants from the distribution system.

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

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Parker Hannifin Manufacturing Ltd
domnick hunter
Process Filtration - Europe
Durham Road
Birtley, Co. Durham
DH3 2SF, England
phone +44 (0)191 4105121
fax +44 (0)191 4105312
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