

Your Partner in Biopharmaceutical Filtration

Adding value to your business

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



ENGINEERING YOUR SUCCESS.

Clear thinking. Clear results.

From research & development through to full-scale bioprocessing, Parker understands the problems faced by biopharmaceutical manufacturers. We are dedicated to providing integrated bioprocessing solutions that are specially developed to reduce your processing costs and ensure product quality and patient safety.



Focused on adding value to your business

The foundations of process improvement

With innovative products, state-of-the-art technical facilities and an international team of specialists, Parker Hannifin understands and supports the specific needs of your process, from research & development through to full-scale production.

Commitment to quality

Parker's biopharmaceutical products are produced using the latest cleanroom technologies in facilities accredited with the all appropriate quality certification. A strong focus on raw materials and controlled release of products ensures repeatable quality throughout our biopharmaceutical range. We not only welcome but strongly encourage facility audits from bio-manufacturers.

Specialized technical expertise

Parker's dedicated technical support team is on hand 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 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 biopharmaceutical industry. Our customers are an integral part of our product development team leading to focused solutions to meet your present and future business needs.



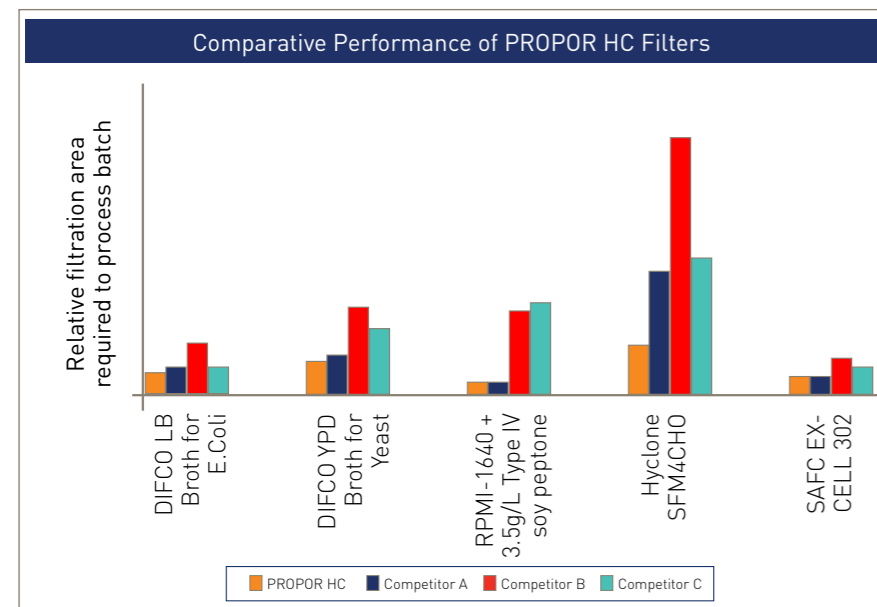
Media preparation

Optimizing filtration systems

Parker has proven experience of successfully optimizing cell culture media filtration systems at several biopharmaceutical customers.

The sterilizing grade PROPOR HC has been specifically designed for maximum capacity featuring a highly asymmetric integral prefilter layer in an optimal dual layer membrane configuration. In combination with

Parker's single-use mixing technology and bioprocess container bags, the PROPOR HC has reduced filtration system sizes while maintaining rapid batch turnaround time.



*For further details please contact Parker domnick hunter.

Custom-designed manifolds

Eliminating contamination risks

Parker understands that every bioprocess is different. We custom-design our single-use systems to meet the individual processing needs of each customer.

Many biopharmaceutical processes use single-use perfusion bioreactor systems which incorporate numerous disposable media bags simultaneously connected to a single bioreactor. To accommodate their unique process, customers are often forced to assemble their own systems.

Parker's custom moulded manifold and bioprocess container systems prevent product losses and contamination associated with hosebarb failures and increase productivity through reduced system set up time.



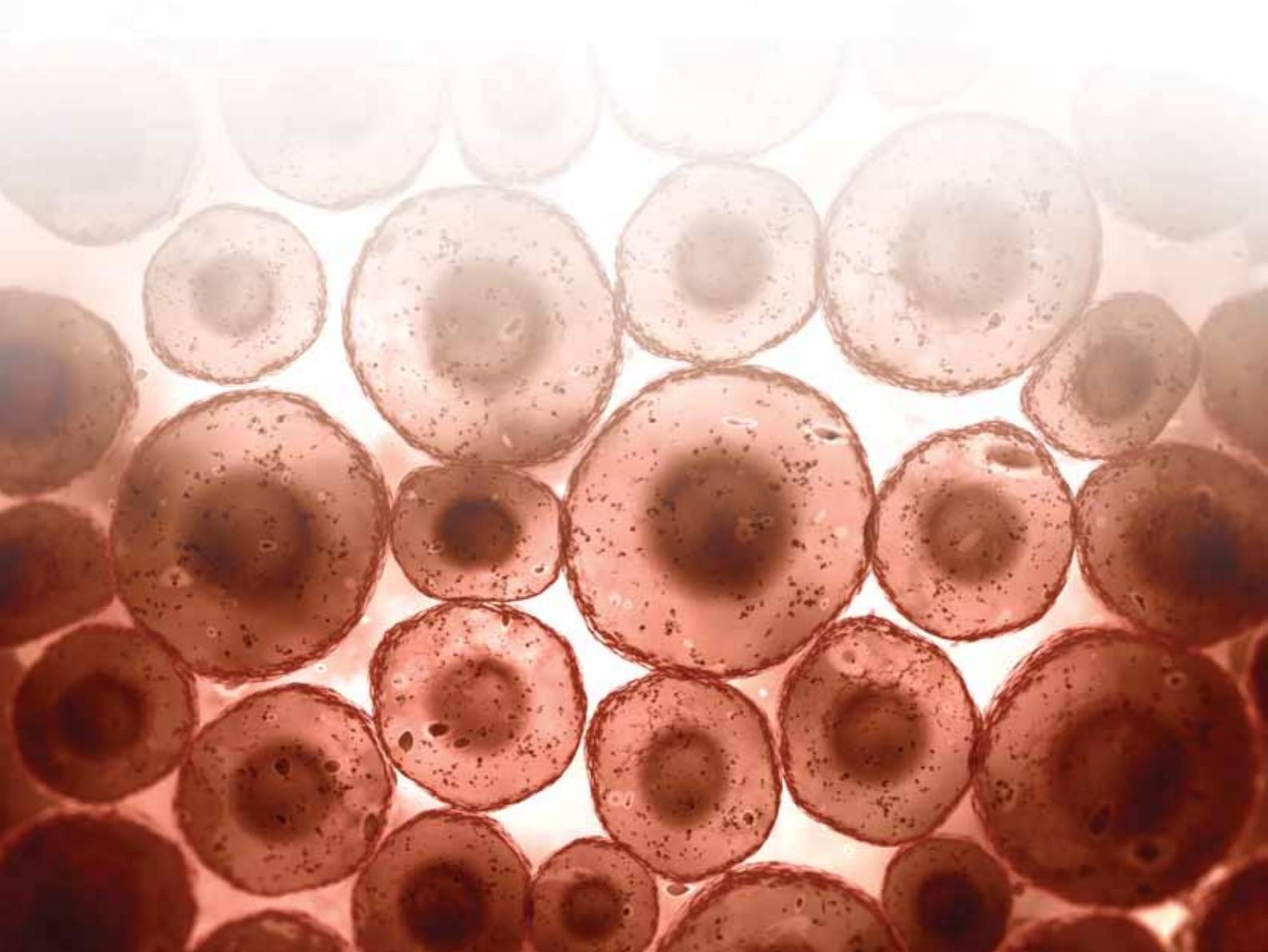
Cell culture harvest

Preventing bottlenecks

Parker domnick hunter filtration solutions help leading biopharmaceutical manufacturers find solutions to bottlenecks in small-scale cell harvesting processes.

Premature filter blockage has led to customers incorporating sedimentation steps at the end of small-scale Chinese hamster ovary (CHO) cell culture runs. Combining the PROPOR HC high capacity dual layer membrane capsule

filter with the optimum prefilter from the PROCLEAR range eliminates the need for sedimentation steps reducing the harvesting process time and increasing productivity.



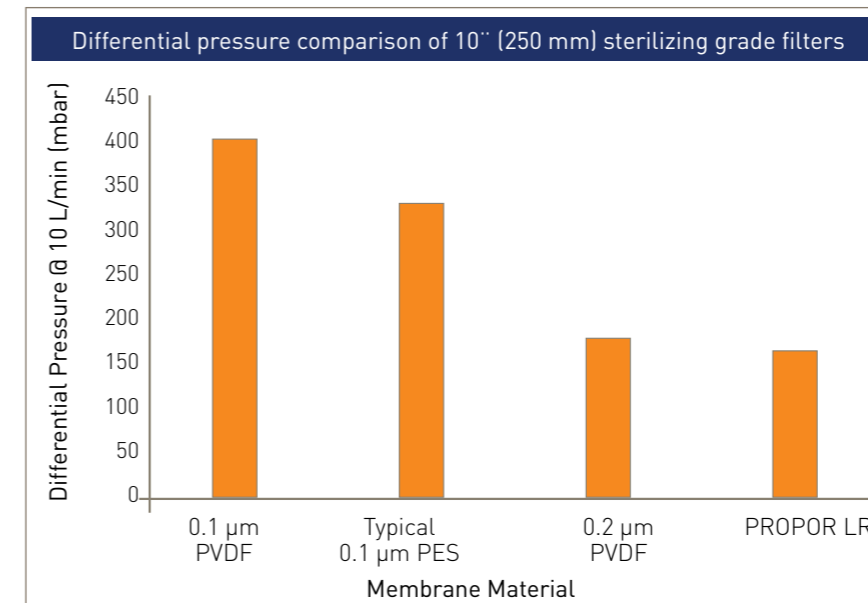
Protecting water systems

Removing diminutive organisms

Specific filtration solutions for purified water systems mean biopharmaceutical manufacturers can enjoy the security of high retention filtration while maintaining flow rates and system size.

The nutrient poor environment of pharmaceutical water systems means waterborne organisms can be small enough to pass through a standard 0.2 micron sterilizing grade filter. The PROPOR LR is directly correlated to *Ralstonia pickettii*, one of the more

commonly found waterborne organisms. It has been specifically designed to remove diminutive organisms from water systems offering higher retention with flow rates comparable to a 0.2 micron system.



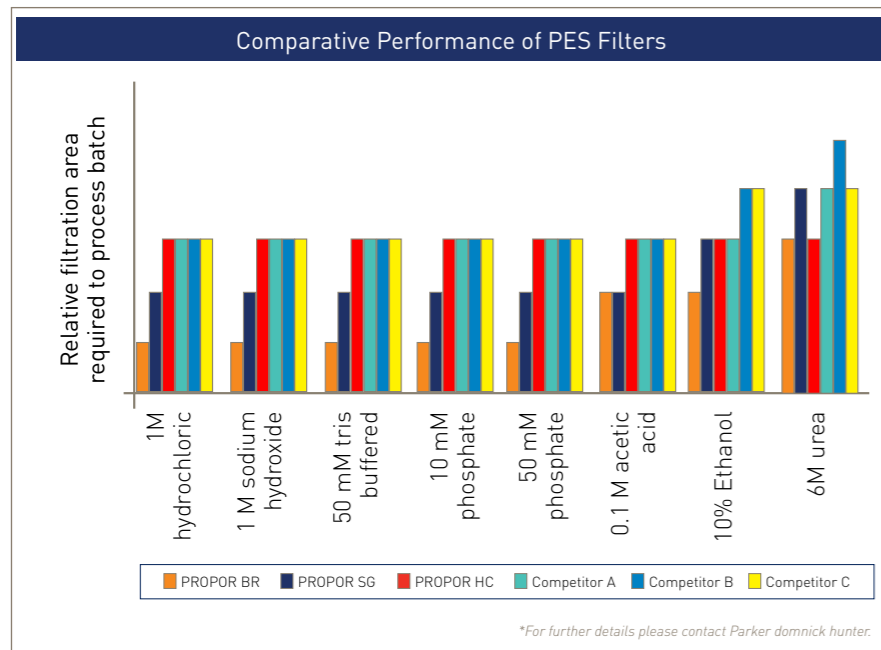
Effective buffer filtration

For faster batch turnaround times

Parker ensures the fast transfer of controlled bioburden buffers and the protection of downstream equipment through effective filtration and buffer preparation systems.

From bioburden reduction to sterilizing grade filtration, the Parker domnick hunter PROPOR range of polyethersulphone filters allows exceptionally high flow rates to prevent delays in buffer processing. These filters are chemically resistant and are

compatible with a broad array of process solutions. Integration of PROPOR filters with Parker's custom manifold transfer systems gives maximum flexibility with minimum assembly time.



Sterile vent filtration

Flexibility in design

Parker's ability to quickly adapt our products to customer applications allows us to meet specific customer requirements throughout the biopharmaceutical industry.

The design of a sterile gas capsule filter from the market-leading Parker domnick hunter TETPOR range was modified to satisfy a particular need at a global biopharmaceutical customer. The capsules were used as vents on portable stainless steel tanks

transporting intermediate vaccine product. Removal of the capsule vent, which was not required, eliminated customer concerns over the vent becoming damaged in use leading to loss of product integrity.



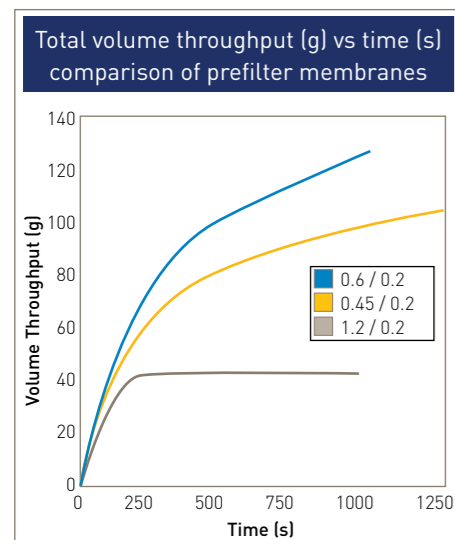
Intermediate product filtration

Collaborative product development

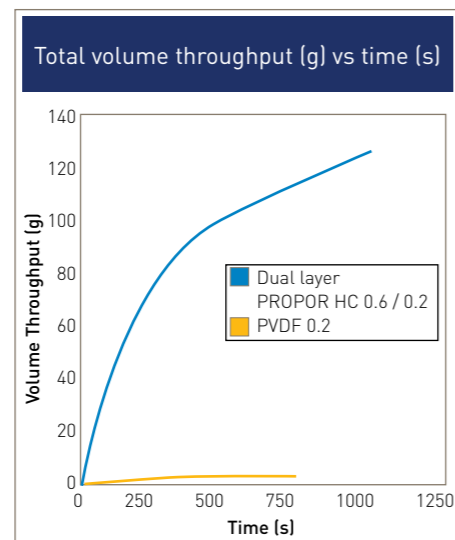
Parker is strongly committed to increasing process productivity for our customers. Product development in partnership ensures customer satisfaction and competitive advantage.

The high capacity PROPOR HC sterilizing grade PES filter was developed in conjunction with an insulin manufacturer who was experiencing premature filter blockage when filtering a product intermediate. Initial filterability trials through to full-scale on-site testing and full

product validation took less than 6 months and guaranteed full batch processing for the customer. The product has since been incorporated very successfully in various applications at a number of biopharmaceutical manufacturers.



Initial filterability trials on discs:
Different prefilter membranes were assessed to determine the optimum configuration for the PROPOR HC high capacity product.



Initial filterability trials on discs:
Improvement over incumbent competitor PVDF sterile filter.

Bioprocess bag systems

Solutions to streamline your process

The sterile transfer of microcarrier beads into the bioreactor can significantly delay biopharmaceutical processes. Parker's tailored bioprocess bag systems facilitate microcarrier transfer.

Biopharmaceutical customers using microcarrier beads to grow cells in attachment cell culture can find sterilization of the microcarriers a long and difficult task. The microcarriers are often autoclaved in small batches prior to addition to the bioreactor and, as the process is scaled up, this brings even greater challenges.

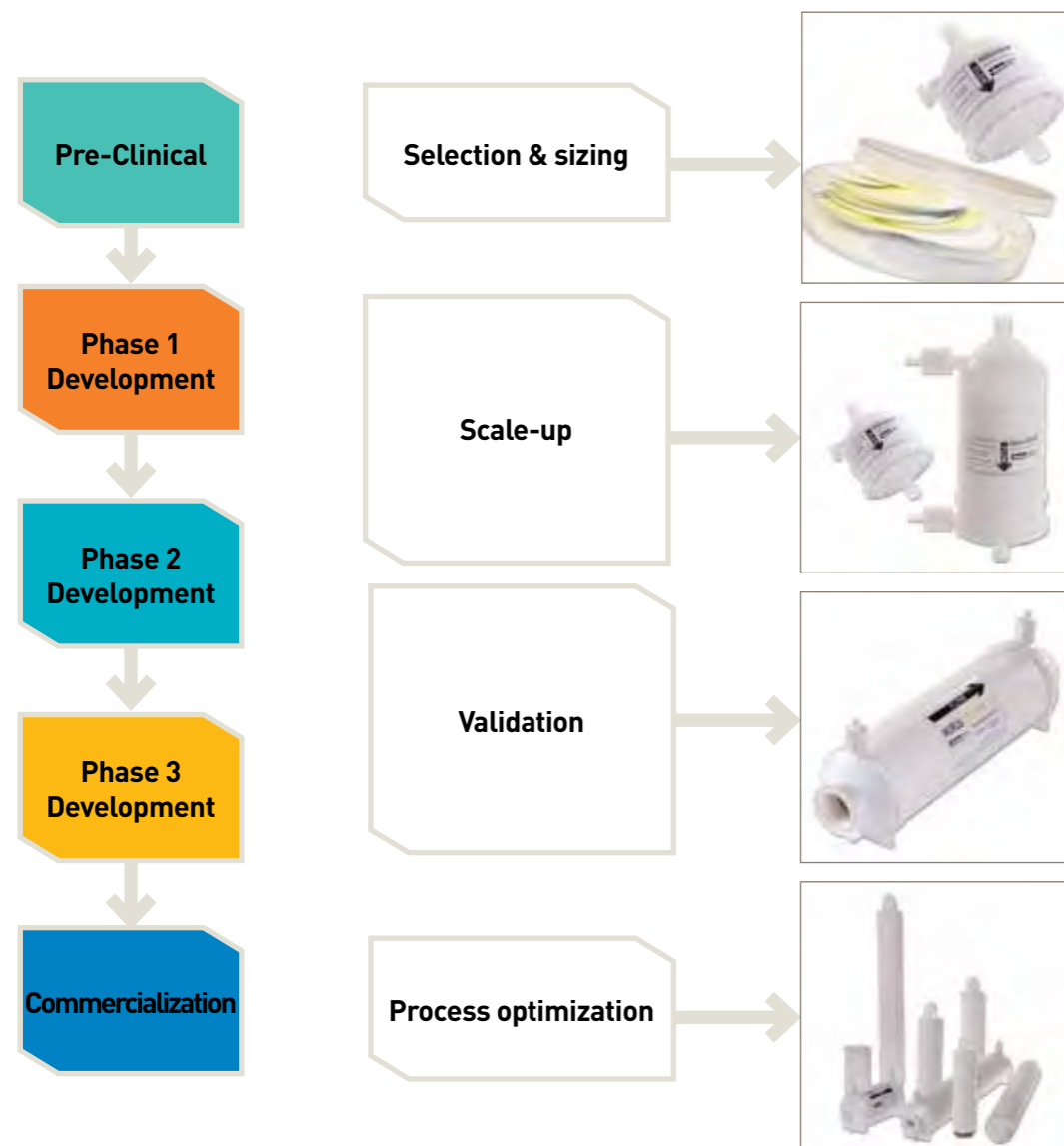
Parker developed a solution by which microcarriers were sterilized by irradiation within a customized bioprocess bag allowing subsequent quick and easy sterile transfer of microcarrier beads streamlining the process and reducing downtime.



Your trusted development partner

From pre-clinical to commercialization

Parker is dedicated to providing specialized collaboration to support a fast and painless drug development process. Our team can integrate with your own to accelerate your development process and increase speed to market.



Selection & sizing

Selecting the optimum filtration product(s) and determining correct system size is critical to providing maximum process performance. The required final filter type is selected and laboratory-scale testing is performed on discs and / or small-scale devices to establish potential system throughput volumes and optimize any required prefiltration stages.



Scale-up

Following the sizing process, the data generated is utilized to specify a small-scale filtration system, typically composed of capsule filter products, which can be assessed under scaled-down, process-representative conditions. Once confirmation of system performance has been established, the size and format of the required final manufacturing-scale filtration system can be determined.



Validation

Once the optimum filtration system has been identified, Parker domnick hunter will work with you to develop and agree a process validation strategy designed to satisfy any applicable quality and regulatory requirements. Filter qualification testing can then be performed in-situ with our assistance or under simulated process conditions within Parker domnick hunter's dedicated test facilities.



Process optimization

By adopting a structured process audit approach, we use our extensive knowledge of filtration to further optimize existing filter systems, to provide significant and tangible benefits to process operations such as cost reduction and improved productivity, while ensuring minimal impact upon validated processes. Training packages are also available to support our customers as they develop their personnel.

Complete quality assurance

Delivered throughout your bioprocess

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



Meeting quality standards

All Parker 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

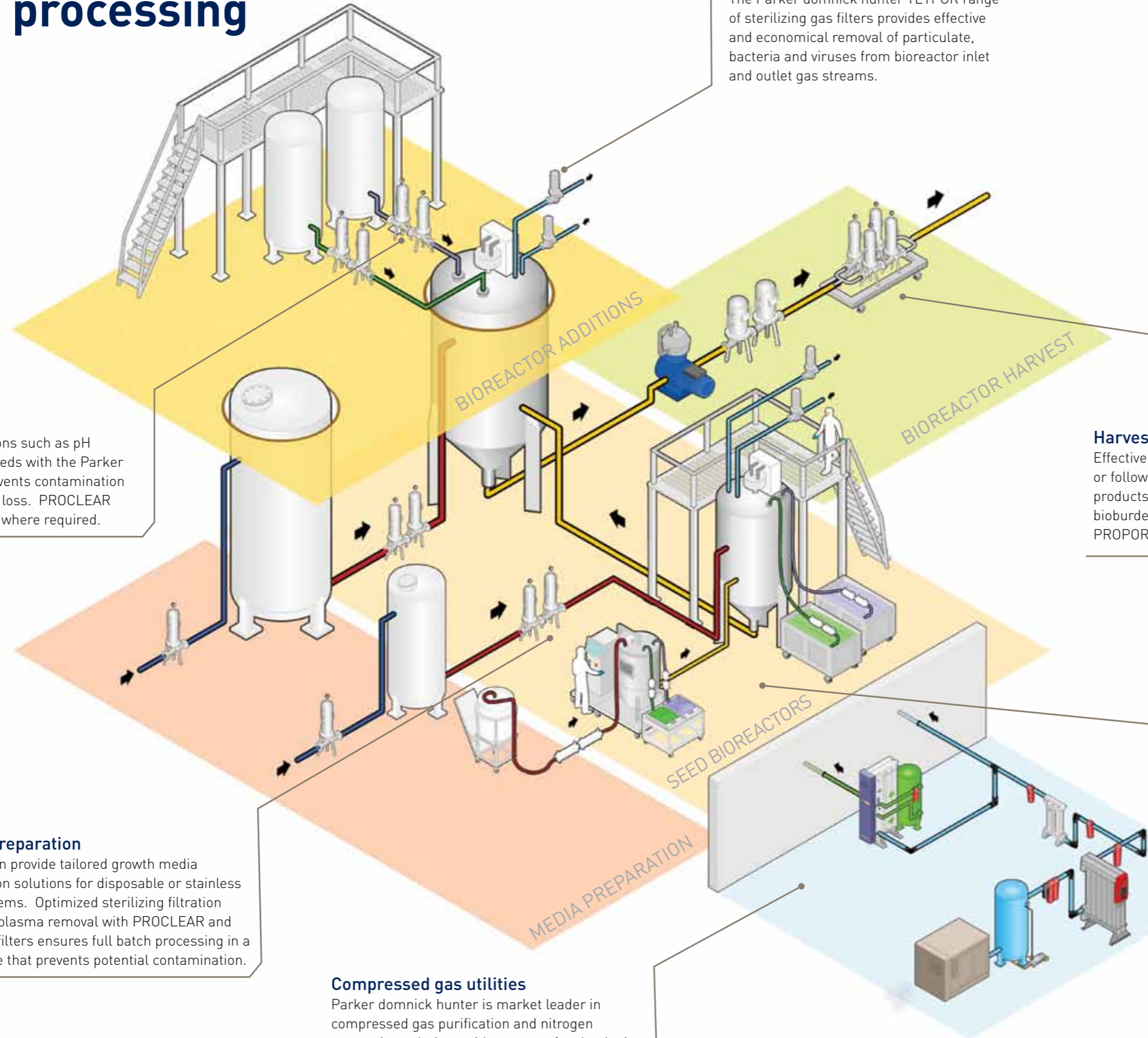
Our focus on raw material selection and our extensive supplier quality assurance programme ensures our base materials conform to current regulations such as FDA, CFR's and cGMP guidelines as well as specifications from our Scientists, Engineers and validation experts. This, together with the use of validated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

A controlled approach

Parker 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.



Upstream processing



Bioreactor additions

Sterile filtration of bioreactor additions such as pH adjustments, antifoam and media feeds with the Parker domnick hunter PROPOR range prevents contamination of cell culture and potential product loss. PROCLEAR filters provide excellent prefiltration where required.

Sterilizing gas filtration

The Parker domnick hunter TETPOR range of sterilizing gas filters provides effective and economical removal of particulate, bacteria and viruses from bioreactor inlet and outlet gas streams.

Harvesting of bioreactors

Effective removal of biomass during bioreactor harvesting or following cell homogenization can be achieved using products from the PROCLEAR filter range followed by bioburden control of the process stream with the PROPOR range.

Media preparation

Parker can provide tailored growth media preparation solutions for disposable or stainless steel systems. Optimized sterilizing filtration and mycoplasma removal with PROCLEAR and PROPOR filters ensures full batch processing in a timeframe that prevents potential contamination.

Compressed gas utilities

Parker domnick hunter is 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.

Single-use processing solutions

Parker domnick hunter MURUS and DEMICAP filter capsules can be combined with our disposable mixing technology, bioprocess containers and assemblies for the preparation, transfer and storage of growth media for bioreactors.

Downstream processing

Steam generation utilities

Parker domnick hunter steam filters have been specifically designed to protect process equipment and pipework from particulate contamination during steam-in-place sterilization of process lines.

Chromatography skid filters

The Parker domnick hunter PROPOR filter range protects chromatography columns and other downstream equipment from bacterial and particulate contamination that can cause fouling and reduce process efficiency.

Vent filtration

Designed specifically to produce sterile air free from particulate, bacteria and viruses, the Parker domnick hunter TETPOR range is ideal for vent filtration to maintain sterility in buffer and intermediate holding tanks.

Buffer filtration

Parker can provide tailored buffer preparation solutions for disposable or stainless steel systems. Filtration of buffers is essential to protect downstream equipment and ensure the quality of the final product. The Parker domnick hunter PROCLEAR and PROPOR ranges can ensure particulate free and controlled bioburden buffers.

Filter integrity testing

Integrity testing of sterilizing grade filters is a fundamental requirement of critical process applications ensuring the biological safety, quality and shelf life of the product. Parker domnick hunter's PORECHECK IV and VALIARIDATA II units are ideal for pharmaceutical production.

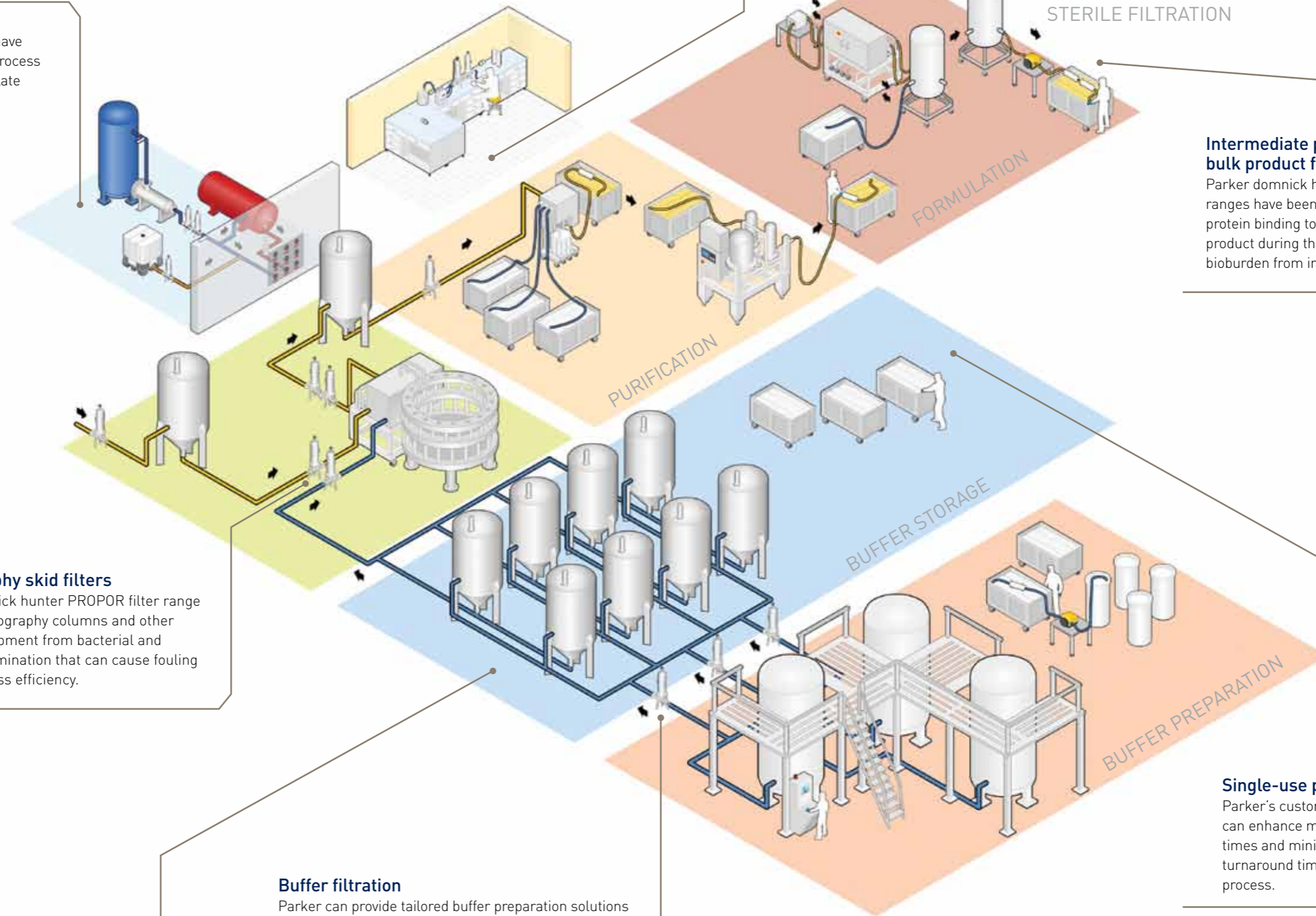
STERILE FILTRATION

Intermediate product stream and final bulk product filtration

Parker domnick hunter PROCLEAR and PROPOR ranges have been specifically designed to exhibit low protein binding to ensure minimal wastage of valuable product during the removal of precipitate and bioburden from intermediate product streams.

Single-use processing solutions

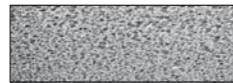
Parker's custom single-use bioprocess solutions can enhance manufacturing flexibility, reduce set up times and minimize process costs increasing batch turnaround time and improving the economy of your process.



Products

Filtration

PROPOR SG



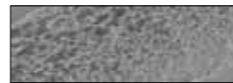
0.1 - 0.45 micron

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 HC



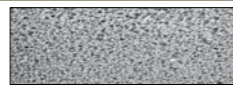
0.2 micron

Polyethersulphone

- Optimized membrane configuration allows up to 10 times the throughput compared to single layer membrane products
- Integral prefilter layer can condense filter trains for greater processing economy

PROPOR HC sterilizing grade filters have been specifically designed for the effective and economical processing of difficult to filter solutions.

PROPOR LR



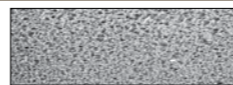
0.1 micron

Polyethersulphone

- Fully validated and integrity testable for assurance of sterility
- Integral prefilter layer increases throughputs for reduction of filter trains
- Exceptional flow rates for quick processing of cell culture media

PROPOR LR filters have been specifically designed for high flow and effective removal of *Ralstonia pickettii* and other dimorphic organisms.

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



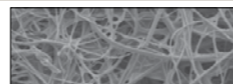
0.6 - 100 micron

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.

PROCLEAR GF



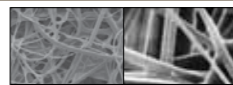
0.6 - 10 micron

Glass Microfibre

- Excellent dirt holding capacity
- Non-fibre releasing glass microfibre media
- Long service life for maximum throughput

PROCLEAR GF filters are designed for reliable and economical removal of particulate and microorganisms from pharmaceutical fluids.

PROCLEAR GP



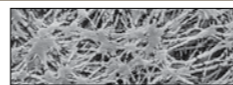
0.5 - 0.6 micron

Glass Microfibre / Polypropylene

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

PROCLEAR GP filters combine glass microfibre and polypropylene media to provide maximum protection to downstream filter membranes and equipment.

TETPOR AIR



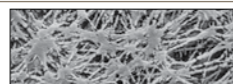
0.2 micron

Expanded PTFE

- Assured biosecurity with absolute rated filtration
- High flow rates with low pressure drops
- High voids volume PTFE membrane

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

HIGH FLOW TETPOR II



0.2 micron

Polytetrafluoroethylene PTFE

- Optimum pleat configuration
- Unrivalled flow rates combined with low pressure drops
- Steam sterilizable up to 225 cycles at 142 °C [287.6 °F]

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.

Single-use systems

MURUS and DEMICAP



- Reduces CIP and SIP validation burden
- Maximizes flexibility
- Minimizes batch turnaround and risk of cross contamination

Single-use filter capsules allow customers to readily integrate Parker filtration medias into their single-use production processes. Designed to minimize hold-up volumes, the capsule range has design features that maximize usability and are fully scalable from development to manufacturing scales.

SpinBag™



- Universal mixing plate and stand fits 2L to 20L bags
- Small 12" x 12" footprint with integrated heater and variable speed control
- 3D SpinBags store flat and can be ordered with custom port configurations and pre-sterilized options

Efficient small volume mixing and stirring with disposable bag technology. The SpinBag system offers a simple solution to the cost, storage and cleaning challenges of traditional rigid bottles and spinner flasks.

Moulded manifolds



- Single or multi-use systems tailored to your application
- Proprietary technology allows for any configuration
- Ys, Ts, crosses, reduces and elbows give maximum flexibility

Cross-linking of elastomer chains ensure each mold is molecularly bonded to the tubing. This permanent connection prevents product loss and contamination commonly experienced with hosebarb failures. Internally, moulds are seamless and crevice-free to eliminate entrapment areas and potential contamination.

Other Parker products

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.

DuraPure™ bioprocess bag systems



- TPE tubing with moulded junctions and sanitary fittings
- Available in the following sizes: 250 mL, 2L, 5L, 10L, 20L, 50L, 100L, 500L and 1000L
- mitos-P, mitos-C platinum-cured tubing with moulded junctions and sanitary fittings

Integrated fluid-handling systems designed for durability and purity. When creating a DuraPure Bioprocess Bag System with our customers, we not only consider the bag, but every component that surrounds it. Each system is designed to seamlessly integrate the rest of your process.

PoGo™ G2 mixing system



- Efficient low shear mixing action
- Fully programmable or manual controls
- Detachable mixing chamber

Parker's robust PoGo™ G2 mixing system uses a fully programmable reciprocating motion that combines fast efficient mixing with low shear effect. Multiple mixing disks on a common shaft create a unique fluid dynamics profile that eliminates dead spots to ensure homogenous mixing.

VALAIRDATA II



- 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 II combines the sound principles of aerosol testing with a compact, portable and ergonomic design reducing test times and improving multi-cartridge system sensitivity.

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.

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