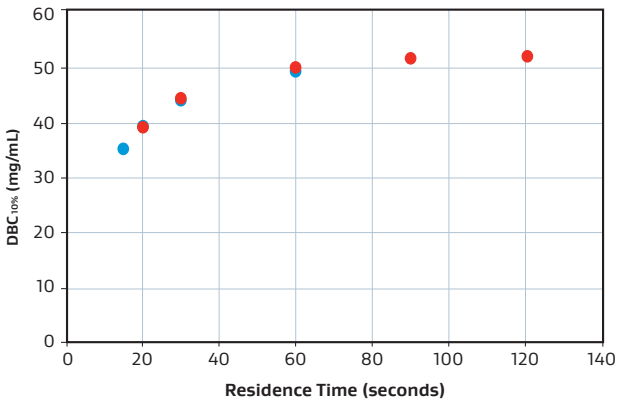
GORE® Protein Capture Device
with Protein A, for clinical and routine bioprocessing
For Rapid Purification of Antibodies

INCREASE PRODUCTIVITY WITH HIGH BINDING CAPACITY AND SHORT RESIDENCE TIME FOR ANTIBODY PURIFICATION

GORE Protein Capture Devices with Protein A are intended for the affinity purification of monoclonal antibodies and other proteins containing an Fc region derived from clarified cell culture harvests in process development to initial GMP clinical applications. The devices use a unique expanded polytetrafluoroethylene (ePTFE) membrane composite that provides a binding capacity advantage at high flow rates with low delta column pressure over 100 cycles. This combination improves the speed of purification over traditional technologies (Figure 1).

Figure 1. Typical binding capacity using human polyclonal IgG. Results may vary based upon molecule or source. Overlay of 58 mL (red) and 250 mL (blue) to demonstrate consistency across size.



The 58 mL through 1 L sizes can be used in process development and pre-clinical, clinical and small batch productions. A smaller, GMP version is available in 9 mL and non-GMP versions are available for screening in 1.0 mL and 3.5 mL.

Key Features and Benefits

Key features

- High dynamic binding capacity (≥40 mg/mL)*
- Short residence time (30 seconds)
- Demonstrated ability to cycle 100 times with CIP
- Low delta column pressure over cycling
- Compatible with existing capital equipment
- GMP ready

Key benefits

- High binding capacity and fast flow rate improve productivity
- Pre-packed for convenience and consistency offering time savings

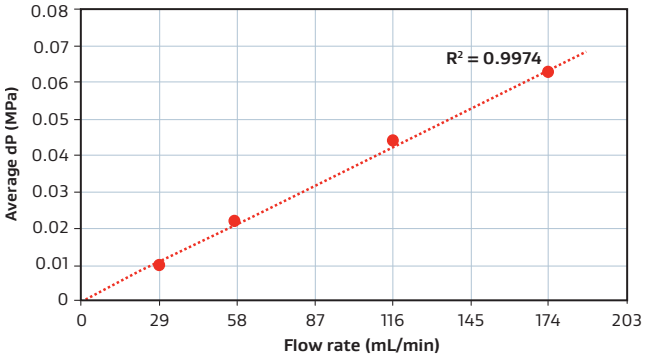
*Initial DBC10% with human polyclonal IgG.

Together, improving life

Improved Performance

Unlike traditional resins, the membrane bed in the GORE® Protein Capture provides a linear relationship between pressure drop and a wide range of flow rates without causing collapse, channeling or alteration of the membrane bed (Figure 2).

Figure 2. Column pressure drop at various flow rates demonstrated with 58 mL



Performance Data

Performance evaluation was performed with a CHO clarified cell culture harvest, trastuzumab biosimilar with a titer of 4 g/L. The extracts were clarified and filtered through a 0.2 µm filter prior to loading.

For purification, the 58 mL Device was loaded to 80% of its DBC10%. Loading was performed at 30 seconds residence time of 116 mL/min, while all other steps were performed at 10 seconds residence time or 348 mL/min. The total cycle time was 12.6 minutes per cycle. The CIP was run with 3 CV and paused for 3 minutes static hold. The chromatograms of cycles 10, 25, 50, 75 and 100 are shown overlaid in Figure 3. Yield, elution and product quality are shown in Figure 4.

Figure 3. Chromatographic overlay of cycle 10 (yellow), 25 (blue), 50 (red), 75 (black), and 100 (green). The shift in loading curves reflect a change in lot harvest, mass was loaded to same amount through cycling.

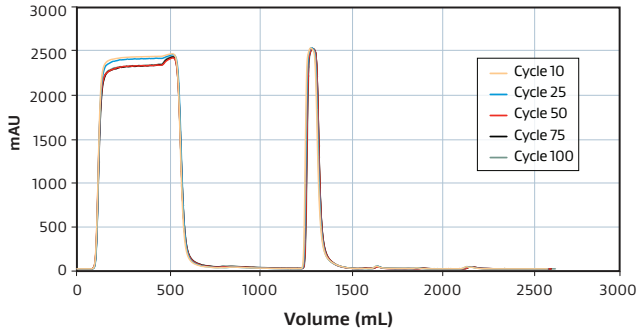
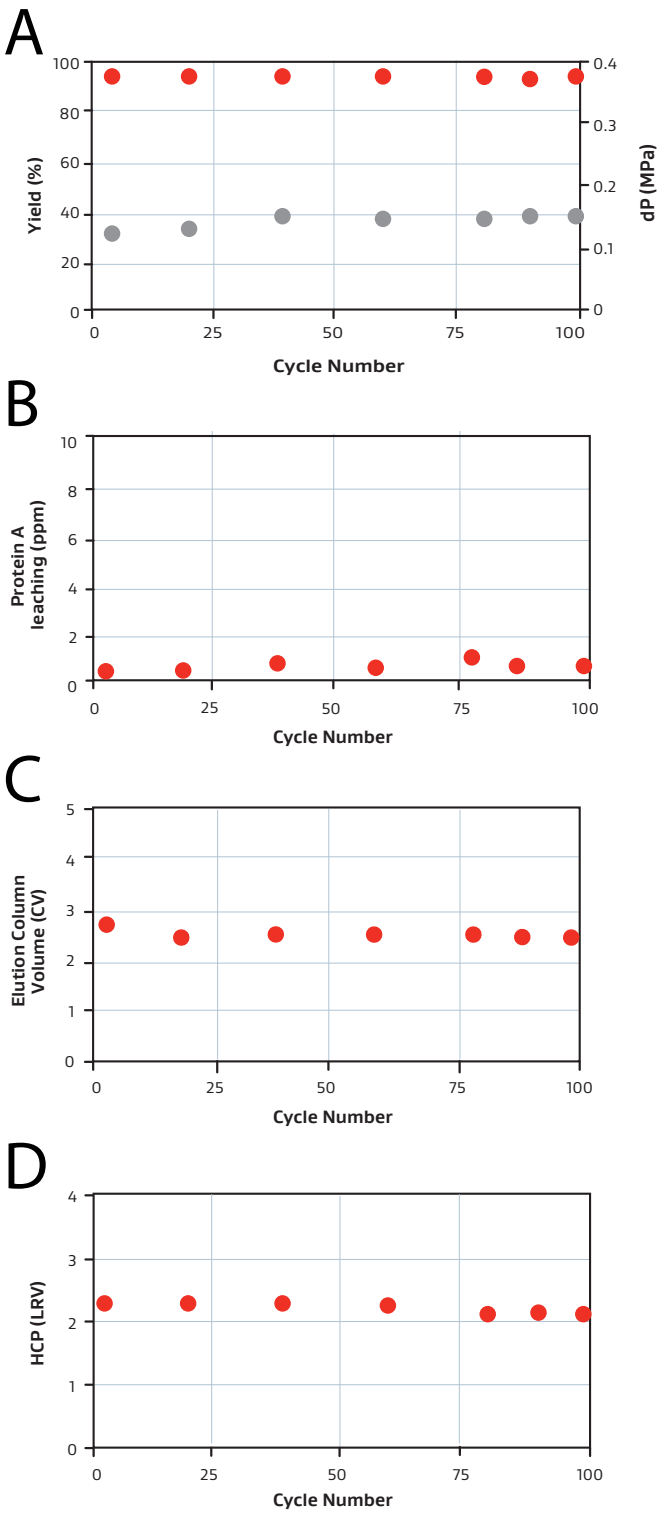


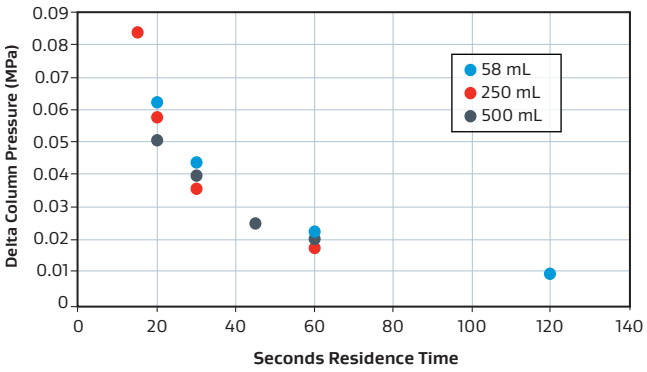
Figure 4. Indicated performance over 100 cycles: A. Yield (Red) and dP (Grey); B. Protein A leaching; C. Elution CVs; D. HCP log reduction.



Performance Scalability with Pressure

Consistent delta column pressure demonstrated across sizes. Slight differences may be attributed to different LC systems used and the associated tubing.

Figure 5. Overlay of example dP versus residence time across 3 sizes corrected for system pressure.



Operating conditions

The typical flow rate at a residence time of 20 seconds or 30 seconds is shown in the table. The user can refer to the Instructions for use for additional information.

	Flow Rate (mL/min)	
Size (mL)	**20srt**	**30srt**
58	174	116
116	348	232
232	696	464
250	750	500
500	1500	1000
1000	3000	2000

Packaging/Storage information

Store device in the refrigerator at 2–8 °C (35.6– 46.4 °F), in a solution of 20% ethanol and 80% deionized water. Based on accelerated shelf life testing, the Devices have a three year shelf life under recommended storage conditions of 2–8°C (35–46°F).

Refer to the *GORE Protein Capture Device Operating Instructions* for detailed operating and handling guidelines.

Regulatory Compliance

GORE® Protein Capture Devices are manufactured following the applicable material quality and regulatory requirements. Contact Gore for current applicable compliance statements.

Quality Statement

GORE Protein Capture Devices are manufactured in a manner that adheres to relevant current Good Manufacturing Practices (cGMP), as defined in the Gore PharmBIO Products quality system which is certified to ISO13485 and ISO15378.

Intended Use

The 58 mL through 1 L GORE Protein Capture Devices are intended for process development, pre-clinical and clinical GMP applications.

Part Number / Ordering Information

Part Number	Description	Quantity
PROA201	58 mL Device	1/box
PROA202	116 mL Device	1/box
PROA203	232 mL Device	1/box
PROA301	250 mL Device	1/box
PROA302	500 mL Device	1/box
PROA303	1 L Device	1/box

Device Characteristics*

	Material of Construction/Details			
Component	**PROA201**	**PROA202/PROA203**	**PROA301**	**PROA302/PROA303**
Membrane	Polytetrafluoroethylene (PTFE) composite	Polytetrafluoroethylene (PTFE) composite	Polytetrafluoroethylene (PTFE) composite	Polytetrafluoroethylene (PTFE) composite
Protein A	Native Recombinant Protein A from *Staphylococcus aureus*	Native Recombinant Protein A from *Staphylococcus aureus*	Native Recombinant Protein A from *Staphylococcus aureus*	Native Recombinant Protein A from *Staphylococcus aureus*
Connectors	5/16-24 flat-bottom threaded fittings	3/4" Tri clamp (0.984" (OD))	1/2-20 flat-bottom threaded fittings	3/4" Tri clamp (0.984" (OD))
Column, flow distributors, housing	Polypropylene	Polypropylene	Polypropylene	Polypropylene
Integrated Air trap inlet and dome	N/A	Cyclic olefin copolymer (COC)	N/A	Cyclic olefin copolymer (COC)
Inegrated Air trap o-ring	N/A	Ethylene Propylene Diene Monomer rubber (EPDM)	N/A	Ethylene Propylene Diene Monomer rubber (EPDM)
Tri clamp gasket	N/A	Platinum-cured silicone	N/A	Platinum-cured silicone
Integrated Air trap diverter	N/A	Polypropylene	N/A	Polypropylene
Integrated Air trap distributor	N/A	PEEK	N/A	Polypropylene
Component - End fitting adapter	N/A	N/A	1/2-20 Male to 5/16-24 Female Fitting Polypropylene	N/A

*See validation guide for complete details.

Gore PharmBIO Products

Our technologies, capabilities, and competencies in fluoropolymer science are focused on satisfying the evolving product, regulatory, and quality needs of pharmaceutical and bioprocessing customers, and medical device manufacturers. GORE Protein Capture Devices with Protein A, like all products in the Gore PharmBIO Products portfolio, are tested and manufactured under stringent quality systems. These high-performance products provide creative solutions to our customers' design, manufacturing, and performance-in-use needs.

NOT INTENDED FOR USE in medical device or food contact applications or with radiation sterilization.

All technical information and advice given here is based on our previous experiences and/or test results. We give this information to the best of our knowledge, but assume no legal responsibility. Customers are asked to check the suitability and usability of our products in the specific applications, since the performance of the product can only be judged when all necessary operating data is available. Gore's terms and conditions of sales apply to the purchase and sale of the product.

Americas | W. L. Gore & Associates, Inc.
402 Vieve's Way, Elkton, MD 21921 • USA
T +1 410 506 1715 Toll-free (US) 1 800 294 4673
Email pharmbio@wlgore.com

Europe | W. L. Gore & Associates, GmbH
Wernher-von-Braun-Strasse 18, 85640 Putzbrunn, Germany
T +49 89 4612 3456 Toll free 0 800 4612 3456
Email pharmbio_eu@wlgore.com

gore.com/pharmbio

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