

**GORE® Molded Assemblies
with the GORE Aseptic
Sampling Valve**
For Bioprocess Operations



CUSTOMIZE AND STREAMLINE ASEPTIC SAMPLING

Custom-configured GORE Molded Assemblies with the GORE Aseptic Sampling Valve offer bioprocess operators a way to streamline the collection of multiple aseptic samples from stainless steel vessels. With each Assembly designed around the needs of your process, Gore's single-use closed system is designed to facilitate efficient, error-free collection. The closed system with color-coded tubing reduces the risk of sampling mix-ups, while needle-free actuation helps to protect operators, and eliminates the needle-disposal waste stream.



GORE Aseptic Sampling Valve with Assemblies can be custom-configured with your choice of containers, including bags, tubes or bottles in a wide range of sizes.

Key Features and Benefits

- Needle-free: Reduces the risk of operator harm and eliminates the need for separate waste streams for needle disposal.
- Lever actuator with audible click: ensures intuitive and accurate usage.
- Color-coded tubing: reduces the risk of operator error when sampling.
- Fully disposable: eliminates the need for cleaning of component parts

Aseptic Sampling Valve Material Set

- Polyetherimide (PEI), Silicone

Performance Summary

- 100% leak-tested
- 100% visually inspected for potential functional and cosmetic defects
- Maintains pressure resistance after SIP
- Biocompatible
- Two-year shelf life

Operating Conditions

- Connects to standard vessel ports, interfacing with bioprocessing sanitary clamp fittings as specified in ASME BPE-2019: BIOPROCESSING EQUIPMENT, Table DT-7-2 Polymeric Hygienic Clamp Ferrule Standard Dimensions and Tolerances (Redesignated as DT-7.1-2 in 2022).
- Compatible with SIP.

Regulatory Compliance

- Manufactured following the applicable material quality and regulatory requirements.
- Please contact Gore for current applicable compliance statements.

Quality Statement / ISO Class 7 Cleanroom

- Valve Assemblies are manufactured, assembled and packaged in ISO class 7 certified cleanrooms in a manner that adheres to relevant Good Manufacturing Processes as defined in the Gore PharmBIO quality system, which is certified to ISO 13485 and ISO15378.
- Each produced lot is controlled according to the agreed customer specification, and Certificates of Compliance provided.
- Assemblies are sterile via gamma irradiation with SAL claim of 10^{-6} validated per the requirements of ISO 11137.

Intended Use

For in-process off-line or at-line collection of multiple aseptic samples from stainless steel vessels.

- In applications including but not limited to:
 - Animal health
 - Monoclonal antibodies
 - Vaccines
- In various steps of the process such as:
 - Buffer preparation
 - Harvest
 - Formulation

Ordering Information

Each assembly is custom-configured to customer specifications. Please contact Gore to discuss your requirements.

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. The 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.

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.

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