Single-Use Consumables

Tubing Manifolds and Container Systems

Parker Prädifa

ENGINEERING YOUR SUCCESS.

Single-Use Solutions For Bio-Processing

In recent years, the obvious advantages of single-use systems (SUS) compared with commonly used steel- and glass-based multi-use alternatives have led to a significant increase in both market acceptance of and demand for these polymer-based devices.

Long-standing experience in polymeric materials and clean-room production in Central Europe combined with extensive know-how of biopharma processes and validation procedures makes Parker Prädifa your perfect partner to identify and maximize the potential of utilizing SUS in your manufacturing operations. Our experts are able to specifically assist you in:

- Developing customized solutions tailored to perfectly fit your production environment
- Setting up a suitable validation procedure according to the safety level required by the specific use of the SUS (incl. leakage testing, particles, endotoxins and sterility)
- Management and coordination of your project from the initial idea through to implementation in volume production processes

As an independent open-architecture supplier, Parker Prädifa offers you maximum flexibility of working with standardized components from established brands. Thanks to our in-house product design and tooling capabilities, we are able to address unique requirements and develop tailored components and solutions to meet your needs, drawing on in-depth materials engineering expertise. For example, we are able to convert existing stainless steel or glass solutions into single-use configurations as well.

Rigid containers combined with state-of-the-art overmolding technology play a key role in our product offering.
Our solutions can be found in applications such as:

- Final filling
- Sampling
- Cold-chain transportation down to -85 °C
- Media preparation
- Buffering
- General fluid transfer

Clean-room molding and overmolding with state-of-the-art machines ensures full process control. Every system is visually inspected using a dedicated LED-supported table for particles detection.

Overmolding Technology

The Right Choice for Critical Processes

Single-use solutions for sampling or final filling applications have to meet special requirements compared with single-use systems in upstream production processes. As one of the final process steps on the way to the finished product, maximum levels of integrity and excellent accuracy in terms of fluid management have to be ensured in sampling and final filling to guarantee a contamination-free and precisely dosed final product.

Our overmolding solutions ensure both maximum safety to prevent contamination due to validated and completely closed systems and fully controlled fluid path dynamics as a result of smooth transitions between the tubing and connector. Depending on specific customer requirements, Parker Prädifa is able to offer its entire overmolding portfolio in pharma-grade silicone or TPE materials.

Our overmolding technology is suitable for the following solutions:

- Tube-to-tube connections
- Overmolded labels
- Tube-to-container connections (molded stoppers)
- Tube-to-hose barb connections (e.g. vent filters and connectors)
- Container integrity seals

Molded Stopper

Overmolded Label

Integrity Seal

Molded Tri-Clamp and Vent Filter

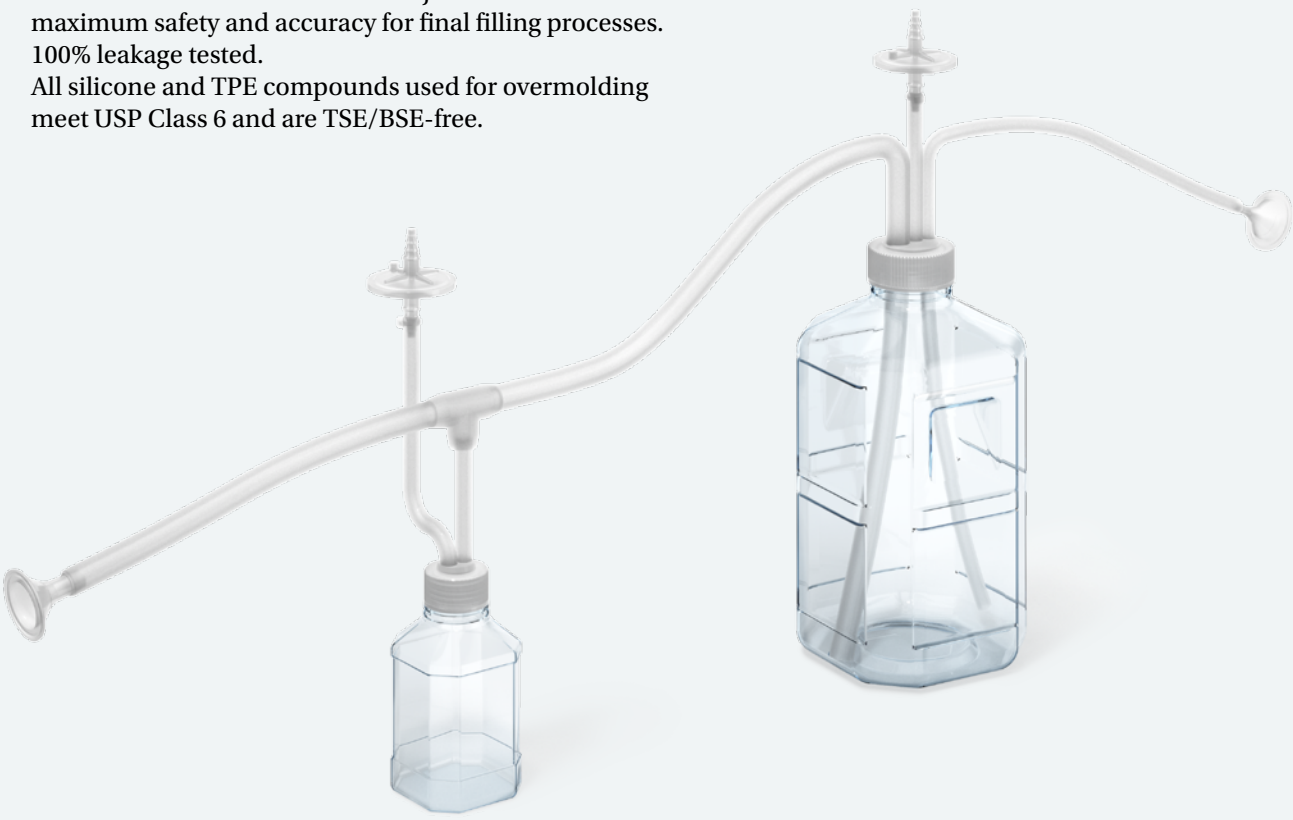
Molded X-Connection

Molded Bag Port Connection

Application and Product Overview

Final Fill Manifolds

Molded connections on all critical joints to achieve maximum safety and accuracy for final filling processes.
100% leakage tested.
All silicone and TPE compounds used for overmolding meet USP Class 6 and are TSE/BSE-free.



Rigid plastic containers are available from 125 ml to 20 l volume

Molded Y-Connections can combine different tubing sizes in one joint

Waste Containers

Waste containers ensure safe and controlled removal of by-products and waste during production by using molded tube-to-container connections. Molded stoppers are available in TPE and silicone with custom tube configurations.

Sampling Systems

Parker's patented integrity seal technology allows customers to work with containers instead of the standard bags in sampling applications while guaranteeing tamper-proof storage and transportation of the sample. The utilization of containers instead of bags improves handling combined with clear and reliable monitoring and evaluation of the fill level. An aseptic luer sampling port is provided to remove test material via needle-free luer-lock syringes.

Application and Product Overview

Bubble Traps

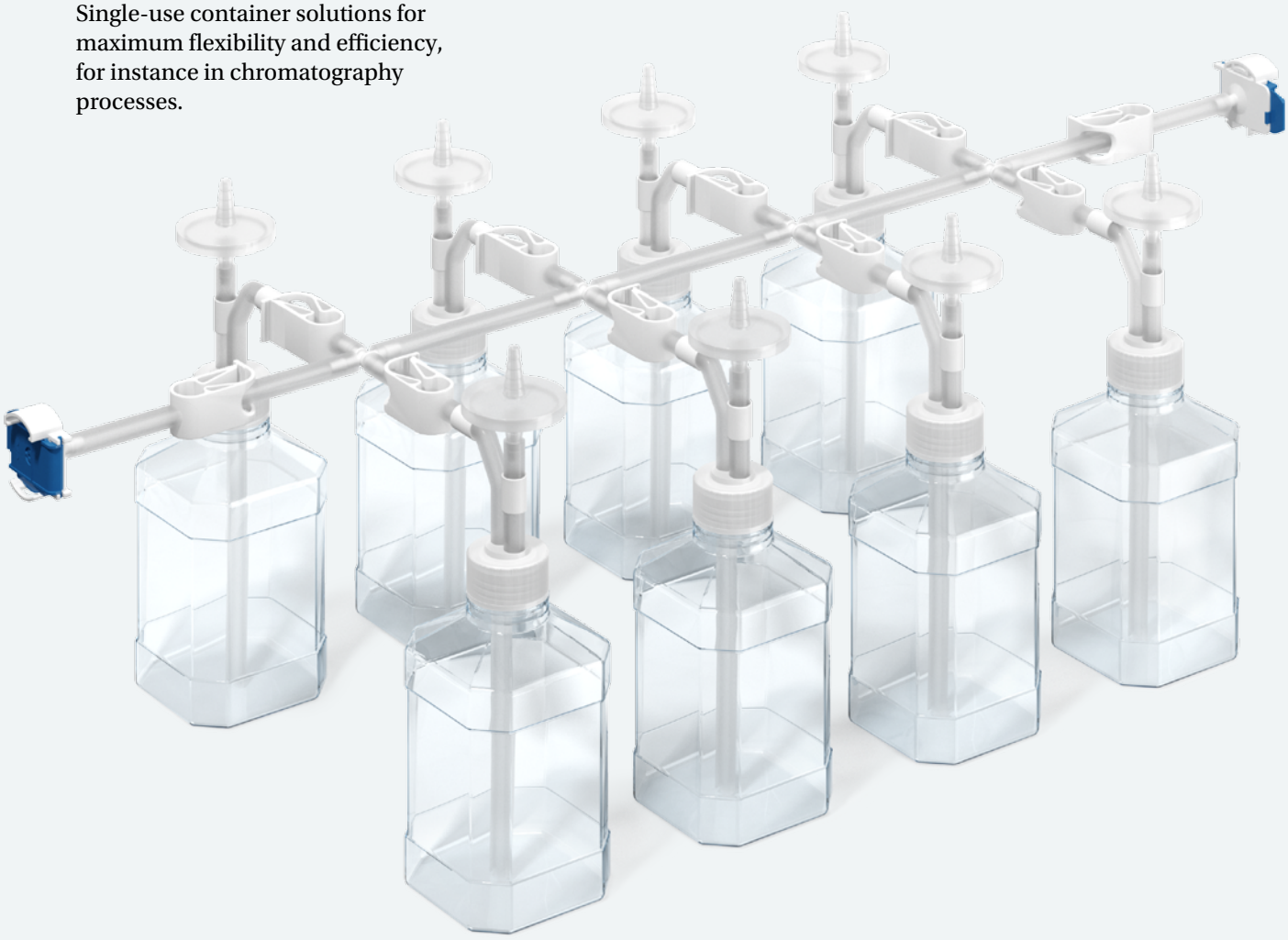
Bubble traps are designed to avoid air entrapments in vaccine production processes.

Cold-Chain Transportation Solutions

Innovative container sealing concepts for cold-chain transportation at -85 °C.
A protective cap prevents tube damage during low-temperature transportation.
Various container sizes and tubing configurations are available.
Integrated anti-foam tube configuration ensures maximum filling process control.

Media Preparation and Buffering

Single-use container solutions for maximum flexibility and efficiency, for instance in chromatography processes.



Open architecture for maximum flexibility and compatibility – successful utilization of integrated single-use components and tubing from various brands.

Validation Guidelines And Procedures

The provision of customized single-use consumables entails project-specific validation in practically every customer project as the configuration of any system is unique to some extent. The majority of the relevant regulations and standards for validating single-use consumables originated from the medical device market or the market for finished pharmaceuticals with high volume production and lower part cost compared with average single-use consumables.

Achieving the right balance between product safety, regulatory requirements and commercial aspects for customized single-use consumables requires in-depth knowledge of all applicable regulations and standards as well as of the technical aspects and risks associated with any product, from the raw materials through to the production technology used. The scope of our validation capabilities encompasses:

- Particle testing
- Bioburden
- Endotoxins
- Leakage (pressure decay testing)
- Sterility
- Shelf-life
- Packaging
- Transportation / shipping

Applicable Regulations and Standards:

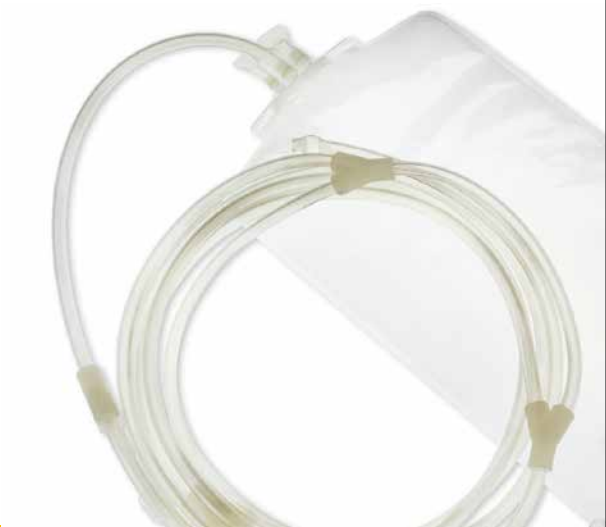
- ISO 13485: Quality Management Systems for Medical Devices
- ISO 14644: Clean-Room Environmental Controls
- ISO 11137: Sterilization of Medical Devices
- ISO 11737: Bioburden
- E.P. 2.6.14 and USP <85>: Bacterial Endotoxins Test
- E.P. 2.9.19 and USP <788>: Particulate
- ASTM F 1980:2007: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- Materials of Construction (free of animal-derived ingredients or meeting EMEA410.01 rev.03)
- USP <661> Extractables / BPOQ Protocol
- ISO 10993 Biocompatibility
- USP <87> / USP <88> Cytotoxicity/Bioreactivity
- Transportation Validation (ISTA-2A or ASTM D7386-12)

Endotoxin Testing USP 85

Typical single-use consumables are frequently used for fluid management in both upstream and downstream processes. Consequently, they have direct product contact and can potentially add undesired materials to the process. Bacterial endotoxins are examples of such undesired materials.

Bacterial endotoxins are gram-negative bacterial products which can be toxic and may cause symptoms such as fever. These materials cannot be completely removed by sterilization as the sterilization process will not inactivate the toxins even when cleaning and sterilization is effective in killing the bacteria.

Consequently, bacterial endotoxin testing is an essential component of batch release testing. Details on test limits and methods are available on request.



Sterility ISO 11137

The sterilization process of any product must be validated to verify that it effectively and reliably kills any organisms that may be present on the pre-sterilized product. If requested, our single-use consumables are sterilized to achieve a sterility assurance level (SAL) of 10^{-6}, which corresponds to the probability of one in a million items being nonsterile.

Validation is performed according to the ISO 11137-2 VDmax 25 method. Based on the annual production volume of every item, the sterilization dose is audited during routine production runs.

Leakage Testing

Parker Prädifa performs leakage testing using pressure decay (destructive and non-destructive) and submergence tests. Pressure decay testing is done with a dedicated device inside a clean room class 7. The device has a sensitivity of 1 Pa monitoring air loss inside single-use assemblies after they have been pressurized and the pressure has been stabilized. The acceptance limits for the pressure decay test are product-specific and heavily depend on the component materials and size as various tubing materials for instance behave differently during a pressure decay test. The test result requires in-depth understanding of material performance characteristics. The submergence air bubble test is performed to verify if the acceptance limits used for every product during pressure decay testing are suitable. Parker pressure decay test results can be used to establish a correlation to integrity testing done after manipulation at the customer's site.

Shelf Life

All sterile products require shelf life testing of the product's packaging as well as its functionality in order to verify the impact of aging on the materials. In order to avoid delays entailed by real-time aging studies of the product(s), accelerated aging tests according to ASTM F 1980:2007 are performed. In accelerated aging tests, it is important not to select excessively high temperature settings even though this reduces testing time and cost. Plastic components in particular may change in terms of mechanical properties and surface characteristics if temperatures for accelerated aging are set too high. Typical shelf life is 24 months but may be extended based on the customer's project-specific requirements.

PTD3028 EN · 01/2017

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