SARTORIUS

Application Note

November 12, 2020

Ključne riječi ili fraze:
Prehrambena industrija, sustavi za punjenje, postrojenje za boce, kontaminacija vode, sterilna filtracija vode, završno ispiranje vodom, tretiranje vodom, integritet filtera

Use of Sartopore® 2, 0.2 µm, 30" Maxicaps® for Water Filtration Upstream of the Washing Hose Used to Clean and Rinse the Bottle-Filler Exterior

Wayne Garafola[1], Alexandra Ivanovsky[2]

1. Sartorius Stedim North America Inc., 565 Johnson Avenue, Bohemia, NY 11716, wayne.garafola@sartorius.com

2. Sartorius Stedim France SAS, ZI des Paluds, Avenue de Jouques – CS 71058, 13781 Aubagne Cedex, alexandra.ivanovsky@sartorius.com

Abstract

External filler cleaning systems used in the food and beverage industry require water free of microorganisms. To achieve this, a sterilizing-grade membrane (made of polyethersulfone) within a polypropylene capsule can be used.

Sartorius has developed an innovative technique that uses Sartopore® 2, 0.2 µm, 30" Maxicaps® for the sterile filtration of water upstream of the washing hose used to clean the bottle filler exterior.

The Sartopore® 2, 0.2 µm, membrane can be sterilized by autoclaving or chemical sanitization. It is a completely regenerable system that can be used for an extended period of time. A ready-to-use capsule system is a new alternative to using a filter cartridge within a stainless steel filter housing.

Materials and Methods

In the food and beverage industry, point-of-use (POU) external filler cleaning systems require water free of microorganisms. This is essential depending on regional legislation (i.e., in France there is an obligation to rinse with drinking-quality water) or product sensitivity (contamination of mineral water is the same as washing water; fruit juice or alcoholic drinks are much less sensitive to contamination).

Figure 1: Washing Hose Outside Bottle Washer

Some users have identified Coliforms or Pseudomonas contamination, including Pseudomonas aeruginosa, in the water leaving cleaning plants. This means the final rinse water from the wash cycle becomes unsuitable for use in the beverage bottling process. The risk is contaminating the filling spout and polluting the bottle intended for the consumer. The quality standards of some mineral and bottled water producers covers the entire environment of the bottle as long as it remains open.

In the beverage industry, medium-pressure cleaning units (10 – 25 bar) are generally used with water pressure of 8 – 16 bar. Higher pressure risks causing contamination to explode into the environment as aerosols. Automatic or manual cleaning units represent a particularly sensitive application because they are not used daily, but once or twice a week at most. The risk is contamination of the entire installation by water stagnation between infrequent uses. For the best quality result and consumer safety, the bottler must require from his supplier an external washing system of hygienic design. The equipment must avoid water stagnation during the standby phases by allowing, for example, regular renewal of water in the non-drainable part of the equipment (also called "dynamic purges"). During periods of prolonged shutdown, the equipment must be able to be completely drained or, failing that, cleaned in place (CIP) before activity resumes.

To ensure non-contamination during cleaning, the microbiological quality of the water arriving at the medium pressure unit is critical. At this point, it has been demineralized and possibly passed through UV to eliminate the microbiological load. Sometimes, this is insufficient, and the user finds contamination at the POU. This contamination can have different origins (i.e., piping biofilm, dead legs, variable pipe sizes, water stagnation) that are difficult to remove without shock sterilization.

Our solution is to install a stainless steel filter housing fitted with a 0.2 µm membrane filter cartridge from the Aquasart® range to sterilize the water upstream of the cleaning unit. If the station is automatic, this equipment requires adequate sizing to respond to the instantaneous flow rates of many different nozzles in the flow range of 9 – 15m³/h (150 – 250 LPM).

With manual stations, the water flow may be lowered to 2 – 5 m³/h (33 – 83 LPM), because flow rate depends on the number of operators requiring flow simultaneously. Both the automatic and manual environment around the filtration equipment must meet filtration best practices and provide for chemical or thermal sterilization at least weekly, with filter integrity checks.

Another solution is that a 0.2 µm sterilizing-grade membrane filter can be installed at the POU upstream of each nozzle. A Sartopore® 2, 0.2 µm, 30" Maxicaps® filter is recommended.

Benefits of Sartopore® 2 Filters in Capsule Form:

- Economical: Eliminates the need to invest in a stainless steel housing and to clean the equipment.
- Flexible: Available with different filtration areas, 0.015 m² – 1.8 m². The effective filtration areas (EFA) allow flow rates of up to 4 – 5 m³/h (66 – 83 LPM).

Figure 2: Single-Use Maxicaps® and MidiCapsules

- Easy to use: Filters are delivered in individual sterilized packaging. When they are used for the first time on site, it is not necessary to sterilize the filters during installation.
- Microbial retention: Sartopore® 2 Maxicaps® is validated as a sterilizing-grade filter according to ASTM F838-15 guidelines.

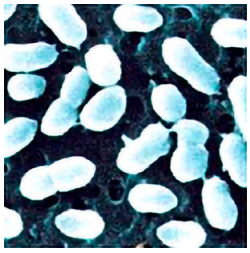

Figure 3: *Pseudomonas diminuta* colonies on a filter membrane

- Retention: Pseudomonas diminuta is 100-percent retained within the Sartopore® 2, 0.2 µm, polyethersulfone membrane.
- Quality control: The integrity of each element is tested by bubble point and diffusion testing before leaving the factory, ensuring absolute reliability.
- Certification: Sartopore® 2 Maxicaps®, Midicapsules, and Capsules comply with EU regulation number 10/2011 of the committee of January 14, 2011, and the latest amendments concerning plastic materials and objects intended to come in contact with food. A validation guide is available for the Sartopore® 2 filter. A quality assurance certificate is placed in each filter box.
- Sterilization: Validation of at least 25 autoclave sterilization cycles at 134 °C, 2 bar.

The Sartorius Solution

For each medium pressure unit, a ready-to-use Sartopore® 2, 0.2 µm, 30″Maxicaps® is installed upstream of the sterile water filtration hose with a flow rate of 4 – 5 m³/h (66 – 83 LPM). This corresponds to a maximum of three users working simultaneously.

Figure 4: Two remote satellite (left and center) and one medium-pressure (right) stations. All stations: a booster station and an integrated satellite POU

Upstream of station, flow rate variable between 1.8 – 5 m³/h (30 – 83 LPM)
At each POU, flow rate 1.3 – 3 m³/h (30 – 50 LPM), depending on type of rinsing nozzle

Results

Booster stations are available in different versions that correspond to the capacity of the pump and the number of users flushing simultaneously. The table below shows filter sizing.

Table 1: Installation Stations

Number of simultaneous flushing users	Instant water flow rate required (≥30 LPM rinsing nozzle)	Sterilizing-grade filter
1 – 3	1.8 – 5.4 m³/h (30 – 90 LPM)	1 × Sartopore® 2, 0.2 µm, Maxicaps® 30″
4 – 6	5.4 – 10.8 m³/h (90 – 180 LPM)	2 × Sartopore® 2, 0.2 µm, Maxicaps® 30″

Installation of Sartopore® 2, 0.2 µm, Maxicaps® includes a 1 – 1.5″ tri-clamp connection on a stainless steel pipe with valves, manometers, upstream and downstream microbiological sampling valves, and Staubli-type quick coupling for carrying out an in-situ integrity test after installation.

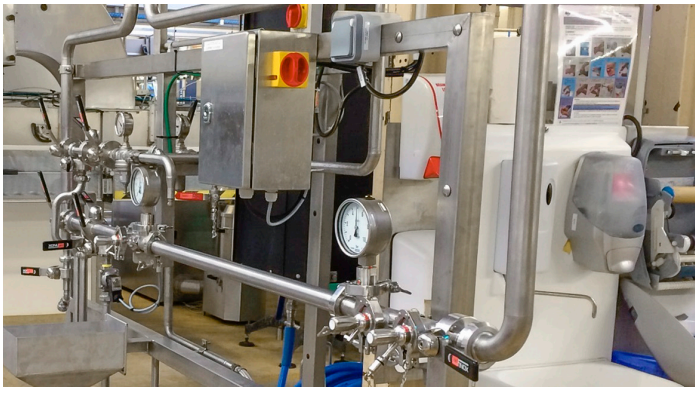

Figure 5A: Process Flow With Spacer Installed

Figure 5B: Process Flow With Sterilizing-Grade Maxicaps Installed

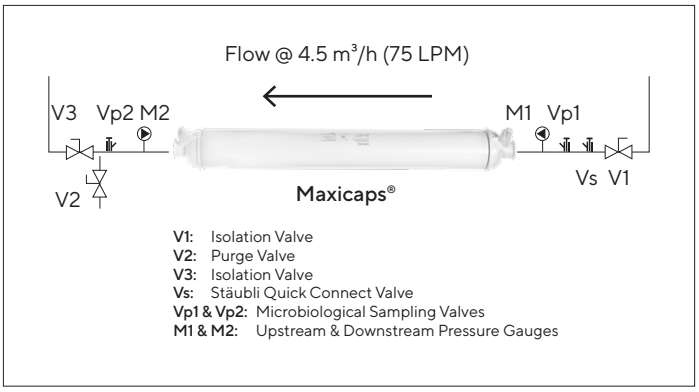

Figure 6: Process Flow Diagram

The filter capsule may be installed in a horizontal or vertical position.

Figure 7: Capsule Filter Horizontal Installation at POU

Figure 8: Capsule Filter Vertical Installation at POU

How often to sterilize the filter capsule was determined by:

- Observing monthly filtrate sampling (using non-sterile air) → contamination.
- Observing monthly filtrate sampling (using sterile air) → contamination after three weeks.
- Autoclaving Maxicaps® every week.

Directions for Use (DFU)

Follow these directions to ensure microbiological safety: On-site laboratory tests have shown that leaving the filter in place for a month results in microbiological contamination.

1. Each week, rotate two Sartopore® 2, 0.2 µm, Maxicaps®: Label #1 (in use) and Label #2 (in autoclave).
2. Perform an installation integrity test to verify that the Sartopore® 2 Maxicaps® 0.2 µm filter remains integral (not been damaged during sterilization and handling).
3. The 15-minute check can be performed automatically by a Sartocheck® Mini integrity tester.
4. To avoid stagnant water within the Sartopore® 2 Maxicaps®, purge the filter and drain it for 15 seconds every hour to remove water in the filter assembly.

Conclusion

Sartopore® 2, 0.2 µm, 30" Maxicaps® are reliable for the sterile filtration of water used with washing hoses employed on bottle fillers. Their design allows for easy installation and repeated use following weekly sterilization cycles. Sartopore® 2, 0.2 µm, 30" Maxicaps® are valid for removal of microorganisms from water used with washing hoses. These filters can be integrity tested to demonstrate that they remain integral following autoclaving cycles.

Germany
Sartorius Stedim Biotech GmbH
August-Spindler-Straße 11
37079 Göttingen
Phone +49 551 308 0

USA
Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

For further contacts, visit
www.sartorius.com

Status: 12 | 02 | 2020