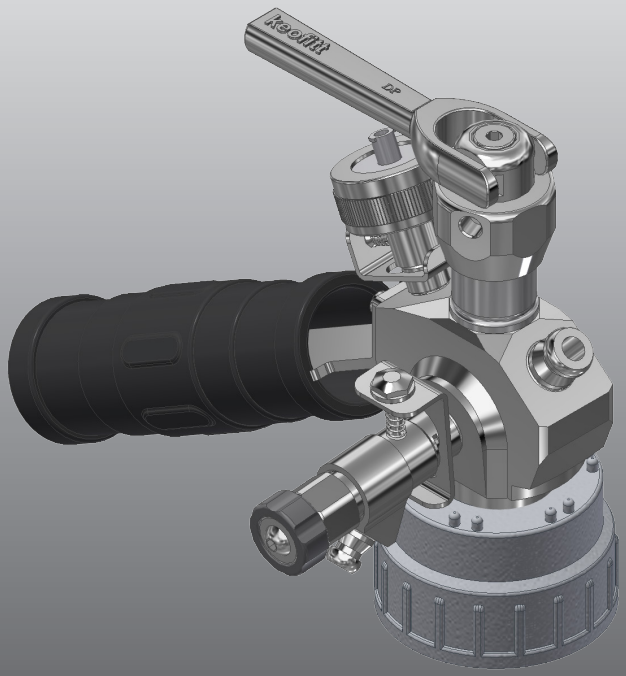
KEOFITT®

WORLD LEADERS IN STERILE SAMPLING™

ASEPTIC SYSTEM

User Manual



DON'T GAMBLE WITH YOUR SAMPLE™

DOCUMENT VERSION LOG

The table below lists previous versions of this User Manual and states the major changes between versions.
This version list is introduced in April 2020.

Version #	Version date	Major changes from previous versions
1	April 2020	Latest version without log

INTRODUCTION:

MANUFACTURER:	Keofitt A/S Kullinggade 31 B+E 5700 Svendborg, Denmark
TYPE:	ASEPTIC SAMPLING SYSTEM
YEAR OF INTRODUCTION:	2020
YEAR OF REVISED DESIGN:	2020
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CONTENTS

1. PRESENTATION

This manual describes the Keofitt Aseptic Sampling System.

The Keofitt Aseptic Sampling System enables the user to take a truly representative sterile sample. The Aseptic Sampling System protects the sample against airborne contamination, while taking the sample and during transfer to the laboratory.

The Keofitt Aseptic Sampling System is based on Keofitt's guarantied high quality, microbiologically safe valve design. The current design is adopted from the Keofitt W9 sampling valve, which is 3-A authorized. The American 3-A Sanitary Standard is normative for the component's ease of cleaning and sterilization and ensures optimum conditions for food products, which is in contact with the component in question.

The Aseptic Sampling System is compatible with all medium (W9) sized Keofitt sampling valves. The Aseptic Sampling System is used in a wide range of processing industries, such as breweries, dairies, juice/soft drinks and the biotechnological and pharmaceutical industries, which all have different requirements and demands.
Various test reports and certificates are to be found on the Keofitt website www.keofitt.dk.

1.1 Definition of terms

In order to ease the reading of this manual and to avoid any misunderstanding, please refer to the definition of terms in the table below:

TERM	DEFINITION
3-A Sanitary Standard, Inc.	3-A SSI is an independent, not-for-profit US corporation dedicated to advancing hygienic equipment design for the food, beverage and pharmaceutical industries.
Acids	An acid is a chemical substance whose aqueous solutions are characterized by a sour taste and the ability to react with bases and certain metals (like calcium) to form salts. Aqueous solutions of acids have a pH of less than 7. A lower pH means a higher acidity, and thus a higher concentration of positive hydrogen ions in the solution. Removes limestone and most mineral deposits.
Alkali	Alkalis are all bases, which form hydroxide ions (OH-) when dissolved in water. The terms "base" and "alkali" are often used interchangeably. Alkalis have a pH value above 7. Alkalis dissolves fat and oil, destroys protein and attacks light metal.
Aseptic sampling	The process of withdrawing a sample from the production equipment through a closed circuit, which has been sterilized and kept sterile with no exposure to the surroundings during the sampling process.
Bio load	See Microbial load.
Bioburden	See Microbial load.
Chemical Sterilant	A few disinfectants will kill spores with prolonged exposure times (3–12 hours); these are called chemical sterilants.
Chlorine	Chlorine is a chemical element with symbol Cl and atomic number 17. It belongs to the halogen group together with for instance iodine. It is a strong oxidizing agent and reacts with many substances. These properties make chlorine compounds efficient disinfectants.

CIP	Abbreviation of Clean-In-Place. The process of cleaning a process component (like a sampling valve) without removing it from the production line.
Cleaning	Removal, usually with detergent and water or enzyme cleaner and water, of adherent visible soil on a surface.
Complexing agent	A substance capable of forming a complex compound with another material in solution. Improves the cleaning properties of a detergent.
Contact time	The time span during which the item is in contact with the detergent or the disinfectant.
Enzymes	Molecules, which are added to cleaning agents to ease the removal of specific organic material. Assures same cleaning effect at a lower temperature.
Disinfectant	Usually a chemical agent that destroys harmful microorganisms but might not kill bacterial spores.
Disinfection	Thermal or chemical destruction of microorganisms. Disinfection is less lethal than sterilization, because it destroys most recognized microorganisms but not necessarily all microbial forms (e.g. bacterial spores).
Detergent	A cleaning agent that has no antimicrobial effect, but in diluted solutions good cleaning properties.
EHEDG	Abbreviation for the European Hygiene Engineering and Design Group. EHEDG is a consortium of equipment manufacturers, food industries, research institutes as well as public health authorities promoting safe food by improving hygienic engineering and design in all aspects of food manufacture.
Electro polishing	Electro polishing is an electrochemical process by which the high points within the microscopic surface texture are removed and the corners rounded. This results in Reduced Product Adhesion, Ease of Cleaning and Improved Corrosion Resistance.
Exposure time	Period in a sterilization/disinfection process during which the item is exposed to the sterilant/disinfectant at the specific sterilization/ disinfection parameters.
Flow path	The path the sample flows from the tank or process equipment to the sample recipient.
Germicidal	The property of an agent to destroy microorganisms.
Microbial load	The number and types of viable microorganisms with which an item is contaminated; also called bio load or bioburden.
Microorganisms	Animals or plants of microscopic size. As used in food and pharmaceutical industries, generally refers to bacteria, fungi, viruses and bacterial spores.
Peracetic acid	A commonly used disinfectant, which is efficient at low temperature and short contact time. Relatively harmless as it decomposes into carbon dioxide (CO_2) and water (H_2O).
Process media	The product in the process equipment and the product from which a sample is taken.
Representative sample	A sample which when it reaches the laboratory is still identical to the process media. A sample which is in no way contaminated or altered during neither the sampling process nor the transport to the laboratory.

Sanitization	The application of a chemical agent that reduces the number of bacterial contaminants to a safe level as judged by the public health authorities. The official sanitizer protocol indicates that 99.999% of the specific test bacteria be killed in 30 seconds under the conditions of the test.
SIP	Abbreviation for Sterilize-In-Place. The process of rendering a process component (like a sampling valve) sterile without removing it from the production line.
Spores	Relatively water-poor resting cells surrounded by an impervious cell wall, which makes them relatively resistant to disinfectants and sterilants. They are dangerous as they can survive in adverse conditions and re-emerge as live bacteria at a later stage.
Sporicidal	The property of an agent that kills spores.
Steaming	The process of using saturated steam under pressure as the sterilizing agent.
Sterile	State of being free from all living microorganisms. In practice, usually described as a probability function, e.g., as the probability of any microorganism surviving sterilization being one in one million.
Sterilant	A few disinfectants will kill spores with prolonged exposure times (3–12 hours); these are called chemical sterilants.
Sterilization	Validated process used to render an item free of all forms of viable microorganisms. In a sterilization process, the presence of micro-organisms is expressed in terms of probability. Although this probability can be reduced to a very low number, it can never be reduced to zero.
Sterility Assurance Level	The probability of a viable microorganism being present on an item after sterilization. Usually expressed as 10–n; a SAL of 10-6 means < 1/1,000,000 chance that a single viable microorganism is present on a sterilized item.
Tensides	A tenside is a surfactant that reduces the surface tension of water and assures a faster and better contact between the detergent and the soil.

1.2 Quick start

The table below gives you an overview of the relevant chapters to read depending on the operations you want to perform to obtain the required hygienic level.

Required hygienic level	4.3 Steaming	5.2 Cleaning the Aseptic Sampling System	5.3 Reassembling and autoclaving the Aseptic Sampling System	5.5 Steam sterilization	5.6 Sampling
Cleaning		✓			✓
Disinfection	✓		✓	✓	✓
Sterilization	✓		✓	✓	✓

2. CLEANING – DISINFECTION – STERILIZATION

This chapter gives introduction to the concepts of cleaning, disinfecting and sterilizing process equipment in general.

2.1 Clean-In-Place (CIP)

Thorough cleaning of the Aseptic Sampling System is a prerequisite for proper disinfection. Cleaning of the valve is the removal of any visible residual product; it be organic or inorganic.
Cleaning is the removal of adhering soil from the environment and from the previous sample (to the extent it has not been removed by the recommended post-sample cleaning). Cleaning is usually performed by flushing with water followed by a thorough washing with an appropriate detergent and finished off with a thorough rinsing with water.
Depending on the actual process media the proper detergent must be determined in cooperation with your usual supplier of detergents. The company Novadan ApS, Kolding, Denmark - www.novadan.dk, has supplied the generic table below for your convenience.

What to clean for	Generic cleaning agents	Comments
Fat	Alkali and Tensides.	Heat will facilitate the cleaning process as the fat melts.
Protein	Alkali, Acids, Tensides and Chlorine.	Coagulation and burning when heated, which makes the product hard to remove.
Sugar, Salt	Water is usually sufficient as the product is water soluble.	Sugar caramelizes when heated, turning into a hard-sticky substance, which is difficult to remove.
Minerals	Acids, Complexing agent.	Often seen as lime scale.
Biofilm	Alkali and Chlorine, Peracetic acid, possibly Enzymes.	Biofilm is an accumulated mass of micro-organisms that is tightly adhered to a surface and cannot be easily removed.
Starch	Alkali and Chlorine.	

2.2 Disinfection

Although CIP removes all visible residues of the process media the valve surfaces will still be contaminated on a microscopic level. Depending on your actual process media it will be necessary to carry out a disinfection operation in order to a) reduce the microbial load to an acceptable level (also referred to as Sanitization) or b) destroy critical microorganisms, but not necessarily all microbial forms (e.g. bacterial spores).
Disinfection of the Aseptic Sampling System is split into 2 operations:

- Initial autoclaving of the system components.
- Steaming of the flow path of the system together with the sampling valve on the process equipment just prior to taking the sample.

Using a liquid chemical disinfectant is generally a valid alternative to steaming an ordinary sampling valve on a process line. However, to take an aseptic sample using the Aseptic Sampling System steaming is generally the preferred method (see explanation in chapter 2.3 Sterilization).
There are several chemical disinfectants. It is important to choose the right one, the right concentration and contact time and the right method for your current application. Your usual supplier of chemical disinfectants can support you in choosing the right disinfectant for your process media and the specific group of microorganisms you are aiming at.

The company Novadan ApS, Kolding, Denmark has supplied the table below, as a preliminary indication of which type of disinfectant to use:

Disinfectant / Microbes to inactivate	**Halogens** (Chlorine)	**Peroxides** (Hydrogen peroxide & Peracetic acid)	**Alcohol** (70%)
Gram-negative **bacteria** Salmonella Campylobacter E. Coli and others...			
Gram-positive **bacteria** **Listeria** **Bacillus cereus** Clostridium and others...			
Bacteria **spores** Bacillus cereus and others...			
Bacteriophage			
Yeast			
Fungi			
Virus			

Legend:	Efficient	Limited effect	Little/No effect

NOTE! The final choice of detergent, disinfectant and method lies with the user, supported by the supplier of the CIP fluids and disinfectants, as it is very much dependent on individual concerns and circumstances.

2.3 Sterilization

Sterilization is a high-level disinfection designed to render the valve free of all forms of viable microorganisms (incl. bacterial spores) to a high level of certainty; the so-called Sterility Assurance Level or SAL. A SAL value of 10-6 means that the probability (or risk) of a single viable microorganism being present on the equipment interior afterwards is only 1 in 1,000,000 which is a generally accepted level for calling an item sterile. Although the probability can be reduced to a very low number, it can never be reduced to zero.
Sterility may in practice only be obtained by steaming. Disinfectants exist that in high concentrations and for a prolonged exposure time will be able to inactivate all forms of microorganisms and render the equipment interior sterile with a high probability; these disinfectants are called chemical sterilants. However, the application of chemical sterilants is most often problematic due to a) a required high concentration, which causes an operator hazard and b) the several hours of exposure time.

NOTE! Furthermore, sterilization with a chemical sterilant may not convey the same sterility assurance as sterilization with steam, because the germicidal and sporicidal kinetics are much less investigated and documented for chemical sterilants compared to steam.

WARNING!

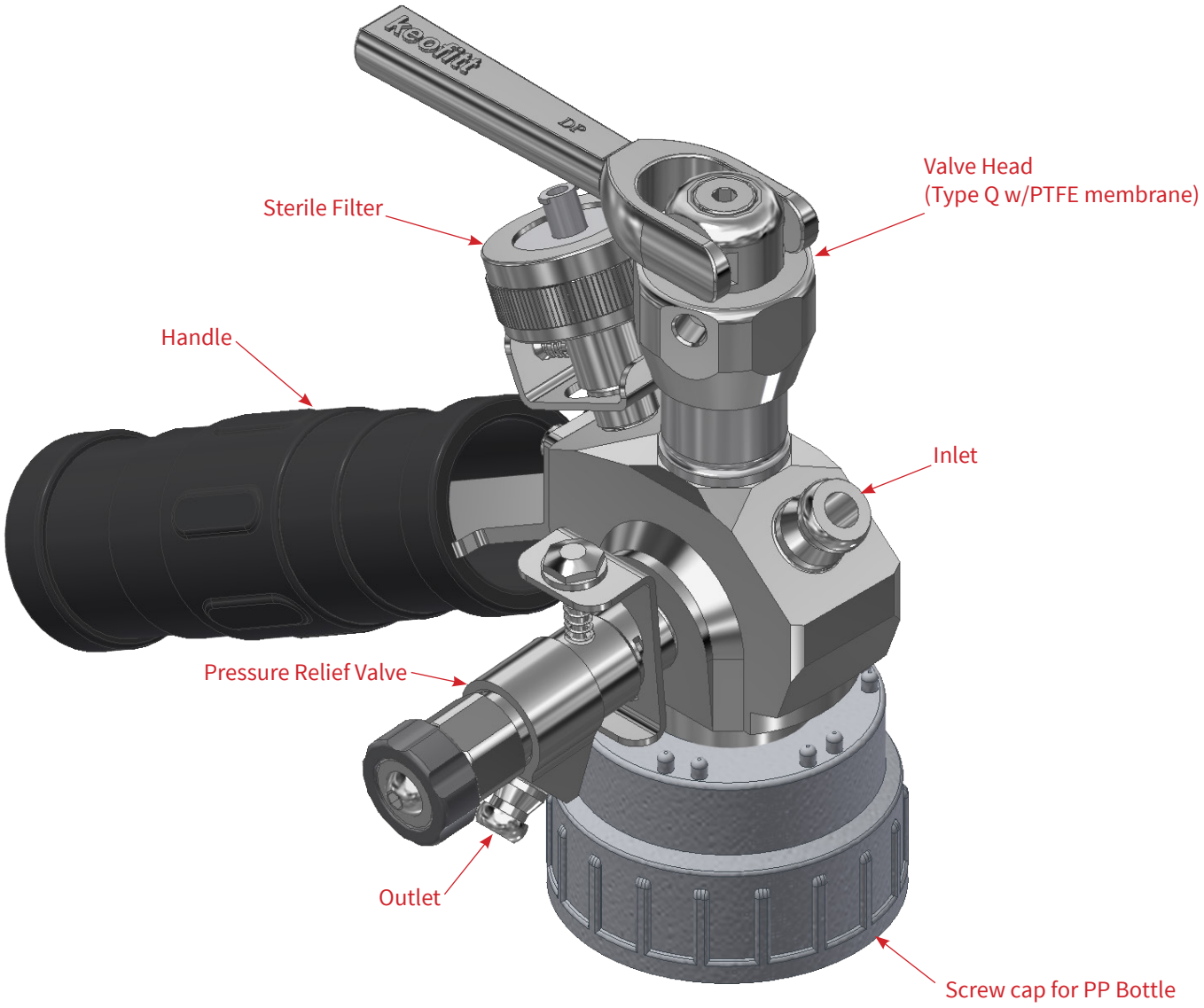
- During sterilization with steam the valve will become hot and care should thus be taken when operating the valve.
- When steaming always use dry saturated steam without condensation at max. 1 bar(g). At higher pressure the membrane may be damaged/split.
- Always remember to use safety goggles when steaming, taking samples and all other operations of the sampling valve.

3. DESCRIPTION OF THE ASEPTIC SAMPLING SYSTEM

The Aseptic Sampling System (hereafter called Aseptic System or just System) is meant to regularly take sterile representative samples from the production process into a plastic bottle. The Aseptic System is therefore designed so that effective cleaning, sterilization and sampling can be carried out regularly without interrupting the production process.

The Aseptic System consists of:

- A system body with inlet, air outlet through sterile filter and steam outlet with a pressure relief valve.
- A valve head with a lever actuator (type Q with PTFE membrane).
- An integrated screw cap (disconnectable).
- A handle with a rubber cover.



Available accessories see chapter 3.5.

The Aseptic System's inlet port is connected to the output port of the production line sampling valve using a PTFE tubing. Supplying steam through the connected parts carries out sterilization of the entire flow path. With the System in its upright position it is auto drainable, such that after steaming any condensate will flow out of the system body.

The Keofitt Aseptic System is based on the acknowledged Keofitt valve design. Steaming does flush, cleaning, rinsing and sterilization in one operation. Steaming is therefore a SIP process (Sterilize-In-Place).

After sterilization and shutting off the steam supply the Aseptic System's valve is opened using the lever handle allowing a flow path into the sample bottle. Subsequently opening of the sampling valve will cause product media from the process to flow into the sample bottle through the sterilized flow path. Product flowing to the bottle causes that air from the bottle will be expelled through the air outlet, where the sterile filter is mounted. To maintain aseptic conditions a sterile filter must be connected to the air outlet prior to autoclaving the system.
When the required sample volume is obtained, the sampling valve at production line and the valve in the Aseptic System must be closed and steam could be administered to rinse the flow path. The Aseptic System now contains a sterile sample of the media in the production line and may be safely carried to the laboratory for analysis.

WARNING!

- During sterilization with steam the sampling valve and the Aseptic System will become hot and care should thus be taken when operating the valves.
- When steaming always use dry saturated steam without condensation at max. 1 bar(g).
- In case of obstruction of the air outlet pressure will build up in the bottle eventually causing it to burst if filled with liquid. To help avoiding too high pressure, a relief valve is mounted at the outlet of the Aseptic System. The relief valve will gradually open when pressure reaches 2-3 bar in the Aseptic System.
- Always remember to use safety goggles when steaming and taking samples and during all other operations of the sampling valve and the Aseptic System.

3.1 Valve head configurations

Valve heads come in the following configurations:

- Lever handle (type Q)

All configurations come with W9™-membrane PTFE.

3.2 Membrane

The valve head is delivered with PTFE membrane.
The PTFE membrane resists all CIP fluids and disinfectants except highly oxidizing acids in high concentrations. For further information, please refer to specific Datasheet for article number 850055.

3.3 Pressure Relief Valve

The Aseptic System comes with a spring actuated relief valve, which is designed to open at approximately 2-3 bar.
The relief valve serves two functions as it is both a closeable outlet for steam and cleaning media (maintain aseptic conditions in the Aseptic System while taking sample) as well as function as relief valve for high pressure build up in the System due to wrong handling.

The relief valve has a plastic turn knob to manually open and close, as it also serves as outlet when

cleaning the aseptic system. When cleaning the Aseptic System, the relief valve must be in its open position to let out cleaning media or steam. When in sampling mode, the relief valve must be in closed position. If a pressure of approx. 2-3 bar is build up in the system, the valve will gradually open and lead out excess air or product sample. At normal sampling procedure, the relief valve will stay in its closed position. If, at some reason the pressure in the system increase to 2-3 bar, e.g. the air outlet is blocked, the relief valve will gradually open and lead out excess air and liquid. When pressure decrease to approximately 0.5 bar, the valve will return to closed position.

3.4 Sterile filter

The Aseptic system comes with a Whatman™ Puradisc™ 25 TF filter, poresize 0.2 µm. The filter can be mounted directly in the air outlet of the Aseptic System via the filters luer connection or be placed in the quick coupling housing for better fixation. For further information on the filter, please refer to the Datasheet article number 260122 or alternatively www.whatman.com.

3.5 Parts and Accessories

Keofitt provide a huge number of spare parts and accessories to the entire range of sampling valves.
These include spare parts like:

- Membranes
- O-rings and gaskets
- Bushings
- Handles

and other accessories like:

- Barbed fittings and tube welding fittings for tubes and hoses
- Adaptors between Tri-clamp, Mini Tri-clamp and Hose Piece (Quick Coupling)
- Fitted PTFE tubing for Quick Coupling and Tri-clamp
- Any length of PTFE tube
- Clamps for Tri-clamp connections
- Click-on steamer
- Circulator
- Sampling bottle systems

4. EVERYDAY USE OF THE ASEPTIC SYSTEM

This chapter introduces the different working steps when using the Aseptic System. For specific operator instructions please refer to chapter 5. ASEPTIC SYSTEM OPERATING INSTRUCTIONS.

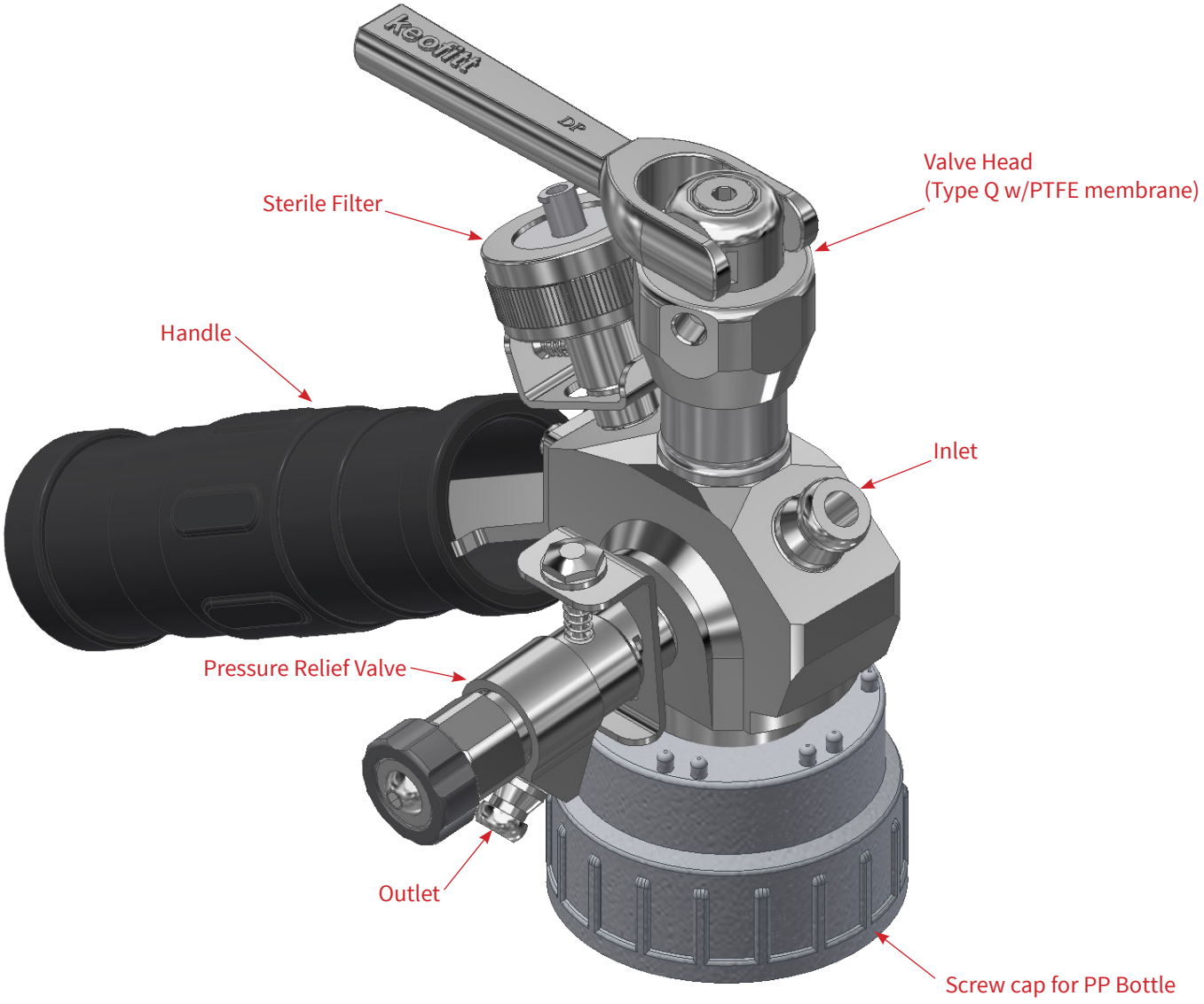
> **NOTE!** For specific instructions on operating the sampling valve on your production line, please read the corresponding user manual carefully.

4.1 Pre-sampling treatment

The Aseptic System is a re-usable system, which must be cleaned and autoclaved prior to each use. The sampling valve on the production line must be prepared for taking samples according to the instructions in its user manual.

4.2 Connections

The System's different connections are seen on the illustration below.



The steam inlet of the sampling valve is connected to a steam supply featuring a shut-off valve to cut the steam supply after sterilization.
The outlet port of the sampling valve is connected to the inlet port of the Aseptic System via a PTFE tube (accessory).

The Aseptic System's Steam Outlet port is connected to drain or similar, taking care to avoid getting injured by the steam jet. Using a steam trap is not recommended here, as it will impede the flow of steam and thus the flushing effect.
The Aseptic System's Air Outlet connects to the interior of the bottle and allows air to be expelled as the sample liquid fills the bottle. In order to maintain the aseptic environment in the system, the air outlet is fitted with a 0.2 µm pore filter (see section. 3.4). It is possible to use both reusable and single use filters for this purpose, please see the table below for comparison.

Solution	Description	Comments
1. Sterile venting filter (replaceable/reusable)	They are either a) a stainless-steel housing with replaceable filter inserts or b) sealed plastic filters, which can be autoclaved many times.	For both types it is critical to discard the filters regularly to avoid using a blocked filter, which may lead to serious pressure build-up in the sample bottle causing it to blast.
2. Sterile venting filter (single use)	Small disc shaped plastic filters with hose barb, luer lock or similar connections.	A cost efficient single-use solution, which may be autoclaved together with the Aseptic System.

4.3 Steaming

Once the Aseptic System is connected to the sampling valve steaming can take place.

Steaming has the advantage that it does flushing, cleaning and sterilization in one operation. However, if steaming is also carried out after sampling, please note that heat from the steam will cause sugary substances to caramelize and substances containing protein to coagulate and burn; see chapter 2.1. In this case rinsing with an appropriate fluid must precede post-sampling steaming.
If no steam is installed near the sampling point, an option is to use a portable steam generator. Keofitt supplies fittings for a Kärcher steam generator.
The steaming process with a Keofitt sampling valve has been validated to obtain sterility after 1 minute of steaming at 121 °C (1 bar(g)).

Documentation is available at the Keofitt Online Service Center on www.keofitt.dk .

5. ASEPTIC SYSTEM OPERATING INSTRUCTIONS

This chapter provides clear instructions on how to operate the Aseptic System. Before sampling the sampling valve and the Aseptic System must be prepared for the sampling process.

5.1 Sampling valve preparations

If the sampling valve has been cleaned properly after the last sampling, there might be no need for any action before steaming.
Otherwise the sampling valve should be cleaned/disinfected/steamed according to the instructions in the sampling valve user manual.
Final sterilization is done when the Aseptic System is connected (see chapter 5.4 and 5.5).

WARNING!

- Carefully follow the guidelines given for any chemicals involved in the cleaning process.
- Always remember to use safety goggles when steaming, cleaning, taking samples and all other operations of the sampling valve.

5.2 Cleaning the Aseptic Sampling System

Cleaning the Aseptic System and preparing it for the next sampling is most efficiently done immediately after the previous sample has been emptied out of the bottle. To clean the Aseptic System properly it must be disassembled.

NOTE! The screw cap may also be disconnected from the Aseptic System body for proper cleaning of the screw cap interior and the internal retention nut.

To dismantle the Aseptic System (including the screw cap) perform the following operations:

1. Disconnect relief valve, filter, all tubing and hoses.
2. Fasten the bottle tight onto the screw cap.
3. Holding the system by the housing and by the screw cap respectively, now unscrew, thereby unscrewing the steel cap flange, the screw cap and the bottle as one assembly.
4. Dismantle this assembly taking care not to lose the O-ring and the gasket.
5. Open the valve using the lever handle.
6. Unscrew the valve head and remove it from the system body.
7. Wash the valve head, system body, relief valve, bottle, hoses and all other parts having been used for sampling.
8. Rinse and dry all parts.

To dismantle the Aseptic System leaving the screw cap in place perform the following operations:

1. Disconnect relief valve, filter, all tubing and hoses.
2. Holding the system housing and the screw cap together, now unscrew the bottle, making sure the bottle flange is not loosened.
3. Remove the clear gasket.
4. Open the valve using the lever handle.
5. Unscrew the valve head and remove it from the system body.
6. Wash the valve head, system body, relief valve, bottle, hoses and all other parts having been used for sampling.
7. Rinse and dry all parts.

WARNING!

- Carefully follow the guidelines given for the chemicals involved.
- Always remember to use safety goggles when steaming, cleaning, taking samples and all other operations of the sampling valve.

5.3 Reassembling and autoclaving the Aseptic System

After proper cleaning the System must be reassembled and autoclaved, following these steps:

1. Screw the valve head on the system body making sure the valve head is in its open position (to avoid damaging the membrane).
2. Leave the valve in its open position.
3. Add a few drops of clean water to the bottle.
4. Screw the bottle on to the cap.
5. Loosen the bottle half a turn to allow heat to access the interior of the bottle.
6. Add the filter to the air outlet.
7. Add relief valve, any tubing, hoses and other items that must be autoclaved (these items may be placed in sterilizable bags for further protection until use).
8. Autoclave the assembly.

After autoclaving perform the following steps:

1. Immediately after opening the autoclave screw the bottle firmly on to the cap.
2. Immediately thereafter close the valve.
3. Immediately thereafter fit any hoses.
4. Take out the assembly and other parts from the autoclave

Having done 1 and 2 you now have a sealed bottle unit, which is sterile on the inside.

5.4 Connecting the Aseptic System

After having autoclaved the Aseptic System take it and its accessories to the sampling point in the production.
Having prepared the sampling valve according to chapter 5.1 perform the following steps:

1. Using a PTFE hose, connect the sampling valve's lower outlet port to the inlet port of the Aseptic System.
2. Connect a hose to the Aseptic System's Steam Outlet and let it go to drain or some appropriate collector of steam (don't use a steam trap which will limit the flow of steam and greatly reduce the flushing effect of the steam jet).

5.5 Steam sterilization

Steam sterilization of the flow path takes place with both the sampling valve and the system valve remaining in their closed positions and relief valve in its open position. Perform the following steps:

1. Make sure the steam supply is connected to the sampling valve's upper inlet port.
2. Open the steam supply and let it flow through the sampling valve and the Aseptic System for sterilization. Allow minimum 1 minute at 121 °C (1 bar(g)).
3. Close the steam supply but leave the hose in place to prevent contamination from the ambient during sampling. If removal of the steam hose is required, immediately fit a sterile rubber or stainless-steel plug onto the sampling valve's upper connector.
4. Close relief valve by turning the knob clockwise.

The valve is now ready to take a sample. The sampling must be performed immediately after steaming to

avoid any contamination of the flow path, the bottle and hence the sample. If the process media is heat sensitive, it may be necessary to wait for the valves to cool off.

WARNING!

- During sterilization with steam the System valve will become hot and care should thus be taken when operating the valve.
- Do not open the System valve while sterilizing with steam, as it would lead steam into the bottle.
- For a System allowed under ATEX

  - II 2 G Ex h IIB T4 Gb
  - II 2 D Ex h IIIC T135°C Db

  both the handle and the top of valve head (type Q) must be cleaned before use.
- Always remember to wear safety goggles when steaming, cleaning, taking samples or any other operations of the sampling valve or the System valve.

IMPORTANT!

- Don't attach a steam trap to the hose from the Steam Outlet as it will impede the flow of steam and hence the flushing effect, and make the sterilization dependent on temperature only, demanding a much longer sterilization time.
- If the steam capacity is low and/or the outlet hose from the valve is long and/or with a large diameter, the temperature will drop, and condensation may occur in the valve chamber. In this case a counter pressure must be established using the pressure relief valve at the System's Steam Outlet.
- Leave the steam hose in place on the sampling valve to maintain the aseptic condition and prevent contamination from the ambient during sampling.

5.6 Sampling

The Aseptic System is now ready to take a sterile sample in an aseptic environment. Take the sample immediately after sterilization (and cooling off, if required) performing the following steps:

1. Open the Aseptic System's valve fully and leave it open.
2. Open the sampling valve slowly until a suitable flow is obtained.
3. Fill the bottle with the required volume of sample.
4. Shut the sampling valve after the sample has been taken.
5. Shut the Aseptic System's valve.
6. Disconnect the hose from the Aseptic System's inlet port.
7. Disconnect the hose from the relief valve from Aseptic System's Steam Outlet port.
8. Clean the sampling valve as appropriate following the instructions from its User Manual.

You now have a sterile sample in the bottle to take to the laboratory.

WARNING!

- When sampling at a high pressure and/or with a low viscosity process media it may flow rapidly into the sample recipient. Therefore, open the sampling valve slowly. Special care must be taken with pneumatically operated sampling valves, as they open abruptly.
- Always remember to wear safety goggles when steaming, cleaning, taking samples or any other operations of the sampling valve.

5.7 Retrieving the sample

After sampling take the Aseptic System to the laboratory.
In a LAF bench unscrew the bottle from the System by holding on to the screw cap. The sample is now ready to be filled into another container or whatever else might be needed for the analysis. After the Aseptic System has been emptied it must made ready for the next sample by performing the cleaning process (chapter 5.2) and the autoclaving (chapter 5.3).

6. TECHNICAL DATA

6.1 Material

Steel parts:	AISI 316L (1.4404)
Membrane:	PTFE (white)
O-ring:	EPDM (black)
Screw cap:	Polypropylene (PP)
Sealing ring:	Thermoplastic elastomer (TPE)

6.2 Certificate

Aseptic system: 3.1*, Ra Cert. incl. measurements**

* A 6-digit code is marked on the valve body. This code refers to a 3.1 certificate which accompanies every consignment of valve bodies. The 3.1 certificate is available at the Keofitt Online Service Center on www.keofitt.dk. Click Certificates and then 3.1.

** The surface roughness is measured for each aseptic system at 3 critical places.
A serial number identifies each aseptic system. A specific surface roughness certificate for each valve body is available on www.keofitt.dk

Membrane: PTFE acc. to FDA, EU10, EC1935, USP88 Class VI, EC2023

6.3 Pressure (max.)

Inlet: Depending of the valve head.
Normal operation is pressure less, as pressure drop is across the sampling valve and the sample flows predominantly by gravity.

6.4 Temperature

Steam: Sterilization using dry, saturated steam at 121 °C / 250 °F and 1 bar(g). Dry, saturated steam at temperatures up to 134 °C /272 °F and 2 bar(g) is possible but might reduce the service life of the membrane.

Process medium: The acceptable operating temperature range for the process medium depends on the choice of membrane as follows:
PTFE: 0°C to 150°C (32-300°F)

Sub-zero Centigrade operation is possible with all membranes. Please consult your local distributor and KEOFITT if occasion arises.

Ambient: The range of acceptable ambient temperatures is limited by the polymer handle and the pneumatic cylinder from -40 °C to 80 °C.

6.5 Surface finish

Internal:	Electropolished Ra ≤ 0.8 µm / 31 µinch
External:	Electropolished Ra ≤ 1.2 µm / 47 µinch

6.6 Viscosity

Viscosity range: 0-1000 cP, with particles up to Ø3 mm in diameter.
Higher viscosity liquids may be sampled, only will the sampling take longer.

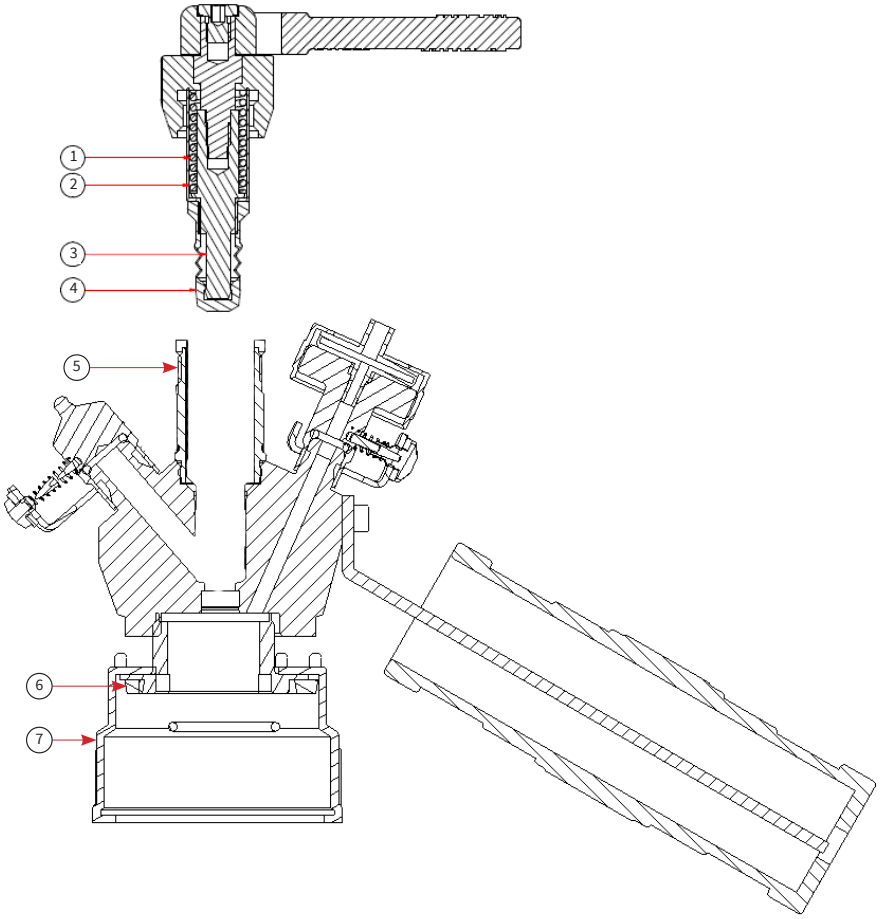
7. MAINTENANCE

7.1 Maintenance

The membrane must be inspected between batches. PTFE membranes should be replaced every 12 months. In the event of intensive cleaning it may be necessary to replace it more frequently. The appropriate replacement frequency should be determined by the user by starting with short intervals and continuously extend the time in use until one reaches the limit of the membrane's durability. Based on the desired safety margin the user then decides on the replacement interval to adapt.

7.2 Spare parts list

1. Spring
2. Steel bushing
3. Lower stem
4. Membrane PTFE (White)
5. Valve body
6. Sealing ring
7. Screw cap



7.3 Replacing a PTFE membrane

The description and illustrations below show a type N with lever handle, but the instructions also apply to other valve head types.

To remove an old membrane from the valve head:

1. OPEN the valve (lever handle position as in illustration A).
2. Unscrew the valve head from the valve body.
3. CLOSE valve head (illustration A).
4. Push the membrane and bushing apart (illustration B) until the tool for membrane fits under it.
5. Insert tool for membrane, between the membrane and the bushing (illustration B).
6. OPEN valve head (illustration C).
7. Now the membrane is loosened from the valve head and can be replaced.

To attach a new membrane to the valve head:

8. Set the valve head to CLOSED position (lever handle position as in illustration B).
9. Place the new membrane on valve head.
10. Mount the membrane bushing with the new PTFE membrane by pressing the tip of the

membrane with your hand until it clicks.

11. Set the valve head in OPEN position (lever handle position as in illustration A).
12. Insert the valve head into the valve body.
13. CLOSE valve head.

IMPORTANT!

- Once the membrane has been removed from the valve head the click system in the membrane might be damaged. Therefore, the membrane might be unsafe for further use and it is recommended not to use the membrane again.
- Do not use hammer or other tool that might scratch the surface of the membrane.