

## ASEPTIC SAMPLING SYSTEM

### USER MANUAL



## 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 October 2015.

<b>Version #</b>	<b>Version date</b>	<b>Major changes from previous versions</b>
1	13 <sup>th</sup> November 2015	Complete revision and new layout.

## **INTRODUCTION:**

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**TYPE:** ASEPTIC SAMPLING SYSTEM  
**YEAR OF INTRODUCTION:** 1998  
**YEAR OF REVISED DESIGN:** 2015  
**LAST UPDATED:** Nov 2015

The English version of this Manual is the governing version and it is the only authorized version. Consequently, KEOFITT cannot be held liable for other versions including translations of this Manual.



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# 1. PRESENTATION

The Keofitt Aseptic Sampling System enables the user to take a truly representative sterile sample. The Aseptic 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 guaranteed high quality, microbiologically safe valve design. The current design is adopted from the Keofitt W9 sampling valve, which is 3-A authorised and EHEDG Type EL Class I certified. The American 3-A Sanitary Standard is normative for the component's ease of cleaning and sterilisation and ensures optimum conditions for food products, which comes in contact with the component in question. The European EHEDG Type EL certificate is issued based on the cleanability of the valve and the test method is an indicator of good inherent hygienic equipment design.

The Aseptic System is compatible with all small (M4) and medium (W9) sized Keofitt sampling valves. The Aseptic System is used in a wide range of industries, such as breweries, dairies, food and the pharmaceutical and biotechnological industries.

## 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:

<b>TERM</b>	<b>DEFINITION</b>
3-A Sanitary Standard	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 sterilised and kept sterile with no exposure to the ambient during the sampling process.
Bioload	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 sterilisation, because it destroys most recognised 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 sterilisation/disinfection process during which the item is exposed to the sterilant/disinfectant at the specific sterilisation/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 bioload 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 <sub>2</sub> ) and water (H <sub>2</sub> O).
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 Sterilise-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 sterilising 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 sterilisation being one in one million.
Sterilant	A few disinfectants will kill spores with prolonged exposure times (3–12 hours); these are called chemical sterilants.
Sterilisation	Validated process used to render an item free of all forms of viable microorganisms. In a sterilisation process, the presence of microorganisms 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 sterilisation. Usually expressed as $10^{-n}$ ; a SAL of $10^{-6}$ means <1/1 million chance that a single viable microorganism is present on a sterilised 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.

## 2. CLEANING – DISINFECTION – STERILISATION

### 2.1 Cleaning

Thorough cleaning of the Aseptic Sampling System is a prerequisite for proper disinfection and sterilisation. Cleaning of the system consists of the removal of any visible residual product, it be organic or inorganic.

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, 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 caramelises 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 microorganisms that is tightly adhered to a surface and cannot be easily removed.
Starch	Alkali and Chlorine	

### 2.2 Disinfection

Although cleaning removes all visible residues of the process media the system 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 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 Sample System steaming is generally the preferred method (see explanation in chapter 2.3 Sterilisation).

If you were to consider using a liquid chemical disinfectant, 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	<b>Halogenes</b> (Chlorine)	<b>Peroxides</b> (hydrogenperoxid & peracetic acid)	<b>Alcohol</b> (70%)
<b>Gram-neg bacteria</b> Salmonella Campylobacter E. Coli and others...	Efficient	Efficient	Efficient
<b>Gram-pos bacteria</b> Listeria Bacillus cereus Clostridium and others...	Efficient	Efficient	Efficient
<b>Bacteria spores</b> Bacillus cereus and others...	Limited effect	Efficient	Little/No effect
<b>Bacteriophage</b>	Limited effect	Efficient	Little/No effect
<b>Yeast</b>	Efficient	Efficient	Efficient
<b>Fungi</b>	Efficient	Efficient	Limited effect
<b>Virus</b>	Efficient	Efficient	Limited effect

Legend:

Efficient	Limited effect	Little/No effect
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**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 dependant on individual concerns and circumstances.

## 2.3 Sterilisation

Sterilisation 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<sup>-6</sup> 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.

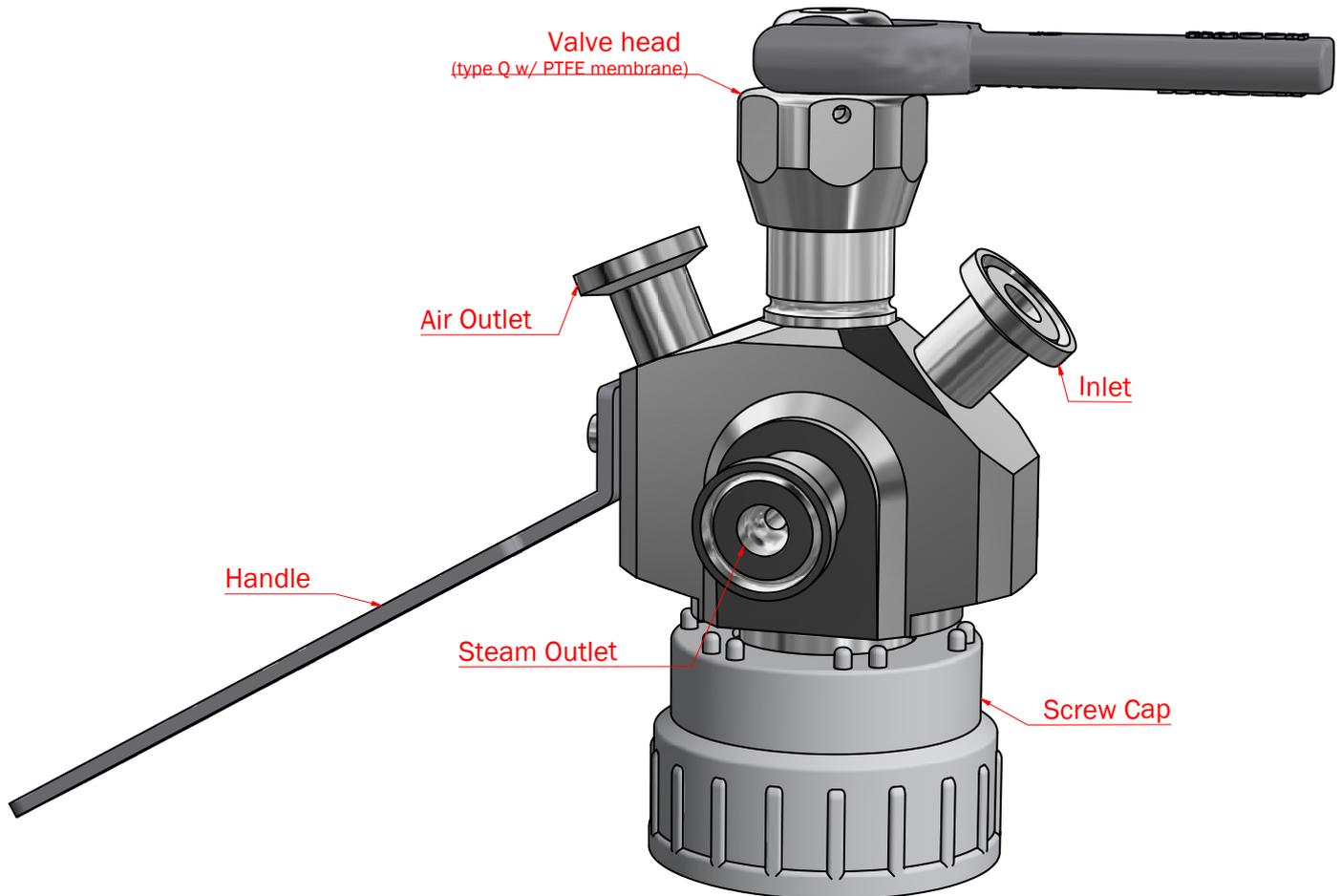
Sterility may in practise only be obtained by steaming. Disinfectants exist that in high concentrations and for a prolonged exposure time will be able to inactivate all forms of microorganisms and render the equipment interior sterile with a high probability; these disinfectants are called chemical sterilants. The reasons for making their usage impractical are a) a required high concentration, which causes an operator hazard and b) the several hours of exposure time.

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

### 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, sterilisation and sampling can be carried out regularly without interrupting the production process.

- The Aseptic System consists of:
- A system body with inlet/outlet ports
- 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 7.3.

The Aseptic System's inlet port is connected to the output port of the production line sampling valve using a PTFE tubing and supplying steam through the connected parts carries out sterilisation 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 and according to an EHEDG-based test carried out by the Biotechnological Institute in Denmark, a sampling valve is sterilised after just 1 minute's supply of steam at a pressure of 1 bar(g), 121 °C. Steaming does flushing, cleaning, rinsing and sterilisation in one operation. Steaming is therefore a SIP process (Sterilise-In-Place).

After sterilisation and shutting off the steam supply the Aseptic System's valve is opened using the lever 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 sterilised flow path. During filling air from the bottle will be expelled through the Air Outlet. To maintain aseptic conditions for the sampling process a sterile filter, a flexible expansion bag, an expansion tank or solution must be

connected to the Air Outlet prior to autoclaving the system.

When the required sample volume is obtained, both valves are 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 sterilisation 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
- Always remember to use safety goggles when steaming and taking samples and during all other operations of the sampling valve and the Aseptic System

## 4. EVERYDAY USE OF THE ASEPTIC SYSTEM

This chapter gives an introduction to the different working steps when using the ASEPTIC SYSTEM. For specific operator instructions please refer to the chapter “ASEPTIC SYSTEM OPERATING INSTRUCTIONS”.

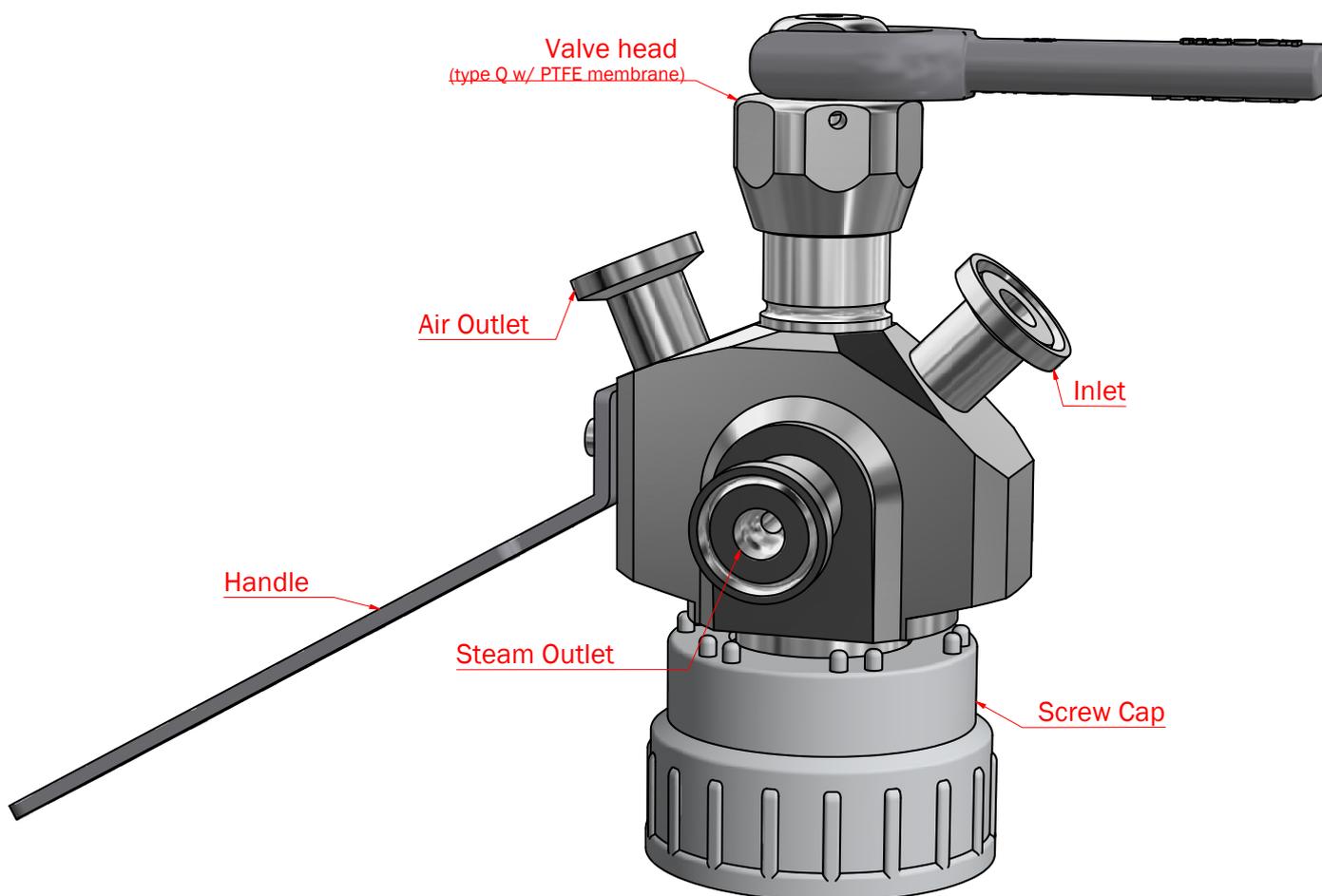
**NOTE!** For specific instructions on operating the sampling valve on your production line, please read the corresponding user manual carefully.

### 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 sterilisation.

The outlet port of the sampling valve is connected to the inlet port of the Aseptic System via a PTFE tube (accessory).

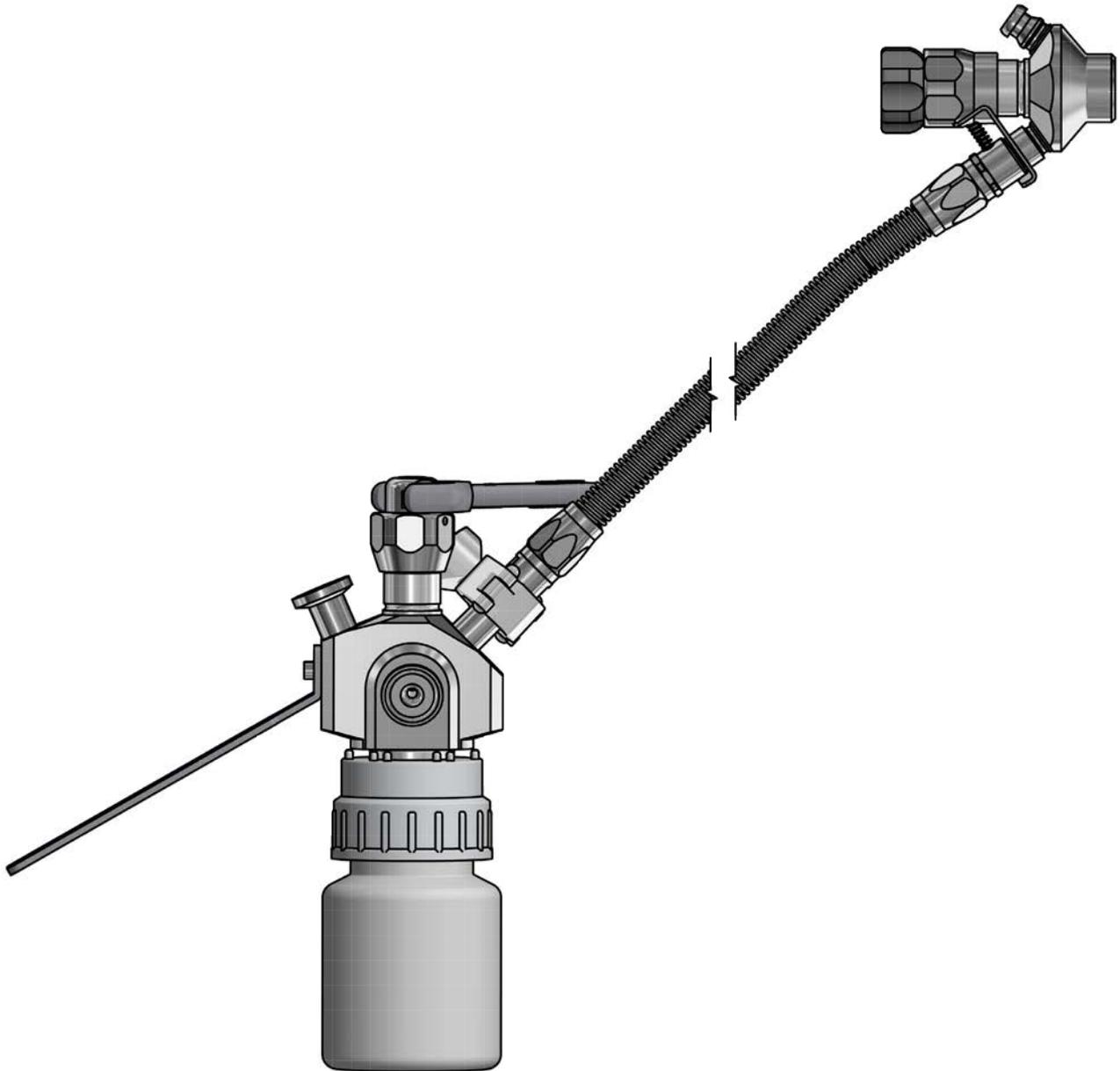
The Aseptic System’s Steam Outlet port is connected to drain or similar taking care to avoid getting injured by the steam jet. Using a steam trap is not recommended here, as it will impede the flow of steam and thus the flushing effect.

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. There are a number of ways to vent the initial air volume in the bottle, as explained in the table below:

<b>Solution</b>	<b>Description</b>	<b>Comments</b>
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.
3. Flexible expansion bag	A flat laid plastic bag will blow up to balance the air displacement when filling the bottle.	An appropriate bag can be used several times and autoclaved with the Aseptic System
4. Expansion tank	An expansion tank the size of the bottle will reduce the pressure build up to 2 bar(a) from 1 bar(a). A larger tank will reduce the pressure build-up further.	A somewhat more bulky solution.
5. Plug (blind cap)	If the bottle is only partly filled and some pressure build-up is acceptable plugging the outlet is an option.	Make sure the pressure stays below the max. pressure specified for the bottle. The pressure build up is limited to the actual pressure in the tank or tubing.

## 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 sterilisation in one operation. However if steaming is also carried out after sampling, please note that heat from the steam will cause sugary substances to caramelise 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](http://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 sterilisation is done when the Aseptic System is connected (see chapter 5.4).



#### WARNING

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

### 5.2 Cleaning the Aseptic 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 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 the cap, 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
6. Unscrew the valve head and remove it from the system body
7. Wash the valve head, system body, 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 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
5. Unscrew the valve head and remove it from the system body
6. Wash the valve head, system body, 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, CIPping, 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. Fit the chosen venting component to the Air Outlet (see examples in chapter 4.2)
7. Add any tubing, hoses and other items that must be autoclaved (these items may be placed in Tyvek sterilisable 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 sterilisation**

Steam sterilisation of the flow path takes place with both the sampling valve and the system valve remaining in their closed positions. 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 sterilisation. Allow minimum 2-3 minutes 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

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 sterilisation 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 sterilising with steam, as it would lead steam into the bottle.
- For a System allowed under ATEX for Group IIGD, Category 2 (zone 1) both the handle and the top of valve head (type Q) must be cleaned before use
- Always remember to wear safety goggles when steaming, CIPping, 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 sterilisation dependant on temperature only, demanding a much longer sterilisation 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 a pressure relief valve or a needle 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 sterilisation (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 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, CIPping, 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 be 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), AISI 304 (1.4301), AISI 303L (1.4305)
Membrane:	PTFE (white)
O-ring:	EPDM (FDA, EU1935/2004)
Sealing ring:	Thermoplastic elastomer (TPE)
Screw cap:	Polypropylen (PP)

### 6.2 Certificate

Aseptic system:	3.1*, Ra Cert. incl. measurements***
Membrane:	PTFE acc. to FDA & BGA

\* 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 [www.keofitt.dk](http://www.keofitt.dk)

### 6.3 Pressure (max.)

Inlet:	6 bar / 87 psi
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Normal operation is pressureless, as pressure drop is across the sampling valve and the sample flows predominantly by gravity.

### 6.4 Temperature (max.)

Process:	-20° C - +120° C / -4° F - +248° F **
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\*\* It is important that the steam is saturated, but dry, as condensation can damage the membrane. (Dry steam at max. 1 bar(g)).

### 6.5 Surface treatment

Inner surface:	Electropolished Ra<=0.8µm / 32µinch
Outer surface:	Electropolished Ra<=1.2µm / 47µinch

\*\*\*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](http://www.keofitt.dk)

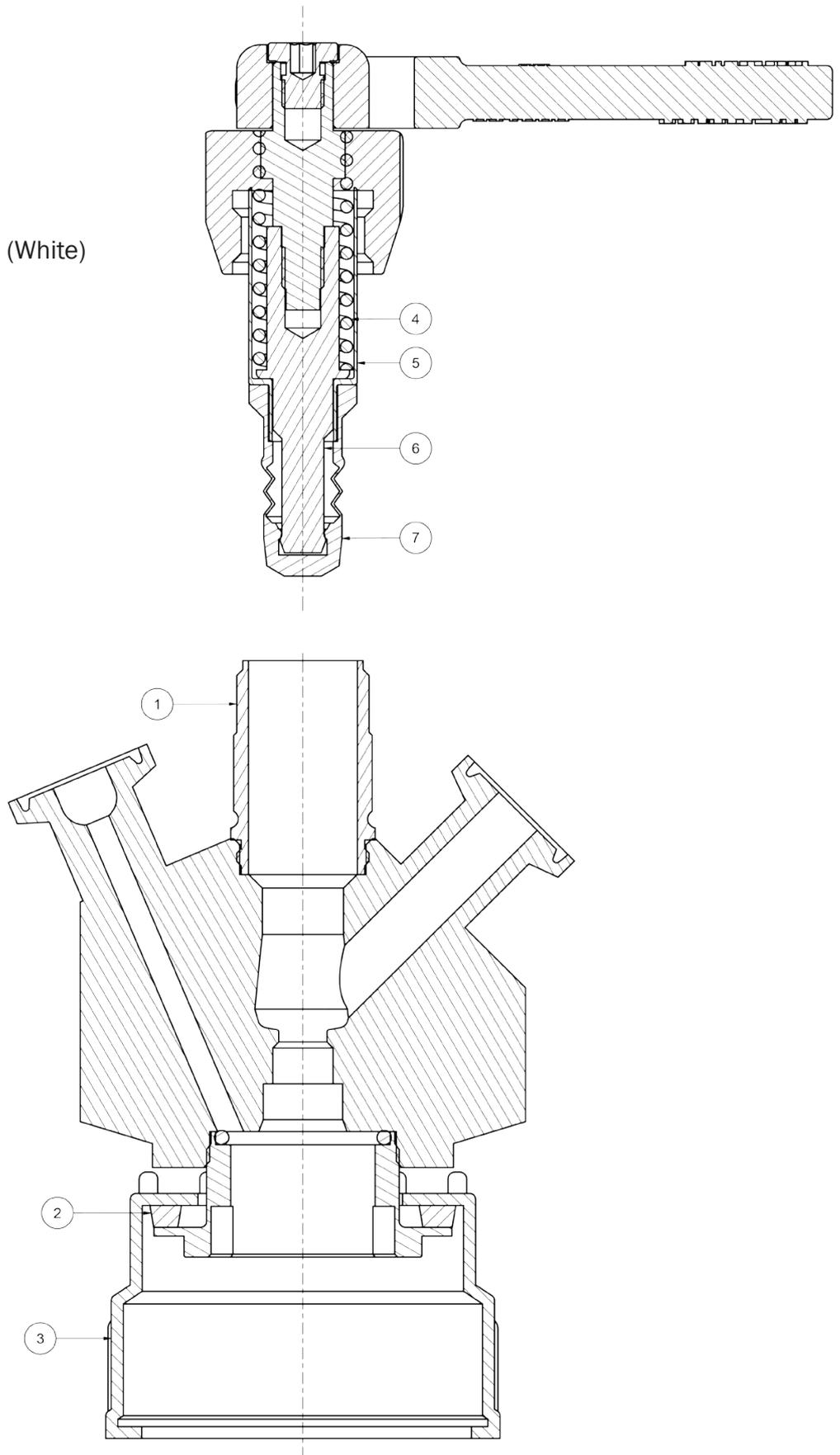
## 7. MAINTENANCE

Keofitt recommends to change the PTFE membrane once a year or earlier as needed. The recommendation is based on 1-5 samples a day.

In the event of intensive sterilisation and cleaning it may be necessary to replace it more frequently.

### 7.1 Spare parts list

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



## 7.2 Keofitt Sampling Bottle Systems

### KEOFITT SAMPLING BOTTLE SYSTEMS

<p>ASEPTIC SAMPLING SYSTEM 260001</p>	 <p>A complex stainless steel aseptic sampling system with a central viewing window, a top-mounted handle, and a side-mounted valve.</p>
<p>SAMPLING BOTTLE HEAD W9 260030</p>	 <p>A compact stainless steel sampling bottle head with a central vertical tube and a side-mounted valve.</p>
<p>SAMPLING BOTTLE HEAD W15 860030</p>	 <p>A stainless steel sampling bottle head with a longer central vertical tube and a side-mounted valve.</p>
<p>SAMPLING BOTTLE HEAD W25 870030</p>	 <p>A stainless steel sampling bottle head with the longest central vertical tube and a side-mounted valve.</p>

SAMPLING BOTTLE SYSTEMS

For further product information - material, dimensions etc. - please refer to the specific datasheet at [www.keofitt.dk](http://www.keofitt.dk)

## 7.3 Keofitt Sampling Bottle Systems - Parts & Accessories

### KEOFITT SAMPLING BOTTLES - PARTS & ACCESSORIES

SAMPLING BOTTLES PARTS & ACCESSORIES			
Bottles	 <p>260325-1 PP BOTTLE 250 ML</p>	 <p>550002 PTFE W/QC 0.5M</p>	 <p>260170 FILLING TUBE 1L</p>
 <p>260525-1 PP BOTTLE 1000 ML</p>	 <p>550002.2 PTFE W/QC/TC 0.5M</p>	 <p>260270 FILLING TUBE 2L</p>	 <p>550003 PTFE W/QC 1.0M</p>
 <p>260625-1 PP BOTTLE 2000 ML</p>	 <p>550004 PTFE W/TC 0.5M</p>	 <p>550005 PTFE W/TC 1.0M</p>	 <p>260326-2 LID PP BOTTLE</p>  <p>900096 ADAPTER W9/TC</p>  <p>800014 ADAPTER TC/1"</p>

For further product information - material, dimensions etc. - please refer to the specific datasheet at [www.keofitt.dk](http://www.keofitt.dk)

## 8. INSTRUCTIONS ON REPLACING PTFE MEMBRANE

To remove an old membrane from the valve head:

1. OPEN the valve (lever 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.

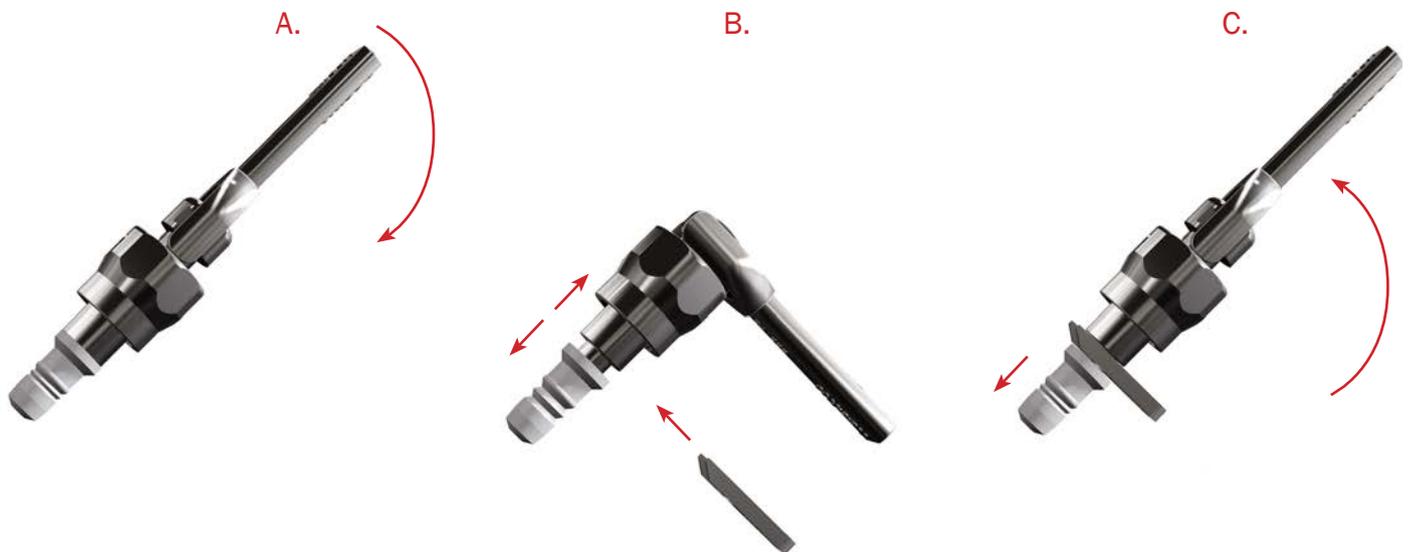
To attach a new membrane to the valve head:

8. Set the valve head to CLOSED position (lever position as in illustration B).
9. Place the new membrane on valve head.
10. Mount the membrane bushing with the new Teflon membrane by pressing the membrane with your hand until it clicks.
11. Set the valve head in OPEN position.
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.



# 9. DATA SHEETS

## 9.1 Valve Head W9 Type Q (PTFE)



### VALVE HEAD W9 TYPE Q PTFE

ART. NO. 855543

#### GENERAL



The KEOFIT CLASSIC W9 Sampling Valve is the original and leading sterilizable sampling valve in the world. Used in all industries for decades. + 320 standard valve configurations. Unique serial no. for each valve ("E" = internal electro polish).



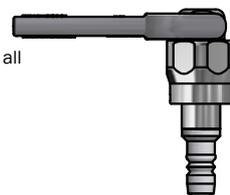
The sampling valve can be used for any process sampling for microbiological, chemical and/or physical analysis.



The valve can be sterilized by means of SIP (EHEDG test) and cleaned by means of CIP (EHEDG certified). Suited for autoclave.



Designed for sampling of liquids with a viscosity of up to approx. 1.000 cP containing no particles larger than Ø3 mm. Sampling of more viscous liquids is possible, only will it take longer (depending on process pressure).



#### FEATURES



Installation: Threaded connection



Operation: Lever handle



Depending on choice of valve body



Membrane: PTFE (TFM 1600 - white)

#### CERTIFICATION\*

· Conforms to 3-A · EHEDG CIP · EU 1935/2004

#### TECHNICAL DATA

##### Material (product contact)

· Membrane PTFE (TFM 1600 - white)

##### Material (without product contact)

· Steel parts AISI 303L (1.4305)  
· Steel parts AISI 316L (1.4404)

##### Membrane

· Article PTFE, WHITE (# 850055)  
· Certification\* FDA · USP · EU 1935/2004

##### Pressure & Temperature

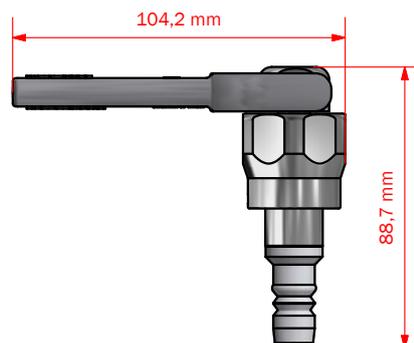
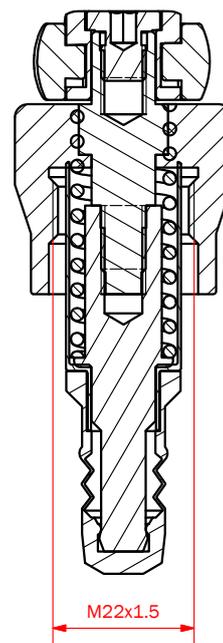
· Pressure 0 - 6 bar (g) / 0 - 87 psi (g)  
· Temperature 1 - 150 °C / 34 - 302 ° F  
· Air supply -

##### Net Weight

· Kg/lbs 0,311 kg / 0,68 lbs

##### Spareparts

778541 PARTS FOR W9 HEAD 855541/42/43/47



\*For further information please visit keofitt.dk

Last updated 04-11-2015

## 9.2 PTFE membrane - art. no. 850055



### MEMBRANE W9/SIMPLEX PTFE

ART. NO. 850055

#### GENERAL



KEOFITT has the widest selection of spare parts and accessories to complete your sampling system



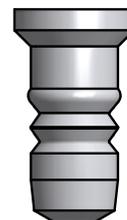
Compatible with all KEOFIT W9 & Simplex valve heads for PTFE membrane



The patented membrane design is an essential part of the hygienic design of the KEOFIT sampling valves



It allows for optimal exposure to CIP and SIP media while also integrating the capacity to remove the membrane from the valve body without the use of tools



#### FEATURES



Compatible with all KEOFIT W9 & Simplex valve heads for PTFE membrane

#### CERTIFICATION\*

FDA · USP · EU 1935/2004

#### TECHNICAL DATA

Material:	PTFE (TFM 1600 - white)
Range of temperature in dry atmospheric air:	-200° - +200 °C / -328° - +392°
Ball hardness (N/mm <sup>2</sup> ):	29
Tensile strength (DIN53455 - N/mm <sup>2</sup> ):	35
Elongation at break (DIN53455 - %):	350
Density (DIN 53479 - g/cm <sup>3</sup> ):	2,17
Shore D (DIN 53505):	57
Thermal conductivity (W/m.k DIN 52612):	0,22
Expansion coefficient (DIN 53752 [K <sup>-1</sup> ]):	12-17x10 <sup>-5</sup>
Flammability:	Inflammable UL 94
Chemical resistance:	Is not attacked by common chemicals with the exception of strongly oxidising acids

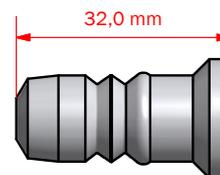
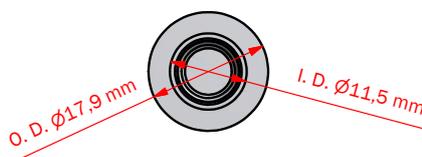
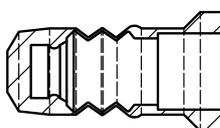
#### SERVICE LIFE

Average service life of a PTFE membrane is 12 months - actual life expectancy must be experimentally determined by the user.

Temp. max.:	1 - 150 °C / 34 - 302 ° F
Steam pressure:	0 - 2 bar (g) / 0 - 29 psi (g)
Process pressure:	0 - 6 bar (g) / 0 - 87 psi (g)
CIP:	NaOH or similar

#### Net Weight

· Kg/lbs	0,004 kg / 0,01 lbs
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Keofitt reserves the right to change technical data without notice!

For complete set of updated data sheets and manuals for Keofitt products please refer to our web page [www.keofitt.dk](http://www.keofitt.dk)



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