KEOFITT®

WORLD LEADERS IN STERILE SAMPLING™

SESAME™ SAMPLING VALVE

User Manual

DOCUMENT VERSION LOG

The table below lists previous versions of this User Manual and states the major changes between versions.

Version #	Version date	Major changes from previous versions
2	November 2016	This is the first version of the SESAME manual

INTRODUCTION:

MANUFACTURER: Keofitt A/S
Kullinggade 31
5700 Svendborg, Denmark

TYPE: SESAME™ SAMPLING VALVE
PATENTS: DK 175721 B1. CN 100501219C.
EP 1. 690 038 B1. US 7,658,201 B2
YEAR OF INTRODUCTION: 2016
MANUAL LAST UPDATED: September 2016

CONTENTS

1. PRESENTATION 7
1.1 Definition of terms 7
1.2 Quick start 9

2. CLEANING – DISINFECTION – STERILISATION 10
2.1 Clean-In-Place (CIP) 10
2.2 Disinfection 10
2.3 Sterilisation 11

3. VALVE FUNCTION 12

4. EVERYDAY USE OF THE VALVE 14
4.1 Pre-production treatment 14
4.2 Chemical cleaning, CIP 14
4.3 Chemical Disinfection 14
4.4 Steam sterilisation 14

5. VALVE OPERATIONS 16
5.1 Chemical CIP 16
5.2 Chemical disinfection 17
5.3 Steam sterilisation 19
5.4 Sampling 21

6. TECHNICAL DATA 22
6.1 Material 22
6.2 Certificate 22
6.3 Pressure (max.) 22
6.4 Temperature 22
6.5 Surface finish 22
6.6 Viscosity: 23
6.7 Flow 23

7. VALVE BODIES 25

8. VALVE HEADS 26

9. PARTS & ACCESSORIES 27

10.MOUNTING INSTRUCTIONS 28
10.1 Location 28
10.2 Before welding 28

11. WELDING INSTRUCTIONS 29
11.1 Welding method 29
11.2 Guideline welding values 29

12. BLOCK DIAGRAMS 30
12.1 Keofitt valve type T (tank) 30
12.2 Keofitt valve type P (pipe) 30
12.3 Keofitt valve type clamp connection 31
12.4 Keofitt valve type Varivent® 31

13. MAINTENANCE 32
13.1 Spare parts list 32
13.2 Disassembly and assembly of valve body and head 33

14. INSTRUCTIONS ON REPLACING THE MEMBRANE 34

15. MEMBRANES 35

1. PRESENTATION

The Keofitt SESAME sampling valve is an enhancement of the renowned classic W9 sampling valve taking representative and uncompromised sampling to new heights.
SESAME is a dual function valve individually controlling both the cleaning (steaming or liquid detergent/ disinfectant) process and the sampling action through a single turn knob. In case of steaming steam supply may be permanently connected and there is no need for a separate steam valve.
From the operator's point of view SESAME offers an easy and failure-proof handling both when cleaning/steaming and for sampling.
As with the W9 valve effective cleaning and disinfection/sterilisation of the sampling valve can be carried out between random samples independently of the course of the production process without compromising the same. The coaxial design and the electro polished valve interior ensure absolute cleanability.
Keofitt valves are used in a wide range of processing industries, such as breweries, dairies, juice/soft drinks and the biotechnological and pharmaceutical 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:

TERM	DEFINITION
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_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 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.

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	4.1 Pre-production treatment	4.2 Chemical cleaning CIP	4.3 Chemical disinfection	4.4 Steaming	5.1 Chemical CIP	5.2 Chemical disinfection	5.3 Steam sterilisation	5.4 Sampling
Cleaning	✔	✔			✔			✔
Disinfection	✔		✔			✔		✔
Sterilisation	✔			✔			✔	✔

2. CLEANING – DISINFECTION – STERILISATION

2.1 Clean-In-Place (CIP)

Thorough cleaning of the valve is a prerequisite for proper disinfection or sterilisation. Cleaning of the valve is the removal of any visible residual product, it be organic or inorganic. It may be done using either steam (continuous steam will eventually lead to sterility; SIP = Sterilise-In-Place) or a suitable liquid detergent.
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 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 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).
The disinfection process may be carried out in one of two ways and to different levels of disinfection depending on a) the initial microbial load distribution, b) the required hygienic level and c) the type, exposure time and concentration of the chemicals used (if using a chemical disinfectant):

- By steaming (in a continued process after steam cleaning)
- By applying one or more suitable liquid chemical disinfectants

There are a number of 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	**Halogenes** (Clorine)	**Peroxides** (hydrogenperoxid & peracetic acid)	**Alcohol** (70%)
Gram-neg **bacteria** Salmonella Campylobacter E. Coli and others...			
Gram-pos **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 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^{-6} means that the probability (or risk) of a single viable microorganism being present on the valve 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 valve 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, 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. VALVE FUNCTION

The valve is designed to regularly take representative samples in the production process. The valve is therefore designed such that effective cleaning, disinfection/sterilisation and sampling can be carried out regularly without interrupting the production process.

> **NOTE!** The membrane has a tripple function: it serves as a dynamic seal towards the process side, it acts as a dynamic seal to activate cleaning/steaming and it constitutes a hygienic static sealing against the valve head.

The table below describes the two fundamentally different ways of preparing the valve for sampling, 1) Chemical cleaning/disinfection and 2) Steaming:

	Method	Description	Pros & Cons
Chemical	**Chemical cleaning**	Liquid detergents are used to clean the valve. CIP = Clean-In-Place	This process is adopted where steam is not available or where the product cannot withstand the exposure to heat. Involves several stages with flushing, cleaning and rinsing between batches.
	Chemical disinfection	A disinfection process using an appropriate chemical liquid disinfectant usually follows the cleaning process. The valve interior is wetted, soaked or flushed with an appropriate disinfectant.	It adds 2 more stages to the CIP: application of disinfectant and final rinse. Involves handling of potentially hazardous chemicals.
Thermal	**Sterilisation**	Steam is supplied for 1 minute just before and immediately after sampling.	Steaming does flushing, cleaning, rinsing and sterilisation in one operation. Steaming is not suitable with heat sensitive products. Steaming entails the risk of burns.

Flushing with water followed by the supply of a chemical detergent through the inlet port, while in “Clean” position, results in cleaning the valve (CIP). It is the perfect, hygienic design and surface finish of the inner part of the valve, which enables easy, efficient and reliable cleaning in a closed state of the valve.
Supplying steam at the steam INLET port and setting the valve at “Clean” results in cleaning and sterilisation. It is the perfect, hygienic design and surface finish of the inner part of the valve, which enables sterilisation in a closed state. According to an EHEDG based test conducted by the Biotechnological Institute in Denmark, the valve is sterile after just 1 minute’s supply of steam at a pressure of 1 bar(g), 121 °C. Steaming is therefore a SIP process (Sterilise-In-Place)

WARNING

- During sterilisation with steam the valve will become hot and care should thus be taken when operating the valve
- The valve is designed for use in working conditions of up to 6 bar(g) pressure and temperatures of up to 121 C. It is therefore important to be aware that the rubber plug (designed for max. 3 bar(g)) or the steel plug (designed for max. 10 bar(g)) may be forced out at high speed, if not seated properly

- When steaming always use dry saturated steam at 1 bar(g). At higher pressure the membrane may be damaged/split
- Always remember to use safety goggles when steaming, CIPping, taking samples and all other operations of the sampling valve

IMPORTANT

- On installations where vacuum will occur, rubber membranes (EPDM, FFKM, Silicone) are at risk of being sucked hard into the valve seat, whereby the valve might not open properly. However attempting to open a sampling valve under vacuum makes no sense, since nothing will flow out, so the incident is rather improbable.
- Rubber membranes will seal perfectly well against vacuum, when the valve is kept closed
- On installations where vacuum will occur, PTFE membranes don't have the risk of being sucked into the valve seat, but as it is a harder and less flexible material a complete tightness against the ambient air may not be secured.
- The membrane is available in 4 different qualities: Silicone, EPDM, PTFE and FFKM
- The Silicone membrane has the advantage that it in general can withstand high temperatures, but it cannot tolerate moisture condensation resulting from steam sterilisation
- The EPDM membrane is better able to cope with the condensation in the steam and at the same time it can be used with a majority of CIP fluids and disinfectants in normal concentrations
- The PTFE membrane resists all CIP fluids and disinfectants except highly oxidising acids in high concentrations
- The FFKM membrane combines the flexible properties of a rubber like EPDM with the outstanding chemical resistance of PTFE in addition to a higher maximum temperature

4. EVERYDAY USE OF THE VALVE

This chapter gives an introduction to how the sampling valve works in different operating conditions. For specific operator instructions please refer to the chapter “VALVE OPERATIONS”.

4.1 Pre-production treatment

Before every new production batch the sampling valve is cleaned and disinfected/sterilised together with the tank or vessel or the entire production line.
Make sure the valve is in its “Sample” position during the initial line CIP to allow cleaning of the valve seat and the membrane contact surface.
Also allow CIP fluid, disinfectant or steam to flow in or out of the outlet hose piece by setting the valve in “Sample” position. Note: If you require the “Clean” port to be CIP’ped perform the CIP also in “Clean” position.
Remember to close the valve after the final rinse and prior to starting up the next production batch.

4.2 Chemical cleaning, CIP

During production and prior to sampling, cleaning takes place with the valve closed and involves the following stages:

1. **Pre-rinse**
   Flushing with water to mechanically remove product residues
2. **Clean**
   Applying a detergent to remove remaining visible product residues
3. **Final rinse**
   Rinse with clean water to remove all traces of detergents

Usually this procedure is followed by disinfection (see below), but for some application CIP might be sufficient. It depends on your (microbiological) requirements, the detergents applied and the process media to clean for. Consult your supplier of CIP fluids.
In some cases where the process media is for instance water, CIP might not even be necessary and you may go directly to disinfection.

4.3 Chemical Disinfection

Disinfection takes place with the valve closed and involves the following stages of which the first 3 are identical to CIP:

1. **Pre-rinse**
   Flushing with water to mechanically remove product residues
2. **Clean**
   Applying a detergent to remove remaining visible product residues
3. **Intermediate rinse**
   Rinse with clean water to remove all traces of detergents
4. **Disinfection**
   Apply an appropriate disinfectant targeting one or more or all microorganisms
5. **Final rinse**
   Rinse with cleaned water to remove all traces of the disinfectant

4.4 Steam sterilisation

Steaming has the advantage that it does flushing, cleaning and sterilisation in one operation. However the 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 you must disconnect any fixed steam supply in order to flush the valve with an appropriate fluid prior to the post-sampling steaming.
If steaming is the preferred procedure, but 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. VALVE OPERATIONS

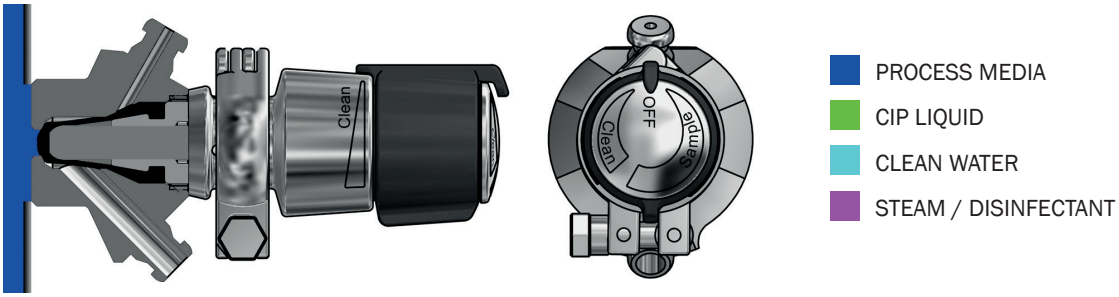
This chapter provides clear instructions on how to operate the sampling valve in different situations. Before sampling the valve must be cleaned followed by disinfection or sterilisation, depending on your requirements.
For the initial cleaning before a new batch please refer to chapter 4.1 Pre-production treatment.

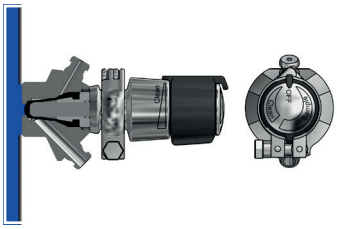
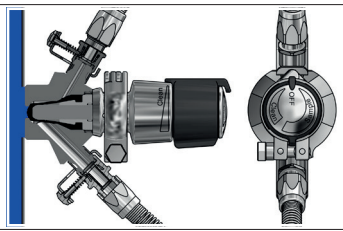
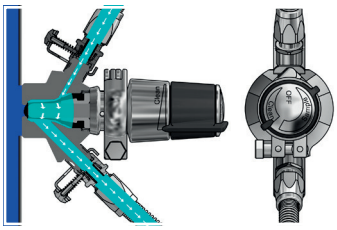
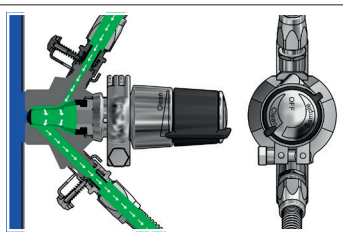
IMPORTANT

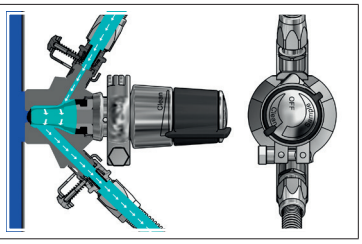
- All illustrations show a sampling valve with Keofitt hose piece connections. All instructions also apply to valve versions with clamp connections; only make sure to use the corresponding fittings.

5.1 Chemical CIP

The CIP takes place with the valve remaining in its closed position.
Perform the following steps:



1.	Remove the plugs, if any, from the INLET and OUTLET ports. In the case of a valve with clamp connections there are no plugs supplied.	
2.	Connect a water hose to the INLET hose piece.	
3.	Connect a hose to the OUTLET hose piece and let the hose go to a drain.	
4.	Flush with clean water by turning the knob towards “Clean”.	
5.	Remove the water hose and let the CIP liquid flow through the upper hose piece. If the CIP liquid must not go to drain, circulate it or collect it in a suitable container and dispose of correctly.	

6.	Reconnect the water hose to the upper hose piece and rinse with clean water by turning the knob towards “Clean”.	

If disinfection is not needed the valve is now ready for taking a sample. If disinfection is required proceed with the steps mentioned in the section “Chemical disinfection” below.
Flush with clean water after sampling. If the process media is sticky, viscous or aggressive or for any other appropriate reason, do repeat the full CIP cycle after sampling.

WARNING

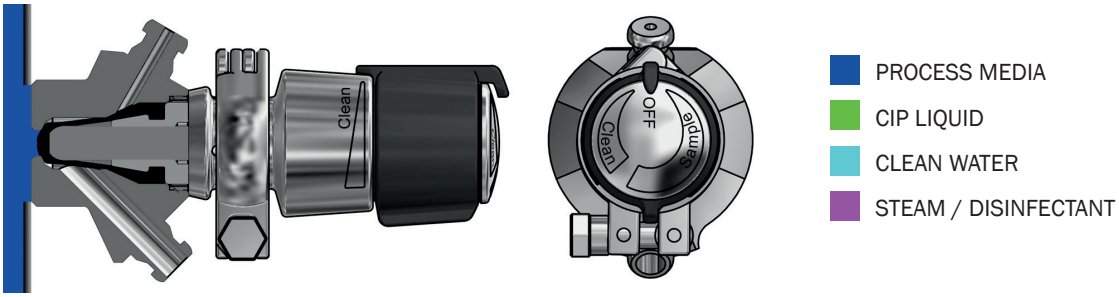
- Carefully follow the guidelines given for the chemicals involved
- Always remember to use safety goggles when steaming, CIPping, taking samples and all other operations of the sampling valve

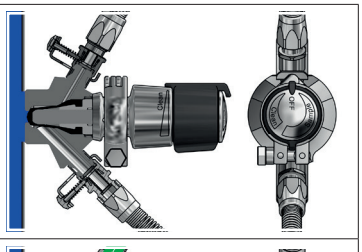
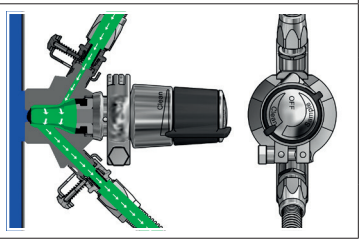
5.2 Chemical disinfection

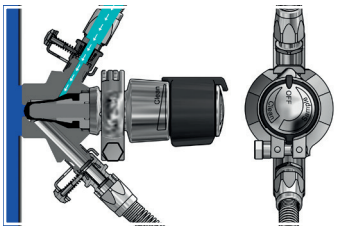
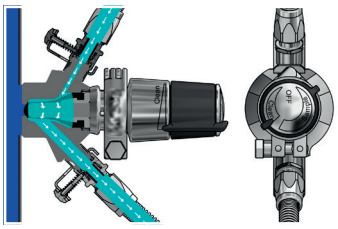
Immediately following the CIP, perform the disinfection, if required. The disinfection takes place with the valve remaining in its closed position.
There are 2 recommended ways to carry out the disinfection:

A) by letting the disinfectant flow through the valve chamber
B) by filling the valve chamber with the disinfectant (advantage: smaller volume of disinfectant needed and quicker and more reliable disinfection)

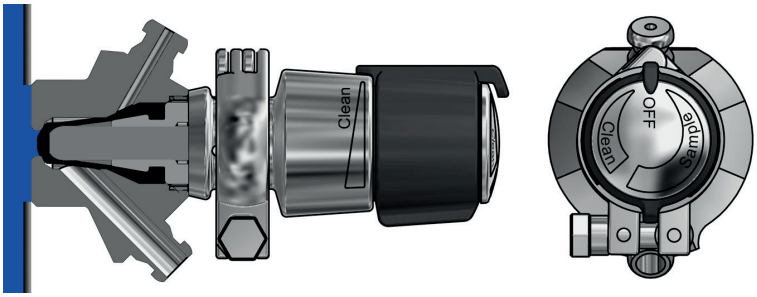
Steps to perform, when adopting A:



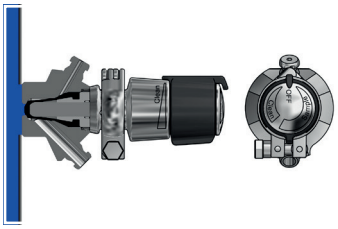
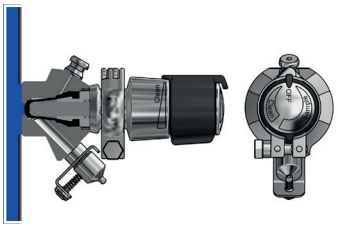
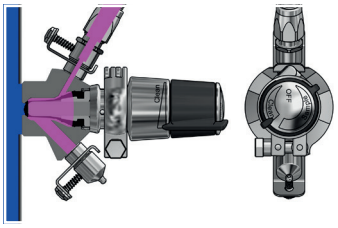
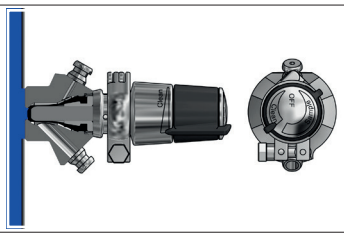
1.	Connect a hose with an empty bottle to the lower hose piece. This bottle or similar recipient is to collect the disinfectant (step 3) and the rinsing water (step 6).	
2.	Fill a flexible bottle with the defined amount of disinfectant.	
3.	Connect the flexible bottle via a hose to the INLET hose piece, turn the valve towards “Clean” and press the disinfectant slowly through the valve to wet the interior of the valve.	
4.	Allow the disinfectant to act for the prescribed time.	

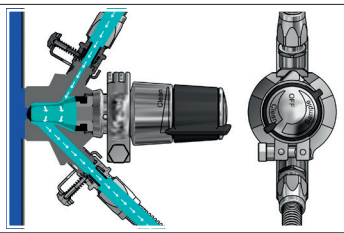
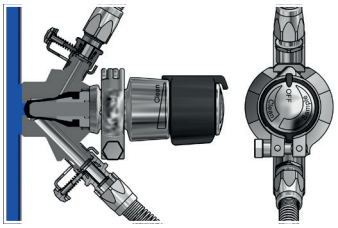
5.	Disconnect the hose from the INLET hose piece and connect a flexible bottle with cleaned water to the INLET hose piece.	
6.	Set the valve in its “Clean” position and rinse through the INLET hose piece by squeezing the bottle, thus pressing the water through the valve chamber.	
7.	Leave the squeezed bottle connected to the INLET hose piece and set the valve in its “Off” position.	

Steps to perform, when adopting B:



PROCESS MEDIA
CIP LIQUID
CLEAN WATER
STEAM / DISINFECTANT

1.	Disconnect any hoses from the INLET and OUTLET.	
2.	Plug the lower hose piece with a rubber plug (or a steel plug). In case of a valve with mini clamp connections the closing of the outlet may be obtained by using a tri clamp blind cap or by squeezing an attached piece of tubing or by any other appropriate means.	
3.	Set the valve in its “Clean” position and fill the valve chamber with the disinfectant through the INLET hose piece. Fill it very slowly to allow air from the valve chamber to escape.	
4.	Leave the valve in its “Clean” position and leave the disinfectant to act for the prescribed time.	
5.	Empty the valve chamber by unplugging the lower hose piece while holding a recipient under the valve allowing the disinfectant to flow out.	

6.	Connect a flexible bottle with cleaned water to the INLET hose piece, set the valve in its “Clean” position and rinse through the upper hose piece.	
7.	Set the valve in its “Off” position and either remove the squeezed bottle or leave in place as an additional protection against the environment.	
8.	Leave the OUTLET open or connect a hose ready to take a sample.	

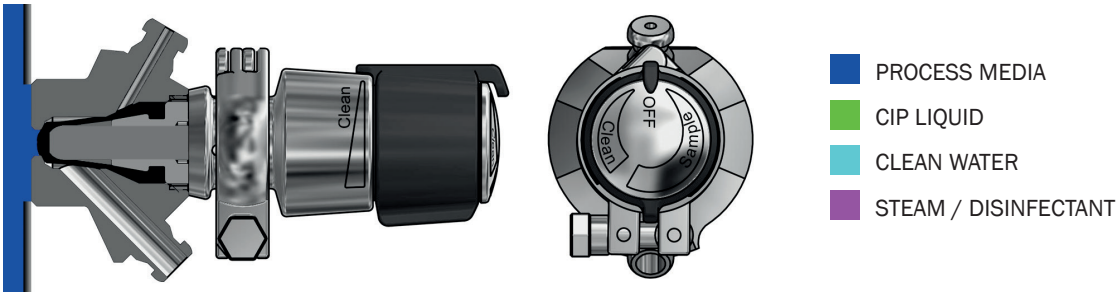
The valve is now ready to take a sample. The sampling must be performed immediately after disinfection to avoid any contamination of the sample.
Flush with water after sampling. If the process media is sticky, viscous or aggressive or for any other appropriate reason, do repeat the full CIP cycle after sampling.

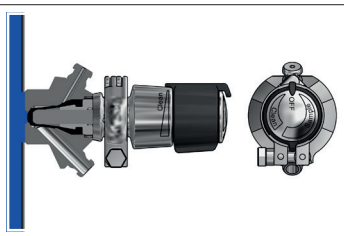
WARNING

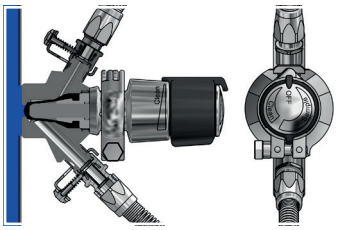
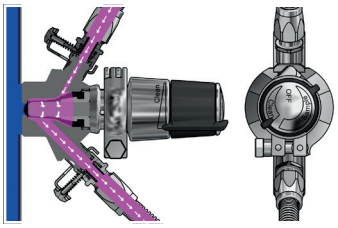
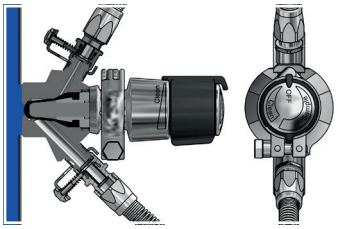
- Carefully follow the guidelines given for the chemicals involved
- Always remember to use safety goggles when steaming, CIPping, taking samples and all other operations of the sampling valve

5.3 Steam sterilisation

Chemical CIP and chemical disinfection are not needed when using steam, as steam does it all. An exception from this is with sugary substances, which caramelise and with substances containing protein, which coagulate and burn; see chapter 2.1. In this case flushing with an appropriate fluid must precede post-sampling steaming.
Steam sterilisation takes place by moving the handle/turn knob from the “Off” to the “Clean” position.
Perform the following steps:



1.	If a permanent steam connection is installed make sure the steam supply is opened. If no permanent steam make sure to connect a steam hose to the INLET.	

2.	Connect a hose to the OUTLET hose piece and let it go to drain. NB: Do not connect a steam trap as it will impede the flow of steam and thus the flushing effect.	
3.	Open the steam supply and let it flow through the valve for sterilisation. Allow 1 minute at 121° C (1 bar(g)).	
4.	Set the valve to “Off”. It is recommended to leave the steam hose in place.	

The valve is now ready to take a sample. The sampling must be performed immediately after steaming to avoid any contamination of the sample.

WARNING

- During sterilisation with steam the valve will become hot and care should thus be taken when operating the valve
- The valve is designed for use in working conditions of up to 6 bar(g) pressure and and process medium temperatures defined by the membranes (see chapter 6 Technical data).
- For valve heads allowed under ATEX for Group IIGD, Category 2 (zone 1) both handle and top of valve heads N and 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

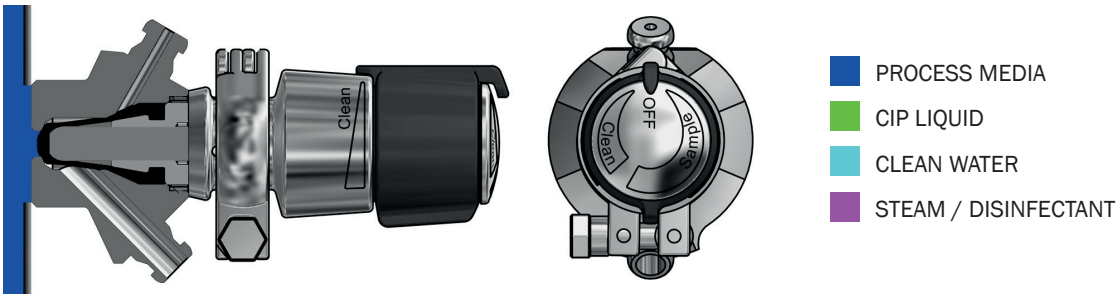
IMPORTANT

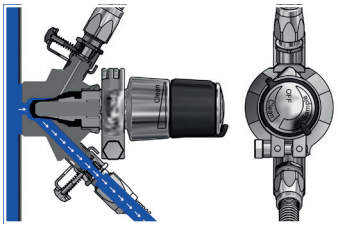
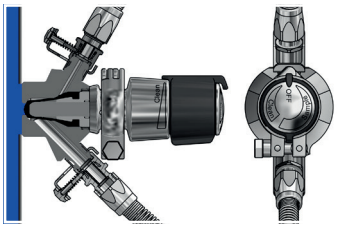
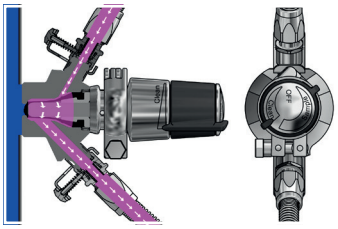
- Don’t attach a steam trap to the hose from the valve steam outlet (lower hose piece) as it will impede the flow of steam and hence the flushing effect, and make the sterilisation dependant on temperature only, demanding a much longer sterilisation time
- If the steam capacity is low and/or the outlet hose from the valve is short 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 outlet
- Leave the steam hose in place to prevent contamination from the ambient during sampling. If removal of steam hose is required, fit a sterile rubber or stainless steel plug onto the upper hose piece

5.4 Sampling

Prepare a recipient for your sample.
For aseptic sampling use steam and a Keofitt Aseptic Sampling Bag (available in different sizes; please see datasheet on www.keofitt.dk). Leave the steam hose in place to prevent contamination from the ambient during sampling.
For all other sampling use a Keofitt Sterile Sampling Bag or a Spike Bag, which provides a closed flow path for your sample protecting it from the ambient. Alternatives are bottles with a screw cap, jars or any other available container.

Take the sample immediately after cleaning/disinfection/sterilisation performing the following steps:



1.	Open the valve by slowly turning the turnknob or the handle clockwise towards “Sample”.	
2.	When required sample volume has been reaches set the turnknob or handle back in its “Off” position to close the valve.	
3.	Perform a post-sample cleaning by flushing the valve with steam, detergent or water (whatever is required by the process medium). Connect a hose to the outlet port in order to lead the steam/ detergent/water to the drain. Turn the turnknob (or the handle) anti-clockwise towards “Clean” and flush for a sufficient time to clean the valve chamber of any sample residues (usually 10 to 30 seconds). The procedure is the same for the type N head (pneumatic), only control the valve by means of the pneumatic cylinders.	

If the process media is sticky, viscous or aggressive or for any other appropriate reason, do repeat a full CIP cycle after sampling in case steam is not available and flushing with water prove insufficient.

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 valve slowly. Special care must be taken with pneumatically operated valves, as they open abruptly
- Always remember to wear safety goggles when steaming, CIPping, taking samples or any other operations of the sampling valve

6. TECHNICAL DATA

6.1 Material

Valve body:	AISI 316L (1.4404 or 1.4435 depending on version. Please refer to corresponding datasheet)
Valve head:	AISI 316L (1.4404)
Membrane:	Silicone (grey) EPDM (black) PTFE (white) FFKM (white)

6.2 Certificate

Valve body:	3.1
Membrane:	Silicone acc. to FDA & BGA EPDM acc. to FDA & BGA 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 the Keofitt Online Service Center on www.keofitt.dk. Click Certificates and then 3.1.

6.3 Pressure (max.)

Process pressure:	10 bar(g) / 145 psi(g)
CIP/SIP:	6 bar(g) / 87 psi(g)
Rubber plug:	3 bar(g) / 44 psi(g)
Steel plug:	15 bar(g) / 218 psi(g)

6.4 Temperature

Steam: Sterilisation 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:

- Silicone: -60 C to 200 C
- EPDM: -40 C to 140 C
- PTFE: -200 C to 200 C
- FFKM: -20 C to 270 C

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

6.5 Surface finish

Internal: Electropolished
Ra<=0.5µm / 20µinch
Ra(mean) = 0.2µm / 8µinch
Ra(std.deviation) = 0.08µm / 3µinch
Valves with internal electropolishing are identified by an E preceding the serial number e.g. E12345678

External: Electropolished
The surface roughness is measured for each valve at 4 critical places.

A serial number identifies each valve body. A specific surface roughness certificate is supplied with every valve. A general surface finish certificate copy is available on www.keofitt.dk

6.6 Viscosity:

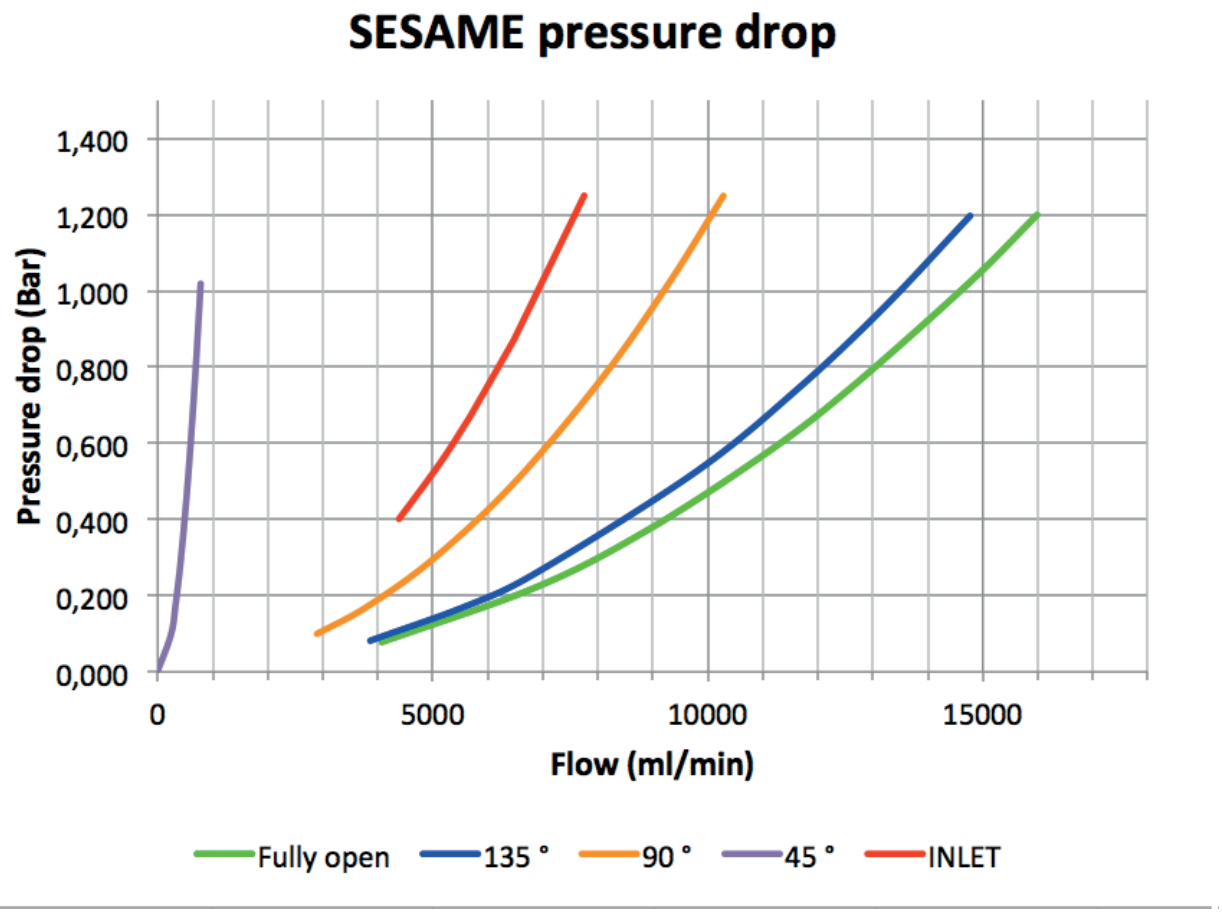
Viscosity range: 0-1000cP, with particles up to 3mm in diameter.
Higher viscosity liquids may be sampled, only will the sampling take longer.

6.7 Flow

The graphs below illustrate (for water at 20°C/68°F) the following:

- Pressure drop across valve as a function of the flow for different positions of the turn knob
- Pressure drop for flow between the INLET and the OUTLET ports

Based on the tank pressure and the requested sample flow the graphs may be used to get an indication of to which degree the valve must be opened.



The generally accepted sampling time is around 10 sec. for small samples and around 30 sec. for larger samples. As usual sample sizes are between 100 ml and 1000 ml the needed flow lies from 600 to 2000 ml/min.
As the pressure on the sample side usually is 0 bar(g) the pressure drop across the valve equals the process pressure (tank pressure or line pressure).

The volume flow through a valve is given by:

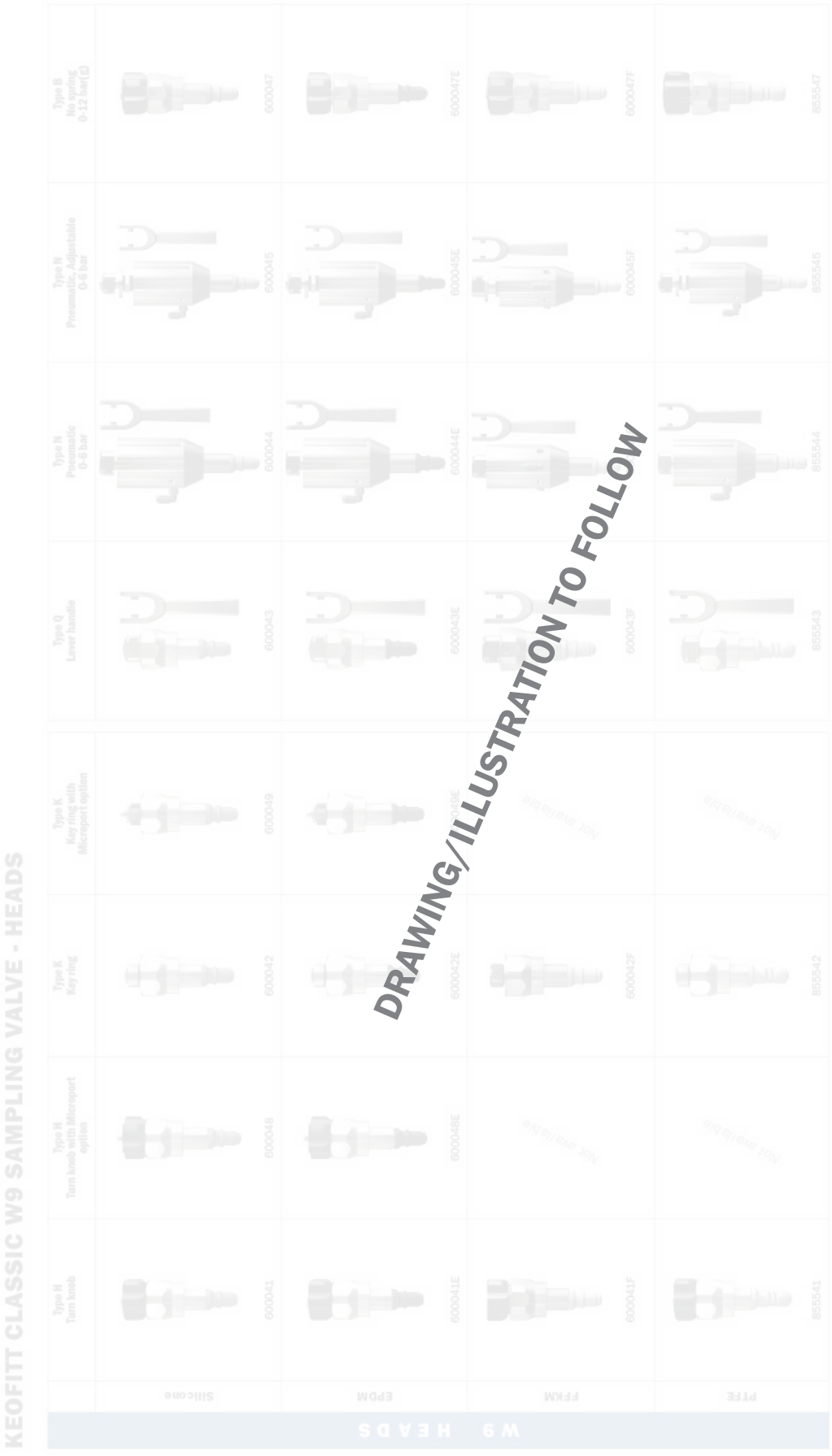
$$k_v = Q\sqrt{\frac{\rho}{1000 \times \Delta p}}$$

Symbol	Unit	Description
k_v	m^3/h	Flow in m^3/h through a valve at a pressure drop of 1 bar as defined in VDE/ VDI norm 2173.
Q	m^3/h	Volume flow through the valve
ρ	kg/dm^3	Density of the fluid. For Water it is 1.
Δp	bar	Pressure drop across valve. As the gauge pressure at the valve outlet usually is 0 bar(g) the pressure drop is often equal to the gauge pressure at the input (the process side)

7. VALVE BODIES

For further product information - material, dimensions etc. - please refer to the specific datasheet at www.keofitt.dk

8. VALVE HEADS



DRAWING/ILLUSTRATION TO FOLLOW

For further product information - material, dimensions etc. - please refer to the specific datasheet at www.keofitt.dk

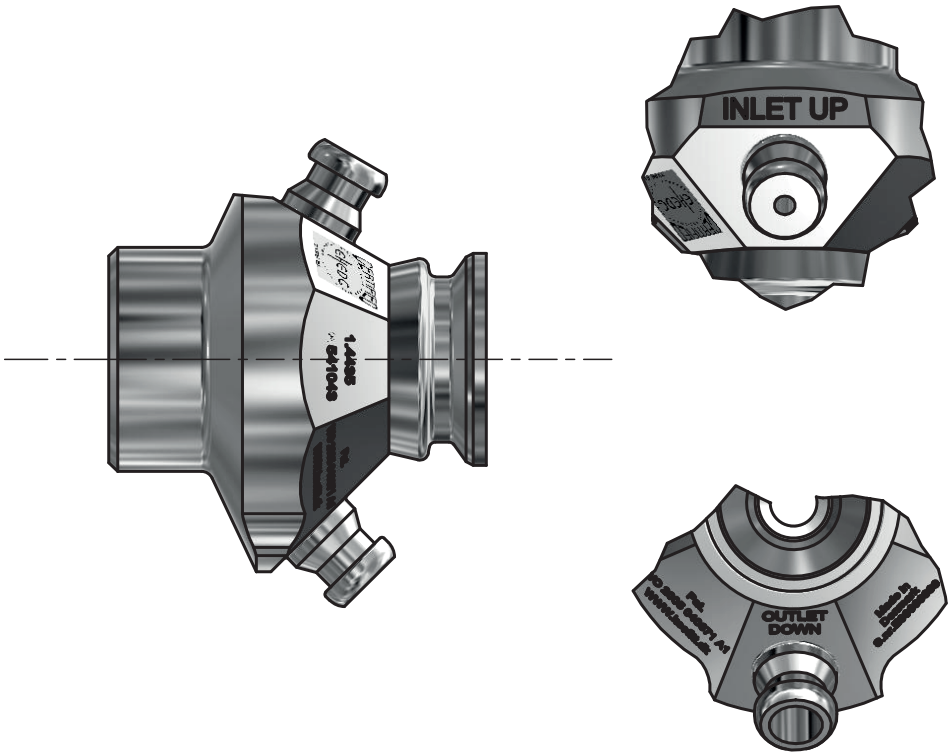
9. PARTS & ACCESSORIES

For further product information - material, dimensions etc. - please refer to the specific datasheet at www.keofitt.dk

10.MOUNTING INSTRUCTIONS

10.1 Location

The valve should always be located with its centre line in a horizontal position and with the two hose pieces in a vertical position with the sample port “OUTLET DOWN” pointing downwards and the inlet port “INLET UP” pointing upwards.



10.2 Before welding

Remember to disassemble the valve body and head. The valve body and head must be separated during welding. All plugs and other attachments must be removed from the valve body, as otherwise heat from the welding process will damage them.

11. WELDING INSTRUCTIONS

Valves for welding are available in two types: T (tank) and P (pipe).

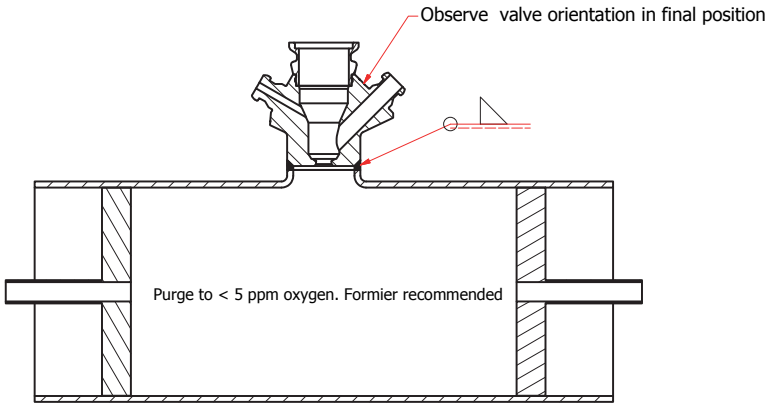
1. For type T (tank) it is necessary to drill a hole ø38 mm into the tank wall, and then fit the valve into this hole flush with the inside of the tank. Welding should be carried out as a penetration welding.
   Material thickness less than 4 mm: Weld from inside. Material thickness greater than 4 mm: Weld from both outside and inside.
   Since type T has a solid end piece, the valve will not be damaged by penetration welding. However, the use of purge gas in the form of either Argon or Formier gas is recommended in order to give the best result.
2. For type P (pipe) penetration welding must be carried out from outside. The valve is machined with a recess-like shoulder on the outside of the end piece which gives approximately the same material thickness (1.5mm material thickness) as in the pipe wall. This machined shoulder can be modified according to the customer's wishes.

IMPORTANT!

- When grinding/polishing the internal weld, the valve seat must not be touched.

11.1 Welding method

The welding result will be best if the following method is used:
A collar is made on the pipe section so that the valve has a flat contact face. This flaring must look like a T-piece, as shown in the example below.



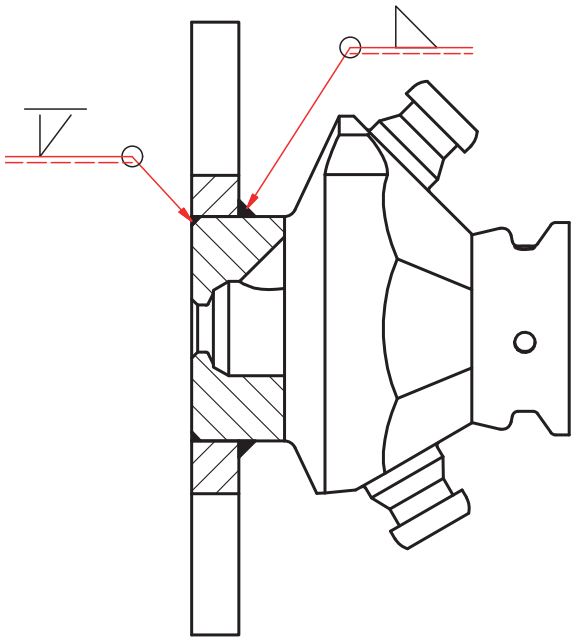
- The pipe section and the valve's hose pieces are sealed with sponge rubber or similar.
- Purge gas such as Argon or Formier gas is fed through the valve body into the pipe section and the system is now filled with 6 times the estimated volume of the pipe section. All O_2 is thus expelled from the system and welding can commence.
- Welding must take place only with the purge gas continually flowing in the system.
- The gas remains in the system until the item is lukewarm, after which the set-up can be dismantled.

11.2 Guideline welding values

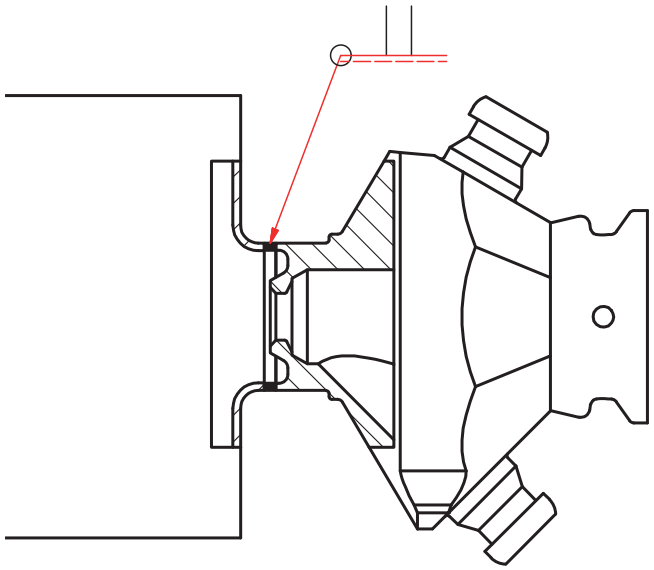
W9™ valve welded onto a 2 mm 3" dairy pipe: 50-60 Amp.
It should be noted that Keofitt can supply all P type valves welded onto a pipe section according to customer specifications. Flaring is thus avoided and only a girth weld is required.

12. BLOCK DIAGRAMS

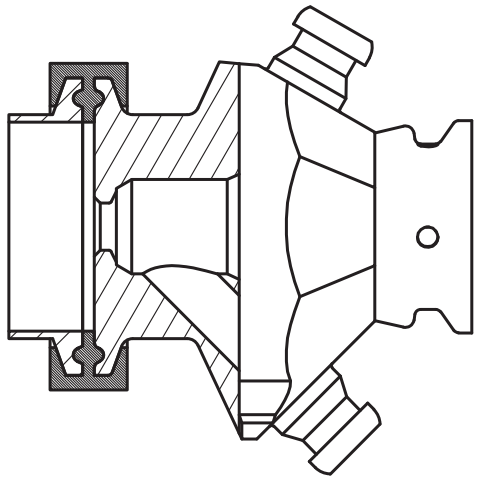
12.1 Keofitt valve type T (tank)



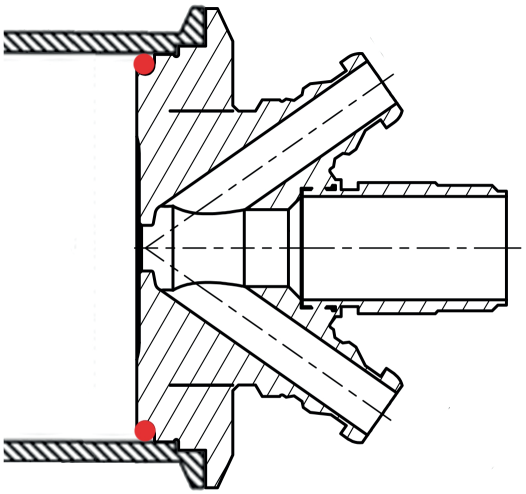
12.2 Keofitt valve type P (pipe)



12.3 Keofitt valve type clamp connection

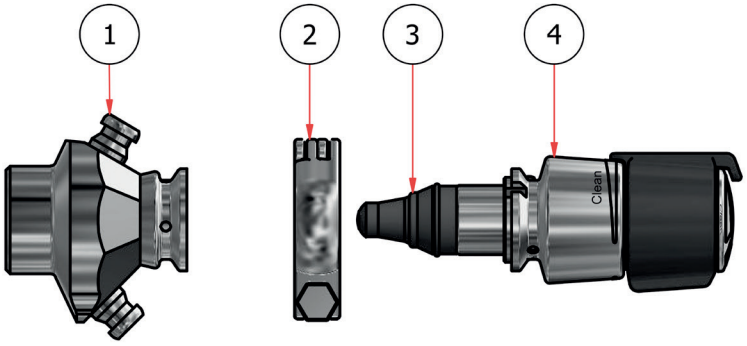


12.4 Keofitt valve type Varivent®

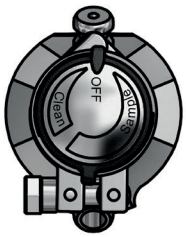


13. MAINTENANCE

The rubber membrane should be replaced every other month. PTFE and FFKM membranes should be replaced every 12 months. In the event of intensive sterilisation and 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 intil 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.
In each individual case a standard operating procedure including maintance intervals should be endorsed based on experience. For disassembly of valve body and valve head, see instructions.



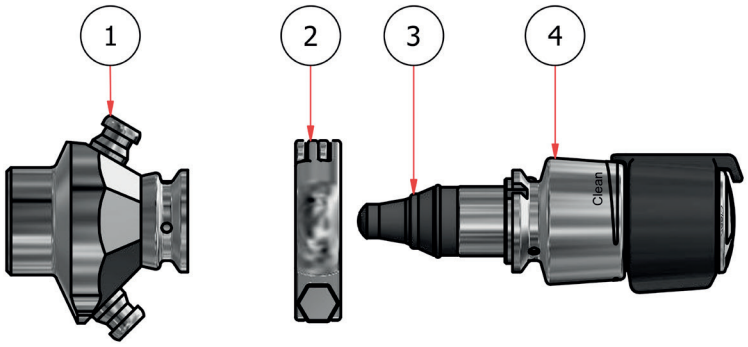
Turn to Clean before disassembly or assembly



13.1 Spare parts list

1. Valve body
2. Clamp
3. Membrane
4. Valve head

13.2 Disassembly and assembly of valve body and head



Turn to Clean before disassembly or assembly

In order to dissassemble and assemble the valve body and valve head please perform the following operations:

Disassembly (type H, Q and N):

1. Make sure any steam or detergent/disinfectant supply is shut off
2. Make sure the valve is in its “Clean” position
3. Loosen and remove the clamp
4. Pull the head out (avoid turning it)

Assembly (Type H, Q and N)

1. Set the valve in its “Clean” position
2. Fit the valve head on to the valve body (any orientation is possible, but usually with “Off” pointing at “INLET UP” on the valve body.
3. Mount the clamp and tighten it using a small spanner (don’t apply excessive force, but make sure the flanges come in full mechanical contact).
4. Reestablish steam or detergent/disinfectant supply

WARNING!

- When replacing the membrane, set the valve head in the OPEN position before it is unscrewed and pulled out of the valve body. Omitting to do so may result in twisting and cutting of the membrane.
- Don’t clean the valve head in an ultrasonic bath or by immersing it in a degreasing liquid, as it will impede the proper functioning of the screw action. When in doubt, contact your local Keofitt dealer
-

14. INSTRUCTIONS ON REPLACING THE MEMBRANE

To remove an old membrane from the valve head:

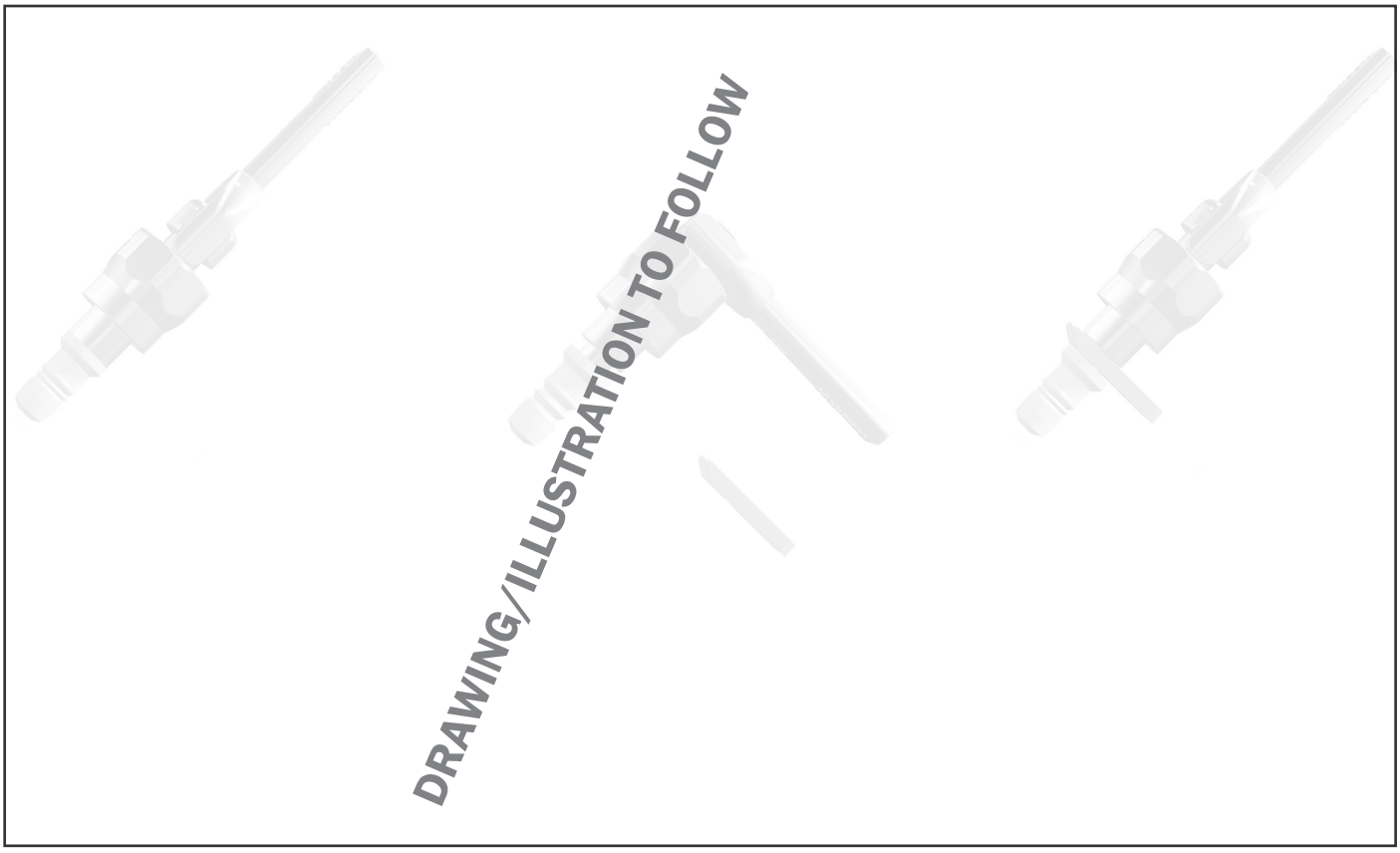
1. Detach the valve head from the valve body as described in chapter 13.2.
2. Set the valve head in its “Sample” position (illustration A)
3. Insert tool (illustration B) for membrane, between the membrane and the steel shoulder (illustration C).
4. Wriggle the tool up and down until the membrane detaches (illustration D).
5. Now the membrane may be removed.

To attach a new membrane to the valve head:

6. Set the valve head to “Off” position.
7. Place the new membrane on valve head and press the new membrane against the steel shoulder in order to allow the membrane to lock into the groove.
8. For PTFE membranes: Press the tip of the membrane hard against a table or similar until it clicks indicating the membrane locking into the valve stem.
   For rubber membranes:
   If necessary push the tip of the membrane sideways until it sits perfectly co-axial with the valve head.
9. Set the valve head in its “Clean” position.
10. Insert the valve head into the valve body and mount the clamp as described in chapter 13.2.
11. Set the valve in its “OFF” position.

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.



15. MEMBRANES

15.1 Silicone membrane - art. no. XXXXXX

KEOFITT
WORLD LEADERS IN STERILE SAMPLING®

10 PC MEMBRANE W9/SIMPLEX SILICONE, GREY

ART. NO. 600051

GENERAL

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

Compatible with all KEOFITT W9 & Simplex valve heads for silicone, EPDM & FFKM membrane

The patented membrane design is an essential part of the hygienic design of the KEOFITT 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 KEOFITT W9 & Simplex valve heads for silicone, EPDM & FFKM membrane

CERTIFICATION*

FDA - USP - EU 1935/2004

TECHNICAL DATA

Type:	Silicone (QBF grey)
Hardness (°Sha):	70 ±3
Tensile strength (MPa):	Min. 8,5
Elongation at break (%):	550 ±80
Density (g/cm3):	1,19 ±0,02
Range of temperature in dry atmospheric air (°C/°F):	-60° - +175°C / -140° - +392°
Compression set, DIN 53517, 24h/175°C (%):	Max. 25
Wear resistance:	Less suitable
Tear resistance:	Very good
Resistance to Weather and Ozone:	Excellent
Resistance to Hydrolysis (water and steam):	Suitable
Resistance to Chemicals (acids/bases):	Suitable
Resistance to mineral oil and gas:	Less suitable
Impermeability to air and gasses:	Not suitable

DRAWING/ILLUSTRATION TO FOLLOW

SERVICE LIFE

Average service life of a Silicone membrane is 2-3 months - actual life expectancy must be experimentally determined by the user.

Temp. max.:	121°C / 250°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
Samples:	1-5 a day

Net Weight

· Kg/lbs	0,030 kg /0,06 lbs

*For further information please visit keofitt.dk

Last updated 18-04-2016

15.2 EPDM MEMBRANE - ART. NO. XXXXXX

KEOFITT
WORLD LEADERS IN STERILE SAMPLING™

10 PC MEMBRANE W9/SIMPLEX EPDM BLACK

ART. NO. 600052

GENERAL

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

Compatible with all KEOFITT W9 & Simplex valve heads for silicone, EPDM & FFKM membrane

The patented membrane design is an essential part of the hygienic design of the KEOFITT 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 KEOFITT W9 & Simplex valve heads for silicone, EPDM & FFKM membrane

CERTIFICATION*

FDA - USP - EU 1935/2004

TECHNICAL DATA

Type:	EPDM (EPL-60 [illegible])
Hardness (°Sha):	61 ±3
Tensile strength (MPa):	Min. 16
Elongation at break (%):	400 ±50
Density (g/cm3):	1,12 ±0,01
Range of temperature in dry atmospheric air (°C/°F):	-40° - +1[illegible] / -40° - +284° F
Compression set, DIN 53517, 24h/175°C (%):	Max. 16
Wear resistance:	Very g[illegible]
Tear resistance:	Very [illegible]
Resistance to Weather and Ozone:	Exc[illegible]
Resistance to Hydrolysis (water and steam):	Excellent
Resistance to Chemicals (acids/bases):	V[illegible]od
Resistance to mineral oil and gas:	N[illegible]uitable
Impermeability to air and gasses:	[illegible] suitable

DRAWING/ILLUSTRATION TO FOLLOW

SERVICE LIFE

Average service life of an EPDM membrane is 2-[illegible]nths - actual life expectancy must be experimentally determined by the user.

Temp. max.:	121°C / 250°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
Samples:	1-5 a day

Net Weight

- Kg/lbs	0,040 kg /0,09 lbs

*For further information please visit keofitt.dk

Last updated 18-04-2016

15.3 FFKM membrane - art. no. XXXXXX

KEOFITT
WORLD LEADERS IN STERILE SAMPLING™

MEMBRANE W9 & SIMPLEX FFKM, WHITE

ART. NO. 600053

GENERAL

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

Compatible with all KEOFITT W9 & Simplex valve heads for silicone, EPDM & FFKM membrane

The patented membrane design is an essential part of the hygienic design of the KEOFITT 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 KEOFITT W9 & Simplex valve heads for silicone, EPDM & FFKM membrane

CERTIFICATION*

FDA - USP - EU 1935/2004

TECHNICAL DATA

Type:	FFKM (Perfluo mer)
Hardness (°Sha):	70 ±5
Tensile strength (MPa):	13
Elongation at break (%):	130
Density (g/cm3):	2,41
Range of temperature in dry atmospheric air (°C/°F):	1° - +27 / 34° - 518°F
Compression set, D395 70h/200°C (%):	24
Wear resistance:	Excell
Tear resistance:	Exce
Resistance to Weather and Ozone:	Ex
Resistance to Hydrolysis (water and steam):	Excellent
Resistance to Chemicals (acids/bases):	E ent
Resistance to mineral oil and gas:	llent
Impermeability to air and gasses:	llent

DRAWING/ILLUSTRATION TO FOLLOW

SERVICE LIFE

Average service life of a FFKM membrane is 12 ths (or more) - actual life expectancy must be experimentally determined by the user.

Temp. max.:	250° C / 482° 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
Samples:	1-5 a day

Net Weight

- Kg/lbs	0,004 kg /0,009 lbs

*For further information please visit keofitt.dk

Last updated 18-04-2016

15.4 PTFE membrane - art. no. XXXXXX

KEOFITT
WORLD LEADERS IN STERILE SAMPLING™

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 KEOFITT W9 & Simplex valve heads for PTFE membrane
- The patented membrane design is an essential part of the hygienic design of the KEOFITT 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 KEOFITT 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° / -328° - +392°
Ball hardness (N/mm2):	29
Tensile strength (DIN53455 - N/mm2):	35
Elongation at break (DIN53455 - %):	350
Density (DIN 53479 - g/cm3):	2,17
Shore D (DIN 53505):	57
Thermal conductivity (W/m.k DIN 52612):	0,22
Expansion coefficient (DIN 53752 [K^-1]):	12-13 x 10^-5
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

32,0 mm
O. D. Ø17,9 mm
I. D. Ø11,5 mm

*For further information please visit keofitt.dk

Last updated 19-12-2014

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

KEOFITT®
WORLD LEADERS IN STERILE SAMPLING™

KEOFITT A/S
Kullinggade 31
DK-5700 Svendborg
Denmark

Phone +45 6316 7080
Fax +45 6316 7081

info@keofitt.dk
www.keofitt.dk