

KEOFITT SAMPLING BAG™

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 April 2022.

Version	Version Date	Major changes from previous versions
1	April 2022	First version of the KEOFITT Sampling Bag™ manual

INTRODUCTION

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TYPE:	KEOFITT SAMPLING BAG™
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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.

CONTENTS

1. PRESENTATION	8
1.1 Definition of terms	8
2. DESIGN AND FUNCTIONING	10
2.1 KEOFITT Sampling Bag™ configuration	10
2.1.1 Inlet and Outlet	11
2.1.2 Handle (carrying and hanging)	12
2.1.3 Retrieval of the sample	12
2.1.4 Label	13
2.1.5 Disposal	13
3. CLEANING - DISINFECTION - STERILIZATION	14
3.1 Clean-In-Place (CIP)	14
3.2 Disinfection	14
3.3 Sterilization-In-Place (SIP)	15
4. ACCESSORIES	16
4.1 Fittings for connecting KEOFITT Sampling Bag™ to the sampling valve	16
4.2 Fittings for closing off the outlet of the KEOFITT Sampling Bag™	17
4.2.1 Quick Coupling KSB Outlet Non-Return Valve (QC KSB Outlet NRV)	19
4.2.2 Quick Coupling KSB Outlet 3/8" Hose barb (QC KSB Outlet Hose barb)	19
4.2.3 Quick Coupling KSB Outlet Stainless steel plug	19
5. HOW TO SAMPLE	21
5.1 Connecting the KEOFITT Sampling Bag™ to the sampling valve	21
5.2 Preparing the sample flow path for sampling	21
5.2.1 Cleaning	22
5.2.2 Disinfection	22
5.2.3 Steam sterilization	22
5.3 Sampling	23
5.3.1 Before sampling operation	23
5.3.2 Sampling operation	24
5.3.3 After sampling operation	25
5.4 Storage of the sample	25
5.4.1 Securing sample integrity	25
5.5 Retrieving the sample	25
5.5.1 Retrieval through cut	26
5.5.2 Retrieval through inlet or outlet	26

1. PRESENTATION

This manual describes the KEOFITT Sampling Bag™ and how to use it for sampling. The KEOFITT Sampling Bag™ is designed for sampling liquids including liquids with high viscosity and liquids containing particles.

The unique design makes it possible to hygienically withdraw a sample from the production process as the KEOFITT Sampling Bag™ can be steam sterilized along with the KEOFITT sampling valve to create a sterile sample flow path. The KEOFITT Sampling Bag™ can be connected to all KEOFITT sampling valves by using stainless steel fittings.

KEOFITT Sampling Bag™ is a single-use bag.

1.1 Definition of terms

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
Aseptic sampling	The process of withdrawing a sample from the production equipment through a closed circuit, which has been sterilized and kept sterile with no exposure to the surroundings during the sampling process
Bacterial spore	Bacterial spores are the “survival” form of certain bacterial genera. They are highly resistant to disinfectants and sterilants. At favorable conditions they can re-emerge as live bacteria
Bioburden	See Microbial load
Chemical sterilant	A few disinfectants will kill spores with prolonged exposure times (3–12 hours); these are called chemical sterilants
CIP	Abbreviation for 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 an enzymatic cleaner and water, of adherent visible soil on a surface
Disinfectant	Usually, a chemical agent that destroys harmful microorganisms but might not kill bacterial spores
Disinfection	Thermal or chemical destruction of microorganisms. Disinfection is less lethal than sterilization, because it destroys most recognized microorganisms but not necessarily all microbial forms (e.g., bacterial spores)
Detergent	A cleaning agent that has no antimicrobial effect, but in diluted solutions good cleaning properties
Flow path	The path the sample flows from the process equipment to the sample recipient
KSB	Abbreviation for KEOFITT Sampling Bag™
Microbial load	The number and types of viable microorganisms with which an item is contaminated; also called bioburden. Often expressed as colony forming units (CFU)
Microorganisms	Animals or plants of microscopic size. As used in food and pharmaceutical industries it generally refers to bacteria, fungi, viruses, and bacterial spores
NRV	Abbreviation for Non-Return Valve. A valve which allows medium to flow in only one direction

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 ₂ O)
Process media	The product in the process equipment and the product from which a sample is taken
QC	Abbreviation for Quick Coupling. Classic KEOFITT coupling used to fit different devices to KEOFITT hose piece connections
QC KSB	Abbreviation for Quick Coupling KEOFITT Sampling Bag™. The quick couplings are specifically made for the inlet and outlet of the KEOFITT Sampling Bag™
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 during transportation to the laboratory
Sample flow path	The entire path the sample will flow from it leaves the production process until it enters the KEOFITT Sampling Bag™
SIP	Abbreviation for Sterilize-In-Place. The process of rendering a process component (like a sampling valve) sterile without removing it from the production line
Steaming	The process of using saturated steam under pressure as the sterilizing agent
Sterile	State of being free from all living microorganisms. In practice, usually described as a probability function, e.g., as the probability of any microorganism surviving sterilization being one in one million
Sterilant	A few disinfectants will kill spores with prolonged exposure times (3–12 hours); these are called chemical sterilants
Sterilization	Validated process used to render an item free of all forms of viable microorganisms. In a sterilization process, the presence of 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
SAL	Abbreviation for Sterility Assurance Level. The probability of a viable microorganism being present on an item after sterilization. Usually expressed as 10 ⁻ⁿ . A SAL of 10 ⁻⁶ means less than or equal to one chance in a million that a single viable cell is present on an 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

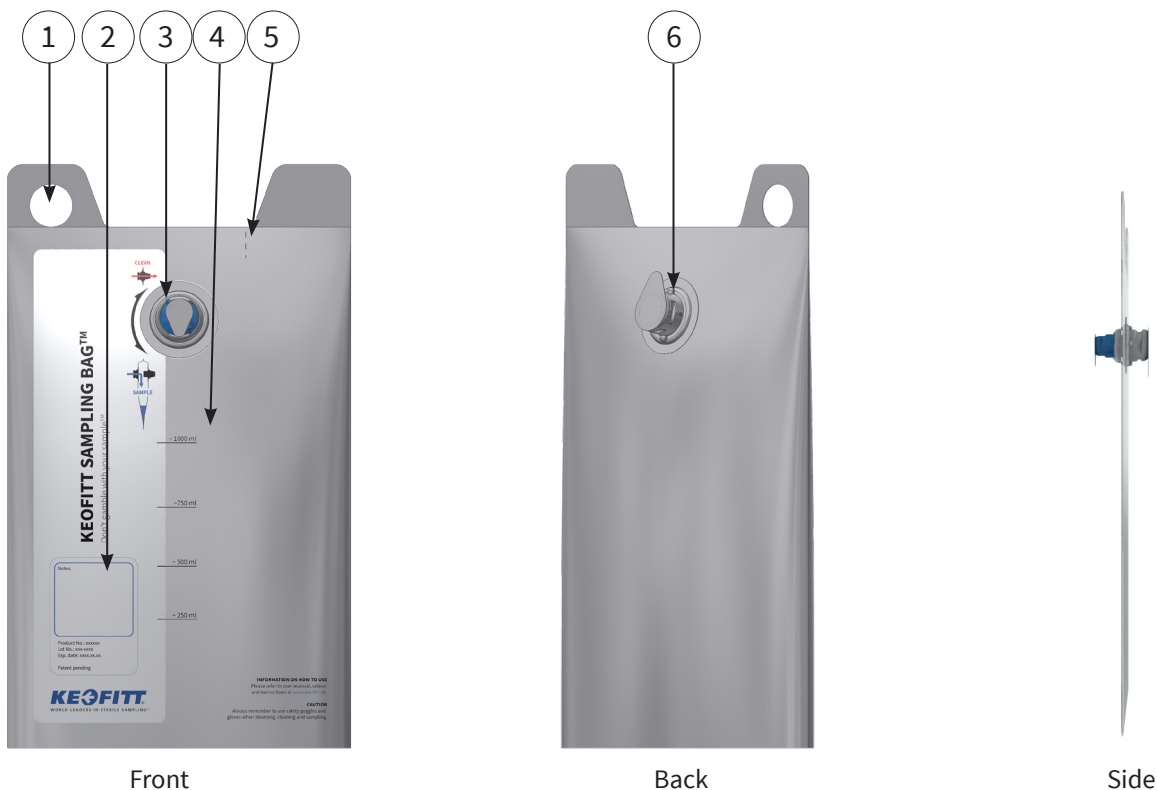
2. DESIGN AND FUNCTIONING

KEOFITT Sampling Bag™ is designed to collect hygienic and representative samples from a production process. By integrating the sample flow path in the design of the KEOFITT Sampling Bag™, the sample can hygienically be transferred from the sampling valve to the KEOFITT Sampling Bag™, without compromising the sample integrity. The inlet and outlet parts of the KEOFITT Sampling Bag™ have multiple functions, as they both serve as a tunnel bypassing the KEOFITT Sampling Bag™ when they are in the sealed **CLEAN** position and serve as normal inlet and outlet for the KEOFITT Sampling Bag™ when they are in **SAMPLE** position.

The inlet of the KEOFITT Sampling Bag™ is connected to the KEOFITT sampling valve and operated by turning the wing on the outlet part according to the arrow indication on the KEOFITT Sampling Bag™. In **CLEAN** position, when the blue wing is aligned with the **CLEAN** symbol, the inlet and the outlet are locked into each other, sealing off the KEOFITT Sampling Bag™, and same time serves as a tunnel bypassing the KEOFITT Sampling Bag™. The tunnel allows liquids or steam to flow via the valve outlet through the tunnel, i.e., bypassing the KEOFITT Sampling Bag™, and into the surroundings. This unique feature secures a hygienic sample flow path. When the blue wing is turned counterclockwise to align with the **SAMPLE** symbol, the KEOFITT Sampling Bag™ is in sampling position, and product can flow into the KEOFITT Sampling Bag™ when pulling the inlet and outlet parts apart. When product flows from the valve outlet via the KEOFITT Sampling Bag™ inlet it will by gravity fall into the KEOFITT Sampling Bag™. This chapter goes through the configuration and features of the KEOFITT Sampling Bag™.

2.1 KEOFITT Sampling Bag™ configuration

The KEOFITT Sampling Bag™ is available in 2 sizes: 1 liter (#151000) and 2.5 liters (#152000). Both versions are provided with volume indications, based on the KEOFITT Sampling Bag™ standing in upright position. In this section you will find description and explanation of the KEOFITT Sampling Bag™ and the different parts (picture 1).



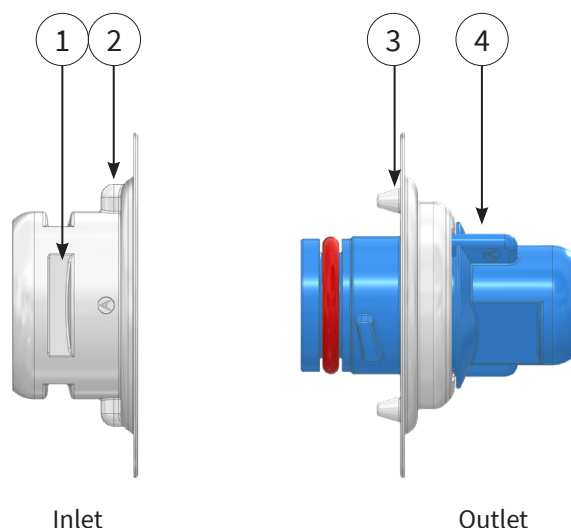
PICTURE 1. KEOFITT Sampling Bag™ in different angles. Relevant parts and indications are numbered for explanation. 1. Hook for carrying, 2. Area for notes, 3. Outlet (blue), 4. Volume indications, 5. Dotted line for cutting to ease closure after pouring out sample, 6. Inlet (white).

2.1.1 Inlet and Outlet

The KEOFITT Sampling Bag™ is equipped with a white inlet and a blue outlet. The inlet and outlet parts are welded to the KEOFITT Sampling Bag™ foil just opposite each other (picture 1). The two plastic parts (picture 2) can be either locked into each other for sealing the KEOFITT Sampling Bag™ or they can be pulled apart for sampling. When the inlet and outlet are locked into each other, they function as a tunnel bypassing the KEOFITT Sampling Bag™. To secure proper sealing of the KEOFITT Sampling Bag™, a click function is integrated in the sealing system. Just before the outlet wing is aligned with the **CLEAN** symbol, a small resistance is felt. The wing must be forced to overcome the resistance (feels like a click) and align with the **CLEAN** symbol for proper sealing. This function guarantees correct sealing of the KEOFITT Sampling Bag™.

INLET

The inlet part is designed as a classic KEOFITT hose piece connection dimensioned \varnothing 15.7 mm to ease sampling of high viscosity products and products with particles. The white inlet part is to be connected to the valve outlet with a stainless steel device (see section 4.1). Two bulges (picture 2) fitting corresponding grooves in the stainless steel device prevents the KEOFITT Sampling Bag™ from rotating when mounted on the valve. The slits (picture 2) enable mounting in the fitting.

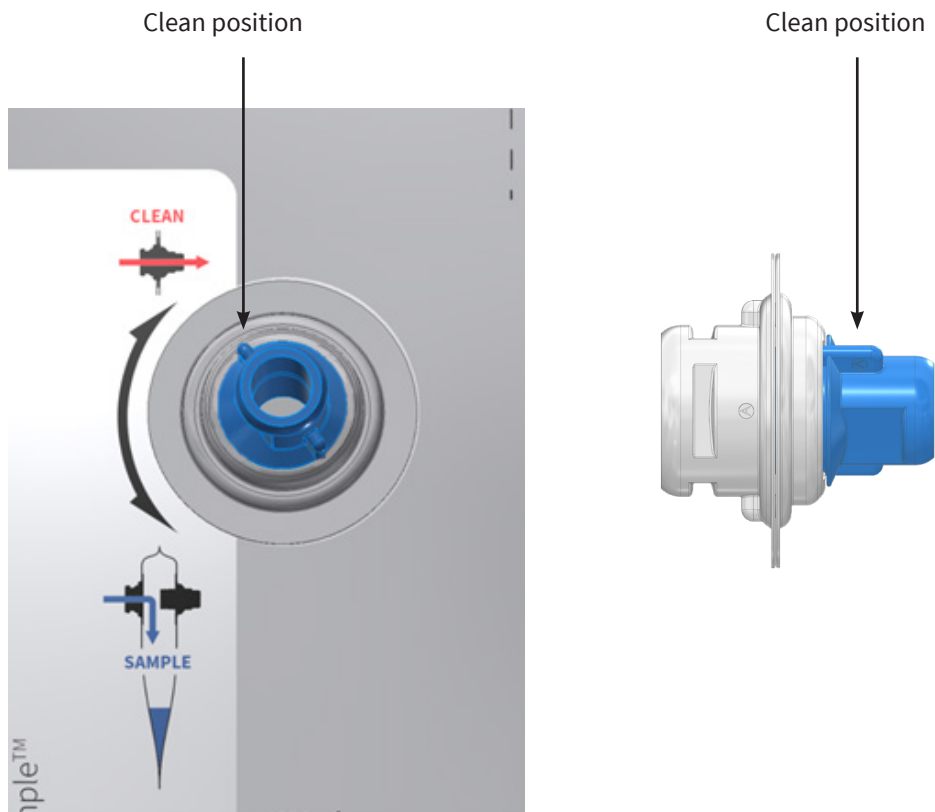


PICTURE 2. KEOFITT Sampling Bag™ inlet (left) and outlet (right). In this position the inlet and outlet parts are pulled apart (wings on the outlet are aligned with the **SAMPLE** symbol) and are thus in sampling position. Different parts are showed and named. 1. Slit, 2. Bulge, 3. Conical shaped bulge, 4. Wing.

OUTLET

The outlet is designed as the classic KEOFITT hose piece \varnothing 9 mm equipped with two wings to facilitate the operation of the KEOFITT Sampling Bag™ (picture 2). The KEOFITT Sampling Bag™ is operated by turning the wings on the outlet. The position of the wings indicates if the KEOFITT Sampling Bag™ is in either sampling position or in sealed position (picture 3). When the wings align with the **SAMPLE** symbol printed on the front of the KEOFITT Sampling Bag™ it is in sampling position. When the wings are aligned with the **CLEAN** symbol printed on the front of the KEOFITT Sampling Bag™ it is sealed, and fluid can pass without entering the KEOFITT Sampling Bag™. In this position cleaning, disinfection, or sterilization of the sample flow path can be done. Two silicone o-rings positioned on the outlet part seal the system. When the wing aligns with the **CLEAN** symbol a click is felt. The click is the assurance for proper sealing.

To facilitate the assembly of the inlet and outlet parts and thereby sealing the KEOFITT Sampling Bag™, the internal of the outlet flange is equipped with a protruding conical shaped bulge (picture 2) matching a cavity on the inside of the inlet part. These grabbing into each other during closing operation eases the assembly.



PICTURE 3. Inlet and outlet part in **CLEAN** position, wings on outlet are aligned with the **CLEAN** symbol. The inlet and outlet parts are assembled creating a tunnel bypassing the bag. In this position the inlet and outlet parts are locked into each other sealing off the KEOFIT Sampling Bag™.

When the KEOFIT Sampling Bag™ is in sampling position (the wings align with the **SAMPLE** symbol), the outlet must be closed off to protect the inside of the KEOFIT Sampling Bag™ from contamination from the surroundings. To close the outlet either a device must be used (please refer to section 4.2) or the protecting aluminium foil can be left in place, advantageously supported by the #150061 Quick Coupling KSB Outlet stainless steel cap.

To protect the tunnel from being contaminated before use, the inlet and outlet are sealed off by aluminium foils welded to the parts. Before use, the aluminium foils are easily removed by hand.

2.1.2 Handle (carrying and hanging)

In upper left corner a punched hole functions as a handle to ease carrying the KEOFIT Sampling Bag™ or it can be used for hanging the KEOFIT Sampling Bag™ on a hook or similar device for storage or emptying purpose.

2.1.3 Retrieval of the sample

To withdraw a sample from or completely emptying the KEOFIT Sampling Bag™, simply cut the corner and pour out the desired amount. It is recommended to wipe the area with alcohol before cutting. To ease the re-sealing, a welded area has been included. A cut can be made along the dotted line to extend the folding area (increase amount of accessible plastic material to be folded) and thereby ease the re-sealing.

Alternatively, either the inlet part or the outlet part can be used for pouring out the sample from the KEOFIT Sampling Bag™. When opening the KEOFIT Sampling Bag™, both inlet and outlet simultaneously serve as openings. Therefore, it is very important to plug the part not in use to avoid pouring sample simultaneously from both parts. To close and seal the KEOFIT Sampling Bag™ gently push the inlet

and outlet together and turn the blue wing to align with the **CLEAN** symbol. Be sure to feel the click as it is the assurance for proper sealing. Please see section 5.5 for further information.

2.1.4 Label

Each KEOFITT Sampling Bag™ carries a label with the following information:

- Article No.
- Lot No.
- Expiry Date
- Area for notes

2.1.5 Disposal

After use the KEOFITT Sampling Bag™ is to be emptied completely before disposal. The KEOFITT Sampling Bag™ itself is very well suited for incineration, but the composition of the actual product being sampled may require a different method of disposal.

3. CLEANING - DISINFECTION - STERILIZATION

To secure an uncompromised sample, it is recommended to clean, disinfect or sterilize the entire sample flow path before sampling. This is done by connecting the KEOFITT Sampling Bag™ to the valve before performing the required procedure. This way the sample flow path can be cleaned, disinfected, or sterilized along with the sampling valve.

In this chapter you will find an introduction to the concepts of cleaning, disinfecting and sterilizing processes in general. For further information about your valve, please refer to the specific valve manual where you can find a thorough description and explanation of the procedures for the specific valve. The manuals can be found on the website: www.keofitt.dk

3.1 Clean-In-Place (CIP)

Thorough cleaning is a prerequisite for proper disinfection or sterilization. Cleaning is the removal of any visible residual product; it be organic or inorganic. It may be done using either a suitable liquid detergent or steam (continuous steam will eventually lead to sterility; SIP = Sterilize-In-Place).

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. Generally recommended flow rate for turbulent flow is 1.5-2.5 m/s.

Depending on the actual process media the proper detergent must be determined in cooperation with your usual supplier of detergents. The company Novadan ApS, Kolding, Denmark - www.novadan.dk, has supplied the generic table below for your convenience.

What to clean for	Generic cleaning agents	Comments
Fat	Alkali and tensides	Heat will facilitate the cleaning process as the fat melts
Protein	Alkali, acids, tensides and chlorine	Coagulation and burning when heated, which makes the product hard to remove
Sugar, salt	Water is usually sufficient as the product is water soluble	Sugar caramelizes when heated, turning into a hard sticky substance, which is difficult to remove
Minerals	Acids, complexing agent	Often seen as lime scale
Biofilm	Alkali and chlorine, peracetic acid, possibly enzymes	Biofilm is an accumulated mass of microorganisms that is tightly adhered to a surface and cannot be easily removed
Starch	Alkali and chlorine	

3.2 Disinfection

Although CIP removes all visible residues of the process media, the valve surface will still be contaminated on a microscopic level. Depending on your actual process media it will be necessary to carry out a disinfection operation 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 the initial microbial load distribution, the required hygienic level and 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 several chemical disinfectants, and 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 – www.novadan.dk, has supplied the table below, as a preliminary indication of which type of disinfectant to use.

	Halogens	Peroxides	Ethanol (70%)
Gram neg	Efficient	Efficient	Efficient
Gram pos	Efficient	Efficient	Efficient
Spores	Limited effect	Efficient	Little/No effect
Phages	Limited effect	Efficient	Little/No effect
Yeast	Efficient	Efficient	Efficient
Fungi	Efficient	Efficient	Limited effect
Virus	Efficient	Efficient	Limited effect
Legend:	Efficient	Limited effect	Little/No effect

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

3.3 Sterilization-In-Place (SIP)

Sterilization is a high-level disinfection designed to render the valve free of all forms of viable microorganisms (incl. bacterial spores) to a high level of certainty, the so-called Sterility Assurance Level or SAL. A SAL value of 10^{-6} means that the probability (or risk) of a single viable microorganism being present on the valve interior afterwards sterilization process is only 1 in 1,000,000 which is a generally accepted level for calling an item sterile. Although the probability can be reduced to a very low number, it can never be reduced to zero.

Sterility may in practice only be obtained by steaming. Disinfectants exist that in high concentrations and for a prolonged exposure time will be able to inactivate all forms of microorganisms and render the 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 required high concentration, which causes an operator hazard and the several hours of exposure time. Furthermore, sterilization with a chemical sterilant may not convey the same sterility assurance as sterilization with steam, because the germicidal and sporicidal kinetics are much less investigated and documented for chemical sterilants compared to steam.

4. ACCESSORIES

Sampling with the KEOFITT Sampling Bag™, requires a fitting for connecting it to the sampling valve (section 4.1). If your sampling procedure require cleaning, disinfection, or sterilization of the entire sample flow path, you will also need a fitting for the outlet (please see section 4.2). All fittings are made of autoclavable stainless steel and are therefore re-usable. In this section you find a detailed description of the different fittings and how to use them.

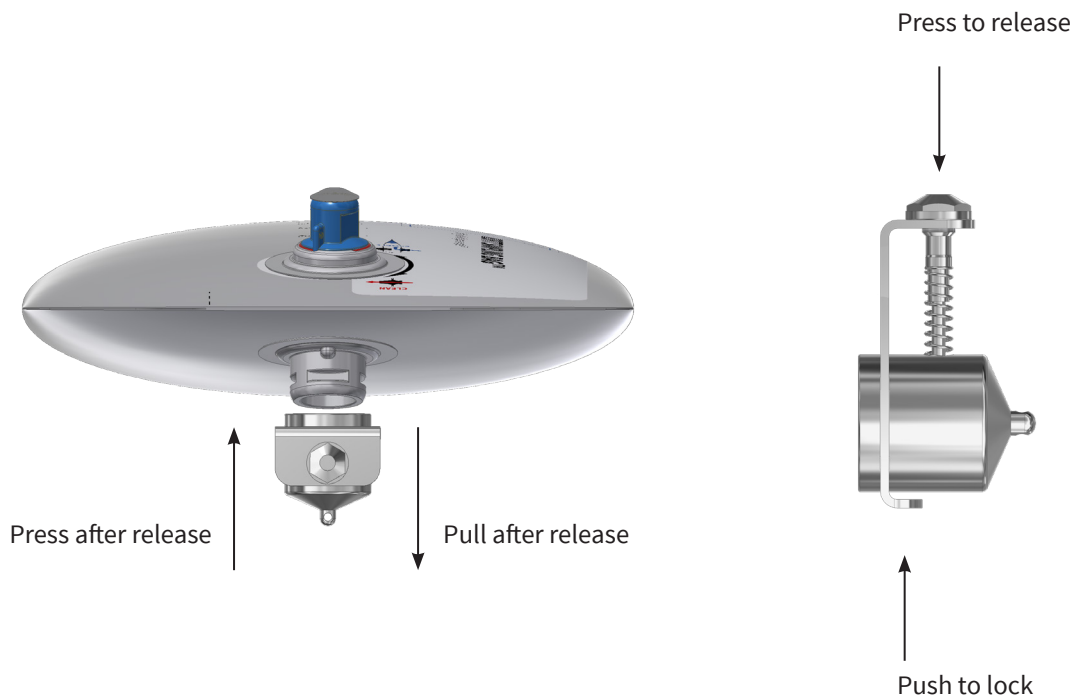
4.1 Fittings for connecting KEOFITT Sampling Bag™ to the sampling valve

The choice of fitting depends on the design of your specific sampling valve outlet. Choose the fitting which corresponds to the outlet of your sampling valve, please refer to table 1.

Item	Product no.	Picture
Quick Coupling KSB Inlet for hose piece	150083	
Quick Coupling KSB Inlet 1/2" clamp	150088	
Quick Coupling KSB Inlet 3/4" clamp	150084	
Quick Coupling KSB Inlet 1" clamp	150085	
Quick Coupling KSB Inlet stainless steel plug	150062	

Table 1. Fittings for connecting KEOFITT Sampling Bag™ to the sampling valve outlet. Choose the fitting that corresponds to the outlet of the sampling valve. For technical information, please refer to the Data Sheet for the specific fitting.

All fittings for the KEOFITT Sampling Bag™ inlet are designed as classic KEOFITT quick couplings. To fit the quick coupling on the KEOFITT Sampling Bag™ inlet, compress the spring loaded lock pin on the quick coupling and place the fitting on the inlet. Make sure the bulges on the KEOFITT Sampling Bag™ inlet part fits with the corresponding grooves in the quick coupling and release the lock pin. Make sure the lock pin has moved fully back to its original position for a secure locking. Please see picture 4 on how to fit the quick coupling to the KEOFITT Sampling Bag™ inlet.



PICTURE 4. Mounting the quick coupling on the inlet. Make sure to fit the grooves in the quick coupling with the corresponding bulges on the inlet part of the KEOFITT Sampling Bag™.

4.2 Fittings for closing off the outlet of the KEOFITT Sampling Bag™

When KEOFITT Sampling Bag™ is in **SAMPLE** position, the fitting on the outlet serves as barrier to the environment when sampling, and when KEOFITT Sampling Bag™ is in **CLEAN** position it must allow for passage of fluid or steam. For this purpose, you can either choose the #150086 Quick Coupling KSB Outlet Non-Return Valve, which automatically opens and closes depending on pressure (please see section 4.2.1) or the #150082 Quick Coupling KSB Outlet 3/8" Hose barb, which is manually operated for opening and closing (please see section 4.2.2).

If your sampling procedure does not require cleaning, disinfection, or sterilization prior to sampling, you can leave the protecting aluminium foil on the outlet as it acts as barrier to the environment and prevents contamination from surroundings while sampling (section 5.6.2). The aluminium foil can advantageously be supported when sampling by mounting #150061 Quick Coupling KSB Outlet stainless steel plug on top of the foil. For an overview of the fittings for the KEOFITT Sampling Bag™ outlet, please refer to table 2.

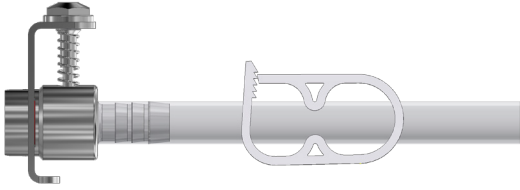
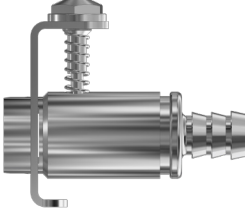
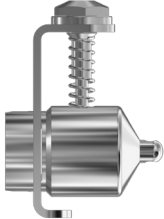
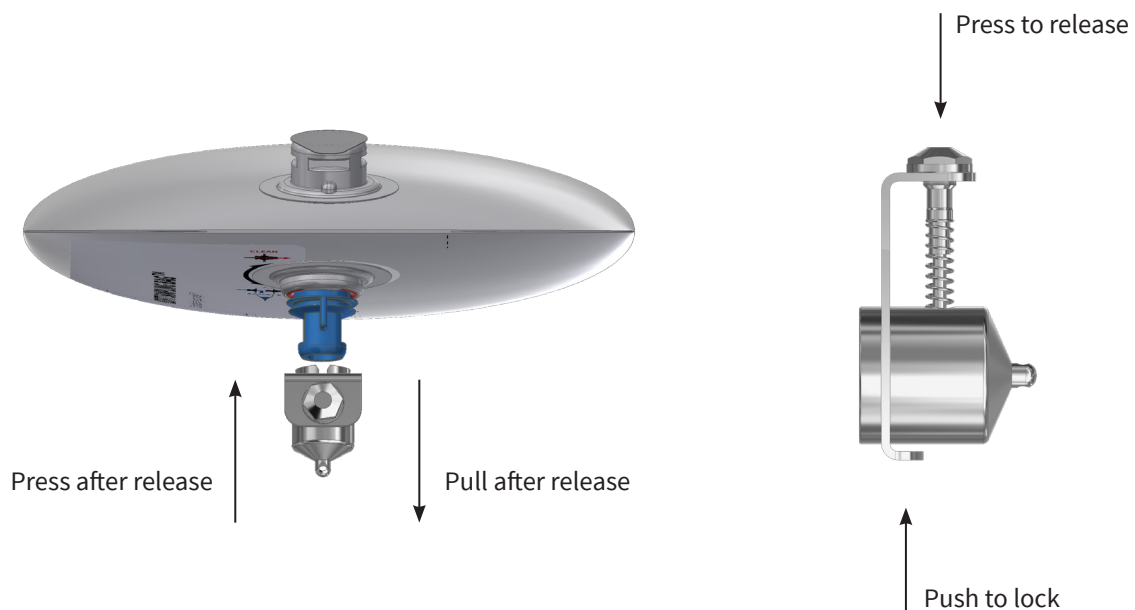
Item	Product no.	Picture
Quick Coupling KSB Outlet 3/8" Hose barb	150082	
Quick Coupling KSB Outlet Non-Return Valve	150086	
Quick Coupling KSB Outlet stainless steel plug	150061	

Table 2. Fittings for closing off the outlet part. For technical information, please refer to the Data Sheet for the specific fitting.

All fittings for the KEOFITT Sampling Bag™ outlet are designed as quick couplings. Be aware that the two slits in the quick coupling fit the wings on the KEOFITT Sampling Bag™ outlet when mounting the fitting. Please see picture 5 for mounting instruction.

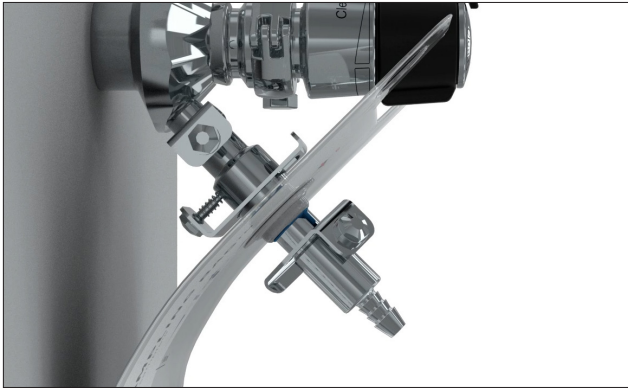
All fittings for the KEOFITT Sampling Bag™ outlet are designed as classic KEOFITT Quick Couplings. To fit the quick coupling on the KEOFITT Sampling Bag™ outlet, compress the spring-loaded lock pin and place the fitting over the outlet. Make sure the wings on the outlet fit with the corresponding cutouts in the quick coupling (picture 5) and release the lock pin. Make sure the lock pin is back in its original position for a secure locking. Please see picture 5 on how to fit the quick coupling to the KEOFITT Sampling Bag™ outlet.



PICTURE 5. Mounting quick coupling on the outlet. Make sure the slits in the quick coupling fit with the wings on the outlet.

4.2.1 Quick Coupling KSB Outlet Non-Return Valve (QC KSB Outlet NRV)

The QC KSB Outlet NRV (#150086), allows for passage of liquids and steam in the direction from the sampling valve to the surroundings, and blocks passage in reverse direction. It is designed to allow passage for liquid or steam when the pressure increases to approx. 0.5-1 bar(g). When pressure decreases it will close. This way it acts as barrier to the environment during sampling. One must be aware, that due to the design of the NRV, a small amount of the CIP (liquid) or SIP (condensate) will remain in the flow path after automatic closing of the NRV. The QC KSB Outlet NRV is mounted on the outlet part of the KEOFITT Sampling Bag™ before cleaning, disinfecting, or sterilizing the sampling valve and the sample flow path. Two cutouts in the quick coupling fits the wings on the KEOFITT Sampling Bag™ outlet part. A hose to drain can be mounted on the QC KSB Outlet NRV if required, please see picture 6. An advantage with this device is the automatic operation which minimize risk of operator errors.



PICTURE 6. Quick Coupling KSB Outlet Non-Return Valve (#150086) mounted on the KEOFITT Sampling Bag™ outlet. KEOFITT Sampling Bag™ is mounted on a Sesame sampling valve. A hose to drain can be mounted if required.

4.2.2 Quick Coupling KSB Outlet 3/8” Hose barb (QC KSB Outlet Hose barb)

By mounting a hose with a pinch clamp on the QC Bag Outlet Hose barb, you can lead fluid media or steam to drain. Engaging the pinch clamp after cleaning, disinfection or steaming protects the sample from contamination from the surroundings when the KEOFITT Sampling Bag™ is in sampling position, please refer to picture 7.



PICTURE 7. Quick Coupling KSB Outlet 3/8” Hose barb (#150082) mounted on the KEOFITT Sampling Bag™ outlet. KEOFITT Sampling Bag™ is mounted on Sesame sampling valve. When cleaning, disinfecting, or sterilizing the pinch clamp must be open to allow for passage of the media (left). Immediately after cleaning, disinfecting, or sterilizing, the pinch clamp must be closed to avoid contamination of the interior (right).

4.2.3 Quick Coupling KSB Outlet Stainless steel plug

If your hygienic level does not require a completely closed sampling circuit, the Quick Coupling KSB Outlet Stainless steel plug (#150061) can be mounted just after cleaning, disinfection or steaming the flow

path (valve and tunnel), please refer to picture 8. As the stainless steel fittings are autoclavable they can, after autoclavation, be stored in 70% ethanol and mounted directly on the outlet, minimizing the risk of contamination.



PICTURE 8. Left: Protecting aluminium foil removed from the outlet for a free flow path of the cleaning, disinfection, or steam media. Right: Immediately after cleaning, disinfecting, or sterilization, mount the Quick Coupling KSB Outlet stainless steel plug. It is recommended to disinfect the stainless steel plug just before mounting.

5. HOW TO SAMPLE

In this chapter you will find a description on how to sample and retrieve the sample from the KEOFITT Sampling Bag™. Depending on your requirement for hygienic sampling, you have several options.

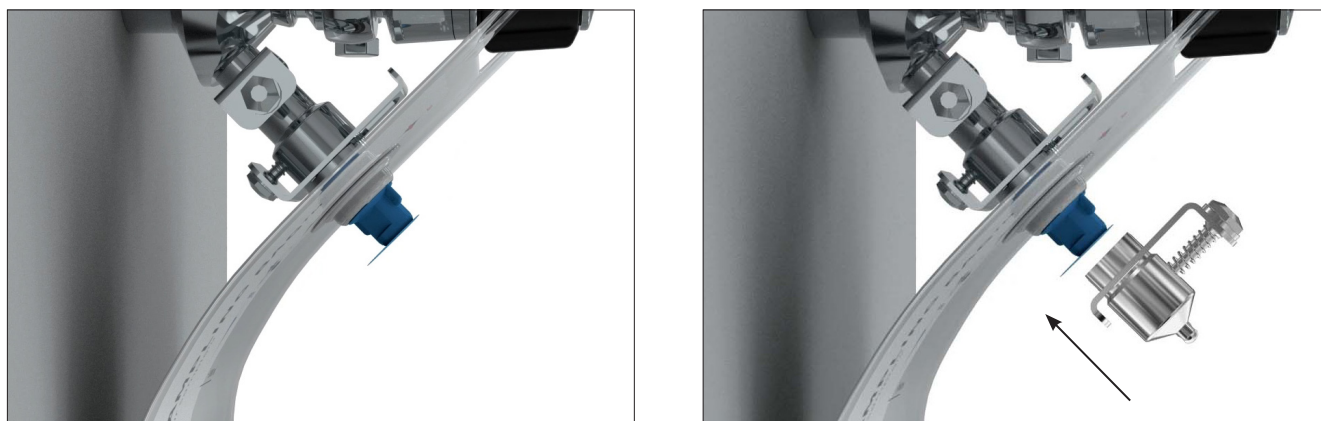
Depending on your hygienic sampling requirements there are several options for pre-sampling procedures. Below you will find information on how to clean, disinfect or sterilize the entire sample flow path to secure an uncompromised sample. You will also find information on how to sample without cleaning, disinfecting, or sterilizing the entire sample flow path. As every manufacturer is unique, there are of course a lot of interpretations that can be necessary to make of the procedures presented in this manual. If you are in doubt about best procedure for your sampling requirements, please contact your local KEOFITT distributor for further discussion.

For details on the cleaning procedure for your specific sampling valve, please refer to the specific valve manual on the website: www.keofitt.dk.

5.1 Connecting the KEOFITT Sampling Bag™ to the sampling valve

The KEOFITT Sampling Bag™ must be connected to the sampling valve outlet with a fitting to the outlet of the sampling valve (section 4.1). Before connecting the KEOFITT Sampling Bag™ to the fitting, the protecting aluminium foil on the KEOFITT Sampling Bag™ inlet must be removed. If your sampling procedure involves cleaning, disinfection, or sterilization of the sample flow path, the protecting aluminium foil on the KEOFITT Sampling Bag™ outlet must be removed to allow media to pass.

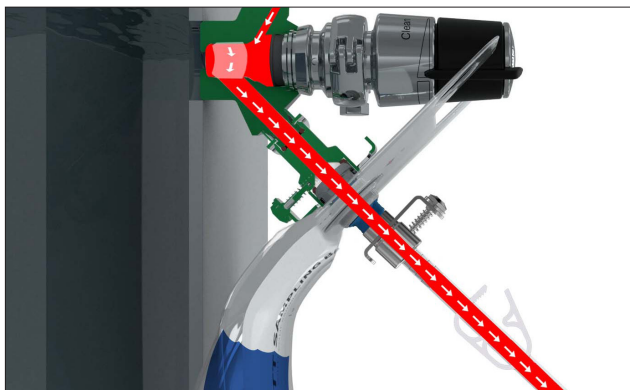
If your hygienic requirements do not involve cleaning, disinfection, or sterilization before sampling, you can advantageously keep the protecting foil on the KEOFITT Sampling Bag™ outlet, please see picture 9. This way the outlet stays sealed, and the sample is protected from contamination from the surroundings while sampling. The aluminium foil on the outlet can be further reinforced by mounting the Quick Coupling KSB Outlet stainless steel plug (#150061).



PICTURE 9. Left: Protecting aluminium foil on the outlet. Right: If no cleaning, disinfecting, or sterilization of the flow path is necessary, the Quick Coupling KSB Outlet stainless steel plug can advantageously be mounted to support the foil when sampling.

5.2 Preparing the sample flow path for sampling

To secure a non-contaminated sample, it is important to clean, disinfect or sterilize the sample flow path before sampling. As the KEOFITT Sampling Bag™ is part of the sample flow path, the KEOFITT Sampling Bag™ must be included in this process (picture 10).



PICTURE 10. KEOFITT Sampling Bag™ mounted a Sesame sampling valve. KEOFITT Sampling Bag™ is in **CLEAN** position and cleaning media, disinfectant, or steam is flowing through the entire sample flow path.

When the KEOFITT Sampling Bag™ is in **CLEAN** position (blue wing is aligned with the **CLEAN** symbol on the front of the KEOFITT Sampling Bag™), the chosen liquid media or steam will flow through the inlet-outlet tunnel and hence bypassing the KEOFITT Sampling Bag™, continuing to the surroundings. As the liquid media or steam is flowing through both the sampling valve and the KEOFITT Sampling Bag™ inlet-outlet tunnel to the surroundings, it will clean, disinfect, or sterilize the entire flow path of the sample.

To secure a free flow of the media to the surroundings, the KEOFITT Sampling Bag™ outlet fitting must be in open position during cleaning, disinfection, or sterilization. The QC KSB Outlet NRV (#150086) will automatically open when pressure increase 0.5-1 bar(g). If using the QC KSB Outlet Hose barb (#150082) the pinch clamp must be manually disengaged.

The pathway must be closed just after cleaning, disinfecting, or sterilizing to protect the hygienic environment just obtained and to prevent contamination of the sample from surroundings during sampling. The QC KSB Outlet NRV (#150086) will automatically close when pressure decreases. This fitting is suitable for low viscosity liquids not containing particles (as particles cannot pass the seat in the Non-Return Valve). If using the QC KSB Outlet Hose barb (#150082) the pinch clamp must be manually engaged. The QC KSB Outlet Hose barb (#150082) allows liquids with high viscosity and liquids containing particles (OD 6 mm) to flow through.

If a totally closed sampling circuit is not required for your specific sampling procedure, an option is to leave out the use of an outlet fitting during cleaning, disinfection, or steaming and as alternative mount an autoclaved or disinfected QC KSB Outlet Stainless steel plug (#150061) immediately after cleaning, disinfecting, or sterilizing the sample pathway. The KEOFITT Sampling Bag™ connectors are described in detail in section 4.2.

5.2.1 Cleaning

With the KEOFITT Sampling Bag™ connected to the sampling valve perform CIP as described in the relevant sampling valve user manual. Before starting your cleaning procedure, make sure the KEOFITT Sampling Bag™ outlet device is open to allow cleaning media a free flow to a suitable container or to drain.

5.2.2 Disinfection

If disinfection is required according to your hygienic standards the cleaning must be followed by the application of an appropriate disinfectant and finished by a final rinsing (water or product flush).

5.2.3 Steam sterilization

Steaming has the advantage that it does flushing, cleaning and sterilization all in one operation. With the

KEOFITT Sampling Bag™ connected to the sampling valve, perform the steaming process as described in the user manual for your sampling valve.

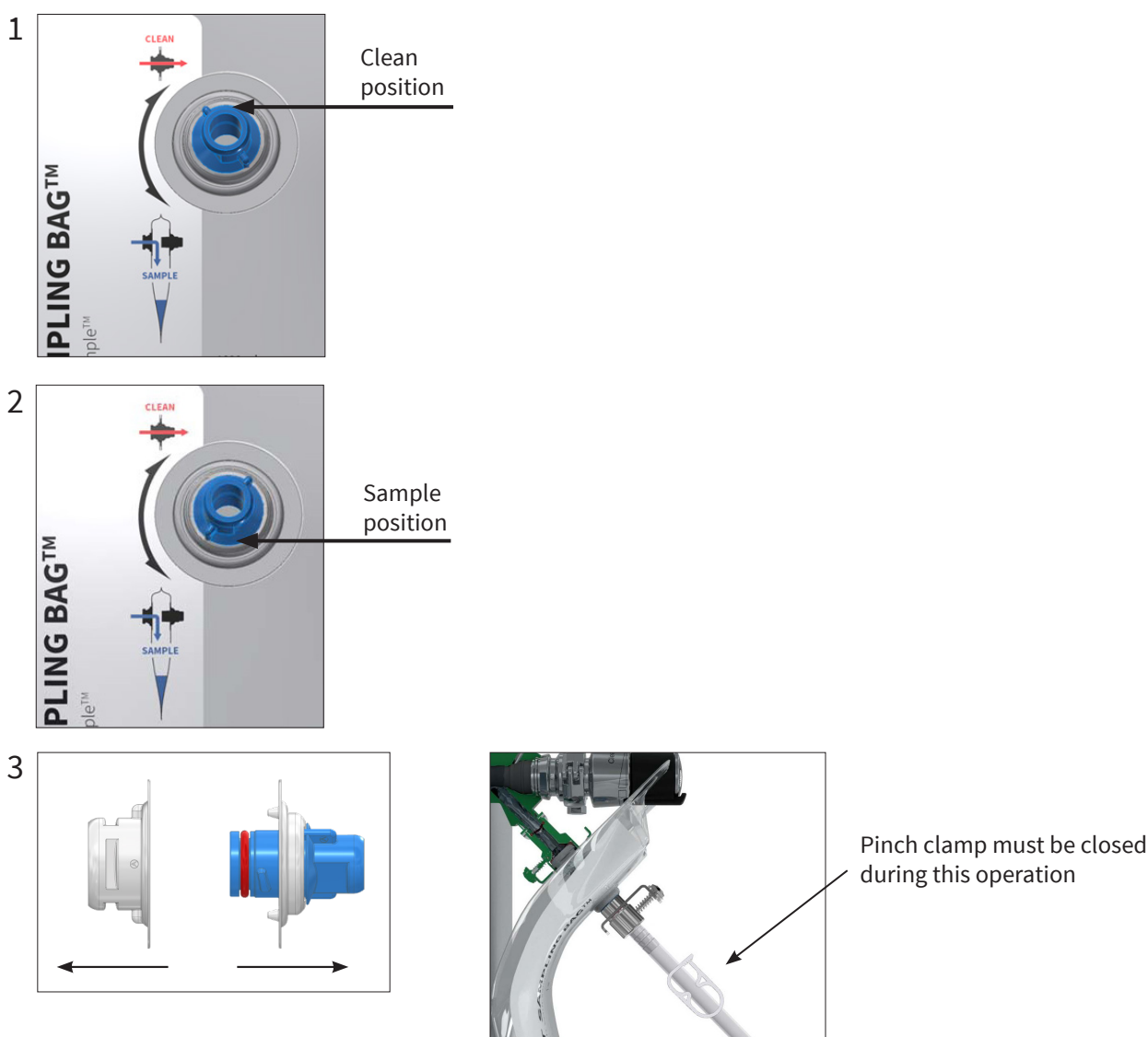
Both the sampling valve, the KEOFITT Sampling Bag™ inlet and outlet and the outlet device will become hot during steaming and care should be taken when operating just after steaming

5.3 Sampling

When you have performed the required cleaning, disinfection, or sterilization you are ready to sample.

5.3.1 Before sampling operation

To let sample into the KEOFITT Sampling Bag™, the flow path bypassing the KEOFITT Sampling Bag™ must be opened. Unlock the inlet and outlet of the KEOFITT Sampling Bag™ by turning the wing on the outlet (e.g., mounted a fitting) counterclockwise approximately 100 degrees to align with the **SAMPLE** symbol on the front of the KEOFITT Sampling Bag™ (picture 11). The Inlet and outlet are now unlocked and can gently be pulled apart, creating the opening into the KEOFITT Sampling Bag™.



PICTURE 11. To open the KEOFITT Sampling Bag™ for sampling, the blue wing on the outlet is turned counterclockwise to align with the **SAMPLE** symbol. The inlet and outlet are now unlocked and can gently be pulled apart to allow sample into the KEOFITT Sampling Bag™. During this operation the outlet must be sealed off as shown, where the pinch clamp on the Quick Coupling KSB Outlet 3/8" Hose barb is closed during sampling.

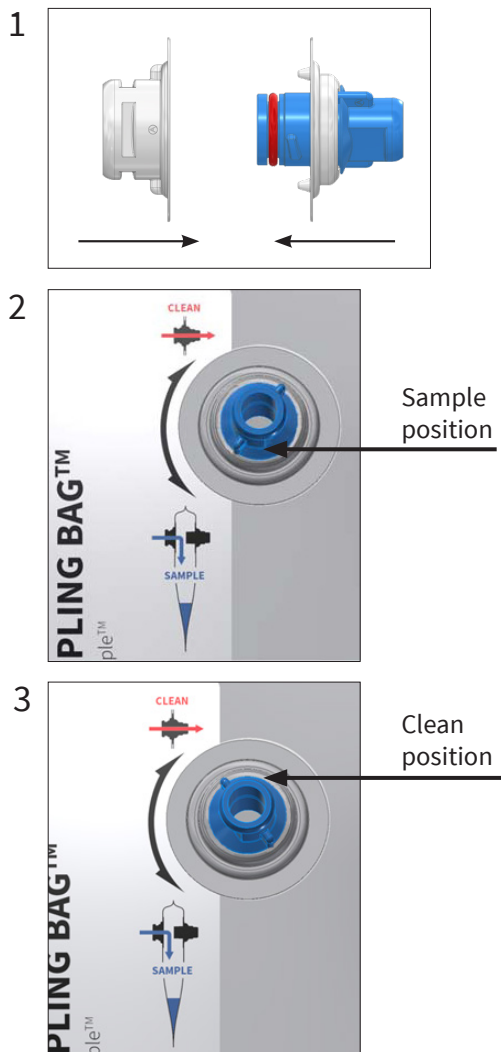
5.3.2 Sampling operation

When the KEOFITT Sampling Bag™ is in sampling position, sample can be taken by opening the valve, as fluid will no longer flow through the tunnel, bypassing the KEOFITT Sampling Bag™, but into the KEOFITT Sampling Bag™ by gravity (picture 12). When desired amount of sample is obtained, the valve is close



PICTURE 12. KEOFITT Sampling Bag™ in sampling position. The product flows through the valve into the open KEOFITT Sampling Bag™. Quick Coupling KSB Outlet 3/8" Hose barb (#150082) is mounted on the outlet of the KEOFITT Sampling Bag™.

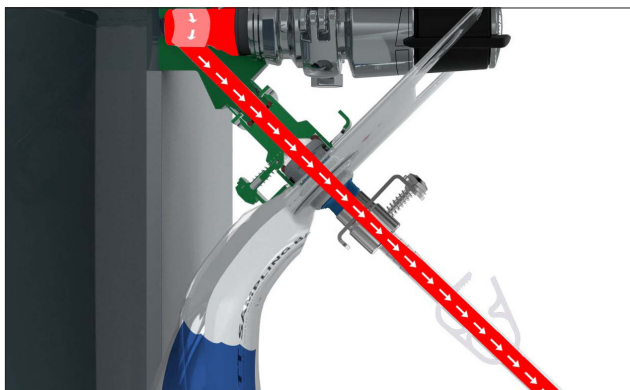
To close the KEOFITT Sampling Bag™ after sampling, the inlet and outlet parts are pushed together and the blue wing on the outlet is turned clockwise back to align with the **CLEAN** position (picture 13). To secure correct sealing of the KEOFITT Sampling Bag™, you will feel a “click” when the wing has reached the correct position, please refer to section 2.1.1.



PICTURE 13. To close the KEOFITT Sampling Bag™, the outlet is gently pushed towards the inlet and when connecting, the wings are turned clockwise, while at the same time pushing inlet and outlet together, until the wings align with the **CLEAN** symbol. You will feel a “click” when the wings have reached correct position for sealing.

5.3.3 After sampling operation

The entire sample flow path or just the valve can now be cleaned, disinfected, or sterilized according to your normal procedure. This is done to secure the valve is free from product residues. If the KEOFITT Sampling Bag™ is included in the procedure, make sure to have a free flow for the chosen media, before flushing, cleaning, disinfection, or sterilization the valve and tunnel (picture 14).



PICTURE 14. KEOFITT Sampling Bag™ with sample. KEOFITT Sampling Bag™ is in **CLEAN** position and liquid media or steam is flowing the entire sample flow path after sampling. Note the pinch clamp on the hose is open to allow passage of the media.

The QC KSB Outlet NRV (#150086) will automatically open when pressure increase 0.5-1bar(g). If using the QC KSB Outlet Hose barb (#150082) the pinch clamp must be manually engaged.

The KEOFITT Sampling Bag™ can also be disconnected from the sampling valve just after sealing it (wing aligns with **CLEAN** symbol, remember to feel the click “bump”). If the KEOFITT Sampling Bag™ is disconnected from the sampling valve prior to cleaning, disinfection, or sterilization, product residues will remain in the KEOFITT Sampling Bag™ inlet-outlet tunnel. If necessary, the product residues can subsequently be removed by rinsing with e.g., water or disinfecting with e.g., 70% ethanol.

5.4 Storage of the sample

When the inlet and outlet has been properly locked together the KEOFITT Sampling Bag™ is sealed and can be stored according to your requirements. For technical details on e.g., min and max temperature, please see the data sheet.

Evaporation through the KEOFITT Sampling Bag™ material is very low and should in most cases not have any implication on storage time. However, if the sample contains dissolved CO₂ (beer and soft drinks) please consult the gas permeability details in the data sheet to assess a suitable maximum storage time. Similar action if the sample is sensitive to oxygen (O₂).

5.4.1 Securing sample integrity

As an extra feature the sample can be protected towards unintentionally opening, by adding an extra sealing to make it tamper proof. The design of the plastic tunnel facilitates a possibility to seal the inlet-outlet tunnel with a strap or alike. If the strap is later broken, it will indicate the KEOFITT Sampling Bag™ has been unintendedly opened.

5.5 Retrieving the sample

You can retrieve the sample from the KEOFITT Sampling Bag™ several ways as described below.

5.5.1 Retrieval through cut

The KEOFITT Sampling Bag™ design leaves a natural space for cutting and pouring/squeezing out sample from the upper right corner. Before cutting it is advised to disinfect the area on the KEOFITT Sampling Bag™ where you plan to cut as well as the tool for cutting. After pouring out your sample the KEOFITT Sampling Bag™ should be re-sealed to prevent leakage and/or contamination if the sample is to be stored further. To ease re-sealing, the KEOFITT Sampling Bag™ is designed with a vertical welding with a dotted line in the top right. By cutting through the dotted line, the snip can now easily be folded and held in place with a clamp (picture 15).



PICTURE 15. Retrieving sample from the KEOFITT Sampling Bag™ by cutting the foil. After pouring out the sample from the opening made by a pair of scissors or the like, the area for folding/closure can be extended by cutting the dotted line.

5.5.2 Retrieval through inlet or outlet

Another way of pouring out sample from the KEOFITT Sampling Bag™ is to use either the inlet or the outlet. Be aware that by opening the KEOFITT Sampling Bag™ (turning the blue wing to **SAMPLE** position and pulling the inlet and outlet apart), both the inlet and the outlet of the KEOFITT Sampling Bag™ will be opened. By blocking one of the parts with a stainless steel plug (#150062 or #150061), you have an easy re-closable opening in the KEOFITT Sampling Bag™ (picture 16). Before opening the KEOFITT Sampling Bag™ for pouring out sample, make sure to remove any product residues in the flow-path-tunnel by cleaning or disinfecting the tunnel according to your hygienic requirements.



PICTURE 16. Retrieving sample via the KEOFITT Sampling Bag™ inlet or outlet. Left: Pouring out sample from the inlet, by blocking the outlet with Quick Coupling KSB Outlet stainless steel plug (#150061). Middle: Pouring out sample from the inlet. Peel-off foil not removed from the outlet during sampling. Right: Pouring out sample from the outlet, by blocking the inlet with Quick Coupling KSB Inlet stainless steel plug (#150062).

If the protecting aluminium foil has not been removed from the KEOFITT Sampling Bag™ outlet during sampling (no cleaning of the sample flow path before and after sampling), the outlet is blocked and secured from contamination when opening the bag for retrieving sample (picture 16).

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

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