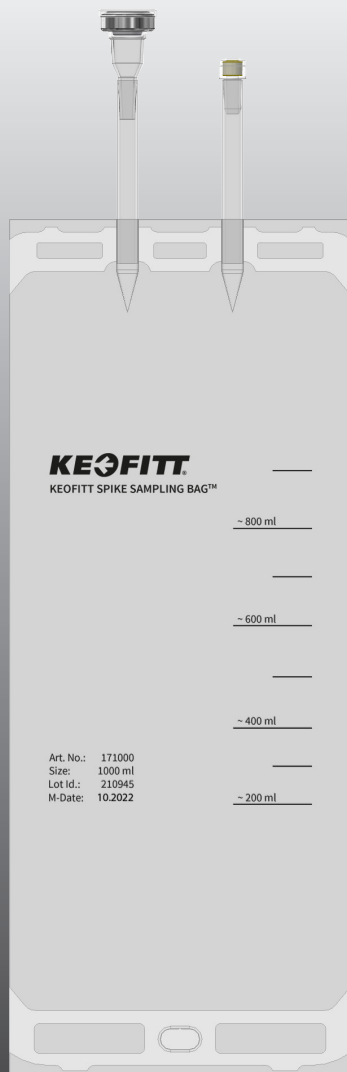


KEOFITT SPIKE SAMPLING BAG

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 September 2022.

Version #	Version date	Major changes from previous versions
1	September 2022	First version

INTRODUCTION:

MANUFACTURER: KEOFITT A/S
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5700 Svendborg, Denmark

TYPE: KEOFITT Spike Sampling bag
YEAR OF INTRODUCTION: 2022
MANUAL LAST UPDATED: September 2022

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

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1. PRESENTATION

The KEOFITT Spike Sampling Bags are cost-effective single-use sampling bags featuring a unique self-sealing septum allowing very thick needles for fast and convenient sampling of most liquids including viscous products.

The KEOFITT Spike Sampling Bags are available in one version as described in the table below:

VERSION	DESCRIPTION	APPLICATION
KEOFITT SPIKE SAMPLING BAG	Made from medical grade PP (polypropylene). Manufactured under Clean Room conditions (class C).	Where sterile sampling is not required, and the use of a sample recipient manufactured under clean room conditions suffices.

The KEOFITT Spike Sampling Bag features a unique septum, which accepts very thick needles (KEOFITT spikes) with 2.5 mm internal diameter. This assures a much faster sampling process than otherwise experienced with hypodermic needles. Despite the thick needle the unique self-sealing septum design protects the sample from contaminants from outside, while at the same time keeping the bag completely tight.

For an optimal and convenient application KEOFITT has designed a thick needle/KEOFITT spike referred to as the KEOFITT spike.

NOTE!

- The KEOFITT Spike Sampling Bag is intended for collection of samples to be analyzed within hours, days or weeks after sampling given appropriate storage conditions.
- For prolonged storage time (months to years) consider the KEOFITT Sterile Sampling Bag.
- For lower gas permeability values (O₂ and CO₂) choose the multilayer KEOFITT Sterile Sampling Bag. When in need for sterilizing the flow path prior to sampling use the KEOFITT Aseptic Sampling Bag.

The product to be sampled should have a maximum viscosity of 1000 cP and should not contain particles larger than approx. 1 mm. in diameter. Products with somewhat higher viscosities may be sampled, only will it take longer.

The KEOFITT Spike Sampling Bag is a single-use product that may be incinerated after use. Actual disposal method depends on the nature of the product to be sampled.

2. KEOFITT SPIKE SAMPLING BAG CONSTRUCTION

2.1 Material

The KEOFITT Spike Sampling Bag is made from PP.

The KEOFITT Spike Sampling Bag is a multi-layer construction with a thickness of $0,19 \pm 0,05$ mm.

The barriers to gasses and water are limited (see gas permeability rates in the datasheet) which supports that samples needs to be analyzed within hours or days after sampling.

2.2 Primary port

The KEOFITT Spike Sampling Bag is equipped with a unique self-sealing septum allowing needles up to 3,5 mm in outer diameter.

The septum is made from Chlorobutyl rubber and sits in a housing made from polycarbonate.

2.3 Sealed septum housing

To protect the septum from becoming contaminated it is sealed off by a polypropylene cap.

Peeling off the polypropylene cap by hand easily gives access to the septum.

2.4 Secondary port

Next to the primary port is a secondary port designed as an integrated piece of tubing also containing a septum. The KEOFITT Spike Sampling Bag is supplied with the outlet port closed. Sample can be partly or fully extracted from the bag with a needle alternatively the hose can be cut open.

Upon a new welding process, using electrical welding pliers or a small welding rig, one may obtain a re-sealing of the bag.

2.5 Label

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

“KEOFITT Spike Sampling Bag”

Article number

Size

Lot id.

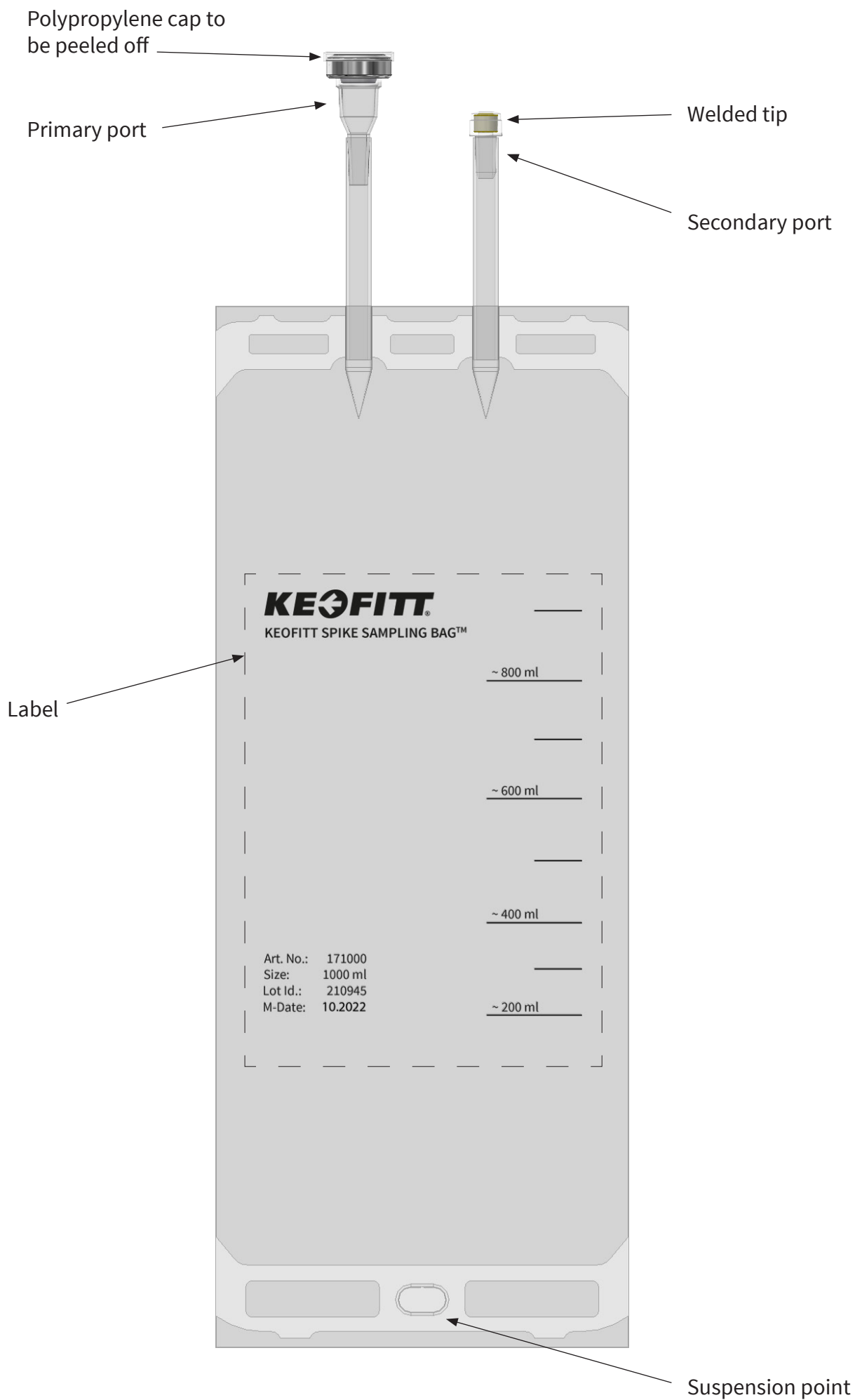
Manufacturing date

2.6 Suspension

The KEOFITT Spike Sampling Bags are foreseen with an integrated fixture for hanging the bag on a hook or similar device. When hanging up the KEOFITT Spike Sampling Bag, the primary and secondary port are pointing downwards. In this position the fluid will flow out of the KEOFITT Spike Sampling Bag by gravity. The KEOFITT Spike Sampling Bag will collapse gradually as it is emptied and is as such self-emptying.

2.7 Disposal

The KEOFITT Spike Sampling Bag (without membrane housing) can be disposed with household waste if in compliance with local or state laws and regulations. If the KEOFITT Spike Sampling Bag is not emptied before disposal, the nature of the sample always must be considered when choosing disposal.



3. KEOFITT SPIKE SAMPLING BAG FUNCTION

The KEOFITT Spike Sampling Bag is designed to provide the user with a safe and convenient way of collecting a liquid sample from a process line.

This chapter describes in detail the functionalities of the KEOFITT Spike Sampling Bag.

3.1 Pre-use storage

When delivered the KEOFITT Spike Sampling Bags are flat collapsed to take up only little space.

The KEOFITT Spike Sampling Bags are not individually wrapped as the aluminum cap covering the septum provides sufficient protection against contamination from the surroundings.

3.2 Pre-sample functions

After removal of the protective polypropylene cap the septum is ready for a needle or a KEOFITT Spike to be introduced through the septum into the KEOFITT Spike Sampling Bag.

As the KEOFITT Spike Sampling Bag is laid flat on delivery the amount of air inside the bag is minimized, which is an advantage especially in case the sample is sensitive to atmospheric air (and oxygen in particular).

3.3 Sampling

With the needle penetrating the septum sampling may now be carried out and it will take place in a closed circuit with no exposure to the ambient.

3.4 Transportation and storage

Once the sample is taken and the KEOFITT Spike Sampling Bag is pulled off the needle the auto-sealing properties of the septum assures complete tightness of the KEOFITT Spike Sampling Bag.

The KEOFITT Spike Sampling Bag requires no special precautions other than what would be considered for a similar sized plastic bottle.

For storage the KEOFITT Spike Sampling Bags may be suspended or laid flat down in many layers.

3.5 Retrieval of the sample

Once the KEOFITT Spike Sampling Bag is in the laboratory the sample may be retrieved either through the primary or secondary port.

3.6 Disposal

After use the KEOFITT Spike Sampling Bag is to be emptied completely before disposal. The KEOFITT Spike Sampling Bag itself is very well suited for incineration (temperature >800°C is strongly recommended), but the composition of the actual product being sampled may require a different method of disposal.

4. HOW TO OPERATE

This chapter explains how to take the sample and how to extract the sample afterwards. The KEOFITT spike bag holder (800017) is hereinafter referred to as the KEOFITT spike.

For other KEOFITT spikes or needles different procedures may apply; please consult the corresponding manuals or instructions.

4.1 Pre-sample preparation

Before taking the sample the sampling valve and the KEOFITT spike must be either cleaned/disinfected or steam sterilized. In either case refer to the User Manual for your sampling valve to perform the correct pre-sample operations.

The KEOFITT spike may be cleaned/disinfected/sterilized together with the sampling valve or the KEOFITT spike may be wrapped and autoclaved in advance and fitted to the cleaned valve just prior to taking the sample.



SAFETY

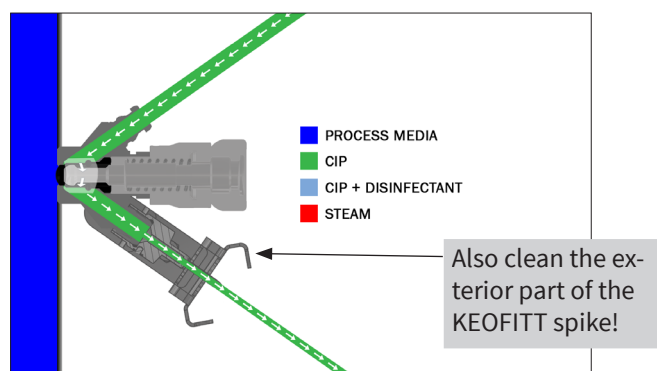
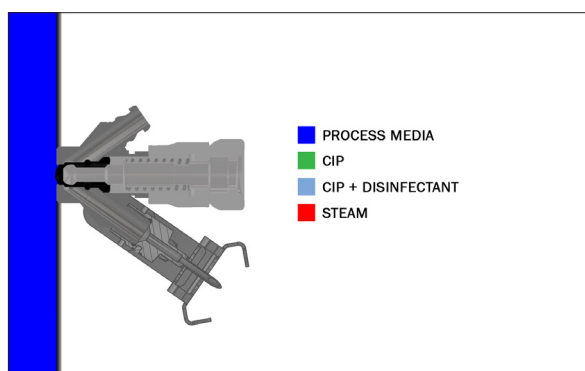
The tip of the needle on the KEOFITT spike has been covered by a protective bar in order to avoid the risk of being impaled upon the protruding KEOFITT spike.

If you are not using a pre-autoclaved KEOFITT spike, there are in principle the following ways to prepare for taking a sample with a KEOFITT Spike Sampling Bag; the choice of solution depends very much on the actual hygiene requirements:

4.1.1 Clean-In-Place (CIP)

With the KEOFITT spike fitted on the sampling valve perform the usual Pre-rinse – Clean - Final Rinse procedures; for cleaning use an appropriate cleaning agent.

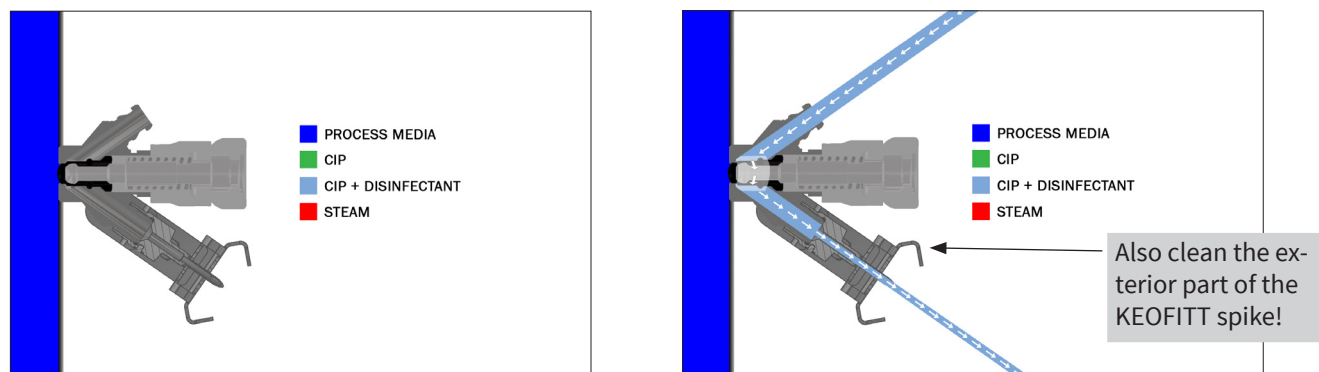
Make sure to also clean the outside of the KEOFITT spike to prevent contaminants being introduced through the septum during the sampling operation.



4.1.2 Disinfection

If disinfection is required by your hygienic standards the three CIP steps above must be followed by the application of an appropriate disinfectant and finished by a final rinsing.

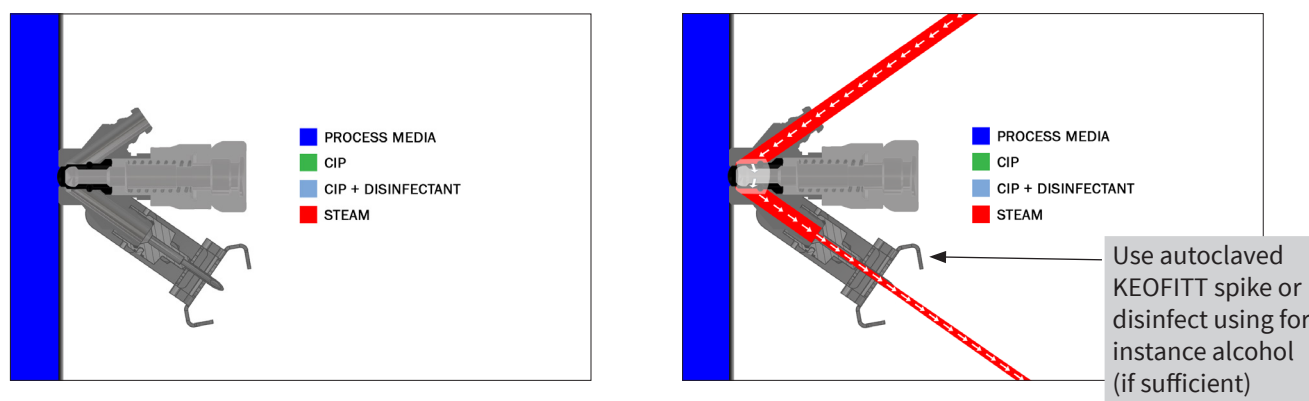
Make sure to also disinfect the outside of the KEOFITT spike to prevent contaminants being introduced through the septum during the sampling operation.



4.1.3 Steam sterilisation

Steaming has the advantage that it does flushing, cleaning and sterilization all in one operation. With the KEOFITT spike fitted on the sampling valve perform the steaming process as described in the Sampling valve User Manual.

Since the outside surface of the KEOFITT spike is not exposed to the steam, it is recommended to use autoclaved KEOFITT spikes; alternatively use a chemical disinfectant like alcohol and soak or rub the outside of the KEOFITT spike just prior to sampling.



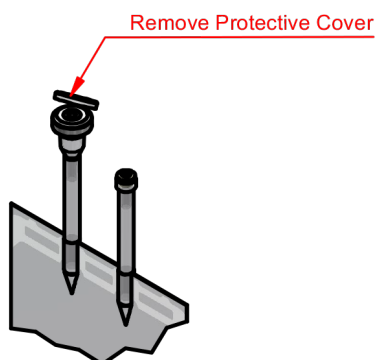
WARNING:

- Take care to avoid outgoing steam if steam is used or sterilization.
- The KEOFITT spike gets very HOT

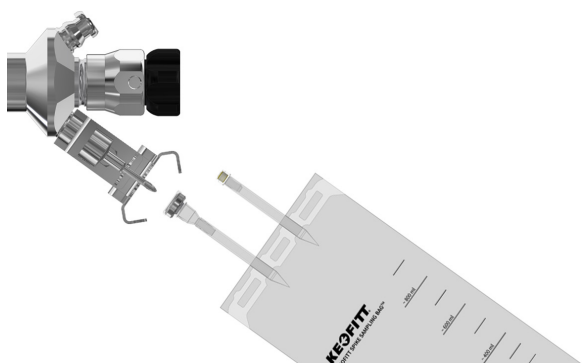
4.2 Inserting the KEOFITT Spike Sampling Bag

When everything is ready to take a sample perform the following steps:

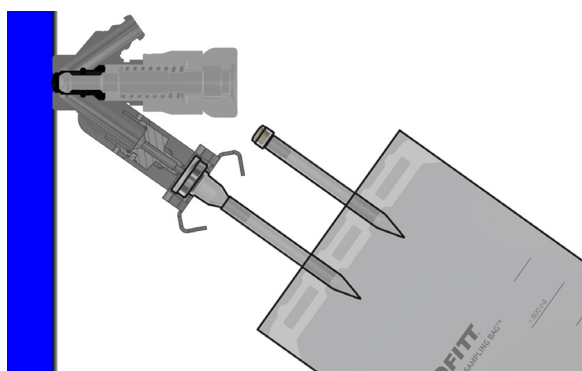
1. Remove the polypropylene cap from the KEOFITT Spike Sampling Bag's septum. Removal is to be done by hand.



2. Push the KEOFITT Spike Sampling Bag against the KEOFITT spike making sure the KEOFITT spike enters the slit in the septum



3. Push the KEOFITT Spike Sampling Bag further until penetration of the septum. Only then the KEOFITT spike is fully inserted



WARNING:

It is crucial that the KEOFITT Spike Sampling Bag is pushed all the way to the bottom of the KEOFITT spike holder to make sure the KEOFITT spike penetrates the septum correct.

4.3 Taking the sample

The actual process of taking a sample consists of the following steps:

1. With the KEOFITT Spike Sampling Bag in place hold it with one hand while opening the sampling valve slowly with the other hand.
2. Allow the liquid to fill the KEOFITT Spike Sampling Bag and turn off the valve once the required volume is obtained.
3. With the sampling valve closed pull the KEOFITT Spike Sampling Bag off the KEOFITT spike.



WARNING:

Do never exceed the nominal volume of the bag.

4.4 Storage of the sample

The sample is now securely contained within the KEOFITT Spike Sampling Bag without any risk of leaking or of any contaminants entering the sample.

Evaporation through the plastic wall 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 in the datasheet to assess a suitable maximum storage time. Similar action if the sample is sensitive to oxygen (O₂).

4.5 Retrieving the sample

The generally used methods of retrieving the sample is one of the following:

1. While suspended introduce a needle or a KEOFITT spike into the secondary port septum of the KEOFITT Spike Sampling Bag
2. As no. 1, but with the KEOFITT Spike Sampling Bag lying flat on a table
3. As no. 1 or 2, but use a syringe to extract a sample of the sample
4. Cut off the welded end of the secondary port and pour part or the entire sample into another container. If necessary, the secondary port may be re-welded for sealing and later cut open again
5. Like no 4, but instead of pouring, connect a piece of tubing to the secondary port by means of a barbed fitting. Connect the other end of the tubing to whatever relevant device or container.

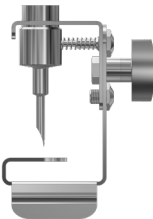
4.6 Disposal

Completely empty the KEOFITT Spike Sampling Bag before discarding it for incineration if incineration (>800°C is strongly recommended) is applicable. Large volumes of liquid will reduce the energy gain from incinerating the plastic KEOFITT Spike Sampling Bag.

If the sample media is of such a nature that the KEOFITT spike bag must not be incinerated, even when emptied, follow the waste instructions relevant for the actual sample media.

5. KEOFITT SPIKE SAMPLING BAGS AND ACCESSORIES

Below is an overview of the available KEOFITT Spike Sampling Bags.

KEOFITT SPIKE SAMPLING BAGS		
		 800017 QUICK COUPLING W9 SPIKE BAG HOLDER
	171000 KEOFITT SPIKE SAMPLING BAG 1000 ML	

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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