

STERISAMPLE[®]

Installation and Operation Manual



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Read this user manual carefully before unpacking Sterisample®.

Legal Note.

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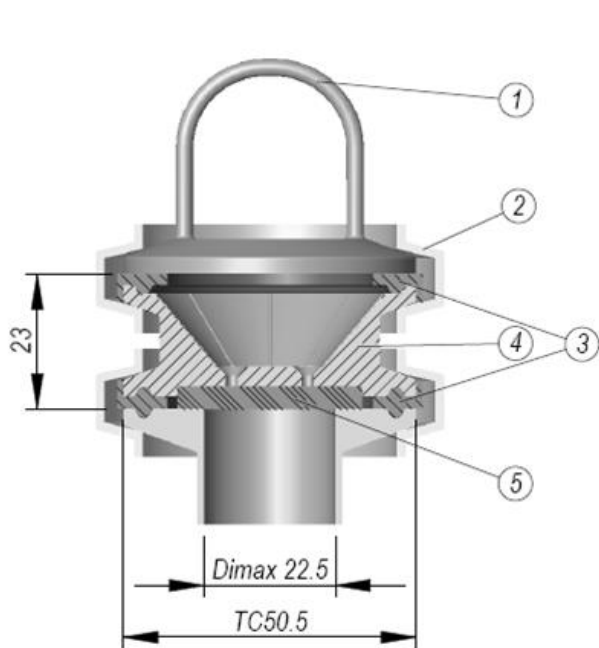
1 Introduction

The hypodermic sample port makes it possible to take samples of the product in an aseptic manner without disrupting the production. It is suitable for a wide range of processes/production lines within the pharmaceutical sector. Prior to sampling, the port is sterilized with alcohol and then sampling takes place by simply penetrating the special silicone membrane with a needle.

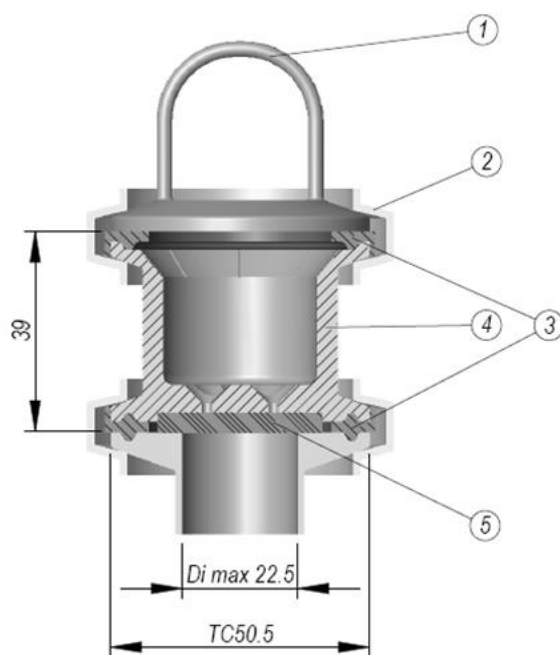
2 General description

The design of the sample port permits connection to any appropriate TC-connection. There is no need for a specially designed connection on the vessel, any standard TC-connection can be used.

The sample port unit consists of a blind flange with finger-pull, two TC-clamps, two TC gaskets, one sample port and one sample port membrane, see the table below and the figure.



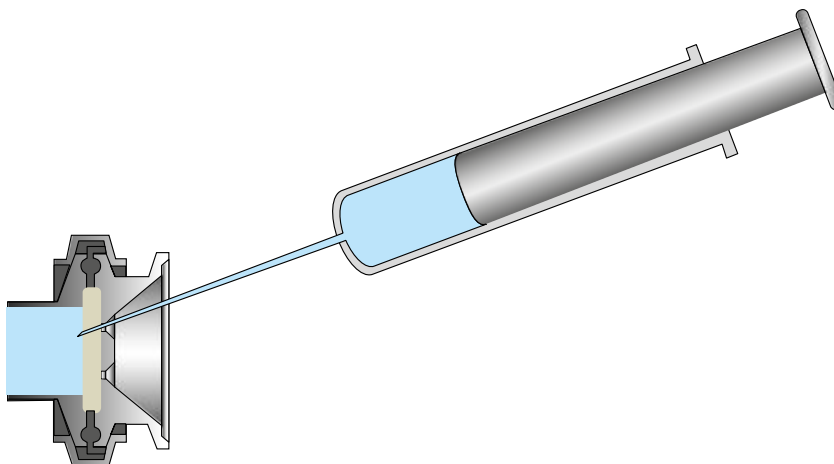
SR112712			
5	1	Membrane	SR110034
4	1	Sample port 50.5	N/A
3	2	TC-gasket 50.5/38	SR110334
2	1	TC-clamp 50.5/38	SR110014
1	1	Blind endcap 50.5/38	SR110335
Item	Qty	Denomination	Part No



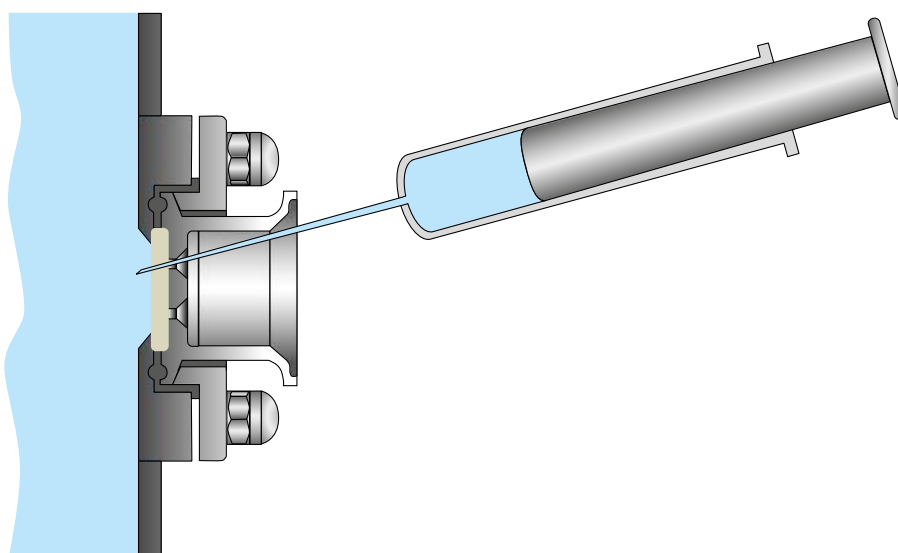
SR112714			
5	1	Membrane	SR110034
4	1	Sample port 50.5	N/A
3	2	TC-gasket 50.5/38	SR110334
2	1	TC-clamp 50.5/38	SR110014
1	1	Blind endcap 50.5/38	SR110335
Item	Qty	Denomination	Part No

There are two types of sample ports depending on where and how it will be installed.

Short Port for pipe with TC-end.



Long Port for vessel using flush mounted Steriflange.

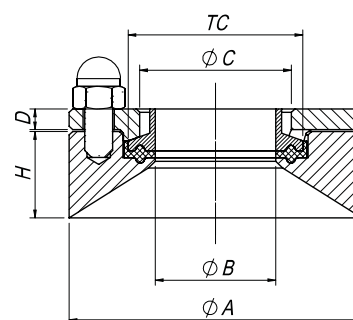


Note that the correct Steriflange must be used with the Long sample port in order to ensure proper sealing of the membrane.

Steriflange according to Tube standard ASTM A270 (mm)

SF ASTM M-100

Part No	Tube	A	B	C	D	TC	H
SR107810	25,4	85	22,1	43,8	6	50,5	12
SR107819							25
SR107828							38
SR107837							51



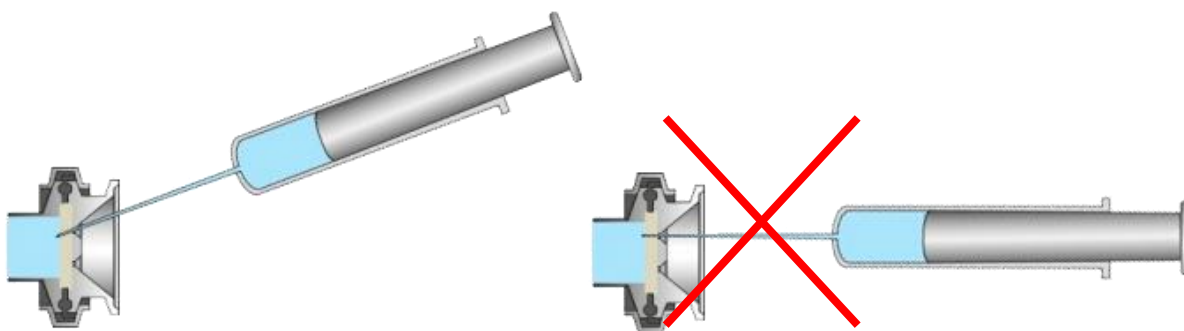
3 Orientation of Sample port

The sample port unit should be mounted so that the membrane is vertically or horizontally orientated. If the sample port unit is mounted with the membrane horizontal the sample port unit should be uppermost.

4 Sampling

The sample port is designed for sampling by using a hypodermic needle. The needle can be adapted to a syringe for sampling of small volumes, or connected to a sampling vessel by a short flexible hose. The sampling equipment should in both cases be sterile.

1. Spray the sample port unit with a 70% alcohol solution (or other equivalent disinfecting solution).
2. Dismount the TC-clamp, TC-gasket and the blind flange. Place the removed parts in a disinfecting solution (use gloves).
3. Spray disinfecting solution on the sample port and the membrane. Wait for approximately 30 seconds.
4. Study the checklist for the correct part number to identify which sampling well should be used (paragraph 6).
5. Insert the needle for sampling. In order to achieve reseal of the puncture spot, it is most important that the recommended insertion angle through the membrane is accomplished. See figure below. Recommended needle diameter is maximum 1mm.



6. Collect the required sample.
7. Pull out the sampling needle.
8. Spray disinfecting solution on the sampling port and the membrane.
9. Mount the TC-gasket, the blind flange and the TC-clamp.
10. Mark on the checklist which sampling well has been used.

Note: Penetration of the sampling port membrane should only be done once through the same sampling well. A penetrated membrane withstands a vessel pressure of 7 barg 80°C.

5. Technical data

If the sample port is connected in a WFI-system, please follow the instruction for exchange of membrane in WFI-system.

This should be done when the checklist for the sample port is completed.

5.1 Replacement procedure

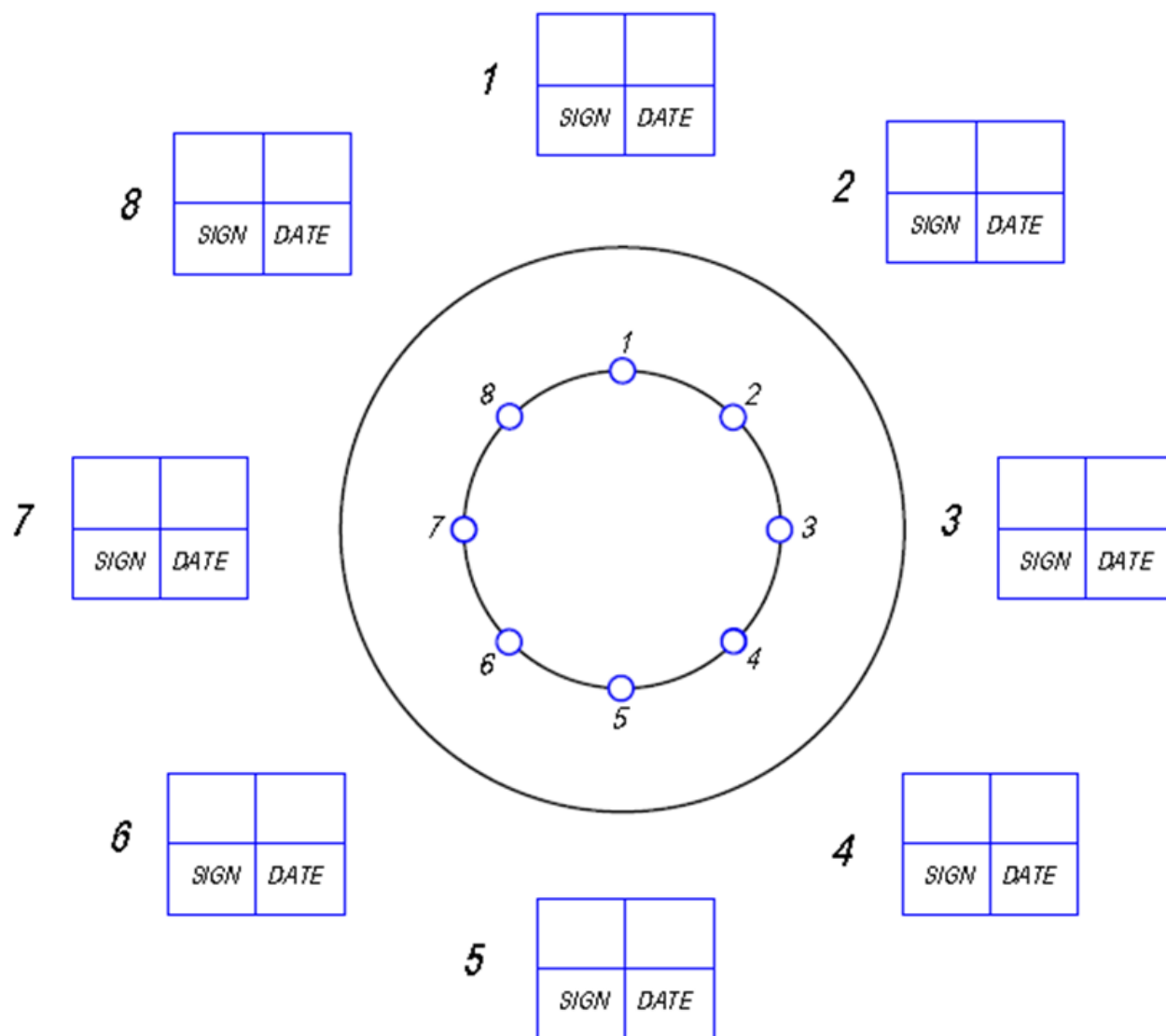
1. Shut down the system to which the sample port is connected. Ventilate the system. Drain the system to avoid spillage.
2. Dismount inner TC-clamp and place the outer parts of the sample port unit in a disinfecting solution.
3. Replace the used membrane. The new membrane should be soaked in disinfecting solution before exchanging.
4. Mount the outer part of sample port unit along with the TC-gasket and TC-clamp.
5. Change of membrane means that the system has been opened. It is therefore recommended that the systems is disinfected or sterilized as soon as possible.

Note: Only an original Steridose membrane can guarantee a leak-free sample port.

6. Checklist for Sample Port

Only one sample should be taken from each sampling well

Change the membrane when all sampling wells have been used.



Steridose is a global brand manufactured at the IDEX Material Processing Technologies plant in Canada. We are highly specialized in the design, development and manufacturing of magnetic coupled mixers and radial diaphragm valves.

Steridose is part of IDEX Corporation, with regional offices in key locations around the world. Steridose is represented in important certifying and standards organizations, most notably and relevant to the pharmaceutical industry, ASME BioProcessing Equipment standards committee (BPE). We help develop the standards and Good Manufacturing Practices that minimize risk for process interference.

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