



Introduction

Biopharmaceutical manufacturing involves multiple processes from cell culture in the upstream, cell harvest and protein purification in the downstream, and final fill and finish of the drug product. Each process step requires aseptic sampling, whether it is to monitor cell density, cell viability and metabolites in bioreactors, sterility and mycoplasma contamination in sterile media, bioburden, endotoxins and sterility in pre and post sterilizing filtration of the drug product. Many of these test applications require small and accurate volumes.

mdi AESS® sampling systems with sampling syringe are designed for up to 5mL precision volume sampling for testing applications involving small volumes. This is specially useful when sampling high value process fluids, for example in manufacture of monoclonal antibodies and orphan drugs. These precision sampling syringes have a least count of 200µl with an accuracy of $\pm 5\%$.

The easy to use accurate volume, precision sampling syringes have been specially designed to ensure sterility of the drawn sample. The plunger moves within a specially designed bellow sealed in the barrel to ensure that there is no microbial ingress from the environment.

Applications

Precision volume aseptic sampling for testing of:

- Cell viability
- Cell density
- Bioburden
- Sterility
- Bacterial endotoxins

Validated for

- Sterility as per USP <71>
- Class VI Plastics as per USP <88>
- Bacterial Endotoxin <0.25EU/ml
- Complies with USP <788> test for particulate matter in injections
- Bioburden level is < 1000 cfu/device device as per ISO 11737-1
- Gamma sterilized up to 50 kGy



Specially designed bellow sealed in the barrel

Specifications

Materials of Construction

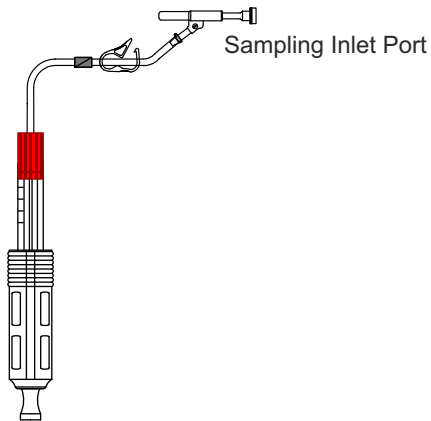
Syringe	Polycarbonate
Plunger	Polypropylene
Gasket	Silicone
Tubing	Thermoplastic Elastomer
	Platinum Cured Silicone
Septum	Platinum Cured Silicone
Needle	316L SS

Steam in Place (Sanitary flange adaptor assembly)	125°C for 30 min
Sterility	Gamma Irradiated

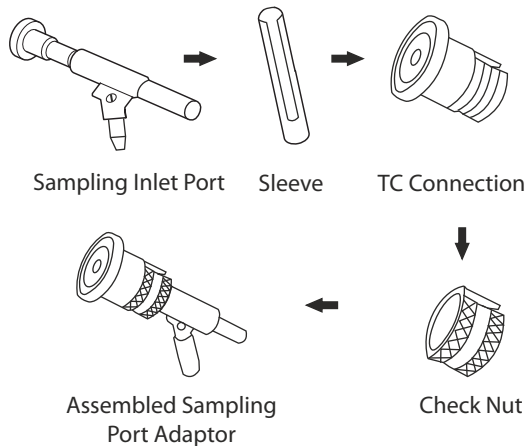
- 100% Integrity tested
- Non Animal Origin: Comply with the requirements laid down in the "Note for Guidance EMEA/410/01, rev.03" for inputs of Non Animal Origin

How to Use

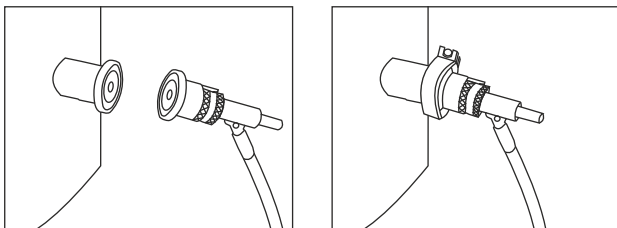
1. Take out the sampling syringe from the packing.



2. Fix the sampling port into the 25 mm ASESS sampling adaptor.

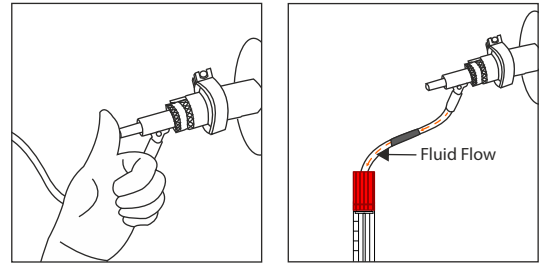


3. Attach the sampling syringe inlet port adaptor to the tri clover sampling port on the bioreactor/collection vessel with the help of a clamp.

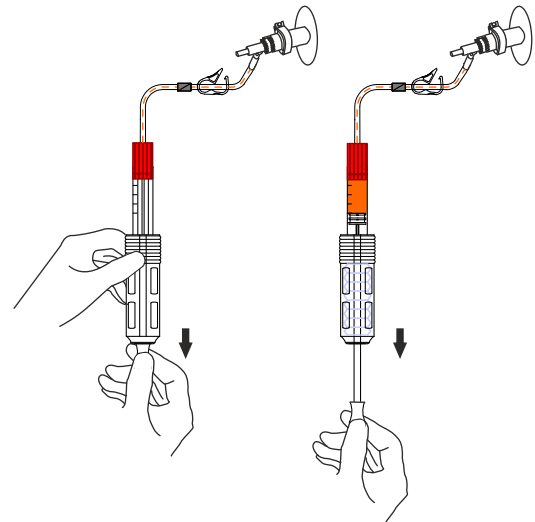


4. Sterilize the Bioreactor/vessel along with the aseptic sampling syringe inlet port by steaming in place the bioreactor vessel at 125°C for 30 minutes.

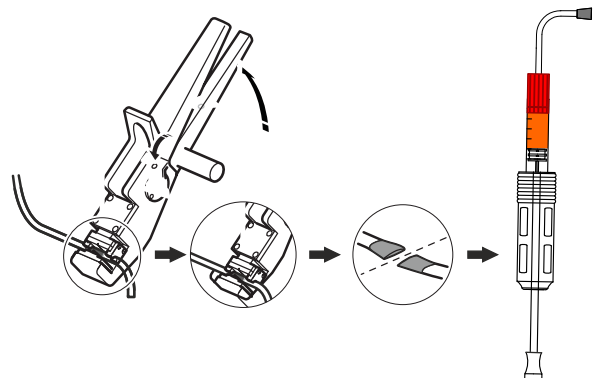
Once the steaming is completed, press the sampling adaptor back of the inlet port to puncture the platinum cured silicone septum within the port with the needle fitted inside to allow the sample fluid to flow into the sampling syringe.



5. Pull the plunger to draw the required volume of fluid for sampling.



6. Pinch and cut to remove the filled sampling syringe.



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