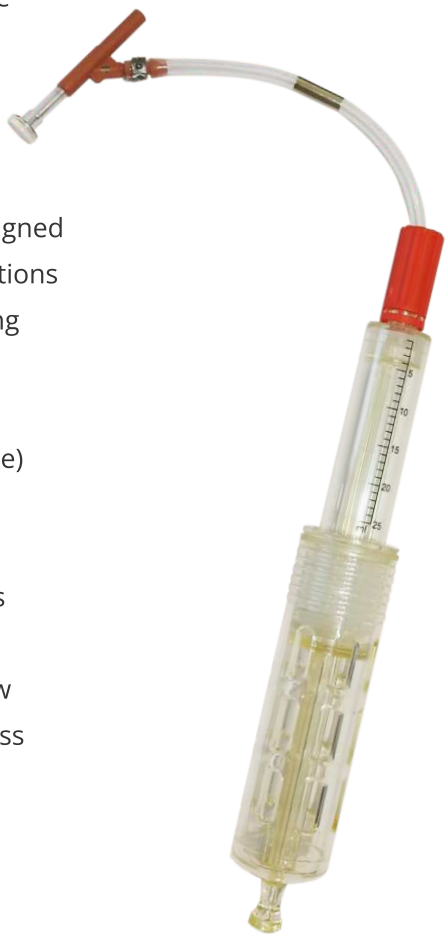
ASESS® Aseptic Sampling Systems with Precision Sampling Syringe

BROCHURE

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 ASESS® sampling systems with sampling syringe are designed for up to 25mL 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 (for 5mL Syringe) and 1mL (for 25mL Syringe) with an accuracy of ±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.

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Clean Room Manufacturing

mdi ASESS® sampling syringes are manufactured in clean rooms certified by external agencies and monitored in-house for viable and non viable particles. Employee hygiene, change rooms, gowning and de-gowning procedures and continuous monitoring of the areas is an essential part of these facilities. These facilities have been designed for unidirectional work flow with appropriate change rooms for personnel and air locks for material movement.

Quality Management Systems

mdi ASESS® sampling syringes are well designed products with in-built quality assurance. ISO-9001:2015 Certified Quality Management System, careful selection of raw materials, validated production processes and testing procedures based on international standards and guidelines such as CFR, PDA, and ASTM, ensures manufacture of consistently high quality sampling syringes.

Regulatory Compliance

mdi ASESS® sampling syringes are deeply characterized and validated to meet international regulatory requirements with regards to bioburden, endotoxins, particulate matter and extracables.

Biosafety

Passes Biological Reactivity test, In-Vivo, as per USP<88> for Class VI plastics.

Bioburden Testing

Bioburden level is < 1000 cfu/device as per ISO 1737-1:2018.

100% Integrity tested

mdi ASESS® sampling syringes are 100% integrity tested.

Non Animal Origin

The materials used for manufacture of mdi ASESS® sampling syringes do not contain substance of animal origin as per EMEA/410/01 Rev. 03.

Sterilization

By Gamma Irradiation: up to 50 kGy

By Autoclave: at 125°C for 30 minutes, 1 cycle

Sterility Assurance

The gamma sterilization process for gamma sterilized sampling syringes has been validated as per ISO 11137 to ensure a sterility assurance level (SAL) of 10^{-6}.

Endotoxin Testing

Aqueous extracts exhibit <0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>.

Fiber Release

Passes test as per USP and comply with USFDA Title 21 CFR Part 210.3(b)(6) for fiber release.

Particle Release

Complies with USP <788> test for particulate matter in injections.

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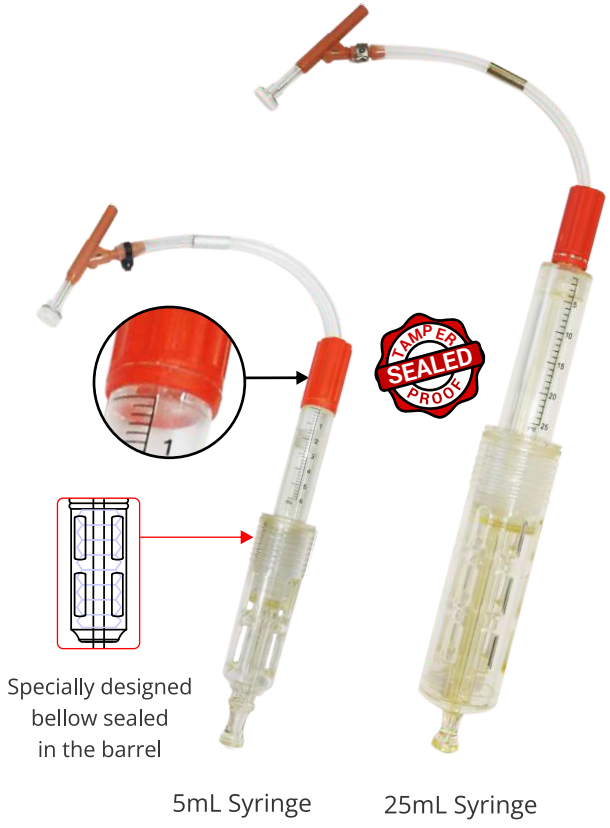
Applications

Precision volume aseptic sampling for testing of:

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



Specifications

Materials of Construction

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

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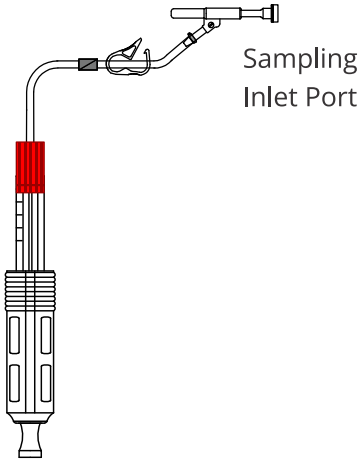
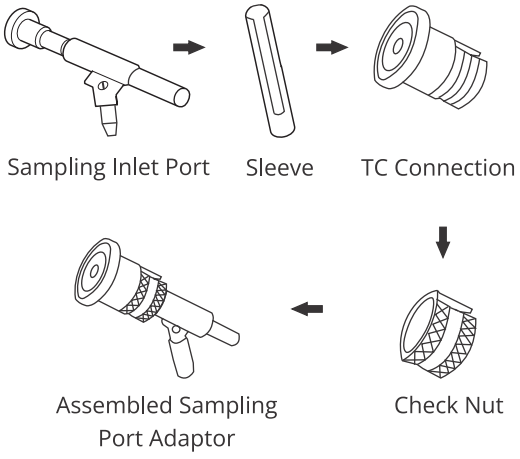
How to Use

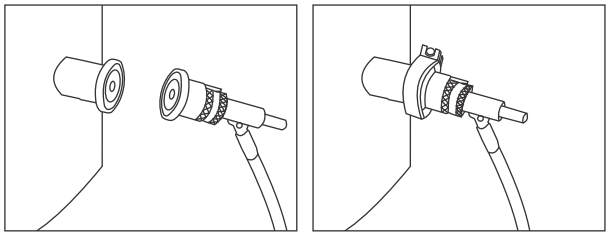
1. Take out the sampling syringe from the packing.



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

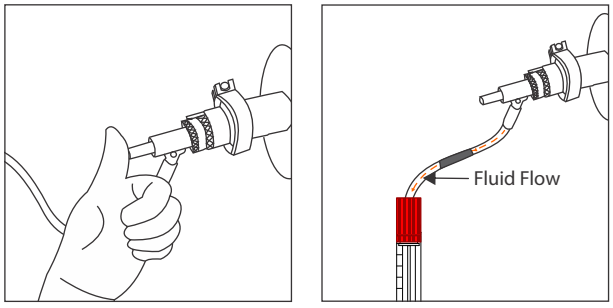


3. Attach the sampling syringe inlet port adaptor to the tri clover sampling port on the bioreactor/ collection vessel with the help of a clamp.

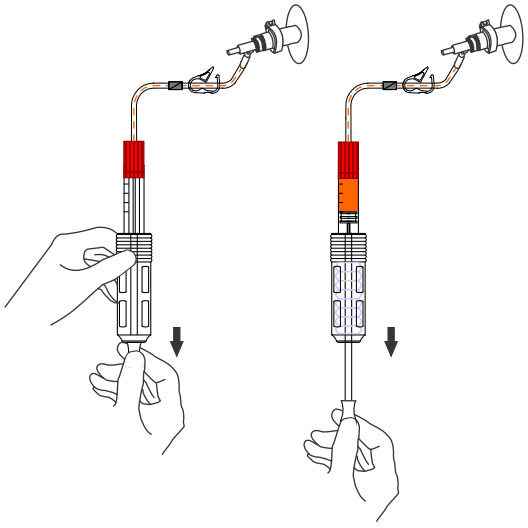


4. Sterilize the Bioreactor/vessel along with the aseptic sampling syringe inlet port by steaming in place the bioreactor vessel at 125°C for 30 minutes.

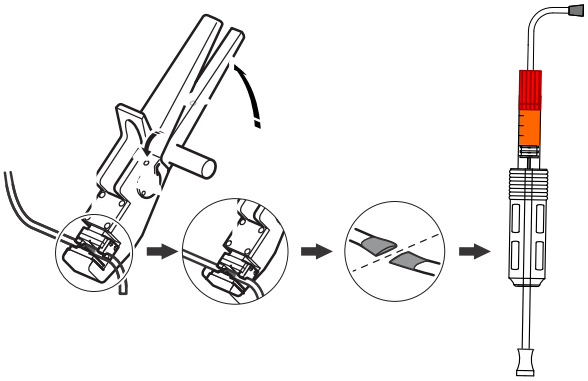
   Once the steaming is completed, press the sampling adaptor back of the inlet port to puncture the platinum cured silicone septum within the port with the needle fitted inside to allow the sample fluid to flow into the sampling syringe.



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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