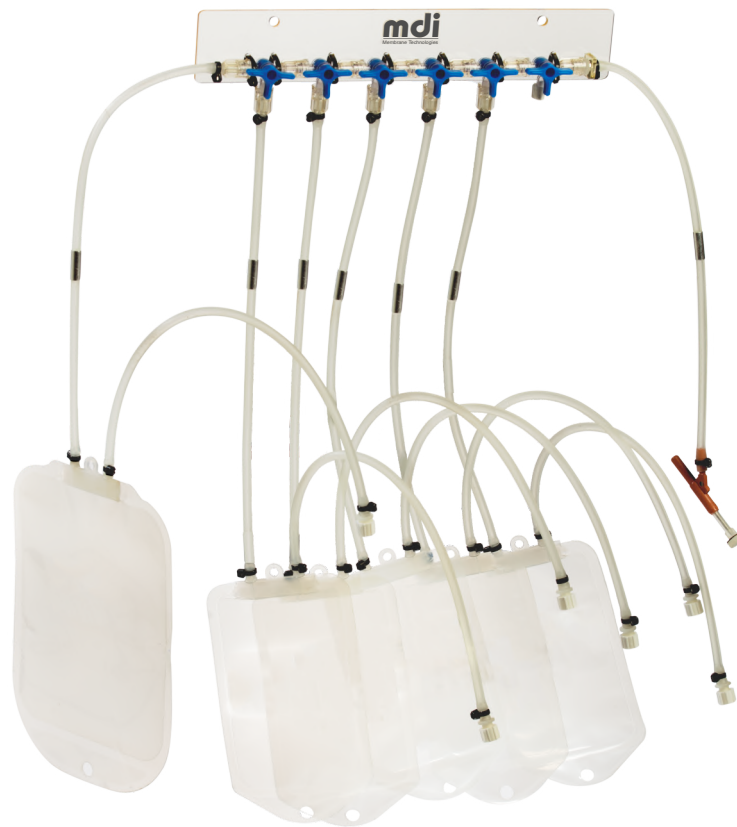


User Guide



ASESS Aseptic Sampling System

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1) Introduction

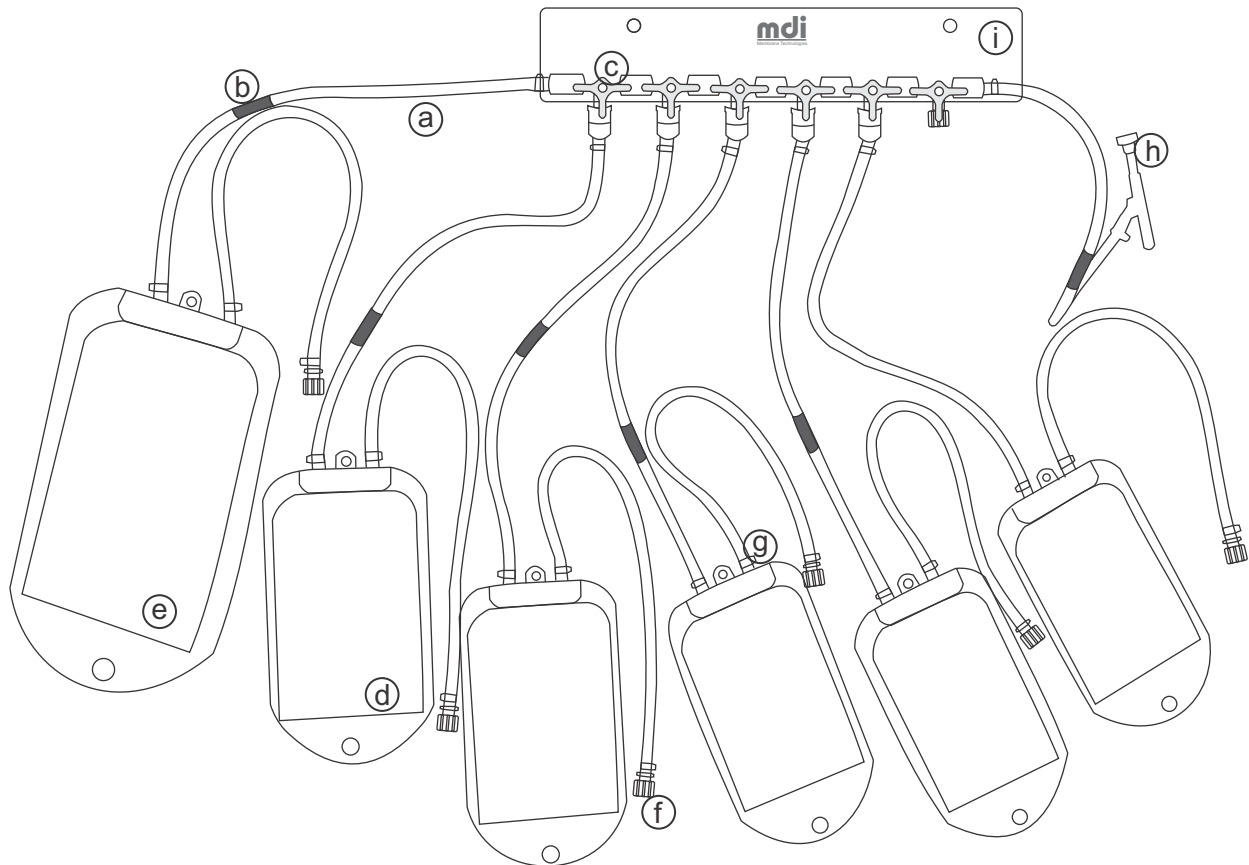
Pharmaceutical and biopharmaceutical processing needs a reliable system for real time aseptic access to bioprocess samples, their transfer, collection, storage and transportation to analytical and microbiology labs while maintaining process sterility. **mdi** ASESS Aseptic Sampling Manifold assembly, offered in different sizes, is a system of choice for sampling biopharmaceuticals and other process fluids for analytical purposes such as bio-burden, endotoxin, sterility testing, pH testing and chemical analysis.

Assembled in ISO Class 7 clean environment conditions, **mdi** ASESS is gamma irradiated, closed, disposable and integral system that ensures aseptic sampling to prevent environmental contamination, during sampling and transfer, that may risk the validity of the subsequent analyses preventing false results and test repetitions.

mdi ASESS constituents such as multilayered, impermeable sampling bags, thermoplastic tubings and platinum cured sampling port septum are of non animal origin and have broad chemical compatibility.

2) Components

- a) Tube
- b) Metallic Clamp Sleeve
- c) Three Way Valve
- d) Sampling Bag
- e) Drain Bag
- f) Outlet with female luer connection with plug
- g) Wire Ties
- h) Sampling Port
- i) Manifold Plate



3) Specifications

Operating Conditions

Operating Temperature	-20°C to 60°C
Operating Pressure	5 psi
Steam in Place (Inlet port fitted in sanitary flange adaptor assembly)	125°C for 30min

Materials of Construction

Bag	Multilayered Film type FBG-1
Tubing	Thermoplastic Elastomer
Septum	Silicone
Needle (1mm or 2mm)	316L SS

Available Capacity

50 ml, 100 ml, 150 ml, 250 ml, 500 ml, 1000 ml
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Sterility

Gamma Irradiation	upto 50 kGy
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4) Procedure of Use (Summary)

Package Description

The ASESS Sampling Manifold System is gamma sterilized double polyethylene bagged.

Attaching the ASESS sampling manifold to the Bioreactor/Vessel

- i) Cut open the polyethylene bags.
- ii) Hang the ASESS Sampling manifold with the help of nylon thread on to the bioreactor/vessel near to the sampling port.
- iii) Fit the Aseptic sampling manifold inlet port in the sanitary flange sampling port adaptor.
- iv) Attach the sampling manifold inlet port adaptor to the tri clover sampling port on the bioreactor/ collection vessel with the help of a clamp.
- v) Sterilize the Bioreactor/vessel along with the aseptic sampling manifold inlet port by steaming in place the bioreactor vessel at 125°C for 30 minutes.
- vi) Close the main cut off valve by rotating the knob towards the left (as shown in the picture).
- vii) 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 upto the main cut off valve.
- viii) Close all the valves of sampling bags by rotating upwards (as shown below) and open the cut off valve by either rotating upwards or downwards. The Initial sample fluid will flow into the drain bag.
- ix) Open the first valve from the right by rotating it towards right once sufficient quantity of fluid is drawn in the drain bag. Sample fluid will flow into the first sampling bag
- x) Close the valve once desired amount of fluid samples for testing has been drawn into the first bag. Open the second valve and repeat the same procedure for all the other as and when required.

Note: To stop the sample fluid to flow into any of the sampling bag midway close the main cut off valve and not just the respective sampling bag valve, else the fluid will flow into the drain bag.
- xi) Pinch and cut to remove the filled sampling bag.
- xii) It is now ready for testing.

Attaching the multiple ASESS sampling manifold to the Bioreactor/Vessel

- i) Cut open the polyethylene bags.
- ii) Hang the multiple ASESS Sampling manifolds with the help of nylon thread on to the bioreactor/vessel near to the sampling port.
- iii) Fit the Aseptic sampling manifold inlet ports of all sampling manifolds in the multipoint sanitary flange sampling port adaptor.
- iv) Repeat steps from iv to xii from above section.

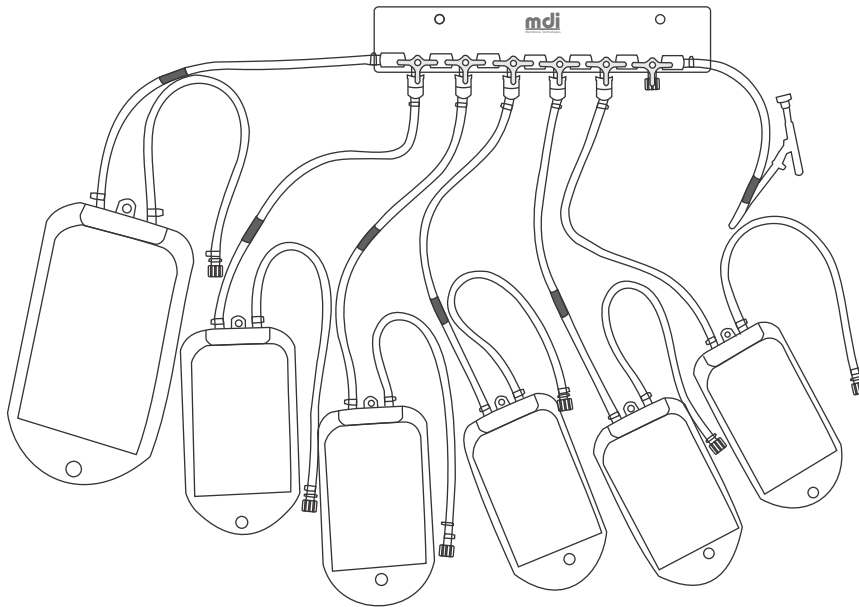
5) Procedure of Use (Description)

Package Description

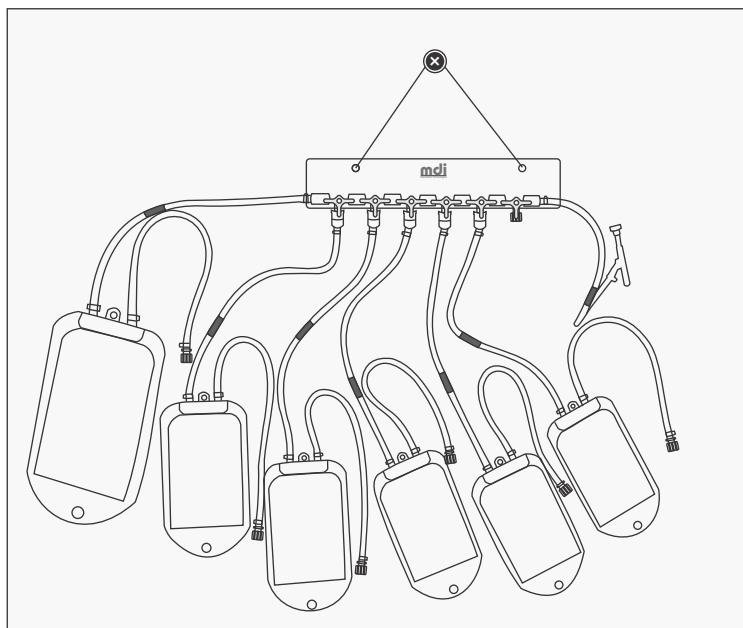
The ASESS Sampling Manifold System is gamma sterilized double polyethylene bagged.

5A) Attaching the ASESS sampling manifold to the Bioreactor/Vessel

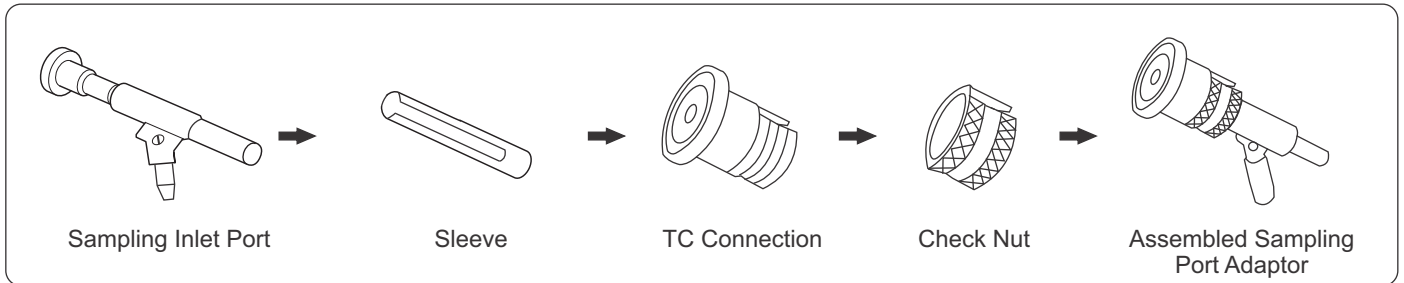
- i) Cut open the polyethylene bags.



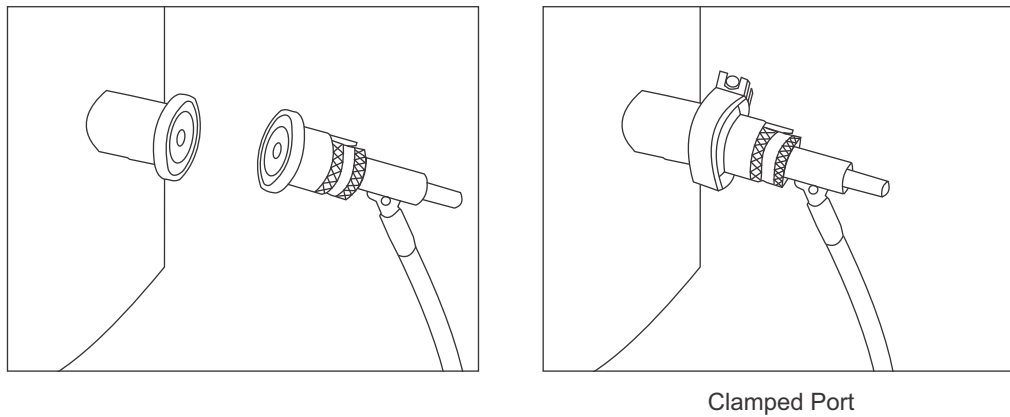
- ii) Hang the ASESS Sampling manifold with the help of nylon thread on to the bioreactor/vessel near to the sampling port.



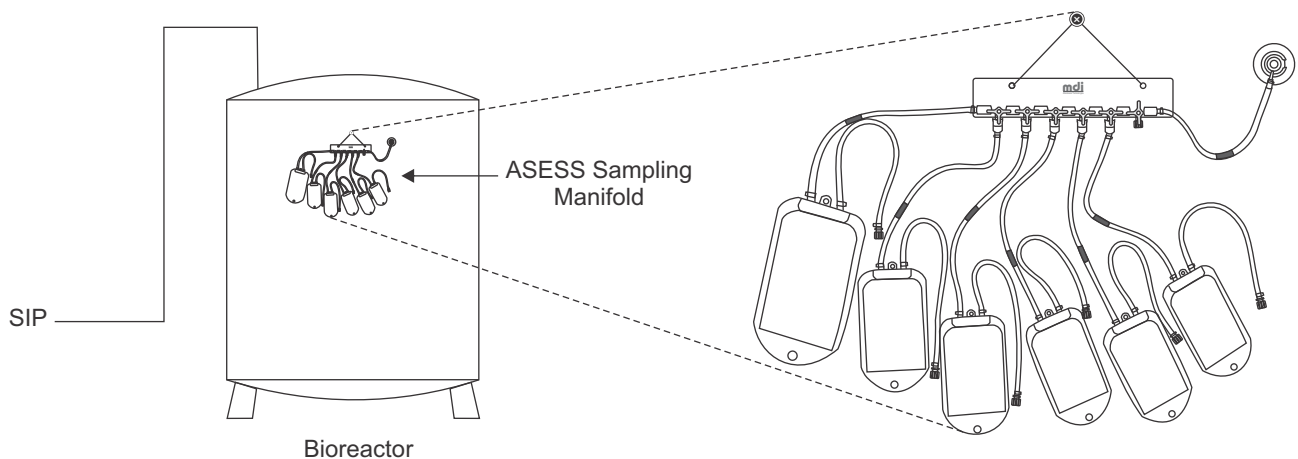
- iii) Fit the Aseptic sampling manifold inlet port in the sanitary flange sampling port adaptor.



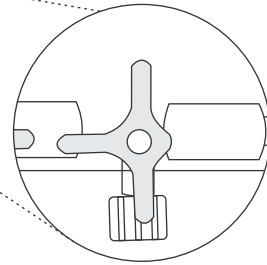
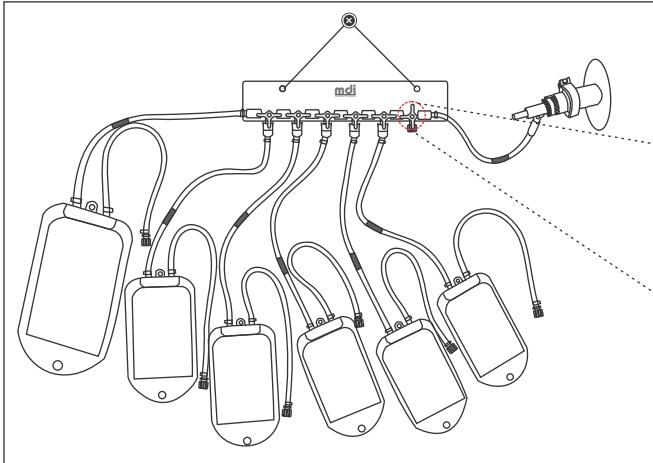
- iv) Attach the sampling manifold inlet port adaptor to the tri clover sampling port on the bioreactor/ collection vessel with the help of a clamp.



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

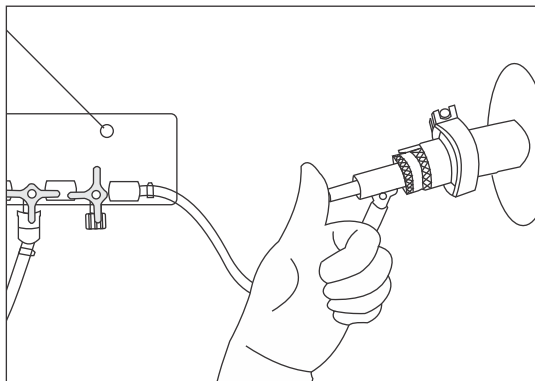


- vi) Close the main cut off valve by rotating the knob towards the left (as shown in the picture).

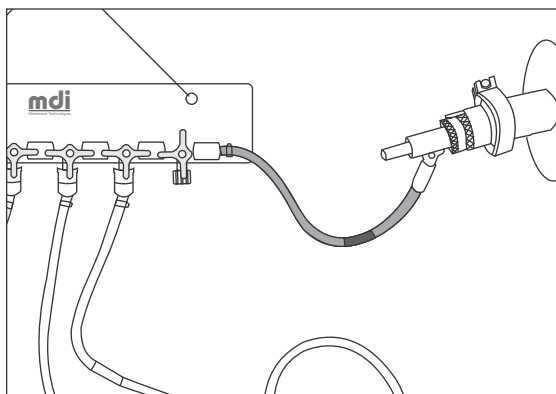


Closed Valve

- vii) 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 upto the main cut off valve.



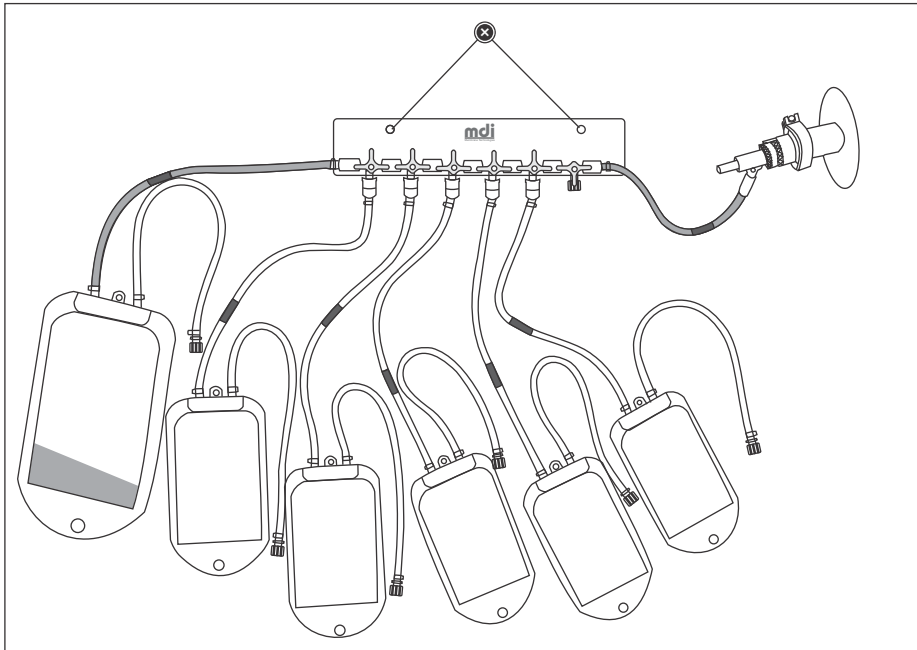
Pressing the Adaptor to puncture the Septum with needle



Flow of fluid from the vessel into the tube upto the main cut off valve

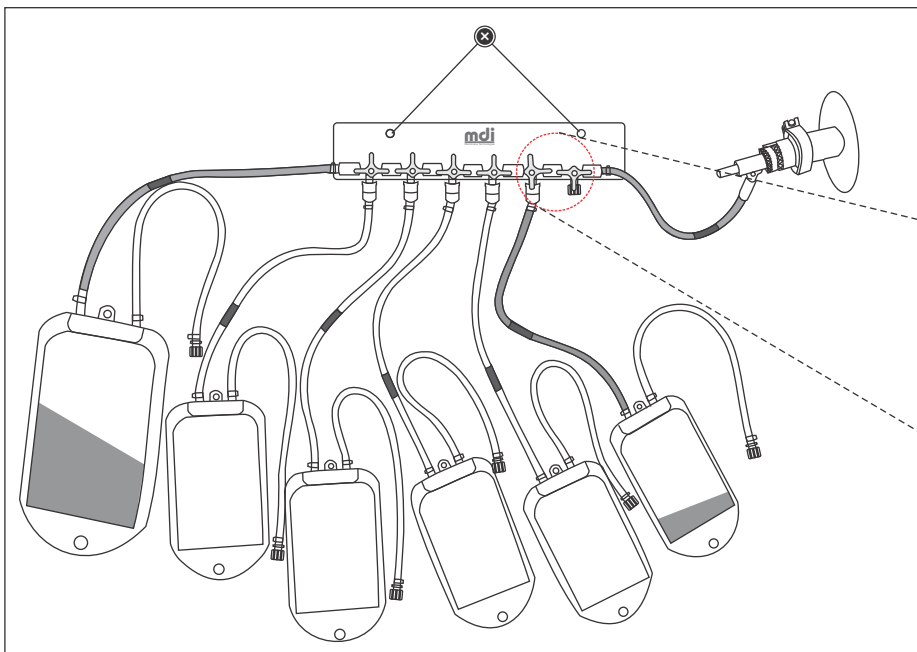
viii) Close all the valves of sampling bags by rotating upwards (as shown below) and open the cut off valve by either rotating upwards or downwards.

The Initial sample fluid will flow into the drain bag.



Sample fluid flowing into the drain bag

ix) Open the first valve from the right by rotating it towards right once sufficient quantity of fluid is drawn in the drain bag.

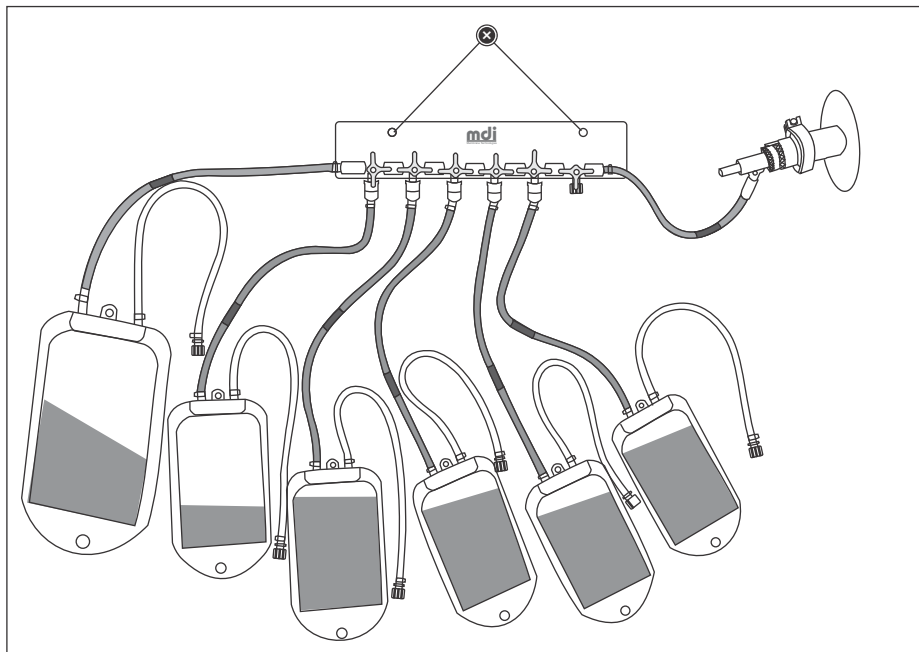


Open Valve

Sample fluid will flow into the first sampling bag

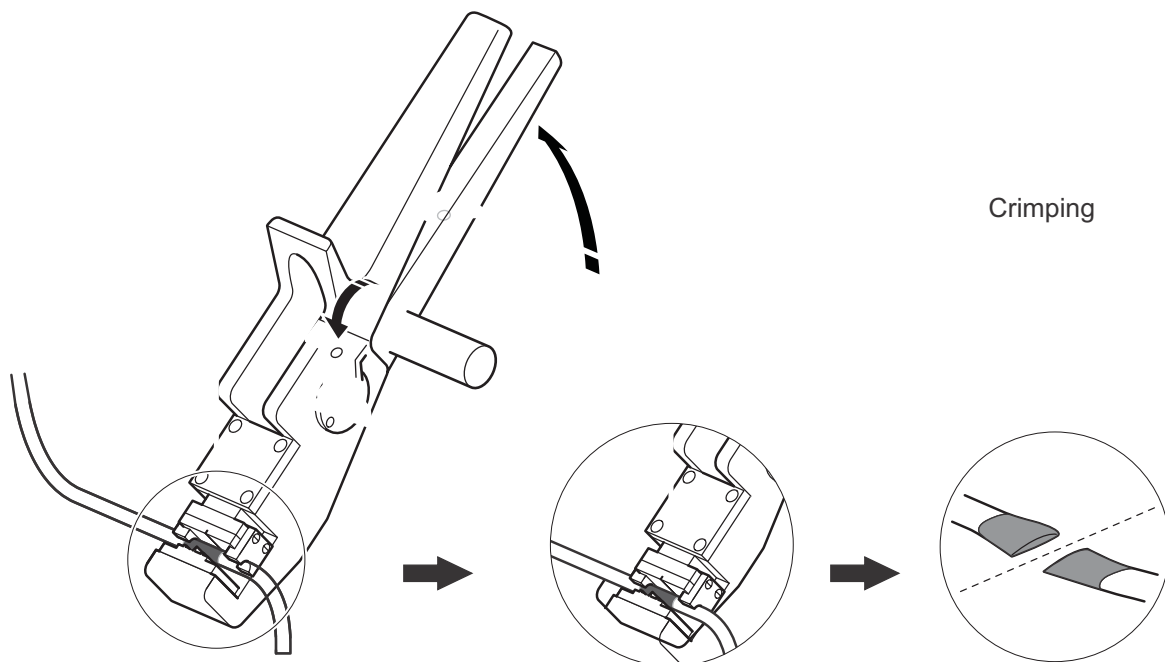
- x) Close the valve once desired amount of fluid samples for testing has been drawn into the first bag. Open the second valve and repeat the same procedure for all the other as and when required.

Note: To stop the sample fluid to flow into any of the sampling bag midway close the main cut off valve and not just the respective sampling bag valve, else the fluid will flow into the drain bag.



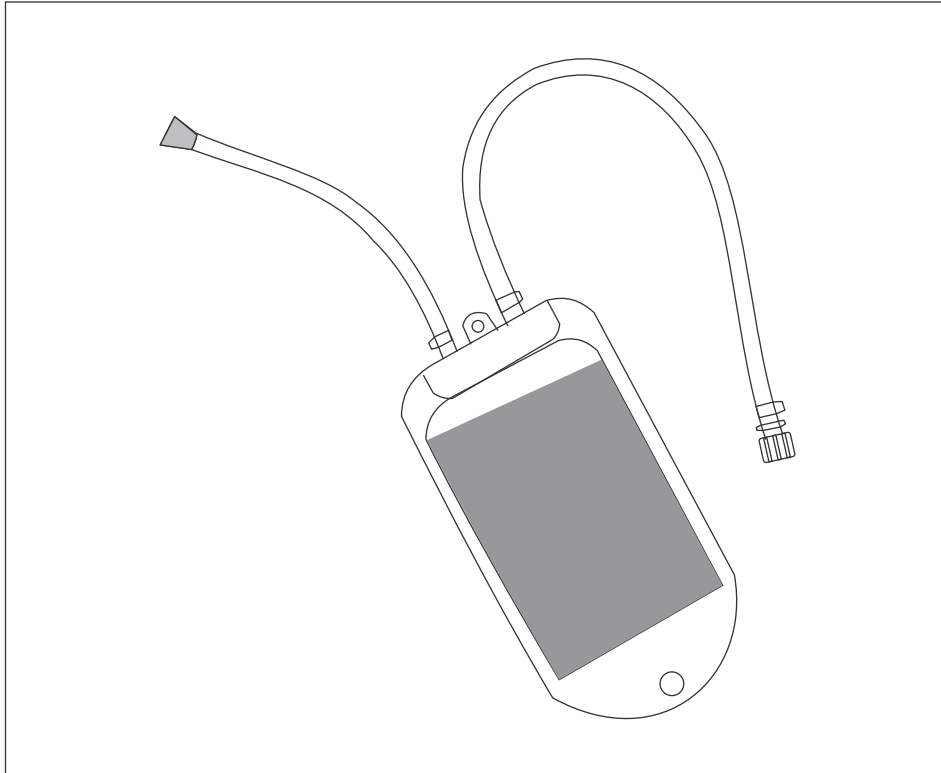
Samples drawn for testing

- xi) Pinch and cut to remove the filled sampling bag.



Crimping

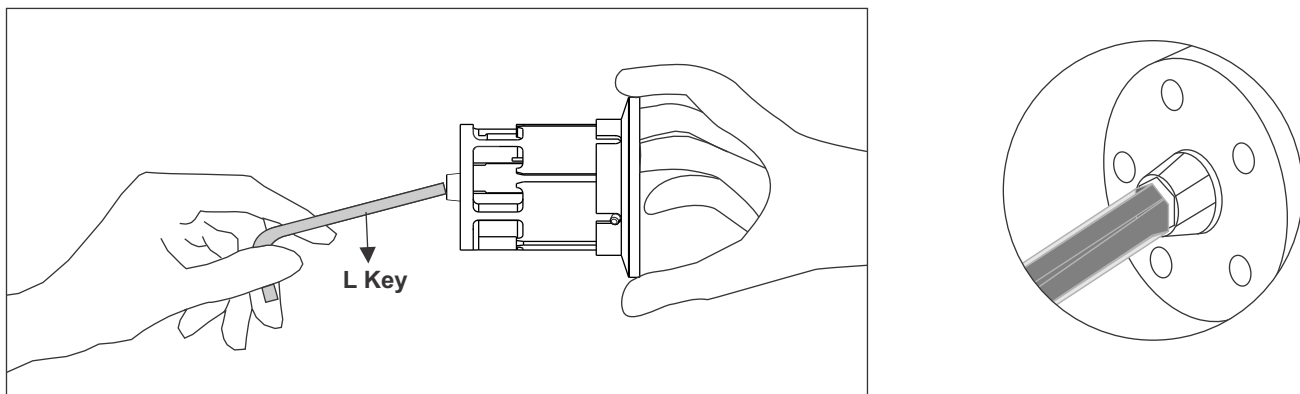
xii) It is now ready for testing.



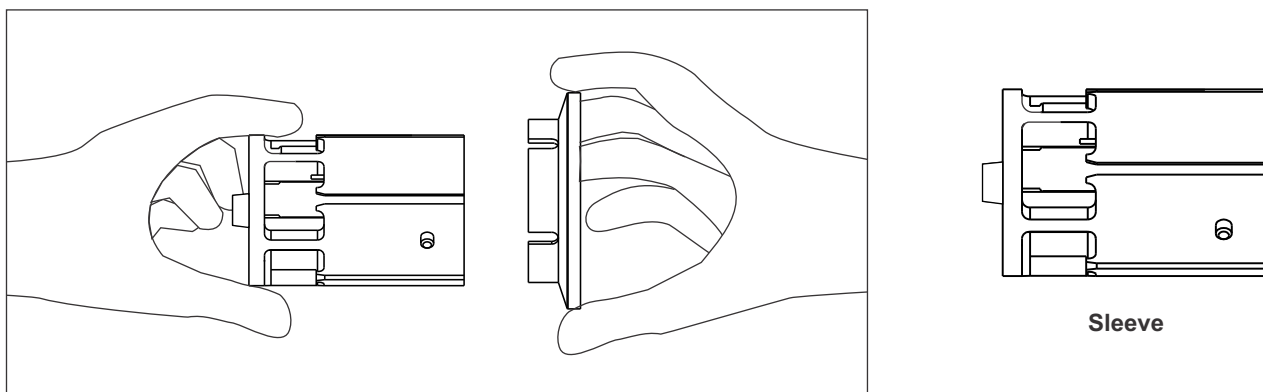
5B) Attaching the Multiple ASESS sampling manifold to the Bioreactor/Vessel



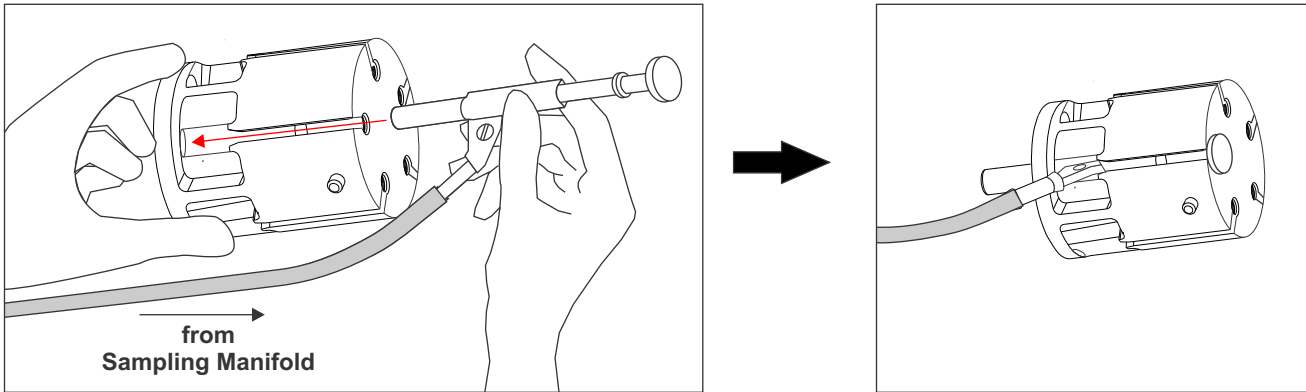
- i) Open the front TC portion of sampling port adapter by opening the nut on the back side of sleeve with the help of L key.



- ii) Detach the front TC portion of sampling port adapter from sleeve.

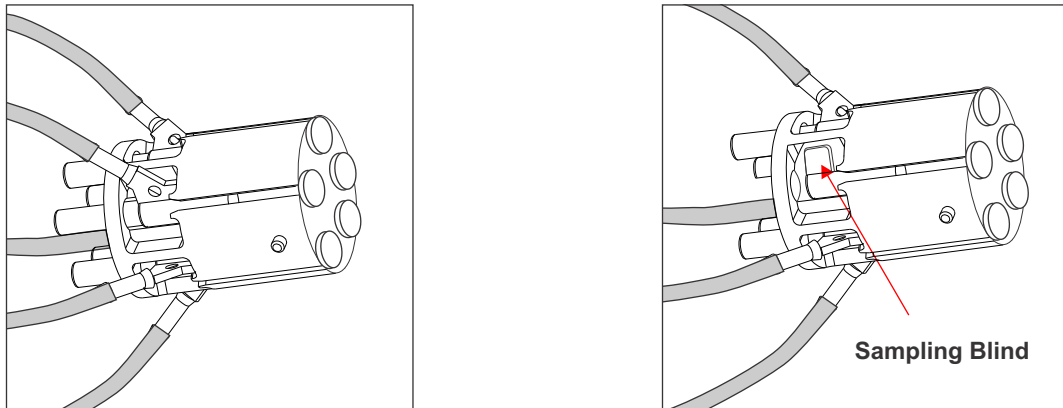


iii) Now insert the sampling port into the grooves provided in the sleeves.

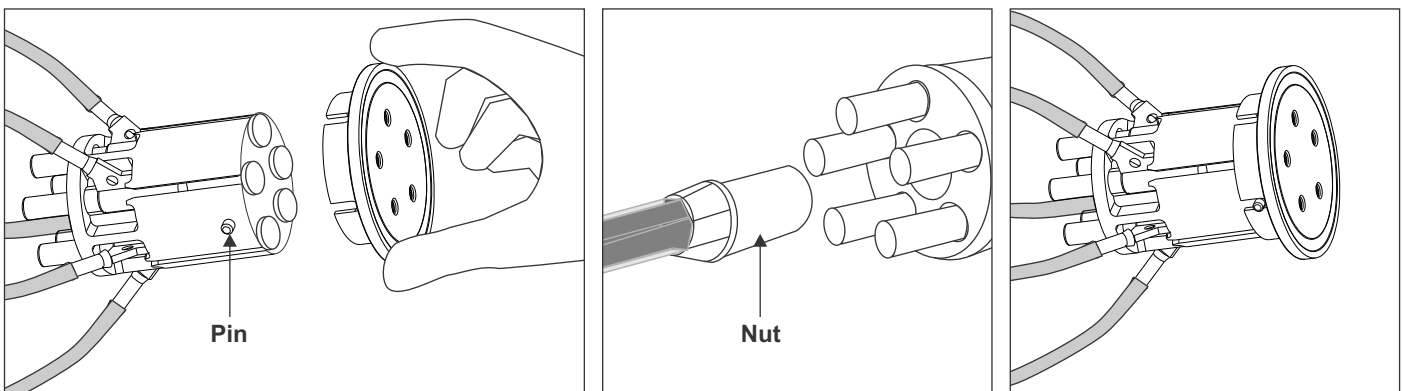


iv) Insert other sampling ports into the other grooves one by one.

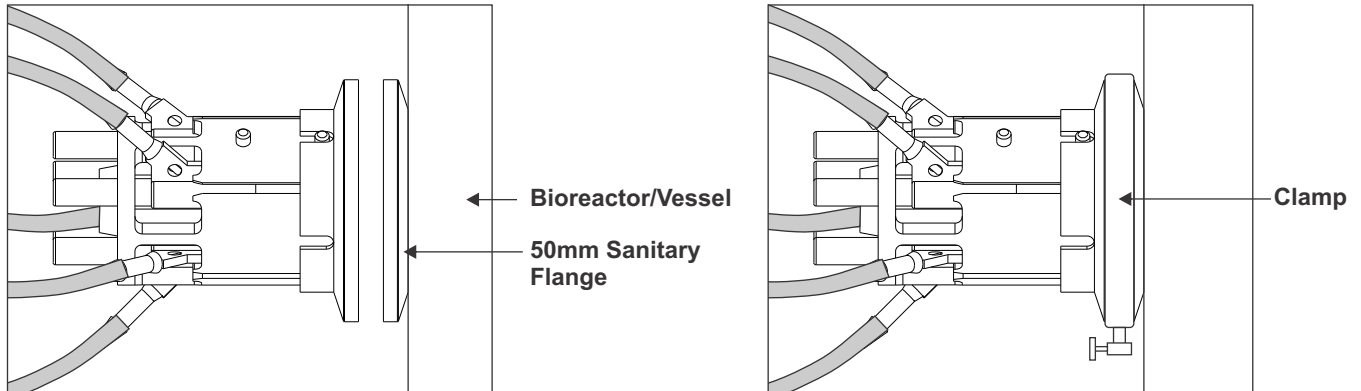
Note: In case if required number of sampling manifolds are less than five, then sampling blind need to be inserted in place of blank groove on sleeve.



v) Attach the SS Sanitary Flange at front of sleeve with the help of nut in the back. Rotate the nut in clockwise direction to fit the nut. Align the SS sanitary flange with the pin on the sleeve. The pin must sit inside one of the groove on the sanitary flange for perfect alignment.



vi) Connect the Sampling port adapter with 50mm sanitary flange on bioreactor/vessel with the help of clamp.



vii) Repeat the **steps from v to xii** from **section 5A**.

Precautions

- Make sure all the clamps tightened properly
- SIP should be done within the specified range of temperature
- While using the sampling manifold must be hung safely on the bioreactor