

Stainless Steel XCell® ATF 4, 6, and 10 Housings

User Guide

For Use with:

- XCell® ATF 4 Housing
- XCell® ATF 6 Housing
- XCell® ATF 10 Housing



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Abbreviations

μm	micron
A2B	ATF to bioreactor
ATF	Alternating tangential flow
DAC	Disposable aseptic connector
FAS	Field Application Specialist
H	Height
HFF	Hollow fiber filter
hr	hour
IPA	Isopropyl alcohol
kDa	kilodalton
L	Length
lb-ft	pound-foot
m	meter
MF	Microfiltration
MU	Multi-use
NaOH	Sodium hydroxide
PA	Pump air side
PES	Polyethersulfone
PL	Pump liquid side
ppm	parts per million
PS	Polysulfone
psi	pounds per square inch
psig	pounds per square inch, gauge
sccm	standard cubic centimeters per minute
SIP	Steam in place
SS	Stainless steel
SSB	Stainless steel bioreactor
SU	Single-use
SUB	Single-use bioreactor
UF	Ultrafiltration
W	Width

California Proposition 65 Warning



Warning This product can expose you to chemicals including lead, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov/product.

1. Introduction

XCell® ATF Technology uses alternating tangential flow (ATF) to intensify upstream processes by retaining cells in suspension cultures, such as mammalian cell culture and viral vectors. An innovative diaphragm pump creates alternating tangential flow, leading to high viable cell densities and increased throughput with lower cost of goods. Typical applications include intensification of the following processes:

- N-1 fed-batch
- Long-term continuous processing
- Vaccine and virus production
- Gene therapy and media exchange

Stainless steel XCell® ATF 4, XCell® ATF 6, and XCell® ATF 10 Housings enable production of high density, high viability cell culture applications with linear flux and low shear for scale-up to 5000+ L. The stainless steel product line includes the housings, XCell® Lab and LS Controllers, software, tubing set kits, pressure sensors, and accessories.

Hollow fiber filters (HFF) used in XCell® ATF Technology are made of Polyethersulfone (PES) or polysulfone and are available in 0.2 and 0.5 µm and 50 kD pore size and 1 mm inner diameter and are scalable across device sizes.

Single-use tubing set kits and accessories are available for the connection of XCell® ATF 4, 6, and 10 Stainless Steel Housings to both stainless steel and single-use bioreactors, simplifying preparation and connectivity and allowing for the proper exchange of cell culture material. XCell® Lab and XCell® LS Controllers operate the diaphragm pump. The housings and tubing set kits are also compatible with legacy C410 Controllers. Additional information on the use of the controllers and XCell® ATF Technology can be found in XCell® Lab Controller User Guide and XCell® LS Controller User Guide. Use of the XCell® ATF 2 Stainless Steel Housing is described in XCell® ATF 2 and 4 Stainless Steel Housings User Guide.

This document describes the major components, set-up, connectivity, and preparation of the stainless steel XCell® ATF 4, 6, and 10 Housings and hollow fiber filters. Users should possess a basic level of skill in the areas of aseptic technique and fluid handling.

For further support in optimizing or troubleshooting, please contact your local Repligen Field Applications Specialist (FAS).

2. Description of XCell® ATF Housings

Stainless steel XCell® ATF Technology includes three sizes of housings and compatible tubing set kits to support a fully scalable process. An integrated diaphragm pump provides alternating tangential flow through a hollow fiber filter which retains large components (i.e., cells) and removes waste or product components (permeate/filtrate). An additional pump continuously removes cell-free permeate from the system.

2.1 Components

- **Filter housing:** stainless steel housing containing hollow fiber filter
- **Diaphragm pump:** spherical housing in which a silicone diaphragm membrane is inflated and deflated by pressurized air or vacuum, creating alternating flow
- **XCell® ATF to bioreactor (A2B) connection:** tubing set kit connecting the housing to a bioreactor
- **Bioreactor adapter:** adapter between the connection assembly and bioreactor port. Typical fittings for stainless steel bioreactors include Ingold or tri-clamp. Single-use bioreactors (SUB) use disposable, aseptic connectors.

Note: *Bioreactor adapter is not provided.*

- **Hollow fiber filter (HFF):** 0.2 or 0.5 µm or 50 kD pore size filter, positioned between the bioreactor and the diaphragm pump
- **Permeate/harvest tubing:** sterile tubing and fittings connecting the housing to the collection vessel. Compatible with a permeate/harvest pump.

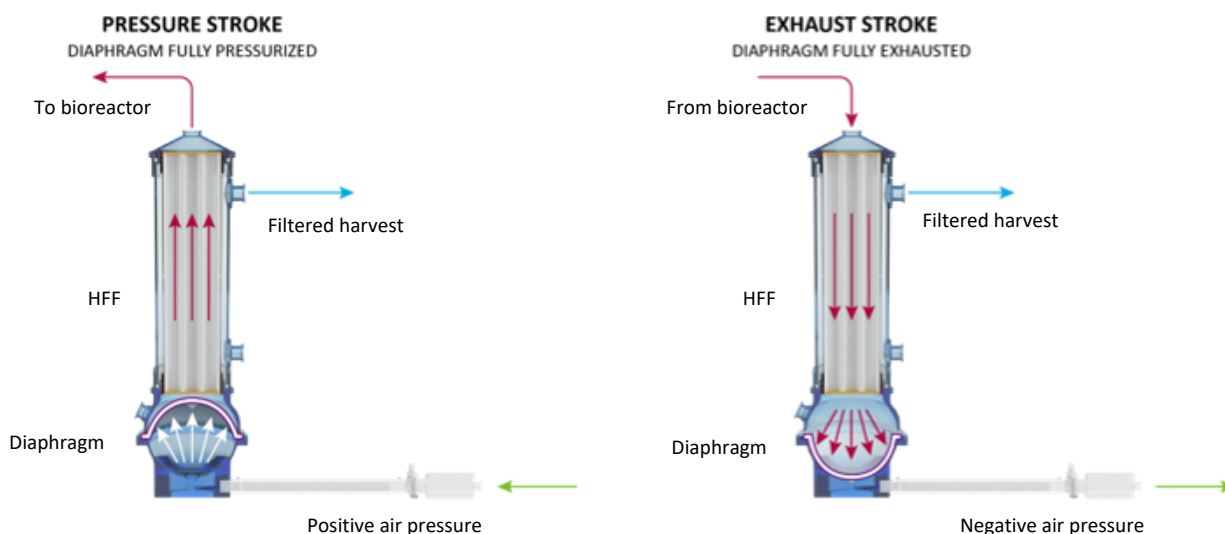
Note: *Permeate/harvest tubing and pump are not provided.*

2.2 XCell® ATF Housing pump cycle

The diaphragm pump of the **Error! Unknown document property name.** Device generates alternating tangential flow (ATF) through hollow fiber filters. ATF is a continuous, low shear, pulsating, and bi-directional flow of cell suspension between a bioreactor and a diaphragm pump (**Figure 1**). Cells move back and forth through the lumen of the hollow fiber filters. Two strokes of the diaphragm pump, the Pressure stroke (P-stroke) and the Exhaust stroke (E-stroke), complete each back-and-forth cycle.

Delivery of positive air pressure to the base of the diaphragm by the pressure control valve in the controller initiates the P-stroke. Positive air pressure pushes the diaphragm up from the *air-side* hemisphere of the device, driving liquid from the diaphragm pump through the lumen of the hollow fiber filters and back to the bioreactor. Replacement of the positive pressure under the diaphragm pump with a vacuum initiates the E-stroke. The vacuum pulls the diaphragm down from the *liquid-side* hemisphere of the device, pulling liquid from the bioreactor through the hollow fiber lumens and towards the diaphragm pump.

Figure 1. Pressure and exhaust strokes



Note: XCell® ATF Housings require a vacuum (negative pressure) to move the diaphragm to its lowest position. Positive pressure from the bioreactor is insufficient to completely deflate the diaphragm, necessitating the use of vacuum to ensure proper XCell® ATF Housing operation.

3. About this document



Several user attention phrases are used throughout this manual. Each phrase should draw the following level of attention:

Table 1. Explanation of user attention phrases

Phrase	Description
Note:	Points out useful information
IMPORTANT	Indicates information necessary for proper instrument operation
CAUTION	Cautions users regarding potentially hazardous situations regarding user injury or damage to the instrument if the information is not heeded
WARNING!	Warns users that serious physical injury can result if warning precautions are not heeded

4. Safety precautions

Table 2. Explanation of symbols

Symbol	Description
Caution 	Risk of danger. Consult Operating Instructions for nature of hazard and corrective actions. Potentially hazardous situation which, if not avoided, may result in property/equipment damage
Safety Alert Symbol 	Hazard to personnel is present, the safety alert symbol is omitted when the hazard is related to property/equipment damage only

5. Specifications

Table 3. Utility requirements

Utility	Requirement	Additional considerations
Primary compressed air	Maximum: 90 psig/6.1 bar	Oil free, dry, filtered gas, (i.e., medical grade air)
Secondary pressure	Typically: 35 psi/2.4 bar	Regulated oil free, dry, filtered air
Vacuum service	Minimum: 12.5 psig	Vacuum supplied by a pump capable of maintaining ~12.5psig with nominal flow as follows: XCell® ATF 4 Housing: 40L/min XCell® ATF 6 Housing: 60L/min XCell® ATF 10 Housing: 200L/min Pump should be clean room compatible
Exhaust		Untreated discharge or user specified
Steam (Steam in place, SIP)	~30lbs/hr.	Applicable only to a steamable connection between XCell® ATF Housing and bioreactor vessel
Condensate drain		For SIP condensate drainage
Altitude	2000 m	This product has been assessed for a maximum altitude of 2000 m.
Pollution degree	Pollution Degree 2	This product is intended to be used in an environment of Pollution Degree 2 (normally only nonconductive pollution can be present). Temporary conductivity that is caused by condensation is to be expected.

Table 4. Dimensions

Filtration Assembly	Dimensions ¹ H, W	Base Plate/L x W
SS XCell® ATF 4 Housing	24", 6"	6" x 10"

SS XCell® ATF 6 Housing	44", 10"	8" x 12"
SS XCell® ATF 10 Housing	44", 14"	14" x 20"

¹ Indicated dimensions are estimates for the filtration assembly, as the connections to the bioreactor and accessories can affect height and effective area.

Housing selection depends on the perfusion rate or total volume throughput in addition to other process conditions (Table 5).

Table 5. Suggested scale of operation

Housing	Bioreactor size (L)
XCell® ATF 4	10 – 50
XCell® ATF 6	50 – 200
XCell® ATF 10	200 – 5000+

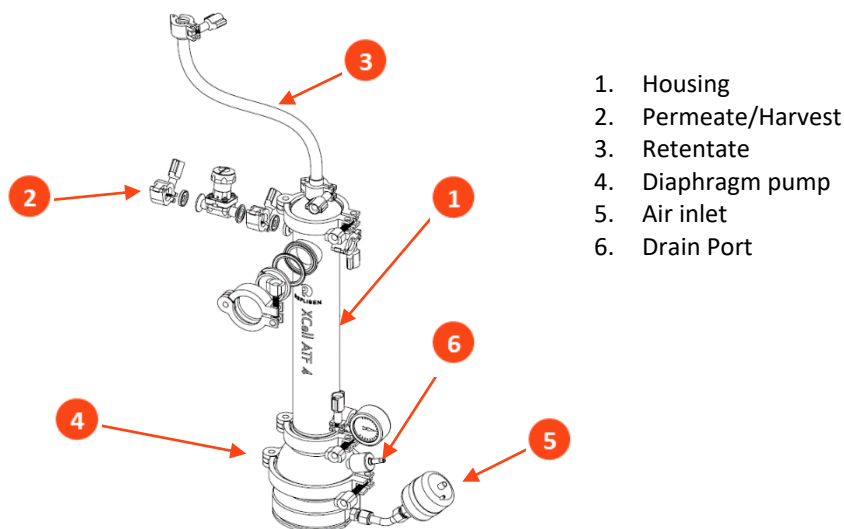
Table 6. Maximum length of ATF to Bioreactor (A2B) connection

Housing	Length (inches)
XCell® ATF 4	24
XCell® ATF 6	39
XCell® ATF 10	46

6. Stainless Steel XCell® ATF 4 Housing

XCell® ATF 4 Housing (**Figure 2**) is recommended for use with 10 – 50 L bioreactors. The assembly of the housing and accessories includes installing the diaphragm and hollow fiber filter into the housing, connecting the tubing set kit to the bioreactor, and connecting the harvest line to the housing. The system is prepared for use by pressure testing, filter wetting, integrity testing, and autoclaving.

Figure 2. XCell® ATF 4 Housing

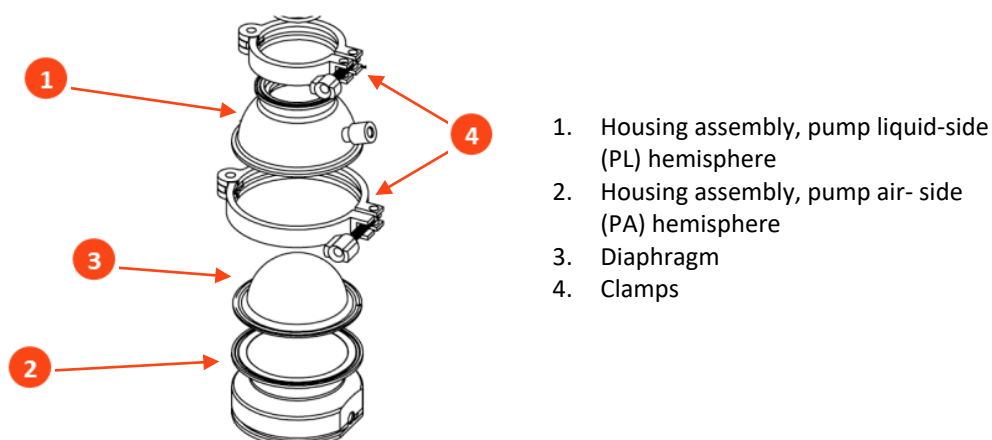


6.1 Stainless steel XCell® ATF 4 Housing assembly

XCell® ATF 4 Housing assembly includes installation of the diaphragm and hollow fiber filter and assembly of the tubing set kit that will connect the housing and the bioreactor and the tubing that will connect the housing and the harvest vessel.

6.1.1 Installing the diaphragm

Important: The silicone diaphragm must be replaced after each run and prior to sterilization. To avoid premature failure, it is important to ensure that the diaphragm is seated in the correct orientation. Use with aqueous liquids only. For use with other fluids contact Repligen for a technical discussion. When used as instructed, the diaphragm is designed to last over one million pressure/exhaust cycles.

Figure 3. Orientation of silicone diaphragm in XCell® ATF 4 Housing**6.1.1.1 XCell® ATF 4 Housing diaphragm placement**

1. Set the pump air-side (PA) hemisphere (**Figure 3, 2**) on a flat surface with the open (concave) side of the hemisphere facing up.
2. Place diaphragm (3) with the convex side oriented up onto the PA hemisphere, and place the PL hemisphere, wide opening down, on top of the diaphragm.
3. Assure the diaphragm gasket O-ring is positioned uniformly around the periphery of the pump O-ring groove. The two hemispheres, with diaphragm in between, should be equally spaced.
4. Clamp (4) the two hemispheres together.
5. Secure the diaphragm pump to the stand.

6.1.2 XCell® ATF 4 Housing hollow fiber filter installation

XCell® ATF 4 Housing accommodates a variety of hollow fiber filters. For support in selecting hollow fiber filters, please contact your local Repligen Field Applications Specialist (FAS).

1. Stand the filter housing vertically, with harvest port up.
2. Insert the HFF into the housing
3. Insert one O-ring into the groove between HFF and housing end-ferrule wall.
4. Place the reducer onto the end, forcing the O-ring into the groove.
5. Clamp the reducer to the housing, compressing the O-ring against the HFF. A seal is formed between the housing, reducer and HFF.
6. On the other end of the filter housing, place the second O-ring into the groove between HFF and housing end-ferrule.
7. Carefully place the filter housing onto the diaphragm pump, forcing the O-ring deeper into the groove.
8. Clamp the filter housing to the diaphragm pump.
9. Assemble the rest of the XCell® ATF Housing, including tubing set kits.

6.2 Filter preparation

To prepare the filter for use, the assembled housing should be pressure tested, wetted, integrity tested and autoclaved.

6.2.1 Pressure testing

Pressure testing ensures that the XCell® ATF 4 Housing assembly is free of leaks and can withstand the required operating pressures. The assembly can be pressure tested with or without a filter module, before or after sterilization. Ideally, the test is performed with a filter prior to autoclaving. Slight variations in the configuration of the external connections are possible depending on the configuration of the equipment purchased and the connections being made to the bioreactor. Refer to the XCell® ATF Technology Filter Preparation and Autoclaving User Guide for instructions.

6.2.2 Filter wetting

Hollow fiber filters require wetting after installation and pressure testing. Slight variations in assembly are possible depending on the configuration of equipment purchased and its intended use. Refer to the XCell® ATF Technology Filter Preparation and Autoclaving User Guide for instructions.

6.2.3 Integrity testing pre-autoclaving

Note: *Repligen strongly recommends the practice of pre-autoclaving integrity testing to ensure a proper assembly prior to autoclaving.*

Refer to the XCell® ATF Technology Filter Preparation and Autoclave User Guide for configurations for both stainless steel and single-use bioreactor integrity tests and testing instructions and criteria.

6.2.4 Autoclaving

The XCell® ATF 4 Housing assembly is autoclaved either before or after integrity testing. The cycle sequence presented is strongly recommended to ensure sterility and to retain filter integrity and performance. The procedure includes three pre-vacuum pulses, which provide proper chamber evacuation for a faster and more consistent ramp to the required temperature. Refer to the XCell® ATF Technology Filter Preparation and Autoclaving User Guide for instructions.

6.2.5 Integrity testing post-autoclaving

Post-autoclaving integrity testing is required only if testing was not performed pre-autoclaving. Refer to the XCell® ATF Technology Filter Preparation and Autoclave User Guide for instructions.

6.3 Connecting XCell® ATF 4 Housing to a bioreactor

Two types of connections between the housing and bioreactor are available. Hard connections are used where steam-in-place (SIP) is an option, such as with stainless steel bioreactors (SSB). Soft connections are used with single-use bioreactors (SUB) and consist of single-use connectors such as AseptiQuik®, and Relymate™ DAC and are connected to the housing prior to autoclaving.

Fluid management for XCell® ATF 4 Housings include retentate (A2B) tubing set kits and accessories that connect the housing with the bioreactor, ensuring proper exchange of cell culture material. Intended for use in pilot scale, clinical, and commercial bioprocessing environments, tubing set kits work with XCell® LS Controllers and legacy C410 controllers. Permeate tubing (not provided) connects the housing to the harvest vessel and should be sterilized by autoclave or attached with a tubing welder or disposable sterile coupling. The permeate tubing should be compatible with the permeate/harvest pump.

Note: *Bioreactor adapters, used to connect tubing set kit to the bioreactor, are not provided.*

6.3.1 Stainless steel XCell® ATF 4 tubing set kits and accessories

Several components are required to connect the XCell® ATF 4 housing to a bioreactor. XCell® ATF 4 autoclavable tubing set kits (**Table 7**) are available in three configurations depending on the type of bioreactor in use and the preferred connectors. All tubing set kits have a pressure rating of 25 psi. Additional accessories (**Table 8**) are required, regardless of the chosen tubing set.

Table 7. XCell® ATF 4 tubing set kit options

Tube set part number	Bioreactor Type	Tubing connection
ATF4-A2B-TC	Stainless steel	Tri-clover
SSATF4-SUB-A2B-RM	Single use	GE ReadyMate™
ATF4-A2B-TCAQ		AseptiQuik®

Table 8. XCell® ATF 4 required accessories

Description	Part number	Single/Multi-use	Pressure rating (psi)	ID (inches)	Material of construction
Vent filter	F46-AIR-LSC	SU	25	NA	PVDF
Permeate Pressure Sensor	SSATF-LSC-PSK	SU	25	3/4	Polycarbonate
Vent tee (Single-use bioreactor only)	ATF4-OPT2	MU	45	3/8	Stainless steel

In addition, use of a SSB requires bivalve assemblies (**Table 9**), which can be steamed in place.

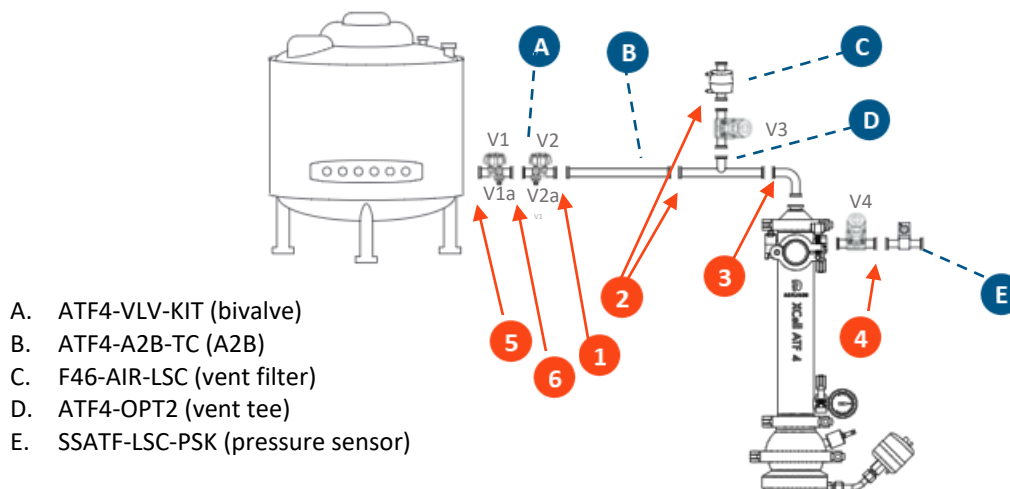
Table 9. XCell® ATF 4 required stainless steel bioreactor accessory

Description	Part number	Single/Multi-use	Pressure rating (psi)	ID (inches)	Material of construction
Bivalve assembly	ATF4-VLV-KIT	MU	45	3/8	Stainless steel

6.3.2 Tubing set kit assembly for XCell® ATF 4 connected to stainless steel bioreactor

Assembly of the housing, tubing set, and accessories is completed prior to autoclaving. Hard connection between the tubing set kit and the stainless steel bioreactor consists of the following parts, available as a unit:

- Two isolation bivalves: one attached to the bioreactor, and one attached to the housing
- A flexible hose between the main branches of the two valves
- A steam inlet: a side valve on one bivalve
- Condensate drain: a side valve on the other bivalve; lowest of the available valves

Figure 4. XCell® ATF 4 connection to stainless steel bioreactor

Following assembly of the housing, tubing set, and accessories, the right side of the system is autoclaved. Simultaneously, the right-facing bivalve is steamed in place so that when the autoclave cycle is complete, that section can be attached to the bioreactor and another steam-in-place cycle can be performed.

Connection instructions (Figure 4):

1. Attach left-facing bivalve (A) to tubing set (B).
2. Attach vent filter (C) to vent tee (D). Connect vent tee (D) to A2B tubing (B).
3. Connect ATF4 housing to vent tee (D).
4. Attach permeate pressure sensor (E) to housing permeate port. Depending on harvest bag port, connect adapter tubing (not supplied) to end of pressure sensor. Open V2, V2a, V3 and V4. Autoclave the entire assembly. Close V2, V2a and V4.
5. Attach the right-facing bivalve (A) to the bioreactor. Open valve V1a and attach trap. Open valve V1. Steam in place. Close V1.
6. Connect bivalves to each other. Open valves V1a and V2a. Valves V1 and V2 are closed. SIP the bivalve connection. Close valves V1a and V2a. Open valves V1 and V2 for operation.

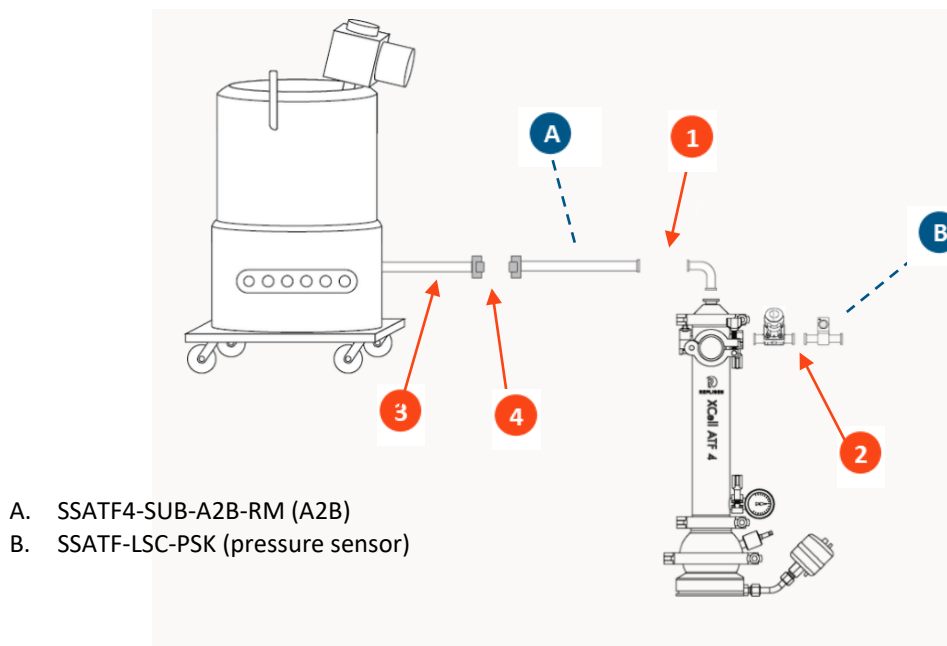
The following steam-in-place procedure is recommended for hard connections:

1. Attach a steam trap to the condensate valve and connect to a drain.
2. Close steam inlet and condensate drain valves.
3. Securely connect a regulated steam source to the steam inlet valve.
4. Open steam service.
5. Slowly open steam inlet valve.
6. Slowly open steam condensate valve.
7. Sterilize connection for about 20 min. at 121° C and ~16 psi.
8. Cool down.
9. Close the condensate valve.
10. Rapidly close the steam inlet valve and immediately open the main valve into the filtration assembly to minimize a pressure drop in the connection.

6.3.2.1 Tube set kit assembly for XCell® ATF 4 connected to single-use bioreactor using GE ReadyMate™ tubing set.

Assembly of the housing, tubing set, and accessories, on the right side of the system is completed prior to autoclaving.

Figure 5. XCell® ATF 4 connection to single-use bioreactor (ReadyMate™)

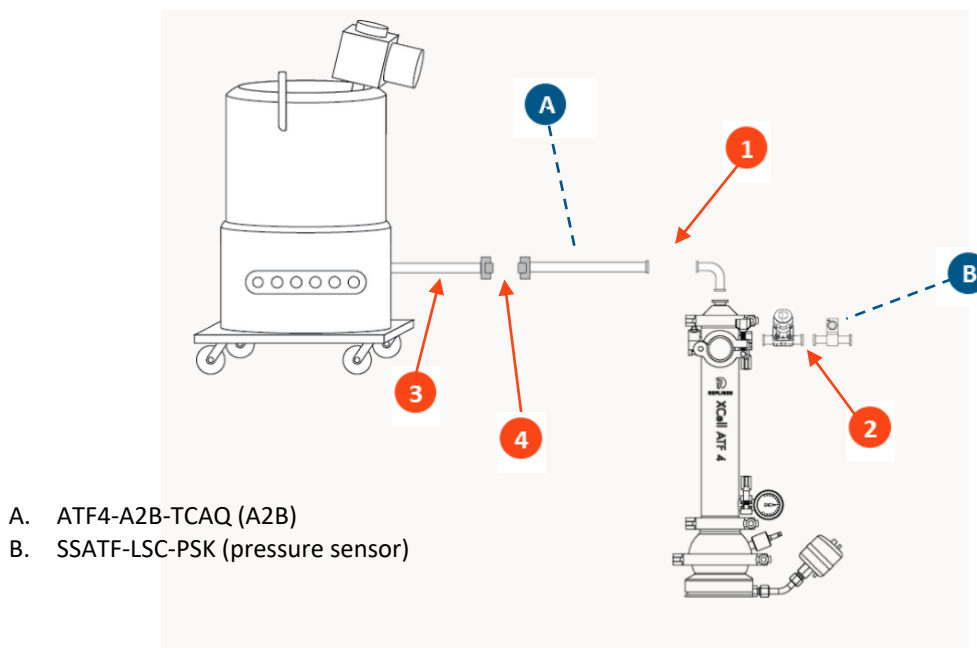


Connection instructions (**Figure 5**):

1. Connect A2B tubing (A) to housing.
2. Attach permeate pressure sensor (B) to housing permeate port. Depending on harvest bag port, connect adapter tubing (not supplied) to end of the pressure sensor. Open all valves. Autoclave the assembly.
3. Determine the recommended aseptic connector for SUB. Connect adapter tubing (not supplied) to SUB. Clamp sterile tubing.
4. Connect assembly to bioreactor.

6.3.2.2 Tube set kit assembly for XCell® ATF 4 connected to single-use bioreactor using AsepticQuik® tubing set.

Assembly of the housing, tubing set, and accessories, on the right side of the system is completed prior to autoclaving.

Figure 6. XCell® ATF 4 connection to single-use bioreactor (AsepticQuik®)

Connection instructions (**Figure 6**):

1. Connect A2B tubing (A) to housing.
2. Attach permeate pressure sensor (B) to housing permeate port. Depending on harvest bag port, connect adapter tubing (not supplied) to end of the pressure sensor. Open all valves. Autoclave the assembly.
3. Determine the recommended aseptic connector for SUB. Connect adapter tubing (not supplied) to SUB. Clamp sterile tubing.
4. Connect assembly to bioreactor.

6.4 Disassembly and maintenance

6.4.1 Removing the housing from the bioreactor

1. Stop the permeate/harvest pump and disconnect the harvest bag from the housing.
2. Stop and disconnect the A2C line from the diaphragm pump.
3. Close or disconnect compressed air and vacuum services from the pneumatic enclosure.
4. Disconnect sensors from the filtration assembly to pneumatic enclosure.
5. If necessary, remove the pneumatic enclosure from the filtration assembly.
6. Close both bivalves connecting the filtration assembly to the vessel.
7. Drain liquid from the connection.
8. Optionally, purge the connection with water, steam, or some other medium.
9. Disconnect the filtration assembly from vessel between the two bivalves.
10. Remove the filtration assembly to an appropriate work area.

6.4.2 HFF Removal

1. Drain the system into an appropriate waste vessel or drain.
2. Remove all sensors from the housing.

3. Remove air inlet filter connected to the diaphragm pump and any other connections to the XCell® ATF Housing.
4. Open the clamp connecting the filter housing to the diaphragm pump and separate.
5. Open the clamp connecting the reducer to the filter housing and separate.
6. Remove the HFF from housing by firmly pressing it from one end.
7. Remove the O-ring at the exposed end of the HFF.
8. Press the HFF in the opposite direction to remove.
9. Prepare filter housing for cleaning and reuse.

6.4.3 Decontaminating the HFF for Disposal

1. Rinse the HFF two times with water to remove residual cells and debris.
2. Decontaminate with either 0.5M NaOH, potassium hydroxide, or bleach for 2 – 24 hours.

Note: 5.25% chlorine is equivalent to 52,500 parts per million (ppm). If household chlorine bleach is used, two working solutions are generally recommended: 5000-6000 ppm for initial decontamination of organic spill material, and 500 - 600ppm for disinfection of cleaned surfaces.

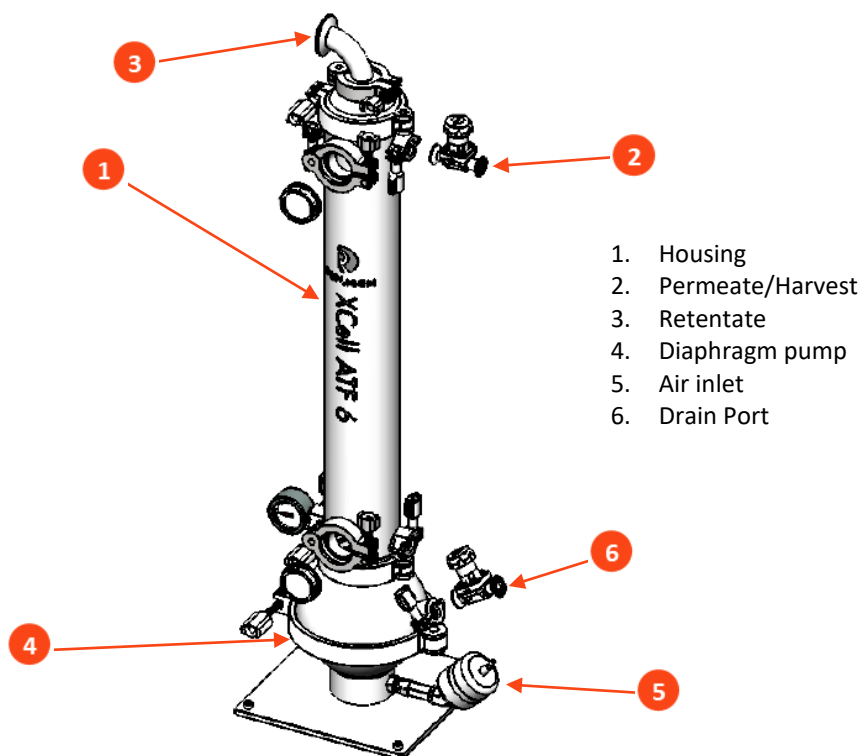
6.4.4 Pump Air Inlet Filter, “O” Rings, Gaskets, and Quick Connects

All consumable items are single use.

7. Stainless Steel XCell® ATF 6 Housing

XCell® ATF 6 Housing (**Figure 7**) is recommended for use with 50 – 200 L bioreactors. The assembly of the housing and accessories includes installing the diaphragm and hollow fiber filter into the housing, connecting the tubing set kit to the bioreactor, and connecting the harvest line to the housing. The system is prepared for use by pressure testing, filter wetting, integrity testing, and autoclaving.

Figure 7. XCell® ATF 6 Housing



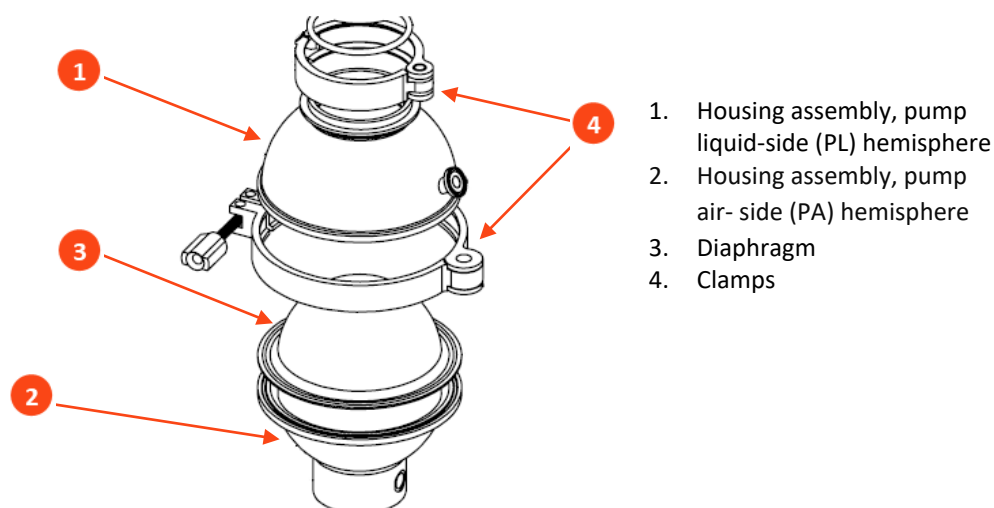
7.1 Stainless steel XCell® ATF 6 Housing assembly

XCell® ATF 6 Housing assembly includes installation of the diaphragm and hollow fiber filter and assembly of the tubing set kit that will connect the housing and the bioreactor and the tubing that will connect the housing and the harvest vessel.

7.1.1 Installing the diaphragm

Important: The silicone diaphragm must be replaced after each run and prior to sterilization. To avoid premature failure, it is important to ensure that the diaphragm is seated in the correct orientation. Use with aqueous liquids only. For use with other fluids contact Repligen for a technical discussion. When used as instructed, the diaphragm is designed to last over one million pressure/exhaust cycles.

Figure 8. Orientation of silicone diaphragm in pump housing XCell® ATF 6



7.1.1.1 XCell® ATF 6 Housing diaphragm placement

1. Set the pump air-side (PA) hemisphere (**Figure 8, 2**) on a flat surface with the open (concave) side of the hemisphere facing up.
2. Place diaphragm (3) with the convex side oriented up onto the PA hemisphere, and place the PL hemisphere, wide opening down, on top of the diaphragm.
3. Assure the diaphragm gasket O-ring is positioned uniformly around the periphery of the pump O-ring groove. The two hemispheres, with diaphragm in between, should be equally spaced.
4. Clamp (4) the two hemispheres together.
5. Secure the diaphragm pump to the stand.

7.1.2 XCell® ATF 6 Housing hollow fiber filter installation

XCell® ATF 6 Housing accommodates a variety of hollow fiber filters. For support in selecting hollow fiber filters, please contact your local Repligen Field Applications Specialist (FAS).

1. Stand the filter housing vertically, with harvest port up.
2. Insert the HFF into the housing
3. Insert one O-ring into the groove between HFF and housing end-ferrule wall.
4. Place the reducer onto the end, forcing the O-ring into the groove.
5. Clamp the reducer to the housing, compressing the O-ring against the HFF. A seal is formed between the housing, reducer and HFF.
6. On the other end of the filter housing, place the second O-ring into the groove between HFF and housing end-ferrule.
7. Carefully place the filter housing onto the diaphragm pump, forcing the O-ring deeper into the groove.
8. Clamp the filter housing to the diaphragm pump.
9. Assemble the rest of the XCell® ATF Housing, including tubing set kits.

7.2 Filter preparation

To prepare the filter for use, the assembled housing should be pressure tested, wetted, integrity tested and autoclaved.

7.2.1 Pressure testing

Pressure testing ensures that the XCell® ATF 6 Housing assembly is free of leaks and can withstand the required operating pressures. The assembly can be pressure tested with or without a filter module, before or after sterilization. Ideally, the test is performed with a filter prior to autoclaving. Slight variations in the configuration of the external connections are possible depending on the configuration of the equipment purchased and the connections being made to the bioreactor. Refer to the XCell® ATF Technology Filter Preparation and Autoclaving User Guide for instructions.

7.2.2 Filter wetting

Hollow fiber filters require wetting after installation and pressure testing. Slight variations in assembly are possible depending on the configuration of equipment purchased and its intended use. Refer to the XCell® ATF Technology Filter Preparation and Autoclaving User Guide for instructions.

7.2.3 Integrity testing pre-autoclaving

Note: Repligen strongly recommends the practice of pre-autoclaving integrity testing to ensure a proper assembly prior to autoclaving.

Refer to the XCell® ATF Technology Filter Preparation and Autoclave User Guide for configurations for both stainless steel and single-use bioreactor integrity tests and testing instructions and criteria.

7.2.4 Autoclaving

The XCell® ATF 6 Housing assembly is autoclaved either before or after integrity testing. The cycle sequence presented is strongly recommended to ensure sterility and to retain filter integrity and performance. The procedure includes three pre-vacuum pulses, which provide proper chamber evacuation for a faster and more consistent ramp to the required temperature. Refer to the XCell® ATF Technology Filter Preparation and Autoclaving User Guide for instructions.

7.2.5 Integrity testing post-autoclaving

Post-autoclaving integrity testing is required only if testing was not performed pre-autoclaving. Refer to the XCell® ATF Technology Filter Preparation and Autoclave User Guide for instructions.

7.3 Connecting XCell® ATF 6 Housing to a bioreactor

Two types of connections between the housing and bioreactor are available. Hard connections are used where steam-in-place (SIP) is an option, such as with stainless steel bioreactors (SSB). Soft connections are used with single-use bioreactors (SUB) and consist of single-use connectors such as AsepticQuik® and Relymate™ DAC and are connected to the housing prior to autoclaving.

Fluid management for XCell® ATF 6 Housings include retentate (A2B) tubing set kits and accessories that connect the housing with the bioreactor, ensuring proper exchange of cell culture material. Intended for use in pilot scale, clinical, and commercial bioprocessing environments, tubing set kits work with XCell® LS Controllers and legacy C410 controllers. Permeate tubing (not provided) connects the housing to the harvest vessel and should be sterilized by autoclave or attached with a tubing welder or disposable sterile coupling. The permeate tubing should be compatible with the permeate/harvest pump.

Note: Bioreactor adapters, used to connect tubing set kit to the bioreactor, are not provided.

7.3.1 Stainless steel XCell® ATF 6 tubing set kits and accessories

Several components are required to connect the XCell® ATF 6 housing to a bioreactor. XCell® ATF 6 autoclavable tubing set kits (**Table 10**) are available in three configurations depending on the type of bioreactor in use and the preferred connectors. All tubing set kits have a pressure rating of 25 psi. Additional accessories (**Table 11**) are required, regardless of the chosen tubing set.

Table 10. XCell® ATF 6 tubing set kit options

Tube set part number	Bioreactor Type	Tubing connection
SSATF6-SSB-A2B-TC	Stainless steel	Tri-clover
SSATF6-SUB-A2B-RM	Single use	GE ReadyMate™
SSATF6-SUB-A2B-AQG		AseptiQuik®

Table 11. XCell® ATF 6 required accessories

Description	Part number	Single/Multi-use	Pressure rating (psi)	ID (inches)	Material of construction
Vent filter	F46-AIR-LSC	SU	25	NA	PVDF
Permeate Pressure Sensor	SSATF-LSC-PSK	SU	25	3/4	Polycarbonate
Vent tee (Single-use bioreactor only)	ATF6-OPT2	MU	45	1	Stainless steel

In addition, use of a SSB requires bivalve assemblies (**Table 12**), which can be steamed in place.

Table 12. XCell® ATF 6 required stainless steel bioreactor accessory

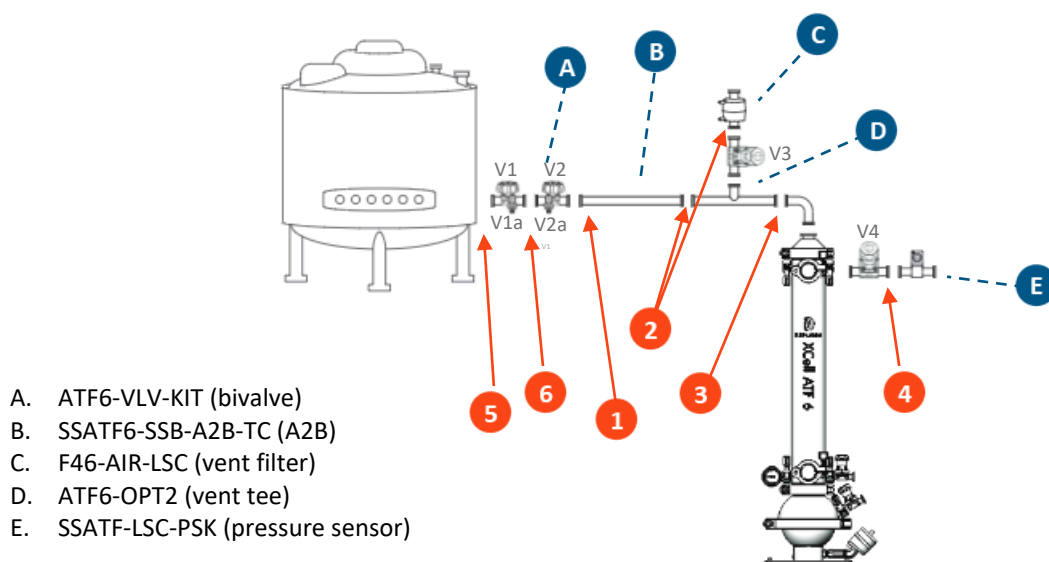
Description	Part number	Single/Multi-use	Pressure rating (psi)	ID (inches)	Material of construction
Bivalve assembly	ATF6-VLV-KIT	MU	45	1.5	Stainless steel

7.3.2 Tube set kit assembly for XCell® ATF 6 connected to stainless steel bioreactor

Assembly of the housing, tubing set, and accessories is completed prior to autoclaving. Hard connection between the tubing set kit and the stainless steel bioreactor consists of the following parts, available as a unit:

- Two isolation bivalves: one attached to the bioreactor, and one attached to the housing
- A flexible hose between the main branches of the two valves
- A steam inlet: a side valve on one bivalve
- Condensate drain: a side valve on the other bivalve; lowest of the available valves

Figure 9. XCell® ATF 6 connection to stainless steel bioreactor



Following assembly of the housing, tubing set, and accessories, the right side of the system is autoclaved. Simultaneously, the right-facing bivalve is steamed in place so that when the autoclave cycle is complete, that section can be attached to the bioreactor and another steam-in-place cycle can be performed.

Connection instructions (**Figure 9**):

1. Attach left-facing bivalve (A) to tubing set (B).
2. Attach vent filter (C) to vent tee (D). Connect vent tee (D) to A2B tubing (B).
3. Connect housing to vent tee (D).
4. Attach permeate pressure sensor (E) to housing permeate port. Depending on harvest bag port, connect adapter tubing (not supplied) to end of the pressure sensor. Open V2, V2a, V3 and V4. Autoclave the entire assembly. Close V2, V2a and V4.
5. Attach the right-facing bivalve (A) to the bioreactor. Open valve V1a and attach trap. Open valve V1. Steam in place. Close V1.
6. Connect bivalves to each other. Open valves V1a and V2a. Valves V1 and V2 are closed. SIP the bivalve connection. Close valves V1a and V2a. Open valves V1 and V2 for operation.

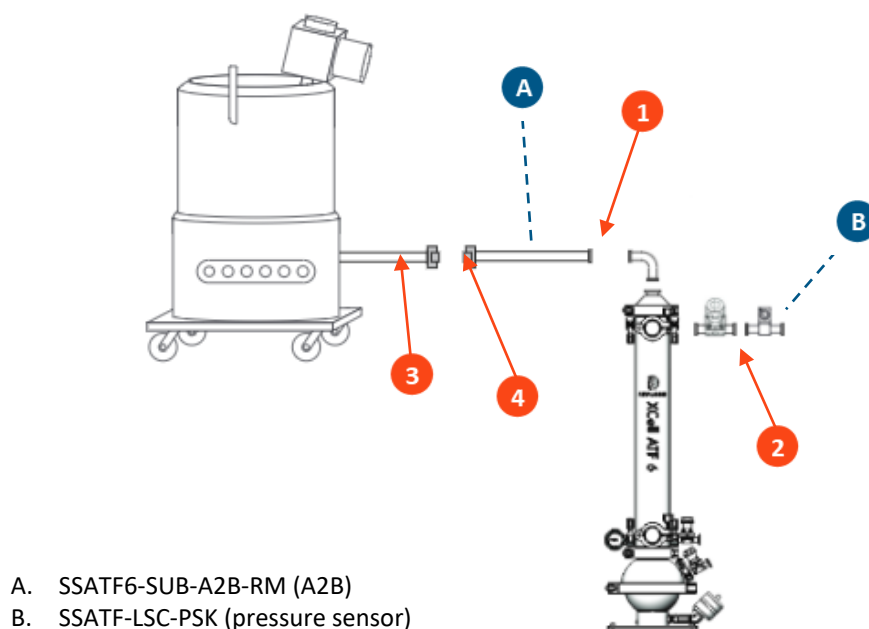
The following steam-in-place procedure is recommended for hard connections:

1. Attach a steam trap to the condensate valve and connect to a drain.
2. Close steam inlet and condensate drain valves.
3. Securely connect a regulated steam source to the steam inlet valve.
4. Open steam service.
5. Slowly open steam inlet valve.
6. Slowly open steam condensate valve.
7. Sterilize connection for about 20 min. at 121° C and ~16 psi.
8. Cool down.
9. Close the condensate valve.
10. Rapidly close the steam inlet valve and immediately open the main valve into the filtration assembly to minimize a pressure drop in the connection.

7.3.2.1 Tube set kit assembly for XCell® ATF 6 connected to single-use bioreactor using GE ReadyMate™ tubing set.

Assembly of the housing, tubing set, and accessories is completed prior to autoclaving.

Figure 10. XCell® ATF 6 connection to single-use bioreactor (ReadyMate™)



Connection instructions (**Figure 10**):

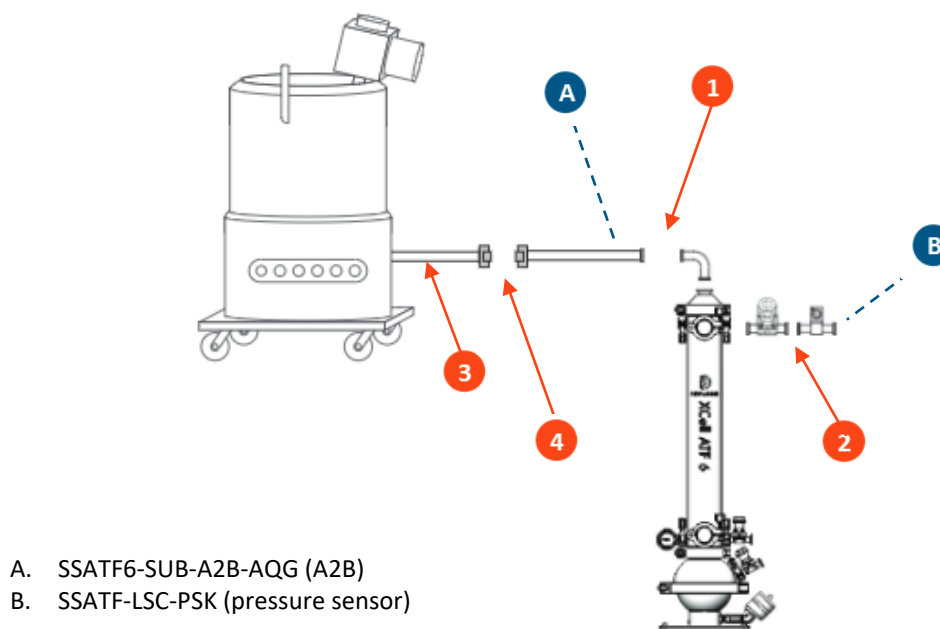
1. Connect A2B tubing (A) to housing.
2. Attach permeate pressure sensor (B) to housing permeate port. Depending on harvest bag port, connect adapter tubing (not supplied) to end of the pressure sensor. Open all valves. Autoclave the assembly.
3. Determine the recommended aseptic connector for SUB. Connect adapter tubing (not supplied) to SUB. Clamp sterile tubing.

4. Connect assembly to bioreactor.

7.3.2.2 Tube set kit assembly for XCell® ATF 6 connected to single-use bioreactor using AsepticQuik® tubing set.

Assembly of the housing, tubing set, and accessories is completed prior to autoclaving.

Figure 11. XCell® ATF 6 connection to single-use bioreactor (AsepticQuik®)



Connection instructions (**Figure 11**):

1. Connect A2B tubing (A) to housing.
2. Attach permeate pressure sensor (B) to housing permeate port. Depending on harvest bag port, connect adapter tubing (not supplied) to end of the pressure sensor. Open all valves. Autoclave the assembly.
3. Determine the recommended aseptic connector for SUB. Connect adapter tubing (not supplied) to SUB. Clamp sterile tubing.
4. Connect assembly to bioreactor.

7.4 Disassembly and maintenance

7.4.1 Removing the housing from the bioreactor

1. Stop the permeate/harvest pump and disconnect the harvest bag from the housing.
2. Stop and disconnect the A2C line from the diaphragm pump.
3. Close or disconnect compressed air and vacuum services from the pneumatic enclosure.
4. Disconnect sensors from the filtration assembly to pneumatic enclosure.
5. If necessary, remove the pneumatic enclosure from the filtration assembly.
6. Close both bivalves connecting the filtration assembly to the vessel.

7. Drain liquid from the connection.
8. Optionally, purge the connection with water, steam, or some other medium.
9. Disconnect the filtration assembly from vessel between the two bivalves.
10. Remove the filtration assembly to an appropriate work area.

7.4.2 HFF Removal

1. Drain the system into an appropriate waste vessel or drain.
2. Remove all sensors from the housing.
3. Remove air inlet filter connected to the diaphragm pump and any other connections to the XCell® ATF Housing.
4. Open the clamp connecting the filter housing to the diaphragm pump and separate.
5. Open the clamp connecting the reducer to the filter housing and separate.
6. Remove the HFF from housing by firmly pressing it from one end.
7. Remove the O-ring at the exposed end of the HFF.
8. Press the HFF in the opposite direction to remove.
9. Prepare filter housing for cleaning and reuse.

7.4.3 Decontaminating the HFF for Disposal

1. Rinse the HFF two times with water to remove residual cells and debris.
2. Decontaminate with either 0.5M NaOH, potassium hydroxide, or bleach for 2 – 24 hours.

Note: 5.25% chlorine is equivalent to 52,500 parts per million (ppm). If household chlorine bleach is used, two working solutions are generally recommended: 5000-6000 ppm for initial decontamination of organic spill material, and 500 - 600ppm for disinfection of cleaned surfaces.

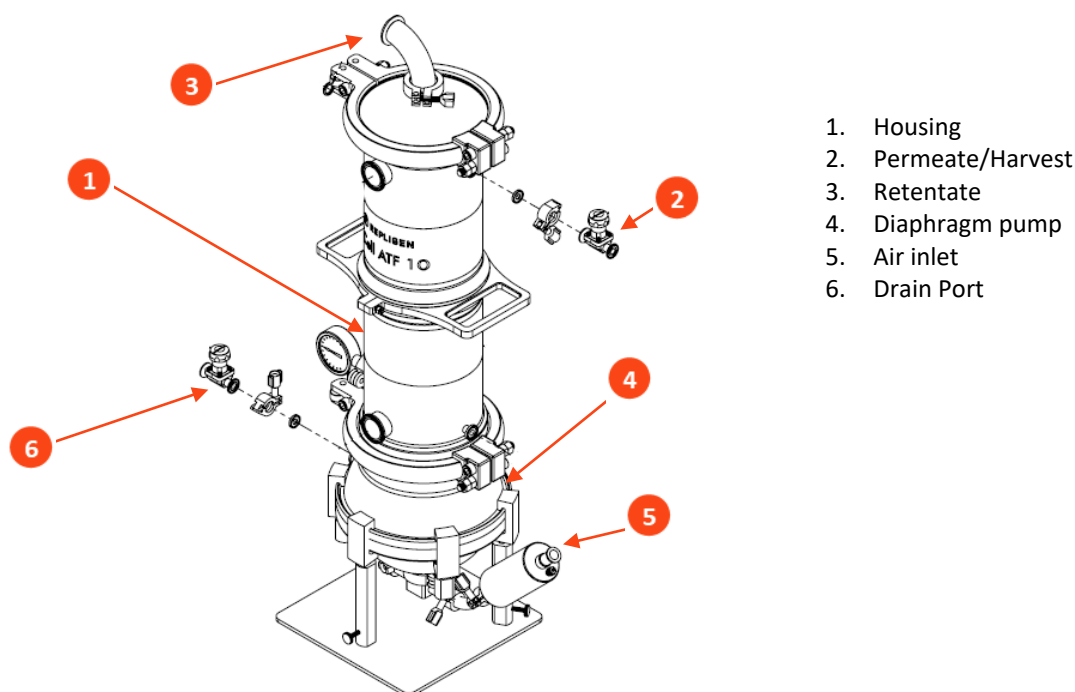
7.4.4 Pump Air Inlet Filter, “O” Rings, Gaskets, and Quick Connects

All consumable items are single use.

8. Stainless Steel XCell® ATF 10 Housing

XCell® ATF 10 Housing (**Figure 12**) is recommended for use with 200 – 5000+ L bioreactors. The assembly of the housing and accessories includes installing the diaphragm and hollow fiber filter into the housing, connecting the tubing set kit to the bioreactor, and connecting the harvest line to the housing. The system is prepared for use by pressure testing, filter wetting, integrity testing, and autoclaving.

Figure 12. XCell® ATF 10 Housing



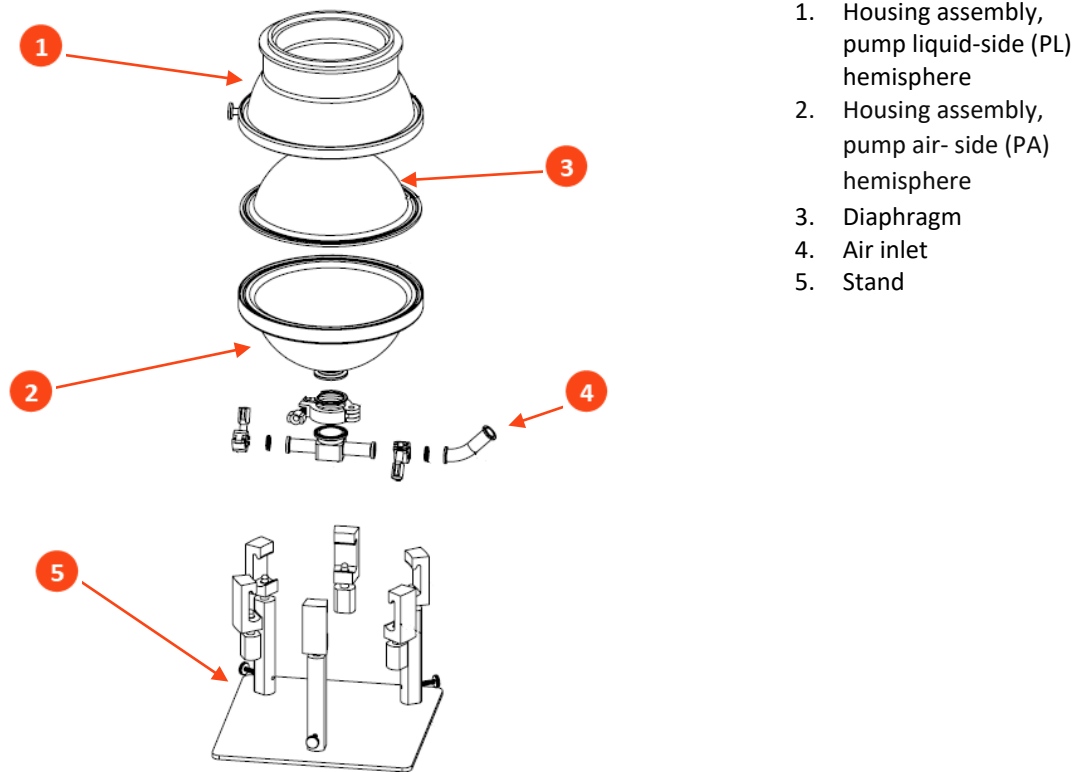
8.1 Stainless steel XCell® ATF 10 Housing assembly

XCell® ATF 10 Housing assembly includes installation of the diaphragm and hollow fiber filter and assembly of the tubing set kit that will connect the housing and the bioreactor and the tubing that will connect the housing and the harvest vessel.

8.1.1 Installing the diaphragm

Important: The silicone diaphragm must be replaced after each run and prior to sterilization. To avoid premature failure, it is important to ensure that the diaphragm is seated in the correct orientation. Use with aqueous liquids only. For use with other fluids contact Repligen for a technical discussion. When used as instructed, the diaphragm is designed to last over one million pressure/exhaust cycles.

Figure 13. Orientation of silicone diaphragm in pump housing XCell® ATF 10



8.1.1.1 XCell® ATF 10 Housing diaphragm placement

1. Set the pump air-side (PA) hemisphere (**Figure 13, 2**) on a flat surface with the open side of the hemisphere facing up.
2. Place diaphragm (3) with the convex side oriented up onto the PA hemisphere, and place the PL hemisphere, wide opening down, on top of the diaphragm.
3. Assure the diaphragm gasket O-ring is positioned uniformly around the periphery of the pump O-ring groove. The two hemispheres, with diaphragm in between, should be equally spaced.
4. Clamp the two hemispheres together.
 - a. Use the long clamps first. Space them 120° apart around the circumference of the pump assembly. Uniformly and sequentially tighten (torque to 30 lb-ft) the clamps, so the diaphragm is compressed evenly around the periphery of the spheres.
 - b. Add the short clamps in between the long clamps and tighten (torque to 20 – 25 lb-ft) as described in Step 4a.
5. Add the air inlet assembly to the air inlet nozzle on the PA hemisphere.
6. Carefully invert the assembled diaphragm pump place onto the stand.
7. Proceed to installation of the HFF.

8.1.2 XCell® ATF 10 Housing hollow fiber filter installation

XCell® ATF 10 Housing accommodates a variety of hollow fiber filters. For support in selecting hollow fiber filters, please contact your local Repligen Field Applications Specialist (FAS).

1. Stand the filter housing vertically, with harvest port up.
2. Insert the HFF into the housing
3. Insert one O-ring into the groove between HFF and housing end-ferrule wall.
4. Place the reducer onto the end, forcing the O-ring into the groove.
5. Clamp the reducer to the housing, compressing the O-ring against the HFF. A seal is formed between the housing, reducer and HFF.
6. On the other end of the filter housing, place the second O-ring into the groove between HFF and housing end-ferrule.
7. Carefully place the filter housing onto the diaphragm pump, forcing the O-ring deeper into the groove.
8. Clamp the filter housing to the diaphragm pump.
9. Assemble the rest of the XCell® ATF Housing, including tubing set kits.

8.2 Filter preparation

To prepare the filter for use, the assembled housing should be pressure tested, wetted, integrity tested and autoclaved.

8.2.1 Pressure testing

Pressure testing ensures that the XCell® ATF 10 Housing assembly is free of leaks and can withstand the required operating pressures. The assembly can be pressure tested with or without a filter module, before or after sterilization. Ideally, the test is performed with a filter prior to autoclaving. Slight variations in the configuration of the external connections are possible depending on the configuration of the equipment purchased and the connections being made to the bioreactor. Refer to the XCell® ATF Technology Filter Preparation and Autoclaving User Guide for instructions.

8.2.2 Filter wetting

Hollow fiber filters require wetting after installation and pressure testing. Slight variations in assembly are possible depending on the configuration of equipment purchased and its intended use. Refer to the XCell® ATF Technology Filter Preparation and Autoclaving User Guide for instructions.

8.2.3 Integrity testing pre-autoclaving

Note: *Repligen strongly recommends the practice of pre-autoclaving integrity testing to ensure a proper assembly prior to autoclaving.*

Refer to the XCell® ATF Technology Filter Preparation and Autoclave User Guide for configurations for both stainless steel and single-use bioreactor integrity tests and testing instructions and criteria.

8.2.4 Autoclaving

The XCell® ATF 10 Housing assembly is autoclaved either before or after integrity testing. The cycle sequence presented is strongly recommended to ensure sterility and to retain filter integrity and performance. The procedure includes three pre-vacuum pulses, which provide proper chamber evacuation for a faster and more consistent ramp to the required temperature. Refer to the XCell® ATF Technology Filter Preparation and Autoclaving User Guide for instructions.

8.2.5 Integrity testing post-autoclaving

Post-autoclaving integrity testing is required only if testing was not performed pre-autoclaving. Refer to the XCell® ATF Technology Filter Preparation and Autoclave User Guide for instructions.

8.3 Connecting XCell® ATF 10 Housing to a bioreactor

Two types of connections between the housing and bioreactor are available. Hard connections are used where steam-in-place (SIP) is an option, such as with stainless steel bioreactors (SSB). Soft connections are used with single-use bioreactors (SUB) and consist of single-use connectors such as AseptiQuik® and Readymate™ DAC and are connected to the housing prior to autoclaving.

Fluid management for XCell® ATF 10 Housings include retentate (A2B) tubing set kits and accessories that connect the housing with the bioreactor, ensuring proper exchange of cell culture material. Intended for use in pilot scale, clinical, and commercial bioprocessing environments, tubing set kits work with XCell® LS Controllers and legacy C410 controllers. Permeate tubing (not provided) connects the housing to the harvest vessel and should be sterilized by autoclave or attached with a tubing welder or disposable sterile coupling. The permeate tubing should be compatible with the permeate/harvest pump.

Note: Bioreactor adapters, used to connect tubing set kit to the bioreactor, are not provided.

8.3.1 Stainless steel XCell® ATF 10 tubing set kits and accessories

Several components are required to connect the XCell® ATF 6 housing to a bioreactor. XCell® ATF 6 autoclavable tubing set kits (**Table 13**) are available in three configurations depending on the type of bioreactor in use and the preferred connectors. All tubing set kits have a pressure rating of 25 psi. Additional accessories (**Table 14**) are required, regardless of the chosen tubing set.

Table 13. XCell® ATF 10 tubing set kit options

Tube set part number	Bioreactor Type	Tubing connection
SSATF10-SSB-A2B-TC	Stainless steel	Tri-clover
SSATF10-SUB-A2B-AQX	Single use	AseptiQuik® X
SSATF10-SUB-A2B-AQL		AseptiQuik® L

Table 14. XCell® ATF 10 Required accessories

Description	Part number	Single/Multi-use	Pressure rating (psi)	ID (inches)	Material of construction
Vent filter	F10-AIR-LSC	SU	25	NA	PVDF
Permeate Pressure Sensor	SSATF-LSC-PSK	SU	25	3/4	Polycarbonate
U-bend with vent port	ATF10-OPT5	MU	45	1	Stainless steel

In addition, use of a SSB requires bivalve assemblies (**Table 15**), which can be steamed in place.

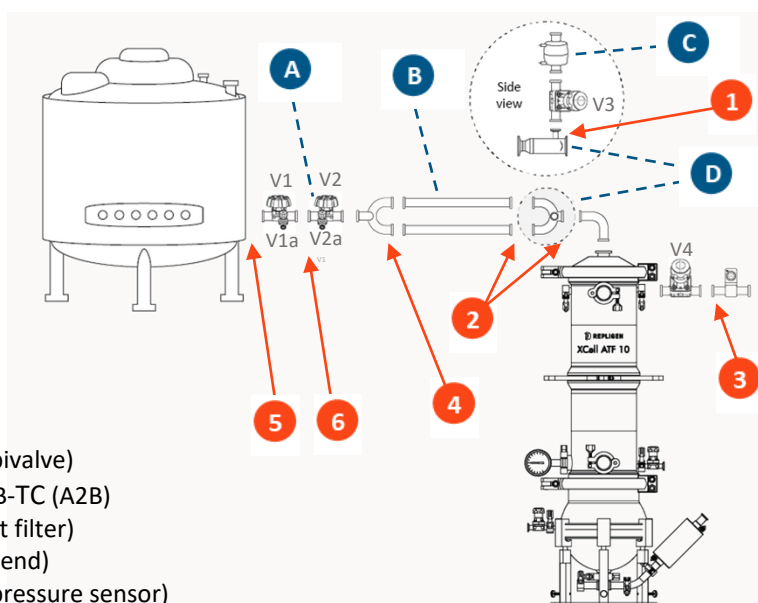
Table 15. XCell® ATF 10 required stainless steel bioreactor accessory

Description	Part number	Single/Multi-use	Pressure rating (psi)	ID (inches)	Material of construction
Bivalve assembly	ATF10-VLV-KIT	MU	45	1.5	Stainless steel

8.3.2 Tube set kit assembly for XCell® ATF 10 connected to stainless steel bioreactor

Assembly of the housing, tubing set, and accessories is completed prior to autoclaving. Hard connection between the tubing set kit and the stainless steel bioreactor consists of the following parts, available as a unit:

- Two isolation bivalves: one attached to the bioreactor, and one attached to the housing
- A flexible hose between the main branches of the two valves
- A steam inlet: a side valve on one bivalve
- Condensate drain: a side valve on the other bivalve; lowest of the available valves

Figure 14. XCell® ATF 10 connection to stainless steel bioreactor

- A. ATF10-VLV-KIT (bivalve)
- B. SSATF10-SSB-A2B-TC (A2B)
- C. F10-AIR-LSC (vent filter)
- D. ATF10-OPT5 (u-bend)
- E. SSATF-LSC-PSK (pressure sensor)

Following assembly of the housing, tubing set, and accessories, the right side of the system is autoclaved. Simultaneously, the right-facing bivalve is steamed in place so that when the autoclave cycle is complete, that section can be attached to the bioreactor and another steam-in-place cycle can be performed.

Connection instructions (Figure 14):

1. Connect vent filter (C) to u-bend (D).
2. Connect u-bend to housing and to A2B tubing set (B).
3. Attach permeate pressure sensor (E) to housing permeate port. Depending on harvest bag port, connect adapter tubing (not supplied) to end of the pressure sensor.
4. Attach left-facing bivalve/u-bend (A) to A2B tubing set (B). Open valves V3 and V4. Autoclave the assembly. Close valves V3 and V4.
5. Attach the right-facing bivalve (A) to the bioreactor. Open valve V1a and attach trap. Open valve V1. Steam in place. Close V1.
6. Connect bivalves to each other. Open valves V1a and V2a. Valves V1 and V2 should be closed. SIP the bivalve connection. Close valves V1a and V2a. Open valves V1 and V2 for operation.

The following steam-in-place procedure is recommended for hard connections:

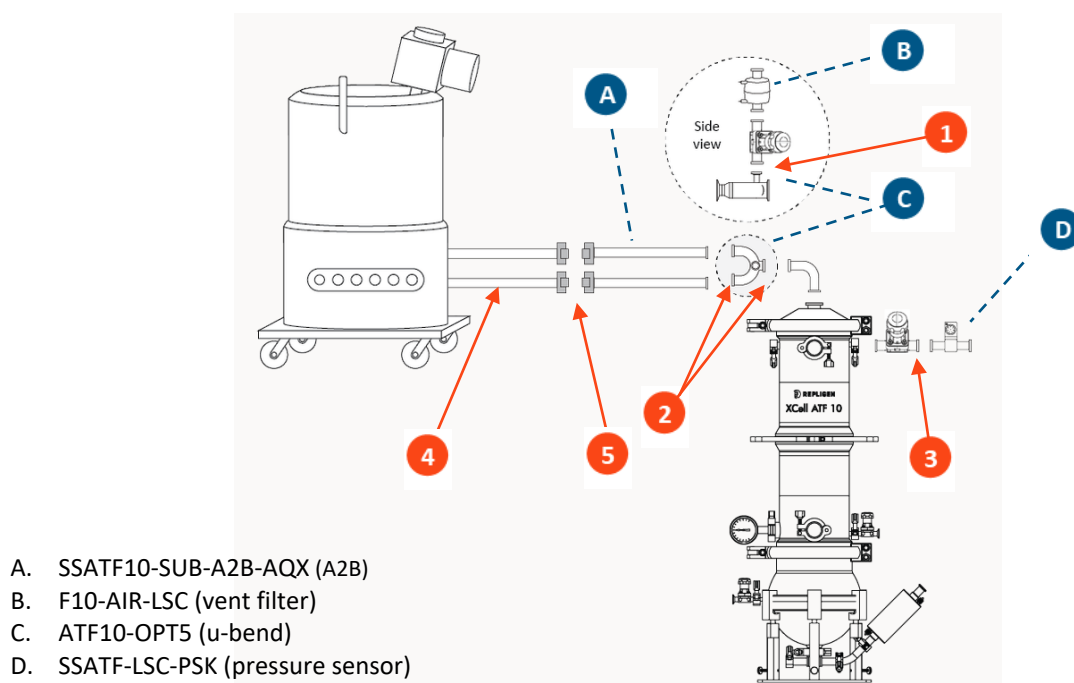
1. Attach a steam trap to the condensate valve and connect to a drain.
2. Close steam inlet and condensate drain valves.
3. Securely connect a regulated steam source to the steam inlet valve.
4. Open steam service.
5. Slowly open steam inlet valve.
6. Slowly open steam condensate valve.
7. Sterilize connection for about 20 min. at 121° C and ~16 psi.
8. Cool down.

9. Close the condensate valve.
10. Rapidly close the steam inlet valve and immediately open the main valve into the filtration assembly to minimize a pressure drop in the connection.

8.3.2.1 Tubing set kit assembly for XCell® ATF 10 connected to single-use bioreactor using AsepticQuik® X tubing set.

Assembly of the housing, tubing set, and accessories, on the right side of the system is completed prior to autoclaving.

Figure 15. XCell® ATF 10 connection to single-use bioreactor (AsepticQuik® X)



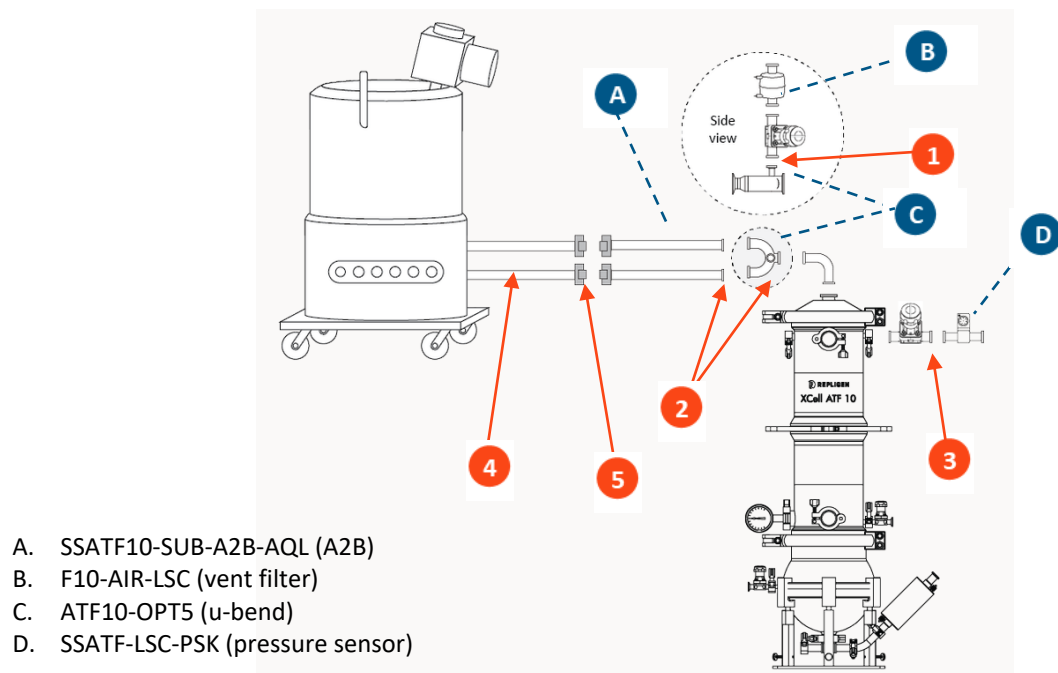
Connection instructions (Figure 15):

1. Connect vent filter (B) to u-bend with vent port (C).
2. Connect u-bend to housing and to A2B tubing set (A).
3. Attach permeate pressure sensor (D) to housing permeate port. Depending on harvest bag port, connect adapter tubing (not supplied) to end of the pressure sensor. Open all valves. Autoclave the assembly.
4. Determine the recommended aseptic connector for SUB. Connect the adapter tubing (not supplied) to SUB. Clamp sterile tubing.
5. Connect assembly to bioreactor.

8.3.2.2 Tubing set kit assembly for XCell® ATF 10 connected to single-use bioreactor using AseptiQuik® L tubing set

Assembly of the housing, tubing set, and accessories, on the right side of the system is completed prior to autoclaving.

Figure 16. XCell® ATF 10 connection to single-use bioreactor (AseptiQuik® L)



Connection instructions (**Figure 16**):

1. Connect vent filter (B) to u-bend with vent port (C).
2. Connect u-bend to housing and to A2B tubing set (A).
3. Attach permeate pressure sensor (D) to housing permeate port. Depending on harvest bag port, connect adapter tubing (not supplied) to end of the pressure sensor. Open all valves. Autoclave the assembly.
4. Determine the recommended aseptic connector for SUB. Connect the adapter tubing (not supplied) to SUB. Clamp sterile tubing.
5. Connect assembly to bioreactor.

8.4 Disassembly and maintenance

8.4.1 Removing the housing from the bioreactor

1. Stop the permeate/harvest pump.
2. Stop and disconnect diaphragm pump pneumatic line from the pump air inlet filter.
3. Close or disconnect compressed air and vacuum services from the pneumatic enclosure.
4. Disconnect sensors from the filtration assembly to pneumatic enclosure.
5. If necessary, remove the pneumatic enclosure from the filtration assembly.

6. Close and disconnect the permeate line.
7. Close both bivalves connecting the filtration assembly to the vessel.
8. Drain liquid from the connection.
9. Optionally, purge the connection with water, steam, or some other medium.
10. Disconnect the filtration assembly from vessel between the two bivalves.
11. Remove the filtration assembly to an appropriate work area.

8.4.2 HFF Removal

1. Drain the system into an appropriate waste vessel or drain.
2. Remove all sensors from the housing.
3. Remove air inlet filter connected to the diaphragm pump and any other connections to the XCell® ATF Housing.
4. Open the clamp connecting the filter housing to the diaphragm pump and separate.
5. Open the clamp connecting the reducer to the filter housing and separate.
6. Remove the HFF from housing by firmly pressing it from one end.
7. Remove the O-ring at the exposed end of the HFF.
8. Press the HFF in the opposite direction to remove.
9. Prepare filter housing for cleaning and reuse.

8.4.3 Decontaminating the HFF for Disposal

1. Rinse the HFF two times with water to remove residual cells and debris.
2. Decontaminate with either 0.5M NaOH, potassium hydroxide, or bleach for 2 – 24 hours.

Note: 5.25% chlorine is equivalent to 52,500 parts per million (ppm). If household chlorine bleach is used, two working solutions are generally recommended: 5000-6000 ppm for initial decontamination of organic spill material, and 500 - 600ppm for disinfection of cleaned surfaces.

8.4.4 Pump Air Inlet Filter, “O” Rings, Gaskets, and Quick Connects

All consumable items are single use.

9. Appendix A: Safety, handling, and conformity information

9.1 Safety

- Repligen XCell® ATF Technology is rated for acceptable sound levels (60 dBA).
- Complete system visual inspection for damage or potential risk to the operator, surrounding personnel, or equipment on a semi-annual basis.

Annual safety inspection and maintenance:

- Conduct a vacuum system leak assessment.
- Replace the air filter between the XCell® ATF Housing and the XCell® LS Controller.
- Inspect air and vacuum connections.
- Inspect the XCell® ATF Housing components, especially the internal and sealing surfaces for damage, rust, cracks, scoring.
- Perform a pressure hold test of the XCell® ATF Housing.

9.2 Handling Instructions



TRANSPORTATION: The Pneumatic Enclosure weighs 13 kg (29 lbs). Care should be taken when lifting and transporting and use of a cart is recommended.



VOLTAGE: The XCell® ATF 4 Housing, XCell® ATF 6 Housing, and XCell® ATF 10 Housing have been assessed for CE regulations under the current applicable Machinery Directives such as Essential Health and Safety Requirements, the Low Voltage Directive, and the Electromagnetic Compatibility Directive and the Pressure Equipment Directives. Please refer to the Declaration of Conformity letter included with the equipment.



NOTE: The XCell® ATF 4 Housing, XCell® ATF 6 Housing, and XCell® ATF 10 Housing have been assessed for CE regulations under the current applicable Machinery Directives such as Essential Health and Safety Requirements, the Low Voltage Directive, and the Electromagnetic Compatibility Directive and the Pressure Equipment Directives. Please refer to the Declaration of Conformity letter included with the equipment.

9.3 Conformity

9.3.1 EU Declaration of Conformity

The XCell™ Housing has been assessed for CE regulations. Refer to Declaration of Conformity provided with the Housing for details.

The XCell® ATF Housing has been marked legibly and indelibly with following information:

- Name and address of the manufacturer
- The serial number
- Designation of series or type

- CE mark
- Year of construction
- The weight of the equipment

9.3.2 Tube set kits

Tube set kits are manufactured under the Repligen Quality Management System certified under current revision of ISO 9001:2015. All product-contact components are USP Class VI, (USP<88>) and/or ISO 10993 tested and free of animal derivatives or are compliant with EMA/410/01 guidelines. Single use tubing set kits conform to ANSI/AAMI/ISO 11137-1/ -2 guidelines for VDmax25 to provide a minimum sterility assurance level (SAL) of 10⁻⁶ for an established irradiation dose. Tube set kits meet the current USP bacterial endotoxin test (USP<85>). Aqueous extracts contain <0.25 EU/mL as determined by the limulus amebocyte lysate test (LAL) and meet the current USP particulate matter in light obscuration particle count tests (USP<788>).

10. Appendix A: Spare Parts

Table 16. XCell® ATF 4 Housing Spare Parts

Item Number	Item Description
ATF4:AIR-ASSY	Assy, Air Inlet, XCell4
ATF4:PH-AA-AIR	Assy, Pump Hemisphere, air side, XCell4
ATF4:PHLA-SMP	Assy, Pump Hemisphere, liquid side, XCell4
SG-2.5-E	Gasket, Sanitary, 2.5" TC
TC-CAP-3/4	Cap, Sanitary, 3/4" TC

Table 17. XCell® ATF 6 Housing Spare Parts

Item Number	Item Description
A6-BASE	Assy, Base Plate, Pump Hemi, XCell6
A6-BASE-SHCS	Socket Head Cap (4) & Set Screw (1x)
A6-H1	Assy, Filter Housing, XCell6
ATF610-TEE	Short Tee, 3/4" TC x 3/4" TC x CPM
ATF6:AIR-ASSY	Assy, Air Inlet, XCell6
ATF6:PH-AA-AIR	Assy, Pump Hemisphere, air side, XCell6
ATF6:PHLA	Assy, Pump Hemisphere, liquid Side, XCell6
CS-10650	Legacy Air Connection, ATF6
SG-1.0-E	Gasket, Sanitary, 1" TC
TC-BRB1	Adapter, Hose Barb, 3/4" TC x 1/4" HB
TC-EL1S	Elbow, 90 Deg, 1.0" TC
V1-S-0.5N	Sanitary Diaphragm Valve, 1/2" TC

Table 18. XCell® ATF 10 Housing Spare Parts

Item Number	Item Description
A10-STAND	Assy, Stand, XCell10
A10:C1-LOCK-A	C Clamp Lock A (Long) for XCell10 pump
A10:C1-LOCK-B	C Clamp Lock B (Short) for XCell10 pump
A10RF-C3	Assy, ASME Clamp, XCell10
A10RF-C3-RELIEF	Assy, ASME Clamp w/ Relief, XCell10
A10RF-HA	Assy, Lifting Handle, XCell10
ATF10 BOLT-ASSY	Assy, 2 nuts & 1 bolt for XCell10
ATF10:AIR-ASSY	Assy, Air Inlet, XCell10
ATF10:PH-AA-AIR	Assy, Pump Hemisphere, air side, XCell10
ATF10:PHLA	Assy, Pump Hemisphere, liquid side, XCell10
ATF610-TEE	Short Tee, 3/4" TC x 3/4" TC x CPM
SG-05-E	Gasket, Sanitary, 1/2" TC
SG-075-E	Gasket, Sanitary, 3/4" TC
SG-1.5-E	Gasket, Sanitary, 1.5" TC
SG-1.5-S	Gasket, Sanitary, 1.5" TC-silicone
SG-6.0-SCH5	Sanitary Gasket, 1.5"TC, Silicone
TC-EL-1.5S	Elbow, 90 Deg, 1.5" TC

Table 19. Connections Spare Parts

Item Number	Item Description
SC-075	Clamp, Sanitary, 1/2"-3/4" TC
SC-1.5	Clamp, Sanitary, 1.5" TC
SC-2.5	Clamp, Sanitary, 2.5" TC
SC-3L	Clamp, Sanitary, 3" TC
SC-4.0	Clamp, Sanitary, 4" TC
SC-6.0	Clamp, Sanitary 6" TC

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