

# XCell® ATF 2 and 4 Stainless Steel Housing

## User Guide

For Use with:

- XCell® ATF 2 Stainless Steel Housing
- XCell® ATF 4 Stainless Steel Housing



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## Abbreviations

A2B	ATF device to bioreactor
A2C	ATF device to controller
ATF	Alternating tangential flow
DAC	Disposable aseptic connectors
DF	Driving force
DP	Driving pressure
E	Exhaust
FAS	Field Applications Specialist
HFF	Hollow fiber filter
HFM	Hollow fiber module
hr	Hour
kD	kilodalton
L	Liter
Lbs	Pounds
m	Meter
M	Molar
min	Minute
mm	millimeter
NaOH	Sodium hydroxide
P	Pressure
PA	Pump air hemisphere
PES	Polyethersulfone
PL	Pump liquid hemisphere
ppm	Parts per million
PRV	Pressure regulator valve
PS	Polysulfone
psi	Pounds per square inch
psig	Pounds per square inch gauge
SIP	Steam in Place
SUB	Single-use bioreactor
μm	micron

## 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](http://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

XCell® ATF 2 and XCell® ATF 4 Stainless steel Housings enable production of high density, high viability cell culture applications with linear flux and low shear for scale-up to 50 L. The stainless steel product line includes the housings, XCell® Lab 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 (PS) 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 2 and 4 Stainless Steel Housings to both glass and single-use bioreactors, simplifying preparation and connectivity and allowing for the proper exchange of cell culture material. XCell® Lab Controllers operate the diaphragm pumps. The housings and tubing set kits are also compatible with legacy C24 Controllers. Additional information on the use of the controllers and XCell® ATF Technology can be found in XCell® Lab Controller User Guide.

This document describes the major components, set-up, connectivity, and preparation of the glass XCell® ATF 2 and 4 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 Stainless Steel Housings

XCell® ATF Technology includes two sizes of housings 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:** XCell® ATF 2 utilizes a fully encapsulated hollow fiber membrane that is attached above the stainless steel diaphragm pump. XCell® ATF 4 includes a stainless steel housing that holds the 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 assembly:** tubing assembly connecting the filtration assembly to a bioreactor or process vessel.
- **Bioreactor adapter:** adapter between the connection assembly and bioreactor port. Typical fittings for glass bioreactors include Ingold or tri-clamp. Single-use bioreactors (SUB) use disposable, aseptic connectors.

**Note:** *Bioreactor adapter is not provided.*

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

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

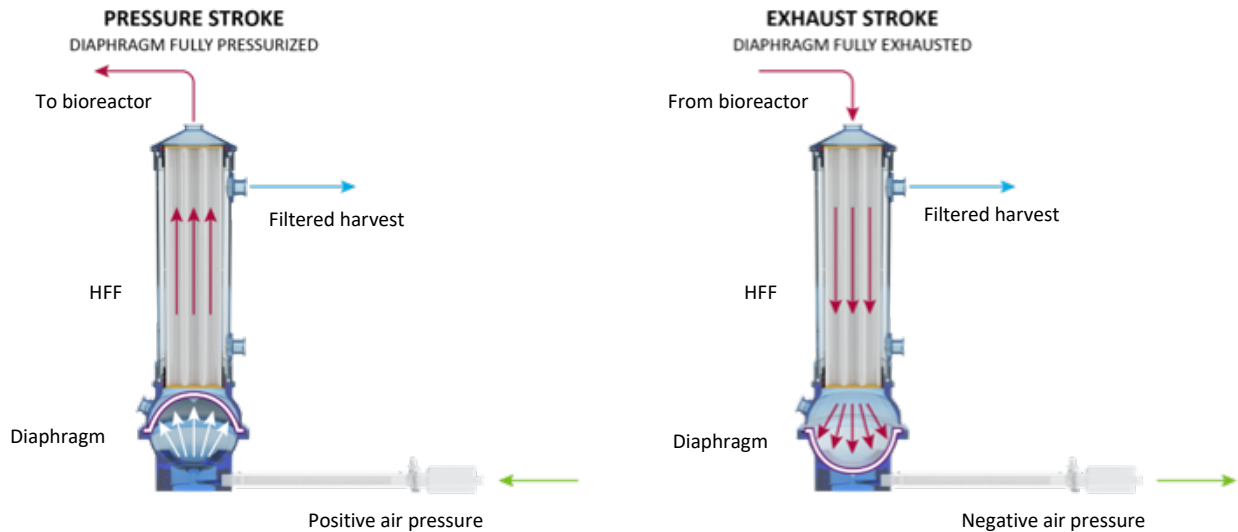
### 2.2 XCell® ATF Housing pump cycle

The diaphragm pump generates alternating tangential flow (ATF) through the hollow fiber filter. ATF is a pulsating, reversible flow of liquid between a process vessel and diaphragm pump.

The process consists of two cycles ([Figure 1](#)), the pressure cycle (P-cycle) and the exhaust cycle (E-cycle). The P cycle occurs when air is fed into the ATF pump, moving the diaphragm up towards the pump liquid-side (PL) hemisphere and driving the liquid from the diaphragm pump through the HFF and into the process vessel.

The E-cycle occurs when vacuum is introduced, thus pulling the diaphragm down towards the pump air-side (PA) hemisphere, and liquid is pulled from the process vessel through the HFF, and back into the diaphragm pump. The diaphragm must travel between the two extremes to complete one cycle. The flow through the hollow fiber filter generates tangential flow in each direction in an alternating fashion.

Figure 1. Pressure and exhaust strokes



**Note:** XCell® ATF Stainless Steel 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 Stainless Steel 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
<b>Note:</b>	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

### 5.1 Utility requirements

Utility requirements for the XCell® ATF 2 and 4 Systems can be found in the XCell® Lab Controller User Guide.

**Table 3. Dimensions**

Filtration Assembly	Dimensions <sup>1</sup> H, W	Nominal footprint (m <sup>2</sup> )
XCell® ATF 2 SS Pump Housing	30", 5"	0.04
XCell® ATF 4 SS Pump Housing	21", 8"	0.13

<sup>1</sup>Indicated dimensions are estimates for the filtration assembly, as the choice of cartridge and the connection 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 4](#)).

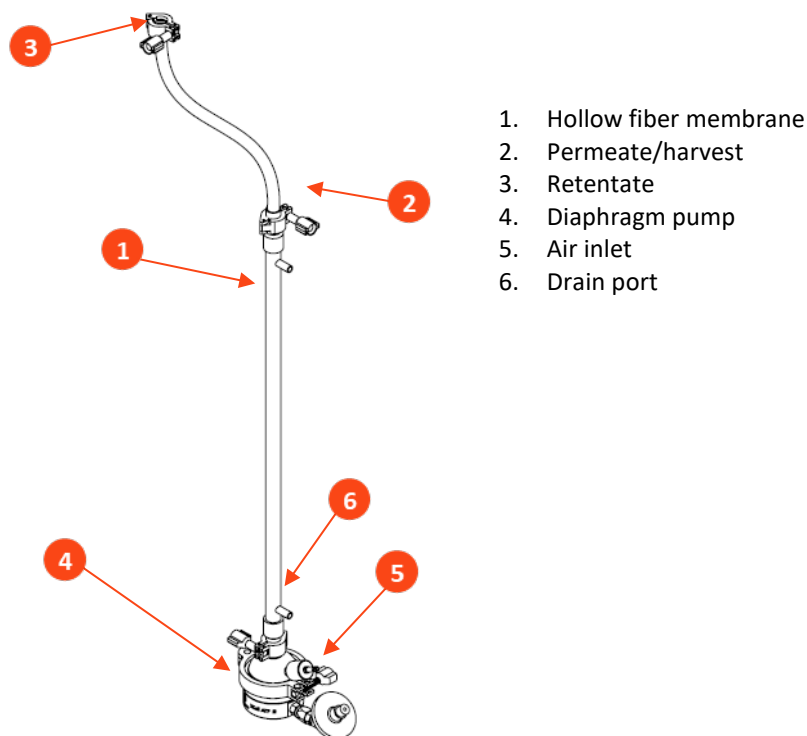
**Table 4. Suggested scale of operation**

Housing	Bioreactor size
XCell® ATF 2	2 - 10 L
XCell® ATF 4	10 - 50 L

## 6. XCell® ATF 2 Stainless Steel Housing

XCell® ATF 2 Stainless Steel Housing (Figure 2) is recommended for use with 2 - 10 L bioreactors. The assembly of the housing and accessories includes installing the diaphragm into the housing, connecting the hollow fiber filter to the housing, and connecting the filter to the bioreactor and the harvest vessel. The system is prepared for use by filter wetting, integrity testing, and autoclaving.

Figure 2. XCell® ATF 2 Stainless Steel Housing



1. Hollow fiber membrane
2. Permeate/harvest
3. Retentate
4. Diaphragm pump
5. Air inlet
6. Drain port

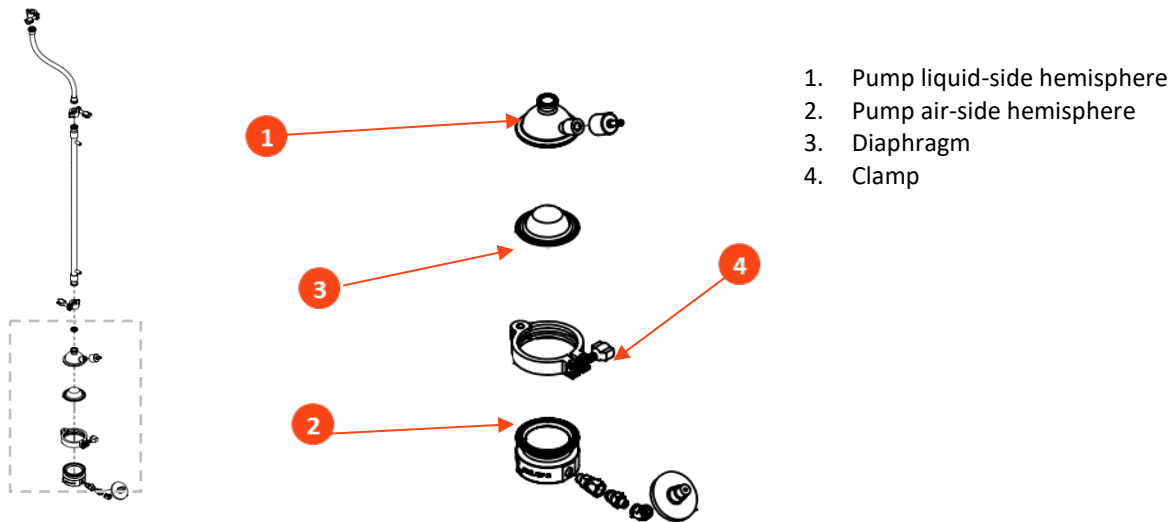
### 6.1 Stainless steel XCell® ATF 2 Housing assembly

XCell® ATF 2 Stainless Steel Housing assembly includes installation of the diaphragm and hollow fiber filter and connection of the tubing from the housing to the bioreactor and the housing to 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 2 Stainless Steel Housing**



- 1. Pump liquid-side hemisphere
- 2. Pump air-side hemisphere
- 3. Diaphragm
- 4. Clamp

**6.2 XCell® ATF 2 Device Diaphragm Placement**

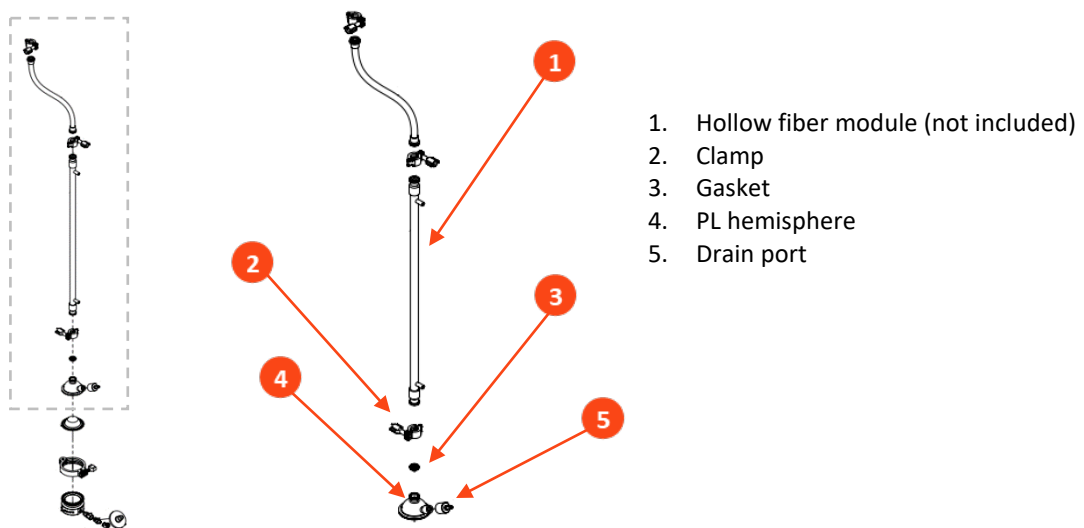
Important: The silicone diaphragm must be replaced after each run, prior to sterilization.

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. Place the pump liquid-side (PL) hemisphere (1) on top. 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.

**6.2.1 XCell® ATF 2 Stainless Steel Housing hollow fiber filter installation**

XCell® ATF 2 Stainless Steel Housing accommodates a variety of hollow fiber modules. For selection support, please contact your local Repligen Field Applications Specialist (FAS).

**Figure 4. XCell® ATF 2 Stainless Steel Housing Installation of HFM**



- 1. Hollow fiber module (not included)
- 2. Clamp
- 3. Gasket
- 4. PL hemisphere
- 5. Drain port

1. Place a sanitary gasket ([Figure 4](#), 3) into the sanitary groove on top of the Pump Liquid-side (PL) hemisphere (4).
2. Connect the HFM (1) to the pump housing by aligning it with the sanitary gasket on the top of the PL hemisphere (4).
3. Secure the connection tightly with a ¾" tri-clamp (2).

### 6.3 Filter preparation

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

#### 6.3.1 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.

#### 6.3.2 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 Autoclaving User Guide for configurations for both glass and single-use bioreactor integrity tests and testing instructions and criteria.

#### 6.3.3 Autoclaving

The XCell® ATF 2 Stainless Steel Housing assembly is autoclaved either before or after integrity testing. XCell® ATF 2 comprises a small-diameter, self-contained hollow fiber filter connected to a diaphragm pump, and can be autoclaved using a pre-programmed liquid cycle at 121°C for 30 minutes. Refer to the XCell® ATF Technology Filter Preparation and Autoclaving User Guide for instructions.

#### 6.3.4 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.

### 6.4 Connecting XCell® ATF 2 Stainless Steel Housing to a bioreactor

XCell® ATF 2 Stainless Steel Housing is generally connected to the bioreactor prior to autoclaving.

Fluid management for XCell® ATF 2 Stainless Steel Housings include retentate (A2B) tubing set kits and accessories that connect the housing with the bioreactor, ensuring proper exchange of cell culture material. The A2B tubing connects to XCell® ATF 2 with a tri-clamp. The bioreactor end of the tubing is available with either a tri-clamp or an AseptiQuik® or Readymate™ disposable aseptic connector. The tubing is connected to the headplate ([Table 5](#)) and feeds into a dip tube (P/N TC-DIP-LAB-.25/.5-250 or TC-DIP-.25/.5-250). Permeate tubing connects to the housing with a hose barb and should be sterilized by autoclave or attached to the harvest vessel with a tubing welder or disposable sterile coupling. The permeate tubing should be compatible with the permeate/harvest pump. Tubing is also provided for the bottom permeate and drain ports, both of which connect with a hose barb.

**Table 5. Headplate fitting part numbers**

Head plate fitting	Bioreactor
HP:MPP-19	3 L Applikon
HP:MPP-M26	5 - 10 L Applikon
HP:BBI-M26	Sartorius/BBI
HP-PG13.5L	Millipore Mobius® CellReady
PG13.5	Generic

#### 6.4.1 XCell® ATF 2 Stainless Steel tubing set kits and accessories

Several components are required to connect the XCell® ATF 2 Stainless Steel Housing to a bioreactor. XCell® ATF 2 autoclavable tubing set kits ([Table 5](#)) 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 6](#)) are required, regardless of the chosen tubing set.

**Table 6. XCell® ATF 2 tubing set kit options**

Tube set part number	Tubing connection	Use
ATF2-A2B-TC	Tri-clamp/tri-clamp	ATF to bioreactor
ATF2-A2B-RMTC	GE ReadyMate™/tri-clamp	ATF to bioreactor
ATF2-A2B-TCAQ	AseptiQuik®/tri-clamp	ATF to bioreactor
ATF2-A2B-AQ	AseptiQuik®/ AseptiQuik®	ATF to bioreactor

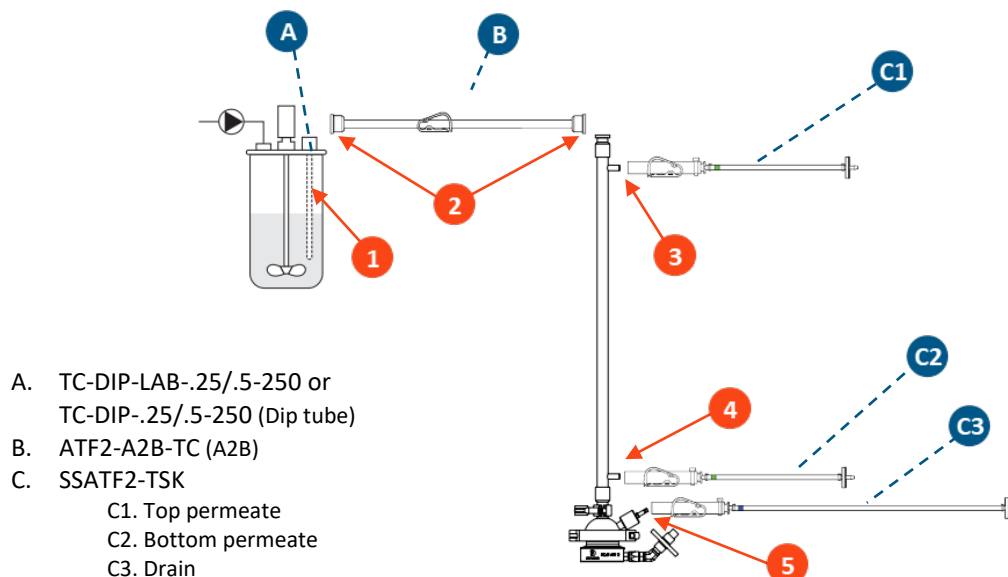
**Table 7. XCell® ATF 2 required accessories**

Description	Part number	Single/Multi-use	Pressure rating	ID	Material of construction
Top and bottom permeate and drain	SSATF2-TSK	SU	25 psi	0.25"	Platinum-cured silicone

### 6.4.2 Tubing set kit for XCell® ATF 2 Stainless Steel Housing connected to glass bioreactor

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

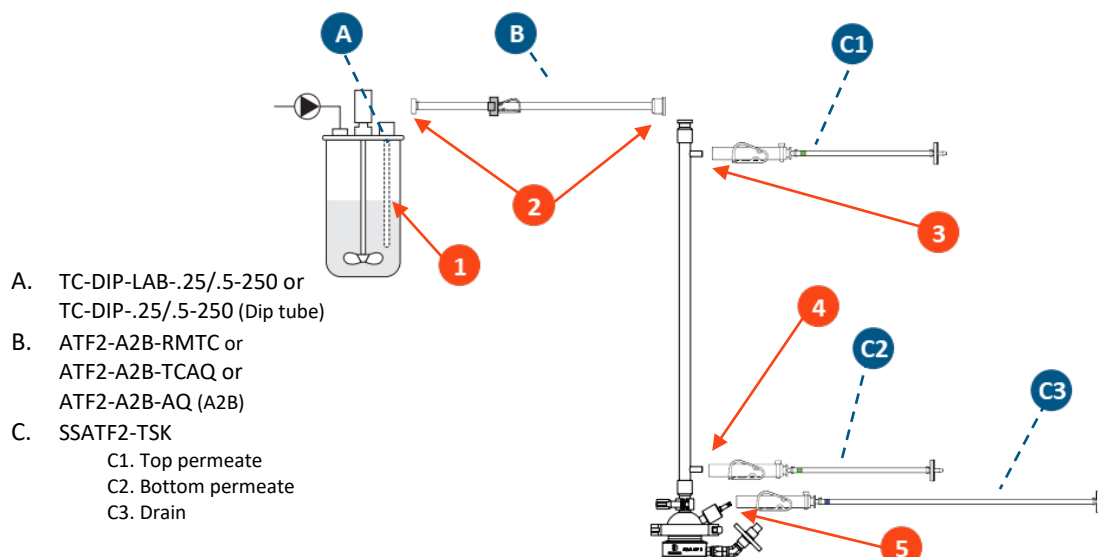
**Figure 5. XCell® ATF 2 Stainless Steel Housing connection to glass bioreactor (tri-clamp)**



Connection instructions ([Figure 5](#)):

1. Ensure dip tube (A) is attached to head plate of bioreactor.
2. Attach A2B tubing (B) to XCell® ATF 2 and bioreactor head plate.
3. Attach top permeate (C1) to hose barb.
4. Attach bottom permeate (C2) to hose barb.
5. Attach drain (C3) to hose barb. Autoclave.

**Figure 6. XCell® ATF 2 Stainless Steel Housing connection to glass bioreactor (AseptiQuik®/ReadyMate™)**



Connection instructions ([Figure 6](#)):

1. Ensure dip tube (A) is attached to head plate of bioreactor.
2. Attach A2B tubing (B) to XCell® ATF 2 and bioreactor head plate.

**Note:** Bioreactor adapter tubing not provided.

3. Attach top permeate (C1) to hose barb.

4. Attach bottom permeate (C2) to hose barb.
5. Attach drain (C3) to hose barb. Autoclave.

## 6.5 Disassembly and maintenance

### 6.5.1 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 valves 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.
10. Remove the filtration assembly to an appropriate work area.

### 6.5.2 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 to the diaphragm pump and separate.
5. Open the clamp connecting the filter to the A2B tubing and separate.
6. Remove the O-ring at the exposed end of the HFF.
7. Press the HFF in the opposite direction to remove.
8. Prepare filter housing for cleaning and reuse.

### 6.5.3 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.

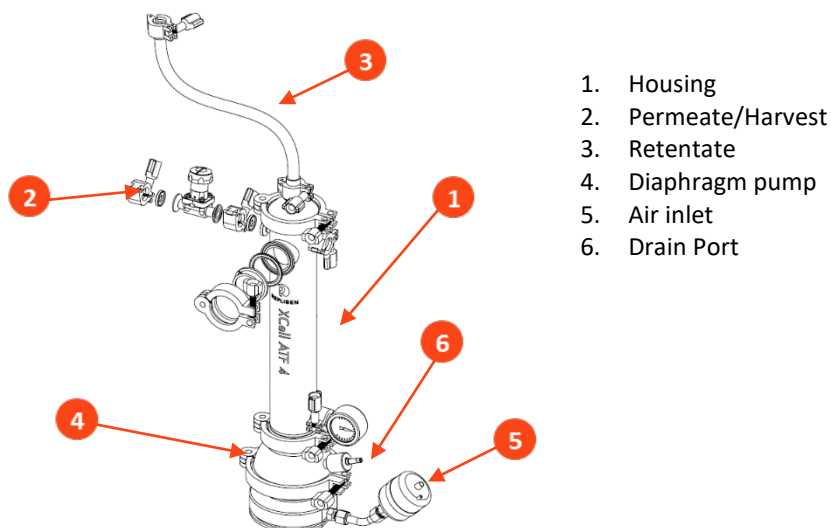
### 6.5.4 Pump Air Inlet Filter, O-Rings, Gaskets, and Quick Connects

All consumable items are single use.

## 7. XCell® ATF 4 Stainless Steel Housing

XCell® ATF 4 Stainless Steel Housing (Figure 7) 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 7. XCell® ATF 4 Stainless Steel Housing



1. Housing
2. Permeate/Harvest
3. Retentate
4. Diaphragm pump
5. Air inlet
6. Drain Port

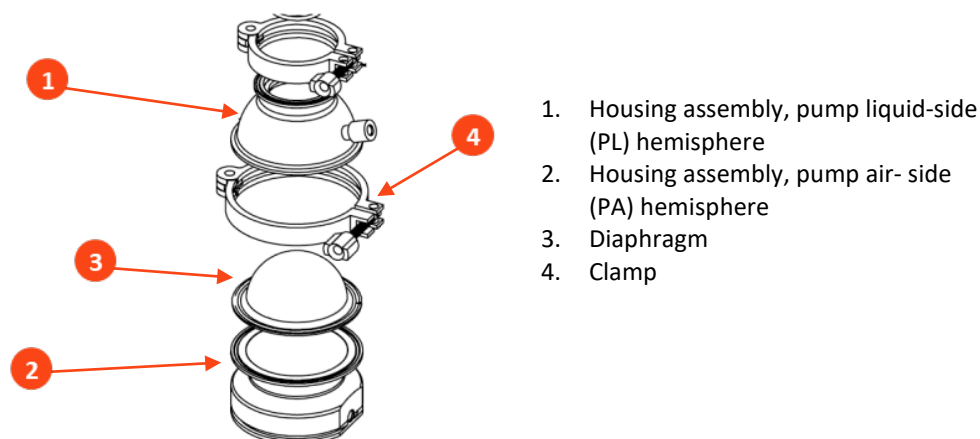
### 7.1 XCell® ATF 4 Stainless steel Housing assembly

XCell® ATF 4 Stainless Steel 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 XCell® ATF 4 Stainless Steel Housing****7.1.1.1 XCell® ATF 4 Stainless Steel 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 4 Stainless Steel Housing hollow fiber filter installation**

XCell® ATF 4 Stainless Steel 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 4 Stainless Steel 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 glass and single-use bioreactor integrity tests and testing instructions and criteria.

### 7.2.4 Autoclaving

The XCell® ATF 4 Stainless Steel 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 4 Stainless Steel Housing to a bioreactor

Fluid management for XCell® ATF 4 Stainless Steel Housings include retentate (A2B) tubing set kits and accessories that connect the housing with the bioreactor, ensuring proper exchange of cell culture material. The A2B tubing connects to XCell® ATF 4 with a tri-clamp. The bioreactor end of the tubing is available with either a tri-clamp or an AseptiQuik® disposable aseptic connector. The tubing is connected to the headplate ([Table 8](#)) and feeds into a dip tube (P/N TC:DIP-10/250 or TC:DIP-10/450). A pressure sensor kit connects to the housing with a tri-clamp and the permeate tubing connects to the pressure sensor. The permeate tubing should be sterilized by autoclave or attached to the harvest vessel with a tubing welder or disposable sterile coupling. The permeate tubing should be compatible with the permeate/harvest pump. Tubing is also provided for the drain port and connects with a hose barb.

**Table 8. Headplate fitting part numbers**

Head plate fitting	Bioreactor
HP:MPP-19	3 L Applikon
HP:MPP-M26	5 -10 L Applikon
HP:BBI-M26	Sartorius/BBI
HP-PG13.5L	Millipore Mobius® CellReady
PG13.5	Generic

### 7.3.1 XCell® ATF 4 Stainless Steel Housing tubing set kits and accessories

Several components are required to connect the XCell® ATF 4 Stainless Steel Housing to a bioreactor. XCell® ATF 4 autoclavable tubing set kits ([Table 9](#)) 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 10](#)) are required, regardless of the chosen tubing set.

**Table 9. XCell® ATF 4 tubing set kit options**

Tube set part number	Tubing connection
ATF4-A2B-TC	Tri-clamp
ATF4-A2B-TCAQ	AseptiQuik®

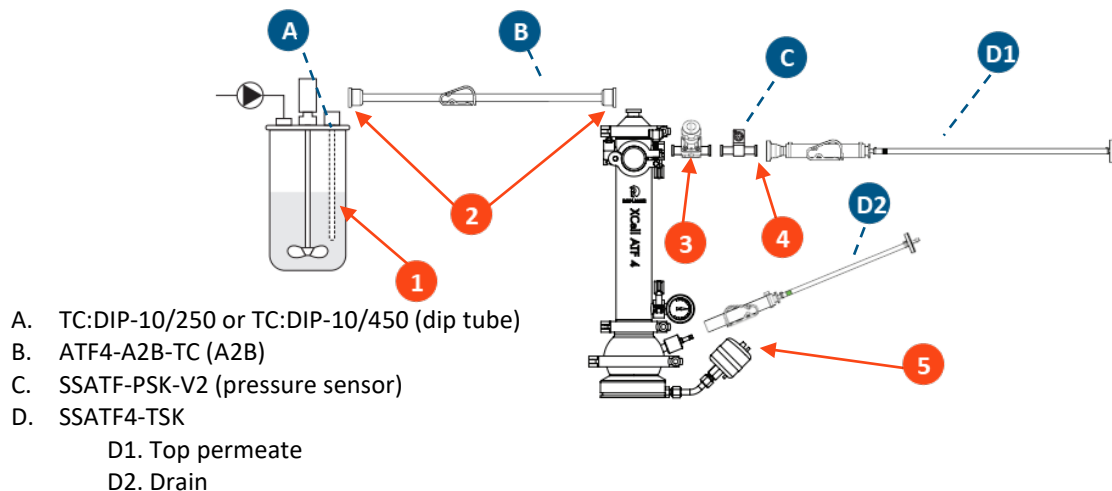
**Table 10. XCell® ATF 4 required accessories**

Description	Part number	Single- or multi-use	Pressure rating	ID	Material of construction
Top permeate and drain	SSATF4-TSK	SU	25 psi	1/4"	Platinum-cured silicone
Dip tube	TC:DIP-10/250 or TC:DIP-10/450	MU	N/A	3/8"	316 L SS
Pressure sensor kit	SSATF4-PSK-V2	SU	25 psi	3/8"	Polycarbonate

### 7.3.2 Tubing set kit for XCell® ATF 4 Stainless Steel Housing connected to glass bioreactor

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

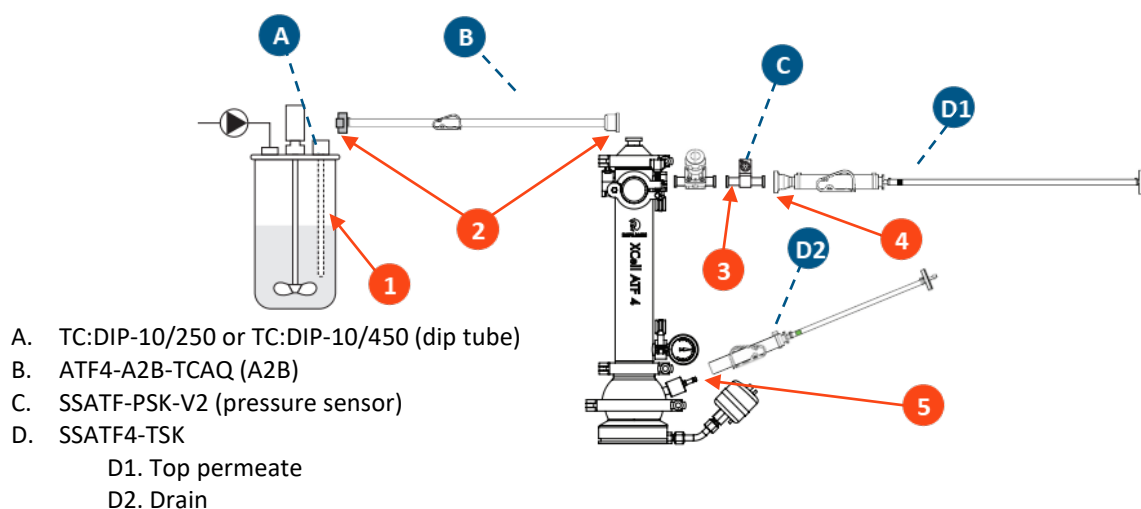
**Figure 9. XCell® ATF 4 Stainless Steel Housing connection to glass bioreactor (tri-clamp)**



Connection instructions ([Figure 9](#)):

1. Ensure dip tube (A) is attached to head plate of bioreactor.
2. Attach A2B tubing (B) to XCell® ATF 4 and bioreactor head plate.
3. Connect pressure sensor (C) to XCell® ATF 4.
4. Attach top permeate (D1) to pressure sensor (C).
5. Attach drain (D2) to hose barb. Autoclave.

**Figure 10. XCell® ATF 4 Stainless Steel Housing connection to glass bioreactor (AseptiQuik®)**



Connection instructions ([Figure 10](#)):

1. Ensure dip tube (A) is attached to head plate of bioreactor.
2. Attach A2B tubing (B) to XCell® ATF 4 and bioreactor head plate.

**Note:** Bioreactor adapter tubing not provided.

3. Connect pressure sensor (C) to XCell® ATF 4.
4. Attach top permeate (D1) to pressure sensor (C).
5. Attach drain (D2) to hose barb. Autoclave.

## 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.

## 8. Appendix 3: Safety, Handling, and Conformity Information

### 8.1 Safety

- Repligen XCell® ATF System 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 Device and the XCell® Lab Controller.
- Inspect air and vacuum connections.
- Inspect the XCell® ATF Device housing components, especially the internal and sealing surfaces for damage, rust, cracks, scoring.
- Perform a pressure hold test of the XCell® ATF Device.

### 8.2 Handling Instructions



**TRANSPORTATION:** The Pneumatic Enclosure weighs 20 kg (44 lbs). Care should be taken when lifting and transporting and use of a cart is recommended.



**VOLTAGE:** The XCell® ATF 4 Device, has 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 2 Device, and XCell® ATF 4 Device 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.

### 8.3 Conformity

#### 8.3.1 EU Declaration of Conformity

The XCell® Device has been assessed for CE regulations, refer to Declaration of Conformity provided with the Device for details.

The XCell® ATF Device 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

### 8.3.2 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<sup>-6</sup> 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 amoebocyte lysate test (LAL) and meet the current USP particulate matter in light obscuration particle count tests (USP<788>).

## 9. Appendix B: Spare parts

**Table 11. XCell® ATF 2 spare parts**

Part Number	Description
A2-PA1	Pump Hemisphere, Air Side, ATF2
D2-S1	Diaphragm, Pump, ATF2
SC-2.5	Clamp, Sanitary, 2 1/2" TC
ZZ-ATF2-A2-PL1	Pump Hemisphere Assembly, Liquid Side, ATF2
A2-SMP3-ASM	Vent Port Stem Assembly ATF2/4
A2-AIR-F	let Assembly 45 deg Female Pipe Elbow
F-AIR2	Air Filter, ATF2
SG-075-E	Sanitary Gasket, 3/4" TC
SC-075	Clamp, Sanitary 1/2-3/4" TC
NA	F2 2 Micron PS Hollow Fiber (Not included)
ATF2-A2B-TC	Silicone Tubing W/ TC Ends, ATF2
NA	7/16-20 Straight Thread x 9/16-18 Swivel
NA	9/16-18 Swivel Thread x 1/8-27 NPT Male Connector
TU-SS-3/8 OD	TUBING, Air Inlet Line, 3/8" SS x Tube x 2.5 LG AISI
D2-S1	Diaphragm, Pump ATF4
A2-SMP3-ASM	sampler Port Stem Assembly, ATF2/4

**Table 12. XCell® ATF 4 spare parts**

Part Number	Description
SC-4.0	Sanitary, 4" TC AISI Type 316L stainless steel 1
SG-2.5-E	Sanitary Gasket, 2 1/2" TC EPDM 2
RM-10266	Hollow Fiber Module PC/PS w/ Hollow Fibers 1
A4H1	Housing Assembly, ATF4 AISI Type 316L stainless steel
O-224-S-GMP	GMP P O-Ring, ATF4
A4-R1	Reducer ATF4
SC-2.5	Clamp Sanitary, 3" TC
ATF4-A2B-TC	Silicone Tubing W/ TC Ends
SC-075	Clamp Sanitary 1/2-3/4" TC
SG-075-E	Sanitary Gasket, 3/4" TC
SG-1.5-E	Sanitary Gasket, 1-1/2" TC
TC-W2-1.5	Window, Sanitary 1.5"TC, With / Rem. Glass Insert
SC-1.5	Clamp Sanitary 1-1/2" TC
TC-PG-W0.750	Pressure Gauge, 3/4 TC 30PSI to -30" Hg
TC-CAP-3/4	Sanitary Cap 3/4"
SG-05-E	Sanitary Gasket, 1/2" TC
V1-S-0.5N	Sanitary Diaphragm Valve, 1/2" w/TC ends
TC-BRB1	Sanitary Adapter, 3/4" Tri-Clamp x 1/4" Hose Barb Fitting



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