

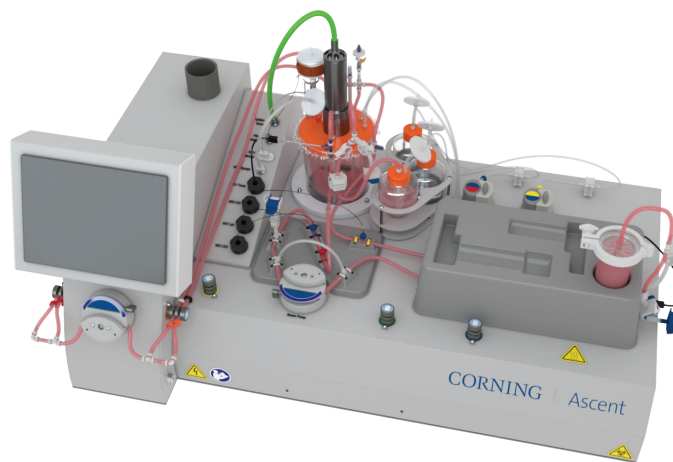
# Corning® Ascent™ Fixed Bed Reactor Process Development System

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The Corning Ascent FBR PD System is designed to enable process development and production scale cell culture capacities for cell and gene therapy workflows. The system is designed to provide viable cell harvest capability that can enable it to be used as seed train and potentially for other applications that require the ability to harvest large quantities of cells, such as regenerative medicine. Three single-use Ascent FBR bioreactor sizes: 1 m<sup>2</sup>, 2.5 m<sup>2</sup> and 5 m<sup>2</sup>, help in the development of a stable and well-defined manufacturing process.

The Corning Ascent FBR PD System is an automated, perfusion bioproduction platform for attachment-dependent cell-based processes. The platform is designed to provide flexibility in protocol development and hands-off operation during use.

The system's consumable set is equipped with disposable sensors for key process parameters (pH, dissolved oxygen, temperature). All fluid-contacting components are pre-assembled, single-use, and irradiated, requiring no autoclaving. The system is designed to be set up and operational in as little as 20 minutes.



## Features and Benefits

Specially treated woven mesh polymer substrate	<ul style="list-style-type: none"><li>• Uniform fluid flow – efficient nutrient delivery and waste removal</li><li>• Uniform cell growth – beneficial cell distribution and confluence at transfection</li><li>• Improves cell health and product yield</li></ul>
FBR designed to harvest viable cells with >90% recovery	<ul style="list-style-type: none"><li>• Enables its use in other application workflows that require cell recovery for downstream use</li><li>• Enables the bioreactor to be used for seed train, streamlining vessel-to-vessel cell transfer</li></ul>
Bioreactor scalability	<ul style="list-style-type: none"><li>• Ascent FBR PD system bioreactors scale from 1 m<sup>2</sup> to 5 m<sup>2</sup>, helping the development of a stable and well-defined manufacturing process</li></ul>
Separate media condition vessel (MCV)	<ul style="list-style-type: none"><li>• Provides flexibility in media volume and dilution strategy for transfection reagents prior to addition</li></ul>
Automated control, including disposable sensors that monitor DO, pH, temperature	<ul style="list-style-type: none"><li>• Reduced labor costs, hands-off operation, reduced risk of human error</li></ul>
Ready to use, irradiated consumables	<ul style="list-style-type: none"><li>• Minimal set-up required, no autoclaving necessary, no probe calibration required. The minimal setup required can save many hours of valuable time.</li></ul>
Closed system	<ul style="list-style-type: none"><li>• Can be run outside a laminar flow hood. Aseptic connectors or tube welding allow for easy benchtop aseptic cell sampling of the bioreactor.</li></ul>

The Corning® Ascent™ FBR PD system consists of a system controller with Human-Machine Interface (HMI) touchscreen control display (Figure 1) and single-use, irradiated components including a bio-reactor, a media conditioning vessel (MCV), and other consumables, such as tubing, connectors, probes, in-line sensors, and bottles.

During cell culture, a recirculation pump circulates media from the MCV through the fixed bed bioreactor. A separate pump aids in removing depleted media from the MCV and replacing it with fresh media during media maintenance. Cell culture pH and nutrient levels are monitored and maintained via feed and base pumps while temperature-controlled heated nests keep the MCV and bioreactor at a constant temperature. At harvest, cells are released or lysed *in situ* from the bioreactor at the user's discretion. The HMI allows the user flexibility to operate the system in manual or automated modes.

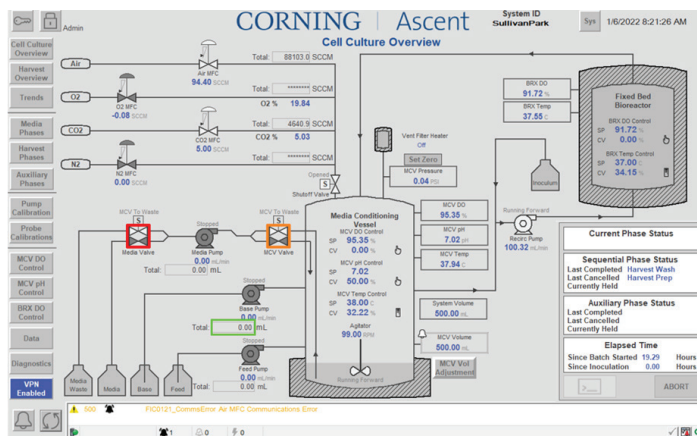
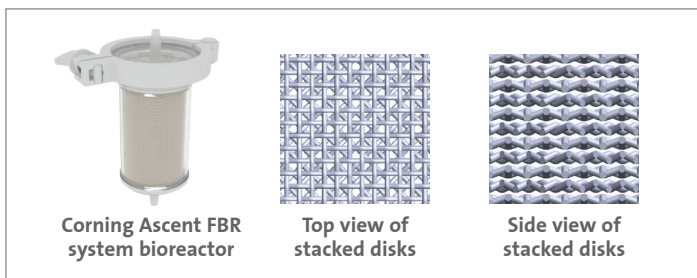


Figure 1. The controller is operated using a touchscreen graphic user interface.

### The Bioreactor Design

The Corning Ascent FBR system's bioreactor features a specially treated and packed polymer mesh that enables uniform, low-shear fluid flow through the bioreactor bed, which promotes evenly distributed cell growth and enhances exposure of cells to nutrients and reagents. This has demonstrated high yields that could result in fewer required runs and significant cost reduction in manufacturing.



The system allows for the removal of the FBR from the controller so it can be moved into a laminar flow hood for sampling. A sanitary twist clamp allows easy access to the segmented sampling mesh located inside the FBR. The 3 sampling mesh disks are divided into 6 segments, each designed for easy removal. Segments may be removed to monitor cell growth within the FBR at various times.

Corning Ascent FBR Pilot and Production systems will be available in multiple surface area sizes, utilizing the same bioreactor technology as the Process Development system to provide linear scalability from 1 m<sup>2</sup> to 1,000 m<sup>2</sup>.

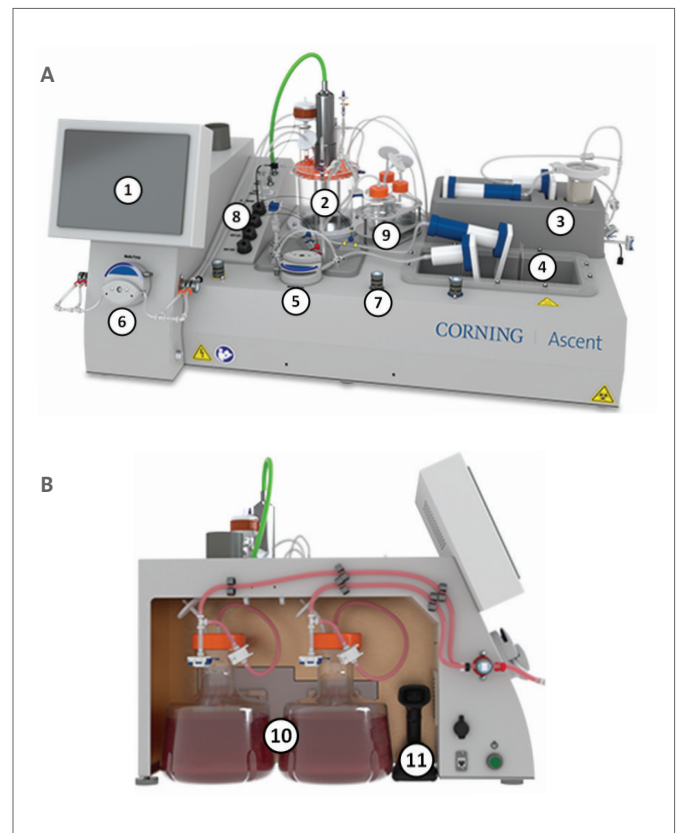


Figure 2. Corning Ascent FBR PD system, top view (A) and showing bottle manifold and bar code scanner, side view (B).

### Main components of the Ascent FBR PD System.

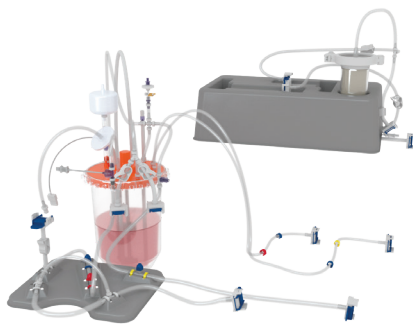
Label	Component
1	Human-Machine Interface (HMI)
2	Media Conditioning Vessel (MCV)
3	Fixed Bed Reactor (FBR) with sterile connectors tray
4	Bioreactor heated nest
5	Recirculation pump
6	Media pump
7	Pinch valve(s)
8	Interface panel
9	Inoculum, base, and feed bottles rack
10	Media Addition and Media Waste bottles
11	Bar code scanner

## Site Requirements

Type	Description
Operating Conditions	<p>The instrument is designed for use under standard operating conditions per UL 61010-1 where:</p> <ul style="list-style-type: none"> <li>Indoor temperature range is 5°C to 40°C. For optimal use, the indoor temperature range shall be between 20°C to 30°C.</li> <li>Maximum relative humidity at 80% for temperatures up to 30°C</li> <li>Maximum altitude up to 2,000 m</li> <li>Pollution degree 2</li> <li>Up to IEC Overvoltage Category II for transient over voltages</li> </ul>
Space Required	<p>A workbench suited to accommodate the equipment dimensions (L x W x H) 53 x 30 x 27 in. (134.62 x 76.2 x 68.58 cm). The workbench shall be sized to allow additional consumables, if required.</p>
System Weight	Base weight (without consumables) is approximately 186 lbs. (84.37 kg).
Power Requirements	<p>Cat. No. 6970, 120 VAC/60 Hz/1-Phase 527 W            Cat. No. 6991, 230 VAC/50 Hz/1-Phase 595 W            One 20 amp. dedicated outlet is required            An uninterruptible power supply (UPS) and a surge protector are recommended.</p>
Gas Connection and Type	<p>All calibrated mass flow controllers (MFCs) are rated for 30 to 35 psig of their respective gases.            Required connection type is 1/4" (6 mm) OD semi-rigid flexible tubing for inlet push connectors.</p>
Communication	Ethernet/IP



Corning Ascent FBR PD Controller



Main Consumables (MCV and BRV) with AseptiQuik® Connectors



Harvest Consumables



Accessory Consumables

## Ordering Information

### Corning® Ascent™ FBR PD Controllers

Cat. No.	Description	Qty/Cs
6970	Ascent FBR PD controller, 120V	1
6991	Ascent FBR PD controller, 230V	1
6992	Ascent FBR PD controller, 100V	1

### Corning Ascent Bioreactor Consumables

Cat. No.	Description	Qty/Cs
6971	Ascent FBR 1 m <sup>2</sup> bioreactor consumable	1
6972	Ascent FBR 2.5 m <sup>2</sup> bioreactor consumable	1
6973	Ascent FBR 5 m <sup>2</sup> bioreactor consumable	1
6974	Ascent FBR 1 m <sup>2</sup> bioreactor consumable with Lynx® connectors	1
6975	Ascent FBR 2.5 m <sup>2</sup> bioreactor consumable with Lynx® connectors	1
6976	Ascent FBR 5 m <sup>2</sup> bioreactor consumable with Lynx® connectors	1

### Corning Ascent Harvest Consumables

Cat. No.	Description	Qty/Cs
6984	Ascent 2L roller bottle with ¼" tubing and AseptiQuik® DC	2
6985	Ascent 3L Erlenmeyer flask with ¼" tubing and AseptiQuik® DC	2
6966	Ascent 5L Erlenmeyer flask with ¼" tubing and AseptiQuik® DC	2
6986	Ascent harvest consumable with 1L wash bottle	1
6987	Ascent harvest consumable with 2L wash bottle	1

### Corning Ascent Accessories

Cat. No.	Description	Qty/Cs
6979	Ascent 500 mL centrifuge tube with ¼" tubing and AseptiQuik® G	2
6980	Ascent 500 mL bottle with ¼" tubing and AseptiQuik® G	2
6981	Ascent 500 mL bottle with ¼" tubing and AseptiQuik® S	4
6982	Ascent 3L Erlenmeyer flask with ¼" tubing and AseptiQuik® G	2
6983	Ascent 5L Erlenmeyer flask with ¼" tubing and AseptiQuik® G	2
6967	Ascent T-adaptor with ¼" tubing and AseptiQuik® S to G	4
6968	Ascent T-adaptor with ¼" tubing and AseptiQuik® G	4
6969	Ascent T-adaptor with ¼" tubing and AseptiQuik® S	4
6993	Ascent Accessory tubing ¼" with AseptiQuik® G	4

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