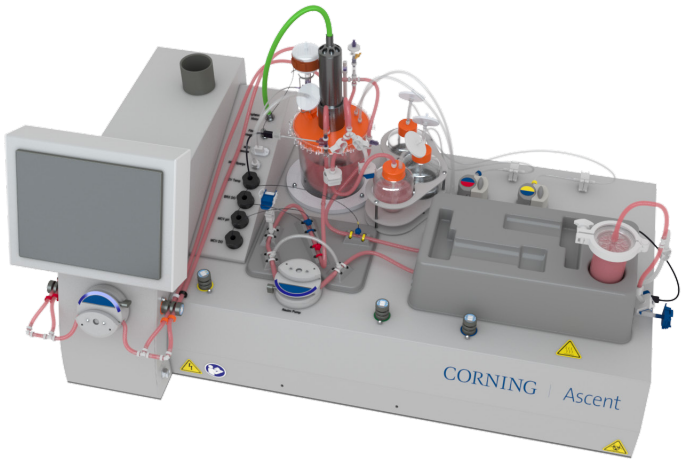
Corning® Ascent® Fixed Bed Reactor System 5

CORNING

The Corning Ascent FBR System 5 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^2, 2.5 m^2 and 5 m^2, help in the development of a stable and well-defined manufacturing process.

The Corning Ascent FBR System 5 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.



Actual instrument component appearance may differ from images.

Features and Benefits

Specially treated woven mesh polymer substrate	• Uniform fluid flow – efficient nutrient delivery and waste removal • Uniform cell growth – beneficial cell distribution and confluence at transfection • Improves cell health and product yield
FBR designed to harvest viable cells with >90% recovery	• Enables its use in other application workflows that require cell recovery for downstream use • Enables the bioreactor to be used for seed train, streamlining vessel-to-vessel cell transfer
Bioreactor scalability	• Ascent FBR System 5 bioreactors scale from 1 m^2 to 5 m^2, helping the development of a stable and well-defined manufacturing process
Separate media condition vessel (MCV)	• Provides flexibility in media volume and dilution strategy for transfection reagents prior to addition
Automated control, including disposable sensors that monitor DO, pH, temperature	• Reduced labor costs, hands-off operation, reduced risk of human error
Ready to use, irradiated consumables	• Minimal set-up required, including single-point calibration. No autoclaving necessary. The minimal setup required can save many hours of valuable time.
Closed system	• Can be run outside a laminar flow hood. Aseptic connectors or tube welding allow for easy aseptic cell sampling of the bioreactor inside a laminar flow hood.

The Corning® Ascent® FBR System 5 consists of a system controller with Human-Machine Interface (HMI) touchscreen control display (Figure 1) and single-use, irradiated components including a bioreactor, 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 addition, removal, and exchange phases. Cell culture pH and oxygen levels are automatically controlled and maintained using sparging gas composition and base pump, while temperature-controlled heated nests ensure constant temperature for both the MCV and bioreactor. The culture media can be sampled to determine nutrient levels, and these levels can be controlled using a feed pump. 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.

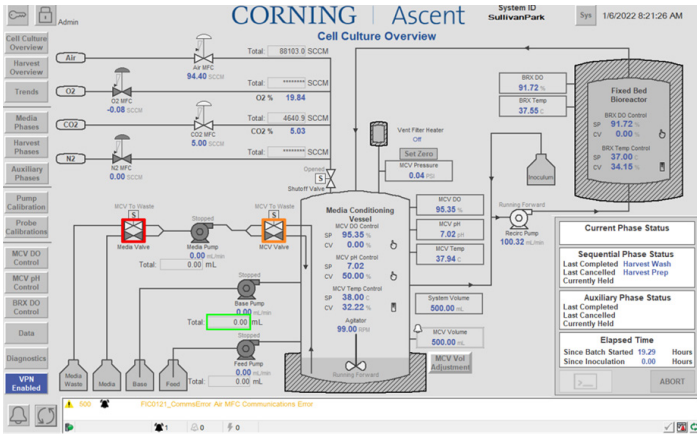
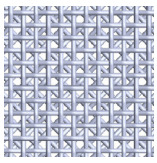


Figure 1. The system is operated using a touchscreen graphic user interface.

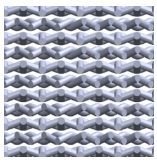
The Bioreactor Design

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.

Corning Ascent FBR system bioreactor



Top view of stacked disks



Side view of stacked disks

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 System 100 and System 1000 will be available in multiple surface area sizes, utilizing the same bioreactor technology as the Ascent FBR System 5 to provide linear scalability from 1 m^2 to 1,000 m^2.

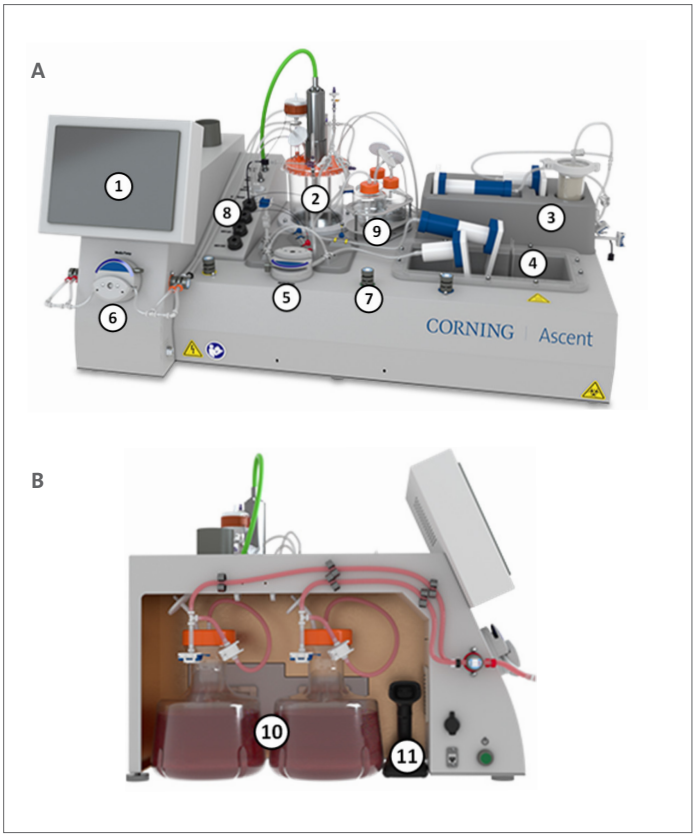


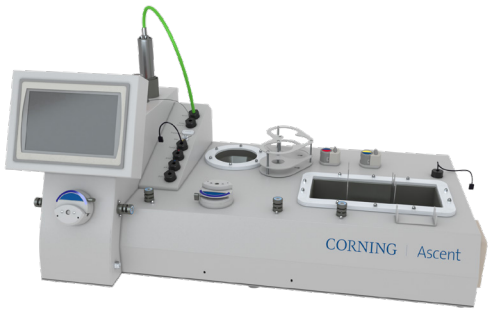
Figure 2. Corning Ascent FBR System 5, top view (A) and showing bottle manifold and bar code scanner, side view (B).

Main components of the Ascent FBR System 5.

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	The instrument is designed for use under standard operating conditions per UL 61010-1 where: • Indoor temperature range is 5°C to 40°C. For optimal use, the indoor temperature range shall be between 20°C to 30°C. • Maximum relative humidity at 80% for temperatures up to 30°C • Maximum altitude up to 2,000 m • Pollution degree 2 • Up to IEC Overvoltage Category II for transient over voltages
Space Required	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.
System Weight	Base weight (without consumables) is approximately 186 lbs. (84.37 kg).
Power Requirements	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.
Gas Connection and Type	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.
Communication	Ethernet/IP



Corning Ascent FBR System 5

Ordering Information

Corning® Ascent® FBR System 5

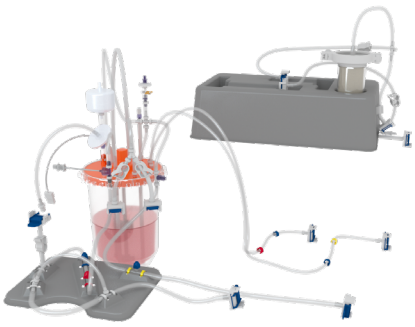
Cat. No.	Description	Qty/Cs
6970	Ascent FBR System 5, 120V	1
6991	Ascent FBR System 5, 230V	1

Corning Ascent Bioreactor Consumables

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

Corning Ascent Consumables and Accessories

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
6960	Ascent In Situ Lysis consumable	1
6957	Ascent FBR Coating consumable with 1L storage bottle and GDC connector	1
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
6961	Ascent Accessory tubing ⅜" with AseptiQuik® G	4
6962	Ascent T-connector with ¼" tubing and AseptiQuik® G-DC to G	4
6963	Ascent Cross connector with ¼" tubing and AseptiQuik® G-DC to G	4
6964	Ascent 1L bottle with ¼" tubing and AseptiQuik® G	4
6965	Ascent 2L bottle with ¼" tubing and AseptiQuik® G	2



Main Consumables (MCV and BRV) with AseptiQuik® Connectors

Harvest Consumables

Accessory Consumables

Warranty/Disclaimer: Unless otherwise specified, all products are for research use or general laboratory use only.* Not intended for use in diagnostic or therapeutic procedures. Not for use in humans. These products are not intended to mitigate the presence of microorganisms on surfaces or in the environment, where such organisms can be deleterious to humans or the environment. Corning Life Sciences makes no claims regarding the performance of these products for clinical or diagnostic applications. *For a listing of US medical devices, regulatory classifications or specific information on claims, visit www.corning.com/resources.

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