DESIGNED BY PERFUSIONISTS. ENGINEERED BY MEDTRONIC.

Affinity Fusion™
Oxygenation System
The Affinity Fusion oxygenation system

- Built on input from more than 500 perfusionists worldwide
- Represents a unique fusion of clinical insight and engineering expertise
- Features 79 new design enhancements

Designed by perfusionists. Engineered by Medtronic.
Proactive Air Management
An entire oxygenation system designed to handle air upfront.
- Unique curved venous inlet reduces blood turbulence and GME generation
- A pre-membrane bubble trap is designed to purge air before it enters the fiber membrane
- An oxygenator with integrated arterial filter removes particulates and air

Uniform Flow Distribution
Designed to reduce blood trauma, lower rates of hemolysis and minimize exposure to foreign surfaces.
- Curved venous inlet for smooth, fluid pathways and low resistance to flow
- Venous inlet tube's flared design reduces blood velocity and resistance to flow
- Cardiotomy cone shape design allows for gentle blood flow
- Oxygenator's radial flow design results in short blood flow paths that avoid areas of stasis

Perfusion-practical Ergonomics
Improved flexibility, ease of use and set-up, and enhanced customization capabilities.
- Orbit holder system with 360 degrees of flexibility
- Ambidextrous design
- Convenient port locations and spacing
- Independent adjustment of the reservoir and oxygenator

Progressive Fiber Filtration
Gas exchange and particulate filtration occur simultaneously, enabled by Medtronic's proprietary Graduated Fiber Bundle Density Technology.
- A fully integrated oxygenator and arterial filter
- A compact, low-prime design
- Radial flow for short, uniform blood paths, minimizing blood's contact with foreign surfaces
- Low pressure drop

Finely tuned, carefully considered parameters, from inlet to outlet.
Designed to achieve the optimal blend of performance providing expanded heat exchange and oxygenation capability, while maintaining low prime and low pressure drop.
The Fusion system delivers Perfusion-practical Ergonomics, providing improved flexibility, ease of use and set-up, and enhanced customization capabilities.

- The unique Affinity Orbit holder system allows 360-degree positioning and placement flexibility.
- Ambidextrous design.
- Independent adjustment of the oxygenator and reservoir.
- Convenient port locations and spacing.
- Non-vented caps for ease of set-up for VAVD procedures (except inlet, outlet and vent/vacuum port).
- Totally clear design for unobstructed visibility of blood, gas and water phases.
- Quick and easy set-up and tear down.

**MORE ROOM TO SHORTEN LINES.**
The Affinity Fusion oxygenation system takes a fundamentally different design approach.

- Proactive air handling
- Uniquely designed for hemocompatibility
- Improved flexibility and ease of use
- Oxygenator with integrated arterial filter
- Expanded heat exchanger and gas transfer capabilities

Both oxygenator and reservoir devices have:

- Blood-contacting materials made from BPA*- and DEHP-free polymers
- 1 to 7 L/min flow rate
- Low system priming volume
- Biocompatible surface coatings

Cardiotomy/Venous Reservoir available in:

- Balance Biosurface

Oxygenator available in two biocompatible surface options:

- Balance Biosurface
- Cortiva BioActive Surface

The Affinity Fusion oxygenation system is indicated for use in an extracorporeal circulation circuit during cardiopulmonary bypass procedures up to 6 hours in duration.

Warning: A strict anticoagulation protocol should be followed and anticoagulation should be routinely monitored during all procedures. The benefits of extracorporeal support must be weighed against the risk of systematic anticoagulation and must be assessed by the prescribing physician.

For a complete listing of indications, contraindications, precautions and warnings, please refer to the Instructions for Use which accompany each product.

* Sampling manifold is not BPA-free.
THE AFFINITY FUSION™
CARDIOTOMY/VENOUS RESERVOIR

- Curved venous inlet, flared walls of the venous inlet down tube and gradual slope of the reservoir contribute to Uniform Flow Distribution
- Separate venous and cardiotomy filter chambers
- Low minimum operating level
- Low dynamic and static hold-up
- Low resistance to flow
- Proactive removal of GME and gross air
- Vacuum Assisted Venous Drainage (VAVD) ready with built-in pressure relief valve and non-vented cardiotomy port covers
- Removable sampling manifold
- Indicated for use for chest drainage collection

Performance claims based on in vitro product validation test results.³
DESIGNED FOR CAREFUL BLOOD HANDLING AND AIR MANAGEMENT.

- **Cardiotomy Cone**: Enables smooth blood flow to the bottom of the chamber
- **30 Micron Depth Filter**: Enables rapid prime and blood breakthrough
- **Flow Diverter**: Directs blood toward the back of the reservoir for gentle flow without obstructing the warning track label at low flow rates
- **Cardiotomy on Pedestal**: Elevated cardiotomy design to reduce venous blood contact with cardiotomy filtration media at low operating levels
- **Curved Cardiotomy Inlets**: For fluid level stability while minimizing blood turbulence at the outlet
- **Venous Cage and Screen**: Small diameter and larger screen pore size for low dynamic hold-up
- **Venous Defoamer**: Non-foaming blood does not contact antifoam at normal operating levels
- **3400 mL Volume Capacity**: For fluid level stability while minimizing blood turbulence at the outlet
- **Recirculation Port**: Efficient blood recirculation for optimal oxygenation
- **Pressure Relief Valve**: Ensures safety and stability during operation
- **Vent/VAVD Port**: Ready for venting or VAVD operation
- **Blood Outlet**: Directs blood toward the back of the reservoir for gentle flow without obstructing the warning track label at low flow rates
- **Elevated Cardiotomy on Pedestal**: For fluid level stability while minimizing blood turbulence at the outlet
- **Gradual Slope**: For reduced resistance to flow, gently slows the blood velocity, positioned at the rear of the reservoir to minimize stasis from inlet to outlet

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician. For a complete listing of indications, contraindications, precautions and warnings, please refer to the Instructions for Use.

Performance claims based on in vitro product validation test results.³
THE AFFINITY FUSION OXYGENATOR

- 260 mL prime volume
- Enhanced gas transfer and heat exchange performance
- Indicated for use as both an oxygenator and arterial filter
- 25µm filtration
- Efficiently handles air and particulates

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Properties:

- **Blood Inlet**
- **Recirculation Port**
- **Cardioplegia Port**
- **Temperature Port**
- **Dual Outlet Port**
- **Sampling Port**

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**Oxygenator Performance Data**

Testing performance per ISO 7199, 2009 standard conditions. Based on in vitro data; may not be indicative of clinical results.

- **O₂ Transfer Rate**
- **CO₂ Transfer Rate**
- **Heat Exchanger Performance Factor**
- **Blood Side Pressure Drop**

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Multiple Gas Vents

Reduces the risk of gas pressure build-up in the oxygenator chamber

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Performance claims based on in vitro product validation test results.³
A FULLY INTEGRATED OXYGENATOR AND ARTERIAL FILTER.

Pre-membrane Bubble Trap
- Placed at top of oxygenator to purge air before it reaches the fiber membrane
- Tangential flow creates centrifugal force that moves air to the center of device and removes through purge line
- Built-in, one-way valve

Electrical Shunt
- Equilibrates voltage between the blood and water pathways
- Reduces the potential for electrostatic discharge that may develop inside the blood pathway due to rotation of the roller pump heads

Plastic Heat Exchanger
- Small tube design of capillaries increases heat exchange performance
- Decreases prime volume
- Minimizes blood-contacting surfaces
- Enables device incineration

Radial Blood Flow Design
- Facilitates a short, uniform blood flow path that avoids areas of stasis
- Minimizes blood’s contact with foreign surfaces

Proprietary Graduated Fiber Bundle Density Technology
- Optimized bundle efficiency
- Manufacturing consistency
- Progressive Fiber Filtration

Progressive Fiber Filtration
Within the graduated fiber bundle assembly, gas exchange and particulate filtration occur simultaneously by means of Progressive Fiber Filtration, which allows for:
- Low pressure drop
- Enhanced gas transfer
- Short, uniform blood flow path
- Efficient particulate filtration
- A compact, low-prime design
- Integrated arterial filter

Caution: Once an oxygenator is primed with blood, adequate heparinization should be maintained per institution cardiopulmonary bypass (CPB) protocol and the blood pathway should be constantly recirculated within the recommended blood flow range.

Performance claims based on in vitro product validation test results.¹
**Affinity Fusion Oxygenation System**

### Functional Platelets Over Time

![Platelet Percentage Chart]

Comparison between Balance-coated and uncoated in vitro bench test circuits of percentage of platelets that are activated with adenosine diphosphosphate (ADP) in circulating heparinized human blood over time. Error bars represent standard deviation. († indicates p<0.05)

### Specification

**Oxygenator**
- **Membrane Type**: Microporous polypropylene hollow fiber
- **Membrane Surface Area**: 2.5 m²
- **Heat Exchange Material**: Polyethylene Terephthalate (PET)
- **Static Priming Volume**: 260 mL
- **Recommended Blood Flow Rate**: 1-7 L/min
- **Maximum Water Side Pressure**: 30 psi
- **Maximum Blood Pressure**: 750 mmHg
- **Arterial Outlet Port**: 3/8”
- **Venous Inlet Port**: 3/8”
- **Arterial Sample Port**: Female Luer Port
- **Recirculation Port**: 1/4”
- **Cardioplegia Port**: 1/4”
- **Gas Inlet Port**: 1/4” Nonbarbed
- **Gas Outlet Port**: 3/8” Nonbarbed
- **Water Ports**: 1/2” Quick Disconnects
- **Filtration**: 25 µm

**Cardiotomy/Venous Reservoir**
- **Reservoir Volume Capacity**: 4500 ml
- **Recommended Blood Flow Rate**: 1-7 L/min
- **Maximum Cardiotomy Flow Rate**: 6 L/min
- **Minimum Operating Level**: 200 at 7 L/min
- **Cardiotomy Filtration**: 30 µm
- **Venous Screen**: 105 µm
- **Venous Inlet, Rotatable**: 1/2” with 3/8” adapter
- **Venous Reservoir Outlet**: 3/8”
- **Vent/VAVD Port**: 1/4” Nonbarbed
- **Cardiotomy Port (4)**: 1/4”
- **Cardiotomy Port (1)**: 3/8”
- **Prime Port**: 1/4” Nonbarbed
- **Recirculation Port**: 1/4”
- **Filtered Luer Lock Ports**: 4
- **Non-filtered Luer Lock Ports**: 2
- **Venous Luer Lock Ports**: 2
- **Positive Pressure Relief Valve Crack**: <5 mmHg
- **Vacuum Pressure Relief Valve Crack**: >100 mmHg average

### Reference

1. Technology licensed under agreement from Biointeractions, Limited, United Kingdom.
2. % Functional Platelets Over Time.
3. Data on file at Medtronic.

For information on Affinity Fusion visit: [www.fusionoxygenator.com](http://www.fusionoxygenator.com)

For information on other Medtronic technologies for extracorporeal circulation, blood processing and diagnostics, visit: [www.perfusion.medtronic.com](http://www.perfusion.medtronic.com)

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**Affinity Fusion Accessories and Holders**

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<th>Product Description</th>
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<td>CB841</td>
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<tr>
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