CONSISTENT PERFORMANCE RELIABLE RESULTS



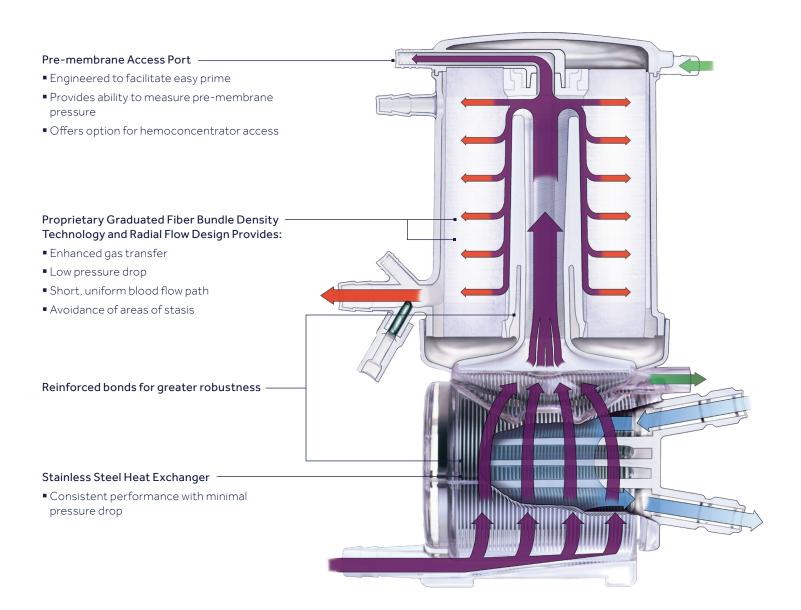
DESIGN THAT SET THE STANDARD



6+ MILLION Produced on single manufacturing line

Affinity NT Oxygenation System

The Affinity NT oxygenation system set the standard for the industry as the first to feature a radial blood flow design and graduated fiber winding.



UNOBSTRUCTED



The design of the system allows for a clear view of the blood, gas, and water phases.

Optimal Visibility Achieved

- Clear lid and housing
- Excellent visibility of venous inlet column on the outside of the cardiotomy

Vacuum-assisted Venous Drainage (VAVD) Compatible

- A negative/positive pressurerelief valve is built into the lid
 150 mm Hg/0-5 mm Hg, which features a special obturator valve cap engineered to ensure valve patency
- Non-venting caps for ease of setup for VAVD procedures (except inlet, outlet, vacuum, and recirculation caps)

Removable Sampling Manifold

 One-way valve and color-coded sampling lines

Versatile Cardiotomy Turret

3/8" and 1/4" filtered ports for priming ease

4000

3500

3000

2750

2500

2250

2000

1300

1800

1400

1200

900

700

500

400

300

300

2750

2500

1250 -

2000

1300

1500

1400

1200

3500

1000

5

Medtronic Affinity NT[™] Oxygenator with Balance™ Biosurface*

°000e

2750

2500

2250

2000

^[008]

1600

1400

1200

700

- Multiple filtered luer ports
- Cardiotomy ports on rotating turret
- Rotating turret easily clears manifold

Optimum Operating Levels

- Maximum capacity of 4,000 ml
- Minimum operating level of 200 ml
- Designed for excellent low-level visualization with color-coded volume measurements and low-level warning label

Excellent Air Handling Capabilities

- Separate venous and cardiotomy inlets
- Designed to prevent blood contact with defoamer unless foam is present
- Final screen provides additional barrier intended to remove air and other potential emboli

Hollow Fiber Oxygenator Total visibility pre-membrane and post-membrane for your priming confidence

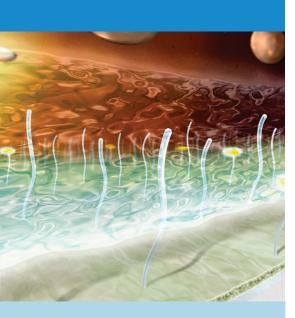
Simple Drop-in Holder

Articulated design is compatible with leftand right-hand setup

BALANCE BIOSURFACE^{*}

A balanced approach to preserving platelet function

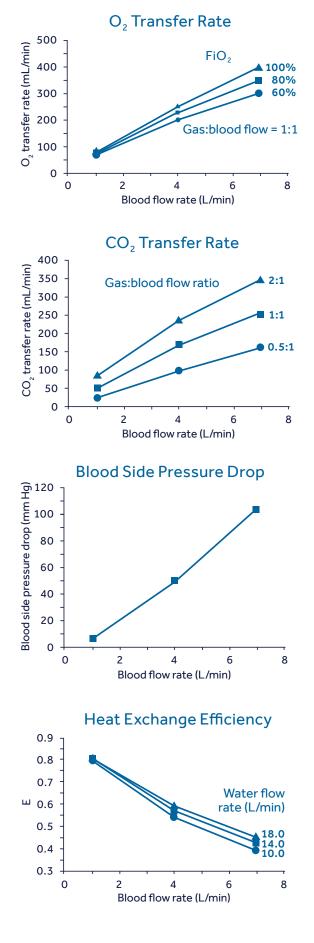
Balance's heparin-free, hydrophilic polymer surface reduces platelet adhesion and activation.¹ Platelet activation has been shown to play a role in systemic inflammatory response.²⁻⁵ Preserve your patients' platelet function with Balance[™] biosurface.¹



- ^{*}Technology licensed under agreement from BioInteractions, Limited, United Kingdom. [†]Representative of the Affinity NT with Balance Biosurface. Bench data on file. Not necessarily predictive of clinical performance results. Medtronic data on file.
- ¹ Medtronic data on file.
 ² Morrell CN, Aggrey AA, Chapman LM, Modjeski KL. Emerging roles for platelets as immune and inflammatory cells. *Blood.* May 1, 2014;123(18):2759-2767.
- ³ Sonmez O, Sonmez M. Role of platelets in immune system and inflammation. *Porto Biomedical Journal*. November-December 2017;2(6):311-314.
- ⁴ Mirza I, Kottke-Marchant K. In: Kottke-Marchant K, ed. An Algorithmic Approach to Hemostasis Testing. 2nd ed. College of American Pathologists; 2016:30-31.
 ⁵ Thomas MR, Storey RF. The role of platelets
- ⁵ Thomas MR, Storey RF. The role of platelets in inflammation. *Thromb Haemost*. August 31, 2015;114(3):449-458.

Balance[™] Biosurface

AFFINITY NT BENCH TEST PERFORMANCE INFORMATION[†]



ORDERING INFORMATION



Affinity NT Oxygenator

Membrane type: microporous polypropylene hollow fibers Membrane surface area: 2.5 m² Static priming volume: 280 ml Recommended blood flow rate: 1-7 L/min Maximum water side pressure: 30 psi Arterial outlet port: 3/8" Venous inlet port: 3/8" Venous inlet port: 3/8" Arterial sample port: female luer port Access port: female luer port Recirculation port: 1/4" Gas inlet port: 1/4" Gas outlet port: 3/8" nonbarbed Water ports: 1/2" quick disconnects

Affinity NT CVR

Reservoir volume capacity: 4,000 ml Recommended blood flow rate: 1-7 L/min Maximum cardiotomy blood flow rate: 6 L/min Minimum operating level: 200 ml Cardiotomy filtration: 30 µm Venous inlet screen: 200 µm Final reservoir screen: 150 µm Positive pressure relief valve crack: < 5 mm Hg Vacuum pressure relief valve crack: > 150 mm Hg

${\sf Affinity}\,{\sf NT}^{\rm \tiny M}\,{\sf Oxygenation}\,{\sf System}$

Indications: The Affinity NT oxygenator with Balance[™] biosurface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool and warm the blood during routine cardiopulmonary bypass (CPB) procedures up to 6 hours in duration. The Affinity NT[™] cardiotomy/ venous reservoir (CVR) is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during routine CPB procedures up to 6 hours in duration.

Contraindication: Use the device only as indicated

Warnings: Follow a strict anticoagulation protocol and routinely monitoranticoagulation during all procedures. Maintain adequate anticoagulation per institution CPB protocol. Clear all gas emboli from the extracorporeal circuit before initiating bypass. Gas emboli are hazardous to the patient. Continually monitor the

Medtronic

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OXYGENATORS

Product Number	Product Description	Units/case
541B	Affinity NT Integrated Uncoated CVR/ Oxygenator with Balance Biosurface	2
511B	Affinity NT Oxygenator with Balance Biosurface	Available in custom tubing packs

ACCESSORIES AND HOLDERS

Model Number	Product Description	Units/case
61399401093	Affinity Oxygenator with Integrated CVR Holder	1
61399401072	Affinity Oxygenator Holder	1
ТР	Temperature Probe	1

For information on other Medtronic technologies for extracorporeal circulation, blood processing, and diagnostics, visit medtronic.com.

extracorporeal circuit for air bubbles or leaks. Do not use the device if air bubbles or leaks are observed during priming or operation as they may result in air embolism to the patient or fluid loss.

Caution: Federal law (USA) restricts this device 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, which accompany each product.

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