

INSPIRE® OXYGENATOR FAMILY

Optimised, powerful perfusion



TO DATE

Minimized impact on hemodilution thanks to the low dynamic operating volume (DOV)

Effective gaseous microemboli (GME) handling

Enhanced biocompatibility - The unique design of the Dual Reservoir ensures activated suction blood sequestration. This, in combination with an uniform biocompatible surface treatment that feature phosphorylcholine (PC)^{1,2}

1) Albes JM, et al. Physiological coagulation can be maintained in extracorporeal circulation by means of shed blood separation and coating. J Thorac Cardiovasc Surg 2003;126:1504–12

2) Shann KG, et al. An evidence-based review of the practice of cardiopulmonary bypass in adults: a focus on neurologic injury, glycemic control, hemodilution, and the inflammatory response. J Thorac Cardiovasc Surg 2006;132:283–90

Leveraging a worldwide leadership

INSPIRE[®]: offering the most complete range of flow sizes to meet adult oxygenation needs

LivaNova products for cardiopulmonary bypass have helped clinicians provide safe and effective perfusion for more than 40 years. **INSPIRE**[®] is a complete family of **adult oxygenators** designed from years of research and laboratory experience, input from **clinical experts** from around the world and the application of advanced manufacturing technologies that adhere to the highest quality standards.

When designing INSPIRE®, our vision was to raise performance expectations and ease of use, while providing clinicians with new options in cardiopulmonary bypass.



RESERVOIR

Designed to Meet All Adult Patient Perfusion Needs and Practices

INSPIRE® is a fully modular oxygenator system. 21 different integrated models can be created by flexibly combining oxygenator modules and venous reservoirs.

To best fit your individual perfusion practice and patients, our range includes INSPIRE® 6, and 8 LPM

Inspire is the combination of 3 types of Reservoir (HVR, HVR Dual, SVR1200) with 4 different types of oxys (Inspire 6, Inspire 6F, Inspire 8, Inspire 8F). It is also avaible as single modules with and without filter in 3 differnet flow rates and also as minibypass

INSPIRE[®] Oxygenator Family Optimised, powerful perfusion

The INSPIRE® family allows clinicians to safely run perfusion while ensuring powerful, consistent performance.

The long path oxygenator membrane with remarkably efficient longitudinal flow design allows high levels of gas exchange at all rated flows.







Designed to Meet All Adult Patient Perfusion Needs and Practices

Minimized impact on hemodilution thanks to the low dynamic operating volume (DOV)

- INSPIRE® is designed to minimize hemodilution, which can in turn lead to a reduction in blood transfusions and post-op Acute Kidney Injury (AKI)¹
- INSPIRE[®] devices are characterized by the lowest minimum operating level in the reservoir (150 ml), outstanding low venous filter dynamic hold-up volume and low prime oxygenator modules.



- Venous collector priming volume Venous filter hold-up volume
- Minimum operating level
- Oxy module priming volume



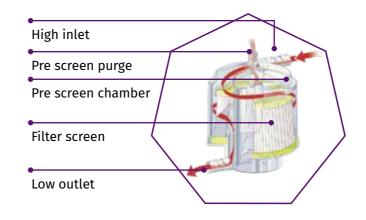
Effective gaseous microemboli (GME) handling

Designed for effective air management The combination of the geometry of the Inspire HVR/HVR Dual and the two-step venous filters contributes to a further reduction in hemodilution and an efficient air handling.



- The combination of a special venous filter and tapered reservoir preventing macro air bubbles from entering the oxygenator.
- Literature studies report correlation between embolic load and neurological deficit^{1,2}

Common Filter Elements:



KG, Likosky DS, Murkin JM, Baker RA, Baribeau YR, DeFoe GR et al. An evidence-based review of the practice of Imonary bypass in adults: a focus on neurologic injury, glycemic control, hemodilution, and the inflammatory ypass in adults: a focus on neuro Cardiovasc Surg 2006;132:283–90

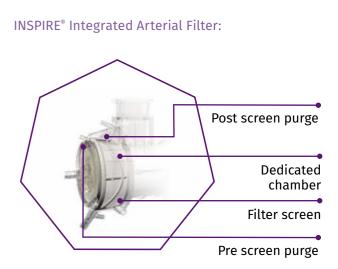
b et al., Adverse effects of low hematocrit during cardiopulmonary bypass in the adult: Should current practice be d- The Journal of Thoracic and Cardiovascular Surgery - June 2003

Technical claims supported by LivaNova data on file. 1. Stehouwer MC, et all. Effect of Oxygenator Size on Air Removal Characteristics: A Clinical Evaluation.ASAIO J. 2016 Jul-Aug 2. Shann KG, et al. An evidence-based review of the practice of cardiopulmonary bypass in adults: a focus on neurologic injury, glycemic control, hemodilution, and the inflammatory response. J Thorac Cardiovasc Surg 2006;132:283-90



design lets the reservoire safely operate at minimum blood level,

The INSPIRE[®] reservoir design and oxygenator geometry contribute to reducing the gaseous embolic load to the patient. The use of INSPIRE® integrated arterial filter further helps improve GME removal capacity.

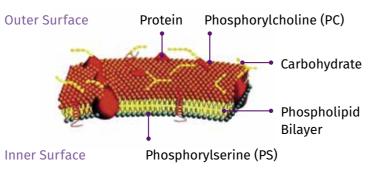


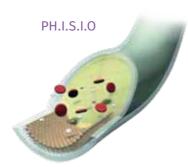
Designed to Meet All Adult Patient Perfusion Needs and Practices

Enhanced Biocompatibility

- LivaNova has designed an uniform biocompatible surface treatment that feature phosphorylcholine (PC).
- INSPIRE® Dual is the only hard-shell venous reservoir that allows activated suction blood separation.
- The unique design of the Dual Reservoir ensures activated suction blood sequestration. This, in combination with an uniform biocompatible surface treatment that feature phosphorylcholine (PC)^{1,2}







1. De Somer F, Van Belleghem Y, Caes F, Francois K, Van Overbeke H, Arnout J et al. Tissue factor as the main activator of the coagulation system during cardiopulmonary bypass. J Thorac Cardiovasc Surg 2002;123:951-8 2. Albes JM, et al. Physiological coagulation can be maintained in extracorporeal circulation by means of shed blood separation and coating. J Thorac Cardiovasc Surg 2003;126:1504-12

INSPIRE[®] Oxygenators

provide safe and effective perfusion for more than 40 years. Adult patient population and oxygenator of choice

Patient Body Weight & Distribution per INSPIRE® Market Assessment Study (MAS) database

≈ 50% < 80 kg		≈ 40% ≤	100 kg	
Others	5 L	/min	6 L/	mi
Small Adult			Full A	d
INSPIRE®				
Optimized Adult				

Before INSPIRE[®], small adult devices were considered the benchmark for optimized perfusion but were limited in flow to 5 l/min. INSPIRE® 6 optimized adult oxygenator systems extend the benefits of small adult devices to a wider patient population.

The INSPIRE® family allows clinicians to safely run perfusion while ensuring powerful, consistent performance.

Compact oxygenator system requiring minimal storage space

> UP TO space saved

* Based on the volume required to store 2 oxygenators, space saved compared to three competitors ranged from 36% to 51% Technical claims supported by LivaNova data on file.

LivaNova products for cardiopulmonary bypass have helped clinicians





INSPIRE[®] Oxygenators

Flexibility and easy handling

- Compact oxygenator system requiring minimal storage space.
- 4.5 litre max. reservoir capacity volume.
 - 4 litre maximum operating volume.
- Maximal system rotational freedom.
- Port orientation, and system priming have been optimized to offer easy set-up and operational flexibility.
- The simple bracket design allows easy and fast mounting of the oxygenator system. Bracket is available with a regular screw clamp and fast lock mechanism.



Inspire HVR and HVR Dual Hard shell venous reservoirs

The Inspire hard-shell venous reservoirs are extracorporeal circulation devices allowing oxygenators to exploit gas exchange for the replacement of patient respiratory function during cardiopulmonary bypass procedures, providing dynamic patient's venous blood collection.

They also defoam and filter venous blood and suction blood through a filtering system made of antifoam agent and filter screen.

The Inspire hard-shell venous reservoirs feature one of the lowest minimum operating levels on the market, which contributes to a reduction of CPB system priming volume and patient blood hemodilution¹



Inspire HVR DUAL is a hard shell venous reservoir with integrated cardiotomy filter and with the ability to allow activated suction blood sequestration and subsequent treatment by an Autotransfusion equipment.

- Inspire Dual is the only hard shell venous reservoir that allows activated suction blood separation.
- Inspire HVR DUAL is a hard shell venous reservoir with integrated cardiotomy filter. It facilitates sequestration of activated suction blood, allowing it to then be treated with an Autotransfusion device.²
- The HVR Dual design makes it possible to switch from suction sequestration mode to conventional single chamber mode at any time.

One bracket fits all family models

The Inspire bracket is reversible. allowing an ergonomic right and left pump console set-up





The minimum operating level is 150 ml They allow blood flow at up to 8 l/min Can be used for post-operative chest drainage Low venous filter design hold-up volume

The precise 41 micron cardiotomy filtration enables effective debris management

Venous filter dual screen contributes to effective air management



^{1.} Habib et al., Adverse effects of low hematocrit during cardiopulmonary bypass in the adult: Should current practice be changed - The Journal of Thoracic and Cardiovascular Surgery - June 2003 2. Shann KG, Likosky DS, Murkin JM, Baker RA, Baribeau YR, DeFoe GR et al. An evidence-based review of the practice of cardiopulmonary bypass in adults: a focus on neurologic injury, glycemic control, hemodilution, and the inflammatory response. J Thorac Cardiovasc Surg 2006;132:283-90

INSPIRE C - Gentle Perfusion

Inspire C closed system helps reduce inflammatory response and improve biocompatibility.¹

- Unique integrated closed system oxygenator
- Designed to minimize impact on hemodilution
- Precise volume control
- Designed for effective air management, reducing gaseous micro-emboli (GME)
- Inspire C has the lowest minimum operating level among adult closed system reservoirs

As a closed oxygenator system, Inspire C has reduced foreign surface area, no defoaming agents and no permanent air-to-blood interface. The integrated and versatile system offers wide choice of set-up options.



Inspire C closed system allows activated suction blood sequestration when cardiotomy line is kept clamped throughout the procedure. This, in combination with a uniform biocompatible surface treatment that features phosphorylcholine (PC).



EASY TO DE-BUBBLE - The thoroughly designed geometry of the system means both macro and micro air bubble are managed extremely well, thanks to the combined action of the carefully designed body shape and venous inlet. The carved backplate and squeezer, and the single layer filter screen with top bypass efficiently handle air in all flow-volume conditions.



The unique flow-volume handling feature allows venous blood deviation to the cardiotomy or venous flow control once cardiotomy line is clamped.



The SVR 1200 molded outlet collector and carved outlet area comfortably allow high-flow low volume operation.



SVR 1200 Soft shell venous reservoir

and helps minimize inflammatory response¹

SVR 1200 is made of soft NO-DEHP PVC and assures collapsability should the volume drop below minimum value.

SVR 1200 is designed with

- Maximum volume capacity of: 1325 ml
- Min operating volume: 265 ml
- Max flow rate: 8l/m

The SVR 1200's soft shell reservoir collapsability is safe and predictable.

- The special "self collapsible" SVR outlet design helps prevent air from being accidentally delivered to the patient when the blood volume drops below minimum level.
- Volume below the minimum operating value will make the SVR 1200 to close in case of venous flow decrease avoiding blood air entering the circuit.



The SVR 1200 soft shell reservoir is designed to limit blood-air contact



SVR 1200 TOP AND DEEP-PURGE DUAL AIR EVACUATION SYSTEM

The top-purge efficiently handles air in most working conditions

The deep-purge efficiently removes air when the squeezer is not in place or the reservoir is partly empty

Inspire C has a unique fine adjustment parallel plate squeezer with continuous volume scale measurement. Set-up available with and without squeezer. When used without a squeezer, Inspire C allows simple free blood volume handling.



Used with the squeezer, Inspire C :

- enables full blood volume control
- maximizes prime recovery prior to CPB
- helps precisely manage the CPB weaning process

The squeezer makes it possible to regulate and then read the approximate volume of fluid contained in the device.



Xtra® Autotransfusion System

INSPIRE[®] is designed to be used in conjunction with the XTRA[®] autotransfusion system.

Inspire HVR DUAL facilitates sequestration of activated suction blood, allowing it to then be treated with an Autotransfusion device.¹

The HVR Dual design makes it possible to switch from suction sequestration mode to conventional single chamber mode at any time.



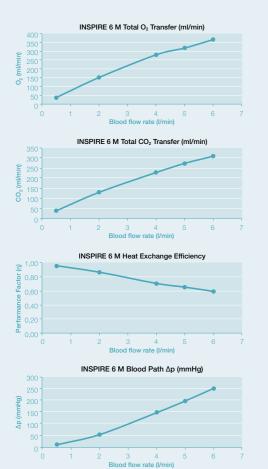
Performance charts

INSPIRE[®] 6 Dual PH.I.S.I.O.

Test Conditions

(Bovine blood - Hb 12±0.2 gr/dl - B.E. 0±2mEq/)

- Venous pCO₂ 45±5 mmHg 0₂ Venous Sat. 65±5%
 Blood Temp. 37±1 °C Q_c, Q_p=1 Fi0, 100% -
- Qw=10±0,5 l/min)



Test Conditions (Bovine blood - Hb 12±0.2 gr/dl - Blood Temp. 37±1 °C)

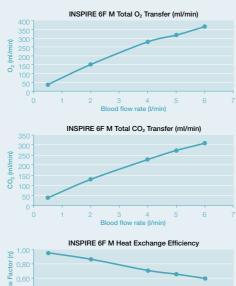


INSPIRE[®] 6F Dual PH.I.S.I.O.

Test Conditions

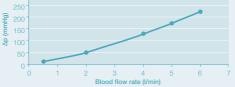
(Bovine blood - Hb 12±0.2 gr/dl - B.E. 0±2mEq/)

- Venous $pCO_2 45\pm5$ mmHg O_2 Venous Sat. $65\pm5\%$
- Blood Temp. 37±1 °C Q_G/Q_B=1 Fi0₂ 100% -Qw=10±0,5 l/min)



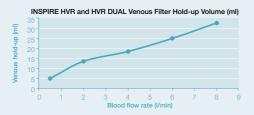
0.40 0.20 0.00 0 1 2 3 4 5 6 Blood flow rate (l/min)

INSPIRE 6F M Blood Path ∆p (mmHg)



Test Conditions (Bovine blood - Hb 12±0.2 gr/dl

- Blood Temp. 37±1 °C)

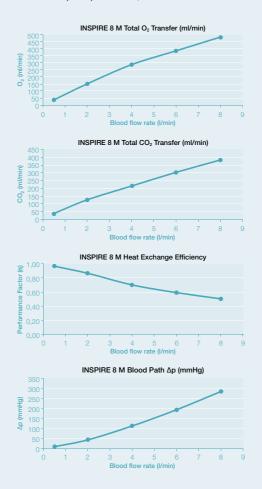


INSPIRE[®] 8 Dual PH.I.S.I.O.

Test Conditions

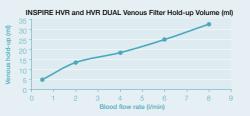
(Bovine blood - Hb 12±0.2 gr/dl - B.E. 0±2mEq/l

- Venous pCO, 45±5 mmHg 0, Venous Sat. 65±5%
- Blood Temp. 37±1 °C Q_G/Q_B=1 Fi0₂ 100% -Qw=11,5±0,2 l/min)



Test Conditions

(Bovine blood - Hb 12±0.2 gr/dl - Blood Temp. 37±1 °C)

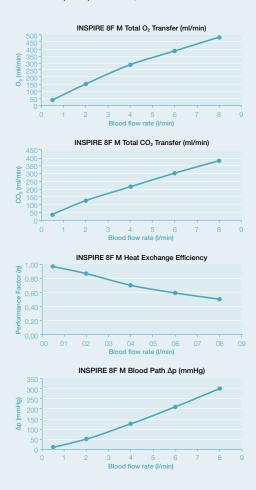


INSPIRE[®] 8F Dual PH.I.S.I.O.

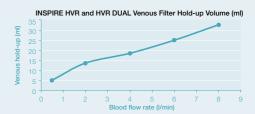
Test Conditions

(Bovine blood - Hb 12±0.2 gr/l - B.E. 0±2mEq/l

- Venous pCO₂ 45±5 mmHg 0₂ Venous Sat. 65±5%
 Blood Temp. 37±1 °C Q_c/Q_p=1 Fi0₂ 100% -
- Qw=11,5±0,2 l/min)



Test Conditions (Bovine blood - Hb 12±0.2 gr/dl - Blood Temp. 37±1 °C)



Technical specifications

INSPIRE[®] 6 PH.I.S.I.O.

402 ml Phosphorylcholine (PHISIO)
4500 ml
4000 ml
150 ml
41 μm polyester outer screen + 120 μm inner polyester net
41 μm polyester screen
6 l/min
184 ml
1,4 m ²
Polyurethane 0,4 m²

INSPI PH.I.S

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RE [®] 6F	N.
5.1.0.	

Oxygenator System	
- Oxygenator system DOV @ max flow - Biocompatible coating	502 ml Phosphorylcholine (PHISIO)
Reservoir	
Max. Volume Capacity (approx.)	4500 ml
Max. Operating Level (approx.)	4000 ml
MIN. Operating Level	150 ml
Filtration Sections Venous reservoir section - Filtering media	41 μm polyester outer scree + 120 μm inner polyester net
Cardiotomy reservoir section - Filtering media	41 µm polyester screen
Oxygenator Module	
Maximum Blood Flow Rate	6 l/min
Static Priming Volume (oxy module + heat exchanger average value)	284 ml
Membrane Section - Surface area (approx. value)	1,4 m²
Heat Exchanger Section - Material type - Surface area (approx. value)	Polyurethane 0,4 m²
Arterial Filter Section - Material type - Micron size - Surface area (approx. value)	Polyester net 38 μ 68 cm²

INSPIRE[®] 6 Dual PH.I.S.I.O.

Oxygenator System	
- Oxygenator system DOV @ max flow - Biocompatible coating	402 ml Phosphorylcholine (PHISIO)
Reservoir	
Max. Volume Capacity (approx.)	4500 ml
Max. Operating Level (approx.) - Non activated blood section - Activated blood section	4000 ml 2700 ml 1300 ml
MIN. Operating Level	150 ml
Filtration Sections Venous reservoir section - Filtering media	41 µm polyester outer screen + 120 µm inner polyester net
Cardiotomy reservoir section - Filtering media	41 μm polyester screen
Oxygenator Module	
Maximum Blood Flow Rate	6 l/min
Static Priming Volume (oxy module + heat exchanger average value)	184 ml
Membrane Section - Surface area (approx. value)	1,4 m ²
Heat Exchanger Section - Material type - Surface area (approx. value)	Polyurethane 0,4 m²

INSPIRE[®] 6F Dual PH.I.S.I.O.

Oxygenator System	
- Oxygenator system DOV @ max flow - Biocompatible coating	502 ml Phosphorylcholine (PHISIO)
Reservoir	
Max. Volume Capacity (approx.)	4500 ml
Max. Operating Level (approx.) - Non activated blood section - Activated blood section	4000 ml 2700 ml 1300 ml
MIN. Operating Level	150 ml
Filtration Sections Venous reservoir section - Filtering media	41 μm polyester outer screen + 120 μm inner polyester net
Cardiotomy reservoir section - Filtering media	41 µm polyester screen
Oxygenator Module	
Maximum Blood Flow Rate	6 l/min
Static Priming Volume (oxy module + heat exchanger average value)	284 ml
Membrane Section - Surface area (approx. value)	1,4 m ²
Heat Exchanger Section - Material type - Surface area (approx. value)	Polyurethane 0,4 m²
Arterial Filter Section - Material type - Micron size - Surface area (approx. value)	Polyester net 38 µ 68 cm²

INSPIRE[®] 8 PH.I.S.I.O.

Oxygenator System	
- Oxygenator system DOV @ max flow - Biocompatible coating	445 ml Phosphorylcholine (PHISIO)
Reservoir	
Max. Volume Capacity (approx.)	4500 ml
Max. Operating Level (approx.)	4000 ml
MIN. Operating Level	150 ml
Filtration Sections Venous reservoir section - Filtering media	41 μm polyester outer screen + 120 μm inner polyester net
Cardiotomy reservoir section - Filtering media	41 μm polyester screen
Oxygenator Module	
Maximum Blood Flow Rate	8 l/min
Static Priming Volume (oxy module + heat exchanger average value)	219 ml
Membrane Section - Surface area (approx. value)	1,75 m ²
Heat Exchanger Section - Material type - Surface area (approx. value)	Polyurethane 0,4 m²

INSPIRE® 8F PH.I.S.I.O.

577 ml Phosphorylcholine (PHISIO)
4500 ml
4000 ml
150 ml
41 μm polyester outer screen + 120 μm inner polyester net
41 µm polyester screen
8 l/min
351 ml
1,75 m ²
Polyurethane 0,4 m²
Polyester net 38 μ 97 cm²

INSPIRE[®] 8 Dual PH.I.S.I.O.



Dxygenator System	
Oxygenator system DOV @ max flow Biocompatible coating	445 ml Phosphorylcholine (PHISIO)
Reservoir	
Nax. Volume Capacity (approx.)	4500 ml
Aax. Operating Level (approx.) Non activated blood section Activated blood section	4000 ml 2700 ml 1300 ml
AIN. Operating Level	150 ml
iltration Sections /enous reservoir section Filtering media	41 μm polyester outer screen + 120 μm inner polyester net
Cardiotomy reservoir section Filtering media	41 µm polyester screen
Dxygenator Module	
Naximum Blood Flow Rate	8 l/min
Static Priming Volume oxy module + heat exchanger average value)	219 ml
Aembrane Section Surface area (approx. value)	1,75 m²
leat Exchanger Section Material type Surface area (approx. value)	Polyurethane 0,4 m²

INSPIRE® 8F Dual PH.I.S.I.O.



Dxygenator System	
Oxygenator system DOV @ max flow Biocompatible coating	577 ml Phosphorylcholine (PHISIO)
Reservoir	
Max. Volume Capacity (approx.)	4500 ml
Max. Operating Level (approx.) Non activated blood section Activated blood section	4000 ml 2700 ml 1300 ml
MIN. Operating Level	150 ml
iltration Sections /enous reservoir section Filtering media	41 μm polyester outer screen + 120 μm inner polyester net
Cardiotomy reservoir section Filtering media	41 µm polyester screen
Dxygenator Module	
Maximum Blood Flow Rate	8 l/min
Static Priming Volume oxy module + heat exchanger average value)	351 ml
Membrane Section Surface area (approx. value)	1,75 m ²
Heat Exchanger Section Material type Surface area (approx. value)	Polyurethane 0,4 m²
Arterial Filter Section Material type Micron size Surface area (approx. value)	Polyester net 38 µ 97 cm ²

INSPIRE® order guide

INSPIRE[®] order guide

Integrated

	ITEM #	DEVICE	DESCRIPTION	UNITS PER CASE
	050713	INSPIRE [®] 6	INSPIRE [®] 6 LPM PHISIO OXY module with integrated PHISIO hard shell venous reservoir	2
	050715	INSPIRE® 6F	INSPIRE [®] 6 LPM PHISIO OXY module with integrated arterial filter and PHISIO hard shell venous reservoir	2
	050717	INSPIRE® 6 Dual	INSPIRE [®] 6 LPM PHISIO OXY module with integrated PHISIO dual chamber hard shell venous reservoir	2
	050719	INSPIRE [®] 6F Dual	INSPIRE [®] 6 LPM PHISIO OXY module with integrated arterial filter and PHISIO dual chamber hard shell venous reservoir	2
2 Street Street	050714	INSPIRE [®] 8	INSPIRE® 8 LPM PHISIO OXY module with integrated PHISIO hard shell venous reservoir	2
050	050716	INSPIRE [®] 8F	INSPIRE [®] 8 LPM PHISIO OXY module with integrated arterial filter and PHISIO hard shell venous reservoir	2
	050718	INSPIRE® 8 Dual	INSPIRE® 8 LPM PHISIO OXY module with integrated PHISIO dual chamber hard shell venous reservoir	2
	050720	INSPIRE [®] 8F Dual	INSPIRE® 8 LPM PHISIO OXY module with integrated arterial filter and PHISIO dual chamber hard shell venous reservoir	2
	050711	INSPIRE® 6 start P	INSPIRE® 6 LPM PHISIO OXY module with integrated hard shell venous reservoir	2
	050712	INSPIRE® 8 start P	INSPIRE® 8 LPM PHISIO OXY module with integrated hard shell venous reservoir	2
	Available only into PTS	INSPIRE [®] 6 C	INSPIRE® 6 LPM PHISIO OXY module with integrated PHISIO 1200 soft shell venous reservoir	N.A.
	050721	INSPIRE [®] 6F C	INSPIRE [®] 6 LPM PHISIO OXY module with integrated arterial filter and PHISIO 1200 soft shell venous reservoir	1
	Available only into PTS	INSPIRE® 8 C	INSPIRE [®] 8 LPM PHISIO OXY module with integrated PHISIO 1200 soft shell venous reservoir	N.A.
	050722	INSPIRE [®] 8F C	INSPIRE [®] 8 LPM PHISIO OXY module with integrated arterial filter and PHISIO 1200 soft shell venous reservoir	1

OXY modules

	ITEM #	DEVICE	DESCRIPTION	UNITS PER CASE
	050700	INSPIRE [®] 6 M	INSPIRE® 6 LPM PHISIO OXY module	2
	050702	INSPIRE® 6F M	INSPIRE® 6 LPM PHISIO OXY module with integrated arterial filter	2
	050701	INSPIRE® 8 M	INSPIRE® 8 LPM PHISIO OXY module	2
	050703	INSPIRE® 8F M	INSPIRE® 8 LPM PHISIO OXY module with integrated arterial filter	2

HVR

	ITEM #	DEVICE	
ale ale	050704	INSPIRE® HVR	INSPIRE® PHISIO ha
12T	050705	INSPIRE® HVR Dual	INSPIRE® PHISIO du
1	050706	INSPIRE [®] SVR 1200	INSPIRE® PHISIO 120

Accessories

	ITEM #	DEVICE	DESCRIPTION	UNITS PER CASE		
	050640	INSPIRE® BKT	Bracket for INSPIRE® OXY modules and integrated oxygenator systems	1		
	48-42-10	INSPIRE® BKT Fast*	Bracket for INSPIRE" OXY modules and integrated oxygenator systems with fast clamp	1		
	050641	INSPIRE® BKTH	Bracket for INSPIRE® HVR and dual HVR reservoirs	1		
	042229000	Temperature probes	Temperature probes	2		
	050642	INSPIRE® BKT Combo	Bracket for combined INSPIRE [®] SVR systems to be used in conjuction with INSPIRE [®] BKT 1200 and 1200 S brackets	1		
	050645	INSPIRE® BKT 1200	Bracket for INSPIRE" SVR 1200	1		
	050646	INSPIRE® BKT 1200 S	Squeezer for INSPIRE [®] SVR 1200 to be used in conjuction with INSPIRE [®] BKT, INSPIRE [®] BKT FAST, INSPIRE [®] BKT 1200 and INSPIRE [®] BKT combo bracket	1		



ICE	DESCRIPTION	UNITS PER CASE
e" HVR	INSPIRE® PHISIO hard shell venous reservoir	2
HVR Dual	INSPIRE® PHISIO dual hard shell venous reservoir	2
SVR 1200	INSPIRE® PHISIO 1200 soft shell venous reservoir	1

Summary of Safety & Performance Information for INSPIRE

1. INDICATIONS FOR USE / INTENDED PURPOSE

Inspire Oxygenator (Models: Inspire 6, Inspire 7, Inspire 8) The devices are indicated for adult and small adult patients undergoing surgical procedures requiring cardiopulmonary bypass.

The devices are extracorporeal circulation devices used to replace the patient respiratory function during cardiopulmonary bypass procedures. They are used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood, and to cool or warm the blood during cardiopulmonary bypass procedures.

The devices must be to be used up to 6 hours or less.

Inspire Oxygenator with integrated arterial filter (Models: Inspire 6F, Inspire 7F, Inspire 8F)

The devices are indicated for adult and small adult patients undergoing surgical procedures requiring cardiopulmonary bypass.

The devices are extracorporeal circulation devices used to replace the patient respiratory function during cardiopulmonary bypass procedures. They are used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood, and to cool or warm the blood during cardiopulmonary bypass procedures. The integrated arterial filter provides filtration against air and solid emboli.

The devices must be to be used up to 6 hours or less

Inspire Cardiotomy/venous reservoir (Models HVR, and HVR dual) The devices are indicated for adult and small adult patients undergoing surgical procedures requiring cardiopulmonary bypass.

The devices are extracorporeal circulation devices allowing oxygenators to exploit gas exchange for the replacement of patient respiratory function during cardiopulmonary bypass procedures., providing dynamic patient's venous blood collection. They also defoam and filter venous blood and suction blood through a filtering system made of antifoam agent and filter screen. Can be used postoperatively for chest drainage.

The devices must be to be used up to 6 hours or less

2. ADVERSE EVENTS

The following table summarizes harms potentially arising during the use of the medical device, including those related to the intrinsic risks of extracorporeal circulation: Systemic Inflammatory Response Syndrome (SIRS), Hypoperfusion / Hypoxia, Embolism / Hypovolemia / Sepsis / Infection / Fever / Shock/ Allergic reactions / Cyto-toxic reactions / Genetic mutation / Cancer / Haemolysis / Organ damage / Acid base imbalance (only for oxygenator) / Cross contamination / User contamination / Environment contamination / Thrombosis / Impaired hemostasis / Blood activation / Bleeding / User skin tears and Pneumothorax (only for cardiotomy/venous reservoir).

The devices should be used by qualified and skilled personnel, able to follow the indications and instructions for use contained in the information provided by the manufacturer.

Please contact us through our website (www.sorinmanuals.com) to receive instructions for use containing full prescribing information including indications, contraindications, warnings, precautions and adverse events.

Summary of Safety & Performance Information for Soft Venous Reservoirs

INDICATIONS FOR USE / INTENDED PURPOSE

The Inspire SVR 1200 is indicated for adult and small adult patients undergoing surgical procedures requiring cardiopulmonary bypass.

The Inspire SVR 1200 is an extracorporeal circulation device allowing oxygenators to exploit gas exchange for the replacement of patient respiratory function during cardiopulmonary bypass procedures, providing dynamic patient's venous blood collection.

The devices collect venous blood and suction blood from the cardiotomy reservoir.

The Inspire SVR 1200 must be used up to 6 hours or less.

The devices should be used by qualified and skilled personnel, able to follow the indications and instructions for use contained in the information provided by the manufacturer.

Please contact us through our website (www.sorinmanuals.com) to receive instructions for use containing full prescribing information including indications, contraindications, warnings, precautions and adverse events.

LivaNova

Health innovation that matters

Manufacturer

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Preparation date: May 2022 IM-7300170-CP_B Please always refer to the Instructions For Use (IFU) manual provided with each product for detailed information, warnings, precautions and possible adverse side effects.

Not all products available in all countries, please consult local label.

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