LivaNova

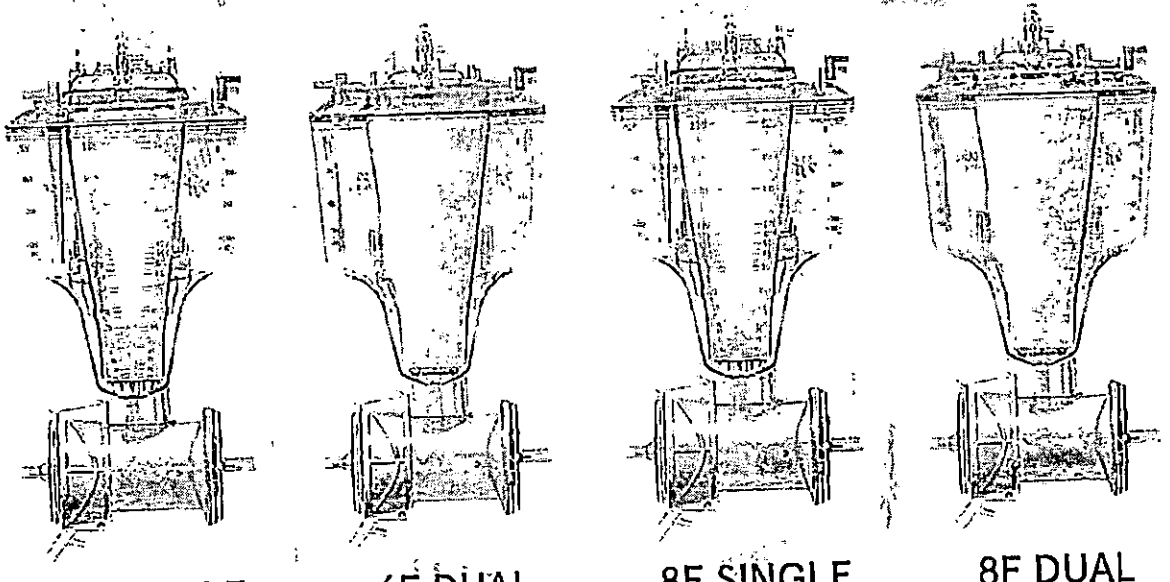
Health innovation that matters

INSPIRE®

Oxygenator Family

WITH INTEGRATED FILTER

Powerful and precise perfusion with advanced GME control



6F SINGLE | 6F DUAL | 8F SINGLE | 8F DUAL

The most modular oxygenator system on the market today

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UNMATCHED PERFORMANCE

OUR VISION FOR INSPIRE WAS TO RAISE PERFORMANCE EXPECTATIONS AND EASE OF USE, WHILE PROVIDING CLINICIANS WITH NEW OPTIONS TO IMPROVE CLINICAL OUTCOMES.

EFFECTIVE GME CONTROL

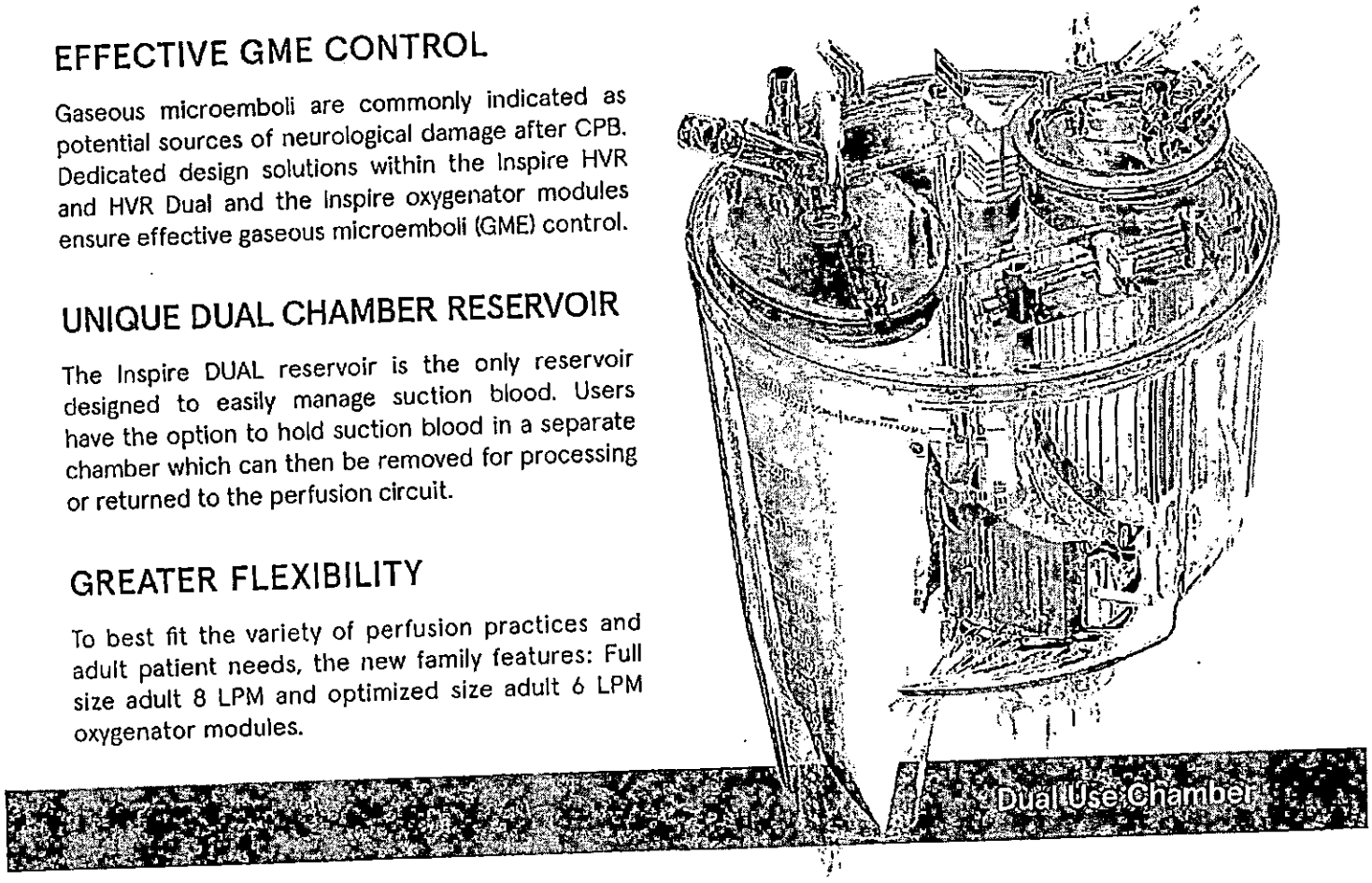
Gaseous microemboli are commonly indicated as potential sources of neurological damage after CPB. Dedicated design solutions within the Inspire HVR and HVR Dual and the Inspire oxygenator modules ensure effective gaseous microemboli (GME) control.

UNIQUE DUAL CHAMBER RESERVOIR

The Inspire DUAL reservoir is the only reservoir designed to easily manage suction blood. Users have the option to hold suction blood in a separate chamber which can then be removed for processing or returned to the perfusion circuit.

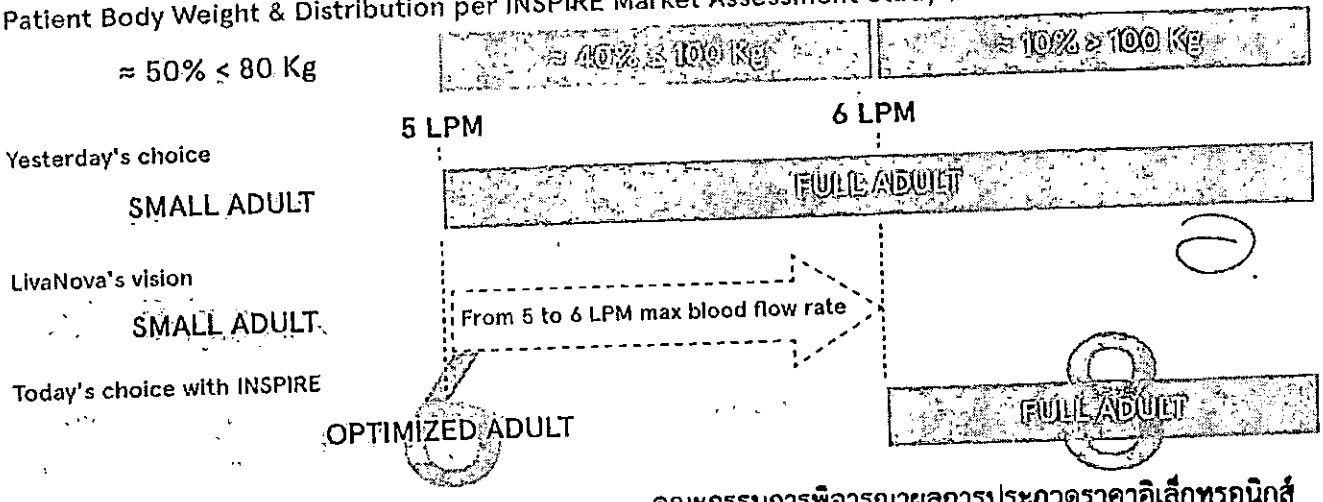
GREATER FLEXIBILITY

To best fit the variety of perfusion practices and adult patient needs, the new family features: Full size adult 8 LPM and optimized size adult 6 LPM oxygenator modules.



DESIGNED TO MEET ALL OF YOUR NEEDS

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



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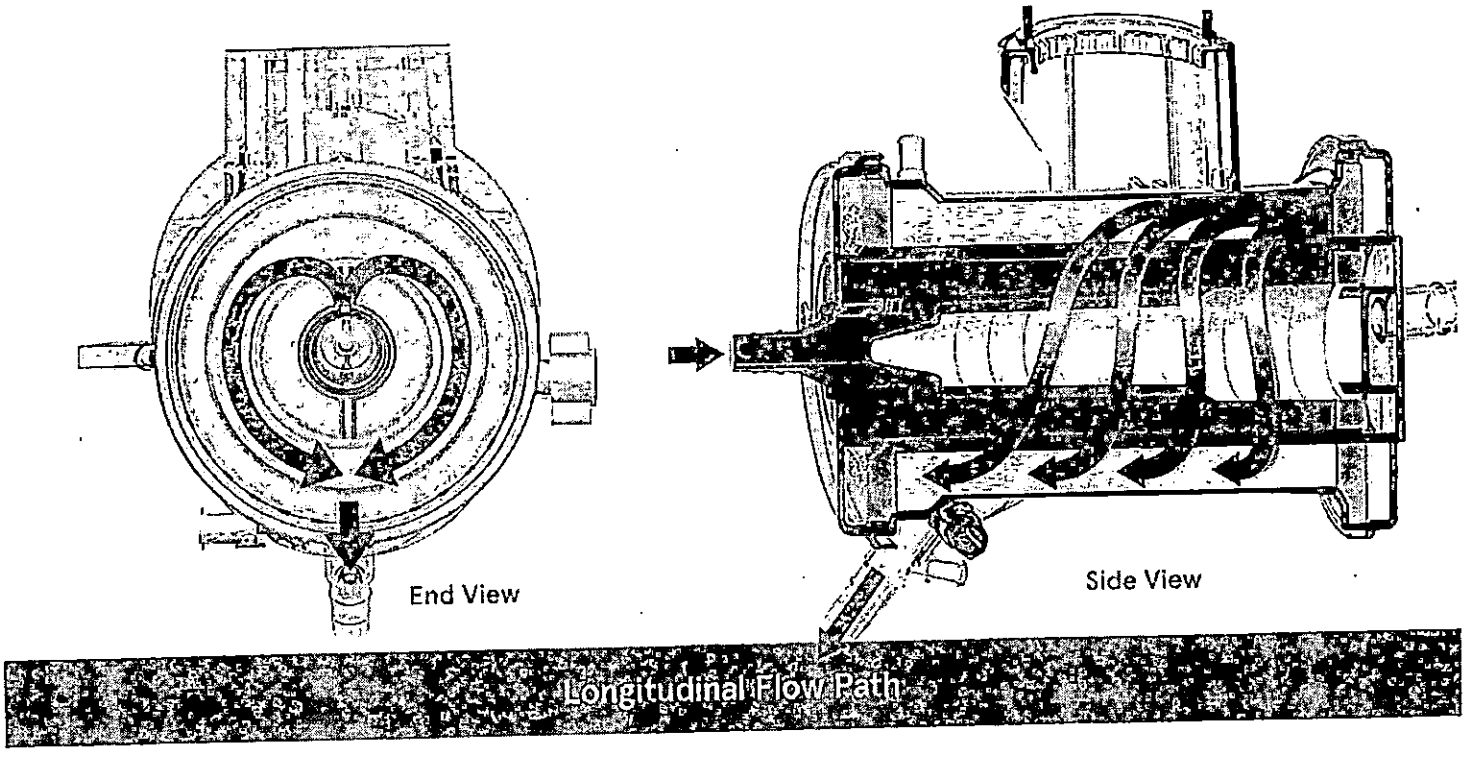
REMARKABLE EFFICIENCY

THE INSPIRE FAMILY OF OXYGENATORS ALLOW CLINICIANS TO SAFELY AND COMFORTABLY RUN PERFUSION WHILE ENSURING POWERFUL, PRECISE AND CONSISTENT PERFORMANCE.

LONG PATH OXYGENATOR

Its long path oxygenator membrane with remarkably efficient longitudinal flow design allows high gas exchange at all rated flows. Its polyurethane heat exchanger is capable of highly efficient heat transfer.

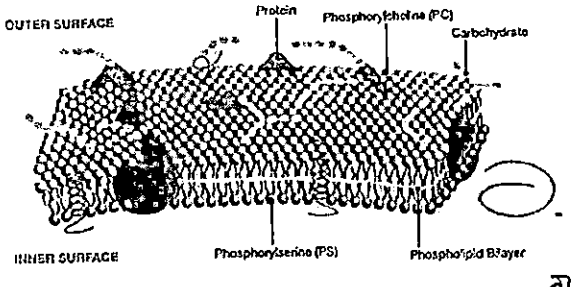


ENHANCED BIOCOMPATIBILITY

Full biocompatibilty encompasses the reduction of multiple sources of cellular activation and inflammatory reaction. Coatings reduce platelet and white blood cell adhesion to the circuit. Suction blood contains activated cells and stimulates additional activation. The combination of sequestering suction blood and using coated circuits offers maximum biocompatible benefit. The Inspire Dual reservoir system provides clinicians with new options for activated suction management. The combination of the Inspire Dual reservoir system, Ph.i.s.i.o. PC coating and XTRA autotransfusion system offers clinicians a comprehensive solution to enhanced biocompatibility.

3.2

Ph.i.s.i.o.
PHOSPHORYLCHOLINE INERT SURFACE
DEVELOPED WITH BIOCOMPATIBLES LTD



Cellular Membrane

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IMPROVED OUTCOMES

MINIMIZING HEMODILUTION CONTRIBUTES TO DECREASED BLOOD TRANSFUSIONS AND IMPROVED CLINICAL OUTCOMES DURING AND AFTER CARDIOPULMONARY BYPASS (CPB).

DYNAMIC OPERATING VOLUME (DOV)

By focusing on a new attribute, the oxygenator system dynamic operating volume (DOV), the INSPIRE family minimizes the system impact on hemodilution. 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.

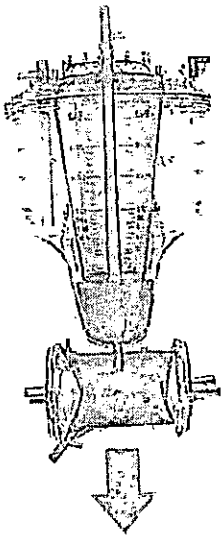
INSPIRE 6F

Venous collector priming volume

Venous filter hold-up volume

Minimum operating level

Oxy module priming volume



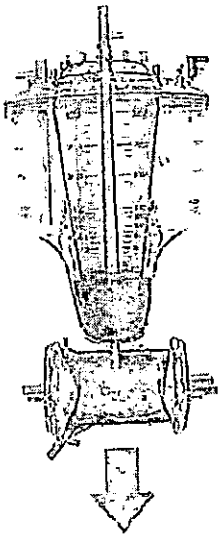
INSPIRE 8F

Venous collector priming volume

Venous filter hold-up volume

Minimum operating level

Oxy module priming volume



Overall impact on Hemodilution of the Oxygenator System at maximum blood flow: 502 ml | 577 ml

INTEGRATED ARTERIAL FILTRATION 3.13

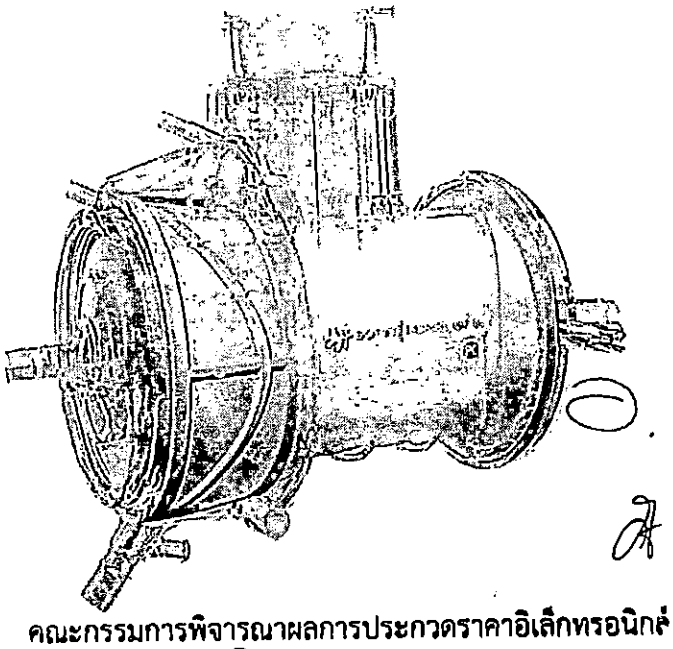
INSPIRE'S integrated arterial filter design preserves the full functionality of a standalone filter, with the convenience of an all-in-one solution. To enhance priming, these filters included pre- and post-screen purge capabilities.

Inspire's Filtration Advantage

Pre Screen Chamber
- Slows blood velocity
- Directs air to center

Pre Screen Purge
- Removes air from filter

Filter Screen
- 38 micron



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ORDER GUIDE

INTEGRATED

ITEM #	DEVICE	DESCRIPTION	UNITS PER CASE	
050715	INSPIRE 6F	INSPIRE 6 LPM PHISIO OXY MODULE WITH INTEGRATED ARTERIAL FILTER AND PHISIO 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	
050716	INSPIRE 8F	INSPIRE 8 LPM PHISIO OXY MODULE WITH INTEGRATED ARTERIAL FILTER AND PHISIO 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	

OXY MODULES

050702	INSPIRE 6F M	INSPIRE 6 LPM PHISIO OXY MODULE WITH INTEGRATED ARTERIAL FILTER	2	
050703	INSPIRE 8F M	INSPIRE 8 LPM PHISIO OXY MODULE WITH INTEGRATED ARTERIAL FILTER	2	

HVR

050704	INSPIRE HVR	INSPIRE PHISIO HARD SHELL VENOUS RESERVOIR	2	
050705	INSPIRE HVR DUAL	INSPIRE PHISIO DUAL HARD SHELL VENOUS RESERVOIR	2	

ACCESSORIES

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	

* To be ordered as an accessory of LivaNova S5 and C5 HLMs

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Health innovation that matters

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www.LivaNova.com

Please always refer to the Instructions For Use (IFU) manual provided with each product for detailed information, warnings, precautions and possible adverse side effects.

IM-01271/A 02/2018

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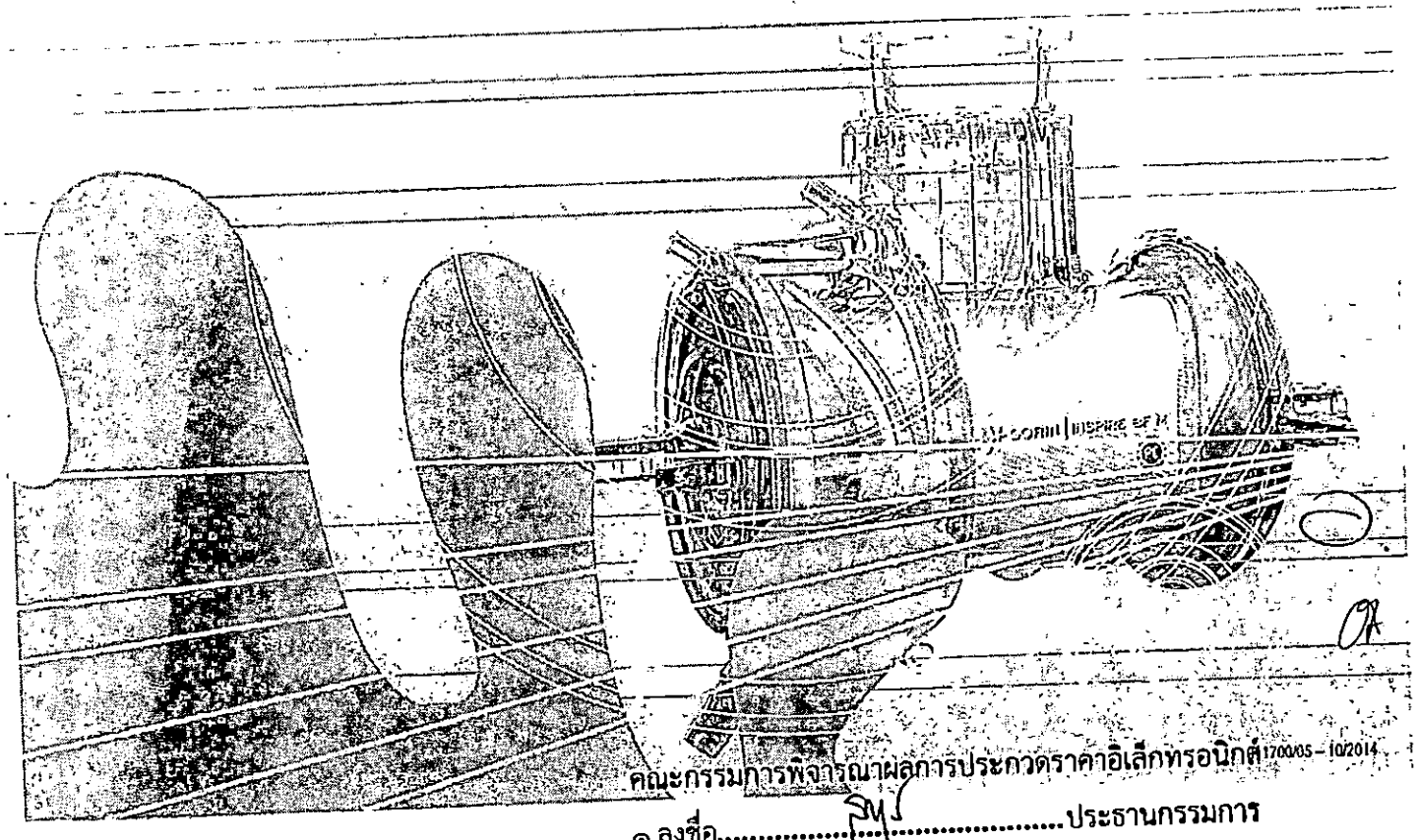
SORIN | INSPIRE 8F M

OXY MODULE PHISIO w / IAF

Oxygenator, extracorporeal membrane • Ossigenatore, membrana extracorporea • Oxygénateur, membrane extracorporelle • Membranoxygenator, extrakorporaler Kreislauf • Oxigenador de membrana extracorpórea • Oxigenador, membrana extracorporal • Οξυγονωτής μεμβράνης εξωσωματικής κυκλοφορίας • Oxygenator, extracorporaal membraan • Oxygenator, extrakorporealt membran • Oxygenator, ekstrakorporal membran • Oksygenaattori, kehonulkoinen kalvo • Oksygenator, ekstrakorporeal membran • Oxygenátor, mimotělní, membránový • Oksygenator membranowy do krążenia pozaustrojowego • Oxygenátor, mimotelový membránový • Oksigenator, zunajtelesni membranski • Oxigenátor, extrakorporális membrán • Ekstrakorporalinis membraninis oksigenatorius • Oksügenaator, kehaväline membraan • Oksigenators, ekstrakorporālā membrāna • Oxigenator, membrană extracorporală • Оксигенатор, екстракорпорална мембрана • Oksijenatör, ekstrakorporeal membran • Оксигенатор мембранный для экстракорпоральной оксигенации • Oksigenator, vantelesna membrana • Oksigenator, vantjelesna membrana



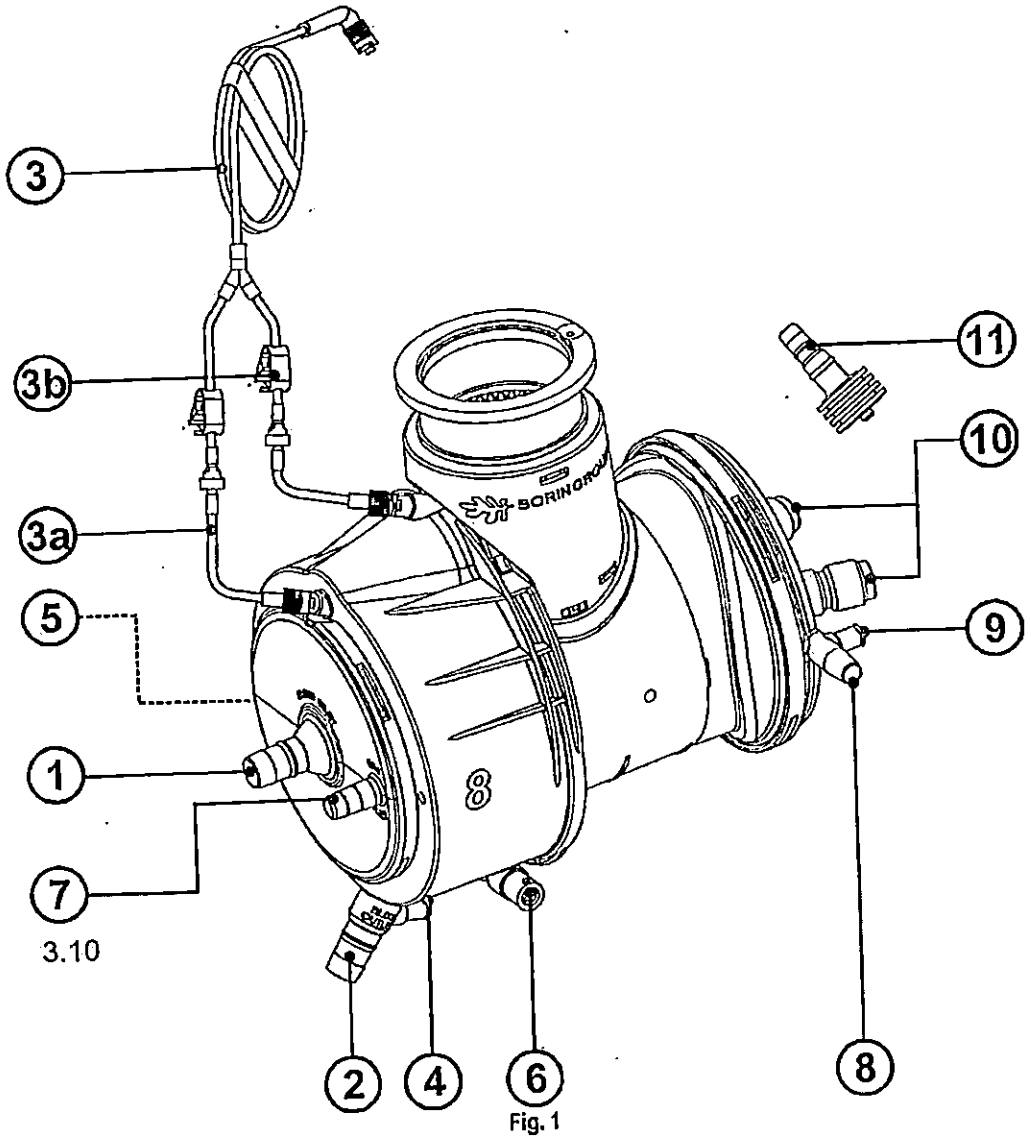


Fig. 1
3.12

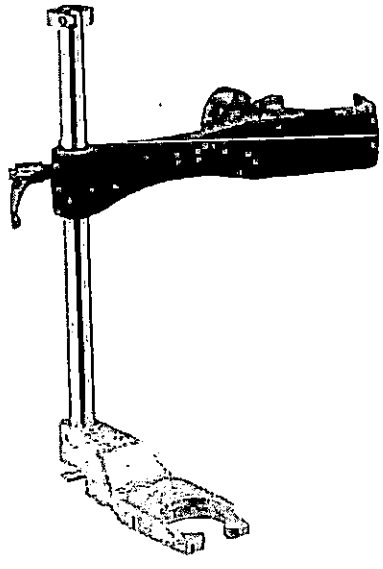


Fig. 2

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References
1. Blood inlet connector
2. Blood outlet connector
3. Double Recirculation/purge line
   3.a Pre filter (white clamp)
   3.b Post filter (red clamp)
4. Arterial sampling connector
5. Blood cardioplegia outlet connector
6. Arterial temperature probe connector
7. Gas inlet connector
8. Gas scavenging connector
9. Capnograph connector
10. Water inlet and outlet connectors
11. Male pos-lock to 1/4" cardioplegia adaptor

Riferimenti
1. Connettore ingresso sangue
2. Connettore uscita sangue
3. Linea di spurgo/ricircolo doppia
   3.a Pre filtro (clamp bianca)
   3.b Post filtro (clamp rossa)
4. Connettore campionamento arterioso
5. Connettore uscita sangue cardioplegia
6. Connettore sonda temperatura arteriosa
7. Connettore ingresso gas
8. Connettore evacuazione gas
9. Connettore capnografo
10. Connettori ingresso e uscita acqua
11. Adattatore di cardioplegia posp-lock maschio da 1/4"

Références
1. Raccord entrée de sang
2. Raccord sortie de sang
3. Double ligne de recirculation/purge
   3.a Avant le filtre (clamp blanc)
   3.b Après le filtre (clamp rouge)
4. Raccord prélèvement artériel
5. Raccord sortie cardioplégie sanguine
6. Raccord sonde de température artérielle
7. Raccord entrée de gaz
8. Raccord évacuation de gaz
9. Raccord capnographe
10. Raccords entrée et sortie d'eau
11. Adaptateur Pos-Lock sur adaptateur de cardioplégie 1/4"

Legende
1. Bluteingangsanschluss
2. Blutauslassanschluss
3. Doppelte Rezirkulations-/Spülleitung
   3.a Vorfilter (weiße Klemme)
   3.b Nachfilter (rote Klemme)
4. Anschluss zur Entnahme arterieller Blutproben
5. Blutkardioplegie-Auslassanschluss
6. Anschluss für die arterielle Temperatursonde
7. Gaseinlassanschluss
8. Gasspülanschluss
9. Kapnographanschluss
10. Wassereinlass- und -auslassanschlüsse
11. Kardioplegieadapter, 1/4", Positionssperre männlich

Referencias
1. Conector de entrada de sangre
2. Conector de salida de sangre
3. Línea de purga/recirculación doble
   3.a Previa al filtro (pinza blanca)
   3.b Posterior al filtro (pinza roja)
4. Conector para toma de muestras de sangre arterial
5. Conector de salida de cardioplejía sanguínea
6. Conector para sonda de temperatura arterial
7. Conector de entrada de gas
8. Conector de evacuación de gases
9. Conector para capnógrafo
10. Conectores de entrada y salida de agua
11. Cierre positivo macho para adaptador de cardioplejía de 1/4"

Referências
1. Conector de entrada do sangue
2. Conector de saída do sangue
3. Linha dupla de recirculação/purga
   3.a Pré-filtro (clamp branco)
   3.b Pós-filtro (clamp vermelho)
4. Conector de amostragem arterial
5. Conector de saída para cardioplegia hemática
6. Conector da sonda de temperatura arterial
7. Conector de entrada do gás
8. Conector de evacuação de gás
9. Conector do capnógrafo
10. Conectores de entrada e saída de água
11. Dispositivo de bloqueio macho para adaptador de cardioplegia de 1/4"

Υπόμνημα
1. Συνδετήρας εισόδου αίματος
2. Συνδετήρας εξόδου αίματος
3. Διπλή γραμμή επανακυκλοφορίας/εξαέρωσης
   3.α Προφίλτρο (λευκός σφιγκτήρας)
   3.β Μετα-φίλτρο (κόκκινος σφιγκτήρας)
4. Συνδετήρας αρτηριακής δειγματοληψίας
5. Συνδετήρας εξόδου αιματικής καρδιοπληγίας
6. Συνδετήρας αισθητήρα αρτηριακής θερμοκρασίας
7. Συνδετήρας εισόδου αερίων
8. Συνδετήρας απαγωγής αερίων
9. Συνδετήρας καπνογράφου
10. Συνδετήρες εισόδου και εξόδου νερού
11. Προσαρμογέας καρδιοπληγίας για σύνδεση αρσενικού pos-lock με συνδετήρα 1/4"

Referenties
1. Bloedingangsaansluiting
2. Bloeduitgangsaansluiting
3. Dubbele recirculatie-/laftaplijn
   3.a Voorfilter (witte klem)
   3.b Nafilter (rode klem)
4. Arteriële monstemame-aansluiting
5. Uitgangsaansluiting voor bloedcardioplegie
6. Aansluiting voor arteriële temperatuurvoeler
7. Gasingangsaansluiting
8. Gasafvoeraansluiting
9. Capnograafaansluiting
10. Wateringangs- en -uitgangsaansluitingen
11. Mannelijke pos-lock voor 1/4" cardioplegie-adapter

Referenser
1. Blodinloppskoppling
2. Blodutloppskoppling
3. Dubbel recirkulations-/avluftningsslang
   3.a Förfilter (vit klämma)
   3.b Efterfilter (röd klämma)
4. Arteriell provtagningskoppling
5. Koppling för blodkardioplegiutlopp
6. Koppling för arteriell temperaturprob
7. Gasinloppsanslutning
8. Gasutloppsanslutning
9. Kapnografanslutning
10. Kopplingar för vatteninlopp och -utlopp
11. Hanpositionslås till 1/4" kardioplegiadapter

Henvisninger
1. Blodindløbskonnektor
2. Blodudløbskonnektor
3. Dobbeltslange til recirkulation/purge
   3.a Præfilter (hvid klemme)
   3.b Postfilter (rød klemme)
4. Arterieprøvetagningskonnektor
5. Blodkardioplegiudløbskonnektor
6. Konnektor til arteriel temperaturføler
7. Gasindløbskonnektor
8. Gasindsamlingskonnektor
9. Kapnografkonnektor
10. Studs til vandindtag og udløb
11. Han pos-lås for 1/4" kardioplegiadapter

Viittaukset
1. Veren sisääntulolitin
2. Veren ulostulon liitin
3. Kaksinkertainen kierto-/tyhjennyslinja
   3.a Esisuodatin (valkoinen ruuvikiristin)
   3.b Jälkisuodatin (punainen ruuvikiristin)
4. Valtimon näytteenottoliitin
5. Veren kardioplegiaulostulon liitin
6. Valtimon lämpötila-anturin liitin
7. Kaasun sisääntulon liitin
8. Kaasunpoistoliitin
9. Kapnografin liitin
10. Veden sisääntulo- ja ulostuloliittimet
11. Koiras-pos-lock 1/4":n kardioplegiasovittimeen

Referanser
1. Blodinngangskobling
2. Blodutgangskobling
3. Dobbelt resirkulerings-/tømmeslange
   3.a Forhåndsfilter (hvitklemme)
   3.b Etterfilter (rød klemme)
4. Arteriell provetakingskobling
5. Utgangskobling for blodkardioplegi
6. Arterielt temperaturmålekobling
7. Gassinntakskobling
8. Gassutskillingskobling
9. Kapnografkobling
10. Vanninnløps- og utløpskoplinger
11. Hannpos.lås til 1/4" kardioplegiadapter

Položky
1. Vstupní konektor pro krev
2. Výstupní konektor pro krev
3. Dvojité recirkulační/odvzdušňovací vedení
   3.a Předřazený filtr (bílá svorka)
   3.b Výstupní filtr (červená svorka)
4. Konektor pro odběr arteriálních vzorků
5. Výstupní konektor pro krevní kardioplegii
6. Konektor arteriální teplotní sondy
7. Vstupní konektor pro plyn
8. Konektor pro zachytávání plynu
9. Konektor kapnografu
10. Konektory pro vstup a výstup vody
11. 1/4" kardioplegický adaptér s vnějším uzávěrem pos-lock

Legenda
1. Złącze wejściowe krwi
2. Złącze wyjściowe krwi
3. Podwójna linia recyrkulacji/oczyszczania
   3.a Przed filtrem (biały zacisk)
   3.b Za filtrem (czerwony zacisk)
4. Złącze do pobierania próbek krwi tętniczej
5. Złącze wyjściowe krwi do kardioplegii
6. Złącze do czujnika temperatury krwi tętniczej
7. Złącze wejściowe mieszanki gazowej
8. Złącze odpowietrzające dla mieszanki gazowej
9. Złącze dla kapnografu
10. Złącza wejściowe i wyjściowe dla wody
11. Reduktor męskiego złącza z blokadą do 1/4 cala do kardioplegii

Legenda
1. Konektor pre privod krvi
2. Konektor krvného výstupu
3. Dvojité recirkulačné/odvzušňovacie vedenie
   3.a Predfilter (biela svorka)
   3.b Následný filter (červená svorka)
4. Konektor arteriálneho odberu vzoriek
5. Konektor kardioplegického krvného výstupu
6. Konektor snímača arteriálnej teplotnej sondy
7. Konektor privodu plynu
8. Prípojka odsávania plynu
9. Konektor kapnografu
10. Prípojky vstupu a výstupu vody
11. Blokovacia poistka s vonkajším závitom pre kardioplegický adaptér 1/4"

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Legenda
1. Dovodni priključek za kri
2. Odvodni priključek za kri
3. Dvojna cevka za recirkulacijo/odzračevanje
   3.a Pred filtrom (beli stiščk)
   3.b Po filtru (rdeči stiščk)
4. Priključek za vzorčenje arterijske krvi
5. Priključek za odvod krvi za kardioplegijo
6. Priključek sonde temperature arterijske krvi
7. Priključek za dovod plina
8. Priključek za odstranjevanje plina
9. Priključek kapnografa
10. Priključka za dovod in odvod vode
11. Nastavek za moški priključek pos-lock na 1/4-palčni priključek za kardioplegijo

Jelzőszámok (Ref.)
1. Vér bemeneti csatlakozója
2. Vér kimeneti csatlakozója
3. Dupla recirkulációs/légtelenítő vezeték
   3.a Elöszürő (fehér kapocs)
   3.b Utöszürő (piros kapocs)
4. Artériás mintavevő csatlakozó
5. Vér kardioplégiás kimeneti csatlakozója
6. Artériás hőmérő csatlakozója
7. Gáz bemeneti csatlakozója
8. Gáz kimeneti csatlakozója
9. Szén-dioxid-regisztráló csatlakozója
10. Víz bemeneti és kimeneti csatlakozók
11. Pozíciózáró dugó az 1/4"-os kardioplégiás adapterhez

Nuorodos
1. Kraujo įleidimo jungtis
2. Kraujo išleidimo jungtis
3. Dviguba recirkuliacijos / valymo linija
   3.a Pradinis filtras (baltas spaustukas)
   3.b Galinis filtras (raudonas spaustukas)
4. Arterinio kraujo mėginių ėmimo jungtis
5. Kraujo kardioplegijos išvado jungtis
6. Arterinio kraujo temperatūros zondo jungtis
7. Dujų įleidimo jungtis
8. Dujų pašalinimo jungtis
9. Kapnometro jungtis
10. Vandens įleidimo ir išleidimo jungtys
11. Įstatoma „pos-lock" jungtis 1/4 col. kardioplegijos adapteriui

Viited
1. Vere sisselaskeava liitmik
2. Vere väljalaskeava liitmik
3. Topelt retsirkulatsiooni-/tühjendusvoolik
   3a Eelfilter (valge klamber)
   3b Järelfilter (punane klamber)
4. Arteriaalse vere proovide võtmise liitmik
5. Vere kardioplegia väljalaskeava liitmik
6. Arteriaalse vere temperatuurianduri liitmik
7. Gaasi sisselaskeava liitmik
8. Gaasi väljutamise liitmik
9. Kapnograafi liitmik
10. Vee sisse- ja väljalaskeava liitmikud
11. Haaratav pos. lukk 1/4-tollisele kardiopleegia adapterile

Atsauces
1. Asins ievades pieslēgvietas savienotājs
2. Asins izvades pieslēgvietas savienotājs
3. Dubultā recirkulācijas/iztukšošanas caurulīte
   3.a Priekšfiltrs (baltā skava)
   3.b Pēcfiltrs (sarkanā skava)
4. Arteriālo asiņu paraugu ņemšanas pieslēgvietas savienotājs
5. Asins kardioplēģijas izvades pieslēgvietas savienotājs
6. Arteriālās termozondes pieslēgvietas savienotājs
7. Gāzu ievades pieslēgvietas savienotājs
8. Gāzu savākšanas pieslēgvietas savienotājs
9. Kapnogrāfijas pieslēgvietas savienotājs
10. Ūdens ievades un izvades pieslēgvietas savienotājs
11. Aptvertais fiksators 1/4 collu kardioplēģijas adapterim

Referinţe
1. Conector intrare sânge
2. Conector ieşire sânge
3. Linie dublă de recirculare/purjare
   3.a Prefiltru (clemă albă)
   3.b Postfiltru (clemă roşie)
4. Conector arterial de eşantionare
5. Conector ieşire cardioplegie sânge
6. Conector sondă pentru temperatura arterială
7. Conector intrare gaz
8. Conector evacuare gaz
9. Conector capnograf
10. Conectori intrare şi ieşire apă
11. Pos-lock de tip „tată" la adaptor cardioplegie de 1/4"

Справки
1. Съединител на входния отвор за кръв
2. Съединител на изходния отвор за кръв
3. Двойна линия за рециркулация/прочистване
   3.a Филтър преди устройството (бяла клампа)
   3.б Филтър след устройството (червена клампа)
4. Съединител за вземане на артериални проби
5. Съединител на изходен отвор за хръвна кардиоплегия
6. Съединител за артериални температурни сонди
7. Съединител за входен отвор за газ
8. Съединител за отвеждане на газ
9. Съединител за капнограф
10. Съединители за входния и изходния отвори за вода
11. Адаптер мъжки накрайник тип "pos-lock" към 1/4" накрайник за кардиоплегия

Referanslar
1. Kan giriş konektörü
2. Kan çıkış konektörü
3. Çift resirkülasyon/boşaltma hattı
   3.a Prefiltre (beyaz klemp)
   3.b Postfiltre (kırmızı klemp)
4. Arteriyel örnek alma konektörü
5. Kan kardiyopleji çıkış konektörü
6. Arteriyel sıcaklık probu konektörü
7. Gaz girişi konektörü
8. Gaz giderici konektör
9. Kapnograf konektörü
10. Su giriş ve çıkış konektörleri
11. Erkek pos-lock 1/4" kardiyopleji adaptörüne

Указатель
1. Входной коннектор крови
2. Выходной коннектор крови
3. Двойная линия рециркуляции/спуска
   3.a Фильтр грубой очистки (белый зажим)
   3.b Фильтр тонкой очистки (красный зажим)
4. Коннектор отбора проб артериальной крови
5. Выходной коннектор кардиоплегии крови
6. Коннектор датчика температуры артериальной крови
7. Входной коннектор газа
8. Коннектор отвода газа
9. Коннектор для капнографии
10. Коннекторы входа и выхода воды
11. Охватываемый замок для адаптера для кардиоплегии 1/4"

Reference
1. Ulazni konektor za krv
2. Izlazni konektor za krv
3. Dvostruki vod za recirkulaciju/pročišćavanje
   3.a Pred filter (bela stezaljka)
   3.b Post filter (crvena stezaljka)
4. Konektor za uzimanje uzoraka arterijske krvi
5. Izlazni konektor za kardioplegijsku krv
6. Konektor sonde za temperaturu venske krvi
7. Ulazni konektor za gas
8. Konektor za čišćenje gasa
9. Konektor za kapnograf
10. Konektori za ulaz i izlaz vode
11. Muški pos-lock port na 1/4" adapter za kardioplegiju

Reference
1. Ulazni konektor za krv
2. Izlazni konektor za krv
3. Dvostruki vod za recirkulaciju/odzračivanje
   3.a Predfiltar (bijela stezaljka)
   3.b Postfiltar (crvena stezaljka)
4. Konektor za uzimanje uzoraka arterijske krvi
5. Izlazni konektor za kardioplegijsku krv
6. Konektor sonde za temperaturu arterijske krvi
7. Ulazni konektor za plin
8. Konektor za čišćenje plina
9. Konektor za kapnograf
10. Ulazni i izlazni konektor za vodu
11. Muški kardioplegijski adapter sa pos-lock na 1/4"

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CONTENTS

A. DESCRIPTION

The Inspire 8F M is a microporous hollow fibre membrane oxygenator with an integrated heat exchanger and an integrated arterial filter. 2.1
The Inspire 8F M is coated with Phisio (PC phosphorylcholine) coating. Devices coated with Phisio are used when a coated blood path is desired. The Phisio coating improves the blood compatibility of the device by reducing platelet adhesion on the coated surfaces.
The device is single use, non-toxic, non-pyrogenic, supplied **STERILE** in individual packaging. Sterilised by ethylene oxide. The level of ethylene oxide residuals in the device is within the limits established by national regulations in the country of use. 2.2

B. TECHNICAL FEATURES

MAXIMUM BLOOD FLOW RATE	8 l/min 3.6
MINIMUM BLOOD FLOW RATE	2 l/min
MINIMUM BLOOD FLOW RATE (up to 2 hours max. duration time)	0,5 l/min
STATIC PRIMING VOLUME (oxygenating module + heat exchanger average value)	351 ml 3.5
RESIDUAL BLOOD VOLUME (oxygenating module + heat exchanger average value)	127 ml
MEMBRANE SECTION	
- Material type	Microporous Polypropylene
- Surface area (approx. value)	1,75 m² 3.1
HEAT EXCHANGER SECTION	
- Material type	Polyurethane 3.4
- Surface area (approx. value)	0,43 m²
ARTERIAL FILTER SECTION 3.13	
- Material type	Polyester net
- Micron size	38 µm
- Surface area (approx. value)	97 cm²
HOUSING	
- Material type	Polycarbonate 3.3
PORT CONFIGURATION:	
- Oxygenator blood inlet	3/8" 3.7
- Oxygenator blood outlet	3/8" 3.8
- Gas inlet	1/4"
- Gas outlet	1/4" 3.9
- Capnograph connector on gas outlet	Female Luer Lock
- Cardioplegia	Valved female pos-Lock
- Arterial sampling	Female Luer Lock
- Arterial blood temperature	Bayonet fitting YSI compatible
- Water inlet-outlet	2 x Male Hansen type 3.11
BIOCOMPATIBLE COATING	Phosphorylcholine (Phisio)
ACCESSORIES	Male pos-lock to 1/4" adaptor

C. INTENDED USE

The Inspire 8F M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. Inspire 8F M integrated arterial filter provides additional protection against air and solid emboli.
The Inspire 8F M is intended to be used for 6 hours or less.
Inspire 8F M can be used with the devices listed in paragraph O (MEDICAL DEVICES FOR USE WITH INSPIRE 8F M).

D. CONTRAINDICATIONS

No contraindications are known if the device is used for the purpose described and in accordance with the stated operating conditions.
Do not use the device for any purpose other than indicated.

E. SAFETY INFORMATION

Information intended to attract the attention of the user to potentially dangerous situations and to ensure correct and safe use of the device is indicated in the text in the following way:

WARNING

WARNING indicates serious adverse reactions and potential safety hazards for the practitioner and/or the patient that may occur in the proper use or misuse of the device as well as the limitations of use and the measures to be adopted in such cases.

CAUTION

Indicates any special care to be exercised by a practitioner for the safe and effective use of the device.

EXPLANATION OF THE SYMBOLS USED ON THE LABELS

	For single use only (Do not reuse)
LOT	Batch code (number) (reference for product traceability)
	Use by (Expiry date)
	Manufactured by
	Date of manufacture
STERILE EO	Sterile - Ethylene oxide sterilised
	Non pyrogenic fluid pathway
	Warning: Do not resterilize.
	Contents sterile only if package is not opened, damaged or broken
REF	Catalogue (code) number
	Attention, see instruction for use
www.sorinmanuals.com	Consult the instructions for use on the website at www.sorinmanuals.com
	This way up
	Fragile; handle with care
ea	Quantity
	Keep away from heat
	Keep dry

The following is general safety information to advise the operator when preparing to use the device.
Specific safety information is also given in the instructions for use at locations in the text where that information is relevant for correct operation.

WARNING

- The User should carefully check the device during set-up and priming for leaks. Do not use if any leak is detected.
- The device must be used in accordance with the instructions for use provided in this manual.
- For use by professionally trained personnel only
- SORIN GROUP is not responsible for problems arising from inexperience or improper use.
- FRAGILE, handle with care.
- Keep dry. Store at room temperature
- Always administer and maintain correct anticoagulant dosage before, during and

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after the bypass and provide its correct monitoring.

- For single use and for single patient use only: during use the device is in contact with human blood, body fluids, liquids or gases for the purpose of eventual infusion, administration or introduction into the body. Due to its specific design the device cannot be fully cleaned and disinfected at the end of use. Therefore, reuse on other patients might cause cross-contamination, infection and sepsis. In addition, reuse increases the probability of product failure (integrity, functionality and clinical effectiveness).
- Sterile Contents/Non-Pyrogenic Fluid Pathway unless package is opened or damaged.
- The device and its accessories must be handled applying sterile techniques.
- The device must not undergo any further processing.
- Do not resterilize.
- Use of phospolipidic drugs in the priming fluid or their infusion in the patient during the case, might facilitate the hydrophylization (plasma breakthrough) of the microporous membrane.
- After use, dispose of the device in accordance with applicable regulations in force in the country of use.
- The device must only be used if STERILE.
- Do not create negative pressure in the oxygenator blood compartment in any possible ways. Microporous membrane does allow blood compartment air embolization in case blood path pressure becomes lower in respect to gas path pressure.
- Inspire 8F M upper point should always be positioned at least 5 cm below the minimum operating level of the venous reservoir used in conjuction with it.
- Inspire 8F M must be used with its dedicated brackets.
- Only purge/recirculation lines preconnected to Inspire 8F M allow adequate operations.
- In case pump console is moved during use make sure that no lines such as gas, blood and water lines are pulled.
- For further information and/or in case of complaint contact SORIN GROUP or the authorised local representative.

CAUTION

- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
- Inner surfaces of the system are Phisio coated, currently SORIN GROUP is not aware of any contraindications to the use of this coated device

F. PREPARATION AND SET-UP

1) POSITION THE BRACKET

Firmly position the Inspire 8F M bracket on the pump structure by means of its fixation clamp (fig.2). The bracket is reversible and allows ergonomic right and left pump console set-up. An allen key is provided with the bracket. Inspire 8F M brackets are also suitable for other Inspire devices.

2) FIX THE OXYGENATOR TO THE BRACKET

WARNING

- Do not use if sterile packaging is damaged, unsealed, or has been exposed to moisture or other conditions that would compromise the sterility of the device.
- Check the expiry date on the attached label. Do not use the device after the date shown.
- The device must be used immediately after opening the sterile packaging.
- The device must be handled aseptically.

Remove the device from its sterile packaging.

WARNING

- Carry out a visual inspection and carefully check the device before use. Transportation and/or storage conditions other than those prescribed may have caused damage to the device.
- Do not use solvents such as alcohol, ether, acetone, etc.: as contact may cause damage to the device.
- Do not allow halogenated liquids such as Halothane and Fluothane to come into contact with the polycarbonate housing of the device. This could cause damage which may compromise the integrity and proper function of the device.

The bracket locking lever must point to the unlocked
Insert the oxygenator onto the appropriate holding clamp.
Turn the locking lever to locked symbol position.
The device will be correctly installed in the bracket only when the locking lever points to locked
The Inspire 8F M and its holder should be positioned so as to allow easy and practical access to the connectors and good visibility of the device. Make sure that Inspire 8F M is positioned below the venous reservoir to which it will be connected.

3) HEATER-COOLER SET-UP

Connect the water lines to the Inspire 8F M water connectors by means of the SORIN GROUP female Hansen connectors or equivalent.

WARNING

- The use of different connectors from those indicated may cause resistance inside the water circuit and reduce the efficiency of the heat exchanger.
- The water temperature at the heat exchanger inlet must not exceed 42 °C (108 °F).
- The water pressure in the heat exchanger must not exceed 1500 mmHg (200 kPa / 2 bar / 29 PSI).

4) CHECK THE HEAT EXCHANGER

WARNING

- Check the heat exchanger by circulating water inside the heat exchanger for a few minutes. There should be no leaks from the water compartment to the outside of the device or to the blood compartment.
- If PVC pump segments are used, water must flow through the heat exchanger prior main blood pump operation in order to avoid static electricity built-up in the heat exchanger.

5) CIRCUIT CONNECTIONS

WARNING

All connections must be secured by means of tie straps.

ARTERIAL LINE: connect the 3/8" arterial line to the oxygenator arterial outlet (fig.1, ref.2).

PUMP LINE: the pump line should be connected between the venous reservoir outlet connector and the oxygenator blood inlet connector (fig.1, ref.1) with attention to the direction of rotation of the main pump.

OXYGENATOR MODULE PURGE/RECIRCULATION LINE: connect the purge/recirculation line end to the recirculation line inlet on the soft venous reservoir (closed system), or to a filtered luer port of the hard shell venous reservoir (open system).

CAUTION

- If oxygenated blood is needed for blood cardioplegia purposes connect the 1/4" blood line of the cardioplegia circuit to the Inspire 8F M blood cardioplegia outlet port using the D523C (male pos-lock to 1/4" adaptor) provided with the product.
- The blood cardioplegia outlet port has a self-sealing valve which allows connection of the D 523C adaptor also when the extracorporeal bypass system is primed, without accidental fluid spillage.

WARNING

- Do not connect the cardioplegia adaptor to the cardioplegia port when priming fluid is flowing or during extracorporeal circulation. Air could enter the oxygenator.

6) SAMPLING SYSTEM

Connect the arterial-venous blood sampling system in use by connecting the arterial sampling line to the arterial sampling luer connector located on the back of the arterial outlet (fig. 1, ref. 4)

Position the stopcock handles of the sampling manifold in closed position.

7) CONNECT THE TEMPERATURE PROBE

The arterial temperature probe connector (fig.1, ref.6) is positioned close to the arterial outlet.
Use SORIN GROUP temperature probe or equivalent YSI compatible temperature probe.

8) CONNECT THE GAS LINE

Connect the 1/4" gas line to the gas inlet connector (fig.1, ref.7).
Ensure that the gas supply is from a suitable air/oxygen mixer such as the Sechrist available from SORIN GROUP or a system with comparable technical features.
A dedicated female luer lock capnograph connector can be found on the gas escape connector (fig.1, ref.9). In case gas scavenging is operated, gas sampling through capnograph connector may give inaccurate expired CO_2 values.

CAUTION

- The gas escape system is designed to avoid any possible risk of blocking the gas outlet; such blockage could cause the immediate passage of gas into the blood compartment.
- The user should check for tubing occlusions and kinks during set-up.
- Check that all connections are securely tight.

9) VAPOROUS ANAESTHESTICS

The oxygenator is suitable for use with Isoflurane and sevoflurane volatile anaesthetics and they shall be administered by means of a suitable narcosis gas evaporator.

If these vaporous anaesthetics are used, some method of scavenging the gas from the oxygenator should be considered.
The protocol, the concentration and the monitoring of the anaesthetic gases administered to the patient, is under the sole responsibility of the physician in charge of the treatment.
Connect a suitable 1/4" scavenging line to the gas outlet connector and make sure that the scavenging system is fitted with appropriate safety devices.

WARNING

The only volatile anaesthetics suitable for use with this device are isofluorane and sevoflurane

WARNING

The methods adopted for vaporous anaesthetic gas scavenging should not increase or reduce in any way the pressure within the oxygenator fibres.

G. PRIMING AND RECIRCULATION PROCEDURE

WARNING

- **Do not use priming solutions containing alcohol; such solutions could compromise the proper functioning of the oxygenating module.**
- **During priming procedure check for leaks. Do not use if any leaks is detected.**

CAUTION

If flushing with low flow CO_2 is desired, first adjust the temperature in the heater-cooler to room temperature and circulate for 5 minutes. This should avoid water condensation appearing at oxygenator module level. CO_2 flushing improves debubbling of the circuit and of Inspire 8F M.

1) KEEP THE GAS FLOW OFF

2) OPEN THE OXYGENATOR PURGE/RECIRCULATION LINE

Check that both pre and post filter clamps of the purge-recirculation line are open (fig.1 ref.3a and fig.1 ref. 3b).

3) CLOSE THE RESERVOIR OUTLET LINE AND THE ARTERIAL LINE

Clamp the reservoir outlet line close to the arterial pump.When using a soft venous reservoir (closed system), clamp the line between the auxiliary cardiotomy and the softshell venous reservoir.
Clamp the arterial line close to the arterial outlet

4) CHECK THE HEAT EXCHANGER

Operate the heater-cooler for a few minutes before priming by flowing water through the heat exchanger. Pay particular attention to possible water leaks.

5) HARD SHELL VENOUS/ CARDIOTOMY RESERVOIR PRIMING

Fill the reservoir with sufficient priming fluid to accomplish debubbling and to allow achieving intended hemodilution.
When using a softshell venous reservoir (closed system), open the auxiliary cardiotomy outlet to fill the softshell venous reservoir.
Operate the appropriate suction line to purge air from the softshell venous reservoir.

6) OXYGENATOR AND CIRCUIT PRIMING

WARNING

- **The pressure level inside the blood compartment of the Inspire 8F M oxygenator module shall not exceed 750 mmHg (100 kPa / 1 bar / 14 PSI).**

If using a roller pump, remove the tubing from the pump raceway.
Remove the clamp from the reservoir outlet line.
Allow gravity to prime the arterial pump (pump boot / centrifugal pump), oxygenator and arterial filter.
As prime fills the arterial filter, a single sharp tap to the filter housing will facilitate breakthrough of the filter screen.
Load the pump boot into the roller head or centrifugal pump into the drive unit.
Remove the clamp from the arterial line.
Slowly increase the arterial flow to 5 lpm.

CAUTION

Debubbling ability of Inspire 8F M improves by lowering prime fluid temperature and raising it again. Light tapping may help address air evacuation.

7) PURGE THE AIR CONTAINED IN THE DEVICE AND IN THE CIRCUIT

Intermittently clamp few times the arterial line near the outlet to evacuate air through the purge ports
Reduce flow down to 200 ml/min, clamp the arterial outlet again.
Lightly tap the arterial filter from base to top to facilitate air removal through the purge ports.
When air is dislodged remove clamp from arterial outlet and increase flow up to 5 lpm
Tap the entire circuit to facilitate the removal of micro bubbles from the tubing walls.

CAUTION

Priming with colloid fluids may require a longer and more thorough debubbling procedure.

8) PRIME OF THE SAMPLING SYSTEM

Priming of the A/V sampling system occurs automatically when the arterial, venous and central stopcock handles are positioned in such a way as to allow the priming fluid to spontaneously flow from the arterial outlet to the venous inlet connector sampling port.

9) CLOSE THE PURGE/RECIRCULATION LINE

Continue purge until visible air is removed.
Clamp both clamps of purge/recirculation line.

10) CLAMP THE VENOUS AND ARTERIAL LINES

Stop the main pump.
Clamp the venous and arterial lines

CAUTION

- **During the priming and purge phases, the arterial/venous lines must be kept at least 30 cm higher than the arterial outlet of the oxygenator.**
- **Do not use pulsatile flow during priming. Sudden changes in flow rate during priming can pull air across the microporous membrane into the blood pathway.**
- **SORIN GROUP recommends to slowly adjust the pump speed control knob to reduce or stop the main flow.**
- **Do not use the main pump on/off switch until the main pump flow is zero.**
- **Do not turn off the Heater-cooler.**
- **Check the correct dosage of anticoagulant in the system before starting the bypass.**
- **The user should inspect the system for correct air removal.**

WARNING

- **If the cardioplegia adaptor (fig.1 ref.11) and a cardioplegia circuit have been connected to the cardioplegia outlet port, check the correct priming of the connected lines.**
- **Do not create a negative pressure at the cardioplegia outlet port. Negative pressure in the blood compartment could cause microbubbles formation.**

CAUTION

- **Prolonged contact time with priming solutions may alter device performance.**

H. INITIATING BYPASS

1) OPEN THE ARTERIAL AND VENOUS LINES

Remove the clamp from the arterial line, then slowly start the bypass activating the main pump. Remove the clamp from the venous line and achieve main blood flow appropriate to patient size.
Constantly check the blood level in the venous reservoir.

2) REACH DESIRED BLOOD FLOW RATE

Adjust flow until hemodynamic balance and the desired flow rate are reached.

CAUTION

Minimum blood flow rate may be lowered down to a minimum of 0,5 l/min up to 2 hours duration time.

3) CHECK THE CORRECT OPERATION OF THE HEAT EXCHANGER

Check the temperature of the venous and arterial blood.

4) SELECTION OF THE APPROPRIATE GAS FLOW AND FiO_2

The suggested gas/blood flow ratio in normothermic conditions is 1:1 with an FiO_2 of 80 to 100%.

WARNING

- **Always open the gas flow after the blood flow. The gas/blood flow ratio must never exceed 2:1 to prevent possible air emboli.**
- **The minimum gas/blood flow ratio should always equal or above 0,5:1 to allow adequate gas exchange.**
- **To obtain charted gas exchange performance, SGI recommends to use a gas/blood flow ratio of 1:1 for all the blood flow rate operating conditions**
- **The pressure in the blood compartment must always exceed that of the gas compartment to prevent gas emboli from appearing in the blood compartment.**
- **Due to design of membrane oxygenators only blood exiting arterial outlet connector is true mixed arterialized blood. Blood taken from cardioplegia outlet connector, due to its position in the oxygenator, supplies arterialized**

blood with a pO_2 value ≥80% in respect to that of arterial blood exiting blood outlet port.

- In case a non occlusive pump is used make sure that positive pressure is always applied to the oxygenator module used in conjuction with the device.
- If CO_2 flooding is used on the operating field an increase in pCO_2 may be observed and gas flow to the oxygenator may need to be adjusted accordingly.

5) BLOOD GAS MONITORING

Measure blood-gas after a few minutes and at regular intervals during bypass operation. Depending on the values found, adjust the relevant parameters as follows:

High pO_2	⟶	Decrease FiO_2
Low pO_2	⟶	Increase FiO_2
High pCO_2	⟶	Increase gas flow rate
Low pCO_2	⟶	Decrease gas flow rate

CAUTION

CAUTION

It is not advisable to draw blood samples from oxygenator and arterial filter purge lines. Blood flowing from purge lines may have O_2 and CO_2 content different from arterialized mixed blood.

I. DURING BYPASS

1) CHECK THE VENOUS RETURN

If a higher venous return flow is necessary lower both the Inspire 8F M and the venous reservoir with respect to the patient position.

WARNING

- The venous reservoir must always be placed at a higher position in respect to the Inspire 8F M.
- The cardiotomy reservoir must always be placed in a higher position with respect to the softshell venous reservoir (closed system).
- The ACT (Activated Clotting Time) must always be higher than or equal to 450 seconds in order to ensure adequate blood anticoagulation within the extracorporeal circulation system.
- If administration of anticoagulant to the patient is necessary, use the luer connector of the central stopcock on the sampling manifold.
- Do not create negative pressure in the oxygenator blood compartment in any possible ways. Microporous membrane does allow blood compartment air embolization in case blood path pressure becomes lower in respect to gas path pressure.

2) ARTERIAL SAMPLING

Insert a sampling syringe into the arterial sampling stopcock luer connector. Position all stopcocks on the sampling manifold to allow arterial blood to flow through the manifold. The pressure on the arterial side will allow flow. Draw the sample of blood from the arterial sample stopcock into the syringe. Turn off the arterial stopcock before removing the syringe.

3) VENOUS SAMPLING

Ensure that the arterial stopcock is closed. Insert a sampling syringe into the venous stopcock luer connector and a flush syringe into the center stopcock luer connector. Open the center stopcock and gently draw at least 10-15 ml of blood prior to taking the venous sample. Close the center stopcock. Open the venous stopcock and draw a sample of venous blood and close the stopcock before removing the syringe. Return this blood through one of the filtered luer connectors positioned on the top of the reservoir.

4) LOW FLOW RECIRCULATION

(Hypothermia associated with circulatory arrest).

a) Reduce the gas flow to not less than 500 ml/min.
b) Open the purge/recirculation line clamps and clamp the venous line.
c) Reduce the main pump flow to 500-800 ml/min across the purge/recirculation line.
d) Clamp the oxygenator arterial line.
e) Recirculate at a maximum flow of 800 ml/min. throughout patient's circulatory arrest. A higher flow may be achieved in case of large A/V shunt line.
f) To restart bypass after circulatory arrest, open the venous and arterial lines and slowly increase the blood flow.
g) Close the recirculation line clamps.
h) Adjust gas flow.

5) CONTINUOUS AIR PURGE

Opened purge/recirculation line clamps allow the continuous purge of blood and any incidental gross air from the oxygenator module during bypass.
In this condition and at full arterial blood flow, the continuous purge diverts some hundred ml/min of blood from patient's systemic flow.

WARNING

- Sorin Group recommends that the pre-filter recirculation/purge line of the integrated arterial filter is kept opened during bypass to reduce the risk of air delivery to the patient.
- In case that the purge/recirculation line of the integrated arterial filter is kept closed Sorin Group recommends the use of minimum level monitoring system for the venous reservoir and bubble detector on the inlet line of Inspire 8F M.
- Always carefully check the level inside the venous reservoir. Greater care should be taken during emptying over particularly low levels and/or reduced flows.
- Do not exceed a maximum recirculation flow of 800 ml/min.
- Spontaneous flow of purge/recirculation line @ 150 mmHg arterial line pressure and 6 l/min main pump blood flow, is approx. 620 ml/min with both purge lines open, 420 ml/min with pre filter purge line open and 420 ml/min with post filter purge line open.

CAUTION

- A minimum of 0.5 l/min gas flow is needed when blood is circulated. Less than 0.5 l/min gas flow may result in inadequate gas exchange
- Water condonsation phenomena inside the microporous fibers (also known as "wet lung") may occure over long time use. Wet lung phenomena may decrease gas exchange. Increase gas flow rate to 10 l/min until gas exchange performance is improved or if possible to 15-20 l/min for about 10 seconds.

6) MINIMIZING GME ACTIVITY

Inspire 8F M has been designed to minimize Gaseous Microemboli (GME) activity. The following recommendations shall be followed in order to obtain the best GME performance from the Inspire 8F M oxygenator:

1) Avoid surgical air from venous return line
2) Strictly control suction flow and the amount of air delivered to the suction lines
3) Avoid fluid injection through the venous line and outside filtered ports.
4) Do not purge arterial blood samples into the venous line.
5) Eliminate all sources that may potentially induce air into the systemic flow upstream and downstream the Inspire 8F M oxygenator.
6) In case that the recirculation/purge line of the integrated arterial filter is kept open connect it to one of the luer lock connectors of the venous inlet of the Inspire HVR or Inspire HVR DUAL reservoir.
7) Avoid sharp temperature shifts of the arterial blood.
8) Use adequate technique by not exceeding min and max recommended operating parameters.

J. SUSPENDING BYPASS

1) Decrease the perfusion flow until the main pump stops.
2) Do not empty Inspire 8F M and the lines connected to it. Keep a minimum blood level inside the device (i.e. 50 ml) which will help resuming bypass in case the need will arise.
3) Clamp the venous and arterial lines. If the interruption lasts more than 3 - 5 minutes, recirculate through the Inspire 8F M and the venous reservoir by opening the oxygenator prime/recirculation line (maximum 800 ml/min if across purge/recirculation line).

K. REINITIATING BYPASS

1) Make sure that the circuit is debubbled.
2) Slowly reopen the venous and arterial lines and start the main pump.
3) Perform perfusion using a suitable technique. Refer to the paragraphs "INITIATING BYPASS" and "DURING BYPASS" in this user's manual.
4) In case of problems or for further clarifications, contact SORIN GROUP or one of its authorized representatives.

CAUTION

- Verify that the cardioplegia circuit connected to the cardioplegia outlet port is properly clamped.

L. TERMINATING BYPASS

Bypass should only be terminated as follows after considering individual patient's condition:

1) Turn the gas flow off.
2) Turn the heater-cooler off.
3) Clamp the venous line when main flow shall be discontinued.
4) Slowly decrease the main flow to zero and clamp the arterial line.

M. BLOOD RECOVERY AFTER BYPASS

1) Recover all the blood contained in the venous line, draining it into the venous reservoir once the surgeon has removed the venous cannulae.
2) Perfuse as much blood as possible through the aortic cannula.
3) Recover the residual blood in a "transfer" bag. Collected blood can immediately be reinfused or processed with autotransfusion equipment.

N. DEVICE CHANGE-OUT

A spare device must always be available during bypass in the unlikely event that the

oxygenator in use requires change-out. Procedures lasting longer than 6 hours or if particular situations where the safety of the patient may be compromised, (insufficient oxygenator performance, leaks, ...), could require change-out. Follow the steps below for oxygenator change-out.

CAUTION

Use sterile technique during the entire replacement procedure.

1) While the patient is still on bypass, remove the new Inspire 8F M oxygenator from its outer packaging and from the sterile wrapper; inspect it for damage.
2) Turn the gas flow off.
3) Turn the main pump off and double clamp the arterial line (5 cm apart) next to the arterial outlet port. Clamp the venous line.
4) Double clamp the pump line next to the oxygenator module (5 cm apart).
5) Turn the heater-cooler off, clamp and remove the water lines.
6) Disconnect the gas line, all monitoring and sampling lines and the temperature probe.
7) Cut the pump line and the arterial line in the section between the two clamps, leaving a sufficient length of tubing to allow connection to the new oxygenator.
8) Remove the oxygenator from the holder.
9) Place a new oxygenator onto the holder. Connect all lines (i.e. pump line to the oxygenator inlet port, arterial line to the oxygenator outlet connector, gas line, water lines...) and temperature probe.

WARNING

In this phase, keep the venous and arterial lines clamped.

10) Open the water lines, turn the heater-cooler on and check the integrity of the new oxygenator heat exchanger.
11) Remove clamp from pump line and open the recirculation line. Prime the new oxygenator and remove the air bubbles, as described in the priming and recirculation procedure.
12) Remove clamps from the venous and the arterial line, close the purge/recirculation line clamps and start the bypass again.
13) Turn the gas flow on and adjust gas flow rate as required. Regulate main blood flow.
14) Add priming solution to the reservoir as required.
15) Verify all connections and secure with tie straps.
16) The blood contained in the replaced oxygenator can be recovered by connecting its arterial line outlet to one of the venous reservoir inlets and gravity drain it.

WARNING

Upon completion of this operation contact SORIN GROUP or an authorised representative to analyse any Inspire 8F M considered defective.

O. MEDICAL DEVICES FOR USE WITH INSPIRE 8F M

CAUTION

The user should observe the warnings and cautions and follow instructions for use accompanying the device.

- The Inspire 8F M may be used in combination with Inspire HVR code 050704 and Inspire HVR DUAL code 050705 hard shell venous/cardiotomy reservoirs.
- A special common interface allows to achieve integrated sterile stand alone devices configuration. Matrix of fig.3 shows full range of available sterile stand alone integrated devices generated by the combination of Inspire 8F M with Inspire HVR DUAL and Inspire HVR.
- The device may be used in combination with a hard shell venous/cardiotomy reservoir of no less than 2 Liters volume capacity, to achieve an open system configuration.
- The device may be used in combination with an adult size softshell venous reservoir and a cardiotomy reservoir of no less than 2 Liters volume capacity, to achieve a closed system configuration.
- All tubing used to make the circuit connections must be of a diameter which is compatible with the dimensions of the connectors on the device (3/8",1/4").
- Inspire BKT bracket code 050640, Inspire BKT FAST bracket code 48-42-10 and Apex bracket code 050235000. Use the above brackets also when Inspire module is integral part of Inspire integrated devices.

CAUTION

- **Brackets shall be cleaned after each use. Only hand cleaning with a soft cloth is allowed. Do not clean with washing machines and do not dip the bracket into washing solutions.**
- **To achieve adequate cleaning and avoid damage or alterations of the bracket, use water, mild soap and other detergents commonly available in the operating room and used for surface cleaning.**
- **The bracket is maintenance free**
- Temperature probes code 042229000 or equivalent temperature probes YSI Series 400 compatible.
- Sechrist mechanical air/oxygen blender SORIN GROUP code 09046 and code 96-490-011, SORIN GROUP electronic air-oxygen blender code 25-28-50 or a system with compatible technical features for control of the oxygen concentration and gas flow.
- Any heating/cooling system may be used, provided that the water line connectors are Hansen 3ST (SORIN GROUP code 09028) or equivalent.
- Currently SORIN GROUP is not aware of any contraindications to the use of the device with occlusive or non-occlusive peristaltic pumps or with centrifugal pumps. The use of other types of pump must be agreed with SORIN GROUP.

P. RETURN OF USED PRODUCTS

Should the user be dissatisfied with anything related to the quality of the product, the product distributor or the authorized local SORIN GROUP representative should be notified.

All parameters considered critical by the user must be reported with particular care and urgency. The following is the minimum information that should be provided:

- Detailed description of the event and, if pertinent, the conditions of the patient;
- Identification of the product involved;
- Lot number of the product involved;
- Availability of the product involved;
- All the indications the user considers useful in order to understand the origin of the elements of dissatisfaction.

SORIN GROUP reserves the right to authorize, if necessary, recall of the product involved in the notification for assessment. If the product to be returned is contaminated, it must be treated, packed and handled in conformity with the provisions of the legislation in force in the country where the product was used.

CAUTION

It is the responsibility of the health care institution to adequately prepare and identify the product for return shipment. Do not return products that have been exposed to blood borne infectious diseases.

ONLY for US customers

If for any reason the product must be returned to the manufacturer, a returned goods authorisation (RGA) number is required from SORIN GROUP USA Inc. prior to shipping. If the product has been in contact with blood or blood fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton or an equivalent carton to prevent damage during shipment, and it should be properly labelled with an RGA number and an indication of the biohazardous nature of the content in the shipment.

CAUTION

It is the responsibility of the health care institution to adequately prepare and identify the product for return shipment. Do not return products that have been exposed to blood borne infectious diseases.

The shipping address for returned goods in the US is:

Sorin Group USA, Inc.
Returned CV Products
14401 West 65th Way
Arvada, CO 80004-3599
FAX (800) 323 4031.

Q. LIMITED WARRANTY

This Limited Warranty is in addition to any statutory rights of the Purchaser pursuant to applicable law.

SORIN GROUP warrants that all reasonable care has been taken in the manufacture of this medical device, as required by the nature of the device and the use for which the device is intended.

SORIN GROUP warrants that the medical device is capable of functioning as indicated in the current instructions for use when used in accordance with them by a qualified user and before any expiry date indicated on the packaging.

However, SORIN GROUP cannot guarantee that the user will use the device correctly, nor that the incorrect diagnosis or therapy and/or that the particular physical and biological characteristics of an individual patient, do not affect the performance and effectiveness of the device with damaging consequences for the patient, even though the specified instructions for use have been respected.

SORIN GROUP, whilst emphasizing the need to adhere strictly to the instructions for use and to adopt all the precautions necessary for the correct use of the device, cannot assume any responsibility for any loss, damage, expense, incidents or consequences arising directly or indirectly from the improper use of this device.

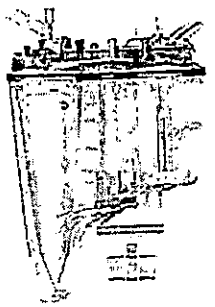
SORIN GROUP undertakes to replace the medical device in the event that it is defective at the time of placing on the market or whilst being shipped by SORIN GROUP up to the time of delivery to the final user unless such defect has been caused by mishandling by the purchaser.

The above replaces all other warranties explicit or implicit, written or verbal, including warranties of merchantability and fitness for purpose. No person, including any representative, agent, dealer, distributor or intermediary of SORIN GROUP or any other industrial or commercial organization is authorized to make any representation or warranty concerning this medical device except as expressedly stated herein. SORIN GROUP disclaims any warranty of merchantability and any warranty of fitness for purpose with regard to this product other than what is expressedly stated herein. The purchaser undertakes to comply with the terms of this Limited Warranty and in particular agrees, in the event of a dispute or litigation with SORIN GROUP, not to make claims based on alleged or proven changes or alterations made to this Limited Warranty by any representative, agent, dealer, distributor or other intermediary.

The existing relations between the parties to the contract (also in the case that it is not drawn up in writing) to whom this Warranty is given as well as every dispute related to it or in any way connected to it as well as anything related to it or any dispute concerning this Warranty, its interpretation and execution, nothing excluded and/or reserved, are regulated exclusively by the Italian law and jurisdiction. The court chosen is the Court of Modena Italy).

Sterile Stand Alone Devices for Use with Reference Device

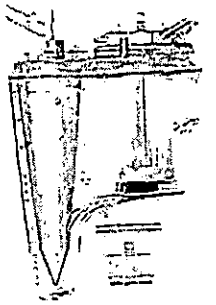
SORIN | INSPIRE HVR DUAL



Dual Hard Shell Venous Reservoir Phisio

REF : 050705

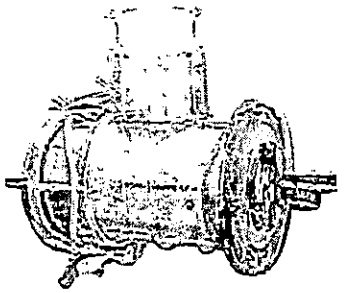
SORIN | INSPIRE HVR



Hard Shell Venous Reservoir Phisio

REF : 050704

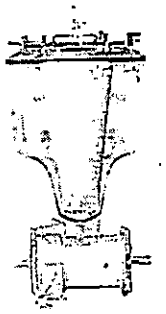
SORIN | INSPIRE BF



Oxy Module Phisio with IAF

REF : 050703

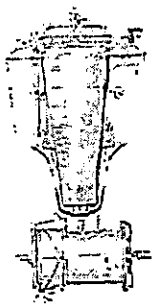
SORIN | INSPIRE BF DUAL



Integrated Phisio Oxy with IAF and Dual HVR Reservoir

REF : 050720

SORIN | INSPIRE BF



Integrated Phisio Oxy with IAF and HVR Reservoir

REF : 050716

Sterile Stand Alone Reference Device

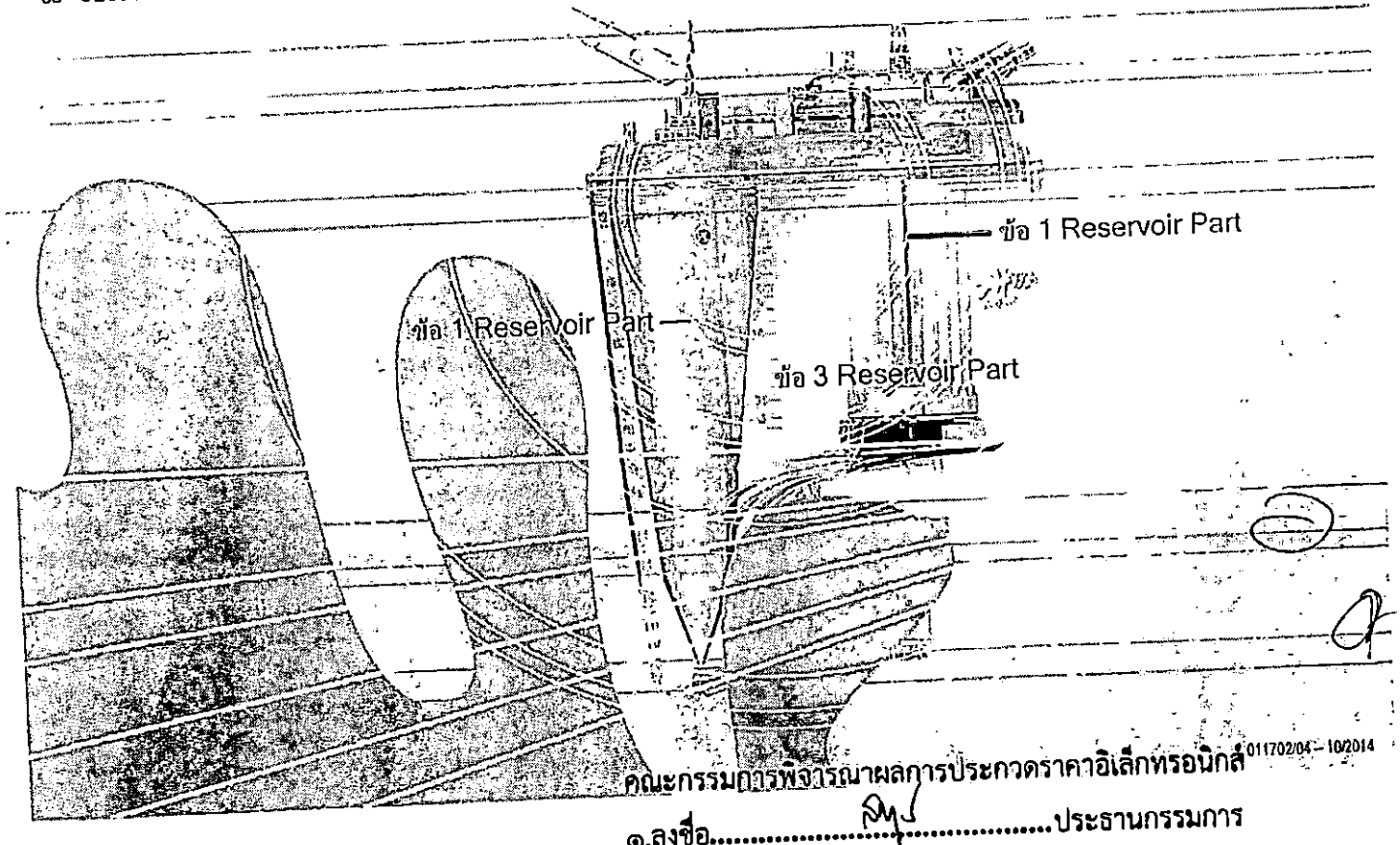
Sterile Stand Alone Integrated Devices Generated by Reference Device and Devices for Use with Reference Device

Fig. 3

SORIN | INSPIRE HVR

HARD SHELL VENOUS RESERVOIR PHISIO

Reservoir, blood cardiopulmonary bypass • Reservoir, bypass cardiopolmonare del sangue • Réservoir, circulation sanguine extracorporelle • Reservoir, kardiopulmonarer Blutbypass • Reservorio, bypass cardiopulmunar • Reservatório, bypass cardiopulmonar do sangue • Δεξαμενή, καρδιοπνευμονική παράκαμψη αίματος • Reservoir, cardiopulmonale bypass • Blodreservoar, hjärt-lung-bypass • Reservoir, kardiopulmonær bypass • Säiliö, veren kardiopulmonaalinen shuntti • Reservoar, kardiopulmonær bypass• Rezervoár, krev, kardiopulmonární bypass • Zbiornik, krążenie pozaustrojowe krwi • Rezervoár, krvný kardiopulmonálny bajpas • Rezevoar, za kri pri kardiopulmunalni premostitvi • Rezervoár, kardiopulmonāris bypass • Rezervuaras, kraujo kardiopulmonarinis šuntas • Mahuti, vere kardiopulmonaarne möödaviik • Rezervuārs, asins kardiopulmonārais apvads • Rezervor, bypass cardiopulmonar • Bypass резервоар, кардиопулмонален байпас • Rezervuar, kan kardiyopulmoner bypass • Резервуар, искусственное кровообращение • Rezervoar za krv kod kardiopulmonarnog bajpasa • Spremnik za krv kod kardiopulmonarnog bajpasa



011702/04 – 10/2014

คณะกรรมการพิจารณาผลการประกวดราคาอิเล็กทรอนิกส์

๑.ลงชื่อ.....ประธานกรรมการ

๒.ลงชื่อ.....กรรมการ

.....กรรมการ

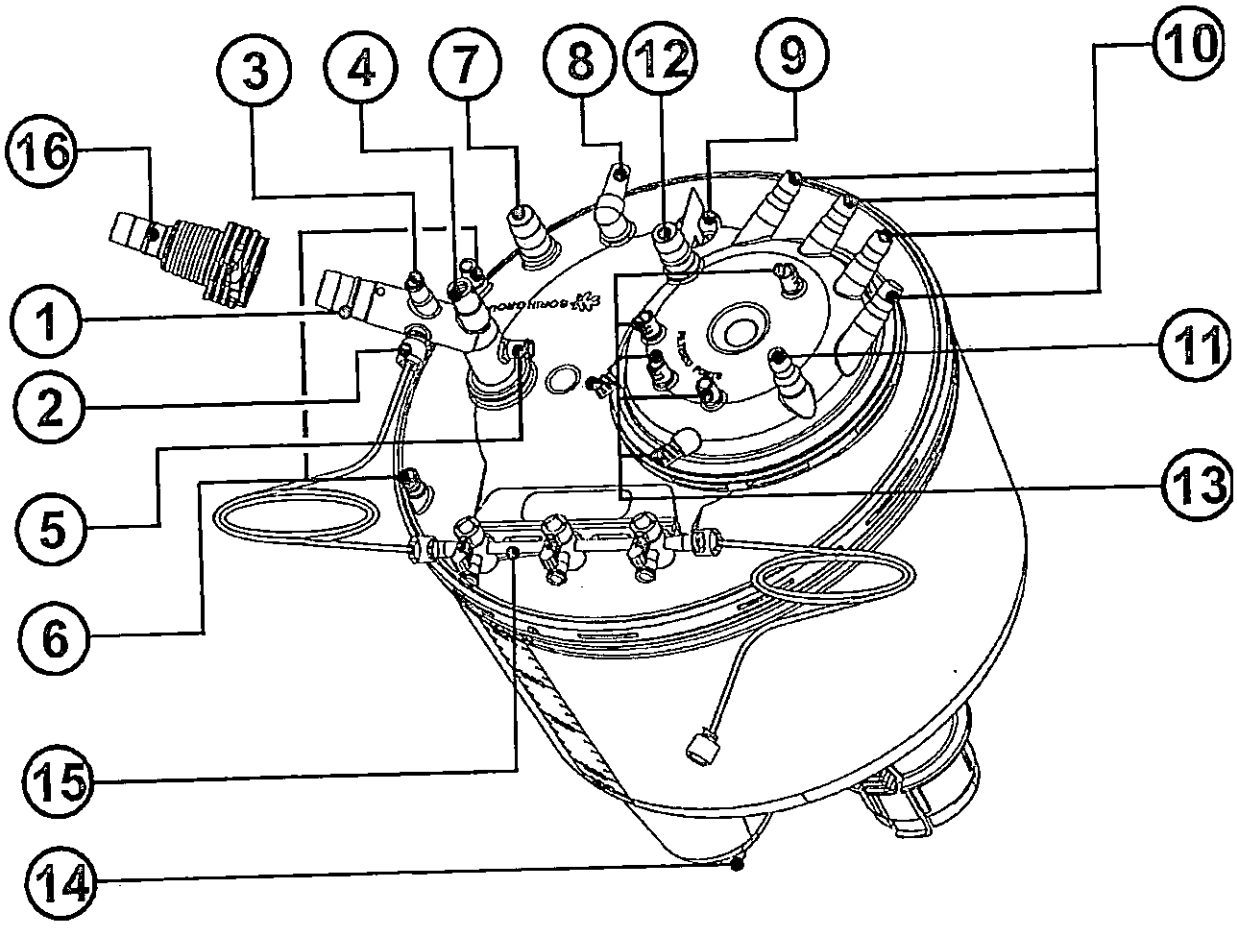


Fig. 1

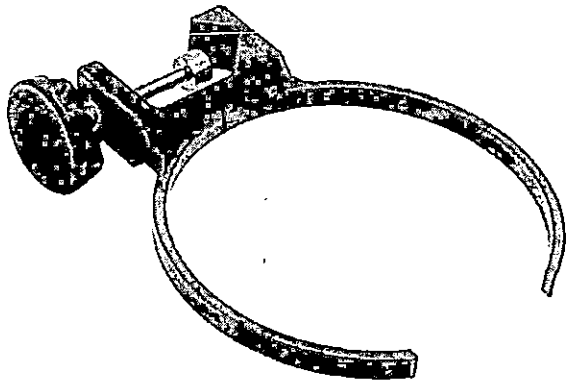


Fig. 2

คณะกรรมการพิจารณาผลการประกวดราคาอิเล็กทรอนิกส์

๑.ลงชื่อ.....ประธานกรรมการ

๒.ลงชื่อ.....กรรมการ

๓.ลงชื่อ.....กรรมการ

References

Ref. 1 1/2" Venous Inlet connector
Ref. 2 Venous sampling connector
Ref. 3 Drug delivery connector
Ref. 4 Venous Temperature probe connector
Ref. 5 Auxiliary luer connector
Ref. 6 Unfiltered luer lock connectors
Ref. 7 Auxiliary/Emergency Cardiotomy Reservoir connector
Ref. 8 Vent/Vacuum connector
Ref. 9 Over/Under Pressure Safety valve
Ref. 10 Suction Inlet connectors 1/4"-3/8"
Ref. 11 Quick prime connector
Ref. 12 3/8" Chest Drainage connector
Ref. 13 Filtered luer lock connectors
Ref. 14 Outlet connector
Ref. 15 A/V sampling manifold
Ref. 16 1/2"-3/8" Venous inlet locking adaptor

Riferimenti

Rif. 1 Connettore ingresso venoso da 1/2"
Rif. 2 Connettore campionamento venoso
Rif. 3 Connettore somministrazione farmaci
Rif. 4 Connettore sonda temperatura venosa
Rif. 5 Connettore luer ausiliario
Rif. 6 Connettori luer lock senza filtro
Rif. 7 Connettore reservoir di cardiotomia ausiliario/d'emergenza
Rif. 8 Connettore di sfiato/vuoto
Rif. 9 Valvola di sicurezza sovra/sotto pressione
Rif. 10 Connettori ingresso aspirazione 1/4"-3/8"
Rif. 11 Connettore riempimento veloce
Rif. 12 Connettore drenaggio toracico 3/8"
Rif. 13 Connettori luer lock con filtro
Rif. 14 Connettore uscita
Rif. 15 Rampa di campionamento A/V
Rif. 16 Adattatore bloccaggio ingresso venoso 1/2"-3/8"

Références

Réf. 1 Raccord 1/2" entrée veineuse
Réf. 2 Raccord prélèvement veineux
Réf. 3 Raccord administration de médicaments
Réf. 4 Raccord sonde de température veineuse
Réf. 5 Raccord Luer auxiliaire
Réf. 6 Raccords Luer-Lock non filtrés
Réf. 7 Raccord réservoir de cardiotomie auxiliaire/de secours
Réf. 8 Raccord évent/vide
Réf. 9 Soupape de sécurité surpression/dépression
Réf. 10 Raccords entrée d'aspiration 1/4"-3/8"
Réf. 11 Raccord remplissage rapide
Réf. 12 Raccord 3/8" drainage thoracique
Réf. 13 Raccords Luer-Lock filtrés
Réf. 14 Raccord sortie
Réf. 15 Rampe de prélèvement artério-veineux
Réf. 16 Adaptateur à verrouiller 1/2"-3/8" pour entrée veineuse

Legende

1: Venöser 1/2"-Einlassanschluss
2: Anschluss zur Entnahme venöser Blutproben
3: Anschluss für die Medikamentengabe
4: Venöser Anschluss für Temperatursonde
5: Zusätzlicher Luer-Anschluss
6: Luer-Lock-Anschlüsse ohne Filter
7: Zusatz-/Notfallanschluss für Kardiotomiereservoir
8: Entlüftungs-/Vakuumanschluss
9: Über-/Unterdruck-Sicherheitsventil
10: 1/4"-3/8"-Einlassanschlüsse Ansaugleitung
11: Schnellfüllanschluss
12: 3/8"-Thoraxdrainageanschluss
13: Luer-Lock-Anschlüsse mit Filter
14: Auslassanschluss
15: Entnahmehahnbank für A/V-Blutproben
16: 1/2"-3/8"-Reduzierstück mit Verriegelung für den venösen Einlass

Referencias

Ref. 1 Conector de entrada venosa de 1/2"
Ref. 2 Conector para toma de muestras de sangre venosa
Ref. 3 Conector de administración de fármacos
Ref. 4 Conector para sonda de temperatura de sangre venosa
Ref. 5 Conector luer auxiliar
Ref. 6 Conectores luer lock sin filtro
Ref. 7 Conector auxiliar/de emergencia para reservorio de cardiotomía
Ref. 8 Conector para ventilación/vacío
Ref. 9 Válvula de seguridad de sobrepresión/subpresión
Ref. 10 Conectores para entrada de aspiración de 1/4"-3/8"
Ref. 11 Conector para cebado rápido
Ref. 12 3/8" Conector para drenaje torácico
Ref. 13 Conectores luer lock con filtro
Ref. 14 Conector de salida
Ref. 15 Llave de tres vías para toma de muestras de sangre arterial/venosa
Ref. 16 Adaptador para la entrada venosa de 1/2"-3/8"

Referências

Ref. 1 Conector da entrada venosa de 1/2"
Ref. 2 Conector de amostragem venosa
Ref. 3 Conector de administração de medicamentos
Ref. 4 Conector venoso para sonda de temperatura
Ref. 5 Conector luer auxiliar
Ref. 6 Conectores luer lock sem filtro
Ref. 7 Conector do reservatório de cardiotomia de emergência/auxiliar
Ref. 8 Conector de ventilação/vácuo
Ref. 9 Válvula de segurança de sobre-pressão/sub-pressão
Ref. 10 Conectores da entrada de aspiração de 1/4"-3/8"
Ref. 11 Conector de enchimento rápido
Ref. 12 Conector de drenagem torácica de 3/8"
Ref. 13 Conectores luer lock com filtro
Ref. 14 Conector de saída
Ref. 15 Colector de amostragem A/V
Ref. 16 Adaptador de bloqueio da entrada venosa de 1/2"-3/8"

Υπόμνημα

1. Συνδετήρας φλεβικής εισόδου 1/2"
2. Συνδετήρας φλεβικής δειγματοληψίας
3. Συνδετήρας χορήγησης φαρμάκων
4. Συνδετήρας αισθητήρα φλεβικής θερμοκρασίας
5. Βοηθητικός συνδετήρας luer
6. Συνδετήρες luer lock χωρίς φίλτρο
7. Συνδετήρας βοηθητικής/επείγουσας σύνδεσης δεξαμενής καρδιοτομίας
8. Συνδετήρας εκτόνωσης πίεσης/κενού
9. Βαλβίδα ασφαλείας θετικής/αρνητικής πίεσης
10. Συνδετήρες εισόδων αναρρόφησης 1/4"-3/8"
11. Συνδετήρας ταχείας πλήρωσης
12. Συνδετήρας θωρακικής παροχέτευσης 3/8"
13. Συνδετήρες luer lock με φίλτρο
14. Συνδετήρας εξόδου
15. Ράμπα Α/Φ δειγματοληψίας
16. Ασφαλιστικός προσαρμογέας φλεβικής εισόδου 1/2"-3/8"

Referenties

Ref. 1 1/2" Veneuze ingangsaansluiting
Ref. 2 Veneuze monsterafname-aansluiting
Ref. 3 Aansluiting voor toediening van medicijnen
Ref. 4 Veneuze temperatuurvoeleraansluiting
Ref. 5 Hulp-luerconnector
Ref. 6 Luer-connectors zonder filter
Ref. 7 Hulp-/noodcardiotomiereservoiraansluiting
Ref. 8 Ontluchtings-/vacuümaansluiting
Ref. 9 Veiligheidsklep over-/onderdruk
Ref. 10 Aanzuigingangsaansluitingen 1/4"-3/8"
Ref. 11 "Quick prime"-aansluiting
Ref. 12 3/8" Thoraxdrainage-aansluiting
Ref. 13 Luer-lockconnectors met filter
Ref. 14 Uitgangsaansluiting
Ref. 15 Verloopstuk A/V-monsterafname
Ref. 16 1/2"-3/8" Veneuze ingangsvergrendelingsadapter

Referenser

Ref. 1 1/2" veninloppskoppling
Ref. 2 Venös provtagningskoppling
Ref. 3 Koppling för läkemedelstillförsel
Ref. 4 Koppling för ventemperaturprob
Ref. 5 Extra luer-koppling
Ref. 6 Ofiltrerade luerlock-kopplingar
Ref. 7 Extra-/Nödfallskoppling för kardiotomireservoar
Ref. 8 Avluftnings-/Vakuumkoppling
Ref. 9 Säkerhetsventil för över-/undertryck
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preparing to use the device.
Specific safety information is also given in the instructions for use at locations in the text where that information is relevant for correct operation.

WARNING

- The user should carefully check the device for leaks during set-up and priming. Do not use if any leak is detected.
- The device must be used in accordance with the Instructions for use provided in this manual.
- For use by professionally trained personnel only.
- SORIN GROUP is not responsible for problems arising from inexperience or improper use.
- FRAGILE, handle with care.
- Keep dry. Store at room temperature.
- Always administer and maintain correct anticoagulant dosage before, during and after the bypass and provide its correct monitoring.
- For single use and for single patient use only: during use the device is in contact with human blood, body fluids, liquids or gases for the purpose of eventual infusion, administration or introduction into the body. Due to its specific design the device cannot be fully cleaned and disinfected at the end of use. Therefore, reuse on other patients might cause cross-contamination, infection and sepsis. In addition, reuse increases the probability of product failure (integrity, functionality and clinical effectiveness).
- Sterile Contents/Non-Pyrogenic Fluid Pathway unless package is opened or damaged.
- The device and its accessories must be handled applying sterile techniques.
- The device must not undergo any further processing.
- Do not resterilize.
- After use, dispose of the device in accordance with applicable regulations in force in the country of use.
- The device must only be used if STERILE.
- Inspire HVR should always be positioned with its minimum operating level at least 5 cm above the upper point of the oxygenator used in conjuction with it.
- An auxiliary/cardiotomy reservoir port allows bypassing regular cardiotomy function in case cardiotomy filter ability is impared.
- The auxiliary/cardiotomy port must always be kept sealed unless its specific use is needed. Unecessary non monitored use may entrain air into the reservoir especially in VAVD conditions.
- During Inspire HVR operation constantly check that the blood level does not fall below the minimum operating level. Level below the minimum operating value may induce air embolism to the oxygenator and to the patient.
- The use of a blood level detector is recommended.
- "Filtered" and "unfiltered" ports allow the administration of fluids and medicaments.
- Drugs which must be administered at low doses should be diluted with saline solution so that they can fully run into the extracorporeal circulation.
- It is recommended to administer all fluids through the filtered ports, even if this should result in a slight delay in the fluid reaching the circulation.
- The Inspire HVR used with vacuum must be carefully used following the instructions "USE OF ACTIVE VENOUS DRAINAGE WITH VACUUM" of this user's manual in paragraph N.
- When using the venous reservoir for post-operative chest drainage carefully follow the instructions in "USE FOR POST-OPERATIVE CHEST DRAINAGE" of this user's manual at paragraph O.
- The special positive and negative overpressure valve built into the Inspire HVR ensures optimal intra- and post-operative performance of the system. The valve is activated and vents positive pressure higher than +5 mmHg (0.7 kPa/ 0.007 bar / 0.1 PSI) and negative pressure lower than -200 mmHg (-26.7 kPa / -0.27 bar / -3.86 PSI). DO NOT OCCLUDE THE VALVE ORIFICE FOR ANY REASON WHATSOEVER.
- Inspire HVR venous reservoirs must be used with its dedicated holder.
- In case pump console is moved during use make sure that no lines such as gas, blood and water lines are pulled.
- For further information and/or in case of complaint contact SORIN GROUP or the authorised local representative.

CAUTION

- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
  Inner surfaces of the system are Phisio coated, currently SORIN GROUP is not aware of any contraindications to the use of this coated device
- Do not push on the over/under safety valve as it can be displaced or its ability to properly work might be impaired.

F. PREPARATION AND SET-UP

1) POSITION THE BRACKET

Firmly position the Inspire HVR bracket on the pump structure by means of its fixation clamp (fig.2). The bracket is reversible and allows right and left pump console set-up.

2) FIX THE RESERVOIR TO THE BRACKET

WARNING

- Do not use if sterile packaging is damaged, unsealed, or has been exposed to moisture or other conditions that would compromise the sterility of the device.
- Check the expiry date on the attached label. Do not use the device after the date shown.
- The device must be used immediately after opening the sterile packaging.
- The device must be handled aseptically.

Remove the device from its sterile packaging.

WARNING

- Carry out a visual inspection and carefully check the device before use. Transportation and/or storage conditions other than those prescribed may have caused damage to the device.
- Do not use solvents such as alcohol, ether, acetone, etc.: as contact may cause damage to the device.
- Do not allow halogenated liquids such as Halothane and Fluothane to come into contact with the polycarbonate housing of the device. This could cause damage which may compromise the integrity and proper function of the device.

Insert the Inspire HVR onto the C clamp of the bracket and check for secure fitting.
The device and its bracket should be positioned so as to allow easy and practical access to the connectors and easy reading of the blood level. Make sure that Inspire HVR is positioned above the oxygenator to which it will be connected.

3) CIRCUIT CONNECTIONS

WARNING

All connections must be secured by means of tie straps.
Remove the yellow tag from the pressure relief valve.
Remove the yellow cap protecting the gas vent/vacuum connector.
VENOUS LINE: Connect the venous line to the 1/2" venous connector (Fig.1, Ref.1). In case a 3/8" venous line is required use the 1/2"-3/8" step down venous inlet locking adaptor (Fig.1, Ref.16).
OUTLET LINE: Connect the device outlet connector (Fig.1, Ref.14) to the main pump line and to the oxygenator module used in conjuction with it. Clamp the device outlet line close to the outlet connector.
SUCTION LINES: Connect suction lines to the suction inlet connectors (Fig.1, Ref. 10).
ACCESSORY LINES: Two types of connectors enable quick fluid administration: Luer lock and 1/4" connectors in the cardiotomy section. Accessory lines may be connected to the appropriate connectors. For precise directions refer to Fig. 1 of this manual.
An additional cardiotomy reservoir may be connected in case of need to the auxiliary/emergency connector of Fig. 1 Ref. 7.
OXYGENATOR MODULE PURGE/RECIRCULATION LINE: Connect the purge/recirculation line of the connected oxygenator to one of the relevant connectors (Fig. 1,Ref. 13).
SAMPLING SYSTEM: connect the arterial sampling line of the sampling manifold to the specific connector of the oxygenator used in conjuction with the Inspire HVR.
CONNECT THE TEMPERATURE PROBE: Connect the Sorin temperature probe to the venous temperature site (Fig.1,Ref. 4).

CAUTION

- The user should check for tubing occlusions and kinks during set-up.
- Check that all connections are securely tight.
- The blu stopcock is indicated for venous blood sampling, the red stopcock is indicated for arterial blood sampling and the white stopcock is indicated for medications or flushing.

G. PRIMING AND RECIRCULATION PROCEDURE

WARNING

- During priming procedure check for leaks. Do not use if any leaks is detected.

Viited	Atsauces	Referinţe
Viide 1 1/2" veenivere sisselaskeava liitmik Viide 2 Veenivere proovide võtmise liitmik Viide 3 Ravimi manustamise liitmik Viide 4 Veenivere temperatuurianduri liitmik Viide 5 Täiendav Luer-liitmik Viide 6 Filtrita Luer-luku liitmikud Viide 7 Täiendav/hädaolukorra kardiotoomia mahuti liitmik Viide 8 Ventilatsiooni-/vaakumiliitmik Viide 9 Üle-/alarõhu turvaventiil Viide 10 Imemisava liitmikud 1/4" – 3/8" Viide 11 Kiire eeltäitmise liitmik Viide 12 3/8" rinnakorvi dreenimise liitmik Viide 13 Filtriga Luer-luku liitmikud Viide 14 Väljalaskeava liitmik Viide 15 A/V proovide võtmise kollektor Viide 16 1/2" – 3/8" veenivere sisselaskeava lukustusadapter	1. atsauce 1/2" venozās ievadatveres savienotājs 2. atsauce Venozo paraugu ņemšanas savienotājs 3. atsauce Medikamentu ievades savienotājs 4. atsauce Venozās termozondes savienotājs 5. atsauce Rezerves „Luer" savienotājs 6. atsauce Bezfiltra „Luer Lock" savienotāji 7. atsauce Rezerves/ārkārtas kardiotomijas rezervuāra savienotājs 8. atsauce Ventilācijas/vakuuma savienotājs 9. atsauce Paaugstinātā/pazemināta spiediena drošības vārsts 10. atsauce Uzsūkšanas ievadatveres savienotāji 1/4"-3/8" 11. atsauce Ātrās uzpildes savienotājs 12. atsauce 3/8" Krūškurvja drenāžas savienotājs 13. atsauce „Luer Lock" savienotāji ar filtru 14. atsauce Izvadatveres savienotājs 15. atsauce A/V paraugu ņemšanas kolektors 16. atsauce 1/2"–3/8" venozās ievadatveres blokēšanas adapteris	Ref. 1 Conector venos de intrare 1/2" Ref. 2 Conector venos de eşantionare Ref. 3 Conector pentru furnizarea medicamentului Ref. 4 Conector pentru sonda de temperatură venoasă Ref. 5 Conector Luer auxiliar Ref. 6 Conectori cu închizătoare Luer nefiltrate Ref. 7 Conector pentru rezervorul de cardiotomie auxiliară/de urgenţă Ref. 8 Conector aerisire/vacuum Ref. 9 Valvă de siguranţă pentru supra/sub-presiune Ref. 10 Conectori pentru intrare aspiraţie 1/4"-3/8" Ref. 11 Conector pentru amorsare rapidă Ref. 12 Conector pentru drenaj toracic 3/8" Ref. 13 Conectori cu închizătoare Luer filtrate Ref. 14 Conector de ieşire Ref. 15 Colector de probe A/V Ref. 16 Adaptor de blocare intrare venoasă 1/2"-3/8"
Справки	Referanslar	Указатель
Справка 1 Входен венозен съединител 1/2" Справка 2 Съединител за вземане на венозни проби Справка 3 Съединител за подаване на лекарство Справка 4 Съединител за венозна температурна сонда Справка 5 Допълнителен луер съединител Справка 6 Нефилтрирани луер съединители Справка 7 Допълнителен съединител/ съединител за резервоар за спешна кардиотомия Справка 8 Съединител за вентилация/вакуум Справка 9 Предпазна клапа за свръхналягане/недостатъчно налягане Справка 10 Съединители за входни отвори за аспирация 1/4"-3/8" Справка 11 Съединител за бърз прайминг Справка 12 3/8" Съединител за дренаж на гръдния кош Справка 13 Филтрирани луер съединители Справка 14 Съединител за изходен отвор Справка 15 Спирателно краче за вземане на артериални/венозни проби Справка 16 1/2"-3/8" Венозен заключващ входен адаптер	Ref. 1 1/2" Venöz Giriş konektörü Ref. 2 Venöz örnek alma konektörü Ref. 3 İlaç iletme konektörü Ref. 4 Venöz Sıcaklık probu konektörü Ref. 5 Yardımcı luer konektörü Ref. 6 Filtresiz luer lock konektörler Ref. 7 Yardımcı/Acil Kardiyotomi Rezervuarı konektörü Ref. 8 Vent/Vakum konektörü Ref. 9 Yüksek/Düşük Basınç Güvenlik valfi Ref. 10 Aspirasyon Giriş konektörleri 1/4"-3/8" Ref. 11 Hızlı sıvı geçirme konektörü Ref. 123/8" Göğüs Drenajı konektörü Ref. 13 Filtreli luer lock konektörleri Ref. 14 Çıkış konektörü Ref. 15 A/V örnek alma manifoldu Ref. 16 1/2"-3/8" Venöz giriş kilitleme adaptörü	Поз. 1 Венозный входной коннектор 1/2" Поз. 2 Коннектор отбора проб венозной крови Поз. 3 Коннектор доставки лекарственного препарата Поз. 4 Коннектор датчика температуры венозной крови Поз. 5 Вспомогательный люэровский коннектор Поз. 6 Нефильтруемые люэровские коннекторы Поз. 7 Вспомогательный/аварийный коннектор кардиотомного резервуара Поз. 8 Вентиляционный/Вакуумный коннектор Поз. 9 Предохранительный клапан повышенного/пониженного давления Поз. 10 Входные коннекторы всасывания 1/4"-3/8" Поз. 11 Коннектор быстрого заполнения Поз. 12 3/8" Коннектор дренажа грудной клетки Поз. 13 Фильтруемые люэровские коннекторы Поз. 14 Выходной коннектор Поз. 15 Коллектора отбора A/B проб Поз. 16 Входной венозный адаптер с замком 1/2"-3/8"
Reference	Reference	
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CONTENTS

A. DESCRIPTION

Inspire HVR (hereafter also called the device) is a hard shell venous reservoir with integrated cardiotomy filter. ข้อ 1 Reservoir Part
The Inspire HVR is coated with Phisio (PC phosphorylcholine) coating. Devices coated with Phisio are used when a coated blood path is desired. The Phisio coating improves the blood compatibility of the device by reducing platelet adhesion on the coated surfaces.
The device is single-use, non-toxic, apyrogenic, supplied STERILE in individual packaging. Sterilized by ethylene oxide. The level of ethylene oxide residuals in the device is within the limits established by national regulations in the country of use.

B. TECHNICAL FEATURES

MAX. VOLUME CAPACITY (approx.)	4500 ml ข้อ 4 Reservoir Part
MAX. OPERATING LEVEL (approx.)	4000 ml
MIN. OPERATING LEVEL	150 ml
MAX. BLOOD FLOW RATE	
- venous blood	8 l/min
- suction blood	4 l/min
- combined blood flow	8 l/min
MINIMUM BLOOD FLOW RATE	2 l/min
MINIMUM BLOOD FLOW RATE (up to 2 hours max. duration time)	0,5 l/min
FILTRATION SECTIONS	
Venous reservoir section	
- Defoaming body	Polyurethane sponge
- Defoaming agent	Silicone based antifoam C
- Filtering media	41 µm polyester outer screen + ข้อ 2 Reservoir Part 120 µm inner polyester net
Cardiotomy reservoir section	
- Defoaming body	Polyurethane sponge
- Defoaming agent	Silicone based antifoam C
- Filtering media	41 µm polyester screen
HOUSING	
- Material type	Polycarbonate ข้อ 3 Reservoir Part
PORT CONFIGURATION	
Venous reservoir section	
- Venous inlet	1/2" – 360° rotating ข้อ 5 Reservoir Part
- Blood sampling	1 x female luer lock
- Drug inject + auxiliary	2 x female luer lock
Cardiotomy reservoir section	
- Suction inlets	4 x 1/4" – 3/8" filtered ข้อ 7 Reservoir Part
- Quick prime	1 x 1/4" filtered
- Medication ports	6 filtered female luer lock
- Chest drainage	1 x 3/8" filtered
Outside all filters	
- Medication ports	2 x unfiltered female luer lock
- Vent / vacuum	1 x 1/4" horizontal
- Aux./Emergency Card. Res.	1 x 3/8" vertical
- Blood outlet	3/8" vertical ข้อ 6 Reservoir Part
BIOCOMPATIBLE COATING	Phosphorylcholine (Phisio)
SAFETY VALVE	Average vent press -200 mmHg and +5 mmHg
ACCESSORIES	A/V sampling manifold with lines
	1/2"-3/8" venous inlet locking adaptor

C. INTENDED USE

Inspire HVR is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It collects, defoams and filters venous blood and suction blood.
Inspire HVR can be used post-operatively for chest drainage.
The Inspire HVR is intended to be used for 6 hours or less.
Inspire HVR can be used with the devices listed in paragraph Q (MEDICAL DEVICES FOR USE WITH INSPIRE HVR).

D. CONTRAINDICATIONS

No contraindications are known if the device is used for the purpose described and in accordance with the stated operating conditions.
Do not use the device for any purpose other than indicated.

E. SAFETY INFORMATION

Information intended to attract the attention of the user to potentially dangerous situations and to ensure correct and safe use of the device is indicated in the text with the following symbols:

WARNING

WARNING indicates serious adverse reactions and potential safety hazards for the practitioner and/or the patient that may occur in the proper use or misuse of the device as well as the limitations of use and the measures to be adopted in such cases.

CAUTION

CAUTION indicates any special care to be exercised by a practitioner for the safe and effective use of the device.

EXPLANATION OF THE SYMBOLS USED ON THE LABELS

	For single use only (Do not reuse)
LOT	Batch code (number) (reference for product traceability)
	Use by (Expiry date)
	Manufactured by
	Date of manufacture
STERILE EO	Sterile – Ethylene oxide sterilised
	Non pyrogenic fluid pathway
	Warning: Do not resterilize.
	Contents sterile only if package is not opened, damaged or broken
REF	Catalogue (code) number
	Attention, see instruction for use
www.sorinmanuals.com	Consult the instructions for use on the website at www.sorinmanuals.com
	This way up
	Fragile; handle with care
ea	Quantity
	Keep away from heat
	Keep dry

The following is general safety information with the aim of advising the operator in

คณะกรรมการพิจารณาผลการประกวดราคาอิเล็กทรอนิกส์
๑.ลงชื่อ.....ประธานกรรมการ
๒.ลงชื่อ.....กรรมการ
๓.ลงชื่อ.....กรรมการ

1) CLOSE THE VENOUS AND ARTERIAL LINES AND RESERVOIR OUTLET LINE
Clamp the venous line. Clamp the arterial line. Clamp the Inspire HVR outlet.

2) HARD SHELL VENOUS/CARDIOTOMY RESERVOIR PRIMING
Fill the Inspire HVR with sufficient priming fluid to accomplish debubbling and to allow achieving intended hemodilution.

3) CIRCUIT PRIMING
Remove the clamp from the device outlet line, open the purge/recirculation line and start the main pump at a reasonably high flow so that the pump loop is primed. Reduce the flow rate to 500-800 cc/min and prime the oxygenator.

4) OPEN VENOUS AND ARTERIAL LINES
Remove the clamp from the venous and arterial lines and increase main pump flow to the maximum value of 6 l/min.

5) PURGE THE AIR CONTAINED IN THE DEVICE AND IN THE CIRCUIT
During this phase it is necessary to tap the entire circuit in order to facilitate the removal of microbubbles from the tube walls. The other devices will be operated according to their individual instructions for use.
Continue purge until visible air is removed.

6) PRIME OF THE SAMPLING SYSTEM
Priming of the A/V sampling system occurs automatically when the arterial, venous and central stopcock handles are positioned in such a way as to allow the priming fluid to spontaneously flow from the arterial outlet of the oxygenator to the venous inlet connector sampling port of the Inspire HVR.
Verify that the center medication port of the sampling manifold has the handle in the off position.

7) CLOSE THE PURGE/RECIRCULATION LINE
Continue purge until visible air is removed and clamp purge/recirculation line of the oxygenator.
Stop the main pump.

8) CLAMP THE VENOUS AND ARTERIAL LINES
Clamp the venous and arterial line

CAUTION

- During the priming and purge phases, the arterial/venous lines must be kept at least 30 cm higher than the arterial outlet of the oxygenator.
- Check the correct dosage of anticoagulant in the system before starting the bypass.
- The user should inspect the system for correct air removal.
- Prolonged contact time with priming solutions may alter device performance.

H. INITIATING BYPASS

1) OPEN THE ARTERIAL AND VENOUS LINES
Remove the clamp from the arterial line, then slowly start the bypass activating the main pump. Remove the clamp from the venous line and achieve main blood flow appropriate to patient size. Constantly check the blood level in the Inspire HVR.

2) REACH DESIRED BLOOD FLOW RATE
Adjust flow until hemodynamic balance and the desired flow rate are reached.

CAUTION

- Minimum blood flow rate may be lowered down to a minimum of 0,5 l/min up to 2 hours duration time.
- Minimize suction flow to reduce the amount of air in the suction lines, as suction blood induces variable degrees of blood activation.

I. DURING BYPASS

1) CHECK THE VENOUS RETURN
If a higher venous return flow is necessary lower both the oxygenator and the Inspire HVR with respect to the patient position.
In case VAVD technique is used, refer to chapter M of the hereby Instruction manual.

WARNING

- The oxygenator must always be placed at a lower position in respect to the Inspire HVR venous reservoir.
- Make sure that the device never works in positive pressure conditions as that could slow or stop blood venous drainage.
- The ACT (Activated Clotting Time) must always be higher than or equal to 450 seconds in order to ensure adequate blood anticoagulation within the extracorporeal circulation system.
- If administration of anticoagulant to the patient is necessary, use the luer connector of the central stopcock on the sampling manifold

2) LOW FLOW RECIRCULATION
(Hypothermia associated with circulatory arrest).
a) Open the purge/recirculation line and clamp the venous line.
b) Reduce the main pump flow to about 500-1000 ml/min and clamp oxygenator arterial line.
c) Recirculate at a maximum flow of 1000 ml/min. throughout patient's circulatory arrest time., The maximum recirculation flow allowed by the oxygenator used in conjunction with Inspire HVR must be verified.
d) Restart bypass by opening the venous and arterial lines and by slowly increasing the blood flow to nominal value.
e) Close the recirculation line.

3) CONTINUOUS AIR PURGE
Opened purge/recirculation line allows the continuous purge of blood and any incidental gross air from the arterial filter during bypass.
In this condition and at full arterial blood flow, the continuous purge diverts blood from patient's systemic flow.

4) USE OF AUXILIARY/EMERGENCY PORT
- In case the auxiliary/emergency port is used make sure that the line connecting to the auxiliary cardiotomy reservoir is full of fluid before opening it to flow.
- Clamp the auxiliary cardiotomy reservoir line always next to the auxiliary/emergency port of Inspire HVR.
- In order to minimize splashing, it is recommended to slowly open the line connecting the auxiliary cardiotomy reservoir to the auxiliary/emergency port. Line can be fully opened to flow when blood level in the reservoir is above the auxiliary/emergency tubing opening.

CAUTION

- Always maintain at least 30 ml level inside the auxiliary cardiotomy reservoir. This prevents air from being sent to the Inspire HVR reservoir.
- If VAVD technique is used, temporarily suspend vacuum before connecting the auxiliary cardiotomy reservoir to the auxiliary/emergency port.
- Do not transfer fluids through the auxiliary/emergency port by means of a pump.
- At regular intervals check the blood/gas values of the venous and the arterial blood.
- The minimum operating level in the venous reservoir is 150 ml. However, to ensure adequate response time in case of reduced venous flow, it is recommended that an adequate volume in addition to the 150 ml minimum level is maintained. This will allow in all conditions a reasonable reaction time to the clinician and to the low level equipment.
- Do not exceed 4000 ml in the venous reservoir.
- The blood level in the Inspire HVR should possibly be kept under continuous control by using a blood level detector.
- Check the anticoagulant level at regular intervals.

5) MINIMIZING GME ACTIVITY
Inspire HVR has been designed to minimize Gaseous Microemboli (GME) activity.
The following recommendations should be followed in order to obtain the best GME performance from the Inspire HVR reservoir:
1) Avoid surgical air from venous return line
2) Minimize suction flow and the amount of air delivered to the suction lines
3) Carefully inject fluids through the venous line and avoid fluid injection outside filtered ports.
4) Do not purge arterial blood samples from syringes into the venous line.
5) Eliminate all sources that may introduce air into the systemic flow upstream and downstream the Inspire HVR.
6) In case that the recirculation/purge line of the arterial filter is kept open connect it to one of the luer lock connectors of the venous inlet of the Inspire HVR reservoir
7) Avoid quick temperature shifts of the arterial blood.
8) Use of VAVD technique increases the presence of micro air into the blood stream
9) Use of auxiliary/emergency port induces gross air into the blood stream that may vary in quality and quantity according to technique.
10) Use adequate technique to not exceed min and max recommended operating parameters.

J. SUSPENDING BYPASS

1) Decrease the perfusion flow until the main pump stops.
2) Do not empty Inspire HVR and the lines connected to it. Keep a minimum blood level (i.e. 50 ml) which will help resuming bypass if needed.
3) Clamp the venous and arterial lines. If the interruption lasts more than 3 – 5 minutes, recirculate through the oxygenator and Inspire HVR by opening the oxygenator purge/recirculation line.

K. REINITIATING BYPASS

1) Make sure that the circuit is debubbled.
2) Slowly reopen the venous and arterial lines and start the main pump.
3) Perform perfusion using a suitable technique. Refer to the paragraphs "INITIATING BYPASS" and "DURING BYPASS" in this user's manual.
4) In case of problems or for further clarifications, contact SORIN GROUP or one of its authorized representatives.

L. TERMINATING BYPASS

1) Gradually clamp the venous line and simultaneously decrease blood flow until the main pump stops completely.
2) Clamp the arterial line.

M. BLOOD RECOVERY AFTER BYPASS

1) Recover all the blood contained in the venous line, draining it into the Inspire HVR venous reservoir once the surgeon has removed the venous cannulae.
2) Perfuse as much blood as possible through the aortic cannula.
3) Recover the residual blood in a "transfer" bag. Collected blood can immediately be reinfused or processed with autotransfusion equipment.

N. USE OF VENOUS DRAINAGE WITH VACUUM

This method may be applied at any time during extracorporeal circulation, provided that the instructions below are followed. Using the SORIN GROUP VAVD connection kits or equivalent separately supplied, and a suitable vacuum regulation device allows Inspire HVR to be used with active venous drainage technique with vacuum. This technique constitutes an alternative or a complement to venous drainage by gravity.

1) Open the kit for venous drainage with vacuum, operating in such a way that sterility of the system is not compromised.
2) Connect tubing end for reservoir connection to the vent connector of the venous reservoir (Ref. 8 in Fig.1) and the tubing end for vacuum connection to the vacuum regulating device. The latter must be connected to the vacuum line.
3) Make sure that all Inspire HVR ports are closed.
4) Close the clamp on the branch of the line connected to the reservoir.
5) If necessary to interrupt or suspend this method, open the clamp on the line branch.

WARNING

- It is advisable not to exceed –50 mmHg (-6.66kPa/-0.07bar/-0.97 Psi) negative pressure applied to the reservoir.
- Periodically check functioning of the vacuum regulating device and the level of vacuum inside the Inspire HVR.
- In case a non occlusive pump is used make sure that positive pressure is always applied to the oxygenator module used in conjuction with the device.
- In case the auxiliary/emergency port is required to be used, temporarily suspend vacuum and allow atmospheric pressure into the Inspire HVR before removing its cap and connecting the external cardiotomy reservoir to the auxiliary/emergency port. Also refer to relevant Indications and warnings of section I. DURING BYPASS of this instruction for use manual.

O. USE FOR POSTOPERATIVE CHEST DRAINAGE

The use of SORIN GROUP Chest Drainage Conversion Kits/Sets, allow Inspire HVR to be converted into a device for chest drainage and follow the patients in the intensive care unit. The function performed by the resulting device is collecting and filtering chest drainage blood after surgical intervention.

CONTRAINDICATIONS

- When protamine has been administered during surgery before the venous reservoir has been removed from the extracorporeal circuit.
- When there is the certainty or suspicion of gross perforations to the chest wall or an air leak in the lungs.
- Open chest and vacuum applied.
- Use of vented chest tubes that do not have vent flow regulation such as stopcocks.
- If the patient undergoes another operation.

WARNING

- Before use ensure that the Inspire HVR venous reservoir has not been contaminated as a result of uncorrect handling which has compromised sterility.
- The Inspire HVR venous reservoir can function as chest drainage activated by the wall vacuum.
- The sterility of the system depends on the degree of asepsis resulting from use of the venous reservoir and the care taken in connecting the kit during the conversion to chest drainage.
- Prepare the vacuum regulating device with integrated valve following the instructions for use of the manufacturer provided with the device.
- Use a vacuum regulating device fitted with a suitable safety valve that prevents accumulation of positive pressure inside the reservoir.
- Periodically check functioning of the vacuum regulating device.
- If the recovered blood exceeds the amount established by postoperative routine, immediately notify the physician in charge.
- If the recovered blood is to be re-infused, an increase in vacuum will be noted in the reservoir. A filtered venting system must therefore be arranged in order to restore the original negative operating pressure.
- The clinician in charge is solely responsible of the quality of transfused blood and of the technique used to re-transfuse recovered blood.

CONVERSION OF THE INSPIRE HVR INTO A CHEST DRAINAGE DEVICE

Immediately after intraoperative use of the Inspire HVR reservoir, convert it into a chest drainage device using the appropriate chest drainage conversion Kits/Sets and operate in such a way not to compromise sterility of the system. In order to obtain the best out of the chest drainage system, set up the operational routine in such a way that the priming fluid of the extracorporeal circuit generously wets the filter of the Inspire HVR reservoir to the maximum possible level; do not for any reason transfer to the reservoir blood that has not been suitably anticoagulated.

1) Seal all the ports of the Inspire HVR.
2) Set-up the device for connection to the patient and to a suitable vacuum regulator fitted with a safety valve.
3) Position the Inspire HVR venous reservoir suitably close to the patient and in any case at a level lower than the patient: for this purpose use the Inspire BKTH bracket securing it to the bed frame.
4) Make the appropriate connections to the patient chest tubes.
5) Connect Inspire HVR to the vacuum, taking care to place a vacuum regulator with a safety valve between the vacuum source and the Inspire HVR reservoir. The vacuum regulator with safety valve must be extremely reliable and accurate.
6) Adjust the desired degree of negative pressure.
7) Ensure that the safety valve functions properly as per instructions for use of the safety valve in use.
8) Start the drainage procedure and periodically check that the system works regularly.

WARNING

- Use by untrained and unqualified personnel is not permitted.
- All the connections to the Inspire HVR reservoir should be carried out with the utmost care and rapidity in order to prevent contamination.
- The connections and the caps should be checked to assure that the system is tight.
- Always keep the device in a vertical position: do not incline it, not even when the patient is being moved.
- The Inspire HVR reservoir must always be placed at a subthoracic level so that its drainage functions can properly be performed.
- Activate the line vacuum following the instructions provided by the manufacturer of the vacuum regulator.
- It is advisable not to exceed –50 mmHg (-6.66kPa/-0.07bar/-0.97Psi) negative pressure applied to the reservoir.
- Periodically check functioning of the vacuum regulating device and the degree of vacuum.
- Periodically check that the device never works in positive pressure conditions as that could stop drainage and impair patient respiratory function.
- Any re-infusion of recovered blood is on the responsibility and at the discretion of the attending physician.
- The recovered blood may become contaminated and hence not be suitable for retransfusion.
- Filter occlusion during high volume chest drainage may cause blood/fluid overflow cardiotomy filter section.

P. DEVICE CHANGE-OUT

A spare device must always be available during bypass in the unlikely event that the Inspire HVR in use requires change-out. Procedures lasting longer than 6 hours or particular situations where the safety of the patient may be compromised (insufficient performance, leaks, etc.), could require change-out. Follow the steps below to change-out the Inspire HVR reservoir.

WARNING

Use sterile technique during the entire replacement procedures.

1) While the patient is still on bypass, remove the new Inspire HVR reservoir from its outer packaging and from the sterile wrapper; inspect it for damage.
2) Stop suction and clamp the suction lines and connect them to the new Inspire HVR reservoir.