TANDEM | LIFE IS NOW LivaNova

LifeSPARC Procedure Guide

24/7 CLINICAL SUPPORT **800 373 1607**

CUSTOMER SERVICE **800 373 7421**

OFFICE **620 Alpha Dr, Suite 2**
Pittsburgh, PA 15238

VISIT **TANDEMLIFE.COM**

TANDEMLIFE LS

Veno-Arterial ECLS

TANDEMHEART LS

LA-FA Bypass

PROTEKDUO LS

RA-PA Bypass

TANDEMLUNG LS

Veno-Venous ECLS

Part No. 7000-0183
Rev 0. 11/14/19

CardiacAssist, Inc.
dba TandemLife
620 Alpha Drive, Suite 2
Pittsburgh, PA 15238

24/7 Clinical Support Hotline:

United States
800.373.1607

International
412.579.6182

Life Support **Simplified.**

This procedure guide is intended to provide a brief overview of the most common applications of the TandemLife® platform, including quick setup instructions, a list of user-supplied equipment and product ordering information.

For more information, please contact your local TandemLife representative, or refer to the LifeSPARC Controller Operations Manual, Device Management Guide, and/or individual product Directions for Use.

SETTING UP THE LIFESPARC CONTROLLER

Initiate Controller Setup

Prior to priming the preconnected pump and/or oxygenator; set up the controller.

- Install two fully charged batteries into the controller.
- Connect the power cord to AC power receptacle on the rear of the dock.
- Plug the power cord into an AC wall outlet.
- Press power button to turn on controller.

SETTING UP THE LIFESPARC PUMP

Prime Pump

- Open package and remove pump.
- Plug the pump power driveline into the pump receptacle below the controller interface.
- Fill the inflow tubing of the pump with 60 cc of saline.
- Tap the pump to dislodge air that may be present in the blood chamber of the pump.
- Fill the inflow tubing of the pump with an additional 60 cc of saline.
- Tap the pump to dislodge air that may be present in the circuit. Verify that all air has been removed.
- Specifically, verify the secondary flow path is free of air by inspecting the underside of the pump.
- Clamp tubing below fluid line.
- Repeat steps above if air is detected.

PRIMING THE LIFESPARC PUMP AND TANDEMLUNG OXYGENATOR WITH THE STERILE PRIMING TRAY

- Open package and remove priming tray components.
- Plug the pump power driveline into the pump receptacle below the Controller interface.
- Plug pump inflow tubing into the priming tray's blue port (blue stripe to blue port).
- Plug pump outflow tubing into priming tray's red port (red stripe to red port).
- Tilt priming tray to the fill ready position away from the blue port.
- Fill priming tray with approximately 4,000 mL of saline.
- Tilt priming tray to the prime ready position to gravity prime the pump.
- Start the pump from the Controller interface.
- Orient oxygenator so the outflow port is at the 12 o'clock position.
- Tap the pump and oxygenator to dislodge air that may be present. Verify that all air has been removed.
- Specifically, verify the secondary flow path is free of air by inspecting the underside of the pump for air.
- Stop pump.
- Clamp the inflow and outflow tubing.
- Tilt the priming tray to the fill ready position and remove tubing from the basin.
- Attach the gas line (green tubing) to the GAS IN port on the TandemLung oxygenator.
- Repeat steps above if air is detected.

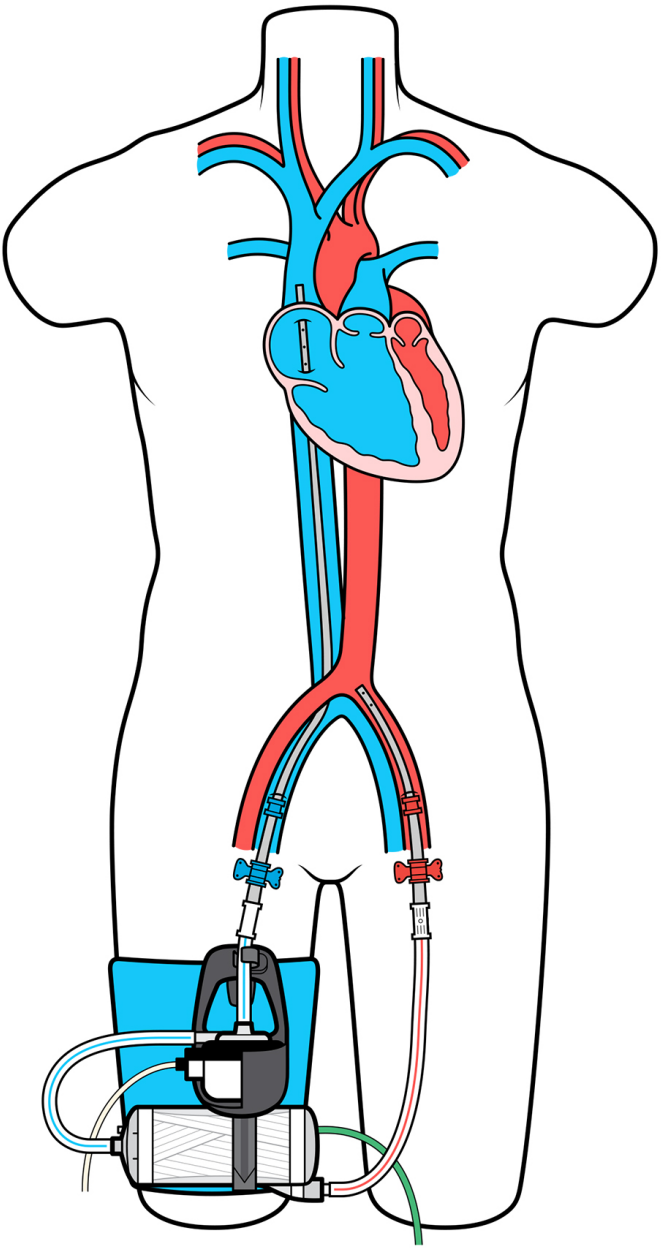
ProtekSolo Transseptal
21 Fr x 62 cm or 21 Fr x 72 cm

ProtekSolo Arterial Cannula
15 Fr x 17 cm or 17 Fr x 17 cm

ProtekSolo Venous Cannula
24 Fr x 60 cm

ProtekDuo Cannula
29 Fr x 46 cm or 31 Fr x 51 cm

ProtekDuo RD Cannula
31 Fr x 36 cm



REQUIRED EQUIPMENT

- LifeSPARC Controller
- LifeSPARC Pump
- TandemLung Oxygenator
- ProtekSolo 24 Fr x 60 cm Cannula
- ProtekSolo 15 Fr or 17 Fr Femoral Arterial Cannula
- User-Supplied Equipment

PROCEDURE STEPS

Controller, pump, and oxygenator setup (see page 4)
Initiate controller setup
- Connect pump driveline to controller
- Prime pump and oxygenator using the priming tray
- Check for air and clamp

Patient procedure
- Gain femoral venous and arterial access
- Insert guidewire for venous and arterial access
- Anticoagulate the patient (ACT at 400)
- Dilate venous and arterial access sites
- Insert venous and arterial cannulae, remove introducers and guidewires, back-bleed, and clamp
- Secure cannula suture wings to patient

Connecting components
- Make wet-to-wet connections to cannulae (venous cannula to pump inlet [blue]; arterial cannula to pump/oxygenator outlet [red])
- Verify the gas line (green tubing) is attached to the GAS IN port and start the flow of oxygen
- Remove venous side clamps and start pump (from controller)
- Release clamps sequentially, checking for air, releasing arterial clamp last
- Adjust pump RPMs to optimize flow
- Confirm cannulae position and secure circuit to patient
- Maintain therapeutic anticoagulation (ACT at 180–220; PTT at 65–80)

TANDEMLIFE LS

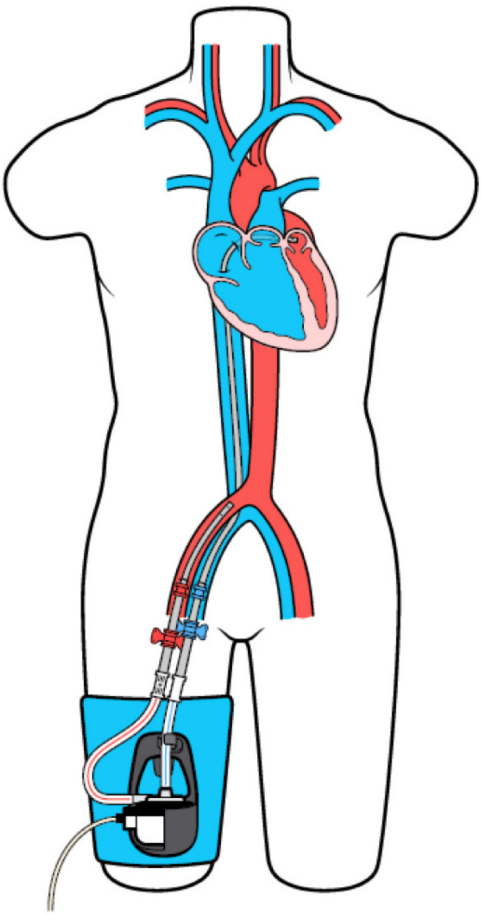
Veno-Arterial

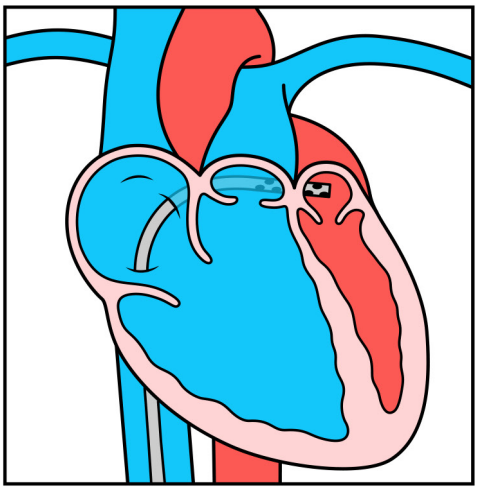
LA-FA Bypass

RA-PA Bypass

Veno-Venous | RA-PA

Veno-Venous | IVC-RA





REQUIRED EQUIPMENT

- LifeSPARC Controller
- LifeSPARC Pump
- ProtekSolo 62 cm or 72 cm Transseptal Cannula
- ProtekSolo 15 Fr or 17 Fr Arterial Cannula
- User-Supplied Equipment

PROCEDURE STEPS

Controller and pump setup (see page 4)
Initiate controller setup
- Connect pump driveline to controller
- Prime pump and tubing
- Check for air and clamp

Patient procedure—transseptal
- Gain femoral venous access
- Perform transseptal puncture, insert guidewire to LA
- Anticoagulate the patient (ACT at 400)
- Dilate venous access and atrial septum with 2-stage dilator
- Insert transseptal cannula and advance to LA, remove obturator/introducer and guidewire, back-bleed, and clamp
- Secure cannula to patient

Patient procedure—arterial access
- Gain femoral arterial access
- Insert guidewire
- Dilate arterial access site
- Insert arterial cannula, remove introducer and guidewire, back-bleed, and clamp
- Secure cannula to patient

Connecting components
- Make wet-to-wet connections to cannulae (transseptal to pump inlet [blue]; arterial to pump outlet [red])
- Remove venous side clamps and start pump (from controller)
- Release clamps sequentially, checking for air, releasing arterial clamp last
- Adjust pump RPMs to optimize flow
- Confirm cannulae position and secure circuit to patient
- Maintain therapeutic anticoagulation (ACT at 180–220; PTT at 65–80)

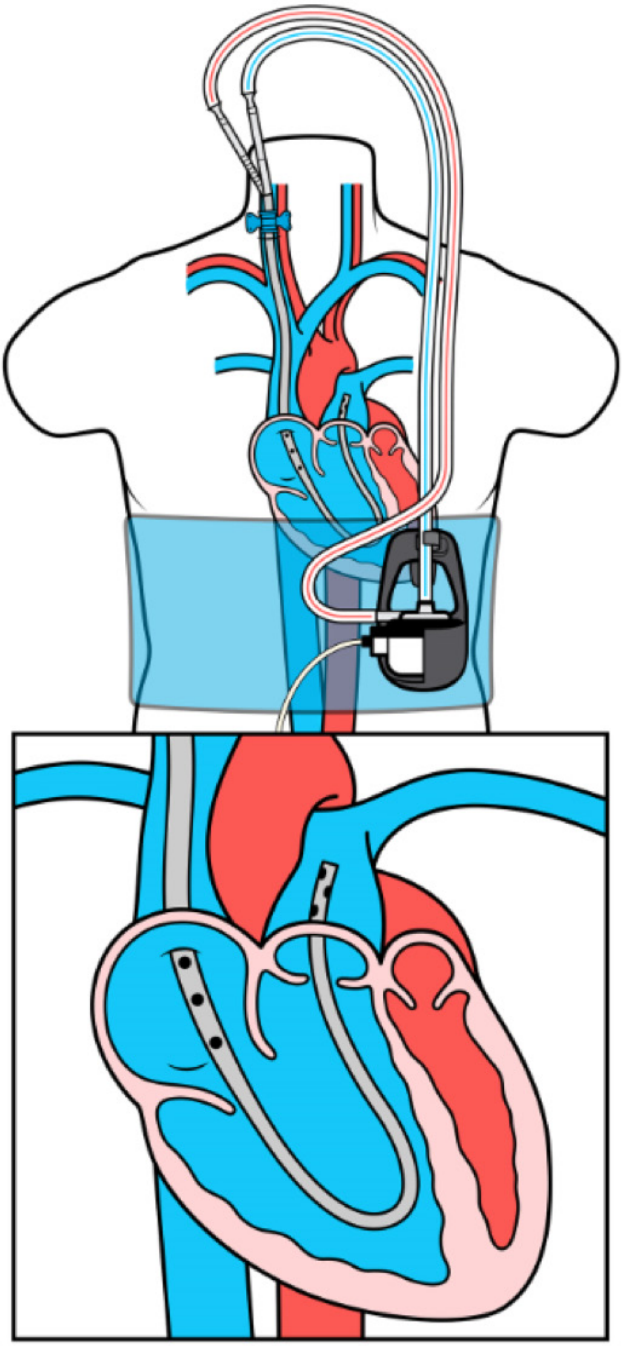
TANDEMHEART LS

LA-FA Bypass

RA-PA Bypass

Veno-Venous | RA-PA

Veno-Venous | IVC-RA



REQUIRED EQUIPMENT

- LifeSPARC Controller
- LifeSPARC Pump
- ProtekDuo 29 Fr or 31 Fr Dual Lumen Cannula
- User-Supplied Equipment

PROCEDURE STEPS

Controller and pump setup (see page 4)
Initiate controller setup
- Connect pump driveline to controller
- Prime pump and tubing
- Check for air and clamp

Patient procedure
- Gain right internal jugular venous (RIJ) access
- Insert PA Catheter and advance to PA
- Insert guidewire and remove PA Catheter
- Anticoagulate the patient (ACT at 400)
- Dilate venous access site
- Insert cannula, remove introducer and guidewire, back-bleed, and clamp port marked “Distal”
- Remove hemostasis cap, back-bleed, and clamp the port marked “Proximal”
- Secure cannula to patient

Connecting components
- Make wet-to-wet connections to cannula (proximal to pump inlet [blue]; distal to pump outlet [red])
- Start pump (from controller)
- Release clamps sequentially, checking for air
- Adjust pump RPMs to optimize flow
- Confirm cannula position and secure circuit to patient
- Maintain therapeutic anticoagulation (ACT at 180–220; PTT at 65–80)

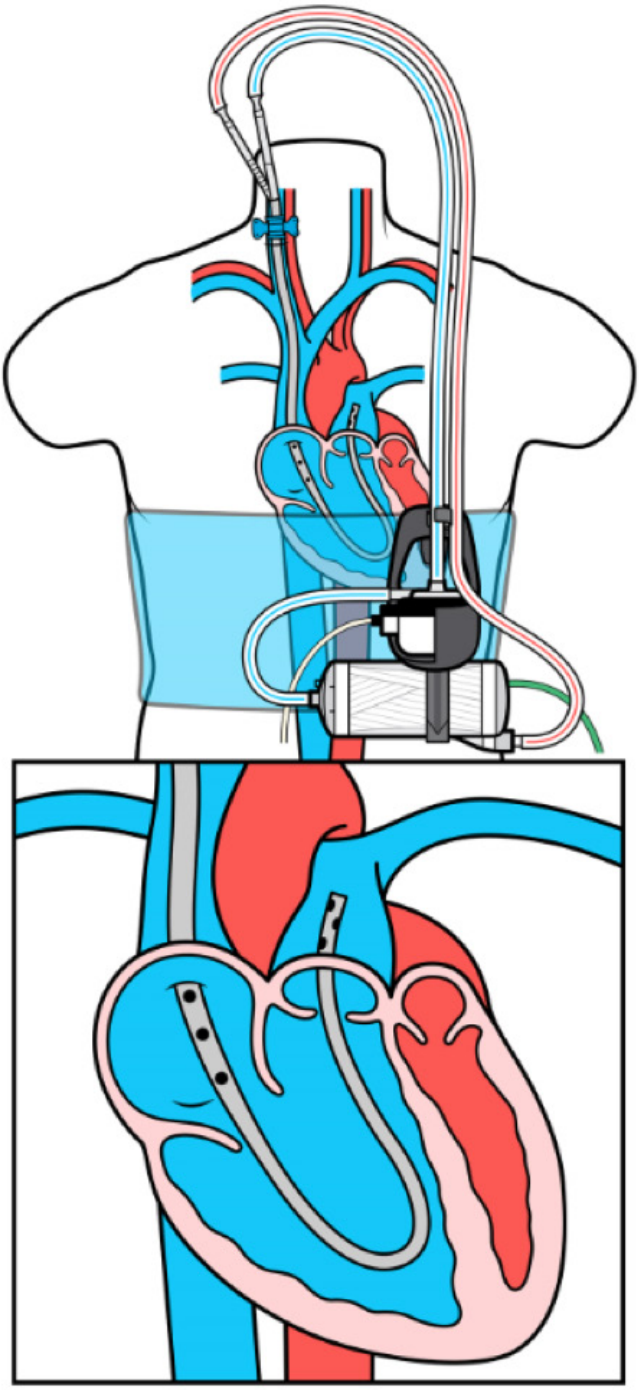
For enhanced mobility, add the VoyagerVest; see DFU for instructions

PROTEK**DUO** LS

RA-PA Bypass

Veno-Venous | RA-PA

Veno-Venous | IVC-RA



REQUIRED EQUIPMENT

- LifeSPARC Controller
- LifeSPARC Pump
- TandemLung Oxygenator
- ProtekDuo 29 Fr or 31 Fr Dual Lumen Cannula
- User-Supplied Equipment

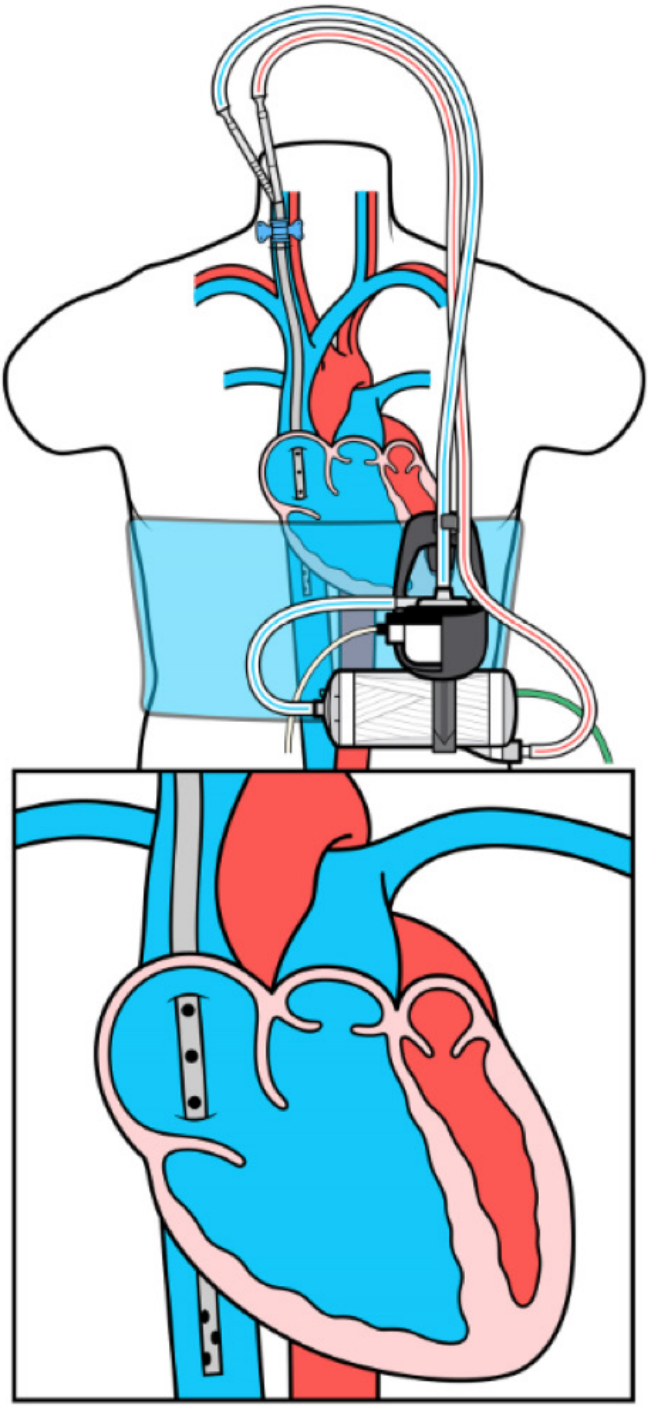
PROCEDURE STEPS

Controller, pump, and oxygenator setup (see page 4)
Initiate controller setup
- Connect pump driveline to controller
- Prime pump and oxygenator using the priming tray
- Check for air and clamp

Patient Procedure
- Gain right internal jugular venous (RIJ) access
- Insert PA Catheter and advance to PA
- Insert guidewire and remove PA Catheter
- Anticoagulate the patient (ACT at 400)
- Dilate venous access site
- Insert cannula, remove introducer and guidewire, back-bleed, and clamp port marked “Distal”
- Remove hemostatsis cap, back-bleed, and clamp port marked “Proximal”
- Secure cannula to patient

Connecting components
- Make wet-to-wet connections to cannula (proximal to pump inlet [blue]; distal to pump/oxygenator outlet [red])
- Verify the gas line (green tubing) is attached to the GAS IN port and start the flow of oxygen
- Start pump (from controller)
- Release clamps sequentially, checking for air
- Adjust pump RPMs to optimize flow
- Check cannula position and secure circuit to the patient
- Maintain therapeutic anticoagulation (ACT at 180–220; PTT at 65–80)

For enhanced mobility, add the VoyagerVest; see DFU for instructions



REQUIRED EQUIPMENT

- LifeSPARC Controller
- LifeSPARC Pump
- TandemLung Oxygenator
- ProtekDuo RD 31 Fr Dual Lumen Cannula
- User-Supplied Equipment

PROCEDURE STEPS

Controller, pump, and oxygenator setup (see page 4)

Initiate controller setup

- Connect pump driveline to controller
- Prime pump and oxygenator using the priming tray
- Check for air and clamp

Patient Procedure

- Gain right internal jugular venous (RIJ) access
- Insert guidewire and advance to IVC
- Anticoagulate the patient (ACT at 400)
- Dilate venous access site
- Insert cannula, remove introducer and guidewire, back-bleed, and clamp port marked “Distal”
- Remove hemostatsis cap, back-bleed, and clamp port marked “Proximal”
- Secure cannula to patient

Connecting components

- Make wet-to-wet connections to cannula (distal to pump inlet [blue]; proximal to pump/oxygenator outlet [red])
- Verify the gas line (green tubing) is attached to the GAS IN port and start the flow of oxygen
- Start pump (from controller)
- Release clamps sequentially, checking for air
- Adjust pump RPMs to optimize flow
- Check cannula position and secure circuit to the patient
- Maintain therapeutic anticoagulation (ACT at 180–220; PTT at 65–80)

For enhanced mobility, add the VoyagerVest; see DFU for instructions

TANDEM | LIFE IS NOW LivaNova

User-Supplied Equipment

5 Fr or 6 Fr venous and arterial sheaths
Transseptal sheath (Mullins, SL1, SL2 most frequently used)
Transseptal needle (BRK, RF)
Toray Inoue wire or 0.035 Amplatz super stiff, exchange length wire
4 sterile perfusion clamps
2-0 silk sutures
Arterial dilators (8, 10, 12, 14 Fr)
0.035 Lunderquist or Amplatz super stiff exchange length wire (ProtekDuo Insertion Kit 5100-0001)
PA Catheter ≤ 90 cm and 0.035 guidewire compatible (ProtekDuo Insertion Kit 5100-0001)
Tubing cutter
18-gauge percutaneous entry needle and scalpel

	TandemLife (Veno-Arterial)	*TandemHeart (LA-FA)*	*ProtekDuo (RA-PA)*	*TandemLung (RA-PA)*	*TandemLung RD (IVC-RA)*
	✓	✓			
		✓			
		✓			
		✓			
	✓	✓	✓	✓	✓
	✓	✓	✓	✓	✓
	✓	✓			
			✓	✓	
			✓	✓	
	✓	✓			
	✓	✓	✓	✓	✓

TANDEMLIFE LS

PROCEDURE KIT:

- LifeSPARC Pump
- TandemLung Oxygenator
- Priming Tray
- ProtekSolo Arterial Cannula (15 Fr or 17 Fr)
- ProtekSolo Venous Cannula (24 Fr)
- Protek Venous Dilators

TANDEMHEART LS

PROCEDURE KIT:

- LifeSPARC Pump
- ProtekSolo Transseptal Cannula (62 cm or 72 cm)
- ProtekSolo Arterial Cannula (15 Fr or 17 Fr)
- 14/21 Fr Two-Stage Transseptal Dilator

PROTEKDUO LS

PROCEDURE KIT:

- LifeSPARC Pump
- ProtekDuo Dual-Lumen Cannula (29 Fr or 31 Fr)
- Protek Venous Dilators

TANDEMLUNG LS

PROCEDURE KIT:

- LifeSPARC Pump
- TandemLung Oxygenator
- Priming Tray
- ProtekDuo Dual-Lumen Cannula (29 Fr or 31 Fr)
- Protek Venous Dilators

TANDEMLUNG LS

RAPID DEPLOYMENT

PROCEDURE KIT:

- LifeSPARC Pump
- TandemLung Oxygenator
- Priming Tray
- ProtekDuo RD Dual-Lumen Cannula (31 Fr)
- Protek Venous Dilators

The procedures listed in this guide represent the observed physician usage of TandemLife products. Procedure guidelines have been composed based on recorded case experiences from physician subject matter experts. TandemLife makes no claim regarding the effectiveness of its products in these procedures and does not recommend off-label use of its products.

FDA Indications for Use:

LifeSPARC Controller and Pump
The LifeSPARC System is intended to pump the blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either: (i) Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or (ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava. For Adults only.

TandemLung Oxygenator
The TandemLung Oxygenator is intended for use in an extracorporeal circuit requiring cardiopulmonary bypass for application duration limited to six hours. Within the specified flow rate range, the device oxygenates the blood and removes carbon dioxide from the blood. Responsibility for clinical application of the oxygenator rests solely with the attending physician.

ProtekSolo 62 and 72 cm Transseptal Cannulae
The Transseptal Cannula Set-EF is intended for transseptal catheterization of the left atrium via the femoral vein for the purpose of providing a means for temporary (six hours or less) left ventricular bypass when connected to the LifeSAPRC extracorporeal blood pump, which returns blood to the patient via the femoral artery or other appropriate site.

ProtekSolo Venous Cannula
The Venous Cannula and Obturator is intended to cannulate vessels, perfuse vessels or organs and/or connect with accessory extracorporeal circulatory support equipment. The cannula obturator is intended to facilitate proper insertion and placement of the cannula within the vessel for extracorporeal circulatory support. These devices are to be used by a trained physician only.

ProtekSolo 15 and 17 Fr Arterial Cannulae
The Femoral Arterial Cannula and Introducer are intended to cannulate vessels, perfuse vessels or organs, and/or connect with accessory extracorporeal circulatory support equipment for a duration of six hours or less. The cannula introducer is intended to facilitate proper insertion and placement of the cannula within the vessel for extracorporeal support.

ProtekDuo 29 Fr, 31 Fr, and ProtekDuo RD 31 Fr Veno-Venous Cannulae
The ProtekDuo Veno-Venous Cannula Set is intended for use as a single cannula for both venous drainage and reinfusion of blood via an internal jugular vein during extracorporeal life support procedures.

VoyagerVest
The VoyagerVest is intended to provide secure attachment of Extracorporeal Life Support (ECLS) components (pump, oxygenator, and tubing) to the patient during cardiopulmonary bypass support.

TANDEM | LIFE IS NOW LivaNova

Customers in Canada and Europe, please contact your local TandemLife representative or distributor for country-specific part numbers.

Reimbursement Support:
Email: reimbursement.tl@livanova.com

Customer Service:
Phone: 800.373.7421
Fax: 412.963.9739
Email: tandemlife.customerservice@livanova.com

Part No. 7000-0183
Rev 0. 11/14/19

CardiacAssist, Inc.
dba TandemLife
620 Alpha Drive, Suite 2
Pittsburgh, PA 15238

24/7 Clinical Support Hotline:

United States
800.373.1607

International
412.579.6182