Procedure Guide

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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.

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For more information, please contact your local TandemLife representative, or refer to the TandemHeart (Escort) Controller Operations Manual, device management guide, and/or individual product Directions for Use.
SETTING UP THE TANDEMHEART® CONTROLLER

Initiate Controller Setup
• Turn on power in back of controller
• Select either “view instructions” or “skip instructions”

Prime Infusate System
• Plug in transducer
• Prime infusate line with saline
• Fill a 20 cc syringe with saline and save

SETTING UP THE TANDEMHEART PUMP

Prime Pump
• Plug in power cable and connect infusate line (from scrub table)
• Inject 15 cc of saline into pump’s lower chamber
• Refill syringe with 15 cc of saline
• Start pump and inject 15 cc of saline with pump running
• Turn pump off and check lower chamber for air (the pump will shut down automatically if it’s on screen three of “View Instructions Mode”)
• Check for air and repeat steps above if bubbles are detected

From scrub table, fill 60 cc syringe with saline
• Slowly inject 60 cc of saline into pump’s upper chamber
• Refill syringe and inject an additional 60 cc of saline into pump tubing
• Tap pump and tubing to ensure all air is removed
• Clamp tubing below fluid line
• Lace infusate tubing into infusion pump and air detector on the side of the controller

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

• Open package and remove priming tray components
• Plug in pump power cord and connect infusate line (from scrub table)
• Inject 15 cc of saline into pump’s lower chamber
• Refill the syringe with 15 cc of saline
• Start pump and inject 15 cc of saline into the pump lower housing
• Turn pump off and check lower chamber for air (the pump will shut down automatically if it’s on screen three of “View Instructions Mode”)
• Attach pump tubing to priming basin, pump inflow (blue stripe to blue port) and pump outflow (red stripe to red port)
• Fill basin corner to corner (approx. 4,000 mL of saline) and tilt basin to prime ready position to gravity prime the upper housing (manipulate the pump and/or lift the priming tray if necessary, to ensure the pump upper housing is filled with fluid)
• Start the pump from the pump ready screen
• Orient the oxygenator so that the outflow port is at the 12 o’clock position and gently tap the oxygenator to remove any air
• Stop pump when satisfied that all air has been removed from the circuit
• Clamp tubing
• Tilt basin back to the opposite position and visually inspect for air
• Lace the infusate tubing into the infusion pump and air detector
REQUIRED EQUIPMENT

- TandemHeart Controller
- TandemHeart 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
- Prime pump’s lower chamber and check for air
- Prime pump’s upper chamber and TandemLung 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])
- Attach the gas line (green tubing) 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)
REQUIRED EQUIPMENT

• TandemHeart Controller
• TandemHeart 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
• Prime pump’s lower chamber and check for air
• Prime pump’s upper chamber, 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)
REQUIRED EQUIPMENT

• TandemHeart Controller
• TandemHeart 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
• Prime pump’s lower chamber and check for air
• Prime pump’s upper chamber, 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
REQUIRED EQUIPMENT
• TandemHeart Controller
• TandemHeart 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
• Prime pump’s lower chamber and check for air
• Prime pump’s upper chamber and TandemLung 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 hemostatis 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])
• Attach the gas line (green tubing) 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
- TandemHeart Controller
- TandemHeart 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
- Prime pump’s lower chamber and check for air
- Prime pump’s upper chamber and TandemLung 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])
- Attach the gas line (green tubing) 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
### User-Supplied Equipment

<table>
<thead>
<tr>
<th>Item</th>
<th>TandemLife (Veno-Arterial)</th>
<th>TandemHeart (LA-FA)</th>
<th>ProtekDuo (RA-PA)</th>
<th>TandemLung (RA-PA)</th>
<th>TandemLung RD (IVC-RA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 Fr or 6 Fr venous and arterial sheaths</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Transseptal sheath (Mullins, SL1, SL2 most frequently used)</td>
<td></td>
<td>✓</td>
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<tr>
<td>Transseptal needle (BRK, RF)</td>
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<tr>
<td>Toray Inoue wire or 0.035 Amplatz super stiff, exchange length wire</td>
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<tr>
<td>1 L bag infusate</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>4 sterile perfusion clamps</td>
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<tr>
<td>60 mL syringe</td>
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<tr>
<td>2-0 silk sutures</td>
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<td></td>
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<td></td>
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<tr>
<td>Anticoagulant</td>
<td></td>
<td></td>
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<tr>
<td>Arterial dilators (8, 10, 12, 14 Fr)</td>
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<td>✓</td>
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<tr>
<td>0.035 Lunderquist super stiff exchange length wire</td>
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<td>✓</td>
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<tr>
<td>(ProtekDuo Insertion Kit 5100-0001)</td>
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<tr>
<td>PA Catheter ≤ 90 cm and 0.035 guidewire compatible</td>
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<td>✓</td>
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<tr>
<td>(ProtekDuo Insertion Kit 5100-0001)</td>
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<tr>
<td>Tubing cutter</td>
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<tr>
<td>18-gauge percutaneous entry needle and scalpel</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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</tr>
</tbody>
</table>
Equipment

**TANDEM LIFE**

**PROCEDURE KIT:**
- TandemHeart Pump
- TandemLung Oxygenator
- Priming Tray
- ProtekSolo Arterial Cannula (15 Fr or 17 Fr)
- ProtekSolo Venous Cannula (24 Fr)
- Protek Venous Dilators

**TANDEM HEART**

**PROCEDURE KIT:**
- TandemHeart Pump
- ProtekSolo Transseptal Cannula (62 cm or 72 cm)
- ProtekSolo Arterial Cannula (15 Fr or 17 Fr)
- 14/21 Fr Two-Stage Transseptal Dilator

**PROTEK DUO**

**PROCEDURE KIT:**
- TandemHeart Pump
- ProtekDuo Dual-Lumen Cannula (29 Fr or 31 Fr)
- Protek Venous Dilators

**TANDEM LUNG**

**PROCEDURE KIT:**
- TandemHeart Pump
- TandemLung Oxygenator
- Priming Tray
- ProtekDuo Dual-Lumen Cannula (29 Fr or 31 Fr)
- Protek Venous Dilators

**TANDEM LUNG RD**

**PROCEDURE KIT:**
- TandemHeart 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:**

**TandemHeart Controller**
The TandemHeart Escort Controller is intended to be used with the TandemHeart System. The TandemHeart System consists of the disposable TandemHeart Blood Pump, a single use, disposable device; the TandemHeart Escort (T.H.E.) Controller, a reusable control system; and disposable accessory items used in conjunction with the TandemHeart System.

**TandemHeart Pump**
The TandemHeart System is intended for extracorporeal circulatory support using an extracorporeal bypass circuit. Intended duration of use is for periods appropriate to cardiopulmonary bypass, up to six hours. It is also intended to be used as an extracorporeal circulatory support system (for periods up to six hours) for procedures not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, mitral valve reoperation, surgery of the vena cava and/or aorta, liver transplant, etc.).

**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 TandemHeart 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.
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
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