

Indications for Use

- TandemHeart Controller: The TandemHeart Escort Controller is intended to be used with the TandemHeart System. The TandemHeart System consists of the TandemHeart Blood Pump, a single use, disposable device; the TandemHeart Escort (T.H.E.) Controller, a reusable control system for the TandemHeart Blood Pump; 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.)
- 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 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. These devices are to be used by a trained physician only.
- ProtekDuo 29 and 31 Fr Venovenous Cannulae: The ProtekDuo Venovenous 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.
- 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.
- Voyager Vest: The Voyager Vest is intended to provide secure attachment of Extracorporeal Life Support (ECLS) components (pump, oxygenator, and tubing) to the patient during cardiopulmonary bypass.