PURPOSE
This practice support document is a guideline only. It provides an overview of the Berlin Heart EXCOR Pediatric VAD (ventricular assist device) and the required nursing care needed to safety monitor the patient.

POLICY STATEMENTS
The RN will manage the patient and be supported by the perfusion department until RN competencies met.

Full medical and surgical management of the Berlin Heart will be provided by the cardiothoracic surgeon.

The perfusion department will provide all Berlin heart education / support.

A Perfusionist is required to accompany the patient on initial transports; 1 RN with demonstrated and validated competency in management of Berlin hearts may accompany the patient during transport without the Perfusionist being present once patient is deemed stable.

Only the cardiovascular surgeons/ perfusionists may change the parameters on the IKUS driver Console

A second IKUS driver will always be located on the unit where the patient is located.

Diagnostic and/or interventional procedures are possible in patients with VAD however Magnetic resonance imaging (MRI) is NOT recommended.

EXCOR pediatric VAD may be used in the following patients:
- Any patient from newborn (>3kg) to adolescent (60kg+)
  - Cardiomyopathy
  - Acute myocarditis
  - Post-cardiomyotomy failure
  - Endstage congenital heart disease
  - Post-transplant graft-failure
  - Severe isolated left ventricular or biventricular dysfunction
  - Bridging to transplant

SITE APPLICABILITY
Operating Room
The Berlin heart is implanted via a median sternotomy using cardiopulmonary bypass (CPB).

PICU
Initial postoperative care will be provided in the PICU under the care of the cardiothoracic surgeon and PICU team.

Transition Phase
When the patient is stable as determined by Cardiac Surgery and the PICU team, then transition to CHU will occur.

Children Heart Unit (CHU)
Berlin heart patient admitted to the CHU will be initially managed by the RN 1:1. This may then be reduced to a lower frequency of nursing management, once in long term therapy on the Berlin heart. This shall be accessed on a patient by patient basis.

Patients who become unstable maybe transferred back to PICU for possible escalation of therapy.
BERLIN HEART TEAM – Roles and Responsibilities

Cardiothoracic surgeon (available 24 hours/7 days a week)
Oversees medical/ surgical management of the patient
Performs or delegates (cardiac NPs only) dressing changes

RN
Bedside care of the Berlin heart patient
Berlin heart blood pump inspections – deposits, filling and emptying, parameter log documentation
Performs IKUS driver safety checks

Perfusion (Available 24 hours/7 days a week)
Perform circuit checks every 24 hours (or more often as clinically indicated)
Emergency contact person for troubleshooting any Berlin heart issues and alarm management of the IKUS driver / blood pumps
May help with transports of the patient in hospital

Cardiac NPs
Perform dressing changes

Transplant Dietitian
Assesses nutritional needs and optimizes nutritional support during VAD therapy and until transplant.

Physical Therapy
Assesses the child’s strength, endurance and mobility before and after implant, optimize activity level

Pharmacy / Hematopathology
Collaborates with the cardiothoracic surgeon and the hemopathologist to obtain adequate anticoagulation

Childlife Specialist, Psychology, Social Work (Multi-organ transplant), Physiology, Transplant RNs
Collaborate with the team to create a care plan that includes strategies to maximize positive adaptation to VAD, future transplant, and optimize care of patient and family.

ECLS CODE
Rapid response to emergencies from the PICU team: PICU fellow and senior resident, respiratory therapist and two PICU RN’s.
Additional member’s on-call 24/7 activated via the ECLS code: Cardiac surgeons, PICU intensivist, 1st on-call perfusionist, 2 OR cardiac nurses, OR charge RN, blood bank and ECMO team leaders.

PRACTICE LEVEL / COMPETENCIES
Nursing care of the patient requiring a Berlin heart is considered an advanced nursing competency. The RN will:
- receive full training and a learning package; competency levels shall be validated orally and/ or written (clinical skill validation)
- complete visual checks, evaluate the filling / emptying behavior of the blood pumps, and detect deposits
- understanding of how to use the manual pump in emergency situations
- Replace the IKUS driver when necessary.

The perfusion department will validate all competency levels and sign off all Berlin heart users
DEFINITIONS

The EXCOR Berlin Heart is a pulsatile, pneumatically driven VAD with implantable silicone cannulas, which sit outside the body (paracorporeal). The EXCOR Berlin heart can provide univentricular support (1 blood pump) or biventricular support (2 blood pumps) and provides short to medium-term assistance to the patient as a bridge to cardiac transplant or recovery of their own heart function (rare).

Blood pump/s: Carmeda bioactive coated blood pumps
Inflow Cannula/s: Atrial (RA) and Apex (LV apex)
Outflow Cannula/s: Arterial (placed in the pulmonary artery and/or aorta, depending on type of VAD)
IKUS console driver: A stationery electro-pneumatic drive system (blue unit) that is attached to the pumps and produces a pulsatile blood flow by pulling and pushing air in and out of the blood pump head creating a negative and positive pressure. The IKUS houses the hand pump (under the laptop) and the attached laptop with parameter log settings

EQUIPMENT

The Berlin Heart folder, located on top of the primary IKUS driver (attached to patient) contains:
- User manual
- Physicians manual
- Learning package
- 4 clamps (only to be used by cardiac surgeon)
- 2 ¼” connectors
- Paperwork – Visual pump inspection, parameter log, safety checklist
- Maglight and batteries
- Mirror

***Emergency blood pumps/accessory packs/connecting sets/cannulas are in the Perfusion department**

PROCEDURES

BERLIN HEART SETTINGS & SAFETY CHECKS

1. Document the following parameter log settings hourly for the first 24 hours then every 4 hours while in ICU and CHU
   - Mode of Operation
   - Left & right systolic pressure (blood pump)
   - Left & right diastolic pressure (blood pump)
   - Left & right rate (bpm)
   - Left & right % Systole
   - Ensure the graph is moving on the laptop

   ***Verify settings are as physician ordered***

2. Visually inspect and document blood pump/s (includes valves), cannulas, connectors and drive line every hour for the first 24 hours then every 4 hours.

   Inspect for:
   - Fibrin
   - Clot formation

   The parameter log settings are password protected and therefore will not be changed unless ordered by physician.

   Note; the set systolic pressure is the positive pressure applied to the pneumatic side of the diaphragm and is not indicative of the patients systolic BP.

   If the graph is not moving the IKUS is operating in emergency pulse mode contact 1st on call perfusionist

   Notify MD/perfusionist immediately if: new clot/fibrin formations are noted or the driving tube is damaged.

   Signs of fibrin and/or clot may signal the need to adjust anticoagulation/antiplatelet therapy or the blood pump may need to be exchanged.

   To ensure driveline is secure and no kinks are
- Air
- Kinks
- Disturbance of flow

Use the Maglight and mirror provided to check the underside of the blood pumps and cannulas

3. Visually inspect and document blood pump/s for adequate filling and ejecting every hour for first 24 hours then every 4 hours. Observe the filling and ejecting over a period of several pump cycles.
   - Normal ejection is 100% emptying of the blood pump
   - Normal filling is 75% or greater of the blood pump

   The filling and ejection of a blood pump is at its best when the membrane surface is completely smooth at the end of systole and end of diastole positions. If the pump is not ejecting completely (100%) and adequately filling (>75%) troubleshoot the cause of the problem and notify the physician immediately if the situation doesn't resolve.

   Optimal ejection (100%) and filling (75% or greater) signifies optimal patient cardiac output.

4. IKUS Driver console to be plugged into a RED wall outlet at all times.

   Red plugs are powered by a generator and will provide power to IKUS driver

5. Check that the manual hand pump is attached to IKUS driver.

   In the event of total loss of power and a depleted backup battery, the hand pump needs to be used to run the blood pumps

6. The mains power switch (toggle switch) **must** always be in the ON [I] position

   To ensure battery is charged

7. Ensure replacement IKUS is in the unit, plugged in to RED outlet with the toggle switch in the ON position [I]

   To ensure battery is charged

**ROUTINE MANAGEMENT**

<table>
<thead>
<tr>
<th><strong>Central Nervous System</strong></th>
<th><strong>Rationale</strong></th>
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<tbody>
<tr>
<td>- Neurovital signs every two hours for the first 24 hours then every 4 hours.</td>
<td>Patients are at risk of neurological events due to the potential of thrombus formation within the blood pumps</td>
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<tr>
<td>- SBS/MAPS scores in PICU every 4 hours and PRN</td>
<td>Ensures adequate patient comfort and provide medication when scores are inadequate.</td>
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<tr>
<td>- NIRS monitoring in PICU every hour and PRN</td>
<td>Identifies decreased perfusion to the brain</td>
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Ensures the blood pumps and cannulas are not manipulated (elevated / twisted) to cause discomfort to the patient and potential wound break down.
## Cardiovascular System

**Assess cardiac output:**
- hourly in PICU
- every 4 hours in CHU

**Examining:**
- pulses, capillary refill (1-2 seconds), peripheral temperature
- Continuous cardio/respiratory monitoring
- Vital signs as per policy
- IV Access as per policy
- Hemodynamic invasive lines – pressure monitoring as per policy
- 4 Quadrant BP on admission post op

Ensures adequate blood flow to all limbs following insertion.
Evaluates oxygen consumption.
Assess patient for adequate peripheral vascular resistance – vasoconstriction versus vasodilation.
Poor emptying of the pump may be a sign of high afterload.

## Drains:

**Chest tube / Blake drains:**
- Strip every 2 hours and record volume in PICU every 2 hours
- In CHU, monitor and record volume as per physicians order.

Notify physician if chest drainage:
- **first 4 hours post operative:** is greater than 5mL/kg/hr during
- **after first 4 hours** is greater than 3mL/kg/hour
- Changes color or consistency.

## Anticoagulation:

- Anticoagulation as per physician order
- Monitor and report laboratory values to physician

Maintain adequate anticoagulation to minimize thrombus formation

## Respiratory

- Continuous Pulse Oximetry as per policy
- Continuous ETCO₂ monitoring while intubated
- Daily CXR while in PICU
- CXR as per physicians order on CHU

Gives an indication of endotracheal tube placement and effective ventilation

## Gastrointestinal

- Nothing by mouth (NPO) immediately post-op
- Advance diet according to physician order.
- Consult dietician to ensure adequate nutritional support and tolerance

Nutritional support aim for 48 hours post op
Optimize nutritional support in VAD patients improves outcomes for transplant.

## Genitourinary

- Strict Intake and output every hour while in PICU and first week in CHU then according to physician order
- Daily weights as per policy

To assess fluid balance and monitor for hypovolemia and fluid overload and the impact on blood pumps for adequate filling
Goal for normal urinary output (1-2 mL / kg / hr).

## Skin

- Reposition every 2 – 4 hours post operatively when patient is hemodynamically stable
- Once stable daily physiotherapy (ROM, positioning and ambulation
- Ambulate per physician order

Early mobilization is a goal of therapy to achieve optimal physical function prior to transplant.
To prevent skin breakdown

## Dressings:

**Sternotomy - dressing change as per Sternotomy and Thoracotomy Post-Surgical Incision Care**

Ensure saturation of dressing is not present to aid wound healing.
### Procedure

**Berlin Cannula Sites** – Cardiac surgeon and cardiac NPs will perform as per Berlin dressing change policy

- Monitor patient for signs of infection at sternal incision, cannula sites, and chest drains.
- Ensure Child life involved for distraction
- Administer pain medication as needed

*Dressing may loosen and need to be changed.*

**Infections are a serious adverse event**

### Pain Management

- See RCP – Pain Management for PICU
- Complete age appropriate pain assessment Q4H and PRN
- Administer adequate analgesia PRN
- Complete pain assessment checklist as per policy

*Ensures adequate patient comfort as medication can provide when scores are inadequate*

### Labs

***Pediatric ICU***

- On arrival:
  - ABG, lactate, LFT (AST, ALT, GGT, Alk Phos, LDH, bilirubin), CBC w/ WBC diff, PT, PTT, STAT
  - ABG every 2 hours X 4, the every 4 hours X 2

- Every AM
  - ABG (ionized calcium), CBC w/ WBC diff, lactate, lytes (K, Na, Cl), BUN, Cr, LFT (AST, ALT, GGT, Alk Phos, LDH, bilirubin)

**UFH Anticoagulation**

- After 4 hours at therapeutic IV dose obtain PT, PTT
- Monitor PT, PTT every 4 hours until therapeutic levels achieved
- Monitor PT and PTT once daily thereafter

**LMWH Anticoagulation PICU**

- At 4 hours post 2nd LMWH dose (28 hours post first dose) obtain an *LMWH Anti-Xa level*
- LMWH anti-Xa level to be repeated every 4 hours after next dose until therapeutic levels achieved
- Monitor once weekly when in therapeutic range
- Refer to cheat sheet
- Valid cross-match not required unless ordered

**Labs**

***Children’s Heart Unit***

- Every Monday:
  - CBC w/ WBC diff (inc plt), lytes (K, Na, Cl), BUN, Cr, LFT (AST, ALT, GGT, Alk Phos,
### LMWH Anticoagulation CHU

- LMWH anti-Xa level to be repeated every 4 hours after next dose until therapeutic levels achieved
- Thereafter monitor LMWH anti-Xa levels once a week
- Valid cross-match **NOT** required unless ordered

### Consults for Consideration

- Child Life Specialist
- Clinical Nurse Specialist cardiology
- Dietician
- Occupational Therapy
- Physiotherapy
- Psychology
- School Teachers
- Social Work
- Spiritual Care

### Transport and ambulation

- Please refer to the Berlin transport (within hospital policy)
- A Perfusionist is required to accompany the patient on initial transports
- 1 RN with demonstrated and validated competency in management of Berlin Hearts may accompany the patient during transport without the Perfusionist being present once patient is deemed stable.

### Documentation

- Critical Care Flowsheet (PICU as per unit policy)
- Module Flow Sheet (3M) – as per unit policy
- Parameter Log BCCH590 – document Berlin Heart preset parameter settings, blood pump inspections and safety checklist.
- Bedside Safety Checklist BCCH592 – Ensure all safety equipment is present.
- Visual Pump Check BCCH591– document to identify location and type of any fibrin / clot

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**LDH, bilirubin)**

**To assist with range of motion and mobilization as soon as possible**

**To assist the patient and family with learning how to perform activities of daily living with a Berlin heart.**

**To assist the patient and family in learning how to manage with life altering condition.**

**To help the patient and family with coping through therapeutic means.**

**To assist the patient and family on a day to day basis with social and emotional needs as necessary.**

**To provide the patient and family with spiritual needs and emotional support as necessary.**

**To Provide time away from the patient care unit**

**Planning is important to ensure all therapies and clinical needs are met.**

**Perfusion to accompany all initial transports off unit**

**This will be reevaluated over the patient trajectory course, on case by case basis’.**

**Perfusion Office ext 7935 or 1st On call Perfusionist via switch**
PATIENT / FAMILY EDUCATION
Parents are a key member of the team
Education about medical issues and sibling support is vital. Please reference
- Berlin Heart Parent Booklet

CROSS-REFERENCES
CC.03.01: Vital Sign Assessment and EoPC Score
CV.02.01A: Peripheral Intravenous Therapy Troubleshooting Guidelines
CV.01.01: Maintaining infusion therapy
CV.01.10: Swabcap
CV.03.11: Citrate locking renal replacement catheters
CV.04.01: PICC Care Guideline
CC.03.04: Oximetry monitoring
CC.09.01: Chest Tubes
CC.16.01: Skin care protocol
CC.03.05: Weight and Height Measurement
CC.16.06: Sternotomy and Thoracotomy Dressing Change
CC.09.38: Berlin Heart Dressing Change
CC.09.39: Berlin Heart Transport
CC.09.39: Berlin Heart Manual Hand Pump

REFERENCES
BC Children’s team site http://teamsites.phsa.ca/sites/berlinheart/default.aspx
Sivarajan, V.B. Bohm, D. 2011. Monitoring of standard hemodynamic parameters: Heart rate, systemic blood pressure, arterial pressure, pulse oximetry and end tidal CO2. Pediatric Critical Care Medicine, 12 (4) S2-S11.
Hospital documents / guidelines from Berlin Heart Centre’s:
- St Louis Children’s hospital, St Louis, MO
- Seattle Children’s Hospital, Seattle, WA
- Texas Children’s Hospital, Houston
- Children’s Hospital of Philadelphia
- Great Ormond Street Hospital for Sick Children, London NHS, UK
- Stollery Children’s Hospital, Edmonton, Canada