Impella Temporary Circulatory Device; Care and Management

Site Applicability

PHC: Cardiac Critical Care (CSICU, CICU only)

Devices: Abiomed Impella 5.0, Impella 5.5 with Smart Assist and Impella CP with Smart Assist (Appendix A)

Practice Level

RN: Advanced, specialized skill Cardiac Critical care nurses only

Responsibilities

1. Implanting cardiology physician(s), cardiac surgeon(s), and perfusionist(s) are responsible for initial set up of the Impella
2. Cardiology physician(s) and cardiac surgeon(s) are responsible for:
    a. Initiating weaning, and determining the mode of weaning
    b. Decreasing the P-Level for the purposes of repositioning or weaning
    c. Verifying Impella position on CXR, echo, and /or fluoroscopy
    d. Repositioning the Impella catheter
        - Cardiac anesthesia may reposition catheter in urgent cases if cardiac surgeon not available using ECHO
        - Perfusionist may reposition the catheter in urgent case with instruction from implanting physician
    e. Tightening the Tuohy connection on the Impella catheter to prevent catheter migration following insertion. Tuohy connection must be tightened all the way to the right once the repositioning sheath is in place and the sterile anti-contamination sleeve has been connected. The Tuohy should be tightened before the patient is moved from the cath lab or the OR table.
    f. Suturing and securing the Impella catheter to the patient's leg with the suture pad.
    g. Removing the Impella catheter.
3. RN's or perfusionist may adjust Impella flow level as ordered by the MRP, implanting physician or as directed by Abiomed Clinical Support team. Only if chest compressions are required can the RN decrease the controller to P-2 without a physician order.

Need to Know

The Abiomed Impella 5.0 *(soon to be discontinued*) 5.5 with Smart Assist and CP with Smart Assist are temporary cardiac assist devices that provides circulatory support for left ventricular failure. The Impella device is an intravascular microaxial blood pump that delivers blood from an inlet in the ventricle through a hollow cannula to an outlet in the ascending aorta. (See Appendix B)

There is a variety of catheter insertion site options:

- Via femoral artery
- Via Axillary artery
- Direct aortic

Device	Peak flow
Impella 5.0	**Up to 5.0 L/min**
Impella 5.5 with Smart Assist	**Up to 6.0 L/min**
Impella CP with Smart Assist	**Up to 4.3 L/min**

- Impella flows (L/Min) corresponds to a programmed performance –level (P-Level).
- The Impella can be set from P-0 (0L/min) to P-9 (up to 6L/min)
- P-2 is used for repositioning, weaning, and during cardiopulmonary resuscitation (CPR) only
- P-2 is the lowest the device should run when the Impella is positioned across the aortic valve
- P-0 and P-1 are used during device removal only
- Systemic Heparin is often used in combination with Heparin Purge fluid

Safety equipment: must be at the bedside (or easily accessible nearby)

1) Back up Abiomed Impella controller: keep accessible and ALWAYS be plugged in
2) Two extra Impella tubing cassettes
3) Extension cord (for emergency AC if Impella controller battery fails during transport
4) Battery takes 5 hours to fully charge so should be plugged in even when not in use
5) Battery life = 1 hour (Keep controller plugged in when not in transit)

Protocol

Immediately following insertion, monitor VS and vascular access sites Q 15 minutes x 4, Q30 minutes x 2, then Q1 and PRN

See Appendix D for Rapid Initial Assessment Checklist

In addition to assessment outlined in B-00-13-10017: Physical Assessment (Critical Care Areas) monitor the following until Impella is discontinued.

Nursing Assessment	Intervention and Rationale
Assess and document Q1H and PRN: • VS (BP, HR, RR) • Hemodynamic monitoring parameters (CVP, PAP, PCWP, CI) as available	• The Impella is dependent on sufficient preload. If CVP is less than 10 and there are suction alarms, signs of hemolysis, or reduced Impella flows (• Consult MRP for fluid replacement order
Impella values and waveforms • P-level, Impella flows, Purge flow, Motor Current, Ao placement signal, LV Placement signal, total CO, Cardiac Power Output (if present)	• Cardiac Output and cardiac Power Output are only present on monitor with Impella Smart Assist Model and if PA catheter in place • Cardiac Output **must be entered manually at minimum Q8 h** *(if CCI or FloTrac System present. Q4 H is recommended)* • Cardiac Output Power is calculated by the Automated Impella controller (AIC) See Appendix C)
• Motor current (green waveform) • Examine waveform and determine if pulsatile or flattened	• The motor current waveform shows the energy intake of the Impella motor. The energy intake will vary depending on motor speed and pressure differences between the inlet and outlet areas on the Impella catheter • The motor current should be pulsatile because it displays differences in energy requires between the inlet in the left ventricle and the outlet in the aorta, relative to the aortic valve. As the aortic valve opens and closes, the Impella detects the differences and displays a pulsatile motor current. If flattening of the motor current waveform occurs, you will get **an Impella Position Wrong** Alarm. Call the MRP or Abiomed hotline for support. • When the motor current waveform is flattened, the Impella is not providing hemodynamic support- **treat patient medically as required**

• Ao Placement signal *(red waveform)* • LV placement signal *(white waveform) with Smart Assist models*	• The **Ao** placement signal is a differential sensor; the signal displays the pressure differential between the ventricle and the aorta. The Impella 5.0 has an electronic differential sensor located next to the motor. The Placement signal is approximately equal to the difference between the aortic pressure and the ventricular pressure. • LV waveform signal displays automatically when running at P4 or higher, including auto mode (P3 or lower, the values and waveform are automatically disabled) • LV waveform adjusts in increments of 1 mmHg from - 60 to 60 mmHg • Only adjust LV placement signal when prompted by the AIC or when changing the purge bag viscosity
• Purge pressure (300 to 1100 mmHg) • Purge flow (mL/h) The Abiomed console maintains the flow rate between 2 to 30 mL/h Heparin Purge infusion use Dextrose 5% and concentration 25 units/hour (default)	• Impella console automatically adjusts purge flow rate to maintain purge pressure • If low/high purge pressure alarms are activated (e.g. PURGE PRESSURE LOW"), follow instructions on the screen, and call Abiomed if needed • Recommended Heparin concentration is 25 units/mL however; if there are issues with elevated PTT or bleeding heparin can be removed from purge infusion for up to 12 hours • Abiomed recommends keeping ACT 160 to 180 Generally at PHC, we use a corresponding PTT range of 55 to 80 seconds
Characteristics of any percutaneous sheath introducer in situ and /or procedural puncture sites: • Observe for signs of bleeding (blood at sites, swelling or palpable hematoma, bruising) • Limb perfusion: colour, warmth, movement and sensation; palate (or Doppler) peripheral pulses; observe capillary refill • Apply Limb oximetry sensors (if femoral cannulation)	Notify MRP immediately if assessment reveal: • Active bleeding or expanding hematoma at any percutaneous sheath insertion and /or puncture site(s) • Signs of diminished peripheral circulation or limb ischemia (e.g. diminished pulse strength, cool skin, pale/dusky skin pallor, mottling, new sensory changes such as numbness/tingling)

Urine: amount output and characteristics of urinary drainage (note colour)	Notify MRP immediately if assessment reveals: • Urine output less than 0.5 mL/kg/hr • Signs of hemolysis: sudden discoloration of urine to tea tinged, rust like, or red/bloody; unexplained decreasing hemoglobin, increasing plasma free hemoglobin level
Assess **skin integrity Q2 H** and PRN • Reposition patient using log roll technique Q2H • Request KCL TheraPulse bed (or similar) if more than 48 hours intubation is anticipated	**If femoral insertion**: • Avoid leg flexion and position head of bed no greater than 30 degrees. Use knee immobilizer as needed to maintain access site straight **If subclavian insertion**: • Ensure there is an individualized mobilization **physician order** • Ensure all connections are tight prior to mobilization • Nurse to accompany patient at all times when ambulating
Assess and document Q4H & PRN • Heart sounds: clarity, Auscultate Impella sounds • Measure and record right and left calf circumference in cm (femoral insertion) • Measure and document the catheter placement at the white hub	• When possible, establish and document baseline calf circumference measurement (prior to device insertion) • Mark calf measurement point with indelible marker to maintain consistent calf circumference measurement • Note black measurement markings on Impella catheter. Each single black marking is 1 cm; 5 cm increments are noted with numbers *If Axillary insertion: document catheter measurement before and after ambulation*
Q 8 hours **For Smart Assist Impella only** • Manually enter the cardiac output at minimum Q8 hours • Adjust LV Placement signal *ONLY* when prompted by screen notification	• After 7 hours from entry, a white screen notification will appear will trigger to enter a new cardiac output • The console will then calculate the CPO (Cardiac Power Output) • LV waveform adjustments occur in increments of 1 mmHg from -60 to 60 mmHg. *(Do not adjust to a value other than the suggested value)*

Perform the following Impella checks at start of every shift and PRN • Ensure backup Impella controller is in room or near patient room and is easily accessible • Ensure two Impella tubing cassettes are in the patient room and easily accessible • Tuohy connection must be tightened to the right and locked to prevent catheter displacement • Check purge solution: Ensure correct solution recommended is Dextrose 5% with Heparin 25 units/mL • Ensure the clear purge clip is attached to the connector cable (located on the pressure reservoir of the clear sidearm)	• Twisting the Tuohy to the right tightens the connection and secures the catheter. Twisting the Tuohy to the left will loosen the catheter • Ensure there is a date label to both the purge solution bag and purge cassette tubing. The dextrose/heparin purge solution bag must be changed every 24 hours. Provide pharmacy with 2 hours notice to allow for preparation of dextrose/heparin purge solution • **To change purge solution:** select the soft button PURGE SYSTEM, select CHANGE PURGE FLUID and then follow the prompts on the console to change the fluid • Is important to prevent tube from kinking
Perform following **daily &PRN** • Inspect clear occlusive dressing at insertion site • **Ensure that the access angle of the Impella catheter is maintained by supporting with a 2 X 2** • Daily ECHO is recommended (as per the provider order) • Blood work is usually performed daily (as per provider order) • Add Plasma Free HgB (or Haptoglobin and LDH) to assess for hemolysis (as per provider order)	• Change initial dressing within 24 hours and then Q72 H and PRN. • Avoid placing adhesive dressing (e.g. Tegaderm) over Tuohy connection or contamination shield • Do not press catheter down so it is flat to skin **Provider is responsible for verifying Impella position via ECHO**

Perform the following Q5 days • If purge solution is D5%, change the purge tubing cassette every 5 days	• Remove replacement cassette from packaging. Note the white clamp underneath the drip chamber; NEVER clamp this, it will create air in the tubing. • Place the replacement purge solution bag onto the IV pole. Spike the bag without inverting to avoid air in the tubing • To change purge cassette: select PURGE SYSTEM, select PURGE SYSTEM CHANGE, follow directions on console (remember to discard the Y-connector filter extension that comes with the new cassette prior to connecting the catheter) • Place a sterile 4 x 4 underneath the yellow-yellow luer connection to maintain sterility. Do not clean any of the components of the infusion Filter or the Pressure Reservoir with Alcohol

Weaning

- See Appendix E for samples of General weaning guidelines and processes
- Weaning process is individualized to the patient by the MRP
- LVEDP/CO Trend screen
  - Displays trends for Mean Ao, LVEDP, Cardiac Output (CO), Native Cardiac Output (NCO) and Impella flow
  - These trends should not be used for diagnostics purposes but can give additional information when weaning and decreasing Impella flow

Following discontinuation of Impella

- VS and Hemodynamic parameter monitoring:
  Q15 min X4; Q30 X2; Q1H X4 and PRN; and then per unit routine (B-00-13-10017)
- Peripheral vascular assessment to the affected extremity immediately after removal:
  Q1H X2; Q2H X3; and then Q4H per unit routine (B-00-13-10017)
- Calf/or arm circumference measurement Q4 H X24 H (if femoral insertion)

Emergency Management:

- If CPR is required, start CPR as per usual, decrease Impella to P-2 *(unless otherwise ordered by MRP*) and notify MRP.
- P-2 is used during CPR to minimize potential damage related to dislodgement during resuscitation. Once cardiac function has been restored, echo should be used to re confirm placement. Increase P-level by two levels at a time until Impella flow catches up to the P-level and desired P-level is achieved.

ABIOMED strongly recommends decreasing Impella to P-2 during CPR but MRP can may give alternative individualized directives- any deviation from ABIOMED recommendations should be discussed with team and entered as a communication order by the MRP

- **If defibrillation and /or cardioversion is required: defibrillate/cardiovert as usual**. During defibrillation and cardioversion, do not touch the Impella catheter, cables, or Impella controller.

  Note: P-level does not need to be adjusted for defibrillation
- **ECHO** should be done after either of these interventions to ensure catheter remains in proper position

Documentation:

1. ***Perfusion Staff will enter in Cerner information related to initial insertion of device***

2. **Nursing documentation**
   Cerner
   - Use the Mechanical Circulatory Support Navigator Band>> Ventricular Assist device>>Create dynamic group>> Impella
   - **Assessment documentation**
     ECLS assessment and Adult Critical Care Assessment 1-2
   - **To capture Vital signs**
     VS section

3. **MAR:** Document Heparin dosing for both Purge cassette system and systemic Heparin (if applicable)

4. **Heart Centre Care Map**

Patient/Family Education & Resources

1. Purpose and function of Impella
2. Routine nursing actions and assessments
3. Other routine assessments (e.g. ECG, CXR, echo)
4. Positioning and mobility restrictions (for femoral insertion>HOB no higher than 30 degrees, leg to remain straight
5. Process and expectations of weaning and removal

Related Documents

1. B-00-12-10021 – Neuro Vascular Assessment (CWMS)
2. B-00-13-10011 – Cardiac Monitoring Protocol
3. B-00-12-10018 – ST Segment Monitoring: Initiating

4. B-00-13-10063– Cardiac Cath Lab: Post Procedure
5. B-00-13-10017 – Physical Assessment (Critical Care Areas)
6. B-00-13-10025 - Cardiac Surgery Post Op Care Protocol
7. B-00-13-10149 - Braden Scale Risk Assessment and Pressure Ulcer Prevention Care Plan
8. www.abiomed.com
9. www.heartrecovery.com

References:

1. Abiomed Inc. (2020). Impella Ventricular support Systems Impella 2.5, Impella 5.0, Impella LD, 5. Instructions for use and clinical reference manual. Abiomed Inc. Danvers, MA. Available online: www.abiomed.com
2. Abiomed Inc.(2020). Impella CP with Smart Assist Instructions for use & Clinical reference Manual Abiomed Inc. Danvers, MA. Available online: www.abiomed.com
3. Abiomed Inc. (2020). Impella 5.5 with Smart Assist Instructions for use & Clinical reference Manual Abiomed Inc. Danvers, MA. Available online: www.abiomed.com
4. Abiomedtraining.com
5. Impella App Medical ,Abiomed Inc

Appendices

Appendix A – Impella Catheters

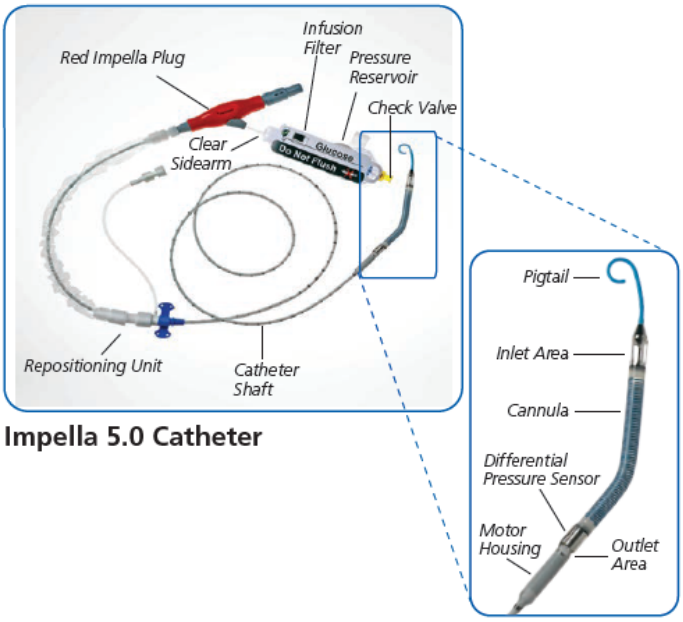
Appendix B – Placement of Impella Catheters

Appendix C – Sample Impella Flow Rates

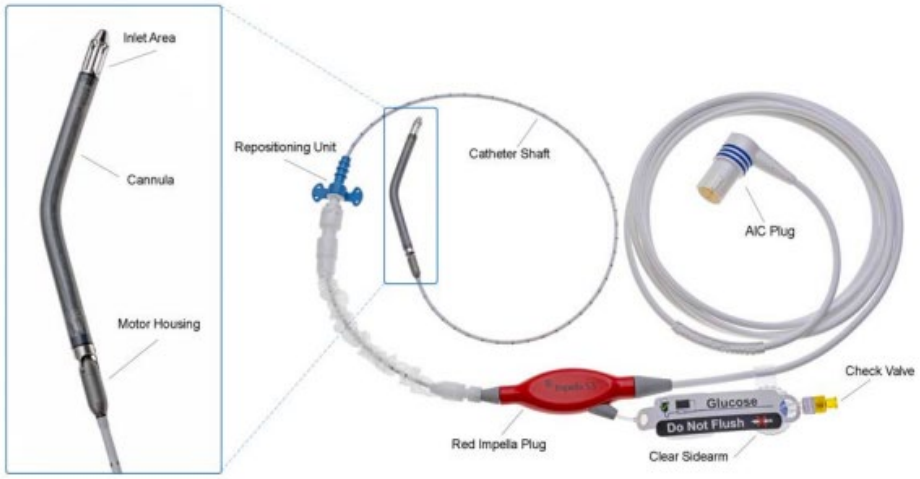
Appendix D – Rapid Initial Assessment Checklist

Appendix E – Impella Weaning and Removal Guidelines

Appendix A – Impella Catheters

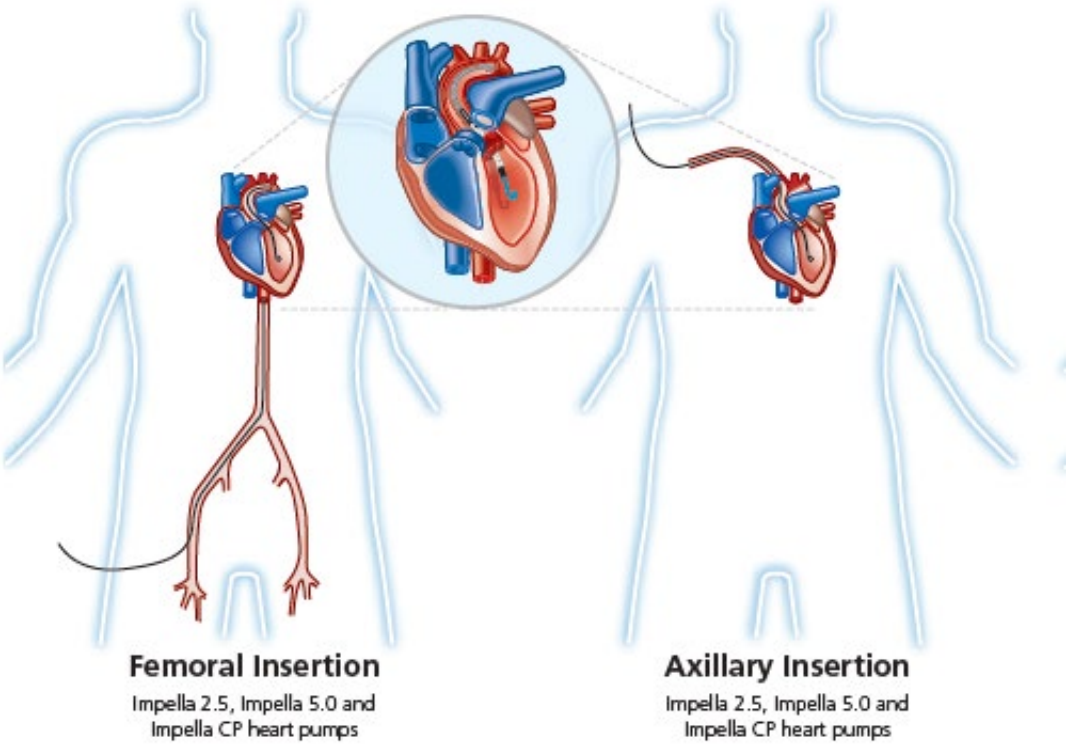


Impella 5.0 Catheter



Impella 5.5 with Smart Assist Catheter

Appendix B. Placement of Impella Catheters



Inserted through the femoral or axillary artery into the left ventricle

Appendix C: Sample Impella Flow Rate charts

Impella 5.0 P- Level flow rates

Impella 5.0, Impella LD

P-level	*Flow Rate (L/min)	Revolutions Per Minute (rpm)
P-0	0.0	0
P-1	0.0 – 1.4	10,000
P-2	0.5 – 2.6	17,000
P-3	0.5 – 3.1	20,000
P-4	0.9 – 3.4	22,000
P-5	1.4 – 3.7	24,000
P-6	1.8 – 4.0	26,000
P-7	2.6 – 4.4	28,000
P-8	3.4 – 4.7	30,000
P-9	4.2 – 5.3	33,000

* Flow rate can vary due to suction or incorrect positioning.

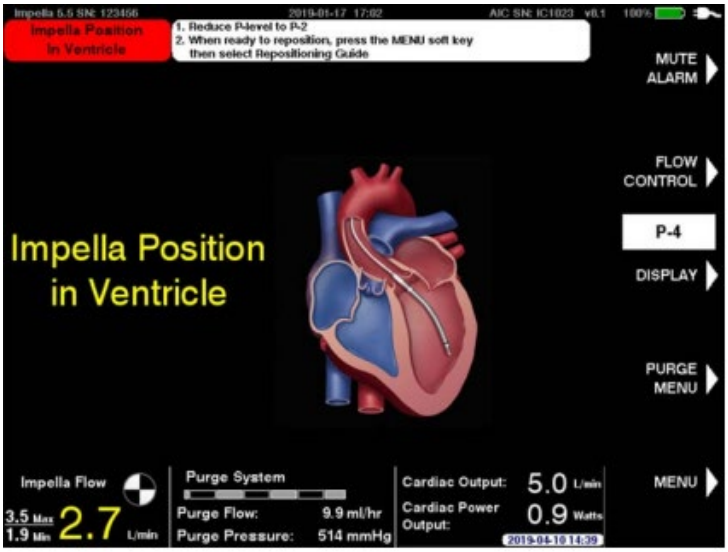
Impella CP with Smart Assist P- Level flow rates

P-level	*Mean Flow Rate (L/min)	Revolutions Per Minute (rpm)
P-0	0.0	0
P-1	0.0 - 0.9	23,000
P-2	1.1 - 2.1	31,000
P-3	1.6 - 2.3	33,000
P-4	2.0 - 2.5	35,000
P-5	2.3 - 2.7	37,000
P-6	2.5 - 2.9	39,000
P-7	2.9 - 3.3	42,000
P-8	3.1 - 3.4	44,000
P-9 **	3.3 - 3.7	46,000

Impella 5.5 with smart Assist P- level flow rates

P-level	Flow Rate (L/min)	Revolutions Per Minute (rpm)
P-0	0.0 - 0.0	0
P-1	0.0 - 1.5	12,000
P-2	0.0 - 3.1	17,000
P-3	0.0 - 3.8	20,000
P-4	0.1 - 4.1	22,000
P-5	0.2 - 4.7	24,000
P-6	1.0 - 4.8	26,000
P-7	1.6 - 5.1	28,000
P-8	2.6 - 5.4	30,000
P-9	4.0 - 5.9	33,000

Home Screen of Impella 5.5 with smart assist



Appendix D: Rapid Initial Assessment Checklist

BASIC SAFETY

- Display Abiomed hotline & clinical rep contact numbers. **Call Abiomed rep once patient has arrived into the unit** (or in some cases perfusion will call from the OR)
- Locate PHC perfusion contact numbers on console
- Attend the Abiomed Academy (if time allows) online Impella education program. Go to www.abiomed trainng.com OR click on Abiomed APP for quick review
- Retrieve correct clinical resource manual (e.g. Impella resource book)
- Check safety equipment: Ensure backup controller is in/or near patient room and is easily accessible
- **If patient requires transport:** retrieve extension cord for emergency connection to AC power (if battery failure)
- **Implanting physician to do the following:** ensure connections are secured (prevent dislodgment movement of Impella catheter- ensure Tuohy connection has been tightened

PURGE SOLUTION & PURGE TUBING

- Check purge solution: Ensure dextrose solution with Heparin additive
- Verify purge tubing is correctly set-up
- Purge connector should be attached directly to all Impella (extra **Y-connector that comes with cassette kit is *no longer used***)

PLACEMENT CONFIRMATION

- Physician to confirm placement with ECHO

ADDITIONAL

- Admission bloodwork drawn (regular coagulation screen , CBC, and lytes
- Consider Systemic Heparin infusion in addition to heparin in purge solution
  Generally: if patient less than 80 kg Purge Heparin is usually sufficient
  If patient more than 80 kg systemic Heparin might need to be add
  Confirm with MRP
- Monitor PTT to keep in range of 55 to 80 seconds (is comparable with Abiomed recommendation of ACT 160 to 180)
- Clarify mobility orders **(If Subclavian insertion)**

Appendix E: Impella Weaning and Removal Guidelines

Guidelines only

Check with Surgeon for Individual Care Plan

- Echo or PA parameter are used to guide weaning process
- How quickly the device is weaned, depends on the level of support the patient has been receiving. Follow physician's orders.
  Do not decrease the P level any lower than P2
  The pump must be at P2 to avoid retrograde flow
- Once weaned, the implanting physician or delegate is permitted to remove the device

Quick weaning

Done under ECHO guidance with the implanting physician at the bedside

Decrease the Performance level by 2. Stay at each level for a minimum of 2 minutes

When P2 reached, wait for a minimum of 5 minutes

Slow weaning

Decrease the Performance level by 2 every 2 to 3 hours for a cardiac index greater than 2.2 as determined by the PA line

When P2 reached, maintain P2 for 2-3 hours and notify implanting physician

Removal

Performance levels must be changed as he the device is being removed.

During the removal the pump must be at P-0 as it is pulled from the patient

Following removal, Monitor site as per Sheath removal Protocol; maintain bedrest for 4 to 6 hours (if femoral cannulation) monitor site and hemodynamics (See Nursing Assessment)

Persons/Groups consulted:

Cardiac surgeon (Transplant and Assist Devices)

Cardiac Anesthesia

Clinical Nurse Specialist Cardiac Program HF

Abiomed Consultant

Abiomed Clinical Educator

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