INSERTION OF A SHORT-TERM EXTERNAL HEART ASSIST SYSTEM WITH CONDUIT

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Advent Health

Coordination and Maintenance Committee Meeting

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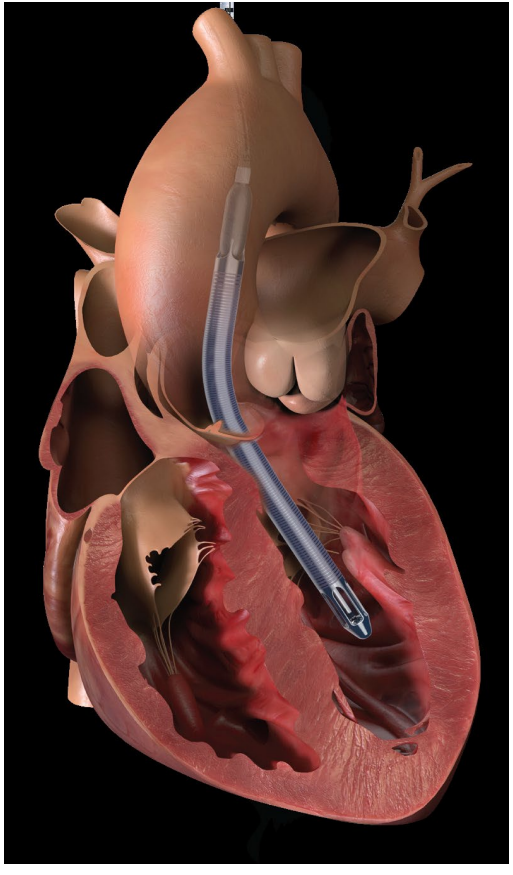
BACKGROUND



Impella 5.5 Heart Assist device

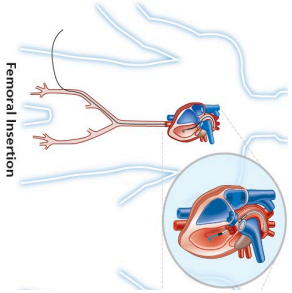
- Medicare patients with advanced heart failure are among the highest acuity patients and most costly.
- Coronary artery disease and heart failure are the number one cause of death in US

THE IMPELLA OF TODAY IS NOT THE IMPELLA OF YESTERDAY

Fifteen years ago, predominant approach for short-term heart assist devices (6 hours up to 4 days)

- Femoral pVAD insertion in the cath lab*
- Limited open procedures performed

Femoral Insertion (leg) in Cath Lab



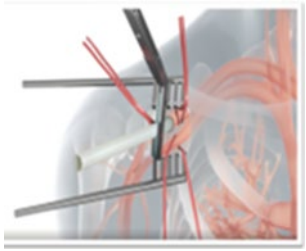
Impella CP

2008 on Market. 2015/16 FDA PMA Approved for High-Risk PCI ≤ 6 hrs & AMI-Cardiogenic Shock (CS) ≤ 4 days

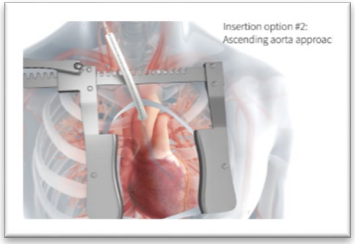
More recently, surgical insertion procedures with longer-term duration devices up to 14 days

- Operating Room procedures
- Requires surgical exposure and cut down, anastomosis, grafts, and allows for patient ambulation

Newer Axillary Insertion with cutdown in OR



Open/Direct Aortic in OR



Impella 5.5

2019 Impella 5.5
FDA PMA Approved Cardiogenic Shock 14 days

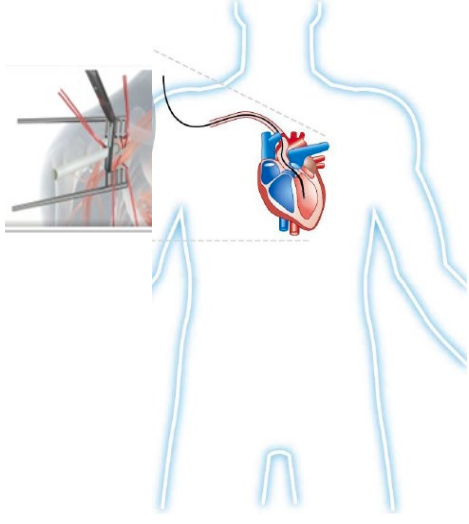
As Short-Term Heart Assist Systems have evolved to treat the **most hemodynamically compromised** patients with higher flow, an additional code is needed to reflect further differentiation between the procedures.

*When anatomy and axillary vessel not viable, Impella CP can be inserted axillary (less than 1% of cases)

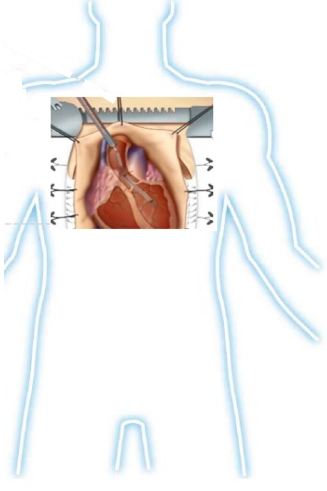
Access Site of Insertion

Impella 5.5

The Impella Catheter is an intravascular microaxial blood pump that supports a patient's circulatory system. The Impella 5.5 Catheter is inserted **via surgical cut-down through the axillary artery** and into the left ventricle.



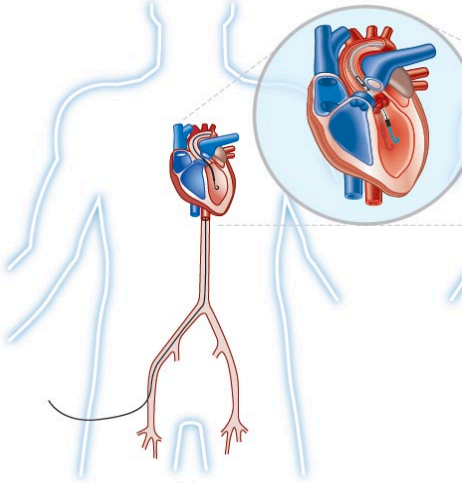
Axillary Insertion, Predominant Use



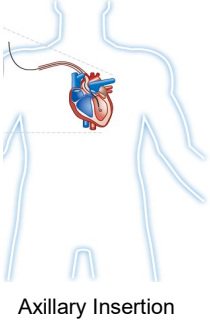
Direct Aortic (open) Insertion

Impella CP

The Impella Catheter is an intravascular microaxial blood pump that supports a patient's circulatory system. The Impella CP® with SmartAssist® Catheter can be **inserted percutaneously** through the femoral or axillary artery and into the left ventricle.



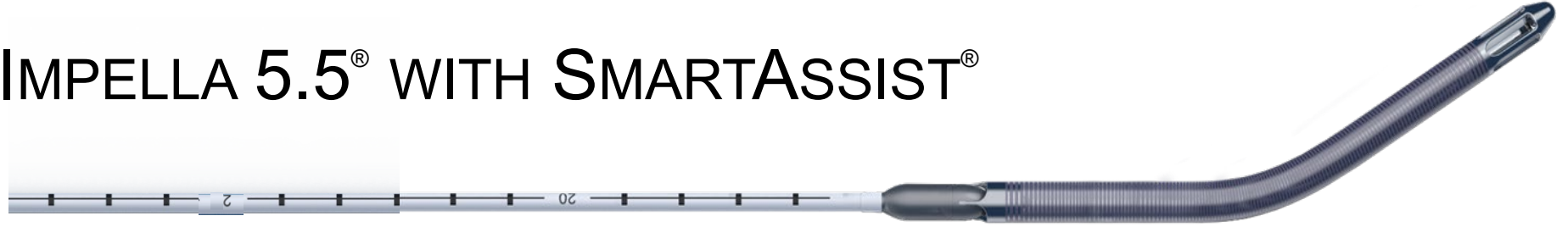
Femoral, Predominant Use



Axillary Insertion

Limited use; when restricted by patient anatomy (less than 1% of cases)

IMPELLA 5.5® WITH SMARTASSIST®



Ease of Insertion
Via the axillary artery or the anterior aorta, surgical graft required

Designed for Longer Duration Support
Facilitates patient ambulation and mobility

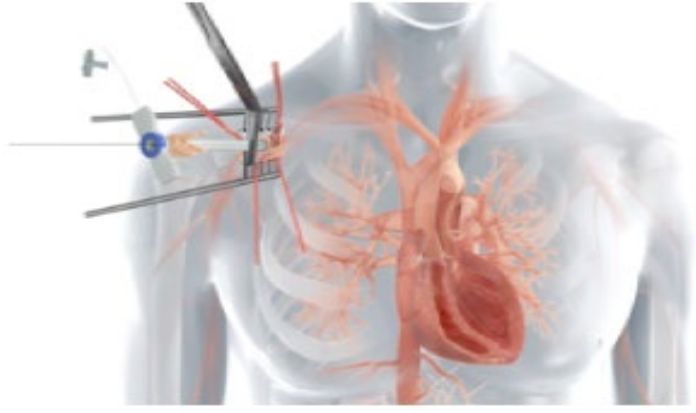
Forward Flow with Maximum Unloading
End organ and coronary perfusion, allowing the heart to rest

Enables Heart Recovery
Minimally-invasive, weanable, heart assist device

Ease of Patient Management
Intelligently position, manage and wean with SmartAssist

IMPELLA 5.5 AXILLARY: A MORE COMPLEX PATIENT

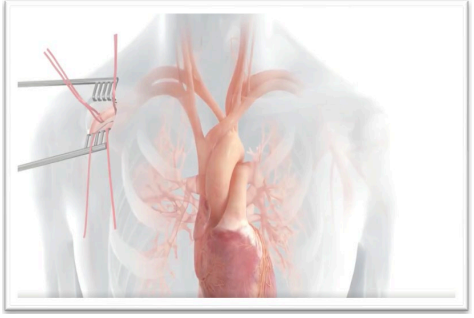
Surgical implantation in the O.R. treats the most hemodynamically compromised patients

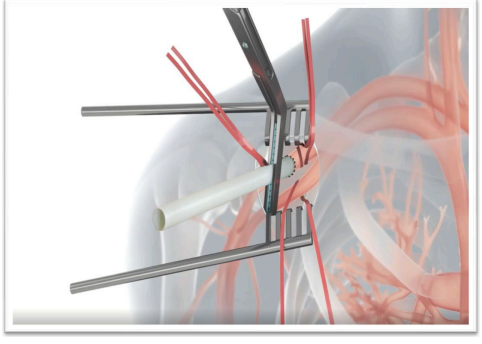


- Full hemodynamic support of 5.5 L/min; comparable to an LVAD
- Axillary insertion/explant
- Anastomosis (graft implantation and connection to vessel)
- Allows patient ambulation
- FDA Label up to 14 days

Newest Technique: Axillary Graft Insertion

1. A 4-5cm infraclavicular incision is made below the middle third of the clavicle. The subcutaneous tissues are dissected using electrocautery with blunt dissection through the pectoralis major fibers. The tendon of the pectoralis minor muscle is identified and gently retracted laterally.
2. The clavipectoral fascia is incised and the axillary artery dissected free and mobilized proximally and distally, preserving the axillary vein and brachial plexus fibers.
3. Systemic heparin is given, and the axillary artery is clamped proximally and distally (can use side-biting clamp) and a longitudinal arteriotomy is performed using a #15blade
4. A 10 mm graft beveled at a 60-degree angle is anastomosed in and end-to-side fashion to the axillary artery using continuous monofilament suture
5. Externalize the graft through the same incision or through a short lateral counter-incision
6. Insert 23 Fr. sheath from axillary kit into graft and secure with provided graft lock





Newest Technique: Axillary Graft Insertion, Cont.

7 Place 0.018” guidewire with the assistance of a diagnostic coronary catheter

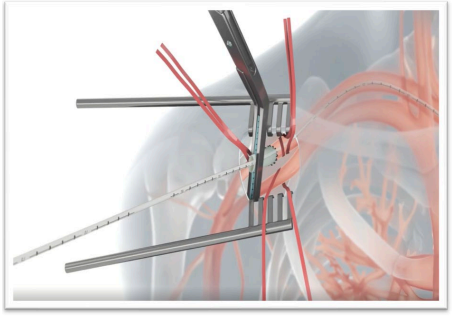
8 Once catheter is removed, insert silicone-coated dilator to lubricate valves of sheath and then remove

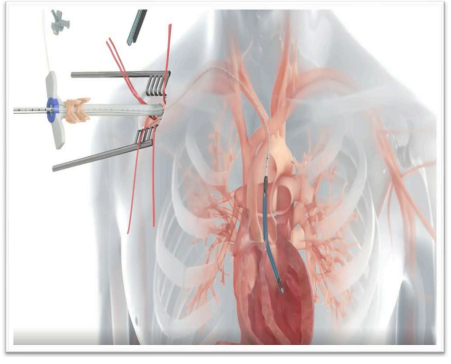
9 Clamp graft at anastomosis and backload Impella 5.5 device onto guidewire

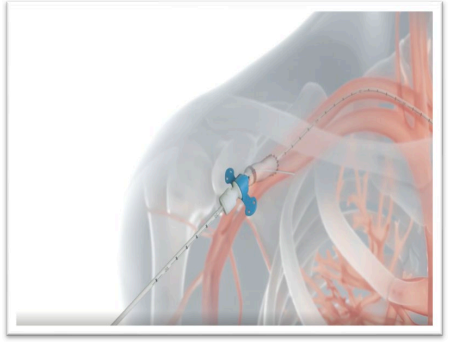
10 Once the device is fully in the graft, remove clamp and advance Impella 5.5 into left ventricle

11 After placement, place soft-jawed clamp at anastomosis; remove peel-away from the graft and peel away. Trim graft so that skin can be closed over graft

12 After ensuring hemostasis, the incision is closed in layers using absorbable suture

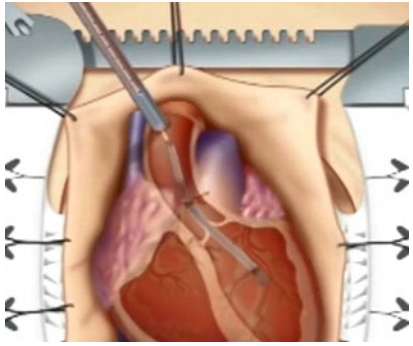






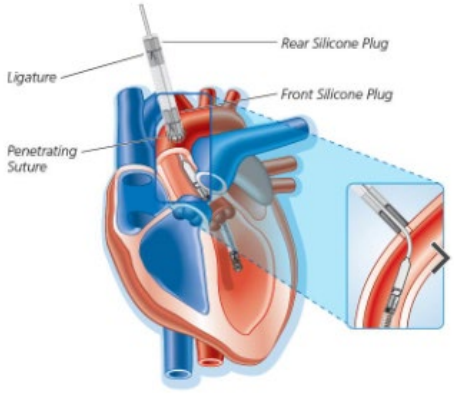
Graft Insertion via Direct Aorta

1. Using the supplied sterile incision template for positioning, place a sidebiter clamp on the aorta at least 7cm above the valve plane and identify the aortic insertion site.
2. Place a partial occluding clamp on the greater curvature of the distal ascending aorta at the insertion site. Make an incision (or punch) no larger than 6mm at the insertion site on the ascending aorta.
3. Create an end-to-side anastomosis with a beveled Dacron vascular graft (10mm x 15cm) to the aorta using continuous monofilament suture.
4. Administer heparin and achieve ACT of at least 250 seconds.
5. When the anastomosis is complete, place a clamp at the distal end of the graft and then release the proximal clamp at the base of the graft. Ensure hemostasis of the anastomosis and re-clamp the graft at the base.
6. Push both pre-loaded silicone plugs flush to the motor and insert into graft
7. With the graft clamped at the base, place the Impella 5.5 catheter into the open end of the graft up to the level of the rear plug

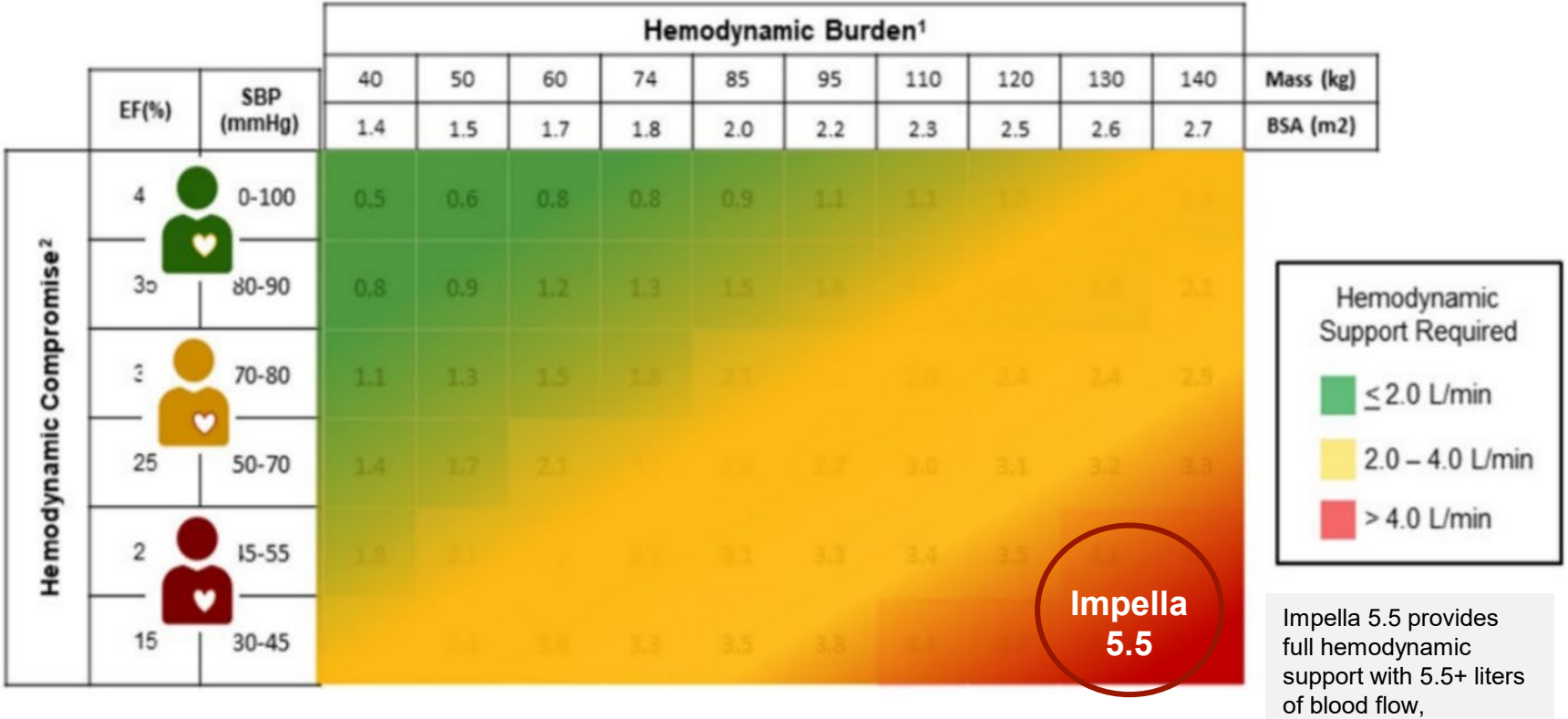


Graft Insertion via Direct Aorta, Cont.

8	When the catheter is in position, secure a tourniquet around the rear silicone plug. Tighten the tourniquet sufficiently to control bleeding around the rear plug while still allowing the catheter to slide through the plug.
9	Release the clamp and advance the Impella 5.5 catheter into the aorta
10	If the patient is on cardiopulmonary bypass (CPB), temporarily reduce flow to allow the heart to fill with blood to facilitate positioning.
11	As soon as the motor housing has passed into the aorta, use a ligature to loosely secure the front silicone plug flush to the graft. The silicone plug should be in the most proximal portion of the graft.
12	While the catheter is being advanced into the aorta do not allow the front plug to advance beyond the base of the graft.
13	To aid in passing the catheter through the aortic valve, apply slight pressure to the posterior aspect of the aortic valve to produce temporary aortic insufficiency.
14	Gently advance the catheter forward, confirming the Impella 5.5 mid-inlet is approximately 5cm below the aortic valve annulus. Confirm catheter position using TEE.
15	Ensure that the front plug is flush against the aorta and secure it by using a penetrating suture ligature. Remove the rear plug and clear vascular graft of excess blood; re-secure rear silicone plug against the front plug and suture. Trim graft.



5.5 Axillary Treats Most Hemodynamic Compromised Patients as Compared to Lesser Flow Devices



Impella 5.5 provides full hemodynamic support with 5.5+ liters of blood flow, supporting patients with the most significant hemodynamic compromise.

1.de Simone G, et al. Stroke Volume and Cardiac Output in Normotensive Children and Adults. Assessment of Relations With Body Size and Impact of Overweight. Circulation 1997;95(7):1837-43
2.Burkhoff D, et al. HARVi – Interactive Cardiovascular Simulation, TCT 2012

QUESTIONS?