Abiomed TCT Update: Key Clinical Data

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U.S. Food and Drug Administration Approvals

- *The Impella 2.5, Impella CP and Impella CP with SmartAssist are indicated for providing temporary (< 6 hours) ventricular support during elective or urgent high risk percutaneous coronary interventions (PCI) performed in hemodynamically stable patients with severe coronary artery disease, when a heart team, including a cardiac surgeon, has determined high risk PCI is the appropriate therapeutic option. Use of the Impella 2.5, Impella CP and Impella CP with SmartAssist in these patients may prevent hemodynamic instability which can result from repeat episodes of reversible myocardial ischemia that occur during planned temporary coronary occlusions and may reduce peri- and post-procedural adverse events.*

- *The Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, Impella 5.5 with SmartAssist and Impella LD Catheters, in conjunction with the Automated Impella Controller, are temporary ventricular support devices intended for short term use (≤4 days for the Impella 2.5, Impella CP and Impella CP with SmartAssist and ≤14 days for the Impella 5.0, Impella 5.5 with SmartAssist and Impella LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (<48 hours) following acute myocardial infarction or open heart surgery, or in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures (including volume loading and use of pressors and inotropes, with or without IBP). The intent of the Impella Support Systems therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.*

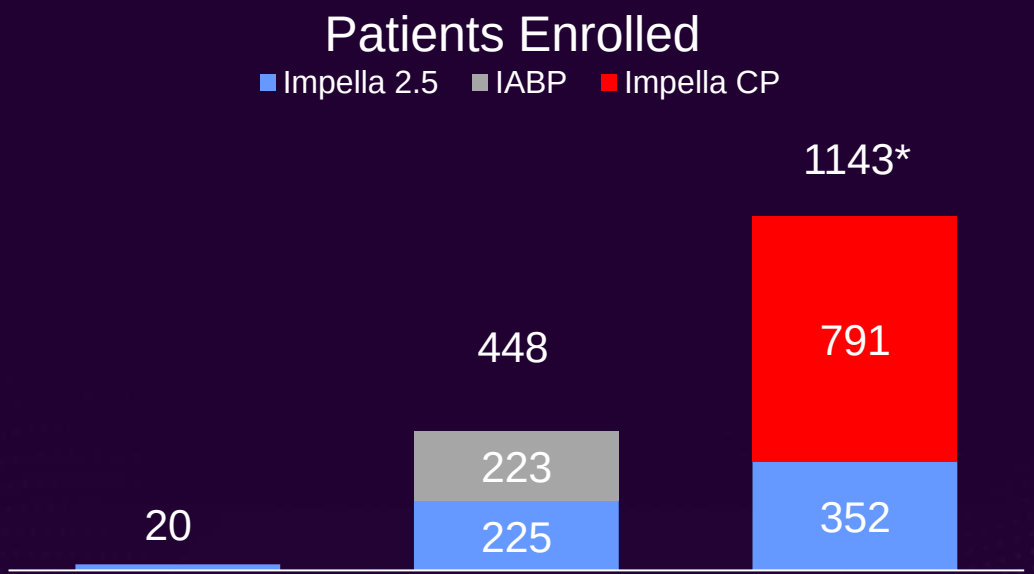
- *The Impella RP® is indicated for providing circulatory assistance for up to 14 days in patients with a with a body surface area ≥ 1.5 m^2 who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery.*

In addition, there are other WARNINGS and PRECAUTIONS associated with Impella devices. Visit http://www.abiomed.com/important-safety-information to learn more.

Impella ECP™, Impella BTR™, and The Impella Pediatric™ are in development and are not approved for use or sale in the US.

PROTECT Study Enrollment

Largest FDA High Risk PCI Study (N=1,611)



*45 Sites
All Comers with HRPCI Indication
1143 Patients enrolled between Mar 2017 and Sept 2019
Ongoing Monitoring

Contemporary Practices of HR-PCI Using Percutaneous MCS: Results from PROTECT III, the Largest Prospective Multi-Center Single-Arm Study

METHODS

- PROTECT III is an ongoing prospective, multicenter, single-arm post-market approval study
- From March 2017 to September 2019, 1,143 patients undergoing elective non-emergent PCI with Impella® pMCS from 45 sites
- Study data were entered by investigational sites into an electronic database and are monitored against source documents/medical records
- The composite Primary Endpoint is adjudicated by an independent clinical events committee
- SYNTAX and Ischemia Scores were adjudicated by angiographic core lab
- Outcomes of patients in the PIII study were compared with those of patients from the PROTECT II RCT, both unmatched and using propensity score matching

Patient Flow

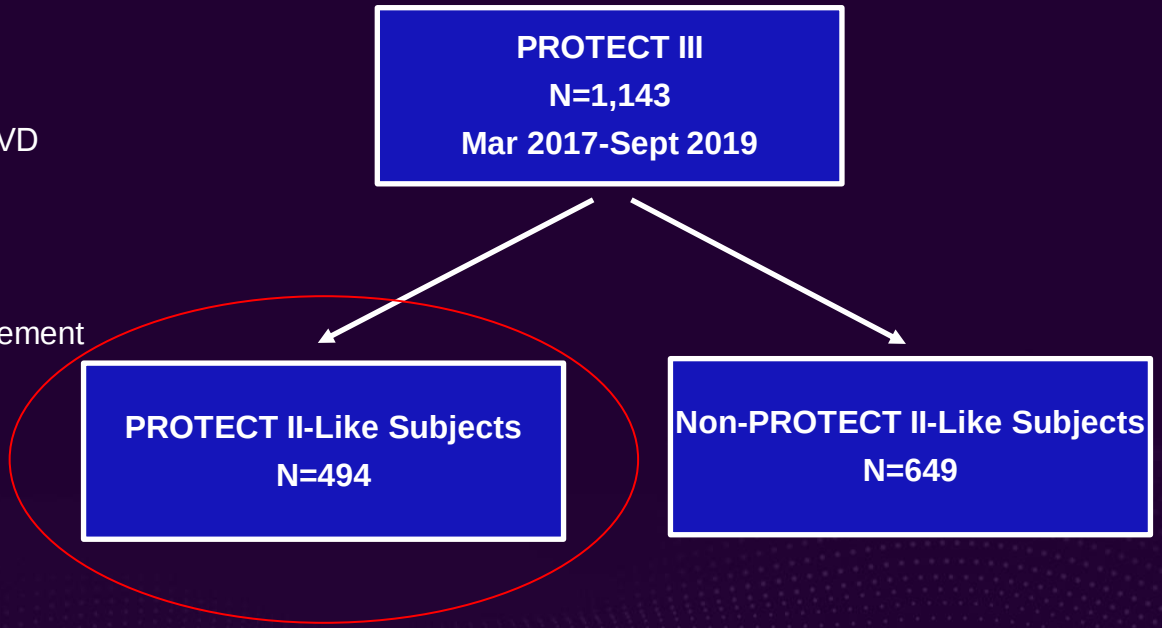
PROTECT II-Like

- LVEF ≤35% with ULM or LVEF≤30% with 3VD

AND

Absence of

- STEMI within 24 hours prior to Impella placement
- Cardiogenic Shock
- Renal failure w/ Cr≥4mg/dL
- Plt count ≤75,000/mm^3

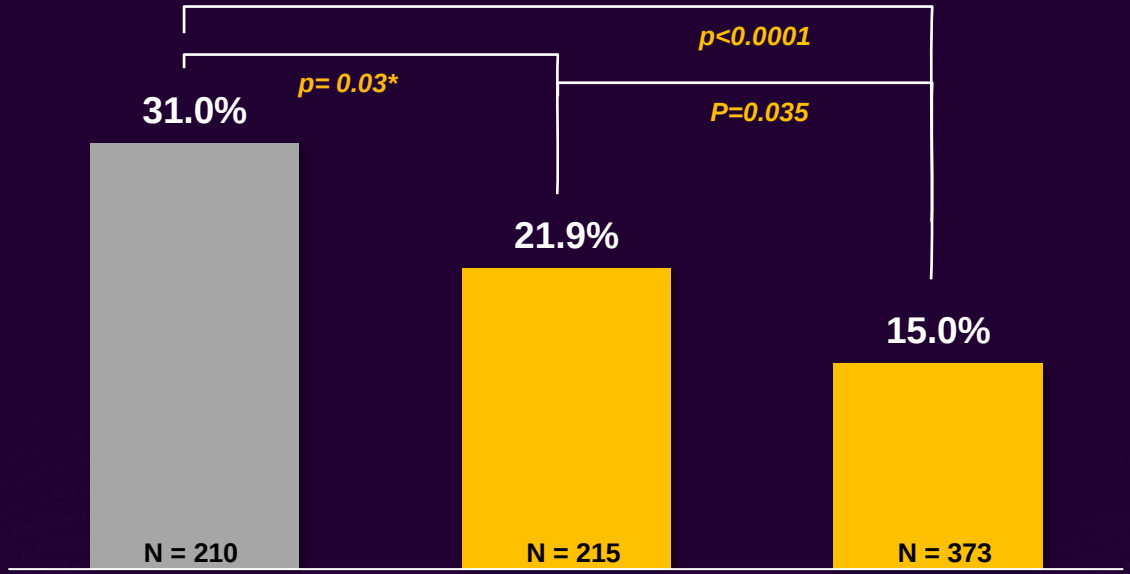


Current analysis compares PROTECT III PROTECT II-like subjects to PROTECT II RCT

BASELINE CHARACTERISTICS VS. PROTECT II

	PROTECT III		PROTECT II			
	All N=1143	Non-PROTECT II-Like N=649	PROTECT II-Like N=494	Impella 2.5® N=216	p-value PII-Like vs PII	p-value PIII vs PII
Age	70.9±11.0	72.17±11.07	69.29±11.18	67.5±11.0	0.05	<0.001
Sex - Female	28.26%	32.05%	23.28%	19.4%	0.257	0.007
Race - Caucasian	77.7%	78.47%	76.85%	83.8%	0.039	0.047
Hypertension	91.3%	88.30%	93.82%	88.0%	0.900	0.124
Diabetes	55.2%	56.56%	54.11%	53.2%	0.414	0.603
Prior Stroke	17.9%	20.28%	15.05%	12.0%	0.290	0.037
Renal Insufficiency	31.2%	34.99%	26.45%	22.7%	0.290	0.012
COPD	23.1%	24.69%	21.16%	26.1%	0.155	0.348
NYHA Class III/IV	73.5%	70.94%	75.69%	67.4%	0.072	0.132
Surgical Turndown	54.07%	51.36%	57.33%	63.43%	0.133	0.012
Prior CABG	14.56%	15.06%	13.91%	39.35%	<.001	<.001
Prior MI	39.76%	39.29%	40.38%	69.30%	<.001	<.001
MAP	89.0±15.5	89.70±16.02	88.10±15.01	88.4±14.6	0.842	0.573
LVEF%	32.4±15.4	43.53±14.67	22.64±7.09	23.4±6.3	0.176	<0.001

90-DAY MACCE: PROTECT III PROTECT II-LIKE PATIENTS VERSUS PROTECT II RCT

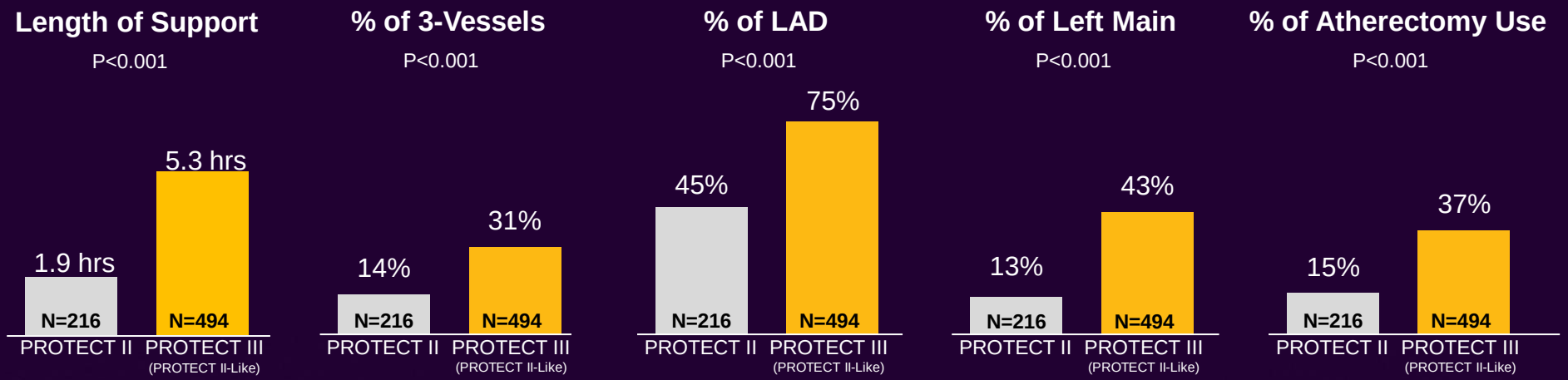


N = number of patients with 90-day follow-up

MACCE: Death, Stroke, MI, Repeat Revascularization

***Dangas et al. *Am J Cardiol.* 2014;113:222-228**

PROTECT III PROTECT II-LIKE PATIENTS SHOW MORE COMPLEX LESIONS



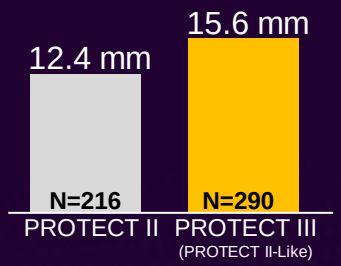
	PROTECT II (Impella 2.5, N=216)	PROTECT III (PROTECT II-Like, N=494)	p-value
# Vessels Treated	1.81±0.67	2.09±0.73	<0.001
LCx	45.89%	62.07%	0.028
RCA	19.20%	35.29%	0.111
Contrast Volume (mL)	267.5±141.7	210.87±113.29	<0.001
Patients discharged from the cath lab on device support	5.63%	14.84%	<0.001

More Complex and More Complete

(Angiographic Core Lab Analysis)

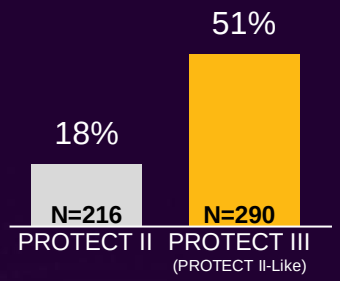
Lesion Length

P<0.001



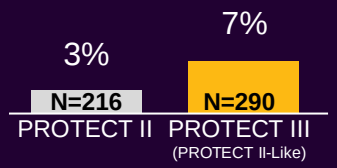
% with Severe Calcification

P<0.001



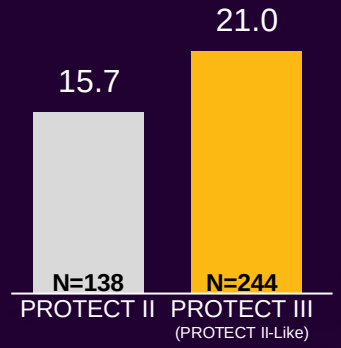
% with CTO

P<0.001



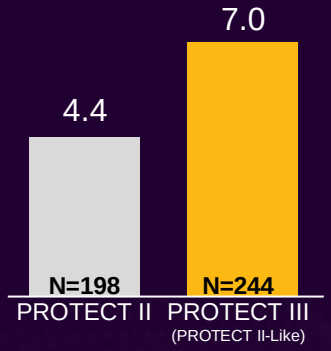
Change in SYNTAX

P<0.001



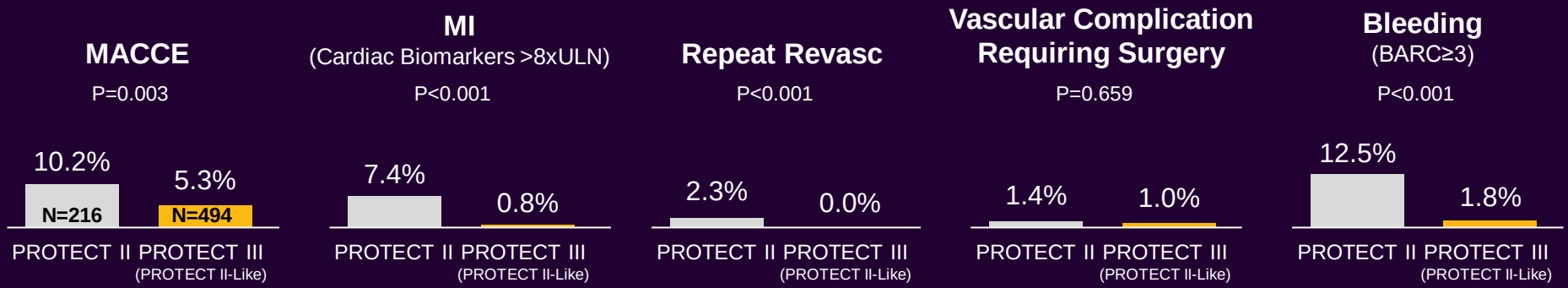
Change in Ischemia Jeopardy Score

P<0.001



	PROTECT II (Impella 2.5, N=216)	PROTECT III (PROTECT II-Like, N=494)	p-value
SYNTAX Score Pre-PCI	30.45±13.19 (138)	27.56±12.37 (245)	0.003
SYNTAX Score Post-PCI	14.79±12.71 (138)	6.58±8.77 (244)	<.001
Ischemia Jeopardy Score Pre-PCI	8.80±2.14 (198)	8.88±2.16 (245)	0.781
Ischemia Jeopardy Score Post-PCI	4.38±3.18 (198)	1.83±2.27 (244)	<.001

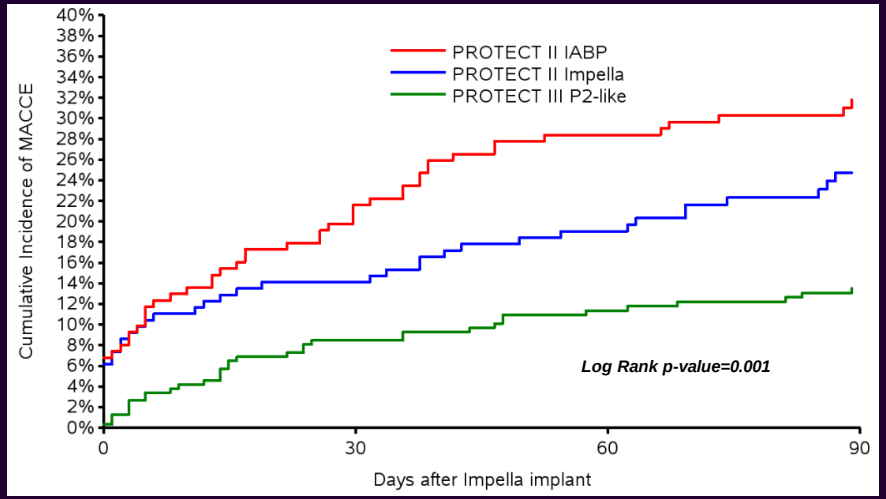
IN-HOSPITAL OUTCOMES



	PROTECT II (Impella 2.5, N=216)	PROTECT III (PROTECT II-Like, N=494)	p-value
Death	4.63%	4.45%	0.917
Stroke/TIA	0.46%	0.40%	0.913
Acute Renal Dysfunction	6.48%	5.47%	0.593
Hypotension During Support	10.19%	2.23%	<.001
Cardiopulmonary Resuscitation or Ventricular Arrhythmia	6.94%	1.62%	<.001

Table includes non-hierarchical outcomes

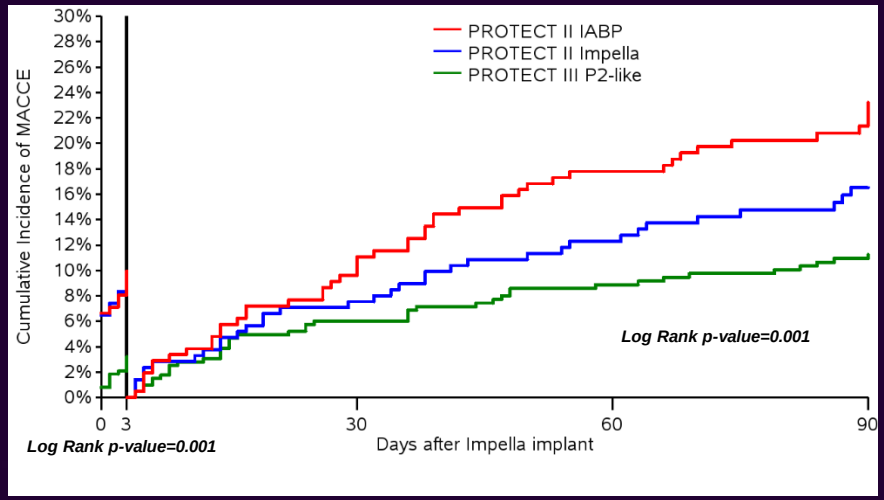
CUMULATIVE MACCE BEFORE PROPENSITY SCORE MATCHING



Time after Impella implant (days)	0	30	60	90
PROTECT III PROTECT II-Like # At Risk	494	340	313	290
PROTECT II Impella # At Risk	216	186	176	129
PROTECT II IABP # At Risk	211	172	154	116

MACCE: Death, Stroke, MI, Repeat Revascularization

LANDMARK 3-DAY POST-PCI BEFORE PROPENSITY SCORE MATCHING



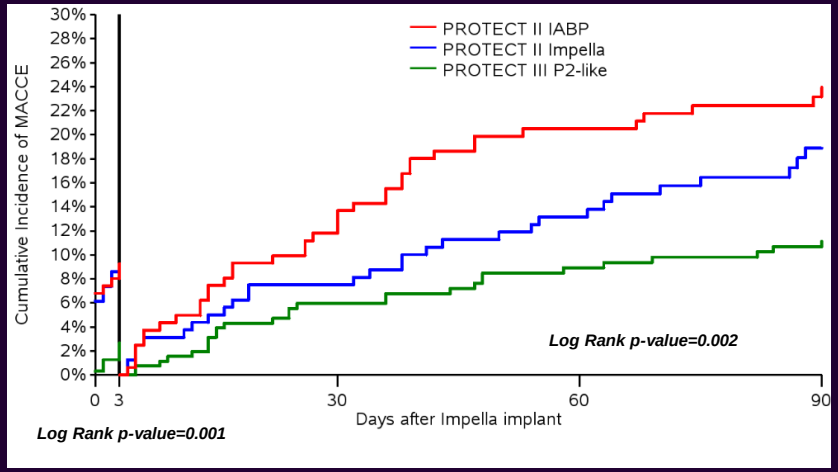
Time after Impella implant (days)	0	3	30	60	90
PROTECT III PROTECT II-Like # At Risk	494	432	340	313	290
PROTECT II Impella # At Risk	216	198	196	185	137
PROTECT II IABP # At Risk	211	194	188	171	132

MACCE: Death, Stroke, MI, Repeat Revascularization

Baseline Characteristics After Propensity Score Matching

	PROTECT III	PROTECT II	
	PROTECT II-Like N=325	Impella & IABP arms N=325	p-value
Age	67.78±11.12	68.22±10.68	0.607
Sex - Female	20.62%	20.0%	0.845
Diabetes	52.62%	52.62%	1.000
Prior MI	55.08%	58.46%	0.384
Renal Insufficiency	25.54%	27.69%	0.534
Prior ACS	20.92%	22.46%	0.384
LVEF%	23.33±6.95	23.21±6.36	0.826

LANDMARK 3-DAY POST-PCI MACCE AFTER PROPENSITY SCORE MATCHING



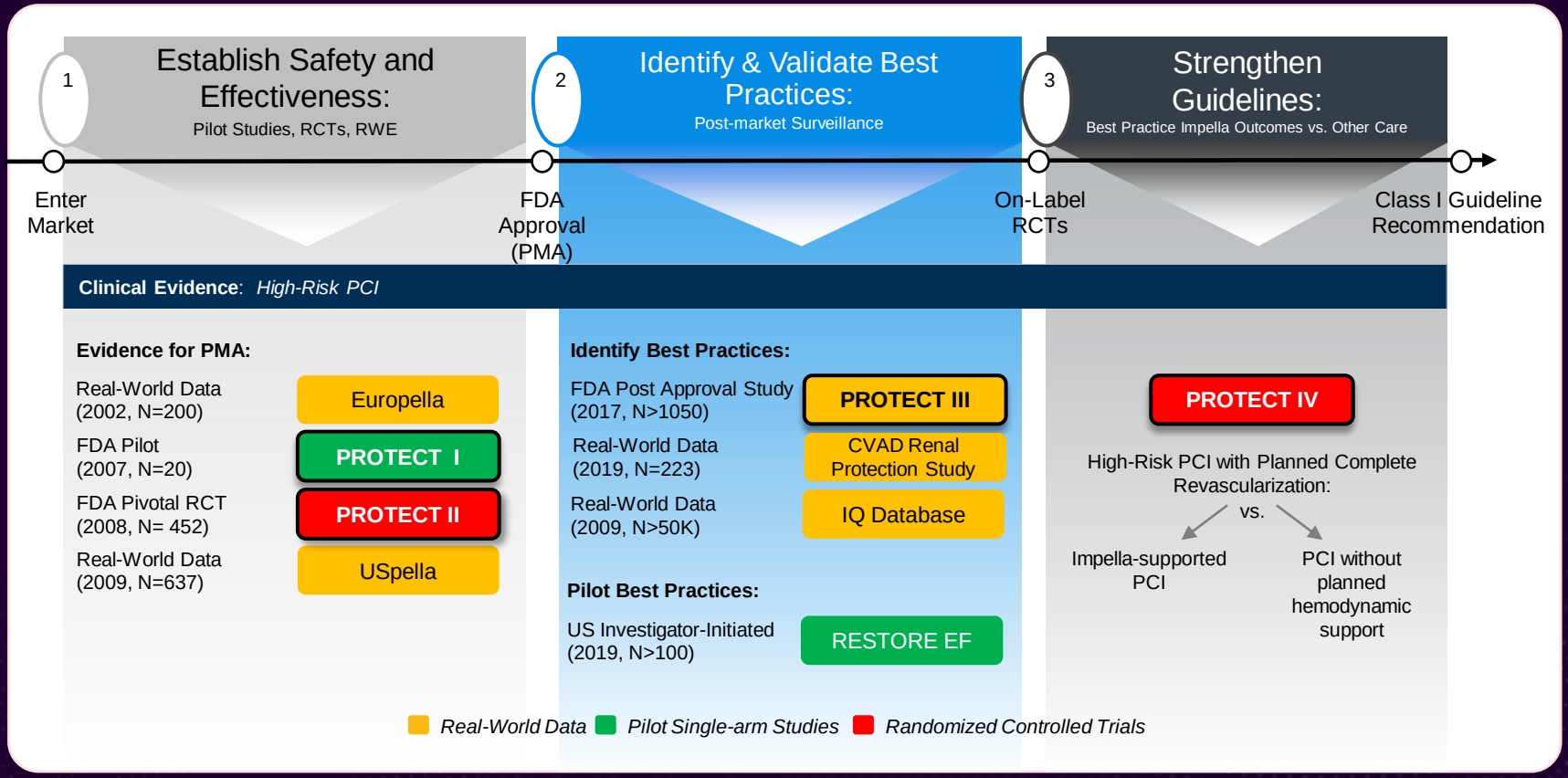
Time after Impella implant (days)	0	3	30	60	90
PROTECT III PROTECT II-Like # At Risk	325	286	227	210	196
PROTECT II Impella # At Risk	163	149	148	138	98
PROTECT II IABP # At Risk	162	149	142	127	102

*PROTECT III P2-like and PROTECT II patients were matched using the following variables: age, gender, LVEF, diabetes, renal insufficiency, prior MI, and ACS presentation

Conclusions

- PROTECT III represents the largest prospective study of the use of Impella MCS for high-risk PCI in the real world with contemporary best practices
- PROTECT III patients were older with more comorbidities and more complex lesions, and underwent more extensive revascularization than PROTECT II patients
- PROTECT III 90-day MACCE rates were improved compared to PROTECT II in both unmatched and matched cohorts
- PROTECT III procedural outcomes show improved in-hospital safety with significantly fewer vascular and bleeding complications compared to PROTECT II

Impella Clinical Evidence Pathway to Class I Recommendation



Intermediate-Term Left Ventricular Function Following Non-Emergent Impella Protected PCI: Restore EF Study

Background and Methods

Background:

1. Increasing anatomic complexity and high-risk co-morbid conditions continue to pose challenges to complete percutaneous coronary revascularization (PCI).
2. PCI with optimal left ventricular support increases the likelihood of complete revascularization which in-turn is associated with improved overall outcomes.

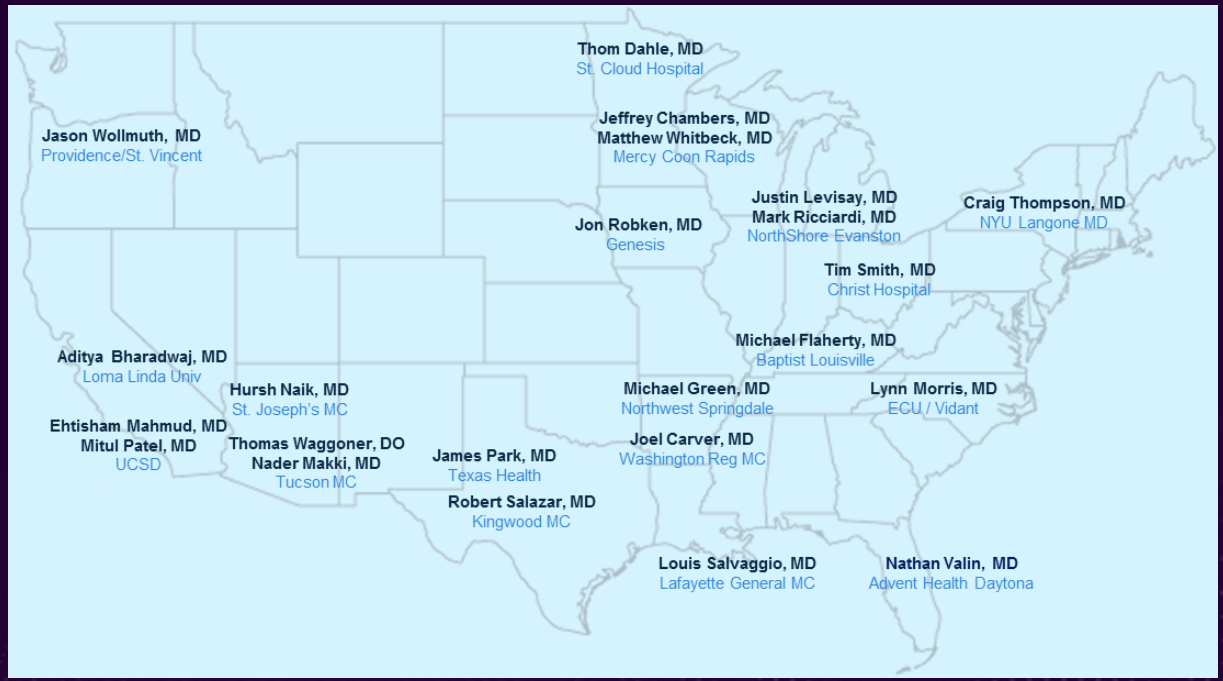
Methods:

1. The Restore EF is a multi-center, prospective, observational, single arm, study of the intermediate-term clinical outcomes in high-risk patients who have undergone pre-procedure hemodynamic support (Impella, Abiomed, Danvers, MA) for non-emergent percutaneous coronary intervention (ProPCI).
2. Assessment of left ventricular ejection fraction (LVEF) at 90-day follow-up visit (60-180 days window) is the primary endpoint.
3. The secondary endpoints included assessment of heart failure and angina symptoms at follow-up.

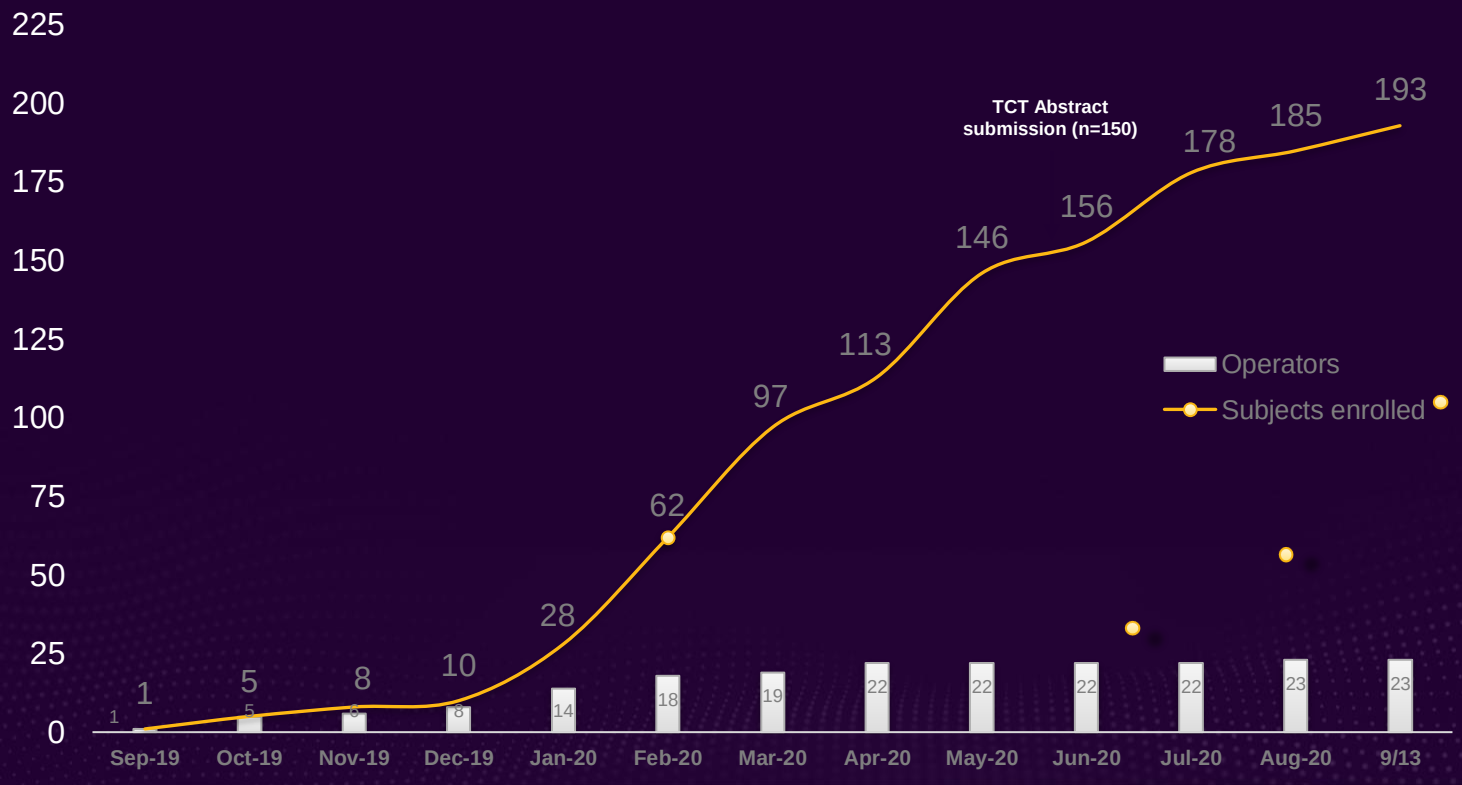
Restore EF Study Sites

The Restore EF includes 23 investigators at 19 US Hospitals

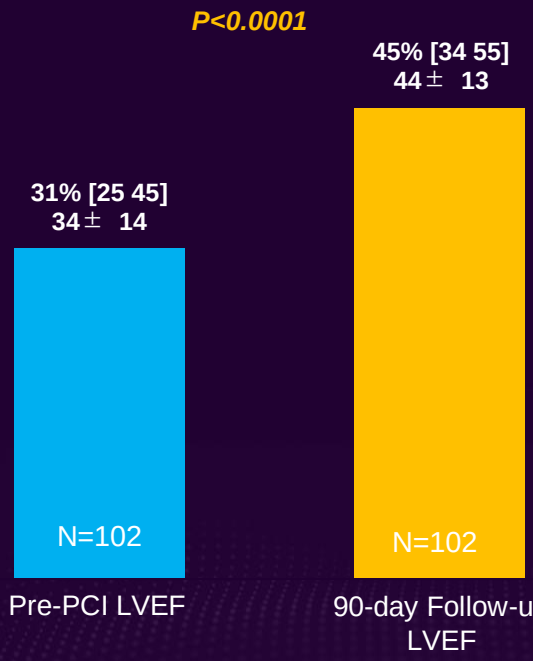
- Study of operators active in the Cath Lab
- IRB approved, Informed consent waiver
- Electronic data capturing system
- Personal information not collected
- Data is not monitored
- Enrollment target > 500 subjects
- Number of operators up to 30



Study Enrollment

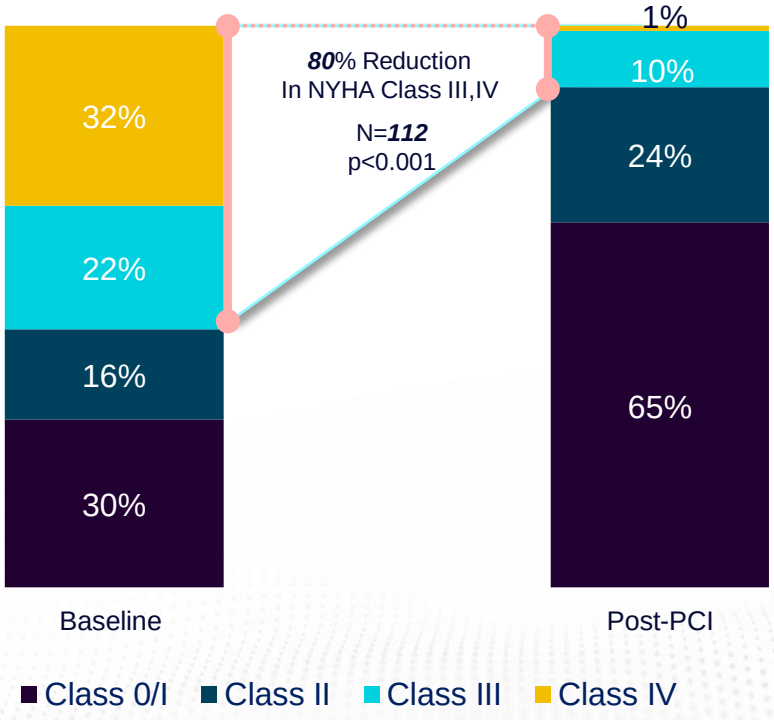


LVEF Improvement at 90-day Follow-up



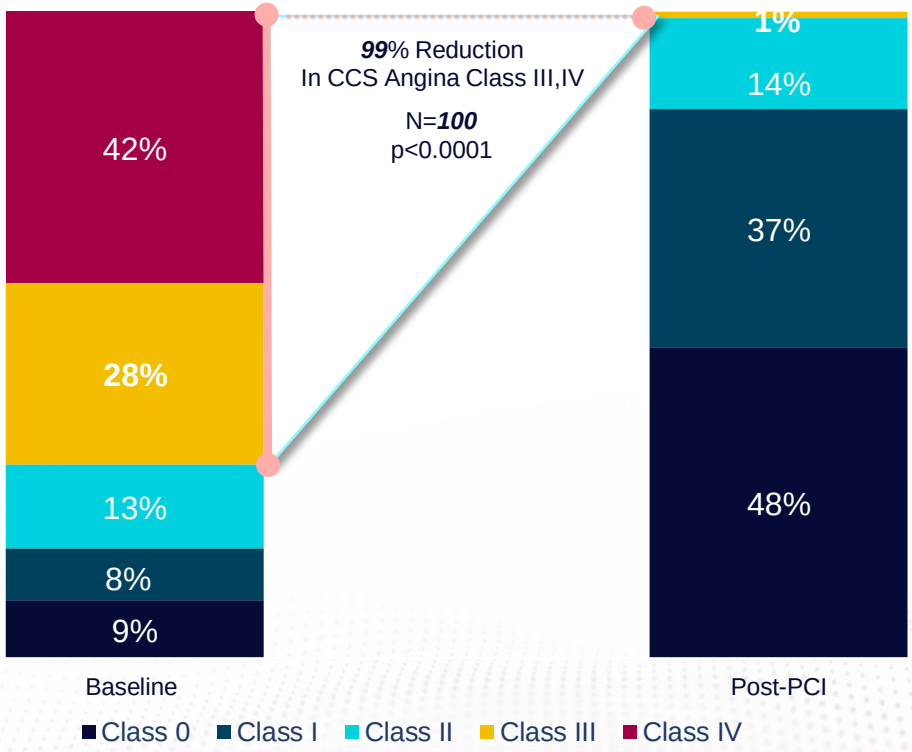
Follow-up period:
Mean ± SD = **125** ± 42 days
Median (q1 *q*3) = ***116*** [*92* 156] days

Heart Failure Symptom Improvement at Follow-up



Follow-up period:
Mean ± SD = ***111*** ± 79 days
Median (q*1* *q3*) = ***104*** [63 141] days

Anginal Symptom Improvement at Follow-up

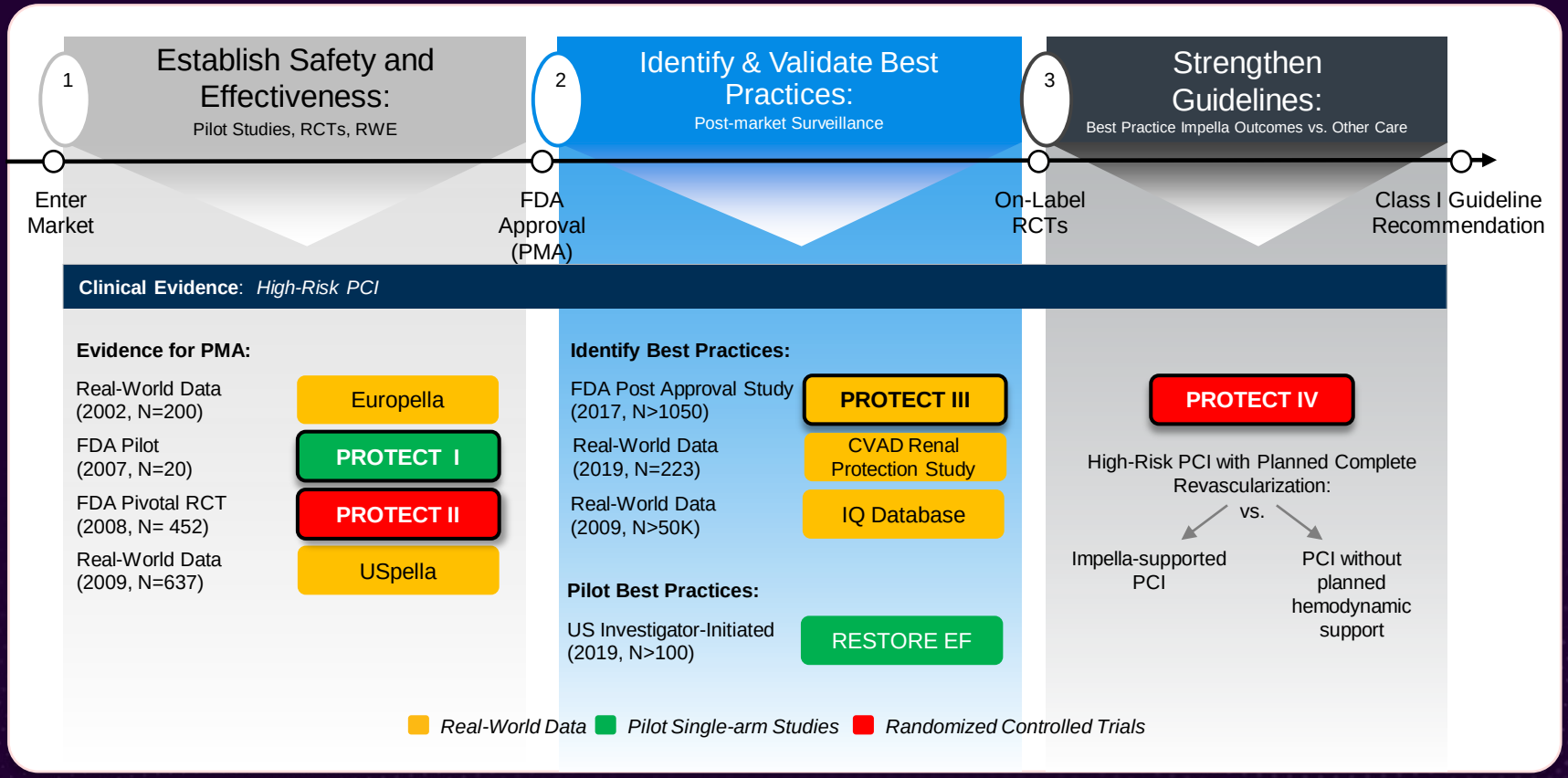


Follow-up period:
Mean ± SD = ***107*** ± 78 days
Median *(q1 q3)* = **101** [57 142] days

CONCLUSIONS

- **RESTORE EF demonstrates that amongst Impella Supported PCI patients, depressed baseline EF is associated with significant LVEF improvement at 90 days**
- **Heart failure and anginal symptoms assessed with NYHA and CCS functional classifications, respectively improved significantly**

Impella Clinical Evidence Pathway to Class I Recommendation



IMPELLA® DEVICE INDICATION & SAFETY INFORMATION

INDICATIONS FOR USE

High-Risk PCI

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Cardiogenic Shock

The Impella 2.5®, Impella CP®, Impella CP® with SmartAssist®, Impella 5.0®, Impella 5.5® with SmartAssist® and Impella LD® Catheters, in conjunction with the Automated Impella Controller™ (collectively, "Impella® System Therapy"), are temporary ventricular support devices intended for short term use (≤ 4 days for the Impella 2.5, Impella CP, and the Impella CP with SmartAssist, and ≤ 14 days for the Impella 5.0, Impella 5.5 with SmartAssist and Impella LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction or open heart surgery or in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures (including volume loading and use of pressors and inotropes, with or without IABP). The intent of Impella System Therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

EMERGENCY USE AUTHORIZATION: Impella Left Ventricular (LV) Support Systems (Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, and Impella 5.5 with SmartAssist) are authorized for emergency use by HCPs in the hospital setting for providing temporary (≤ 4 days for Impella 2.5, Impella CP, and Impella CP with SmartAssist; and ≤ 14 days for Impella 5.0 and Impella 5.5 with SmartAssist) LV unloading and support to treat critical care patients (i.e. patients in the intensive care unit) with confirmed COVID-19 infection who are undergoing ECMO treatment and who develop pulmonary edema while on V-A ECMO support or late cardiac decompensation from myocarditis while on V-V ECMO support. The Impella LV Support Systems have neither been cleared or approved for the authorized indication for use. The Impella LV Support Systems have been authorized for the above emergency use by the FDA under an EUA. The Impella LV Support Systems have been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

IMPORTANT RISK INFORMATION FOR IMPELLA DEVICES

CONTRAINDICATIONS: The Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, Impella 5.5 with SmartAssist and Impella LD are contraindicated for use with patients experiencing any of the following conditions: Mural thrombus in the left ventricle; Presence of a mechanical aortic valve or heart constrictive device; Aortic valve stenosis/calcification (equivalent to an orifice area of 0.6 cm^2 or less); Moderate to severe aortic insufficiency (echocardiographic assessment graded as ≥ +2); Severe peripheral arterial disease precluding placement of the Impella System; Significant right heart failure*; Combined cardiorespiratory failure*; Presence of an Atrial or Ventricular Septal Defect (including post-infarct VSD)*; Left ventricular rupture*; Cardiac tamponade*

*This condition is a contraindication for the cardiogenic shock indication only.

POTENTIAL ADVERSE EVENTS: Acute renal dysfunction, Aortic valve injury, Bleeding, Cardiogenic shock, Cerebral vascular accident/Stroke, Death, Hemolysis, Limb ischemia, Myocardial infarction, Renal failure, Thrombocytopenia and Vascular injury

In addition to the risks above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella devices.
Visit **http://www.abiomed.com/important-safety-information** to learn more.

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The Impella 2.5®, Impella CP®, Impella CP® with SmartAssist®, Impella 5.0®, Impella 5.5® with SmartAssist® and Impella LD® Catheters, in conjunction with the Automated Impella Controller™ (collectively, "Impella® System Therapy"), are temporary ventricular support devices intended for short term use (≤ 4 days for the Impella 2.5, Impella CP, and the Impella CP with SmartAssist, and ≤ 14 days for the Impella 5.0, Impella 5.5 with SmartAssist and Impella LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction or open heart surgery or in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures (including volume loading and use of pressors and inotropes, with or without IABP). The intent of Impella System Therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

EMERGENCY USE AUTHORIZATION: Impella Left Ventricular (LV) Support Systems (Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, and Impella 5.5 with SmartAssist) are authorized for emergency use by HCPs in the hospital setting for providing temporary (≤ 4 days for Impella 2.5, Impella CP, and Impella CP with SmartAssist; and ≤ 14 days for Impella 5.0 and Impella 5.5 with SmartAssist) LV unloading and support to treat critical care patients (i.e. patients in the intensive care unit) with confirmed COVID-19 infection who are undergoing ECMO treatment and who develop pulmonary edema while on V-A ECMO support or late cardiac decompensation from myocarditis while on V-V ECMO support. The Impella LV Support Systems have neither been cleared or approved for the authorized indication for use. The Impella LV Support Systems have been authorized for the above emergency use by the FDA under an EUA. The Impella LV Support Systems have been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

IMPORTANT RISK INFORMATION FOR IMPELLA DEVICES

CONTRAINDICATIONS: The Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, Impella 5.5 with SmartAssist and Impella LD are contraindicated for use with patients experiencing any of the following conditions: Mural thrombus in the left ventricle; Presence of a mechanical aortic valve or heart constrictive device; Aortic valve stenosis/calcification (equivalent to an orifice area of 0.6 cm^2 or less); Moderate to severe aortic insufficiency (echocardiographic assessment graded as ≥ +2); Severe peripheral arterial disease precluding placement of the Impella System; Significant right heart failure*; Combined cardiorespiratory failure*; Presence of an Atrial or Ventricular Septal Defect (including post-infarct VSD)*; Left ventricular rupture*; Cardiac tamponade*

*This condition is a contraindication for the cardiogenic shock indication only.

POTENTIAL ADVERSE EVENTS: Acute renal dysfunction, Aortic valve injury, Bleeding, Cardiogenic shock, Cerebral vascular accident/Stroke, Death, Hemolysis, Limb ischemia, Myocardial infarction, Renal failure, Thrombocytopenia and Vascular injury

In addition to the risks above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella devices.
Visit **http://www.abiomed.com/important-safety-information** to learn more.