Q3 FY 2020 Earnings Call
Financial Results & Operational Highlights
FINANCIAL RESULTS, Q3 FY 2020

Revenue ($M) & Growth Rate

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Revenue ($M)</th>
<th>Growth Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q3'19</td>
<td>$201</td>
<td>+30%</td>
</tr>
<tr>
<td>Q4'19</td>
<td>$207</td>
<td>+19%</td>
</tr>
<tr>
<td>Q1'20</td>
<td>$208</td>
<td>+15%</td>
</tr>
<tr>
<td>Q2'20</td>
<td>$205</td>
<td>+13%</td>
</tr>
<tr>
<td>Q3'20</td>
<td>$222</td>
<td>+10%</td>
</tr>
</tbody>
</table>

Cash ($M)

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Cash ($M)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q3'19</td>
<td>$458</td>
</tr>
<tr>
<td>Q4'19</td>
<td>$513</td>
</tr>
<tr>
<td>Q1'20</td>
<td>$527</td>
</tr>
<tr>
<td>Q2'20</td>
<td>$551</td>
</tr>
<tr>
<td>Q3'20</td>
<td>$596</td>
</tr>
</tbody>
</table>

Gross Margin %

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Gross Margin %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q3'19</td>
<td>83.0%</td>
</tr>
<tr>
<td>Q4'19</td>
<td>83.2%</td>
</tr>
<tr>
<td>Q1'20</td>
<td>82.1%</td>
</tr>
<tr>
<td>Q2'20</td>
<td>83.0%</td>
</tr>
<tr>
<td>Q3'20</td>
<td>82.0%</td>
</tr>
</tbody>
</table>

Operating Margin %

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Operating Margin %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q3'19</td>
<td>31.1%</td>
</tr>
<tr>
<td>Q4'19</td>
<td>31.6%</td>
</tr>
<tr>
<td>Q1'20</td>
<td>29.2%</td>
</tr>
<tr>
<td>Q2'20</td>
<td>29.4%</td>
</tr>
<tr>
<td>Q3'20</td>
<td>31.7%</td>
</tr>
</tbody>
</table>
U.S. Utilization Mix, Q3 FY 2020

Revenue by Impella Device

- Impella CP (79%)
- Impella 5.0 (10%)
- Impella RP (3%)
- Impella 2.5 (8%)

Utilization by Indication

- Emergent (54%)
- Protected PCI (42%)
- Other (4%)

U.S. Hospital Site Penetration

- CP & 2.5: 1,425
- 5.0 & 5.5: 640
- RP: 521
- Potential Sites*: 1,788

*1,113 of 1,788 hospitals have surgical back-up. Per National In-Patient (NIS), MedPar, Definitive Healthcare 2018
**ABIOMED FY 2020 GUIDANCE**

**Abiomed FY’20 Guidance**

**Revenue**
$846M - $877M  
+10 - 14% YOY

**Operating Margin %**
28 - 30%
ABIOMED REGULATORY HISTORY WITH MCS USAGE TRENDS AND SAFETY DATA

FEBRUARY 6, 2020
**IMPELLA® HEART PUMPS SUPPORT AND RECOVER HEART MUSCLE AND ENABLE MINIMALLY INVASIVE PROCEDURES**

**IABP (1976*)**

Percutaneous Insertion
Not a Heart Pump

---

**PERCUTANEOUS ECMO (1980s)**

Perfuses the Body
Loads the Heart

---

**IMPELLA (2008)**

Percutaneous Insertion
Unloads the Heart

---

*IABP grandfathered in 1976*
IMPROVING PATIENT OUTCOMES BY LEADING IN CLINICAL RESEARCH AND REAL-WORLD EVIDENCE FROM 2004 – 2020

7 FDA STUDIES & 5 FDA POST-MARKET STUDIES

VALIDATES SAFE & EFFECTIVE

IMPELLA DATA SUPPORTING FDA INDICATIONS 2004 - 2020

<table>
<thead>
<tr>
<th>Scientific Evidence</th>
<th>Total # of Patients</th>
<th># of Impella® Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recover I FDA Study (2005 – 2008)</td>
<td>17</td>
<td>17</td>
</tr>
<tr>
<td>ISAR Shock</td>
<td>26</td>
<td>13</td>
</tr>
<tr>
<td>U.S. Impella Registry</td>
<td>494</td>
<td>494</td>
</tr>
<tr>
<td>Recover Right (Impella RP) (2013 – 2019 PAS)</td>
<td>126</td>
<td>126</td>
</tr>
<tr>
<td>Literature review</td>
<td>2,537</td>
<td>692</td>
</tr>
<tr>
<td>Total</td>
<td>3,074</td>
<td>1,342</td>
</tr>
</tbody>
</table>

PROTECT I FDA Study (2006 – 2007) | 20 | 20 |
PROTECT II FDA Study RCT (2007 – 2010) | 452 | 225 |
PROTECT III FDA PAS (2017 – Present) | >1,061 | >1,061 |
U.S. Impella Registry | 1,322 | 709 |
cVAD Study | 693 | 464 / 229 LVEF>53% / LVEF>35% |
Literature Review | 2,537 | 756 |
Total | >3,400 |

Cardiogenic Shock
44% (n=3,044)
HRPCI Elective & Urgent
Other 15% (n=1,027)
Other 17% (n=20,095)
Cardiogenic Shock 36% (n=41,889)

FDA PRE & POST MARKET STUDIES

RECOVER II CGS FDA RCT (2007–2009, Discontinued for lack of enrollment)
STEMI DTU Pilot RCT, STEMI DTU Pivotal RCT Ongoing
Physician Initiated Studies: NCSI, Shock Working Group, Inova Shock Team, DanGer RCT

RECOVER II CGS FDA RCT (2007–2009, Discontinued for lack of enrollment)
STEMI DTU Pilot RCT, STEMI DTU Pivotal RCT Ongoing
Physician Initiated Studies: NCSI, Shock Working Group, Inova Shock Team, DanGer RCT

IMPPELLA QUALITY (IQ) DATABASE

VALIDATES BEST PRACTICES

<table>
<thead>
<tr>
<th>科学证据</th>
<th>总患者人数</th>
<th>Impella®患者人数</th>
</tr>
</thead>
<tbody>
<tr>
<td>恢复I FDA研究 (2005-2008)</td>
<td>17</td>
<td>17</td>
</tr>
<tr>
<td>ISAR冲击</td>
<td>26</td>
<td>13</td>
</tr>
<tr>
<td>美国Impella登记</td>
<td>494</td>
<td>494</td>
</tr>
<tr>
<td>恢复右Impella RP) (2013-2019 PAS)</td>
<td>126</td>
<td>126</td>
</tr>
<tr>
<td>文献回顾</td>
<td>2,537</td>
<td>692</td>
</tr>
<tr>
<td>总计</td>
<td>3,074</td>
<td>1,342</td>
</tr>
</tbody>
</table>

PROTECT I FDA研究 (2006-2007) | 20 | 20 |
PROTECT II FDA研究RCT (2007-2010) | 452 | 225 |
PROTECT III FDA研究(PAS) (2017-至今) | >1,061 | >1,061 |
美国Impella登记 | 1,322 | 709 |
cVAD研究 | 693 | 464 / 229 LVEF>53% / LVEF>35% |
文献回顾 | 2,537 | 756 |
总计 | >3,400 |

USP Stmt: Recover II CGS FDA RCT (2007-2009, Discontinued for lack of enrollment)
STEMI DTU Pilot RCT, STEMI DTU Pivotal RCT Ongoing
Physician Initiated Studies: NCSI, Shock Working Group, Inova Shock Team, DanGer RCT

IRB Exempt / HIPAA Compliant
1,469 US Hospitals (2009 - 2019)
Data from U.S., Germany and Japan

January 2020

FOR INVESTORS ONLY
### Summary of Safety Data by Devices*

<table>
<thead>
<tr>
<th>VASCULAR COMPLICATIONS</th>
<th>HIGH-RISK PCI</th>
<th>STEMI</th>
<th>CARDIOGENIC SHOCK</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.9%&lt;sup&gt;1&lt;/sup&gt;</td>
<td>4.3%&lt;sup&gt;4&lt;/sup&gt;</td>
<td>14.3%&lt;sup&gt;7&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>1.4%&lt;sup&gt;1&lt;/sup&gt;</td>
<td>4.0%&lt;sup&gt;3&lt;/sup&gt;</td>
<td>8.6%&lt;sup&gt;5&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>16.9%&lt;sup&gt;8&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MAJOR BLEEDING</th>
<th>STEMI</th>
<th>CARDIOGENIC SHOCK</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.4%&lt;sup&gt;1&lt;/sup&gt;</td>
<td>3.1%&lt;sup&gt;4&lt;/sup&gt;</td>
<td>14.3%&lt;sup&gt;7&lt;/sup&gt;</td>
</tr>
<tr>
<td>5.7%&lt;sup&gt;2&lt;/sup&gt;</td>
<td>6.0%&lt;sup&gt;3&lt;/sup&gt;</td>
<td>10.1%&lt;sup&gt;5&lt;/sup&gt;</td>
</tr>
<tr>
<td>40.8%&lt;sup&gt;8&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>STROKE</th>
<th>STEMI</th>
<th>CARDIOGENIC SHOCK</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.4%&lt;sup&gt;1&lt;/sup&gt;</td>
<td>1.9%&lt;sup&gt;4&lt;/sup&gt;</td>
<td>2% - 8%&lt;sup&gt;10&lt;/sup&gt;</td>
</tr>
<tr>
<td>0.9%&lt;sup&gt;1&lt;/sup&gt;</td>
<td>2.0%&lt;sup&gt;3&lt;/sup&gt;</td>
<td>4.2%&lt;sup&gt;5&lt;/sup&gt;</td>
</tr>
<tr>
<td>13% - 20%&lt;sup&gt;8,9&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

*Impella data is derived from 7 FDA studies and 5 post-approval studies. PROTECT II FDA Randomized Controlled Trial compared adverse events directly to IABP. There are no independent FDA IDE studies for ECMO and IABP.*

---

1. PROTECT II Study, Data on File
5. Impella AMI-CS Post-Approval Study, cVAD Study
Impella Clinical Evidence Pathway to Class I Recommendation

General Approach and Milestones

1. Establish Safety and Effectiveness:
   - Pilot Studies, RCTs, RWE

2. Identify & Validate Best Practices:
   - Post-market Surveillance

3. Strengthen Guidelines:
   - Best Practice Impella Outcomes vs. Other Care

Enter Market

PMA

On-Label RCTs

Class I Guideline Recommendation

- 2008: Impella 2.5® (510k)
- 2009: Impella 5.0® (510k)
- 2012: Impella CP® (510k)
- 2013: Impella RP® (IDE)

2015: High-Risk PCI
2016: AMI Cardiogenic Shock
2017: Right Heart Failure

2020: We are Here

Establish Safety and Effectiveness: Pilot Studies, RCTs, RWE

Identify & Validate Best Practices: Post-market Surveillance

Strengthen Guidelines: Best Practice Impella Outcomes vs. Other Care

Clinical Evidence: High Risk PCI

Evidence for PMA:
- Real-World Data (2002, N=200)
- FDA Pilot (2007, N=20)
- FDA Pivotal RCT (2008, N=452)
- Real-World Data (2009, N=637)

Identify Best Practices:
- FDA Post Approval Study (2017, N>1050)
- Real-World Data (2019, N=223)
- Real-World Data (2009, N>50K)

Pilot Best Practices:
- US Investigator-Initiated (2019, N>100)

Class I Guideline Recommendation
PROTECTED PCI: IMPELLA® REDUCES ADVERSE EVENTS & IMPROVES QUALITY OF LIFE

MACCE = Death, Stroke, MI, Repeat revascularization

FDA Randomized Controlled Trial: Protect II (Impella 2.5®)

IABP
N=211

Impella 2.5™
N=216

P=0.042

29% reduction


MACCE, Major Adverse Cardiac and Cerebrovascular Event, defined as death, stroke, MI, repeat revascularization

FOR INVESTORS ONLY
PROTECT Study Enrollment

Only FDA RCT Ever Conducted for Hemodynamically Supported High-Risk PCI

Patients Enrolled (N=1,366)
- Impella 2.5
- IABP
- Impella CP

PROTECT I
FDA Pilot
2006-2007

PROTECT II
FDA Pivotal RCT
2007-2010

PROTECT III
FDA Post-Approval Study
2017-2019 (Ongoing Enrollment)
PROTECT III Outcomes Compared to PROTECT II

Composite Major Adverse Cardiac and Cerebrovascular Events (MACCE) at 90 Days

<table>
<thead>
<tr>
<th></th>
<th>PROTECT II RCT</th>
<th></th>
<th>PROTECT III</th>
</tr>
</thead>
<tbody>
<tr>
<td>IABP</td>
<td>N = 210</td>
<td>31.0%</td>
<td>P = 0.033</td>
</tr>
<tr>
<td>Impella 2.5</td>
<td>N = 215</td>
<td>21.9%</td>
<td></td>
</tr>
<tr>
<td>Impella 2.5 / CP</td>
<td>N = 469</td>
<td>16.8%</td>
<td>P &lt; 0.0001</td>
</tr>
</tbody>
</table>

MACCE = Death, Stroke, MI, Repeat Revascularization

N = number of patients with 90-day follow-up
High Risk PCI

Impella Clinical Evidence Pathway to Class I Recommendation

1. Establish Safety and Effectiveness:
   Pilot Studies, RCTs, RWE

2. Identify & Validate Best Practices:
   Post-market Surveillance

3. Strengthen Guidelines:
   Best Practice Impella Outcomes vs. Other Care

Clinical Evidence: High Risk PCI

Evidence for PMA:
- Real-World Data (2002, N=200)
- FDA Pilot (2007, N=20)
- FDA Pivotal RCT (2008, N=452)
- Real-World Data (2009, N=637)
- Europella
- PROTECT I
- PROTECT II
- USpella

Identify Best Practices:
- FDA Post Approval Study (2017, N>1050)
- Real-World Data (2019, N=223)
- Real-World Data (2009, N>50K)
- PROTECT III
- CVAD Renal Protection Study
- IQ Database

Pilot Best Practices:
- US Investigator-Initiated (2019, N>100)
- RESTORE EF

PROTECT IV
- High-Risk PCI with Planned Complete Revascularization:
  vs.
- Impella-supported PCI
- PCI without planned hemodynamic support

1. Enter Market
2. PMA
3. On-Label RCTs
4. Class I Guideline Recommendation

Legend:
- Real-World Data
- Pilot Single-arm Studies
- Randomized Controlled Trials
Cardiogenic Shock

Impella Clinical Evidence Pathway to Class I Recommendation

1. Establish Safety and Effectiveness:
   Pilot Studies, RCTs, RWE

2. Identify & Validate Best Practices:
   Post-market Surveillance

3. Strengthen Guidelines:
   Best Practice Impella Outcomes vs. Other Care

Clinical Evidence: Cardiogenic Shock

Evidence for PMA:
- EU CE Safety Study (2006, N=20)
- FDA Pilot (2007, N=17)
- Real-World Data (2009, N=401)
- Impella RP HDE Study (2013, N=60)

Attempted RCTs:
- FDA Pivotal RCT (2007, N=1)
- EU RCT (2007, N=18)
- EU RCT (2012, N=120)

Identify Best Practices:
- RECOVER III
- Impella RP PAS
- Shock Working Group
- IQ Database

Pilot Best Practices:
- DCSI → NCSI
- Inova System
- DanShock → DanGer

Real-World Data
Pilot Single-arm Studies
Randomized Controlled Trials
KEY FINDINGS IN IQ AND CVAD

Impella Pre-PCI associated with Improved Survival in AMI/CVS

IQ Database¹

<table>
<thead>
<tr>
<th>IABP/Inotropes Pre-PCI</th>
<th>Impella Pre-PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>52%</td>
<td>59%</td>
</tr>
</tbody>
</table>

¹ Abnormal Inotrope Quality Database: US MACH 3 Study 08-06: Jan 2012. Survival to hospital discharge. N.A. Abnormal

cVAD Registry²

<table>
<thead>
<tr>
<th>IABP/Inotropes Pre-PCI</th>
<th>Impella Pre-PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>41%</td>
<td>65%</td>
</tr>
</tbody>
</table>

² cVAD survival to hospital discharge

Hemodynamic Monitoring associated with Improved Survival in AMI/CVS

IQ Database¹

<table>
<thead>
<tr>
<th>No Hemodynamic Monitoring</th>
<th>Hemodynamic Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>49%</td>
<td>63%</td>
</tr>
</tbody>
</table>

¹ Abnormal Inotrope Quality Database: US MACH 3 Study 08-06: Jan 2012. Survival to hospital discharge. N.A. Abnormal

cVAD Registry²

<table>
<thead>
<tr>
<th>No Hemodynamic Monitoring</th>
<th>Hemodynamic Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>68%</td>
<td>76%</td>
</tr>
</tbody>
</table>

² cVAD survival to hospital discharge

Increased Inotrope Exposure is associated with Mortality in AMI/CVS

Mortality and Number of Inotropes from cVAD Registry¹

<table>
<thead>
<tr>
<th>Number of Inotropes/Pressors</th>
<th>Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>32%</td>
</tr>
<tr>
<td>1</td>
<td>54%</td>
</tr>
<tr>
<td>2</td>
<td>65%</td>
</tr>
<tr>
<td>3</td>
<td>65%</td>
</tr>
<tr>
<td>4+</td>
<td>74%</td>
</tr>
</tbody>
</table>

¹ Mortality and Number of Inotropes from cVAD Registry. P<0.001 (N=287)

Figure 1: Mortality percent based on immediate post-op inotropic requirement

60% 50% 40% 30% 20% 10% 0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

Mortality Percent

Number of Inotropes/Pressors

0 1 2 3 4+ 0 1 2 3 4+ SEMELIS LE et al, J Card Surg 1999
**Cardiogenic Shock Studies**: 

<table>
<thead>
<tr>
<th>Study</th>
<th>Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scheidt et al. (1973)</td>
<td>17%</td>
</tr>
<tr>
<td>Lee et al. (1988)</td>
<td>50%</td>
</tr>
<tr>
<td>Hochman et al. (1999)</td>
<td>49%</td>
</tr>
<tr>
<td>Dagmar et al. (2016)</td>
<td>52%</td>
</tr>
<tr>
<td>Thiele et al. (2017)</td>
<td>52%</td>
</tr>
<tr>
<td>Inova² (2019)</td>
<td>82%</td>
</tr>
<tr>
<td>NCSI (2019)</td>
<td>72%</td>
</tr>
</tbody>
</table>

2. Tehrani B, et. al. JACC, 2019;73:1659-1669

**IMPELLA NCSI Protocol Demonstrates Reduced Mortality in Real-World Clinical Practice**

- **Survival Based on CPO and Inotrope Usage**
  - Immediately Post IMPELLA & PCI (N=159)
  - # Inotropes
    - 0: 77% (N=13)
    - 1: 44% (N=10)
    - ≥2: 25% (N=19)
  - CPO (Watts)
    - ≤0.6: 93% (N=25)
    - 0.6 to <0.8: 64% (N=12)
    - ≥0.8: 81% (N=32)

**NCSI Update**
- 79 sites enrolled into NCSI
- 250 patients enrolled nationally
- 500 total patients screened (with 49% = cardiogenic shock)

**National Cardiogenic Shock Initiative**

- 72% Survival
- 98% Native Heart Recovery

- NCSI PROTOCOL DEMONSTRATES REDUCED MORTALITY IN REAL-WORLD CLINICAL PRACTICE
INCREASING ADOPTION OF BEST PRACTICES IMPROVING OVERALL AMICS OUTCOMES

Distribution of Impella survival to explant at sites treating > 4 patients¹

Pre-PMA
Apr 2015 – Mar 2016

376 Hospitals, 3111 Impella Patients

Median: 51%

Post-PMA (Year 4, YTD)
Apr 2019 – Sep 2019

553 Hospitals, 4441 Impella Patients

Median: 70%

Translates to 4,400 more patients surviving to explant since PMA

**IMPELLA RP SURVIVAL OUTCOMES – PRE VS. POST APPROVAL**

**Survival**
**Longest available of 30 day / Discharge / Next Therapy**

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Impella RP</th>
<th>Centrimag</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA Recover Right Study</td>
<td>72%</td>
<td>42%</td>
</tr>
<tr>
<td>(2012-2014)</td>
<td>N=60</td>
<td>N=38</td>
</tr>
<tr>
<td>FDA Right Side Support Study</td>
<td>43%</td>
<td></td>
</tr>
<tr>
<td>(2007-2008)</td>
<td>N=7</td>
<td></td>
</tr>
</tbody>
</table>

**Impella RP Post Approval Study (PAS)**
- **Sep 2017 – Jun 2018**
  - N=7
  - 6%
  - N=16
  - 18%
  - *FDA Physician Letter Feb 2, 2019*
- **Jun 2018 – Jun 2019**
  - N=15
  - 87%
  - N=28
  - 14%
- **Impella RP PAS Total**
  - N=22
  - 72%
  - N=44

---

Cardiogenic Shock

Impella Clinical Evidence Pathway to Class I Recommendation

1. Establish Safety and Effectiveness:
   - Pilot Studies, RCTs, RWE

2. Identify & Validate Best Practices:
   - Post-market Surveillance

3. Strengthen Guidelines:
   - Best Practice Impella Outcomes vs. Other Care

Evidence for PMA:
- EU CE Safety Study (2006, N=20)
- FDA Pilot (2007, N=17)
- Real-World Data (2009, N=401)
- Impella RP HDE Study (2013, N=60)

Attempted RCTs:
- Discontinued due to low enrollment
  - FDA Pivotal RCT (2007, N=1)
  - EU RCT (2007, N=18)
  - EU RCT (2012, N=120)

Clinical Evidence: Cardiogenic Shock

Identify Best Practices:
- FDA Post Approval Study (2017, N>350)
- FDA Post Approval Study (2017, N>66)
- Real-World Data (2015, N>2000)
- Real-World Data (2009, N>40K)

Pilot Best Practices:
- US Investigator-Initiated (2016, N>300)
- US Investigator-Initiated (2016, N>204)
- EU RCT (2018, N>140)

Evidence for PMA:
- ISAR Shock
- RECOVER I
- USpella
- RECOVER Right
- RECOVER II
- IMPRESS STEMI
- DANSHOCK
- RECOVER III
- Impella RP PAS
- Shock Working Group
- IQ Database
- RECOVER IV
- AMI Shock PCI: Impella support pre-PCI with 5.5/RP/Oxygenation escalation vs. Other Treatment Protocols Including any kind of circulatory support excluding Impella devices

1. Evidence for PMA
2. Identify Best Practices
3. Strengthen Guidelines

On-Label RCTs

Class I Guideline Recommendation

Enter Market

PMA
Clinical Guidelines for Impella® Heart Pumps

Protected PCI

2014 AHA/ACC Guideline for the Management of Patients With Non–ST-Elevation Acute Coronary Syndromes (Circulation)
- Revascularization in Heart Failure: Class I
  - Revascularization strategy based on degree, severity, and extent of CAD; cardiac lesions; extent of LV dysfunction; prior revascularization
- PVADs: Large amount of ischemic territory/poor LV function

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention (J Am Coll Cardiol)
- High-risk patients: Class IIb
- CLASS III: HARM without hemodynamic support; for PCI at hospitals without on-site cardiac surgery

Cardiogenic Shock & Other Guidelines

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention (J Am Coll Cardiol)
- PCI and Cardiogenic Shock: Class I

2012 Use of Mechanical Circulatory Support: American Heart Association (Circulation)
- Acutely decompensated heart failure patients: Class IIa

2013 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support (J Heart Lung Transplant)
- Temporary mechanical support for patients with multi-organ failure: Class I

2013 ACCF/AHA Guideline for the Management of Heart Failure (J Am Coll Cardiol)
- "Bridge to Recovery" or "Bridge to Decision" for patients with acute, profound hemodynamic compromise: Class IIa

2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction (Circulation)
- STEMI and Cardiogenic Shock: Class IIb
- STEMI and Urgent CABG: Class IIa

2019 HRS/EHRA/APHRS/LAHRS Expert Consensus Statement on Catheter Ablation of Ventricular Arrhythmias (Heart Rhythm)
- HF and EP collaboration regarding High-Risk VTA: Class I
- Hemodynamic Support During VTA: Class IIa
- Hemodynamic Support for Unstable VT: Class IIb
## FDA Approved and Cleared Indications

<table>
<thead>
<tr>
<th>Product</th>
<th>Clearance / Approval</th>
<th>High-Risk PCI</th>
<th>AMI CGS</th>
<th>Cardiomyopathy CGS</th>
<th>PCCS</th>
<th>Right Heart Failure</th>
<th>FDA Duration of Support Approved/Cleared</th>
<th>FDA Approved/Cleared for Transportation</th>
</tr>
</thead>
<tbody>
<tr>
<td>IABP MAQUET, Teleflex</td>
<td>510(k)(^1)</td>
<td>On-Label</td>
<td>On-Label</td>
<td>On-Label</td>
<td>Off-Label</td>
<td>Short-Term</td>
<td>Approved</td>
<td></td>
</tr>
<tr>
<td><strong>ECMO Peripheral</strong> MAQUET, Abbott, Medtronic, LivaNova (TH)</td>
<td>510(k)(^2)</td>
<td>Off-Label</td>
<td>Off-Label</td>
<td>Off-Label</td>
<td>Off-Label</td>
<td>Less than 6 hours</td>
<td>MAQUET Cleared</td>
<td></td>
</tr>
<tr>
<td><strong>Extracorporeal Pumps Left/Right Heart Support</strong></td>
<td>510(k)</td>
<td>Off-Label</td>
<td>Off-Label</td>
<td>Off-Label</td>
<td>CentriMag On-Label 30 days</td>
<td>Less than 6 hours</td>
<td>NOT Approved</td>
<td></td>
</tr>
<tr>
<td>Tandem Heart (LivaNova) CentriMag (Abbott/Thoratec)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Percutaneous Pumps Left/Right Heart Support</strong></td>
<td>FDA PMA(^4) APPROVED</td>
<td>On-Label</td>
<td>On-Label</td>
<td>On-Label</td>
<td>On-Label</td>
<td>5 to 14 Days</td>
<td>Approved</td>
<td></td>
</tr>
<tr>
<td>Abiomed (Impella 2.5, CP, 5.0, RP)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. 510(k) clearance is defined as substantially equivalent to other 510(k) products cleared. Established 1976
2. FDA 515i Process, 510(k) Cleared ECMO as Bypass
3. Humanitarian Device Exemption (HDE), is defined as safe with probable benefit, limited to smaller populations (<8K) per year.
4. FDA PMA approval is defined as safe and effective and meets FDA risk/benefit requirements.

IABP – MS-DRG 270 ~$32,000, ECMO – MS-DRG 003 ~$118,720, Extracorporeal Pumps can be billed to MS-DRG 001 ~$173,090 or MS-DRG 002 ~$87,780, Percutaneous Pumps – MS-DRG is 215 ~$80,715
**United States: Contemporary PCI, CABG & Mechanical Circulatory Support (MCS) in 2018**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCI (In-Patient &amp; Out-Patient, Excludes Diagnostic only)</td>
<td>955,000</td>
</tr>
<tr>
<td>Non-Surgical, High-Risk Patients with CAD not Treated with PCI</td>
<td>319,000</td>
</tr>
<tr>
<td>Heart Surgery, CABG Utilizing Heart and Lung Machine with Open Chest (ECMO)</td>
<td>217,000</td>
</tr>
<tr>
<td>Cardiogenic Shock</td>
<td>165,100</td>
</tr>
<tr>
<td>IABP</td>
<td>51,700</td>
</tr>
<tr>
<td>Impella</td>
<td>23,437</td>
</tr>
<tr>
<td>Peripheral ECMO</td>
<td>21,087</td>
</tr>
<tr>
<td>Current Addressable Market (121K HRPCI, 165K CGS, 10K Right Heart)</td>
<td>296,000</td>
</tr>
</tbody>
</table>

**Key Statistics:**
- PCI: 955,000
- Non-Surgical, High-Risk Patients with CAD not Treated with PCI: 319,000
- Heart Surgery, CABG: 217,000
- Cardiogenic Shock: 165,100
- IABP: 51,700
- Impella: 23,437
- Peripheral ECMO: 21,087
- Current Addressable Market: 296,000

---

1. All payer data 2018, Definitive Healthcare
2. Tsai TT, JACC: Cardiovascular Interventions. 2014;7:1-9
3. Hannan, et.al. Circulation. 2006;113:2406-2412,
4. Saroa, G. et.al, Am J Cardiol. 2010 Nov 15;106(10):1369-75,
MORE IMPELLA SAFETY DATA
## PROTECT II Additional Impella Safety Endpoints

<table>
<thead>
<tr>
<th></th>
<th>IABP (n=210)</th>
<th>Impella 2.5⁺ (n=215)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stroke</strong></td>
<td>2.4%</td>
<td>0.9%</td>
<td>0.240</td>
</tr>
<tr>
<td><strong>Vascular Complications²</strong></td>
<td>1.9%</td>
<td>1.4%</td>
<td>0.680</td>
</tr>
<tr>
<td><strong>Aortic Valve Damage</strong></td>
<td>0%</td>
<td>0%</td>
<td>NA</td>
</tr>
</tbody>
</table>

---

1. 90 days per protocol population
2. Vascular complications from PROTECT II RCT = Cardiac, thoracic, or abdominal operation, or vascular operation for limb ischemia

---

**Bleeding Rates Reduced Over Time in High-risk PCI**

Continuous improvement with innovation, experience and best practices

---

1. FDA PMA Submission, Data on file (bleeding requiring transfusion)
3. Available USA publications and FDA studies with device-specific major bleeding rates or bleeding requiring transfusion
# Bleeding Rates in STEMI and Cardiogenic Shock

Major or Significant Bleeding or Requiring Transfusion in FDA and Large Studies

<table>
<thead>
<tr>
<th></th>
<th>STEMI DTU ¹</th>
<th>AMI-CGS PMA ²</th>
<th>AMI-CGS PAS ³</th>
<th>AMI-CGS IABP SHOCK II ⁴</th>
<th>CGS IABP ⁵</th>
<th>CGS TandemHeart ⁵</th>
<th>ECMO ⁶</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=50</td>
<td>6.0%</td>
<td>15.7%</td>
<td>10.1%</td>
<td>17.3%</td>
<td>14.3%</td>
<td>42.1%</td>
<td>40.8%</td>
</tr>
<tr>
<td>N=51</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N=34</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N=300</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N=14</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N=19</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N=1,866</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. FDA PMA Supplement, Data on file (bleeding requiring transfusion)
3. FDA Post-Approval Study, Data on file (bleeding requiring transfusion)
4. Thiele H et al., NEJM 2012; 367:1287-129 (bleeding requiring transfusion)
5. Burkhoff D et al., Am Heart J 2006;152:469.e12469.e8 (Major or significant bleeding)
6. Cheng R et al., Annals Thoracic Surgery 2014; 97: 610-6 (Major or significant bleeding)

2. Mean patients treated by Impella Centers: Mean: 61; Median: 37