Executive Summary

The table below provides the key metrics for drug-eluting balloons (DEB) for coronary and peripheral applications in the lower extremity in the APAC market.

### DEB for Coronary and Peripheral Applications*, Key Metrics in the APAC market

<table>
<thead>
<tr>
<th>Diagnosed Prevalence (2012)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary artery disease (CAD)</td>
<td>5.7  million</td>
</tr>
<tr>
<td>Peripheral artery disease (PAD)</td>
<td>2.6  million</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2012 DEB Market Sales ($m)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan</td>
<td>$0.00m</td>
</tr>
<tr>
<td>China</td>
<td>$25.9m</td>
</tr>
<tr>
<td>India</td>
<td>$26.1m</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$52.0m</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2012 APAC Market Sales by Type of Disease ($m)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary market</td>
<td>$16.1m</td>
</tr>
<tr>
<td>Peripheral market</td>
<td>$35.9m</td>
</tr>
<tr>
<td>Iliac artery market</td>
<td>$7.7m</td>
</tr>
<tr>
<td>Femoropopliteal artery market</td>
<td>$17.1m</td>
</tr>
<tr>
<td>Infrapopliteal artery market</td>
<td>$11.1m</td>
</tr>
</tbody>
</table>

### Pipeline Assessment

**Stage of clinical development**
- Number of DEB in the early development stage: 3
- Number of DEB in the preclinical stage: 1
- Number of DEB in the early clinical stage: 8
- Number of DEB in the late clinical stage: 3

### Key Events (2012–2019)

- Commercial launch of pipeline DEB, such as BioPath and BioStream for peripheral and coronary applications, in 2013 in the EU
- CE Mark approval and commercial launch of Magic Touch DEB, developed by Concept Medical, in 2013 in the EU
- Commercial launch of pipeline DEB, such as Drug-Coated AngioSculpt and Passeo-18 Lux, in 2014 in the EU
- Commercial launch of marketed coronary and peripheral DEBs, such as IN.PACT and Lutonix DCB, in 2016 and 2017 in Japan

### 2019 DEB Market Sales ($m)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan</td>
<td>$76.6m</td>
</tr>
<tr>
<td>China</td>
<td>$63.6m</td>
</tr>
<tr>
<td>India</td>
<td>$58.4m</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$198.6m</strong></td>
</tr>
</tbody>
</table>

*Peripheral applications include arteries in the lower extremity such as the iliac, femoropopliteal, and infrapopliteal arteries.

**Sales of Drug-Eluting Balloons by Region**

In 2012, the sales of DEB for coronary artery disease (CAD) and peripheral artery disease (PAD) in the lower extremity in APAC were $52m. We estimate the 2013 sales of DEB for coronary and peripheral applications to be $65m across the three APAC countries covered in this report, which are Japan, China, and India.

DEB can be used for select coronary and peripheral indications, including in-stent restenosis (ISR), small-vessel disease, bifurcation lesions, and femoropopliteal artery and below-the-knee (BTK) lesions. DEB angioplasty can improve the clinical outcomes for these select indications and the quality of life for patients suffering from these debilitating diseases.

By the end of the forecast period, sales of DEB will grow to $199m at a Compound Annual Growth Rate (CAGR) of 21%.
Executive Summary

The key drivers for this market during the forecast period are:

- The rising prevalence of CAD and PAD in the markets covered in this report
- The need for effective therapies that reduce the risk of complications such as restenosis and thrombosis, and the need for target lesion revascularization (TLR) associated with bare metal and drug-eluting stenting
- The cost savings for healthcare payers resulting from the reduced need for repeat revascularization procedures and prolonged dual antiplatelet therapy
- Reducing the need for stent-in-stent procedures, where DEB can become the gold standard of treatment for ISR
- The technical feasibility of future interventions
- The increase in patients’ disposable income and government insurance coverage in the emerging markets, such as China and India
- The approval and launch of coronary and peripheral DEB, such as IN.PACT, SeQuent Please, Lutonix DCB, Dior, Protégé, Elutex SV, and Magic Touch in these markets.

The emerging markets, including China, and India, are an outlet of expansion and a source of additional revenue for DEB manufacturers to increase their global presence.

APAC Drug-Eluting Balloons Market

Percutaneous coronary interventions (PCI) and endovascular therapies, such as angioplasty and stenting, are widely used in clinical practice to treat patients with CAD and PAD. DEB are an emerging, innovative technology that can be effectively used for the treatment of select coronary and peripheral indications, including ISR, small-vessel disease, bifurcation lesions, and superficial femoral artery (SFA) and BTK lesions. The peripheral market in the lower extremity presents greater opportunity and value for DEB, where they have the potential to become primary therapy for femoropopliteal and infrapopliteal artery disease. In 2012, the APAC coronary and peripheral markets for DEB were estimated to be $16m and $36m, respectively, where DEB for peripheral applications accounted for 69% of the overall market.

As shown in the figure below, the coronary and peripheral DEB markets are expected to grow steadily in the future as the next generation of DEB platforms enters the market, long-term clinical data become available, appropriate reimbursement rates are established, and high selling prices decrease. In addition, there is a tendency to use multiple DEB per procedure, especially for femoropopliteal and infrapopliteal applications.
Within the peripheral DEB market in the lower extremity, the femoropopliteal revascularization market for DEB has the largest market share, accounting for 47% of the peripheral DEB market, followed by that for infrapopliteal (BTK) revascularization.

Unlike in the femoropopliteal and BTK artery markets, DEB are not widely used to treat patients with iliac artery disease. Stenting remains the treatment of choice for treating the iliac arteries, given its high procedural and clinical success. The femoropopliteal and infrapopliteal DEB markets are approximately four to five times that of the iliac market.

Unmet Needs Remain a Challenge

Although stent technologies have evolved over the years, complications such as thrombosis and restenosis, negative vessel remodeling, delayed endothelelialization and healing, lack of homogenous drug distribution, and the need for prolonged dual antiplatelet therapy remain. Patients with ISR who are treated with drug-eluting stents (DES) have high risk of clinical failure, where performing stent-in-stent procedures leads to the formation of multiple layers of metal and increases the risk of chronic inflammation and recurrent stenosis. Currently, there is no effective therapy for treating patients with ISR, a challenge that DEB can address. In addition, treating small coronary vessel disease and the side branches of coronary bifurcations is challenging, given that these lesions are associated with a high risk of restenosis, and outcomes with stenting are suboptimal.

In the peripheral vasculature, treating the femoropopliteal and infrapopliteal arteries is difficult, given the diffuse nature of the atherosclerotic disease, long lesions with heavy calcifications, and exposure to high external forces.

For patients with severe critical limb ischemia (CLI), effective therapies are needed to prevent major amputation, which can reduce the quality of life for these patients.
Executive Summary

Low-profile drug-delivery systems need to be developed to reduce the risk of restenosis and thrombosis, and improve long-term patency. Effective therapies need to be developed to treat complex lesions and challenging patient populations, such as chronic total occlusions (CTOs), long lesions, diabetes mellitus, and acute myocardial infarction (heart attack). In addition, the high restenosis rates associated with standard balloon angioplasty warrant the development of effective alternative therapies. With DEB, the antiproliferative benefits of a DES are maintained without the complications of a permanent implant left behind or late stent thrombosis.

Key Players in the Drug-Eluting Balloon Market

As illustrated in the figure below, the DEB market for treating CAD and PAD in the lower extremity is a small but dynamic market with several key players, including Medtronic, B. Braun, Eurocor, C.R. Bard, Biotronik, and Cook Medical. The competitive landscape consists of large, mid-size, and small companies that have developed DEB to target specific patient populations within the coronary and peripheral markets. Companies such as Blue Medical, Cardionovum, and Minvasys are strong potential competitors in the market.

DEB developed by these companies have received the CE (Conformité Européene [European Conformity]) Mark and are commercially available.

GlobalData believes that as the next generation of DEB enters the market, the current key players will need to retain and acquire market share by improving the clinical performance of their existing products. They will also need to increase their presence in the emerging markets in order to take away revenue from their competitors in the future.
Executive Summary

APAC Drug-Eluting Balloons Market Future Outlook

DEB provide short-term, homogenous local drug delivery and enhanced vessel healing, with no permanent metal implant left behind. In the future, DEB can become the gold standard of treatment for coronary and peripheral ISR. In interventional cardiology, optimizing the outcomes of stenting with DEB does not have the same value as in the peripheral market. In the coronary market, there are already excellent DES that provide optimized treatment for the patient, where DES are considered to be the standard of treatment. DEB-only or DEB with stenting approaches can be used to treat niche coronary indications, such as small-vessel disease, bifurcations, and CTOs. However, in endovascular therapy, DEB can become a primary treatment for femoropopliteal artery and BTK lesions, where stenting is associated with high rates of restenosis and poor outcomes.

Device manufacturers are developing innovative DEB platforms to improve the mechanical properties of DEB, minimize drug loss and trauma to the vessel wall, incorporate limus-based anti-proliferative drugs, and ensure efficient drug delivery. GlobalData believes the adoption of innovative technologies, such as DEB, will increase slowly in the APAC region as long-term clinical and cost-effective data become available, appropriate reimbursement rates are implemented, and the selling prices decrease.

What Do Physicians Think?

Physicians are optimistic about the adoption of DEB for treating CAD and PAD in the lower extremity in the future.

“I am very enthusiastic and positive about this technology. With DEB, there are advantages linked to, I would say, every aspect that is characterizing and limiting DES….With DEB, there is no substance that is potentially stimulating an inflammatory reaction, where there is [a] risk of thrombosis or restenosis.”

Key Opinion Leader

“I think that DEB will get cheaper, given the increased competition, and they will be used for indications where [the] outcomes of stenting are unsatisfactory….These factors will drive the use of DEB.”

Key Opinion Leader

Physicians want to see long-term clinical data to evaluate and compare the clinical effectiveness of DEB.

“We want to see clinical trials with good data…we want to use devices that are cost-effective and best for the patient.”

Key Opinion Leader
Executive Summary

“The clinical data subset is very weak right now. That is why the technology is lagging behind…we do not have any robust clinical data to support the use of DEB in these clinical situations. Until we have these data, it will be very difficult to have any strong indication in the future as well.”

Key Opinion Leader

“We need to have more clinical data to support this idea. If the data is positive and they [DEB] are better than DES in these lesion subsets, then it will change the whole paradigm and everyone will use DEB.”

Key Opinion Leader

The current design of DEB platforms needs to be improved to increase the predictability of the treatment and increase adoption in clinical practice.

“I think the next development step will be to design DEB that is as much as possible similar to the best-in-class standard angioplasty balloon. DEB need to be developed with better trackability…[in order to] favor advancement of the device through complex anatomy.”

Key Opinion Leader

“To adopt DEB into my practice, I need to see clinical data that it works. I need to see data that demonstrates DEB technology is reliable, where every time you treat a patient with a DEB, it is going to work similarly.”

Key Opinion Leader

As cost-containment policies are implemented, the widespread adoption of expensive DEB technologies is questioned.

“I think price and access to devices are going to be issues. The current financial environment in healthcare is very uncertain….I would not be surprised that in a year or two, we will be told to prove [that] using one device over another [is better] for cost-containment purposes.

Key Opinion Leader

“DEB need to come down in price….The cost of devices per patient should not exceed $600 to $800 in total [in order] to provide [an] incentive to hospitals and increase adoption.”

Key Opinion Leader
# Table of Contents

## 1 Table of Contents

1.1 List of Tables .................................................................................................................. 18
1.2 List of Figures .................................................................................................................. 24

## 2 Introduction .................................................................................................................. 27

2.1 Catalyst .......................................................................................................................... 28
2.2 Related Reports .............................................................................................................. 29

## 3 Disease Overview .......................................................................................................... 30

3.1 Overview ....................................................................................................................... 30
3.1.1 Coronary Artery Disease ......................................................................................... 30
3.1.2 Peripheral Artery Disease ...................................................................................... 30
3.2 Anatomy and Physiology ............................................................................................. 31
3.2.1 Coronary Arteries ................................................................................................. 31
3.2.2 Peripheral Arteries of the Lower Extremity ........................................................... 32
3.3 Pathophysiology .......................................................................................................... 34
3.3.1 Coronary Artery Disease ....................................................................................... 34
3.3.2 Peripheral Artery Disease ...................................................................................... 35
3.4 Clinical Presentation .................................................................................................... 36
3.4.1 Symptoms ............................................................................................................... 36
3.4.2 Risk Factors .......................................................................................................... 39
3.4.3 Disease Classification .................................................................................................. 40
3.4.4 Diagnosis ............................................................................................................... 42
# Table of Contents

3.4.5 Clinical Outcomes ......................................................................................................................... 45

3.5 Epidemiology ......................................................................................................................................... 78

3.5.1 Coronary Artery Disease ...................................................................................................................... 78

3.5.2 Peripheral Artery Disease .................................................................................................................... 81

3.6 Economic Impact of Coronary and Peripheral Artery Disease ................................................................. 84

3.6.1 Cost of Coronary Artery Disease ......................................................................................................... 84

3.6.2 Cost of Peripheral Artery Disease ....................................................................................................... 85

4 Competitive Assessment .......................................................................................................................... 86

4.1 Overview .................................................................................................................................................. 86

4.2 Product Profiles by Company ................................................................................................................ 88

4.2.1 Aachen Resonance ................................................................................................................................. 89

4.2.2 B. Braun .................................................................................................................................................. 91

4.2.3 Biotronik ................................................................................................................................................ 97

4.2.4 Blue Medical ......................................................................................................................................... 100

4.2.5 Cardionovum ........................................................................................................................................ 107

4.2.6 C.R. Bard .............................................................................................................................................. 113

4.2.7 Concept Medical Research .................................................................................................................. 119

4.2.8 Cook Medical ....................................................................................................................................... 123

4.2.9 Eurocor .................................................................................................................................................. 125

4.2.10 Medrad (Bayer Healthcare) ............................................................................................................... 139

4.2.11 Medtronic .......................................................................................................................................... 142

4.2.12 Minvasys .......................................................................................................................................... 150

5 Unmet Needs ............................................................................................................................................. 153
### Table of Contents

5.1 Need for Better Clinical Outcomes in Specific Lesions .......................................................... 153

5.1.1 Chronic Total Occlusions ................................................................................................. 153

5.1.2 Small-Vessel Coronary Lesions ....................................................................................... 154

5.1.3 Long Lesions .................................................................................................................. 154

5.1.4 Heavily-Calcified and Uncrossable/Undilatable Lesions .................................................. 155

5.1.5 Bifurcation Lesions .......................................................................................................... 155

5.2 Need for Better Revascularization of the Femoropopliteal Artery ........................................... 156

5.3 Difficulty in Treating the Infraopopliteal Artery .................................................................... 158

5.4 Eliminating Mechanisms of Failure with Balloon Angioplasty ............................................. 159

5.5 Addressing Challenges of Stenting ....................................................................................... 161

5.5.1 Risk of Post-Procedural Complications ......................................................................... 161

5.5.2 In-Stent Restenosis ........................................................................................................ 162

5.5.3 Stent-In-Stent Procedures .............................................................................................. 164

5.5.4 Prolonged Dual Antiplatelet Therapy ............................................................................... 165

5.5.5 Lack of Homogenous Drug Distribution ......................................................................... 166

5.5.6 Delayed Healing .............................................................................................................. 166

5.5.7 Stent Fracture .................................................................................................................. 167

5.5.8 Negative Vessel Remodeling ......................................................................................... 168

5.5.9 Long-Term Vessel Patency ............................................................................................. 168

5.6 Need for Effective Therapy for Specific Patient Populations ............................................... 169

5.7 Lack of Clinical Data ........................................................................................................... 170

5.8 Addressing the Complications of Bypass Surgery ............................................................... 170

5.9 Need to Improve Medical Therapy ....................................................................................... 171
# Table of Contents

5.10 Comparative Studies on Exercise Therapy for PAD .................................................. 172

6 Pipeline Products ........................................................................................................... 173

   6.1 Overview .................................................................................................................. 173

   6.2 Pipeline by Stage of Development ........................................................................... 174

   6.3 Pipeline Product Profiles ......................................................................................... 176

       6.3.1 NF-κB Decoy Oligo DEB ................................................................................. 176

       6.3.2 Drug-Coated AngioSculpt ............................................................................... 178

       6.3.3 BioPath ............................................................................................................. 181

       6.3.4 BioStream ........................................................................................................ 182

       6.3.5 Boston Scientific Drug-Coated Balloon .......................................................... 183

       6.3.6 Coroflex DEBlue .............................................................................................. 184

       6.3.7 Covidien Drug-Coated Balloon .......................................................................... 186

       6.3.8 Caliber Therapeutics DEB ............................................................................... 188

       6.3.9 Elixir Medical Corporation DCB ........................................................................ 189

       6.3.10 LifeTech Scientific Corporation DEB .............................................................. 189

       6.3.11 Micell Technologies Drug-Coated Balloon ...................................................... 189

       6.3.12 Drug-Coated Chocolate DEB ........................................................................ 191

       6.3.13 Passeo-18 Lux ................................................................................................ 193

       6.3.14 Vascular Nanotransfer Technologies Drug-Coated Balloon ............................. 194

       6.3.15 WOMBAT DCB ............................................................................................. 195

7 Clinical Trial Analysis .................................................................................................. 197

   7.1 Overview .................................................................................................................. 197

   7.2 Clinical Trials to Watch ........................................................................................... 197
## Table of Contents

7.2.1  Drug-Eluting Balloons ................................................................. 197
7.2.2  Vascular Stents ........................................................................... 210

8  Industry Overview............................................................................. 216

8.1  Procedure Trends ........................................................................... 216
  8.1.1  Factors Contributing to the Rise of Coronary and Peripheral Interventions .................................................... 216
  8.1.2  Coronary Artery Disease .............................................................. 216
  8.1.3  Peripheral Artery Disease ............................................................ 218

8.2  Physician Decision-Making Process ................................................ 220

8.3  Market Access .................................................................................. 222
  8.3.1  Regulatory Process ...................................................................... 223
  8.3.2  Adoption ...................................................................................... 225
  8.3.3  Reimbursement Trends in the Asia-Pacific Region ..................... 228

8.4  Regulatory Issues/Recalls ................................................................ 231
  8.4.1  Regulatory Issues ...................................................................... 231
  8.4.2  Product Recalls .......................................................................... 232

8.5  Mergers and Acquisitions/Partnerships .......................................... 232
  8.5.1  Biosensors International and Eurocor ........................................ 232
  8.5.2  Boston Scientific Corporation and Guidant Corporation ........... 233
  8.5.3  Covidien and ev3, CV Ingenuity .................................................. 233
  8.5.4  C.R. Bard and Lutonix ................................................................. 234
  8.5.5  Micell Technologies and Maxcor Lifescience ............................. 234
  8.5.6  Medrad and Bayer .................................................................... 235
  8.5.7  Medtronic and Invatec ............................................................... 235
# Table of Contents

9 Current and Future Players ................................................................. 236
  9.1 Overview .................................................................................. 236
  9.2 Trends in Corporate Strategy ...................................................... 237
  9.3 Company Profiles ..................................................................... 240
    9.3.1 Aachen Resonance ............................................................ 240
    9.3.2 AnGes MG ...................................................................... 241
    9.3.3 AngioScore ...................................................................... 243
    9.3.4 AVIDAL Vascular .............................................................. 245
    9.3.5 B. Braun .......................................................................... 247
    9.3.6 Biosensors International ..................................................... 249
    9.3.7 Biotronik .......................................................................... 251
    9.3.8 Blue Medical ..................................................................... 253
    9.3.9 Boston Scientific Corporation ............................................ 255
    9.3.10 Caliber Therapeutics ......................................................... 257
    9.3.11 Cardionovum .................................................................. 259
    9.3.12 Concept Medical Research ............................................... 261
    9.3.13 Cook Medical .................................................................. 263
    9.3.14 Covidien .......................................................................... 265
    9.3.15 C.R. Bard ........................................................................ 267
    9.3.16 Elixir Medical Corporation ............................................... 269
    9.3.17 Eurocor .......................................................................... 271
    9.3.18 LifeTech Scientific Corporation ........................................ 273
    9.3.19 Medtronic ....................................................................... 275
Table of Contents

9.3.20 Micell Technologies .................................................................................................................. 277
9.3.21 Minvasys .................................................................................................................................. 278
9.3.22 TriReme Medical ...................................................................................................................... 280
9.3.23 Vascular Nanotransfer Technologies ....................................................................................... 282

10 Market Drivers, Opportunities, Barriers and Substitutes ............................................................... 284

10.1 Market Drivers .............................................................................................................................. 284
10.1.1 Rising Prevalence of Disease .................................................................................................... 285
10.1.2 Viable Treatment for Select Indications ................................................................................... 286
10.1.3 No Metal Left Behind ............................................................................................................... 291
10.1.4 Avoid Stent-in-Stent Procedures ............................................................................................. 292
10.1.5 Reduce the Need for Prolonged Dual Antiplatelet Therapy ...................................................... 293
10.1.6 Enhanced Vessel Healing and Better Patency ........................................................................... 293
10.1.7 Technical Feasibility of Future Interventions ......................................................................... 294
10.1.8 DEB as an Adjunctive Therapy ................................................................................................. 295
10.1.9 Limb Amputation ...................................................................................................................... 295
10.1.10 Cost Savings ............................................................................................................................ 296
10.1.11 Availability of Long-Term and Cost-Effective Data ................................................................. 297
10.1.12 Launch of DEB in the US ......................................................................................................... 297

10.2 Opportunities ............................................................................................................................... 298
10.2.1 Improve DEB Design ................................................................................................................ 298
10.2.2 DEB Hybrid Systems (DEB + Stent) .......................................................................................... 302
10.2.3 Target Indications Where Stenting is Not Satisfactory ............................................................. 303
10.2.4 Challenges in Treating the Femoropopliteal and Infrapopliteal Arteries ................................. 306
# Table of Contents

10.2.5 Target Challenging Patient Populations ................................................................. 307
10.2.6 Launch DEB in the Japanese Market ................................................................. 308
10.2.7 Emerging Markets ............................................................................................... 309

10.3 Market Barriers ........................................................................................................ 309
10.3.1 Slow Adoption ...................................................................................................... 309
10.3.2 High Selling Prices ............................................................................................... 313
10.3.3 Lack of Reimbursement ....................................................................................... 314
10.3.4 US FDA Regulatory Challenges ......................................................................... 315
10.3.5 Healthcare Cost-Cutting and Reimbursement ..................................................... 316
10.3.6 Availability of Venture Capital ............................................................................ 317
10.3.7 Medical Device Excise Tax .................................................................................. 318

10.4 Market Substitutes ................................................................................................... 318
10.4.1 Vascular Stents .................................................................................................... 318
10.4.2 Liquid Drug Delivery Catheter ............................................................................ 322

11 Drug-Eluting Balloon Market Analysis ........................................................................ 325

11.1 APAC Market Overview ......................................................................................... 325
11.2 Market Analysis by Type of Disease ....................................................................... 326
11.2.1 Coronary Artery Disease ..................................................................................... 326
11.2.2 Peripheral Artery Disease in the Lower Extremity ............................................. 327
11.3 Market Distribution by Indication ........................................................................... 329
11.4 Primary Versus Adjunctive Therapy ....................................................................... 331
11.5 Comparative Market Analysis ................................................................................ 333
11.5.1 Coronary Artery Disease .................................................................................... 333
# Table of Contents

11.5.2 Peripheral Artery Disease in the Lower Extremity .................................................. 335

## 12 Country Outlooks & Forecasts .................................................................................. 337

12.1 Overview ..................................................................................................................... 337

12.2 Japan ............................................................................................................................ 338

12.2.1 Overview ............................................................................................................... 338

12.2.2 Market Analysis ....................................................................................................... 338

12.3 China ............................................................................................................................ 341

12.3.1 Overview ............................................................................................................... 341

12.3.2 Market Analysis ....................................................................................................... 341

12.4 India ............................................................................................................................ 344

12.4.1 Overview ............................................................................................................... 344

12.4.2 Market Analysis ....................................................................................................... 344

## 13 Appendix ...................................................................................................................... 347

13.1 Bibliography ................................................................................................................ 347

13.2 Abbreviations .............................................................................................................. 372

13.3 Report Methodology .................................................................................................... 376

13.3.1 Overview ............................................................................................................... 376

13.3.2 Coverage ............................................................................................................... 376

13.3.3 Secondary Research .............................................................................................. 376

13.3.4 Forecasting Methodology ...................................................................................... 377

13.4 Physicians and Specialists Included in this Study .................................................... 379

13.5 Physician Survey ......................................................................................................... 382

13.6 About the Authors ....................................................................................................... 383
Table of Contents

13.6.1 Analysts.................................................................................................................383
13.6.2 Global Head of Healthcare....................................................................................384
13.7 About MediPoint.......................................................................................................385
13.8 About GlobalData....................................................................................................385
13.9 Disclaimer..................................................................................................................385
1.1 List of Tables

Table 1: Classification Systems for Determining the Severity of PAD Symptoms ................................................ 38
Table 2: Risk Factors Associated with CAD and PAD .......................................................................................... 39
Table 3: Types of Atherosclerotic Lesions ........................................................................................................ 41
Table 4: Treatment Guidelines to Improve the Symptoms of CAD* .................................................................. 46
Table 5: TASC II Classification of Iliac Artery Lesions ..................................................................................... 48
Table 6: TASC II Classification of Femoropopliteal Artery Lesions ................................................................. 49
Table 7: TASC II Classification of Infrapopliteal Artery Lesions ...................................................................... 50
Table 8: Types of Coronary Artery Bypass Grafting ......................................................................................... 61
Table 9: Complications of Coronary/Peripheral Artery Bypass Surgery ....................................................... 62
Table 10: Indications for Using Drug-Eluting Balloons ..................................................................................... 65
Table 11: Drug-Eluting Balloon Coating Characteristics ................................................................................. 68
Table 12: Drugs Incorporated Into Drug-Eluting Stents .................................................................................. 71
Table 13: Types of Lesions Treated Using Atherectomy .................................................................................. 74
Table 14: Prevalence of CAD in the Population Age ≥ 65 Years in the APAC Market (millions), 2010–2019 .... 79
Table 15: Prevalence of PAD in the Population Age ≥ 65 Years in the APAC Market (millions), 2010–2019 .... 82
Table 16: Direct and Indirect Healthcare Costs .................................................................................................. 84
Table 17: APAC DEB Market ($m) for Treating Coronary and Peripheral Artery Disease, 2012 ....................... 86
Table 18: Marketed DEB Products .................................................................................................................... 88
Table 19: Elutax SV Product Portfolio .............................................................................................................. 89
Table 20: Elutax SV SWOT Analysis, 2013 ....................................................................................................... 91
Table 21: SeQuent Please Product Portfolio ...................................................................................................... 92
Table 22: SeQuent Please SWOT Analysis, 2013 ............................................................................................ 97
Table 23: Pantera Lux Product Portfolio .......................................................................................................... 98
Table of Contents

Table 24: Pantera Lux SWOT Analysis, 2013 ................................................................. 100
Table 25: Pioneer Product Portfolio ................................................................................. 101
Table 26: Pioneer SWOT Analysis, 2013 .................................................................. 103
Table 27: Protégé Product Portfolio ............................................................................. 104
Table 28: Protégé SWOT Analysis, 2013 ................................................................ 107
Table 29: Restore DEB Product Portfolio .................................................................. 108
Table 30: Restore DEB SWOT Analysis, 2013 ......................................................... 109
Table 31: Legflow DEB Product Portfolio .................................................................. 110
Table 32: Legflow DEB SWOT Analysis, 2013 .......................................................... 112
Table 33: Other DEB Products Developed by Cardionovum ...................................... 113
Table 34: Lutonix Product Portfolio ........................................................................... 114
Table 35: Lutonix SWOT Analysis, 2013 .................................................................. 119
Table 36: Magic Touch Product Portfolio .................................................................. 120
Table 37: Magic Touch SWOT Analysis, 2013 ......................................................... 122
Table 38: Advance 18 PTX Product Portfolio ............................................................... 123
Table 39: Advance 18 PTX SWOT Analysis, 2013 .................................................... 125
Table 40: Dior Product Portfolio ................................................................................ 126
Table 41: Dior SWOT Analysis, 2013 ....................................................................... 132
Table 42: Freeway Family of DEB Product Portfolio .................................................. 133
Table 43: Freeway Family of DEB SWOT Analysis, 2013 ........................................ 136
Table 44: Magical Product Portfolio .......................................................................... 137
Table 45: Magical SWOT Analysis, 2013 ................................................................ 139
Table 46: Cotavance Product Portfolio ...................................................................... 140
Table 47: Cotavance SWOT Analysis, 2013 ............................................................... 142
## Table of Contents

- Table 48: IN.PACT Family DEB Product Portfolio ................................................................. 143
- Table 49: IN.PACT SWOT Analysis, 2013 ........................................................................... 150
- Table 50: Danubio Product Portfolio ..................................................................................... 151
- Table 51: Danubio SWOT Analysis, 2013 ........................................................................... 152
- Table 52: Global DEB Pipeline Products ................................................................................. 175
- Table 53: NF-κB Decoy Oligo DEB SWOT Analysis, 2013 ..................................................... 178
- Table 54: AngioSculpt SWOT Analysis, 2013 ..................................................................... 180
- Table 55: BioPath SWOT Analysis, 2013 ............................................................................ 182
- Table 56: BioStream SWOT Analysis, 2013 ........................................................................ 183
- Table 57: Boston Scientific DEB SWOT Analysis, 2013 ....................................................... 184
- Table 58: Coroflex DEBlue SWOT Analysis, 2013 ............................................................... 186
- Table 59: Covidien DCB SWOT Analysis, 2013 .................................................................. 188
- Table 60: Micell Technologies’ DCB SWOT Analysis, 2013 ................................................ 190
- Table 61: Drug-Coated Chocolate DEB SWOT Analysis, 2013 .......................................... 192
- Table 62: Passeo-18 Lux SWOT Analysis, 2013 ................................................................. 194
- Table 63: Vascular Nanotransfer Technologies DCB SWOT Analysis, 2013 ....................... 195
- Table 64: WOMBAT DCB SWOT Analysis, 2013 .............................................................. 196
- Table 65: Reimbursement Classification of Medical Devices in Japan .................................. 229
- Table 66: Aachen Resonance Company Profile ..................................................................... 240
- Table 67: Aachen Resonance, Marketed DEB Product ......................................................... 241
- Table 68: Aachen Resonance SWOT Analysis, 2013 ........................................................... 241
- Table 69: AnGes MG Company Profile ............................................................................... 242
- Table 70: AnGes MG, Pipeline DEB Product ....................................................................... 243
- Table 71: AnGes MG SWOT Analysis, 2013 ..................................................................... 243
## Table of Contents

Table 72: AngioScore Company Profile........................................................................................................244
Table 73: AngioScore, Pipeline DEB Product.................................................................................................244
Table 74: AngioScore SWOT Analysis, 2013 ...............................................................................................245
Table 75: AVIDAL Vascular Company Profile.............................................................................................245
Table 76: AVIDAL Vascular, Pipeline DEB Product.....................................................................................246
Table 77: AVIDAL Vascular SWOT Analysis, 2013 ..................................................................................247
Table 78: B. Braun Company Profile...........................................................................................................247
Table 79: B. Braun, Marketed and Pipeline DEB Products...........................................................................248
Table 80: B. Braun SWOT Analysis, 2013 ..................................................................................................249
Table 81: Biosensors International Company Profile ..................................................................................250
Table 82: Biosensors International, Pipeline DEB Products ......................................................................250
Table 83: Biosensors International SWOT Analysis, 2013 ...................................................................251
Table 84: Biotronik Company Profile........................................................................................................252
Table 85: Biotronik, Marketed and Pipeline DEB Products .......................................................................252
Table 86: Biotronik SWOT Analysis, 2013 ................................................................................................253
Table 87: Blue Medical Company Profile..................................................................................................254
Table 88: Blue Medical, Marketed DEB Products .....................................................................................255
Table 89: Blue Medical SWOT Analysis, 2013 ........................................................................................255
Table 90: Boston Scientific Corporation Company Profile ......................................................................256
Table 91: Boston Scientific Corporation, Pipeline DEB Product .................................................................256
Table 92: Boston Scientific Corporation SWOT Analysis, 2013 ..............................................................257
Table 93: Caliber Therapeutics Company Profile .....................................................................................257
Table 94: Caliber Therapeutics, Pipeline DEB Product ..............................................................................258
Table 95: Caliber Therapeutics SWOT Analysis, 2013 .........................................................................259
Table of Contents

Table 96: Cardionovum Company Profile.................................................................259
Table 97: Cardionovum, Marketed and Pipeline DEB Products ........................................260
Table 98: Cardionovum SWOT Analysis, 2013..............................................................261
Table 99: Concept Medical Research Company Profile......................................................261
Table 100: Concept Medical Research, Marketed DEB Product ..........................................262
Table 101: Concept Medical Research SWOT Analysis, 2013.............................................263
Table 102: Cook Medical Company Profile.....................................................................263
Table 103: Cook Medical, Marketed DEB Product ..........................................................264
Table 104: Cook Medical SWOT Analysis, 2013.............................................................265
Table 105: Covidien Company Profile............................................................................266
Table 106: Covidien, Pipeline DEB Product ..................................................................266
Table 107: Covidien SWOT Analysis, 2013..................................................................267
Table 108: C.R. Bard Company Profile ........................................................................267
Table 109: C.R. Bard, Marketed DEB Products ..............................................................268
Table 110: C.R. Bard SWOT Analysis, 2013................................................................269
Table 111: Elixir Medical Corporation Company Profile.................................................269
Table 112: Elixir Medical Corporation, Pipeline DEB Product ...........................................270
Table 113: Elixir Medical Corporation SWOT Analysis, 2013..........................................270
Table 114: Eurocor Company Profile .............................................................................271
Table 115: Eurocor, Marketed DEB Products ..................................................................272
Table 116: Eurocor SWOT Analysis, 2013....................................................................272
Table 117: LifeTech Scientific Corporation Company Profile.........................................273
Table 118: LifeTech Scientific, Pipeline DEB Product.....................................................274
Table 119: LifeTech Scientific SWOT Analysis, 2013......................................................274
Table of Contents

Table 120: Medtronic Company Profile .................................................................275
Table 121: Medtronic, Marketed DEB Products ..................................................276
Table 122: Medtronic SWOT Analysis, 2013 .......................................................276
Table 123: Micell Technologies Company Profile ...............................................277
Table 124: Micell Technologies, Pipeline DEB Product ........................................278
Table 125: Micell Technologies SWOT Analysis, 2013 .......................................278
Table 126: Minvasys Company Profile ..................................................................279
Table 127: Minvasys, Marketed DEB Product .....................................................279
Table 128: Minvasys SWOT Analysis, 2013 .........................................................280
Table 129: TriReme Medical Company Profile .....................................................280
Table 130: TriReme Medical, Pipeline DEB Product ............................................281
Table 131: TriReme Medical SWOT Analysis, 2013 .............................................281
Table 132: Vascular Nanotransfer Technologies Company Profile ......................282
Table 133: Vascular Nanotransfer Technologies, Pipeline DEB Product ...............283
Table 134: Vascular Nanotransfer Technologies SWOT Analysis, 2013 ...............283
Table 135: APAC Coronary and Peripheral DEB Market ($m) Forecast, 2010–2019 ..326
Table 136: APAC DEB Market ($m) for Treating PAD in the Lower Extremity, 2010–2019.................327
Table 137: Percent of Patients with CAD or PAD Receiving Stenting with DEB Angioplasty, APAC, 2012 and 2018 (N=33) .................................................................331
Table 138: DEB Sales ($m) Forecast for Japan, 2010–2019 ..................................339
Table 139: DEB Sales ($m) Forecast for China, 2010–2019 ..................................341
Table 140: DEB Sales ($m) Forecast for India, 2010–2019 ..................................344
Table 141: Physicians Surveyed, By Country .......................................................382
## 1.2 List of Figures

- Figure 1: Coronary Arteries of the Human Heart ................................................................. 31
- Figure 2: Peripheral Arteries of the Lower Extremity .......................................................... 32
- Figure 3: Pathophysiology of Coronary Artery Disease ....................................................... 34
- Figure 4: Pathophysiology of Peripheral Artery Disease ....................................................... 35
- Figure 5: Treatment Modalities – Coronary Artery Disease .................................................. 52
- Figure 6: Percent of Patients with CAD Who Receive Each Therapy Option Only, APAC, 2012 and 2019 (N=16) ........................................................................................................... 53
- Figure 7: Treatment Modalities – Peripheral Artery Disease ................................................... 54
- Figure 8: Percent of Patients with PAD Who Receive Each Therapy Option Only, APAC, 2012 (N=17) ................................................................. 55
- Figure 9: Percent of Patients with PAD Who Receive Each Therapy Option Only, APAC, 2012 (N=17) ................................................................. 55
- Figure 10: Drug-Eluting Balloon ............................................................................................ 64
- Figure 11: Types of Stents Used to Treat CAD and PAD ........................................................ 70
- Figure 12: Bare Metal Stent .................................................................................................... 70
- Figure 13: Drug-Eluting Stent ................................................................................................. 71
- Figure 14: Covered Stents ....................................................................................................... 72
- Figure 15: Bioabsorbable Stent – Remedy ............................................................................. 73
- Figure 16: Types of Atherectomy ............................................................................................ 75
- Figure 17: Prevalence of CAD in the Population Age ≥65 Years in the APAC Market (millions), 2010–2019 ......................................................................................................................... 79
- Figure 18: Prevalence of PAD in the Population Age ≥65 Years in the APAC Market (millions), 2010–2019 ......................................................................................................................... 82
- Figure 19: APAC DEB Market Share for Treating Peripheral Artery Disease in the Lower Extremity, 2012 ............................................................ 87
- Figure 20: Image of the Protégé DEB .................................................................................... 105
- Figure 21: Percent of CAD and PAD Patients with Acute Vessel Recoil After Standard Balloon Angioplasty, APAC, 2012 and 2018 (N=33) .......................................................................................... 160
# Table of Contents

Figure 22: Percent of CAD and PAD Patients with Thrombosis After Stenting, APAC, 2012 and 2018 (N=33) .................................................................................................................................................. 162

Figure 23: Percent of CAD and PAD Patients with ISR, APAC, 2012 and 2018 (N=33) .............................................. 163

Figure 24: Percent of CAD and PAD Patients Who Receive Stent-In-Stent Procedures, APAC, 2012 and 2018 (N=33) ................................................................................................................................................. 164

Figure 25: Percent of CAD and PAD Patients with Stent Fracture, APAC, 2012 and 2018 (N=33) ......................... 167

Figure 26: Global DEB Pipeline Products by Stage of Development, 2013 ............................................................... 174

Figure 27: AngioSculpt Scoring Balloon Expansion Profile ......................................................................................... 179

Figure 28: Drug-Coated Chocolate DEB .................................................................................................................. 191

Figure 29: Population (≥ 65 years) of CAD Patients Receiving Interventional Procedures, APAC*, 2010–2019 ........................................... ........................................................................................................... 217

Figure 30: Population (≥ 65 years) with PAD Receiving Interventional Procedures for the Peripheral Arteries in the Lower Extremity, APAC*, 2010–2019 ........................................................................................................ 218

Figure 31: Population (≥ 65 years) with PAD Receiving DEB Angioplasty for the Peripheral Arteries in the Lower Extremity, APAC*, 2010–2019 ........................................................................................................ 219

Figure 32: DEB Market for Treating CAD and PAD in the Lower Extremity, Company Share (%), 2012........ 236

Figure 33: DEB Market for Each Type of Disease, Company Share (%), 2012 ......................................................... 238

Figure 34: Importance of Each Therapy Attribute in Adopting DEB for the Treatment of CAD and PAD, Global, 2012 (N=112) ................................................................................................................................. 299

Figure 35: APAC DEB Market ($m) for Treating Coronary Artery Disease and Peripheral Artery Disease in the Lower Extremity, 2010-2019 ........................................................................................................ 325

Figure 36: APAC DEB Market ($m) for Treating PAD in the Lower Extremity, 2010–2019 ..................................... 328

Figure 37: APAC DEB Market Share for Peripheral Artery Revascularization in the Lower Extremity, 2012 and 2019 .................................................................................................................................................. 329

Figure 38: APAC DEB Market Distribution (%) by Indication, 2012 and 2018 (N=33) ............................................. 330

Figure 39: Percent of Patients with CAD Receiving Each Type of Interventional Technique Only, APAC, 2018 (N=16) ........................................................................................................................................... 334
Figure 40: Percent of Patients with Lower Limb PAD Receiving Each Type of Interventional Technique Only, APAC, 2018 (N=17)..................................................................................................................................................335

Figure 41: APAC DEB Market Revenue ($m), 2019 ..................................................................................................................................................337

Figure 42: Japanese DEB Market ($m) for Coronary and Peripheral Applications, 2010–2019 ..........................339

Figure 43: Chinese DEB Market ($m) for Coronary and Peripheral Applications, 2010–2019.........................342

Figure 44: Indian DEB Market ($m) for Coronary and Peripheral Applications, 2010–2019 .........................345
2 Introduction

Coronary artery disease (CAD) and peripheral artery disease (PAD) are global public health and socioeconomic issues that affect millions of lives each year. Percutaneous coronary interventions (PCI) and endovascular therapies, such as stenting and angioplasty, have been widely adopted to treat CAD and PAD in the lower extremity. Vascular stents, such as bare metal and drug-eluting stents are often used in clinical practice to treat coronary and peripheral artery lesions. However, for indications such as in-stent restenosis (ISR), small-vessel disease, coronary bifurcations, and femoropopliteal artery and below-the-knee (BTK) lesions, stenting is associated with poor clinical outcomes, reiterating the need for alternative therapies. In addition, implanting permanent stents, such as drug-eluting stents (DES) and bare metal stents (BMS), into the vessel can increase the risk of chronic inflammation, restenosis, and thrombosis.

Emerging technologies, such as drug-eluting balloons (DEB), address the challenges and complications of stenting in these subsets of lesions. DEB provide fast, short-term, homogenous, local drug delivery, preserve the anatomy of the vessel, promote enhanced vessel healing, and reduce the need for prolonged dual antiplatelet therapy without leaving any metal behind. Medical device companies have developed a range of DEB for coronary and peripheral applications in the lower extremity. The majority of these DEB have paclitaxel as the antiproliferative drug of choice, with different drug coating technologies and balloon/catheter designs. In this report, DEB are defined as drug-coated angioplasty balloon catheters.

This report focuses on the DEB market for treating CAD and PAD in the lower extremity in the APAC region. The APAC DEB market is determined for the three countries covered in the report, which are Japan, China, and India. This report identifies the unmet needs in the market for treating CAD and PAD in the lower limb, provides an understanding of physicians' perceptions and decision-making process in using DEB, and evaluates the adoption of DEB in the future. From GlobalData’s analysis, it is evident that the current adoption of DEB for coronary and peripheral applications is slow. However, the DEB market for peripheral applications is larger compared with that for coronary applications. DEB are currently not commercially available in Japan. Large-scale, long-term, cost-effectiveness studies need to be conducted to demonstrate their clinical efficacy and DEB need to be integrated appropriately into the existing reimbursement systems.
Introduction

To successfully market DEB, companies need to design novel platforms that address the challenges in treating femoropopliteal and infrapopliteal artery lesions, coronary bifurcations, and small-vessel disease, and show that they have superior clinical performance to the stents that are used to treat these lesions.

2.1 Catalyst

Minimally-invasive techniques, including stenting and angioplasty, have become the standard of care for patients with CAD and PAD in the lower extremity. Modern developments in endovascular interventions have led to a paradigm shift in the treatment of PAD in the lower extremity towards endovascular therapy. Although vascular stents, including bare metal, drug-eluting, and covered stents, offer treatment solutions for patients, they do not provide sustained clinical outcomes in lesions such as ISR, small-vessel disease, coronary bifurcations, and superficial femoral artery (SFA) and BTK lesions. In the peripheral vasculature, the femoropopliteal and infrapopliteal arteries are challenging to treat, given the diffuse nature of the atherosclerotic disease and long and heavily-calcified lesions. In the femoropopliteal arteries, the high plaque burden, slow vascular flow, and exposure to high mechanical forces increase the risk of stent compression and fracture. Alternative effective technologies need to be designed to address these unmet needs.

Compared with the coronary and peripheral vascular stent markets, the DEB market is a much smaller market. However, it is a dynamic market that allows device manufacturers to develop a range of platforms to target different coronary and peripheral indications. Low-profile DEB technologies are being developed to reduce the risk of complications of stenting such as restenosis and thrombosis, improve long-term vessel patency, and reduce barotrauma to the vessel. DEB-only and DEB as an adjunct therapy can be used to treat complex and challenging lesions and optimize stenting. Given the lack of effective therapies, DEB can become the gold standard of treatment for coronary/peripheral artery ISR. In addition, DEB may become a primary therapy for treating peripheral lesions in the lower extremity, where stenting can be used as a “bailout” strategy.
Introduction

As more long-term clinical data that demonstrate the superior therapeutic benefits of DEB and reimbursement become available, the adoption of DEB by the medical community will increase slowly in the future. As CAD and PAD present enormous public health and socioeconomic issues, and use of stents continues to increase, it is important to find effective treatment modalities that ensure long-term quality results for patients. This report looks at the current DEB market for CAD and PAD in the lower extremity in various regions, and evaluates the adoption and opportunities for this technology in the three markets in APAC.
13.7 About MediPoint

MediPoint is the flagship product for GlobalData’s Medical team. Each MediPoint report is built from the ground up by our team of healthcare analysts in the US and UK. Each report includes input from experienced physicians and leading key opinion leaders (KOLs). Running throughout each report in the series, “What Physicians Think” quotes provide a unique insight into how healthcare professionals are reacting to events within the industry, and what their responses could mean for industry strategists.

13.8 About GlobalData

GlobalData is a leading global provider of business intelligence in the healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in drug research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports, and forecasts. Our analysis is supported by a 24/7 client support and analyst team. GlobalData has offices in New York, Boston, London, India, and Singapore.

13.9 Disclaimer

All Rights Reserved.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form by any means, electronic, mechanical, photocopying, recording, or otherwise without the prior permission of the publisher, GlobalData.