The table below provides the key metrics for peripheral vascular stents for the lower extremity in the EU market.

| Peripheral Vascular Stents for the Lower Extremity*, Key Metrics in the EU Market |
|---------------------------------|---|
| Diagnosed Prevalence (2012)     | 2.4 million |
| 2012 Peripheral Vascular Stent Market Sales | $449m |
| 2012 Market Sales by Type of Vascular Stent ($m) |
| Bare Metal Stent Market         | $324m |
| Drug-Eluting Stent Market       | $53.9m |
| Covered Stent Market            | $78.2m |
| Bioabsorbable Stent Market      | $9.39m |

**Pipeline Assessment**

**Stage of clinical development**
- Number of stents at preclinical phase: 11
- Number of stents at early clinical phase: 4
- Number of stents at late clinical phase: 3

**Type of Vascular Stent**
- Bare metal stents (BMS): 28%
- Drug-eluting stents (DES): 5%
- Covered stents: 17%
- Bioabsorbable stents (BAS): 50%

**Key Events (2012–2019)**

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Level of Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial launch of DES, Yukon, developed by Translumina for treating below-the-knee lesions in 2014 in the EU</td>
<td>↑↑</td>
</tr>
<tr>
<td>Commercial launch of BAS, such as the Esprit Bioabsorbable Vascular Scaffold (BVS) and Stanza, in 2015 in the EU</td>
<td>↑↑</td>
</tr>
</tbody>
</table>

**2019 Peripheral Vascular Stent Market Sales**
- $896m

**Sales of Peripheral Vascular Stents by Region**

The figure below shows the sales of peripheral vascular stents for the lower extremity in 2012 in the European Union (EU) market, which was $449m. We estimate 2013 sales of peripheral vascular stents for the lower extremity to be $496m across the five EU countries covered in this report, which are France, Germany, Italy, Spain, and UK.

Vascular stents used to treat PAD in the lower extremity include bare metal, drug-eluting, covered, and bioabsorbable stents. Peripheral stenting is associated with improved clinical outcomes and quality of life for patients suffering from this debilitating disease.

By the end of the forecast period, sales of peripheral vascular stents will grow to over $895m at a Compound Annual Growth Rate (CAGR) of 10%, as shown in the figure below.

The key drivers for this market during the forecast period are:
- The rising prevalence of PAD in the markets covered in the 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 the current bare metal stents.
- The cost savings for healthcare payers resulting from the reduced need for repeat revascularization procedures
- The approval and launch of BAS, such as the Esprit BVS, Stanza, and Remedy, in the markets covered in this report

In the EU, Germany is leading the way with peripheral vascular stenting and has the largest market share in 2012; other European countries, such as France, are not far behind.
EU Peripheral Vascular Stent Market

Currently, BMS have the largest market share in the peripheral vascular stent market for the lower extremity, followed by covered stents. The BMS market is an approximately $324m market that is more than four to six times the size of the covered and drug-eluting stent markets, respectively. Self-expanding nitinol stents account for over 60% of BMS used to treat iliac, femoropopliteal, and infrapopliteal artery lesions. Covered stents have been used for specific cases where the patient has good run-off, including treating atherosclerotic disease in the common iliac arteries and in-stent restenosis. Drug-eluting and bioabsorbable stent currently have the smallest market shares. However, as adoption of these stent technologies increases in the future, they will take market share away from bare metal and covered stents.

Among the peripheral artery indications in the lower extremity, the iliac and femoropopliteal arteries currently have the largest market share in the peripheral vascular stent market, as shown in the figure below. The iliac and femoropopliteal vascular stent markets are expected to increase to over $200m and $400m by 2019, respectively. Given the challenges in treating the femoropopliteal arteries, the femoropopliteal vascular stent market is an attractive market for drug-eluting and bioabsorbable stents.

The adoption of stents for infrapopliteal lesions is lower than for iliac and femoropopliteal lesions. The iliac and femoropopliteal vascular stent markets are approximately two to three times the size of the infrapopliteal vascular stent market. Balloon angioplasty still remains the preferred method of treatment for treating infrapopliteal (below-the-knee [BTK]) lesions.
Unmet Needs Remain a Challenge

Stent technology has evolved over the years to address the challenges of treating patients with PAD. Treating femoropopliteal and infrapopliteal arteries is difficult, given the diffuse nature of atherosclerotic disease, long lesions with heavy calcifications, and exposure to high external forces. For patients with severe chronic limb ischemia (CLI), effective therapies are needed to prevent major amputation, which can reduce the quality of life for these patients.

Complications, such as restenosis and thrombosis, remain a concern. Effective therapies need to be developed to reduce the number of stent-in-stent procedures that are performed, where additional permanent stents are implanted into patients. Low-profile stent systems that have an optimal balance between radial force and flexibility need to be developed to prevent chronic inflammation and stent fracture. In addition, physicians have called for other treatment improvements, such as reducing or eliminating the need for dual anti-platelet therapy that is administered when implanting bare metal, covered, and drug-eluting stents.

A fully-degradable and absorbable stent can lower the risk of restenosis and thrombosis, and ensure quality long-term results for the patient.

Key Players in the Peripheral Vascular Stent Market

As illustrated in the figure below, the peripheral vascular stent market for the lower extremity is a large and dynamic market with several key players, including Cook Medical, W.L. Gore & Associates, Cordis Corporation, Abbott Vascular, Medtronic, Covidien, and Bard Peripheral Vascular. The competitive landscape consists of large, mid-size, and small companies that have developed stents to target specific patient populations within the peripheral vascular stent market. Companies such as IDEV Technologies, Atrium Medical Corporation, NovoStent Corporation, and Terumo Corporation are strong potential competitors in the market. Peripheral vascular stents developed by these companies have received the CE (Conformité Européene [European Conformity]) Mark and/or Food and Drug Administration (FDA) approval, and are commercially available.

GlobalData believes that as innovative stent technologies enter 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.
Peripheral Vascular Stent Market for Treating Peripheral Artery Disease in the Lower Extremity, Company Share (%), 2012

- Abbott Vascular
- Boston Scientific
- Bard Peripheral Vascular (C.R. Bard)
- Biotronik
- Cook Medical
- Cordis Corporation (Johnson & Johnson)
- Covidien
- Medtronic
- W.L. Gore & Associates
- Others

Source: GlobalData

“Others” category includes the companies Atrium Medical Corporation, IDEV Technologies, OptiMed, and Terumo Corporation

Peripheral Vascular Stent Market Future Outlook

The peripheral vascular stent market for the lower extremity in the future will be primarily dominated by drug-eluting and bioabsorbable stents. Although bare metal and covered stents will continue to be used, the drug-eluting and bioabsorbable stent markets are expected to demonstrate significant growth, especially for treating the femoropopliteal artery. Drug-eluting stents, such as the Zilver PTX and Xience Prime BTK, are expected to take market share away from bare metal and covered stents. In April 2013, Cook Medical initiated voluntary global recall of its Zilver PTX stent due to complaints of separation of the delivery system at the inner catheter tip. The company has conducted an exhaustive quality assessment and audit of the affected components to ensure the safety and satisfactory performance of the delivery system in the future.

Bioabsorbable stents provide temporary scaffolding to the vessel and then disappear over time, leaving behind a healed artery. BAS technology is in its infancy and has a long road ahead before it is widely adopted into clinical practice. This technology has the potential to revolutionize the stent industry and improve treatment outcomes for patients with PAD.

GlobalData believes the adoption of innovative stent technologies, such as drug-eluting and bioabsorbable stents will increase in the future as long-term clinical data become available, appropriate reimbursement rates are implemented, and the selling price decreases.

What Do Physicians Think?

Adoption of stents to treat PAD in the lower extremity is expected to continue to increase in the future.

“Five years ago, stenting was only performed as a bailout procedure after failed balloon angioplasty. Nowadays, we know [peripheral] stenting is not only better, but it is beneficial, especially for treating long lesions.”

Key Opinion Leader, January 2013

“I think peripheral stenting is already the standard of care, and I think it will continue to be in the future, except for the infrapopliteal arteries.”

Key Opinion Leader, January 2013

Physicians are optimistic about the adoption of vascular stents, such as drug-eluting and bioabsorbable stents, to treat PAD in the future.

“Drug-eluting stents have a good future. They will be widely adopted, as they already have better patency rates and durability. Patients do not experience restenosis or target lesion revascularization [as] often as compared to [bare metal stents].”

Key Opinion Leader, January 2013
“I think bioabsorbable stents are a very exciting technology. The benefit of having a biodegradable stent is that if and when it fails, you can go back and do it again.”

Key Opinion Leader, November 2012

“If you could have a stent that is bioabsorbable, medicated, and disappears within six months, then of course, that is going to be the technology of choice. You have eradicated in-stent restenosis and fully deployed a strategy to release medication within the vessel.”

Key Opinion Leader, February 2013

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

“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, January 2013

“Adoption of bioabsorbable stents depends on the clinical data. If it is shown to be cost-effective, then I would probably use it in 100% of my patients.”

Key Opinion Leader, October 2012

As cost-containment policies are implemented, widespread adoption of expensive stent 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 using one device over another for cost-containment purposes.

Key Opinion Leader, February 2013

“If the costs [of bioabsorbable stents] continue to be four times the cost of drug-eluting stents, I cannot think of a hospital that can afford that.”

Key Opinion Leader, October 2012
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2 Introduction

Peripheral artery disease (PAD) is a global public health and socioeconomic problem that affects millions of lives each year. Endovascular therapies, such as stenting, have been widely adopted to treat PAD in the lower extremity. Peripheral vascular stents including bare metal, drug-eluting, covered, and bioabsorbable stents, which are associated with improved clinical outcomes compared with balloon angioplasty alone. The peripheral vascular stent market is currently dominated by bare metal stents (BMS) — specifically, self-expanding nitinol stents — for treating atherosclerotic disease in the iliac, femoropopliteal, and infrapopliteal arteries. Adoption of stents for treating infrapopliteal artery lesions is low, where balloon angioplasty still remains the preferred method of treatment. Given the challenges in treating lesions in the femoropopliteal and infrapopliteal arteries, there is a growing need to develop novel stent platforms that can reduce the risk of restenosis and the need for target lesion revascularization (TLR), and improve long-term vessel patency. As innovative technologies, such as drug-eluting and bioabsorbable stents, enter the market, adoption of these stents will increase over time, especially for femoropopliteal and infrapopliteal applications. Bioabsorbable stents (BAS), which provide transient support to the vessel, are viable alternatives to permanent bare metal, drug-eluting, and covered stent implants. In this report, BAS are defined as fully-biodegradable stents that completely disappear from the vessel over time.

This report focuses on the vascular stents market for treating PAD in the lower extremity in the EU. The peripheral vascular stent market is determined for the five EU countries covered in the report, which are France, Germany, Italy, Spain, and UK. This report identifies the unmet needs in the market for treating PAD in the lower limb, provides an understanding of physicians’ perception of different types of peripheral vascular stents, and evaluates their adoption in the future. Through GlobalData’s analysis, it is evident that the current peripheral vascular stent market for the lower extremity is saturated with BMS, followed by covered stents. However, increased adoption of innovative stent technologies, such as DES, will decrease the use of bare metal and covered stents specifically for treating the femoropopliteal and infrapopliteal arteries. In the five countries covered in the report, widespread adoption of new stent technologies, such as BAS, will be slow. Large-scale, long-term studies need to be conducted to demonstrate clinical efficacy, and new stent technologies need to be integrated appropriately into the existing reimbursement systems. To successfully market peripheral vascular stents, companies need to design novel stent platforms that address the challenges in treating femoropopliteal and infrapopliteal artery lesions and show superior clinical performance to the stents currently in the peripheral vascular stent market.
2.1 Catalyst

Modern developments in endovascular interventions have led to a paradigm shift in the treatment of PAD in the lower extremity towards minimally invasive techniques, such as stenting. Peripheral vascular stents, including bare metal, drug-eluting, covered, and bioabsorbable stents, offer innovative treatment solutions for patients with PAD. Bare metal and covered stents have been widely adopted in clinical practice, where they are associated with maintaining high patency in the iliac arteries. The femoropopliteal and infrapopliteal arteries are challenging to treat, given the diffuse nature of 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. Effective stent technologies need to be designed to address these unmet needs.

The peripheral vascular stent market is a large and dynamic one that allows stent manufacturers to develop different types of vascular stent platforms for different types of arteries in the lower extremity. Low-profile stent technologies are being developed to reduce the risk of complications, such as restenosis, thrombosis, and stent fracture, and improve long-term vessel patency. As drug-eluting and bioabsorbable stents address the unmet needs of the current peripheral vascular stent market, they will represent the future of stents for treating PAD in the lower extremity. As more long-term clinical data become available demonstrating their superior therapeutic benefits, adoption of drug-eluting and bioabsorbable stents by the medical community will increase in the future. As PAD presents enormous global public health and socioeconomic issues, it is pertinent to find effective treatment modalities that ensure long-term quality results for patients. This report looks at the current peripheral vascular stent market for the lower extremity in the five EU countries and evaluates the adoption and opportunities for this technology in these markets.

2.2 Related Reports

- Bioabsorbable Stents – Global Market Analysis and Forecasts
  GDME0164MAR / Published December 2012
12.7 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.

12.8 About GlobalData

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