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Current Developments in the European PCI Devices Market

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Coronary artery disease (CAD) is one of the major causes of death worldwide affecting both women and men. Sedentary lifestyles along with hereditary factors are some of the major reasons for deaths due to CAD (Antman et al. 2008). Mortality due to these conditions has increased to the extent that it is attracting attention the world over, resulting in concentrated ef for ts to curb it. This has led to a huge number of surgeries and preventive treatments being performed. European healthcare systems are increasingly opting for treatments that are effective and less time-consuming, and have shorter recovery times with regards to CAD. As a consequence, healthcare across Europe has evolved from corrective bypass surgeries to interventional procedures. Over the last decade, there have been huge investments in research to discover innovative and minimally-invasive methods to treat CAD, as these minimally-invasive interventional procedures are not only less time-consuming, but are also cost-effective.

With minimally invasive technology becoming a well-established treatment f or CAD in Europe, percutaneous coronary intervention (PCI) has become the standard when compared to surgery (Anderson et al. 2007). PCI usually involves inserting catheters and guide wires through the groin or arm to deliver stents and balloons to the narrowed coronary arteries. It is estimated that in 2014 alone more than 1.3 million PCI procedures were performed in Europe* (Frost & Sullivan 2015). T he number o f PCI procedures performed is expected to grow steadily due to better reimbursement, increased diagnosis and awareness among patients.

Percutaneous Coronary Intervention Segmentation

The PCI market is segmented into coronary stents, catheters, accessories, and embolic protection devices (EPD) (see Figure 1) (Frost & Sullivan 2015). T he coronary stents segment includes drug eluting stents (DES), bare metal stents (BMS), and bioabsorbable stents (BAS). Catheters for angiography, percutaneous transluminal coronary angioplasty (PTCA), thrombectomy, at herectomy an d ablation a re included in t he catheter segment. guide wires, introducers and stand-alone balloons form the accessories segment (see Figure 1).

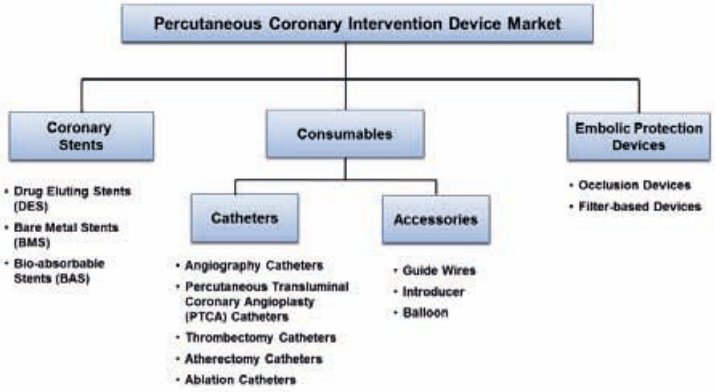

Figure 1. PCI Market: Segmentation, Western Europe, 2014

Current Market Scenario

The Western European** PCI market was estimated to be U.S. $2,038.3 million in 2014 (Frost & Sullivan 2015). It is a mature market and is expected to grow at a compound annual growth rate (CAgR) of 1% in the next five years. An ageing population, associated with increased incidence of CAD, drives the uptake for PCI procedures. There is also a growing interest among patients about their wellbeing, and they are seeking to aggregate information from various sources about their condition. This change in patient attitude is also expected to drive the PCI market. The coronary stent segment accounted for almost 56.2% of the PCI market. Within the coronary stent segment, DES contributed to a majority share due to its increased penetration within hospitals. BMS accounted for most of the remainder of the pie, while BAS represented a very small share in this segment (see Figure 2).

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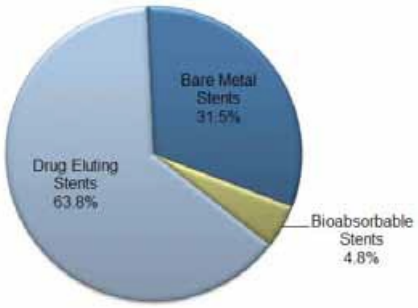

Figure 2. Coronary Stents: Percent Sales Breakdown by Sub-segments, Western Europe, 2014

The use of coronary stents in PCIs has risen rapidly in recent years. Studies show that more than 90% of PCI procedures in Europe involve a coronary stent, as it has shown remarkable improvements in restenosis rates (Steinhubl et al. 2002). While the number of coronary stenting procedures performed across Western Europe is expected to grow, the average selling price (ASP) of stents is declining, resulting in a significant reduction in the coronary stents segment. However, the exception to the decline in the coronary stents segment will be BAS, which are expected to be increasingly adopted in the coming years due to better prevention of stent thrombosis found in DES.

The European consumables segment, consisting of catheters, guide wire and introducer sheaths, accounted for around 40% of the revenue generated within the PCI market in 2014 (Frost & Sullivan 2015). The catheter segment is primarily driven by the high volume of PCI as well as diagnostic procedures carried out throughout Europe. guide wires and introducers are required for every interventional procedure, thereby making procedures the principal catalyst in unit and subsequent revenue growth. As the number of PCI procedures increases, the average number of guide wire and sheaths per procedure will also increase, thus driving market revenue. However, opposing this growth is a decline in ASPs, due to the increasing commodity status of these simple devices.

Embolic protection devices (EPDs) are devices that can minimise or eliminate the risks and complications of embolism. Thisdevice safely traps and removes much of the debris that may be dislodged during interventional procedures. The Western European EPD segment accounted for 3.7% of the revenue generated within the PCI market in 2014 (Frost & Sullivan 2015). The EPD segment is currently dominated by filterbased systems (70%) when compared to occlusion-based systems. Technological advancements and therapeutic effectiveness, along with growing acceptance, aid in greater uptake of EPD.

Germany remains the market leader amongst Western Europe, and accounted for almost 30% of revenue generated within the PCI market. In the past 10 years, the number of catheterisation laboratories in germany has dramatically increased, along with coronary angiography rates, which have quadrupled, resulting in almost a 10-fold increase in the number of PCI procedures performed. The United Kingdom and France occupied the second and third position and accounted for 38.2% in terms of revenue generated for the PCI market. Increased awareness about CAD and PCI treatment is driving patients to undergo diagnostic checkups that could lead to interventional follow-up, thus aiding the market revenue within these countries.

Industry Challenges

One of the major factors that has had a significant negative impact on all PCI segments is decreasing ASP. Industry participants have been aggressive in their use of pricing as a competitive tool, especially in the coronary stents segment, to gain increased penetration. Due to this heightened competition, ASPs of stents are decreasing swiftly, as manufacturers further employ discounting and bundling tactics to gain greater market share, thus affecting market revenue.

Another major reason contributing to the reduction in ASPs is the lack of overwhelming innovation in the market to stabilise current prices. Although competitors continue to roll out newgeneration stents and balloons, major differences between products are difficult to distinguish. Due to this, many products such as balloons, guide wire, and introducers have become more commoditised, inciting greater price competition amongst the numerous competitors in the market.

Lack of reimbursement in certain PCI segments such as EPD further restrains the PCI market. The cost of adding an EPD to the PCI procedure cost is significant, and its usage is affected by current reimbursement policies. In many cases reimbursement of EPD has been a little difficult, as they are not part of the devices implanted in the body. Securing adequate reimbursement and recognition of the device as a necessary part of the procedure still remains a challenge. Reimbursement is further affected by budget restrictions within hospitals, and hinders the acceptance of an additional product as part of the procedure.

New Developments in PCI Devices

One of the limitations associated with DES is the increased risk of late stent thrombosis, as they remain within the artery wall, which can be a source of chronic vessel wall inflammation, and in turn may interfere with the endothelial function. To counter this, BAS and drug eluting bio-absorbable stents (DEBAS) were introduced, as they are absorbed by the body without compromising the integrity of the vessel. Products such as ABSORB® BVS from Abbott Vascular (CE mark in 2011) and DESolve® BRS from Elixir Medical (CE mark in 2014) fall under this category.

Additionally, in recent years drug eluting balloons (DEBs) and drug-coated balloons (DCBs) have emerged as potential alternatives to effectively combat restenosis. DEB technology has demonstrated safety and efficacy in patients with in-stent restenosis. DEB is still in its nascent stage; however, it is expected to grow substantially. DEB is expected to affect not only the standard PTA balloon market, but also to threaten the stent market. It is predicted that in the coming years DEBs have the potential to be considered the gold standard of treatment by providing an effective and cost-saving solution. Medtronic plc is one of the leading market participants in the DEB segment.

Competitive Environment

The PCI market in Western Europe had more than 40 active participants in 2014, and this number is expected to increase with new participants entering the market every year. The top three PCI participants contributed to around 64% of total market revenue (Frost & Sullivan 2015).

Currently, Boston Scientific is the market leader in terms of revenue generated in the PCI devices market. Its broad product portfolio and good research and development budget are some of the critical factors for its effective penetration across all regions in Europe. Its recent acquisition of Bridgepoint Medical (2012) is aiding combating coronary chronic total occlusions (CTOs) by providing novel solutions for its treatment.

Medtronic and Abbott Laboratories occupy the second and third position, respectively, and have almost similar market shares. Medtronic has leveraged its established infrastructure and market presence to gain business in the PCI segment. Its introduction of the export advance aspiration catheter for thrombus removal in 2013 is expected to have a big impact on its revenue.

The Cordis Corporation, due to the discontinuation of its DES products in 2011, has lost its market share. However, with the recent (2015) acquisition of Cordis by Cardinal Health, Cardinal Health is expected to garner market shares from Boston Scientific and Medtronic and remain one of the top three players in the PCI market.

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Conclusion

With the PCI market in a mature stage, companies are continuously trying to differentiate themselves from their competitors in order to increase their market share. Factors such as brand identification and loyalty retention measures are expected to significantly drive companies to realise this. Increased brand loyalty through a better relationship with end users and a more effective post-sales service will be the motto for companies to maintain advantage.
Western Europe is an ideal place for the PCI devices market, as there is an everincreasing demand for more sophisticated products to tackle complex conditions. This is an ideal opportunity, which small manufacturers could leverage on and develop expertise in that field, giving them a competitive advantage in the market over established participants for complex coronary conditions. Exploitation of new markets is expected to drive sales for small manufacturers and help them to establish a concrete brand name and loyalty associated with their products.
The full report is available from www.frost.com/sublib/display-report.do?id=MA97-01-00-00-00

Key Points

- the Western European percutaneous coronary intervention devices (PCI) market is in its mature stage.
- the current focus is on innovations like bio-absorbable stents and drug eluting bio-absorbable stents that have the potential to drastically influence the stent segment.
- Decreasing average selling price, seen in every segment within the PCI market, restrains revenue growth significantly.

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