Coronary Artery Disease Technologies

innovation and market growth

a ***white paper*** from Smithers Apex

Providing knowledge for niche, emerging and high growth industries

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Coronary artery disease is a narrowing of the inside diameter (lumen) of the arteries on the surface of the heart as the result of accumulated plaque, inflammation and other causes. The restricted blood flow deprives the heart muscle of oxygen and nutrients and inhibits removal of CO_2 and cellular waste products. The end result can be the localized death of heart muscle tissue (aka, myocardial infarction), heart attack and death.

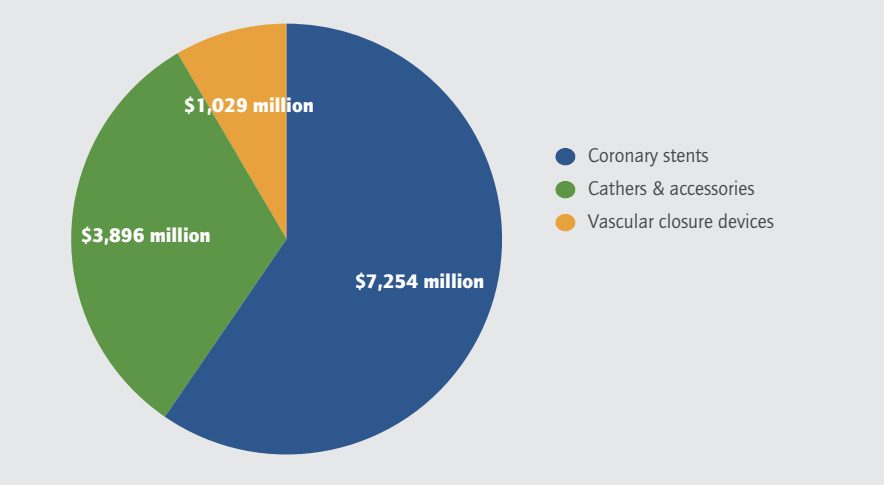
For the vast majority of cases of coronary artery disease, the treatment options are typically limited to angioplasty alone or with stents or coronary artery bypass grafting. Aside from the advent of new device and equipment technologies to perform coronary artery bypass via catheter or otherwise in minimally invasive formats (such as minimally invasive direct coronary artery bypass, or MIDCAB), the market for the treatment of coronary artery bypass is largely represented by interventional cardiology, comprised of the following products:

- Global sales of coronary guide wires, balloon dilatation catheters, guiding catheters and accessories
- Stents
- Vascular closure devices

Although there are recognised advantages for revascularisation using coronary artery bypass grafting (CABG) for specific indications, the global trend is for a continued decrease in the number of CABG procedures and an increase in the number of percutaneous coronary intervention procedures. Typically about 90% of all percutaneous coronary intervention procedures use a coronary stent in the developed economies with approximately 75% of all procedures that use stents do so with drug-eluting stents (DES) and this percentage continues to increase. In the emerging nations and countries with less sophisticated healthcare systems, the percentage of coronary stents used in percutaneous coronary intervention procedures is lower as is the number of procedures using DES.

It is generally true that the universe of coronary artery disease patients is almost entirely made up of a balance between those treated via CABG and those treated via interventional cardiology. Further, it stands that any erosion of CABG volume is accompanied by a commensurate increase in interventional cardiology volume.

Of the three segments examined, the coronary stent market is far the largest with global revenues estimated at $7,254 million in 2014 or the equivalent of 59.6% of the total market.



Share of Global Interventional Cardiology Market by Market Segment 2014

Source: Smithers Apex

Persistent Price Pressure, Persistent Demand

A hallmark of coronary artery disease, like many medtech markets, is that treatment is not optional. Despite a down economy, pressure for cost-savings in the healthcare, a 90% occluded left anterior descending coronary artery demands to be treated. In the face of both heavy cost-savings in healthcare and persistent demand from patients — as well as competition from lower-priced competitors — the inescable solution is downward pressure on prices.

Among the highest priced products in interventional cardiology, and representing the biggest overall cost in this market, coronary stents have been the biggest targets for price reductions. Although there has been a fall in average selling prices over the last decade due to the rationalization of the reimbursement structures and improvements in purchasing procedures and processes, these products still command premium product pricing. This is particularly true of the new and innovative material technologies and product designs such as Bioabsorbable Drug-Eluting Vascular Scaffolds (BVS) that have and continue to be introduced to the market.

Evolution of the Interventional Cardiology Market

The global market for interventional cardiology technologies is largely of two minds, with the Europe and U.S. (especially) being pinched enough on cost that sales growth would be flat, but for recent innovations that are shoring up market values. Simultaneously, the strength and growth in Asia Pacific economies are readily affording current and emerging innovations in interventional cardiology.

U.S.

Demand for treatment of coronary artery disease is steadily on the rise in the U.S., stemming from the aging population and its higher prevalence for the disease. It is inevitable that with the increased prevalence of cardiovascular disease in the U.S. there will be a corresponding increase in demand for treatments for cardiovascular conditions, leading specifically to an increase in interventional cardiology and a resulting increase in the number of stents to treat ischemic heart disease.

Projections of Crude CVD Prevalence % 2010–2030 in the United States					
Year	**All CVD***	**Hypertension**	**CAD****	**HF*****	**Stroke**
2010	36.9	33.9	8.0	2.8	3.2
2015	37.8	34.8	8.3	3.0	3.4
2020	38.7	35.7	8.6	3.1	3.6
2025	39.7	36.5	8.9	3.3	3.8
2030	40.5	37.3	9.3	3.5	4.0
% change	9.9	9.9	16.6	25.0	24.9

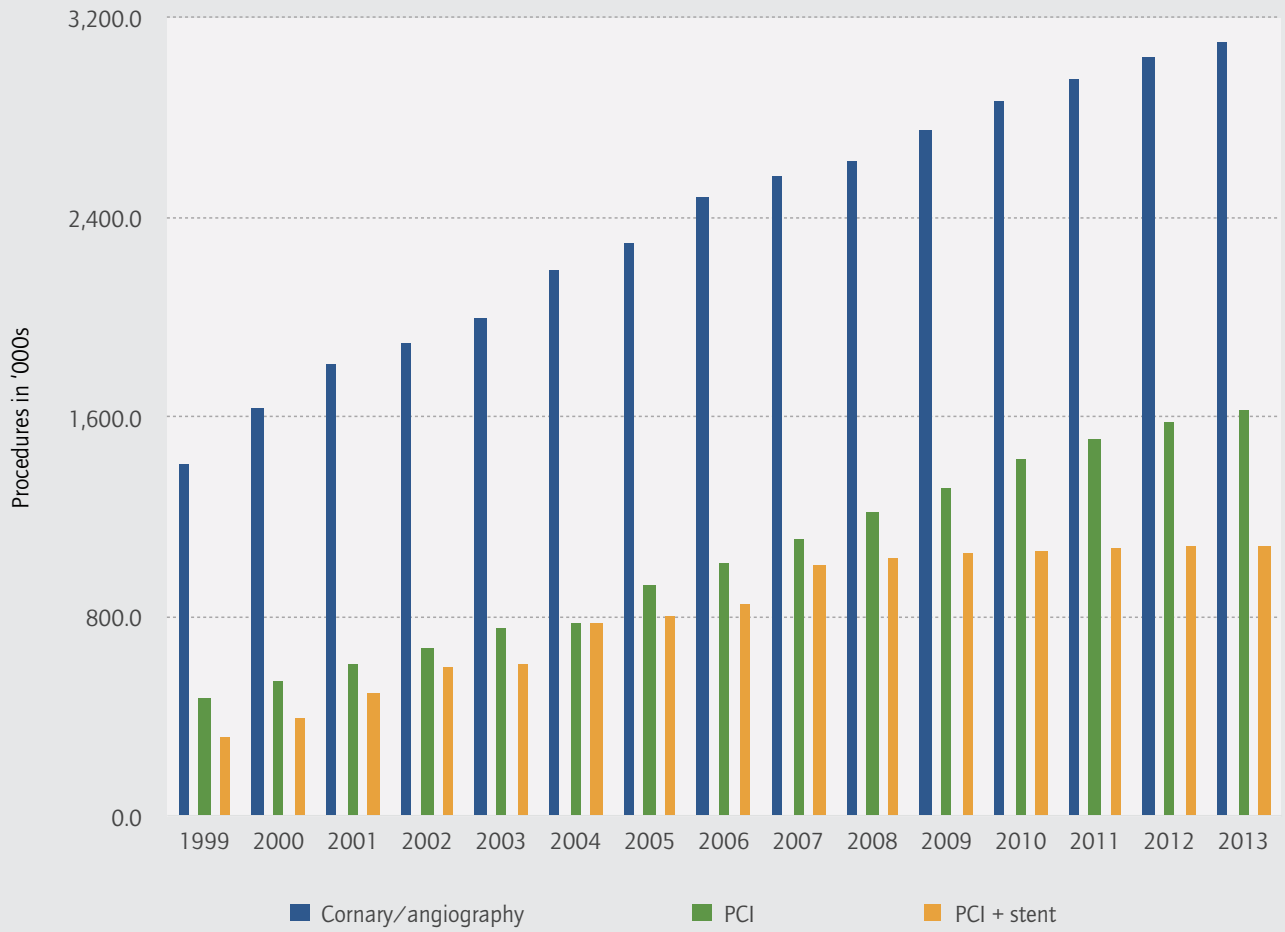
*Note: * Cardiovascular Disease; ** Coronary Artery Disease; *** Heart Failure*

Two forces that are protecting the U.S. from price erosion and sales decline are the continued development of interventional technologies to improve treatment (such as bioresorbable stents, drug-eluting balloons) and the FDA change in balloon-tipped catheters from Class III to Class II devices, enabling approval via the less rigorous 510(k) process. Otherwise, the continued patient volume arising from high prevalence coronary artery disease in the aging population is all that protects manufacturers from truly flat or declining sales.

Europe

Coronary angiography, a principal means to diagnose coronary artery disease, has been steadily growing in Europe, with strong year-over-year increases in numbers of precedures. Commensurate with diagnosis is, of course, treatment of patients with confirmed coronary artery disease, and to a lesser extent the use of percutaneous coronary intervention, alone or combined with stents, has tracked the angiography growth. It is clear, however, that each recent year the growth rates are not quite as rebust as theyear before and that the trend in the interventional cardiology market is that sales have begun to level.

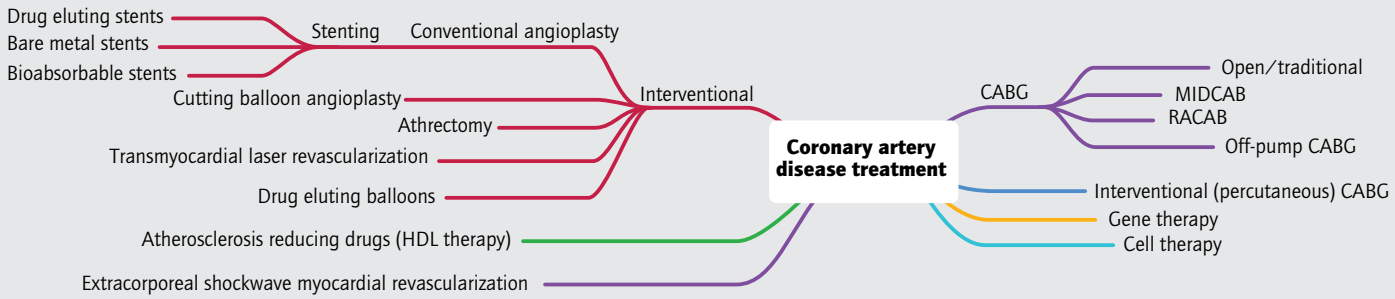
Drivers and limiters of the growth of interventional cardiology in Europe reflect those in the U.S. to a certain degree. Pricing pressures exist, but not to the extent that they do in the U.S. Europe is undergoing continued regulatory changes (or refinements), but



Growth in Coronary Angiography, Percutaneous Coronary Intervention (PCI) and Stent Procedures in Europe, 1999–2013

Source: The European Association of Percutaneous Cardiovascular Interventions (EAPCI)

these have not had clear negative or positive impact on interventional cardiology. It remains a generally accepted condition, however, that products reach market faster in Europe compared to the U.S., which lowers the cost of development, enables innovators to gain early



market share and otherwise stimulate the kind of innovation that can stave off the inevitable press pressures that can encumber markets with less innovation.

Asia Pacific

While coronary intervention procedure volumes in the developed world have begun to level, the booming economies, particularly in the Asia Pacific region, are witnessing a year-on-year, double digit growth. The aging population, shifting disease pattern, increased health awareness, growing private hospital sector, increasing local government support and expenditure but most importantly a growing middle class has all contributed to this phenomenal growth. Part of the increase is due to the trend to create smaller centers across the larger countries such as India and China as well as medium volume centers increasing the volumes of interventional procedures. The increasing PCI capabilities are also perhaps reflected in more proportion of interventions are performed in extreme age groups; younger <40 years and older > 70 years; left main angioplasty (1.3 %), graft angioplasty (1.7%), CTO (≈10%) and multivessel PCI (29.8%) and high DES penetration (74.5%). An important concern for coronary interventions is the quality of the procedure.

The resulting Asia Pacific market for interventional cardiology is more robust than western markets, as illustrated below, which represents the angioplasty catheter and related technologies (excludes stents and vascular closure devices).

Future Coronary Artery Disease Treatment

Many different procedures, devices, drugs, and other options have been conceived and

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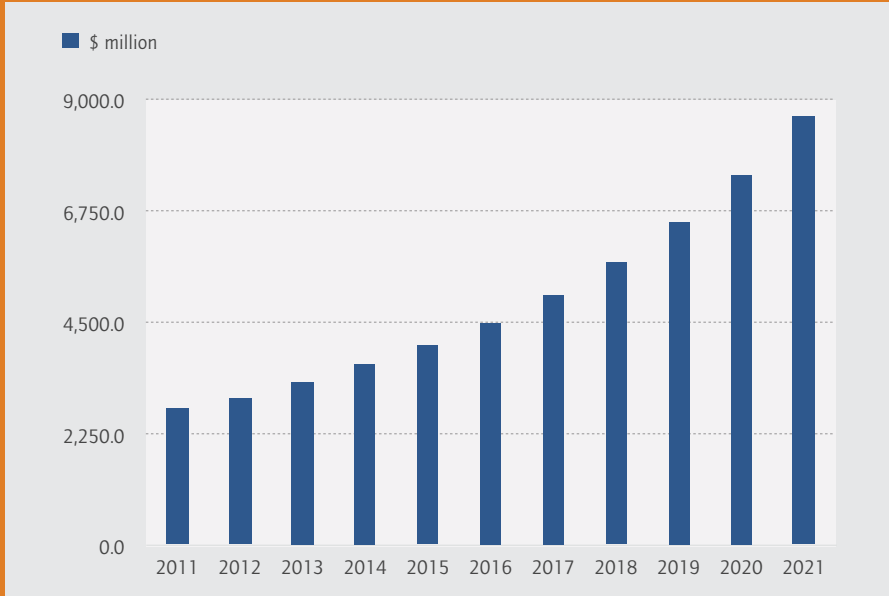
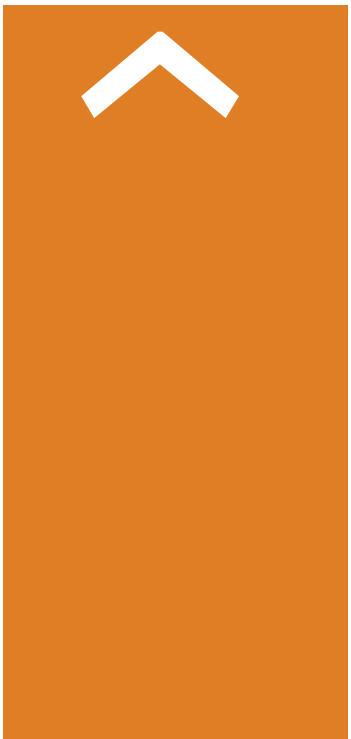


put into clinical practice or research and development to target coronary artery disease (see figure). These range from circumventing the blocked arteries by implanting arteries or veins taken from elsewhere in the body (coronary artery bypass grafting), inserting a balloon catheter to be inflated in the blood vessel and open the lumen by compressing the plaque (angioplasty), inserting a catheter to cut away the plaque (atherectomy), inserting an expandable metal or other tube into the lumen to hold it open (stenting), firing lasers to create multiple tiny holes in cardiac tissue to stimulate growth of new blood vessels (transmyocardial laser revascularization), using special drugs to pharmaceutically reduce and eliminate the plaque and many others.

The spectrum of current and potential options for the treatment of coronary artery disease are illustrated below. The conventional approaches are shown in the "interventional" and "CABG" branches at top left and right, respectively.

Within the next ten years, it is unlikely that there will be significant shift of patient volume out of the realm of coronary artery bypass grafting and interventional procedures, and within this time frame the competitive battle is among and between those two procedure types.



The Future of Coronary Heart Disease Medical Devices to 2021

The Smithers Apex report *The Future of Coronary Heart Disease Medical Devices to 2021* is available for purchase.

The Future of Coronary Heart Disease Medical Devices to 2021 details the current and emerging device technologies and global markets in the treatment of coronary heart disease as impacted by the clinical practice trends in interventional cardiology and coronary artery bypass grafting and the device innovations coming to market and proliferating in established western and emerging growth markets.

The report provides detailed current and forecast data and opportunities for active companies and other market stakeholders. The report has been produced through primary and secondary research gathered from companies, clinicians, public and private healthcare datasets, and combined with firsthand industry perspectives on the markets, its competitors and its clinical and industry practices.

To download *The Future of Coronary Heart Disease Medical Devices to 2021* market report brochure, please visit: http://www.smithersapex.com/products/market-reports

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