

# PART I

# Cardiovascular

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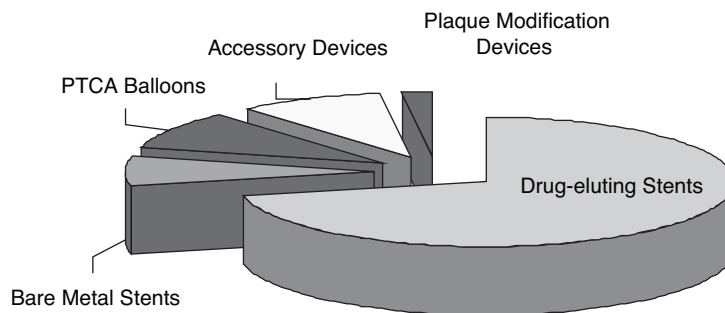
# Cardiovascular Devices

## 1.1 US Markets for Interventional Cardiology

The US interventional cardiology (IC) market was valued at nearly \$4 billion in 2004. The market consists of BMS, DES, PTCA balloons, accessory devices (PTCA guide wires, diagnostic catheters, PTCA guiding catheters, IVUS catheters, and introducer sheaths), and plaque modification devices (coronary atherectomy, thrombectomy, EPDs, and CTO devices). The continued adoption of DES will radically change the landscape of stenting procedures, with nearly all stented procedures employing a DES (versus a BMS) by 2009. Despite its lucrative stance, DES market growth will temper slightly through the forecast as DES devices saturate the market. Growth will, however, flourish in the plaque modification segment, as physicians move toward more frequent use of EPDs in PCI procedures. EPD penetration in PCI procedures will more than quadruple by 2009 as a growing number of physicians adopt EPDs as a preventative measure against potential AMI.

In addition to DES and EPD adoption, rising procedure volumes, expanding applications, and new product launches will incite growth through the forecast period. The exhibit below displays the IC market in 2004.

**BMS:** Bare-Metal Stent(s)  
**CTO:** Chronic Total Occlusion  
**DES:** Drug-eluting Stent(s)  
**EPD:** Embolic Protection Device(s)  
**IC:** Interventional Cardiology  
**IVUS:** Intravascular Ultrasound  
**PCI:** Percutaneous Coronary Intervention  
**PTCA:** Percutaneous Transluminal Coronary Angioplasty

**Exhibit 1.1** Interventional Cardiology Market, by Segment, US, 2004 (Graphical Format)

Source: Millennium Research Group.

## Market Drivers and Limiters

**Exhibit 1.2** Drivers and Limiters of the Interventional Cardiology Market, US

<i>Market Drivers</i>	<i>Market Limiters</i>
Complex patient cases	Pharmacologic alternatives
Growing patient population	Declining average selling prices
Introduction of new technologies	Volume discounts and bundling
New device approvals	Decreasing rates of restenosis
Positive clinical data	Lack of long-term clinical data
Increasing procedure volumes	Negative thrombectomy clinical results
Drug-eluting stents	Drug-eluting stents
Stent design enhancements	EPD filter basket performance

Source: Millennium Research Group.

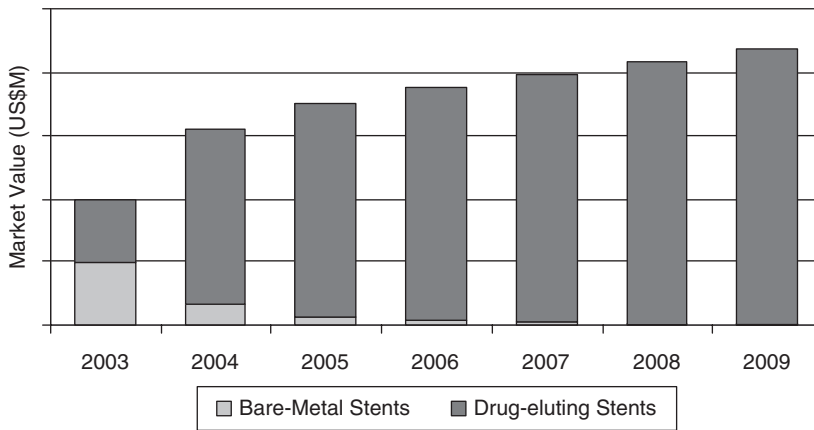
## Coronary Stents

The 2004 coronary stent market, including DES and BMS, was valued at over \$3 billion, which is more than 50% revenue growth over 2003. Market growth will be driven by the increased penetration of DES and the subsequent rise in the number of patients eligible for interventional treatment. Revenues will be limited by price erosion as well as the decline in repeat cases, caused by the overall reduction in rates of restenosis.

1.1 US Markets for Interventional Cardiology

In 2004 there were two competitors, Boston Scientific and Cordis, with approved DES products in the US market. As illustrated in the exhibit below, the market will see healthy revenue growth over the forecast period.

**Exhibit 1.3** Coronary Stent Market, US, 2003–2009 (Graphical Format)

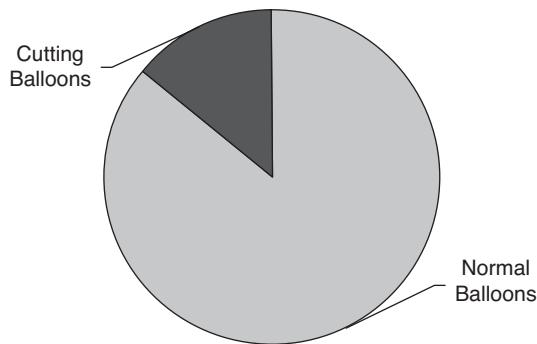


Source: Millennium Research Group.

**PTCA Balloons**

In 2004, the percutaneous transluminal coronary angioplasty (PTCA) balloon catheter market was valued at nearly \$400 million, a slight decrease from 2003. The market for PTCA balloons includes both normal and cutting balloons. The

**Exhibit 1.4** PTCA Balloon Market, by Type, US, 2004 (Graphical Format)



Source: Millennium Research Group.

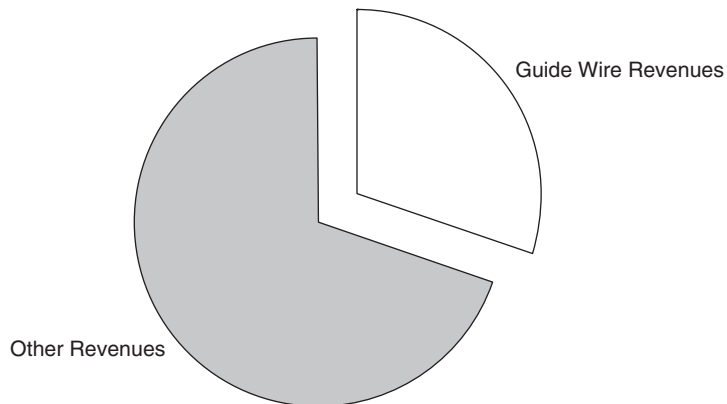
market will reach a state of slow steady growth with few shifts in value occurring over the forecast period. Drivers of revenue include the increase in procedure volumes and complex patient cases, while limiters include average selling price (ASP) decline caused by physician practices such as direct stenting, as well as price pressures. As displayed in the exhibit below, the market for PTCA balloons was comprised primarily of normal balloons in 2004.

## PTCA Guide Wires

In 2004, the US market for PTCA guide wires was valued well at over \$100 million, as shown in the exhibit below. Growth in this market is leveraged by increasing procedure volumes, which are driving unit sales over the forecast period. The positive effect of growing unit sales is, however, offset by declining ASPs due to the commoditization of workhorse guide wires, product bundling, and volume discounting.

Nonetheless, a number of manufacturers have developed and are now marketing specialty guide wires, and sales of these devices will offset the contraction of ASPs to some extent. Specialty guide wires are proficient in dealing with specific cases, such as CTOs. Eager to advantage from the increased efficacy of these guide wires, physicians will purchase them with increased frequency over the forecast, thereby driving penetration of specialized guide wires and mitigating overall ASP decline.

**Exhibit 1.5** PTCA Guide Wire Revenues, As % of Total Accessory Devices Revenues, US, 2004  
(Graphical Format)



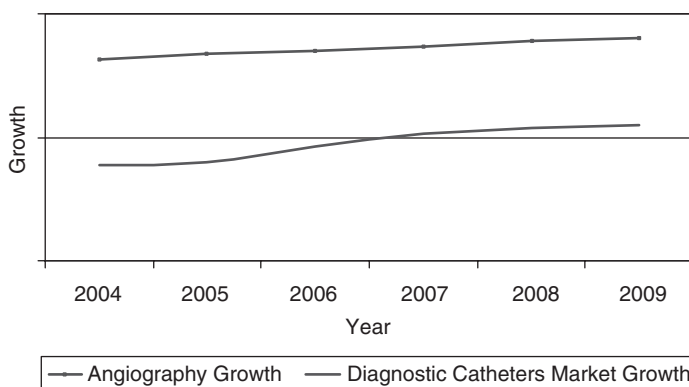
Source: Millennium Research Group.

## Diagnostic Catheters

Diagnostic catheters are employed during angiographies to diagnose CAD and to determine whether a percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) is necessary. Accordingly, the growing volume of angiographies in the US will serve as the primary driver of diagnostic catheter market growth. As aging baby boomers move into categories at higher-risk for CAD, the volume of angiography procedures in the US will increase. Compounding procedure growth this is the rising awareness of CAD, which will increase the likelihood that an individual will request, or agree to, an angiography.

Over the forecast period, market growth market will be slightly tempered by increased penetration of DES. The purchase of DES monopolizes a large portion of budgets allocated for interventional procedures, leaving a marginal balance to be used to purchase accessories such as diagnostic catheters; thus, the increased penetration of DES will place downward pressure on the diagnostic catheter ASPs over the forecast period. Subsequently, the diagnostic catheter market will not grow as quickly as angiography volumes, as illustrated in the exhibit below.

**Exhibit 1.6** Angiography Growth versus Diagnostic Catheter Market Growth, US, 2004–2009  
(Graphical Format)



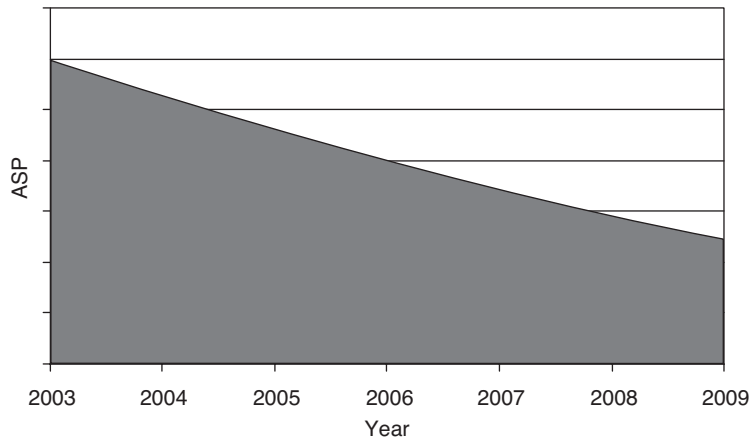
Source: Millennium Research Group.

## PTCA Guiding Catheters

In 2004, the PTCA guiding catheters market generated over \$75 million in revenues. Employed during PCI procedures, PTCA guiding catheters serve as conduits through which PTCA balloons or stents are delivered to diseased vessels. Over the forecast period, the growing volume of PCI procedures will be

the main source of market growth. US PCI volumes are growing in on account of rising angiography volumes. Analogous to most other markets for accessory devices, growth in the PTCA guiding catheters market will be tempered by ASP contraction, as shown in the exhibit below.

**Exhibit 1.7** PTCA Guiding Catheter ASP, US, 2003–2009 (Graphical Format)



Source: Millennium Research Group.

ASPs will decline over the forecast period because, like many other accessory devices, PTCA guiding catheters are commodity products. PTCA guiding catheters are often difficult to differentiate based on performance, and the device's technological potential has been exhausted, meaning that few improvements can be made to command a higher price. Consequently, manufacturers have few other alternatives aside from competing on price.

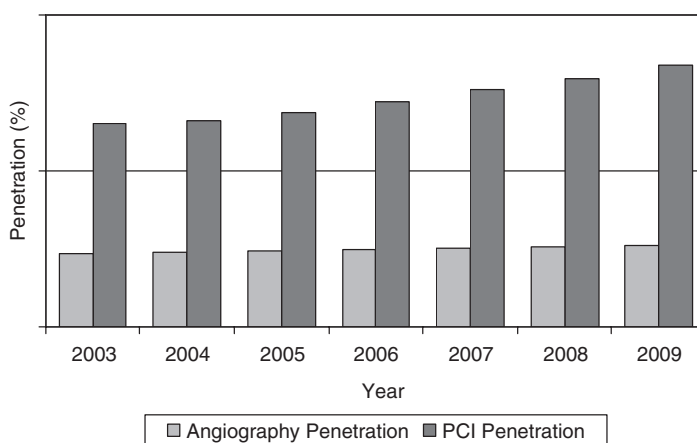
## IVUS Catheters

IVUS catheters are advanced diagnostic catheters that employ ultrasound technology to generate a three-dimensional image of the vessel wall. Practitioners use these images to more accurately diagnose CAD and ease stent placement during a PCI procedure. Accordingly, IVUS penetration in PCI procedures was higher than penetration in angiographies in 2004, as shown in the exhibit below.

The most significant driver in the IVUS catheter market is the desire among interventionalists to benefit from the advanced capabilities of IVUS catheters. Furthermore, growing diagnostic and interventional procedure volumes and increased stent penetration are also contributing to the market's rapid growth. Combined, these factors will cause the market for IVUS catheters to be the fastest growing segment of the interventional accessories market over the forecast period.



## 1.1 US Markets for Interventional Cardiology

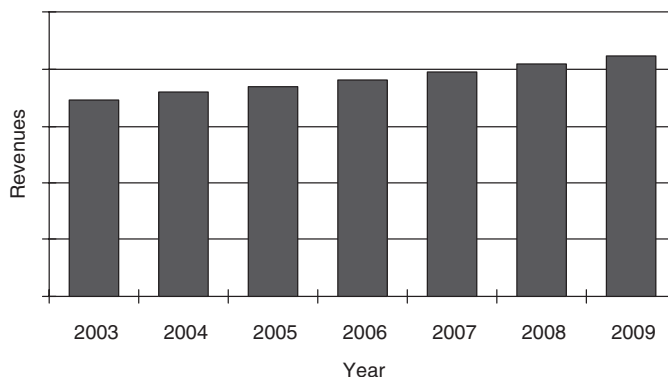
**Exhibit 1.8** IVUS Catheter Angiography and PCI Penetration, US, 2003–2009 (Graphical Format)

Source: Millennium Research Group.

## Introducer Sheaths

The US market for introducer sheaths was valued at over \$30 million in 2004. Introducer sheaths are required for diagnostic and interventional procedures, thereby correlating market growth to procedure volume growth; however, declining ASPs due to product bundling are significantly mitigating growth in this market.

Comparable to other accessory devices, introducer sheaths are commodity products that carry slim profit margins. Manufacturers often bundle introducer sheaths with other devices and sell them at or below cost in an attempt to augment the sales of other more profitable devices, such as DES. Despite product bundling placing downward pressure on the ASPs, the introducer sheath market will still see marginal growth over the forecast period, as shown in the exhibit below.

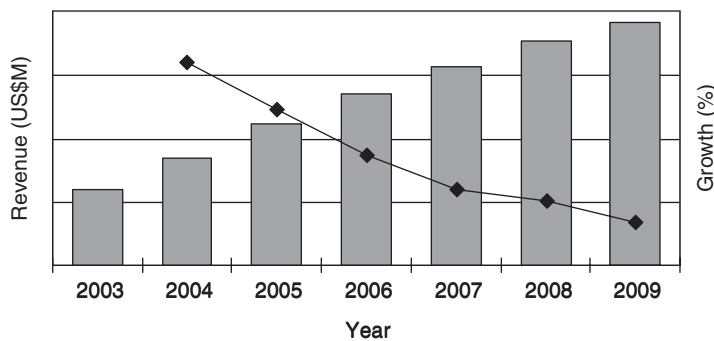
**Exhibit 1.9** Introducer Sheath Market, US, 2003–2009 (Graphical Format)

Source: Millennium Research Group.

## Thrombectomy Devices

In 2004, the US market for thrombectomy devices was valued in excess of \$30 million, and contributed the largest portion of revenues to the total plaque modification market. Thrombectomy are used to remove thrombi and blood clots from occluded vessels. Over the forecast period the market will see notable expansion from continued demand by physicians for access to thrombus treatment. Furthermore, the growing obesity epidemic in the US will increase the potential patient pool for thrombectomy procedures, in turn fueling market growth. In 2004, market leader Possis Medical issued disappointing clinical results regarding the use of its AngioJet system in acute myocardial infarction (AMI) patients, which will limit the routine adoption of AngioJet, and, to a certain degree, other thrombectomy devices. Despite this clinical data, however, ICs continue to use and demand thrombectomy devices in native coronary conditions, driving the market at a CAGR through 2009, whereupon the market will more than double in value. The exhibit below displays the US market for thrombectomy devices.

**Exhibit 1.10** Thrombectomy Devices Market, US, 2004 (Graphical Format)



Source: Millennium Research Group.

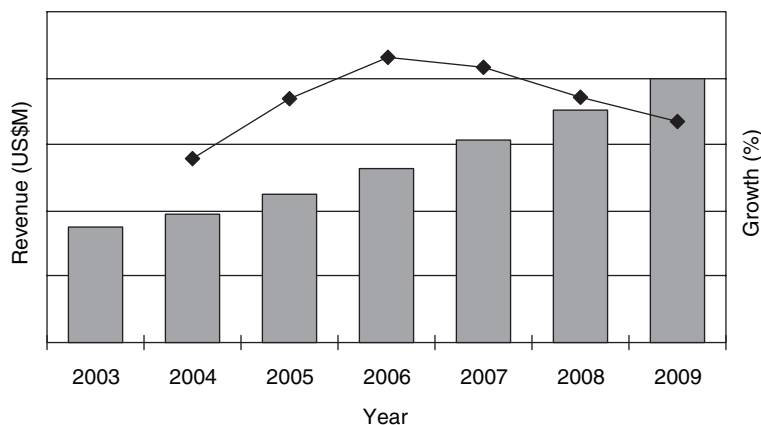
## Coronary Atherectomy Devices

The US market for coronary atherectomy devices, consisting of rotational, directional, and laser-based devices, was valued at slightly under \$30 million in 2004. Contributing to market growth is the demand for DES by CTO patients. CTO patients typically require a coronary atherectomy in advance of stent implantation. Furthermore, the growing base of potential patients, driven by the baby boomer population and rising obesity rates, will augment procedures volumes over the forecast period. Despite its benefits to CTO patients, the increase in DES use will contribute to a decline in the prevalence of ISR, thereby diminishing the

## 1.1 US Markets for Interventional Cardiology

requirement of atherectomy as additional treatment. This limitation will, however, only temper growth slightly. By the end of the forecast period the US atherectomy market will more than double in value, as displayed in the exhibit below.

**Exhibit 1.11** Coronary Atherectomy Market, US, 2003–2009 (Graphical Format)



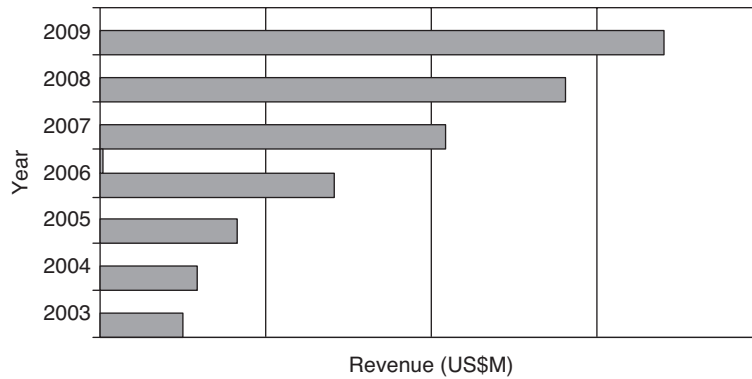
Source: Millennium Research Group.

## Embolic Protection Devices

As displayed in the exhibit below, the US market for EPDs was valued in excess of \$20 million in 2004, and will soar to a value of over \$100 million by 2009. EPDs are specially-designed guide wires that work to prevent and collect dislodged debris within a vessel to prevent distal embolization and eventual AMI. The market will benefit from the recent introduction of new and second-generation EPD devices, while continued positive clinical results and the potential for expanding indications will contribute to the market's notable growth. Device uptake will be limited by ease-of-use issues. EPDs constructed on a filter basket platform are cited by some ICs as being challenging to work with, creating some uncertainty about routine adoption. Further limiting revenues will be declining average selling prices (ASPs), due in part to competition between higher-priced occlusion balloon devices and more moderately priced filter basket designs. These limiters will, however, only bear lightly on the market, which is expected to flourish over the of the forecast period.

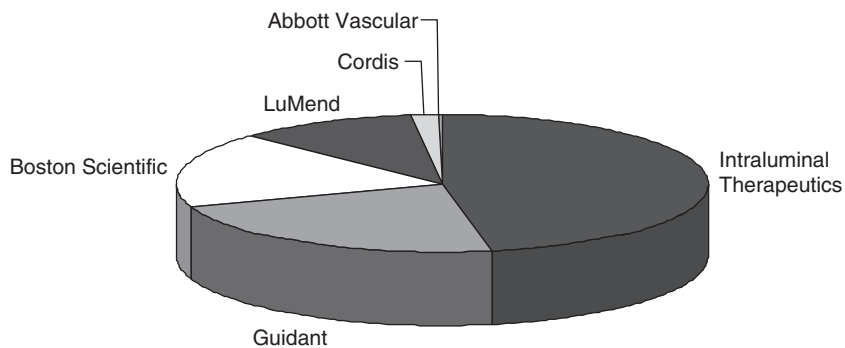
## Chronic Total Occlusion Devices

The US market for CTO devices was valued in excess of \$15 million in 2004, and is comprised of six guide wires and three specialty devices. The guide wires

**Exhibit 1.12** EPD Market, US, 2003–2009 (Graphical Format)

Source: Millennium Research Group.

covered include the Asahi Confianza, Cross-IT, Pilot, PT2, Miraclebros, and the Shinobi. The 3 specialty devices covered are the Safe-Cross System, Crosser System, and the Frontrunner. All of these devices are designed to leverage the interventional cardiologist's ability to cross a difficult lesion such as a CTO, which is becoming more important as DES are increasing the prospective PCI patient population with more complex cases. Prior to the introduction of CTO devices, few practitioners were confident in treating CTO patient with PCI. With the advent of rising positive clinical outcomes of specialty devices reaching both patients and practitioners, the penetration of PCI-based CTO treatment is rising. Over the forecast period, penetration of PCI treatment of CTO will continue to increase as manufacturers continue to develop CTO device technologies and as positive clinical outcomes continue to accumulate, more than tripling market value by 2009. The exhibit below displays an overview of the leading competitors in the CTO market in 2004.

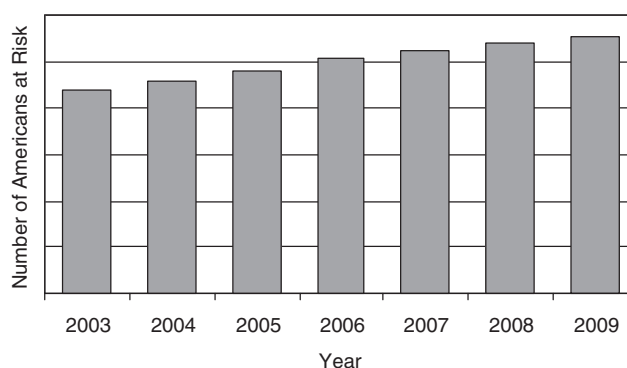
**Exhibit 1.13** Leading Competitors in the CTO Devices Market, US, 2004 (Graphical Format)

Source: Millennium Research Group.

## Vulnerable Plaque

Vulnerable plaque, which is plaque hidden within the vessel walls, is seen as the segment with the greatest opportunity for growth in cardiovascular medicine. Despite over 1.1 million heart attacks having occurred in the US in 2004, there were no approved devices available that were specifically indicated to screen for vulnerable plaque as of March 2005. Almost 46 million Americans were at risk of developing vulnerable plaque in 2004, or 15.7% of the total US population, and over the forecast period this percentage will grow. This indicates that there is a great need and a potential market for vulnerable plaque screening.

**Exhibit 1.14** Population at Risk of Vulnerable Plaque, US, 2003–2009



Source: Millennium Research Group.

## Competitive Analysis

The US markets for Interventional Cardiology report includes coverage of the following companies:

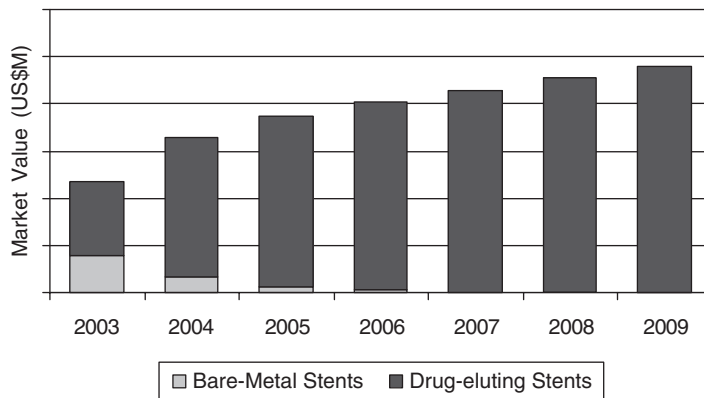
- Abbott Vascular
- Arrow
- Bard
- Boston Scientific
- Cook
- Cordis
- ev3
- Guidant
- Intraluminal Therapeutics
- LuMend
- Mallinckrodt
- Medtronic
- Merit Medical
- Possis Medical
- Spectranetics
- St. Jude Medical
- Terumo
- USCI
- Vascular Solutions
- Volcano Therapeutics
- Wilson-Cook

## 1.2 US Markets for Coronary Stents

### Market Overview

The 2004 coronary stent market was valued at over \$3 billion, an almost 40% increase over 2003. Market growth will be driven by the increased penetration of drug-eluting stents (DES) and the subsequent rise in the number of patients eligible for interventional treatment. Revenues will be limited by price erosion as well as the decline in repeat cases, caused by the overall reduction in rates of restenosis. The exhibit below displays the coronary stent market in the US.

**Exhibit 1.15** Coronary Stent Market, US, 2003–2009 (Graphical Format)



Source: Millennium Research Group

## Market Drivers and Limiters

### Exhibit 1.16 Drivers of US Coronary Stent Market

<i>Market Driver</i>	<i>Explanation</i>
Introduction of drug-eluting stents	The high selling price and rapid penetration of DES will drive growth in market revenues.
Growing patient population	Patients that were previously ineligible for PCI procedures, such as complex cases, are now candidates due to the introduction of DES.
New stent materials	The introduction of the cobalt alloy as an alternative to stainless steel will increase the price that manufacturers can charge.
Difficult cases	Advanced stent designs, as well as DES, will increase the potential to treat difficult cases, such as patients with multiple lesions, as well as increase the average number of stents placed per procedure.
CABG cases	The efficacy of coronary stenting vis-à-vis CABG has increased with the emergence of DES; therefore, previous candidates for CABG will now also be eligible for PCI treatment.
Use of intravascular ultrasound (IVUS)	With more frequent use of IVUS, operators may be able to avoid gaps between stents and match the length of the balloon as closely as possible with the length of the stent in order to avoid injury outside the stent. The improved patient outcomes will increase the preference for PCI treatment.
Stent design enhancements	With the development of longer stents to cover the entire lesion, and stent-delivery system modification, patient outcomes will improve and drive the demand of stents.
Market Acceptance	Over the forecast period, smaller labs will start to demand DES to the same degree as large labs, driving unit sales of DES.
Patient Demand	With the outbreak of media surrounding the launch of DES, patients will demand this premium device, driving unit sales of DES.
Reimbursement	DES continue to be reimbursed at a higher rate than BMS, although this differential will decrease in 2004.
Expansion of product offering	Pending approval from the FDA, the availability of stents in various diameters will allow manufacturers to provide the appropriate DES stent size for 100% of stent candidates in US.

Source: Millennium Research Group

### Exhibit 1.17 Limiters of the US Coronary Stent Market

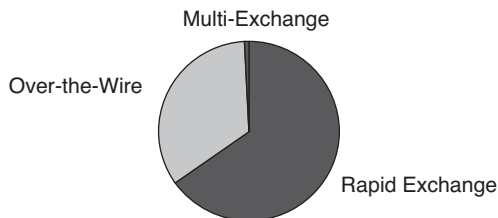
<i>Market Limiter</i>	<i>Explanation</i>
Lack of long-term clinical data	There is a lack of clinical data to support use of DES for some indications. BMS are still preferred for very small or large vessels, AMI, SVG, ISR, focus lesions, and bifurcations.
Decline in ASP	As demand for BMS falls in comparison to DES, the price will fall also due to bundling and more competitors fighting for a piece of a smaller pie.
Decreasing rates of restenosis	The rate of restenosis among simple cases will decline with the uptake of DES, causing the number of repeat procedure to decrease.

Source: Millennium Research Group

## Delivery Platforms: Rapid Exchange, Over-the-Wire, and Multi Exchange

There are two primary categories of catheter design: rapid-exchange (RX) and over-the-wire (OTW). Both catheter designs are delivered to the blockage site using a guide wire. The major difference in the two designs is where the guide wire is placed. As seen below, RX delivery platforms comprised almost two-thirds of stent units in the US in 2004.

**Exhibit 1.18** Coronary Stent Revenues, by Delivery Platform and Quarter, US, 2004 (Graphical Format)



Source: Millennium Research Group

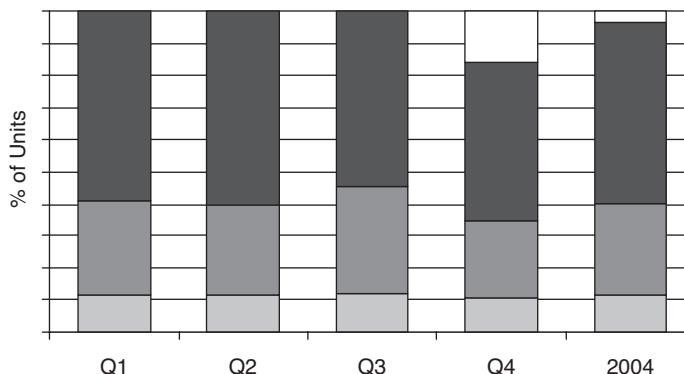
## Coronary Stent Material: Stainless Steel and Cobalt Chromium

Until recently, coronary stent platforms were made from stainless steel. In 2003, however, Guidant launched the first cobalt alloy stent—its Multi-Link Vision stent—in the US. Soon thereafter, Medtronic launched its Driver cobalt alloy stent, having already introduced both the Driver and the Micro-Driver in Europe. Cobalt chromium alloy has demonstrated its ability to provide the necessary radial strength but with thinner struts than stainless steel. Thinner struts allow the operator to more easily navigate tortuous anatomy and reach difficult-to-access lesions; moreover, thinner struts are thought to result in lower rates of restenosis. Cobalt alloy is also denser than stainless steel and can therefore easily be viewed under fluoroscopy, helping the physician precisely place the stent and view the clinical result within the anatomy. The exhibit below displays the cobalt chromium stent unit share, by brand and quarter in 2004.



## 1.2 US Markets for Coronary Stents

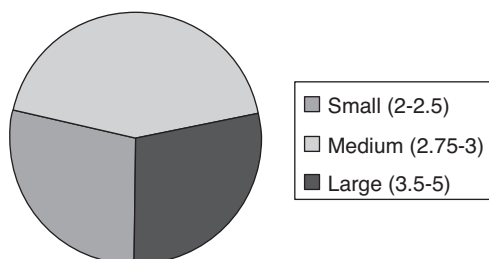
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**Exhibit 1.19** Cobalt Chromium Stent Unit Share, by Brand and Quarter, US, 2004 (Graphical Format)

Source: Millennium Research Group

## Coronary Stent Diameter &amp; Length

Small and large diameter stents together comprise over half of stent units, with medium diameter stents comprising the remainder. Small and medium vessel patients are particularly good candidates for drug-eluting therapies because their vessels are considered to be at a higher risk of restenosis. DES have been placed to a greater extent in medium and long lesion cases because patients with very long lesions are considered among the most difficult to treat and vulnerable to restenosis. The presence of long lesions is only one factor that can place a patient at higher risk for restenosis (reblockage). Other factors include narrow vessels, longer stent length, and diabetes because diabetic patients generally have more inflammatory responses to treatment for blocked vessels and a greater likelihood of cell proliferation (regrowth) that can lead to reblockage. The exhibit below displays the coronary stent unit share, by diameter in the US in 2004.

**Exhibit 1.20** Coronary Stent Unit Share, by Diameter, US, 2004 (Graphical Format)

Source: Millennium Research Group.

## Market Forecast and Leading Competitors

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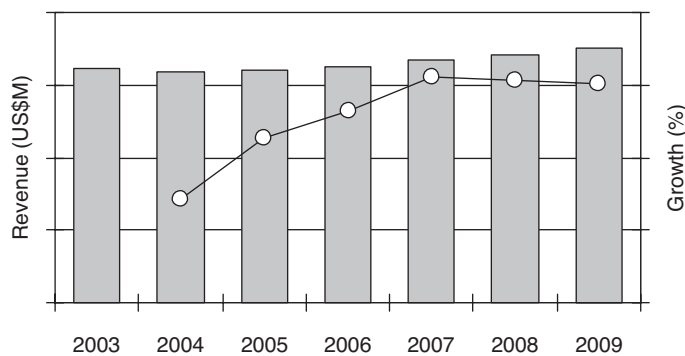
In 2004, the US coronary stent market was valued at over \$3 billion. Over the forecast period, the ratio of bare-metal stents to DES revenues will decline. The coronary stent market experienced high growth in 2004, due to the first full year of DES availability combined with deeper DES procedural penetration. Moreover, the entrance of Boston Scientific's TAXUS paclitaxel-eluting stent to the market provided an opportunity for some degree of price competition, causing a decline in the ASP of DES and providing an alternative device to CYPHER. Boston Scientific was also able to compensate for the supply shortage faced by Cordis.

## 1.3 US Markets for PTCA Balloons

### Market Overview

In 2004, the percutaneous transluminal coronary angioplasty (PTCA) balloon catheter market was valued at nearly \$400 million, a slight decrease from 2003. The market will reach a state of slow steady growth with few shifts in value occurring over the forecast period. Drivers of revenue include the increase in procedure volumes and complex patient cases, while limiters include average selling price (ASP) decline caused by physician practices such as direct stenting, as well as price pressures. The exhibit below displays the US PTCA balloon catheter market from 2003 to 2009.

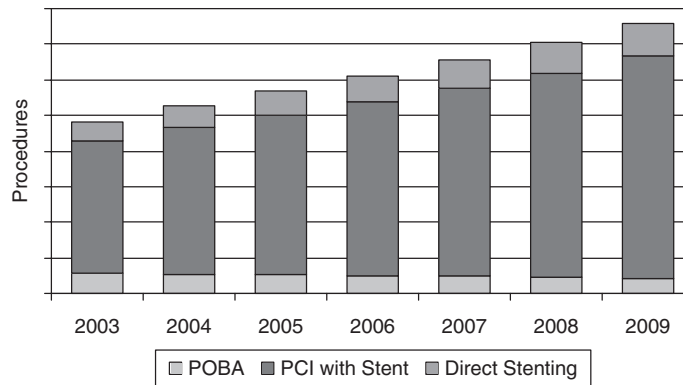
**Exhibit 1.21** PTCA Balloon Catheter Market, US, 2003–2009 (Graphical Format)



Source: Millennium Research Group.

### Procedures

PTCA balloon catheters are employed during PTCA procedures, of which over 1 million were performed in 2004. Drivers of procedures include the rise in patient population, while limiters of procedures include the decline in plain old balloon angioplasty (POBA) procedures and the rise in direct stenting. The exhibit below shows percutaneous interventional procedures in the US.

**Exhibit 1.22** Percutaneous Interventional Procedures, US, 2003–2009 (Tabular Format)

Source: Millennium Research Group.

Note: PCI = Percutaneous Coronary Intervention.

## Market Drivers and Limiters

**Exhibit 1.23** Drivers of the US PTCA Balloon Catheter Market, 2004

<i>Market Driver</i>	<i>Explanation</i>
Rising procedure volume	Demand for PCI procedures will increase due to an aging baby-boomer population and the introduction of DES.
Growth in units per procedure	Increasing procedure complexity will drive the number of units used per procedure.
Introduction of new technology	The launch of new generations of PTCA balloons, with incremental improvements in performance, will justify price stability in a market otherwise moving towards commoditization.

Source: Millennium Research Group.

**Exhibit 1.24** Limiters of the US PTCA Balloon Catheter Market, 2004

<i>Market Limiter</i>	<i>Explanation</i>
Commoditization	The inability to observe vast differences between devices will narrow opportunities to charge premium prices, resulting in a decline in ASP.
Entrance of new competitors	As new competitors enter the market, price competition will intensify.
Volume discounts	When manufacturers offer volume discounts, the ASP will decline, resulting in a decrease in market revenues.
Drug-eluting stents	The high initial cost of DES will inspire purchasers to demand accessory devices, such as PTCA balloon catheters, to be sold at a discount.
Direct stenting	The practice of direct stenting, placing a stent without using a balloon, will decrease the PTCA balloon sales over the forecast period.

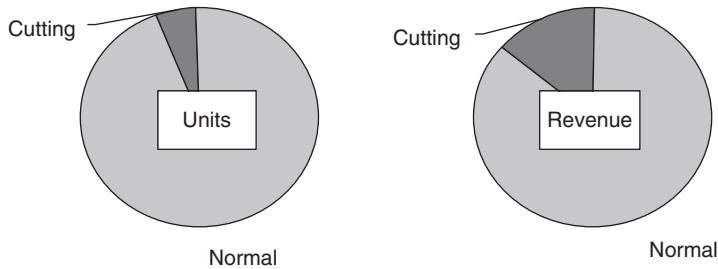
Source: Millennium Research Group.

## Type

There are two types of balloons included in this report: normal angioplasty balloons and cutting balloons. Boston Scientific markets and distributes the cutting balloon, having gained the technology via its acquisition of Interventional Technologies in 2000.

The cutting balloon represents a modification of normal balloon angioplasty that is useful for both balloon angioplasty and atherectomy procedures. Cutting balloons are designed for challenging situations such as ostial lesions, fibrotic/calcified lesions, long lesions, and small vessels. The device can be used as a stand-alone treatment or as an adjunct before stenting. The exhibit below displays PTCA balloon catheter unit and revenue share in 2004.

**Exhibit 1.25** PTCA Balloon Catheter Unit Share and Revenue Share by Type, US, 2004 (Graphical Format)

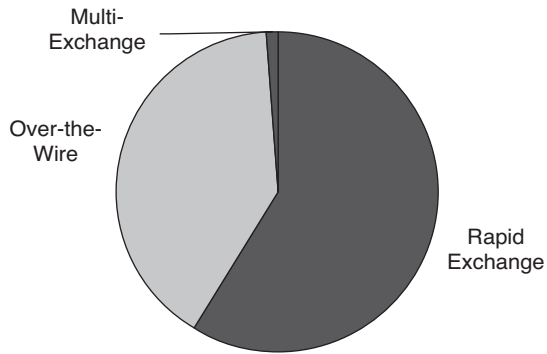


Source: Millennium Research Group.

## Delivery

There are two categories of catheter design: rapid-exchange (RX) and over-the-wire (OTW). Both catheter designs are delivered to the blockage site using a guide wire. The major difference in the two designs is where the guide wire is placed. For RX catheters, guide wires are placed in a lumen on the tip of the device. In OTW catheters, the guide wire is on the inside of the devices. The major benefit in RX technology is that a single operator can securely control the filter during all device exchanges. Additionally, RX technology offers a reduction in procedure time and reduction in fluroscopy time. The multi-exchange (MX) delivery platform was introduced by Medtronic after the company was banned from selling RX catheters and stent delivery systems in the US. The exhibit below displays PTCA balloon catheter unit shares, by delivery platform, in 2004.

**Exhibit 1.26** PTCA Balloon Catheter Unit Share, by Delivery Platform, US, 2004  
(Graphical Format)

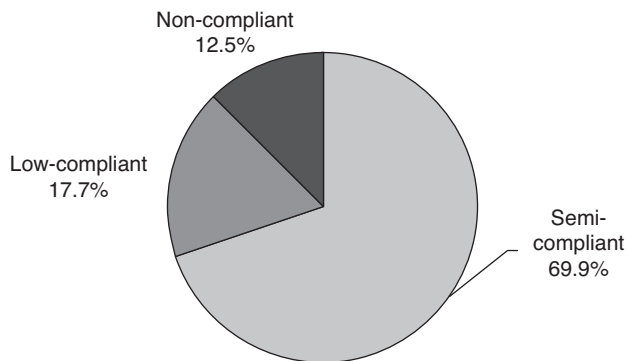


Source: Millennium Research Group.

## Compliance

The application and outcome of a procedure will vary depending on the type of balloon material. When describing how the material stretches once inflated, the term “compliance” is used. All else being held equal, the less a balloon stretches, the greater force it will exert and the less it is considered compliant. If the balloon deforms under pressure, the balloon material stretches around the lesion and the concentration of force is not focused at the stenosis, posing risk to healthy tissue. The exhibit below displays PTCA balloon catheter unit share by material.

**Exhibit 1.27** PTCA Balloon Catheter Unit Share, by Balloon Material, US, 2004  
(Graphical Format)



Source: Millennium Research Group.

## Market Forecast

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In 2004, over 1 million PTCA balloon catheters were sold. Going forward, unit sales will increase as result of the increase in procedure volume. The average number of PTCA balloons used per procedure will increase by slightly due to a rise in procedure complexity. Direct stenting will limit the number of units placed per procedure.

Market revenues in the PTCA balloon catheter market will also be limited by the decline in ASP. This gradual pricing decrease is linked to pricing pressures from market attempts to absorb the initial added costs of drug-eluting stents (DES). Though DES are forecast to lower the cost of treating coronary artery disease in the long-run, the premium price at which DES are sold has placed some degree of pressure on the prices of the accessory products used during PCI procedures. Furthermore, as the volume of PCI procedures increases, balloon manufacturers are expected to increasingly offer bulk discounts, which will result in a decline in the ASP of PTCA balloon catheters.

## Competitive Analysis

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With the most PTCA balloons approved by the Food and Drug Administration, including four cutting balloons, Boston Scientific is considered the preeminent manufacturer of PTCA balloons.

Guidant is the second leading competitor in the PTCA balloon market and drove over 30% of normal balloon catheter revenues in 2004. Medtronic holds a particularly strong position in the OTW semi-compliant segment, generating over 16% of revenues in 2004.

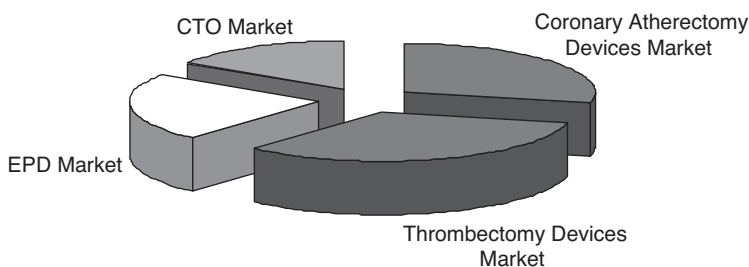
## 1.4 US Markets for Plaque Modification Devices

### Plaque Modification Overview

The plaque modification market, consisting of devices used to treat intra-vessel plaque, was valued in excess of \$100 million in 2004, and consists of four main segments; coronary atherectomy devices, thrombectomy devices, embolic protection devices (EPDs), and chronic total occlusion (CTO) devices. The continual promotion of positive clinical data will augment sales of these devices over the forecast period, while patient and physician demand for less-invasive methods of plaque modification will further support the notable market growth expected through 2009. By segment, the EPD market will contribute the largest percentage of overall growth because the market is expected to more than triple in size by the end of the forecast period. EPD penetration in coronary interventional procedures is growing as a number of physicians readily adopt EPDs as preventative measures against potential stroke.

New device technologies, the increased use of drug-eluting stents, expanding applications, and physician demand will all work to neutralize small shifts in average selling prices and concerns over device performance, pushing the market compound annual growth rate (CAGR) well in excess of 20% between 2005 and 2009.

**Exhibit 1.28** Plaque Modification Market, As a Percentage of Total, by Segment, US, 2004  
(Graphical Format)



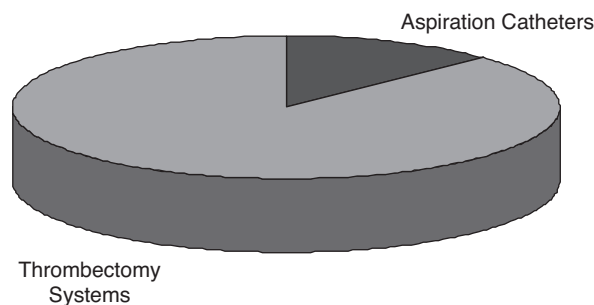
Source: Millennium Research Group.



## Thrombectomy Devices

In 2004, the US market for thrombectomy devices was valued in excess of \$30 million, and contributed the largest portion of revenues to the total plaque modification market. Thrombectomy devices, comprising both advanced thrombectomy systems (e.g. Possis Medical Medical's AngioJet) and catheter-based devices (e.g. Medtronic's Export Aspiration Catheter—see the exhibit below), are used to remove thrombi and blood clots from occluded vessels. Over the forecast period the market will see notable expansion from continued demand by physicians for access to thrombus treatment. Furthermore, the growing obesity epidemic in the US will increase the potential patient pool for thrombectomy procedures, in turn fueling market growth. In 2004, market leader Possis Medical issued disappointing clinical results regarding the use of its AngioJet system in acute myocardial infarction (AMI) patients, which will limit the routine adoption of AngioJet, and, to a certain degree, other thrombectomy devices. Despite this clinical data, however, ICs continue to use and demand thrombectomy devices in native coronary conditions, driving the market at a CAGR through 2009, whereupon the market will more than double in value.

**Exhibit 1.29** Thrombectomy Market, As a Percentage of Total, by Product Segment, US, 2004  
(Graphical Format)



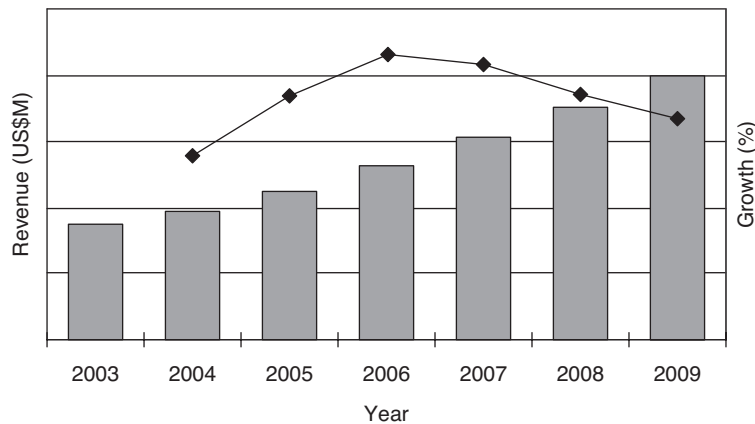
Source: Millennium Research Group.

## Coronary Atherectomy Devices

The US market for coronary atherectomy devices, consisting of rotational, directional, and laser-based devices, was valued at slightly under \$30 million in 2004. Contributing to market growth is the demand for DES by CTO patients. CTO patients typically require a coronary atherectomy in advance of stent implantation. Furthermore, the growing base of potential patients, driven by the

baby boomer population and rising obesity rates, will augment procedures volumes over the forecast period. Despite its benefits to CTO patients, the increase in DES use will contribute to a decline in the prevalence of ISR, thereby diminishing the requirement of atherectomy as additional treatment. This limitation will, however, only temper growth slightly. By the end of the forecast period the US atherectomy market will more than double in value, as displayed in the exhibit below.

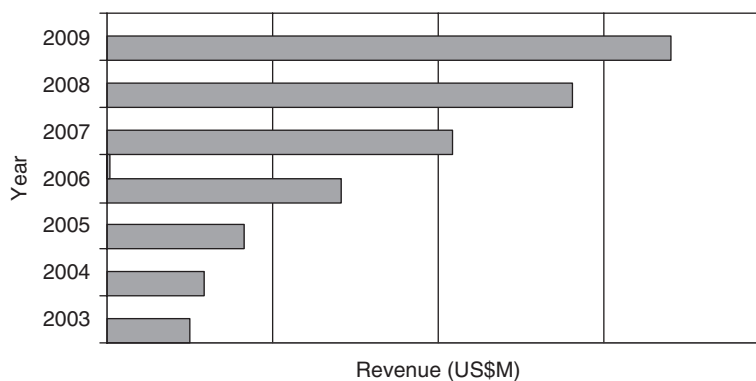
**Exhibit 1.30** Coronary Atherectomy Market, US, 2003–2009 (Graphical Format)



Source: Millennium Research Group.

## Embolic Protection Devices

As displayed below, the US market for EPDs was valued in excess of \$20 million in 2004, and will soar to a value of over \$100 million by 2009. EPDs are specially-designed guide wires that work to prevent and collect dislodged debris within a vessel to prevent distal embolization and eventual stroke and/or AMI. The market will benefit from the recent introduction of new and second-generation EPD devices, while continued positive clinical results and the potential for expanding indications will contribute to the market's notable growth. Device uptake will be limited by ease-of-use issues. EPDs constructed on a filter basket platform are cited by some ICs as being challenging to work with, creating some uncertainty about routine adoption. Further limiting revenues will be declining average selling prices (ASPs), due in part to competition between higher-priced occlusion balloon devices and more moderately priced filter basket designs. These limiters will, however, only bear lightly on the market, which is expected to flourish over the of the forecast period.

**Exhibit 1.31** EPD Market, US, 2003–2009 (Graphical Format)

Source: Millennium Research Group.

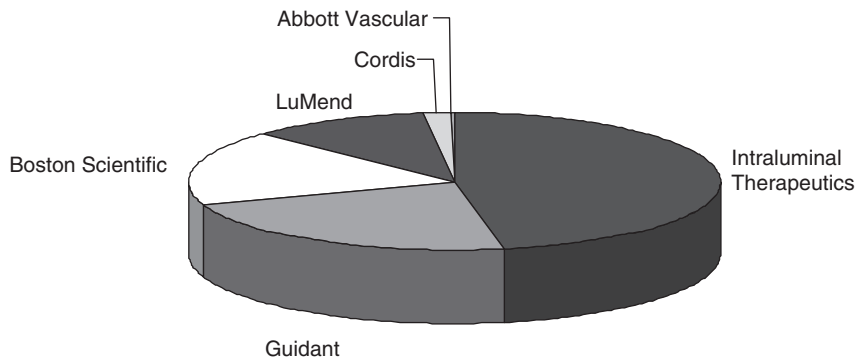
## Chronic Total Occlusion Devices

The US market for CTO devices was valued in excess of \$15 million in 2004, and is comprised of six guide wires and three specialty devices. The guide wires covered include the Asahi Confianza, Cross-IT, Pilot, PT<sup>2</sup>, Miraclebros, and the Shinobi. The 3 specialty devices covered are the Safe-Cross System, Crosser System, and the Fronrunner. All of these devices are designed to leverage the interventional cardiologist's ability to cross a difficult lesion such as a CTO, which is becoming more important as DES are increasing the prospective PCI patient population with more complex cases. Prior to the introduction of CTO devices, few practitioners were confident in treating CTO patient with PCI. With the advent of rising positive clinical outcomes of specialty devices reaching both patients and practitioners, the penetration of PCI-based CTO treatment is rising. Over the forecast period, penetration of PCI treatment of CTO will continue to increase as manufacturers continue to develop CTO device technologies and as positive clinical outcomes continue to accumulate, more than tripling market value by 2009. The exhibit below displays an overview of the leading competitors in the CTO market in 2004.

## Vulnerable Plaque

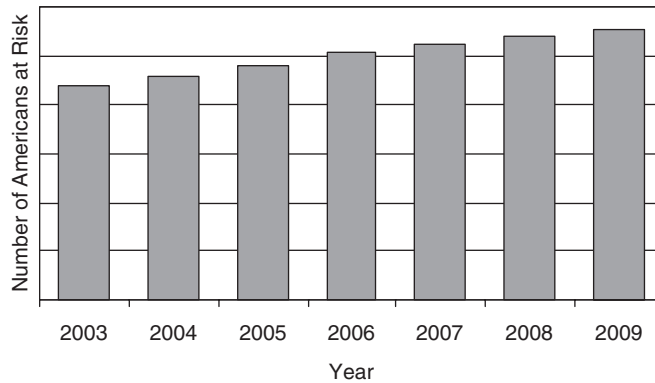
Vulnerable plaque, which is plaque hidden within the vessel walls, is seen as the segment with the greatest opportunity for growth in cardiovascular medicine. Despite over 1.1 million heart attacks having occurred in the US in 2004, there were no approved devices available that were specifically indicated to screen for vulnerable plaque as of March 2005. Almost 46 million Americans were at risk

**Exhibit 1.32** Leading Competitors in the CTO Devices Market, US, 2004 (Graphical Format)



Source: Millennium Research Group.

**Exhibit 1.33** Population at Risk of Vulnerable Plaque, US, 2003–2009



Source: Millennium Research Group.

of developing vulnerable plaque in 2004, or 15.7% of the total US population, and over the forecast period this percentage will grow. This indicates that there is a great need and a potential market for vulnerable plaque screening.

## Competitive Analysis

Competitors covered within the plaque modification market include:

- Boston Scientific
- Possis Medical

#### 1.4 US Markets for Plaque Modification Devices

- Medtronic
- Intraluminal Therapeutics
- Guidant
- Spectranetics
- LuMend
- Vascular Solutions
- Cordis
- ev3
- Abbott Vascular

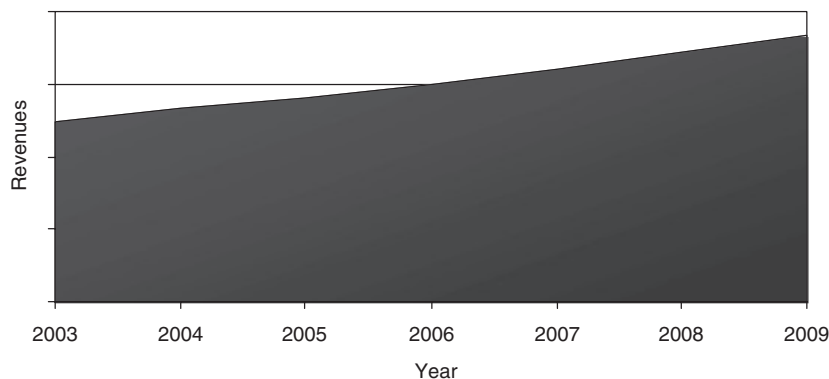
## 1.5 US Markets for Interventional Cardiology Accessory Devices

### Accessory Devices Market Overview

In 2004, the US market for accessory devices, comprising PTCA guide wires, diagnostic catheters, guiding catheters, intravascular ultrasound (IVUS) catheters, and introducer sheaths, generated nearly \$400 million in revenues. In the last decade, responding to physician demand for less-invasive and more effective interventional accessories, manufacturers have invested significant resources towards improving the performance of these devices. Subsequently, by 2004, the majority of the technological potential of accessory devices had been exhausted, and most of the devices had become commodities with slim profit margins. Turning focus away from improving commodity accessories, manufacturers have recently begun marketing accessories that are specialized for procedures and/or incorporate new functionalities.

Specialty accessories, such as guide wires designed for treatment of chronic total occlusions (CTO), and accessories that incorporate new functionalities such as IVUS catheters, enable physicians to diagnose or treat coronary artery disease (CAD) more effectively, and therefore command higher prices relative to basic accessories. Sales of these accessory types will leverage total market growth such that the market will reach a value well in excess of \$500 million by 2009 (as shown below).

**Exhibit 1.34** Accessory Devices Market Revenues, US, 2003–2009



Source: Millennium Research Group.

## Market Drivers and Limiters

### Exhibit 1.35 Drivers of the Accessory Devices Market, US

<i>Market Driver</i>	<i>Explanation</i>
Rising procedure volumes	Angiography and PCI procedure volumes will increase over the forecast period as the boomer population moves into age segments at higher risk for CAD. Furthermore, growing awareness of CAD and the increased penetration of DES will also expand the prospective patient population with more complex cases.
Accessory specialization	Frontline interventional accessories have, by and large, exhausted any further technological potential. With few improvements that can be made, manufacturers are unable to charge premiums on accessories that already carry very slim profit margins. Accordingly, some manufacturers are turning focus toward developing specialty accessories for use in specific procedural circumstances. Specialty accessories can justify a cost premium, and sales of these accessories will assist in sustaining higher ASPs.
DES penetration	The penetration of DES has increased the prospective patient population with more complex cases. These cases often require a greater number of interventional accessories to be employed; thus, increased penetration of DES is driving unit sales of interventional accessories.

Source: Millennium Research Group.

### Exhibit 1.36 Limiters of the Accessory Devices Market, US

<i>Market Limiter</i>	<i>Explanation</i>
Volume discounts and bundling	Hospitals and/or purchasing groups will often purchase large volumes of accessories in bulk on the condition that they receive volume discounts. Moreover, manufacturers are now selling bundles of accessories that incorporate other products such as DES. As part of the bundle, accessories are often sold at or below cost, in part to capture the much loftier profit margin attributable to another bundled device. The increased prevalence of these two trends is placing downward pressure on accessory device ASPs.
DES penetration	The increased penetration of DES is negatively impacting the market for accessories in two ways. Firstly, the cost of buying DES is absorbing a large part of funds allocated for interventional procedures, leaving a marginal balance to be used to purchase interventional accessories. Resultantly, purchasers demand that interventional accessories be discounted. Secondly, the use of DES is more effective in treating CAD, thereby minimizing the likelihood of restenosis and repeat procedure. This, in turn, will decrease the volumes of repeat procedures.
Technological potential	The potential for further technological evolution in frontline accessory devices is limited. Furthermore, the extent to which interventional accessories can be specialized is limited. It is therefore becoming increasingly difficult for manufacturers to differentiate their products and charge premiums on these accessories.

Source: Millennium Research Group.

## PTCA Guide Wires

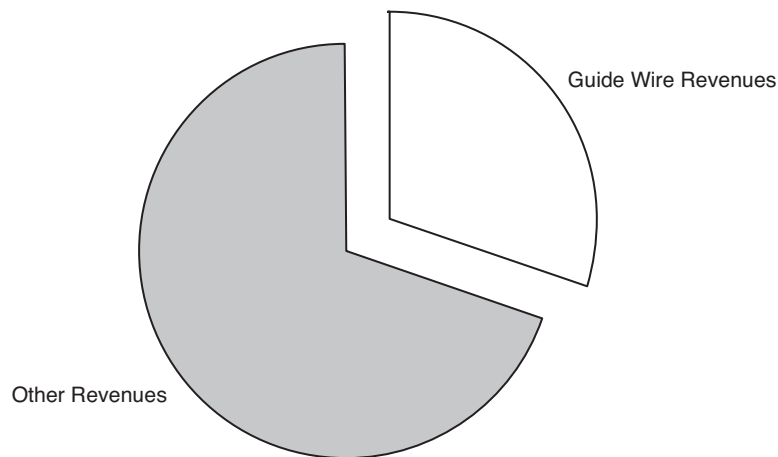
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In 2004, the US market for percutaneous transluminal coronary angioplasty (PTCA) guide wires was valued well at over \$100 million, making it the largest segment in the total accessory device market (as shown below). Growth in this market is leveraged by increasing procedure volumes, which are driving unit sales over the forecast period. The positive effect of growing unit sales is, however, offset by declining ASPs due to the commoditization of workhorse guide wires, product bundling, and volume discounting.

Nonetheless, a number of manufacturers have developed and are now marketing specialty guide wires, and sales of these devices will offset the contraction of ASPs to some extent. Specialty guide wires are proficient in dealing with specific cases, such as CTOs. Eager to advantage from the increased efficacy of these guide wires, physicians will purchase them with increased frequency over the forecast, thereby driving penetration of specialized guide wires and mitigating overall ASP decline.

**Exhibit 1.37** Guide Wire Market Revenues, As a Proportion of Total Accessory Devices Revenues, US, 2004

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Source: Millennium Research Group.

## Diagnostic Catheters

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Diagnostic catheters are employed during angiographies to diagnose CAD and to determine whether a percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) is necessary. Accordingly, the growing volume of angiographies in the US will serve as the primary driver of diagnostic catheter market growth. As aging baby boomers move into categories at higher-risk for CAD, the volume of

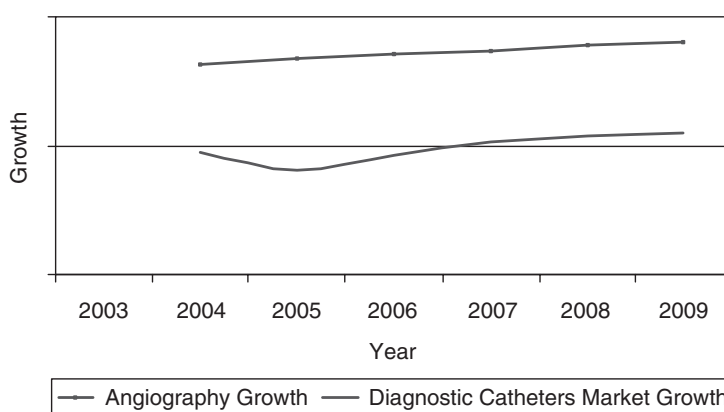


## 1.5 US Markets for Interventional Cardiology Accessory Devices

angiography procedures in the US will increase. Compounding procedure growth this is the rising awareness of CAD, which will increase the likelihood that an individual will request, or agree to, an angiography.

Over the forecast period, market growth market will be slightly tempered by increased penetration of drug-eluting stents (DES). The purchase of DES monopolizes a large portion of budgets allocated for interventional procedures, leaving a marginal balance to be used to purchase accessories such as diagnostic catheters; thus, the increased penetration of DES will place downward pressure on the diagnostic catheter ASPs over the forecast period. Subsequently, the diagnostic catheter market will not grow as quickly as angiography volumes, as illustrated in the exhibit below.

**Exhibit 1.38** Angiography Growth versus Diagnostic Catheter Market Growth, US, 2004–2009

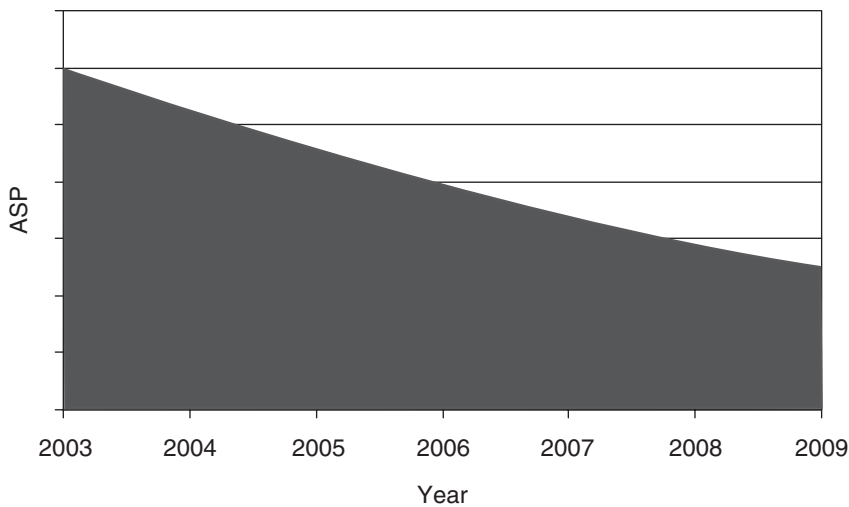


Source: Millennium Research Group.

## PTCA Guiding Catheters

In 2004, the PTCA guiding catheters market generated over \$75 million in revenues. Employed during PCI procedures, PTCA guiding catheters serve as conduits through which PTCA balloons or stents are delivered to diseased vessels. Over the forecast period, the growing volume of PCI procedures will be the main source of market growth. US PCI volumes are growing in on account of rising angiography volumes. Analogous to most other markets for accessory devices, growth in the PTCA guiding catheters market will be tempered by ASP contraction, as shown below.

ASPs will decline over the forecast period because, like many other accessory devices, PTCA guiding catheters are commodity products. PTCA guiding catheters are often difficult to differentiate based on performance, and the device's technological potential has been exhausted, meaning that few improvements can be made to command a higher price. Consequently, manufacturers have few other alternatives aside from competing on price.

**Exhibit 1.39** PTCA Guiding Catheter ASP, US, 2003–2009

Source: Millennium Research Group.

## IVUS Catheters

IVUS catheters are advanced diagnostic catheters that employ ultrasound technology to generate a three-dimensional image of the vessel wall. Practitioners use these images to more accurately diagnose CAD and ease stent placement during a PCI procedure. Accordingly, IVUS penetration in PCI procedures was higher than penetration in angiographies in 2004, as shown in the exhibit below.

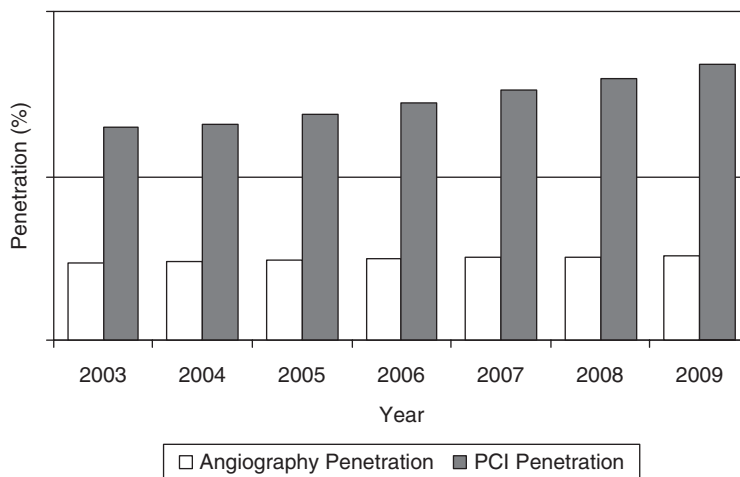
The most significant driver in the IVUS catheter market is the desire among interventionalists to benefit from the advanced capabilities of IVUS catheters. Furthermore, growing diagnostic and interventional procedure volumes and increased stent penetration are also contributing to the market's rapid growth. Combined, these factors will cause the market for IVUS catheters to be the fastest growing segment of the interventional accessories market over the forecast period.

## Introducer Sheaths

The US market for introducer sheaths was valued at over \$30 million in 2004. Introducer sheaths are inserted into the body during an intervention and act as a conduit through which various diagnostic and interventional devices may access the vasculature. Introducer sheaths are required for diagnostic and interventional procedures, thereby correlating market growth to procedure volume

## 1.5 US Markets for Interventional Cardiology Accessory Devices

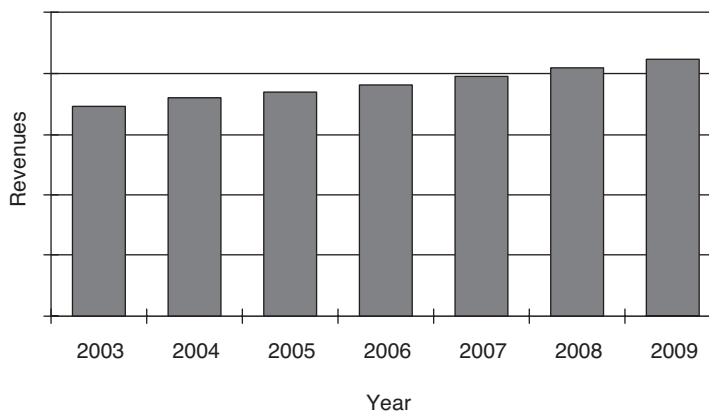
35

**Exhibit 1.40** VUS Catheter Angiography and PCI Penetration, US, 2003–2009

Source: Millennium Research Group.

growth; however, declining ASPs due to product bundling are significantly mitigating growth in this market.

Comparable to other accessory devices, introducer sheaths are commodity products that carry slim profit margins. Manufacturers often bundle introducer sheaths with other devices and sell them at or below cost in an attempt to augment the sales of other more profitable devices, such as DES. Despite product bundling placing downward pressure on the ASPs, the introducer sheath market will still see marginal growth over the forecast period, as shown in the exhibit below.

**Exhibit 1.41** Introducer Sheath Market, US, 2003–2009

Source: Millennium Research Group.

## 1.6 *European Markets for Interventional Cardiology*

### Market Overview

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**CAD:** Coronary Artery Disease

**DES:** Drug-eluting Stent(s)

**EPD:** Embolic Protection Device

**IC:** Interventional Cardiology

**IVUS:** Intravascular Ultrasound

**PCI:** Percutaneous Coronary Intervention

**PTCA:** Percutaneous Transluminal Coronary Angioplasty

In 2004, the European market for IC devices, comprising coronary stents, PTCA balloons, PTCA guide wires, PTCA guiding catheters, diagnostic catheters, introducer sheaths, IVUS catheters, and EPDs, generated well over \$1 billion in revenues. Unit sales were driven primarily by the increasing volumes of angiographies and PCIs, spurred by rising rates of CAD across Europe. As DES penetration continues to escalate over the forecast period, the number of PCI procedures performed will rise as a result of the increased treatment of more complex cases. This market driver will, however, be neutralized by declining ASPs across almost every IC product segment. DES will occupy the majority of hospital budgets; therefore, accessory pricing will fall as a result of product bundling and volume discounting offered to stent purchasers. Furthermore, limited reimbursement in certain regions for DES and advanced accessory technologies, namely IVUS and EPDs, has hindered the adoption of these devices despite the potential clinical benefits derived from their use. Nevertheless, the quick uptake of premium-priced DES and incremental unit growth in the other segments of the European IC market will substantially drive revenues year over year, eventually generating more than \$2 billion by 2009.

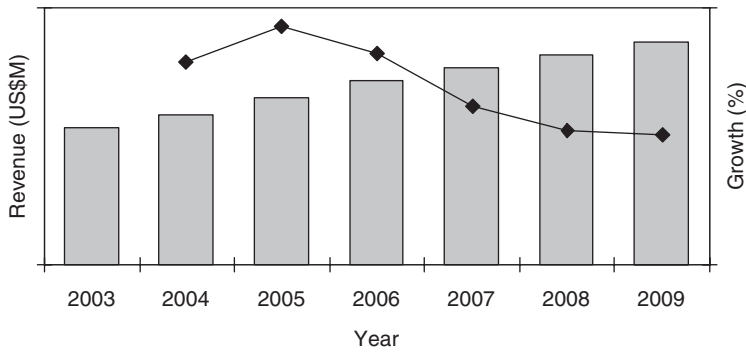
### Procedure Overview

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CAD is the most common form of heart disease in Europe and one of the leading causes of death worldwide. Risk factors for CAD that are prevalent in Europe and have contributed to the rise in procedure volumes include smoking, obesity, diabetes, inactivity, hypertension, and high cholesterol levels. Over the forecast period the aging European population will also raise the incidence of CAD, in turn augmenting the levels of all procedure types performed. In 2004, more than 650,000 PCI

1.6 European Markets for Interventional Cardiology

**Exhibit 1.42** ExInterventional Cardiology Market, by Type, Europe, 2003–2009

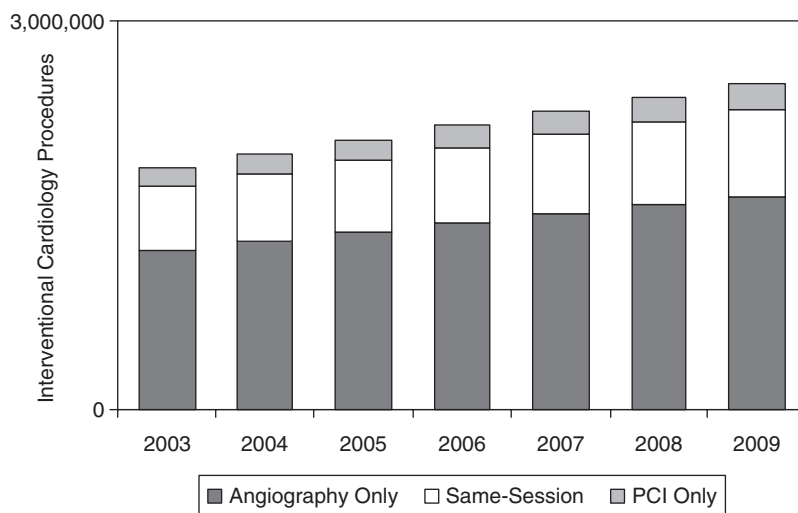


Source: Millennium Research Group.

procedures and more than 1,825,000 diagnostic angiographies were performed in Europe. PCI is an alternative to surgery that involves inserting catheters and guide wires through the groin or arm to deliver stents and balloons to the narrowed coronary arteries. Diagnostic angiographies, which enable physicians to map out the pathway leading to a lesion using catheters and contrast material, are performed alone or in advance of an intervention. Same-session procedures represent occurrences where an intervention immediately follows an angiography.

Germany contributed the greatest number of angiography and PCI procedures in 2004 due to the country's large population and expanded health care network.

**Exhibit 1.43** Interventional Cardiology Procedures, by Type, Europe, 2003–2009



Source: Millennium Research Group.

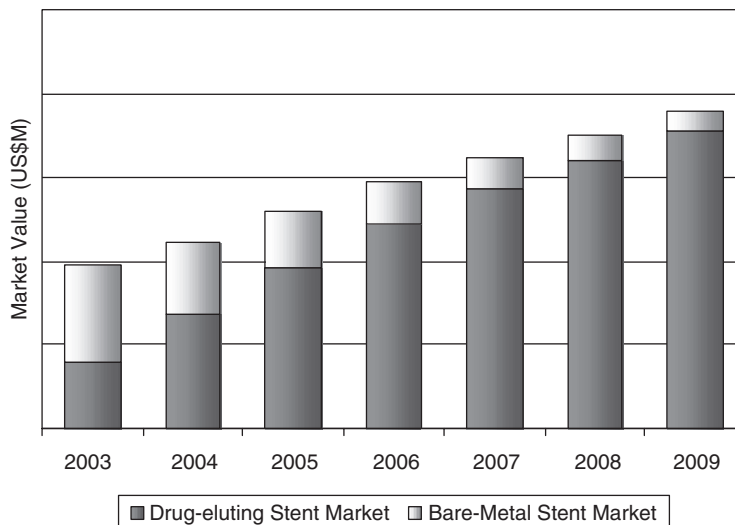
## Coronary Stent Market Overview

The European coronary stent market, comprising DES and bare-metal stents (BMS), was valued in excess of \$850 million in 2004. The use of coronary stents in PCIs for the treatment of CAD has risen rapidly over recent years. Currently, over 90% of PCI procedures in Europe involve a coronary stent because they have shown remarkable improvements in restenosis rates and patient outcomes compared to plain old balloon angioplasty (POBA).

Despite price reductions in each of the DES and BMS markets, the overall ASP in the coronary stent market will rise because market units are rapidly shifting towards the premium-priced DES segment.

Stent procedures and units will continue to escalate over the forecast period but not as dramatically as market revenues. Revenue growth over 2003 was nearly 15% as the penetration of premium-priced DES units has led to an overall rise in the market average selling price (ASP), while causing a tremendous shift away from BMS units. While BMS displays clear advantages over POBA, DES offers even further benefits, particularly for patients at high-risk to develop restenosis and those with complex lesion types. Despite the reduction in repeat interventions due to the efficacy of DES, the total market will increase at a compound annual growth rate (CAGR) around 10% from 2005 to 2009.

**Exhibit 1.44** Coronary Stent Market, by Type, Europe, 2003- 2009



Source: Millennium Research Group.

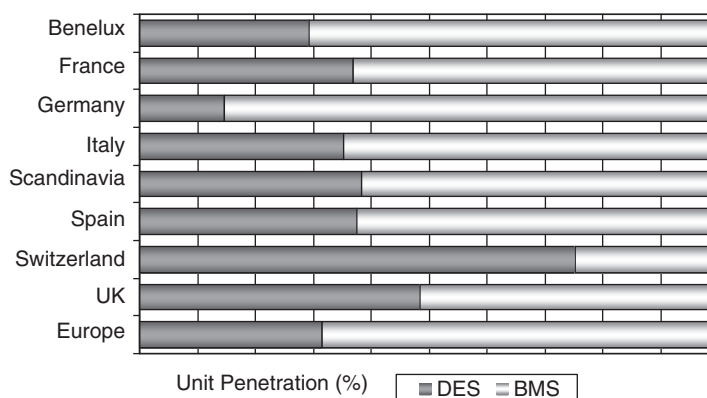
## Drug-eluting and Bare-Metal Stent Market Overviews

DES deliver a pharmacologic agent to the diseased wall of the artery in order to reduce the likelihood of future restenosis. The success and rapid uptake of DES since the introduction of Cordis' CYPHER stent in 2002 has sparked tremendous interest in the market by both manufacturers and physicians. In 2004, over 30% of coronary stents units in Europe were DES, with penetration varying significantly between countries and regions. Reimbursement approval and budget constraints are the major deterrents of DES adoption to date, however, units and revenues will grow significantly over the forecast period. Driving this growth will be the reduction in ASPs, increase in PCI procedures, expanding patient population eligible for DES treatment, product enhancements, and physicians' eagerness to use the latest technology. Furthermore, more manufacturers are slated to enter the DES scene, creating greater awareness to a market that will see revenue climb in excess of \$1.4 billion by 2009.

In 2004, Switzerland had the fastest DES unit penetration while Germany was the slowest.

The technological advancements made in the DES market have led to an accelerating decline in the demand for BMS. In 2004, revenues generated in the BMS market were close to 25% lower than the previous year. BMS were a revolutionary breakthrough as an effective alternative to balloon angioplasty for treating CAD, but positive clinical DES data continues to mount support for the newer technology. As a result, BMS units will continue to slip over the forecast period. This will also perpetrate erosion in ASPs because high prices can not be sustained in a deteriorating market. The European BMS market will gear towards a commodity market with companies resorting to price competition and many focusing greater attention towards developing DES products. Overall BMS market value will fall below \$100 million by 2009.

**Exhibit 1.45** Coronary Stent Unit Share, by Region, Europe, 2004



Source: Millennium Research Group.

## PTCA Balloon Market Overview

The European percutaneous transluminal coronary angioplasty (PTCA) balloon market, comprising both normal and cutting balloons, was worth in excess of \$180 million in 2004. Slow growth will occur through 2009 due to opposing market forces counteracting each other—PCI procedures are on the rise yet ASPs continue to decline.

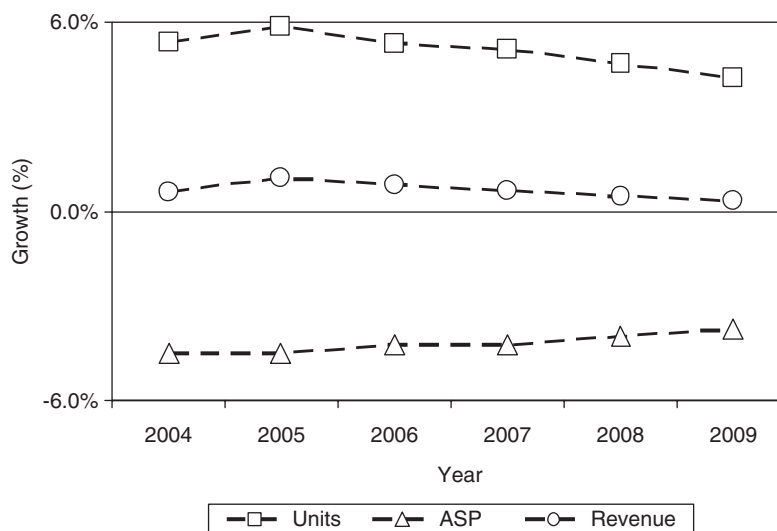
Direct stenting will limit the growth of PTCA balloons, although the majority of PCI procedures still use balloons to pre- or post-dilate the vessel.

The majority of PCI procedures use PTCA balloons to pre- or post-dilate the vessel, yielding high unit demand despite the practice of direct stenting. Over the forecast period, this upward procedure and unit trend will continue as more coronary artery bypass graft (CABG) surgeries shift to PCIs and better success rates are achieved with DES.

Furthermore, the average number of balloons used per procedure will be slightly elevated because more challenging cases will be treated via PCI. Pre-dilation is particularly beneficial in these circumstances to facilitate delivery of the stent and to assess how tough the lesion is.

The other major trend prevalent in the European PTCA balloon market is the downward shift in ASPs. This progressive erosion is primarily the result of volume discounting, bundling, and cross-selling strategies. In addition, with the slowdown in technological innovation, PTCA balloons have become more of a

**Exhibit 1.46** PTCA Balloon Market, Europe, 2003- 2009



Source: Millennium Research Group.



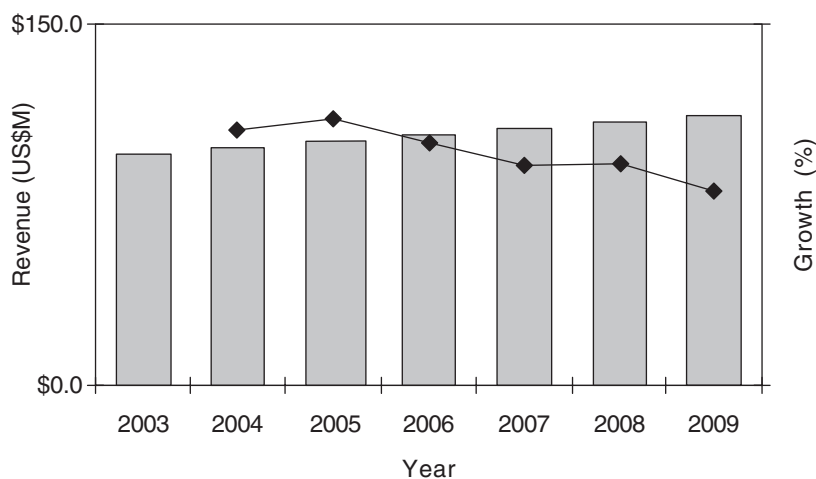
commoditized product, inciting greater price competition amongst the numerous competitors in the market. The exhibit below displays growth in the PTCA balloon market in Europe.

## PTCA Guide Wire Market Overview

In 2004, the European market for PTCA guide wires was valued in excess of \$100 million, as displayed in the exhibit below. PTCA guide wires are required for every interventional procedure, thereby making procedures the principle catalyst in unit, and subsequent revenue growth. Over the forecast period, the volume of PCI procedures will experience fair growth due to the increasing use of DES, which enable physicians to treat coronary conditions previously referred to surgery. As such, unit growth will closely mirror procedure growth over the forecast, though ASP erosion due to increasing price competition will place downward pressure on the market. ASP decline will be tempered, ever so slightly, but the increasing use of premium-priced specialty-designed guide wires, which are intended to ease the crossing of complex or highly-stenosed coronary lesions. The increasing use of these specialty wires is only one of the many drivers competing against ASP mitigation, and will contribute to positive market growth.

PTCA guide wires are required for every interventional procedure.

**Exhibit 1.47** PTCA Guide Wire Market, Europe, (US\$), 2003–2009



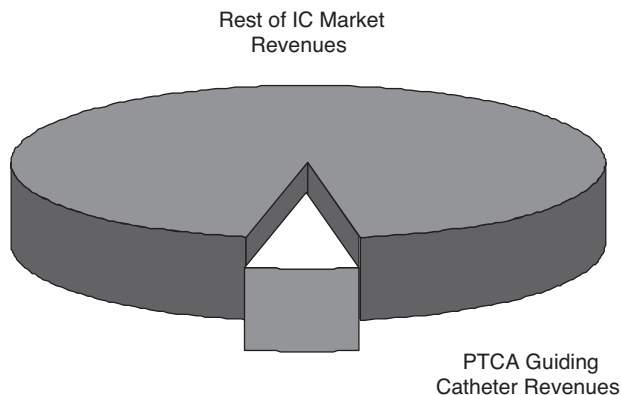
Source: Millennium Research Group.

## PTCA Guiding Catheter Market Overview

Like PTCA guide wires, guiding catheters are required with every intervention to access the lesion site.

In 2004, the European market for PTCA guiding catheters was valued in excess of \$80 million. PTCA guiding catheters are required for every interventional procedure, thereby making procedures the principle catalyst in unit, and subsequent revenue growth. Through 2009 the average European unit per procedure ratio will remain relatively steady with two opposing forces neutralizing growth. From one perspective the number of guiding catheters will increase per procedure due to the increasing penetration of DES, which enable to the treatment of more complex coronary situations, including multivessel patients. Contrasting this growth is a move towards the standardization of catheter French sizing, which is pushing towards miniaturization. This will limit the need to change catheters mid-procedure, essentially reducing units per procedures. PTCA guiding catheter ASPs will see decline over the forecast period largely due to the devices' further entrenchment into commoditization. Despite this decline, the market for guiding catheters will continue to see positive growth through 2009.

**Exhibit 1.48** PTCA Guiding Catheter Revenues, As a % of Total IC Market Revenues, Europe, (US\$), 2004



Source: Millennium Research Group.

## Diagnostic Catheter Market Overview

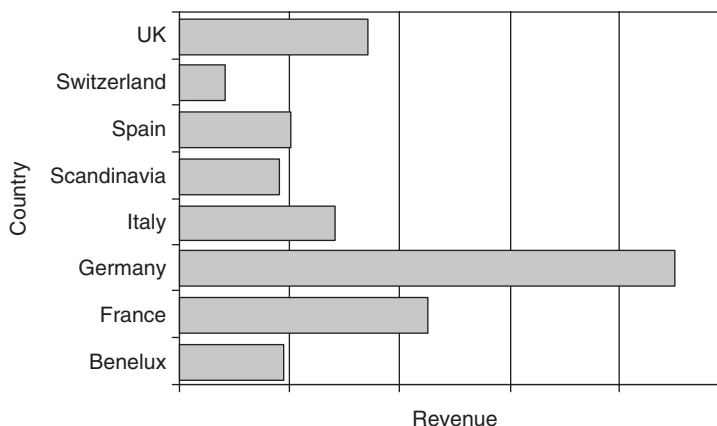
In 2004, the European market for diagnostic catheters market generated more than \$80 million in revenues, primarily a result of the high volume of diagnostic procedures performed. Germany, which accounted for the largest number of angiography

## 1.6 European Markets for Interventional Cardiology

procedures in Europe, was the most lucrative market for diagnostic catheters in 2004. Diagnostic catheters are employed during diagnostic angiographies to diagnose CAD and to determine whether an interventional or coronary artery bypass grafting procedure is required. Over the forecast period, the diagnostic catheter market will be driven heavily by the aging European population which is moving into higher-risk categories for CAD. Mitigating procedure growth is ASP decline. Diagnostic catheters have essentially reached their technological potential, limiting further advancements to justify incremental price increases. As such, manufacturers are now resorting to price competition and product bundling, both which send ASPs downward.

Diagnostic catheters are used to identify lesions and/or related concerns during an angiography procedure.

**Exhibit 1.49** Diagnostic Catheter Revenues, by Region, Europe, (US\$), 2004



Source: Millennium Research Group.

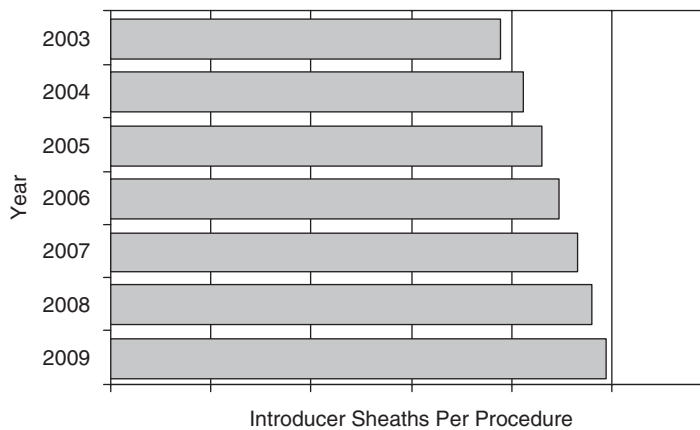
## Introducer Sheath Market Overview

The European market for introducer sheaths was valued in excess of \$40 million in 2004. Introducer sheaths are devices used as conduits during a percutaneous procedure, through which various diagnostic and interventional devices may access the vasculature while limiting blood loss. Introducer sheaths are required during diagnostic and interventional procedures, thereby linking unit sales to procedure growth. The volumes of European diagnostic and interventional procedures are growing through the forecast, providing stable unit growth for manufacturers. As the number of multi-vessel and complex cases treated by intervention increases, the average number of sheaths per

Introducer sheaths are commodity devices often bundled with other accessories.

procedure will follow suit. This is justified through the increasing need to change sheaths mid-procedure to accommodate devices of varying sizes. Opposing this growth is a decline in average selling prices (ASPs), due to the increasing commodity status of these simple devices. Unable to effectively distinguish devices among competitors, more manufacturers are competing on price, creating ASP erosion. Though ASPs will decline through the forecast, procedure volumes will maintain the market through 2009, yielding a positive market CAGR.

**Exhibit 1.50** Introducer Sheaths per Procedure, Europe, 2003–2009



Source: Millennium Research Group.

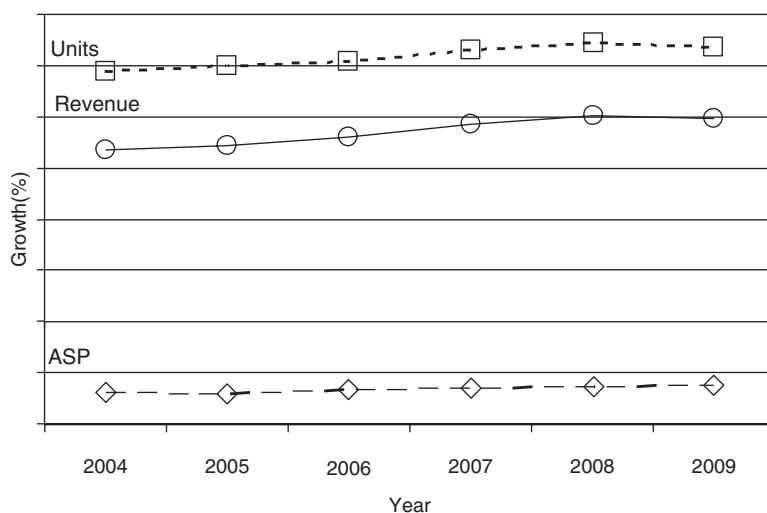
## IVUS Catheter Market Overview

IVUS catheters may be used for better, more accurate stent placement. Limited reimbursement has hindered routine adoption in Europe.

In 2004, the European market for intravascular ultrasound (IVUS) catheters was valued at nearly \$15 million. IVUS catheters are advanced diagnostic catheters that employ ultrasound technology to generate a three-dimensional image and detailed information about the vessel wall. Practitioners use this image to more accurately diagnose CAD, and to precisely place a stent during a percutaneous coronary intervention procedure. Driven by growing positive clinical data, advancements in IVUS technology, and the increasing penetration of drug-eluting stents (DES), the market for IVUS catheters will grow at a CAGR in excess of 7% over the forecast period. Limiting the market are negligible reimbursement rates in all European regions. Without adequate reimbursement IVUS catheter use is limited to the discretion of European physicians,

## 1.6 European Markets for Interventional Cardiology

limiting the catheter use to the most severe patient profiles. Moreover, limited reimbursement and hospital budgets have forced some physicians to reuse IVUS catheters, impacting unit sales and comprising the visual quality of the catheters. Despite these limitations, the market will grow through the forecast, eventually more than doubling by 2009.

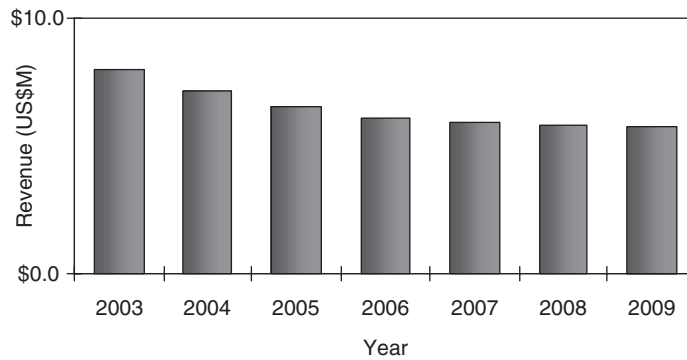
**Exhibit 1.51** IVUS Catheter Market Growth, Europe, 2004–2009

Source: Millennium Research Group.

## Embolic Protection Device Market Overview

The European market for embolic protection devices (EPDs) in coronary settings was valued at over \$7 million in 2004. EPDs are specially-designed devices that collect dislodged debris within a vessel to prevent distal embolization and other adverse coronary events. Though clinical data from the US suggests the importance of embolic protection, the European market has not responded heavily to these results, largely due to a lack of notable reimbursement for EPD usage. Moreover, the influx of competition from second-generation and new devices will expand price competition, driving ASPs downward. Despite the use of EPDs by some forward-thinking European physicians, the lack of notable reimbursement will severely limit the overall market, such that it will decline over the forecast period, as illustrated in the exhibit below.

The EPD market is largely dominated by filter-based systems, which capture free-floating fragments present in the vessel after a PCI procedure.

**Exhibit 1.52** Embolic Protection Market, Europe, (US\$), 2003–2009

Source: Millennium Research Group.

## Competitive Analysis

The European Markets for Interventional Cardiology Accessory Devices report includes coverage of the following companies:

Aachen Resonance	Boston Scientific	Kensey Nash	Plasmachem
Abbott Vascular	Clearstream	Mallinckrodt	Radi Medical
Acrostak	Cook	Maxxim	Smiths Medical
AMG	Cordis	Medex	Sofradim
Argon Medical	Curative	Medtronic	Sorin Biomedica
Arrow	Eucatech	MeoMedical	St. Jude Medical
Asahi Intecc	Eurocor	Merit Medical	Terumo
Atrium Medical	Ev3	Minvasys	Togo Medikit
Avantec	Hexacath	Neich Medical	Translumina
B Braun	Guidant	Occam	Volcano Therapeutics
Biotronik	Iberhospitex	Orbus	W.L. Gore
Blue Medical	Inflow Dynamics	Phytis	Zento Medical
Bolton Medical	Invatec		

Source: Millennium Research Group.

## 1.7 European Markets for Coronary Stents

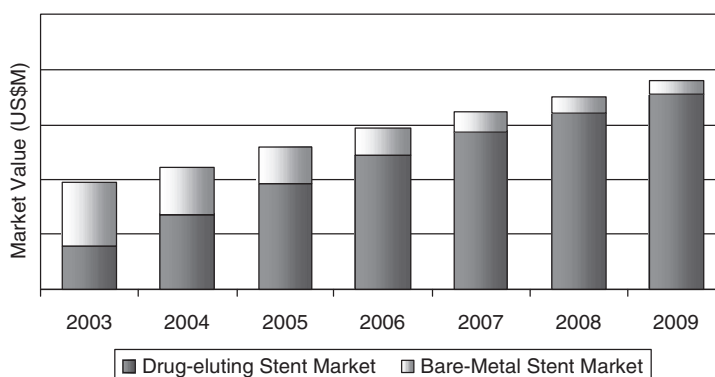
### Market Overview

The European coronary stent market, comprising drug-eluting stents (DES) and bare-metal stents (BMS) was valued in excess of \$850 million in 2004. The use of coronary stents in percutaneous coronary interventions (PCI) for the treatment of coronary artery disease (CAD) has risen rapidly over recent years. Currently, over 90% of PCI procedures in Europe involve a coronary stent because they have shown remarkable improvements in restenosis rates and patient outcomes compared to plain old balloon angioplasty (POBA).

Increased penetration of DES drove the growth of coronary stent units, procedures, ASPs, and revenues in 2004.

Stent procedures and units will continue to escalate over the forecast period but not as dramatically as market revenues. Revenue growth over 2003 was nearly 15% as the penetration of premium-priced DES units has led to an overall rise in the market average selling price (ASP), while causing a tremendous shift away from BMS units. Though BMS displays clear advantages over POBA, DES offers even further benefits, particularly for patients at high-risk to develop restenosis and those with complex lesion types. Despite the reduction in repeat interventions due to the efficacy of DES, the total market will increase at a compound annual growth rate (CAGR) over 9% from 2005 to 2009.

**Exhibit 1.53** Coronary Stent Market, by Type, Europe, 2003–2009



Source: Millennium Research Group.

## Market Drivers and Limiters

### Exhibit 1.54 Drivers of the Coronary Stent Market, Europe

<i>Market Driver</i>	<i>Explanation</i>
Increase in PCI procedures	The rising incidence of CAD in Europe, along with a shift from CABG due to the introduction of DES, will fuel PCI procedure growth. Recent studies, particularly the ARTS II trial sponsored by Cordis, have shown positive results of DES that are comparable to CABG. Such outcomes will continue to influence conversion from CABG to PCI with DES. Interventional treatment also allows cost savings for the hospital. Furthermore, operation time and patient recovery time are reduced using a PCI procedure.
Growing patient population	Increased awareness for CAD and PCI treatment will encourage patients to undergo diagnostic checkups that could lead to interventional follow-up. The heightened publicity for DES will also spur patient demand for the latest technology. Complex lesions and multiple vessel cases will be treated more often with stents given the benefits it provides and future designs that will target difficult procedures. More high-risk patients, such as diabetics, will be referred to DES due to the advantages of lowering restenosis rates.
DES penetration	The higher ASP and accelerating penetration of DES will result in surging market revenues over the forecast period.
Clinical results	Impressive clinical results, demonstrated in multiple studies, will drive physician acceptance of DES and help future devices gain faster approval.
Product enhancements	Boston Scientific and Cordis have each recently launched upgraded delivery systems for their respective DES products. These enhancements will reduce positioning complications and better handle challenging lesions. BMS products have also experienced recent innovation in the form of cobalt alloy stents. Cobalt alloy is stronger than stainless steel and the thinner struts offer better flexibility and deliverability.

Source: Millennium Research Group.

### Exhibit 1.55 Limiters of the Coronary Stent Market, Europe

<i>Market Limiter</i>	<i>Explanation</i>
Budget restraints	The high cost of DES is a challenge for hospitals and health care systems facing tight budgetary constraints. As such, several may opt to use BMS, particularly for simple de novo lesions. National reimbursement is not yet available in Germany, the largest market for PCI procedures in Europe.
Falling ASPs	Due to heightened competition in the BMS market, ASPs are eroding quickly as manufacturers employ discounting and bundling tactics to gain greater market share. In addition, reduced demand is limiting the prices that companies can charge for BMS. DES ASPs are falling as well due to pressures from hospitals for manufacturers to lower prices to balance their budgets. As more companies enter the DES in future years, the ASP will continue to decline because of natural competitive forces. The entry of Boston Scientific in 2003 has already demonstrated this trend.
Decreasing rates of restenosis	Despite overall PCI procedures increasing, this rise is mitigated by the reduction in restenosis and repeat interventions. Both DES and BMS have improved patient outcomes considerably from POBA.

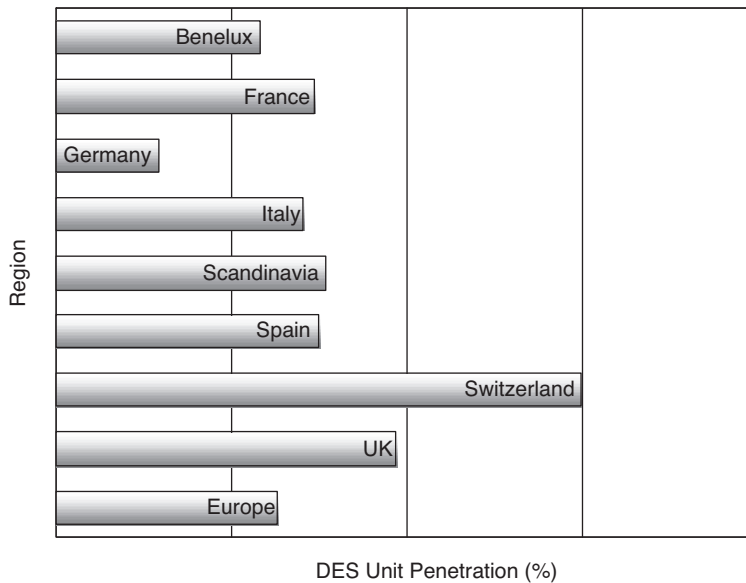
Source: Millennium Research Group.



## DES Market

DES deliver a pharmacologic agent to the diseased wall of the artery in order to reduce the likelihood of future restenosis. The success and rapid uptake of DES since the introduction of Cordis' CYPHER stent in 2002 has sparked tremendous interest in the market by both manufacturers and physicians. In 2004, over 30% of coronary stents units in Europe were DES, with penetration varying significantly between countries and regions. Reimbursement approval and budget constraints are the major deterrents of DES adoption to date, however, units and revenues will grow significantly over the forecast period. Driving this growth will be the reduction in ASPs, increase in PCI procedures, expanding patient population eligible for DES treatment, product enhancements, and physicians' eagerness to use the latest technology. Furthermore, more manufacturers are slated to enter the DES scene, creating greater awareness to a market that will have tripled its current revenues by 2009.

**Exhibit 1.56** DES Unit Penetration, by Region, Europe, 2004



Source: Millennium Research Group.

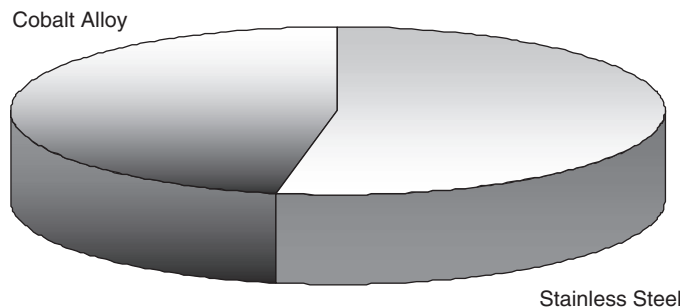
## BMS Market

The technological advancements made in the DES market have led to an accelerating decline in the demand for BMS. In 2004, revenues generated in the BMS market were close to 25% lower than the previous year. Initially, BMS were considered a

revolutionary breakthrough as an effective alternative to balloon angioplasty for treating CAD, but positive clinical DES data continues to mount support for the newer technology. As a result, BMS units will continue to slip over the forecast period. This will also perpetrate erosion in ASPs because high prices can not be sustained in a deteriorating market. The European BMS market will gear towards a commodity market with companies resorting to price competition and many focusing greater attention towards developing DES products. Overall BMS market value will fall below \$100 million by 2009.

One recent innovation to BMS products was the introduction of cobalt alloy stents, beginning with Guidant's MULTI-LINK Vision in December 2002 and Medtronic's Driver in January 2003. Cobalt alloy stents have thinner struts than their stainless steel predecessors, rendering the device more flexible and deliverable, particularly when operating in difficult anatomy. Vision and Driver have become leading products in the European BMS market, and more companies are investing in cobalt alloy technology, both for BMS and DES devices. The exhibit below displays revenue shares, by material, in the BMS market.

**Exhibit 1.57** BMS Revenue Share, by Material, Europe, 2004



Source: Millennium Research Group.

## Competitive Analysis

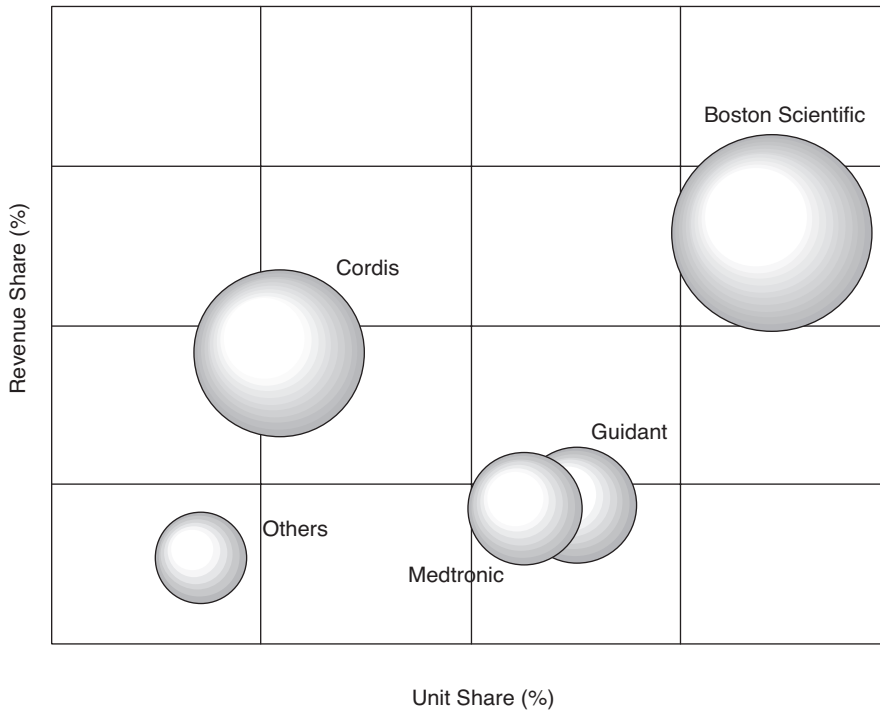
Boston Scientific and Cordis were the primary competitors in the 2004 European DES market, totaling the vast majority of units and revenues. The lucrative opportunities in this market have benefited each company and solid clinical evidence in sponsored trials continued to drive adoption of TAXUS and CYPHER. More competitors, including Medtronic, will enter the market over the forecast period and cause both an increase in DES demand and reduction in price.

In the European BMS market, Guidant and Medtronic were the 2004 market leaders due to broader product portfolios that span different BMS materials and specific patient subsets. Unlike the DES market, the BMS market is saturated

1.7 European Markets for Coronary Stents

with a multitude of competitors, which will lead to intense price competition over the forecast period. Several leading BMS manufacturers are in the development or testing stages for DES, furthering the attention and resources that will be allocated to the DES market. Because DES are heavily based upon BMS platforms, prospective DES competitors will not entirely ignore the BMS market despite rapidly declining revenues and ASPs. The exhibit below displays the leading competitors in the coronary stent market in Europe in 2004.

**Exhibit 1.58** Leading Competitors in the Coronary Stent Market, Europe, 2004



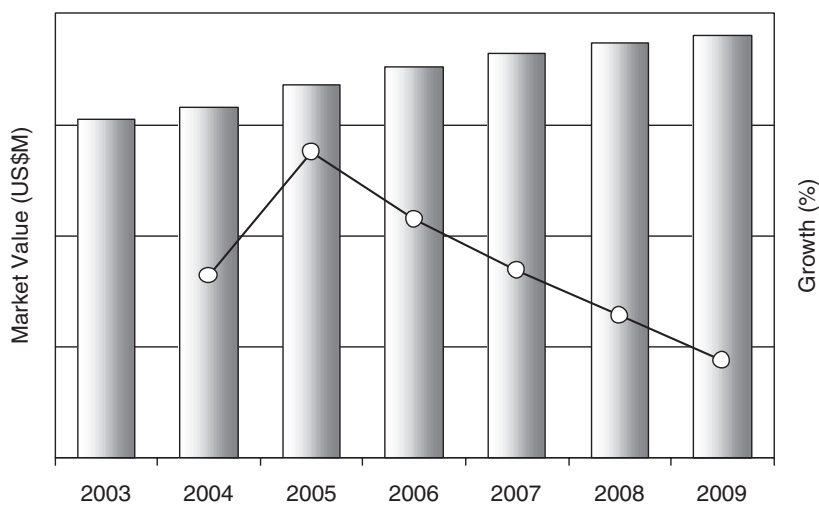
Source: Millennium Research Group.

## 1.8 European Markets for Ptca Balloons

### Market Overview

The European percutaneous transluminal coronary angioplasty (PTCA) balloon market, comprising both normal and cutting balloons, was worth in excess of \$180 million in 2004. This value was only a slight increase over 2003 due to opposing market forces counteracting each other. Percutaneous coronary interventions (PCI) are on the rise, therefore, increasing unit demand and consumption; however, with price competition mounting, the average selling price (ASP) is dropping in all European regions and limiting the overall amount of revenue generated. Over the forecast period, the European PTCA balloon market will grow very slowly as it follows the trend towards commoditization (see below).

**Exhibit 1.59** PTCA Balloon Market, Europe, 2003- 2009



Source: Millennium Research Group.

## Procedures

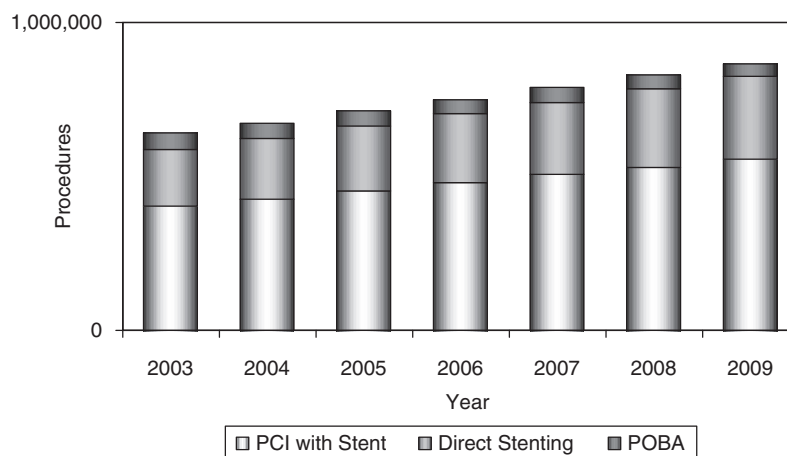
Coronary artery disease (CAD) is the most common form of heart disease in Europe and one of the leading causes of death worldwide. Risk factors for CAD that are prevalent in Europe and have contributed to the rise in procedure volumes include smoking, obesity, diabetes, inactivity, hypertension, and high cholesterol levels. The aging population will also raise the incidence of CAD and the need for high-quality therapeutic solutions such as percutaneous coronary interventions (PCI). PCI is an alternative to surgery that involves inserting catheters and guidewires through the groin or arm to deliver stents and balloons to the narrowed coronary arteries. In 2004, over 670,000 PCIs were performed in Europe.

In the past, the gold standard PCI treatment was plain old balloon angioplasty (POBA), where a PTCA balloon would be used on its own to compress plaque and restore patency to the artery. Since the introduction of bare-metal stents and then drug-eluting stents (DES), POBA procedures have deteriorated with great celerity due to relatively poorer clinical results and patient outcomes. PTCA balloons are now used primarily to pre-dilate the vessel in preparation for stenting or to post-dilate the vessel to optimize placement of the stent. Over 60% of PCI procedures used a PTCA balloon in conjunction with a stent in 2004.

Direct stenting, inserting a stent without balloon pre- or post-dilation, is also a growing practice in Europe. It offers the benefits of reduced cost and procedure time; however, the profile and deliverability of certain stents make them difficult to cross challenging lesions and tortuous anatomy. Over the forecast period, direct stenting will moderately increase, contributing to an overall PCI procedure compound annual growth rate (CAGR) nearing 5%.

The exhibit below displays PCI procedures in Europe, by type.

**Exhibit 1.60** PCI Procedures, by Type, Europe, 2003–2009



Source: Millennium Research Group.

## Market Drivers and Limiters

### Exhibit 1.61 Drivers of the PTCA Balloon Market, Europe

<i>Market Driver</i>	<i>Explanation</i>
Growth of PCI procedures	The rising incidence of CAD in Europe, along with a shift from CABG will fuel PCI procedure growth and the demand for balloon units.
Complex lesions	The improved efficacy of DES in lowering restenosis and target vessel failure rates will increase the number of complex lesions and challenging cases that are treated with a stent. For these procedures, pre-dilation with a balloon is particularly important to provide more data about the diseased vessel and to facilitate placement of the stent. The rise in complex PCI procedures will also slightly boost the number of balloon units used per procedure.
Cautious behavior	The growth in direct stenting will be limited by apprehensions over the deliverability of certain stents. As a result, physicians will be inclined to still use balloons, evidenced by the majority of PCI procedures that employ stents and balloons in conjunction.

Source: Millennium Research Group.

### Exhibit 1.62 Limiters of the PTCA Balloon Market, Europe

<i>Market Limiter</i>	<i>Explanation</i>
Decline in POBA	POBA rates have decreased rapidly since the introduction of coronary stents. By 2009, POBA will only constitute approximately 5% of total PCIs in Europe, therefore, limiting the amount of procedures involving a PTCA balloon catheter.
Direct stenting	POBA procedures will not entirely shift to PCI with stent procedures due to the gradual growth of direct stenting. Because direct stenting does not mandate the use of balloons, unit sales will suffer as a result. Benefits of direct stenting include cost savings and reduced procedure time. As the deliverability and crossability of stents are enhanced over the forecast period, more physicians will be inclined to practice direct stenting.
Decreasing ASP	The adoption of high-priced DES will shrink remaining budgets for other interventional products such as PTCA balloons. Manufacturers will likely comply with purchaser pressure to lower prices, especially because stents are the more critical profit driver of the major balloon competitors. Volume discounts and bundling practices will also lead to a decrease in the market ASP for balloons. Heightened competition will cause prices to drop, particularly given the commoditized state of the market and the increasing ease that smaller manufacturers can imitate product technology.
Lack of technological innovation	Also contributing to the reduction in ASPs is the lack of overwhelming innovation in the PTCA balloon market to stabilize current prices. Although competitors continue to roll out new generation balloons, major differences between products are difficult to distinguish. Cutting balloons have not made a significant impact in the European market. The advantages of cutting balloons have been mitigated by the success of DES. In addition, normal balloons are often sufficient enough to pre- or post-dilate most lesion types, therefore, discouraging users to pay premium prices for cutting balloons.

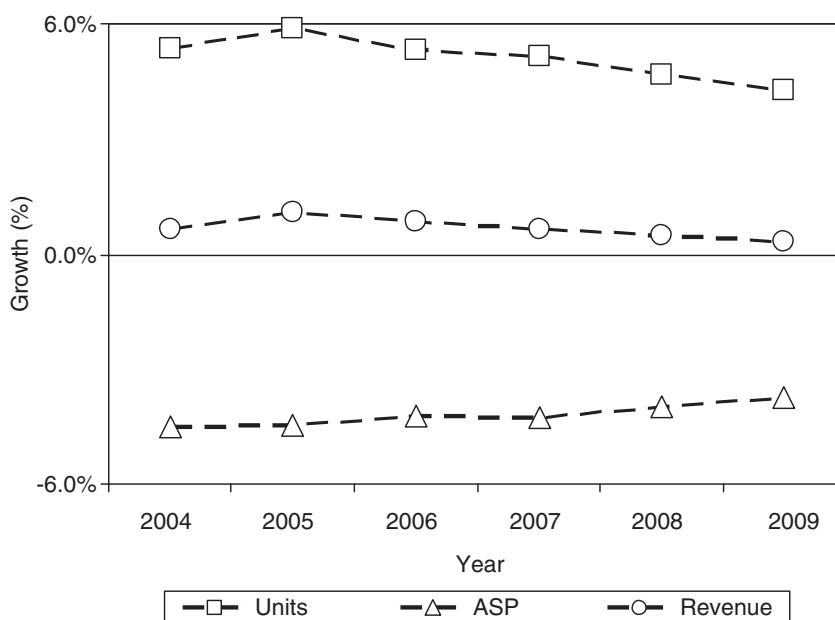
Source: Millennium Research Group.

## Base Year Review and Market Forecast

In 2004, rising PCI procedures was the major catalyst of increased unit sales over each quarter of the year. The majority of PCI procedures use PTCA balloons to pre- or post-dilate the vessel, therefore, balloons are still in high demand despite the practice of direct stenting. Over the forecast period, this upward procedure and unit trend will continue due to more coronary artery bypass graft (CABG) surgeries shifting to PCIs and better success rates with DES. Furthermore, the average number of balloons used per procedure will be slightly elevated because more challenging cases will be treated via PCI. Pre-dilation is particularly beneficial in these circumstances to facilitate delivery of the stent and to assess how tough the lesion is.

The other major trend prevalent in the 2004 European market was the downward shift in ASPs that will also persist throughout the forecast period. This progressive erosion was primarily the result of volume discounting, bundling, and cross-selling strategies. In addition, with catheterization labs PTCA balloons have become more of a commoditized product, inciting greater price competition amongst the numerous competitors in the market. ASPs fell approximately 4% over 2004.

**Exhibit 1.63** PTCA Balloon Market Growth, Europe, 2003–2009



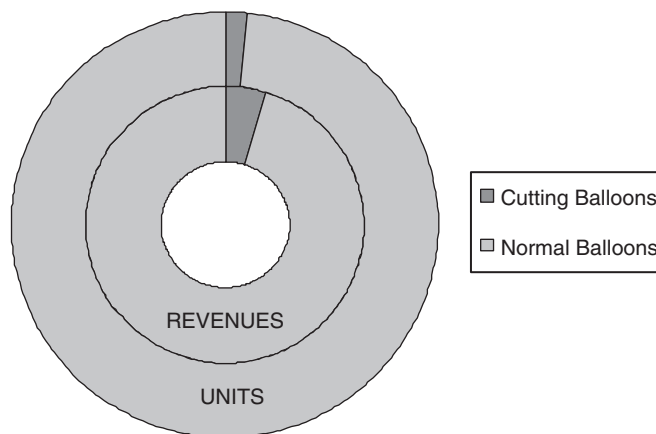
Source: Millennium Research Group.

## Balloon Type

This report covers both normal angioplasty balloons and cutting balloons. Cutting balloons are used particularly for complex situations such as ostial, fibrotic/calcified, bifurcated, and extra long lesions. Thin microblades attached to the exterior surface are able to efficiently shave away tightly compressed plaque under these challenging conditions. Due to their non-compliant nature, cutting balloons also minimize excessive expansion of the vessel wall.

Cutting balloons remain very much a niche market in Europe, comprising less than 5% unit and revenue share. Many European interventional cardiologists feel normal PTCA balloons do an adequate job, overriding the need to pay premium prices for cutting balloons. In 2004, the ASP of a cutting balloon was more than three times as expensive as a normal balloon. Moreover, DES and other atherectomy devices can be used as substitutes so it is unlikely that physician preference for cutting balloons will change dramatically over the forecast period.

**Exhibit 1.64** PTCA Balloon Market, by Type, Europe, 2004



Source: Millennium Research Group.

## Balloon Compliance

Compliance is a term used to describe the extent to which a balloon catheter will expand once inflated under different levels of pressure. Three classifications are used in this report: semi-compliant, low-compliant, and non-compliant. In general, the less a balloon stretches, the less it is considered compliant. In contrast, if the balloon readily conforms to the contours of the surrounding lesion and arterial wall, it is regarded to be more compliant.

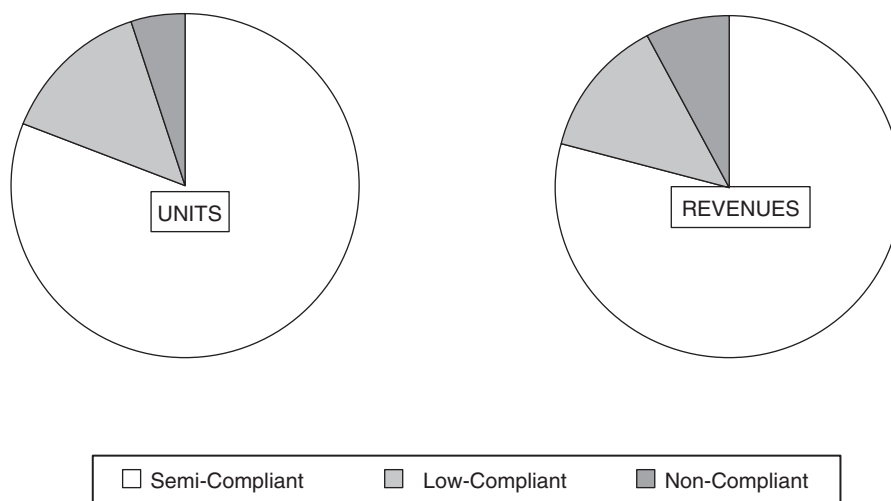


## 1.8 European Markets for Ptca Balloons

Semi-compliant balloons comprised over 80% of PTCA balloons in the 2004 European market. Semi-compliant balloons use softer materials, leading to better crossability and deliverability. Furthermore, the added flexibility helps physicians maneuver the balloon catheter, particularly if they initially sized the vessel incorrectly.

Non-compliant balloons better maintain their shape and this property allows the balloon to exert more force to the target lesion. As such, they are especially useful for heavily calcified or occluded arteries, as well as for stent post-dilation. In addition, under high pressures, balloon diameter growth is reduced so there is less chance of the balloon expanding outside the diseased area and affecting healthy tissue. Low-compliant balloons possess a mix of semi-compliant and non-compliant balloon characteristics, although not to the full extent of either.

**Exhibit 1.65** PTCA Balloon Market, by Compliance, Europe, 2004



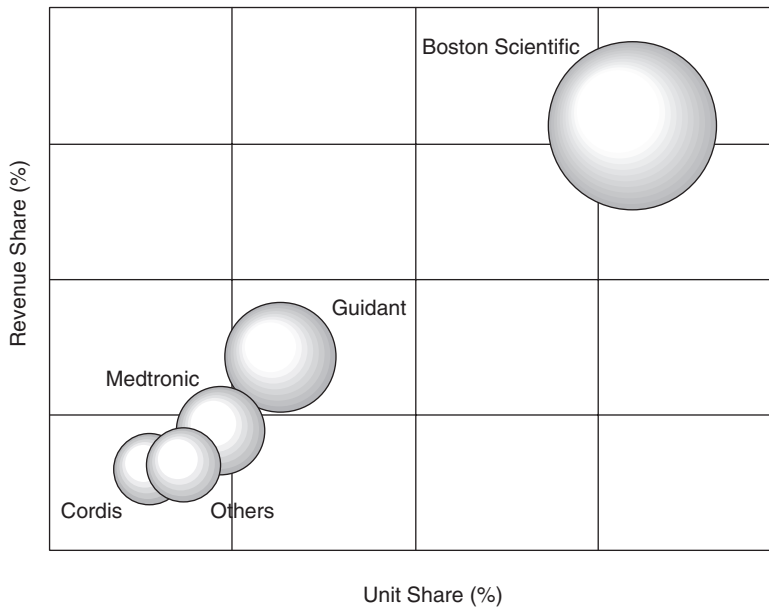
Source: Millennium Research Group.

## Competitive Analysis

Boston Scientific was the European PTCA balloon market leader in 2004. The company has the widest range of balloons available, including the leading Maverick 2 Monorail brand and a full line of cutting balloons. Together with Guidant, Medtronic, and Cordis, these four manufacturers totalled over 90% of revenues generated during the year. Each of these companies is also a leader in the coronary stent market, so they benefit from widespread account penetration and the ability to bundle balloons with other interventional cardiology accessory devices.

Other smaller market players include Abbott Vascular, Acrostak, Atrium Medical, Avantec, B Braun, Biotronik, Blue Medical, Bolton Medical, Clearstream, Eucatech, Hexacath, Iberhospitex, Invatec, Minvasys, Neich Medical, Occam, Sorin Biomedica, Terumo, and Translumina. Many of these companies compete with low-priced balloons that lie below the market average. The slowdown in product innovation has also lowered entry barriers for manufacturers who do not have the resources to invest in extensive research and development.

**Exhibit 1.66** Leading Competitors in the PTCA Balloon Market, Europe, 2004



Source: Millennium Research Group.

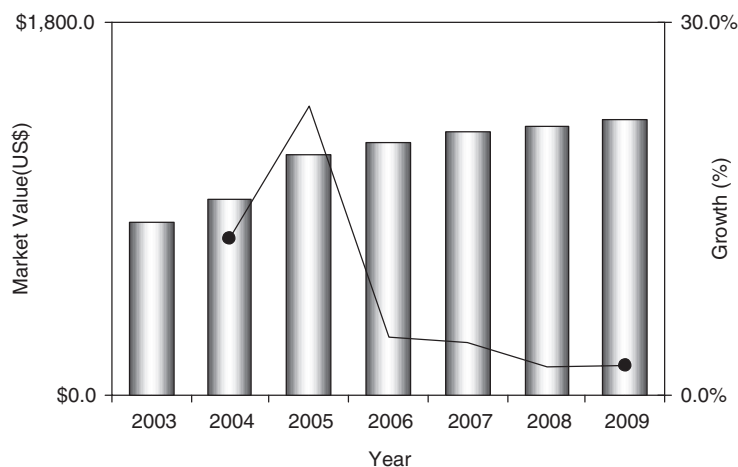
## 1.9 Japanese Markets for Interventional Cardiology

### Japanese Interventional Cardiology Device Market

Valued at over \$900 million in 2004, the Japanese interventional cardiology (IC) market is the second-largest worldwide. From 2005 to 2009, the market is forecast to increase at a compound annual growth rate (CAGR) exceeding 3%. The introduction of drug-eluting stents (DES), changes in the Japanese regulatory environment, and an aging Japanese population will serve to significantly drive the value of the IC market in Japan. The market will be limited by changes to medical device reimbursement policies made by the Japanese Ministry of Health, Labour and Welfare (MHLW) that will limit average selling prices (ASPs) and result in the decline in certain market segments. The exhibit below displays the Japanese IC market from 2003 through to 2009.

Because of Cordis' DES release in early 2004, the IC market competitive landscape was transformed. The CYPHER DES led Cordis to become Japan's market share leader in 2004.

**Exhibit 1.67** IC Market, Japan, 2003–2009 (Graphical Format)



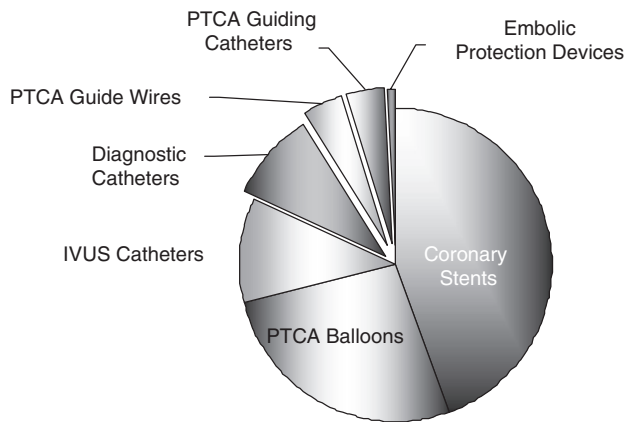
Source: Millennium Research Group.

The IC market, as covered in this report, comprises the following devices:

- Coronary stents: BMS and DES
- PTCA balloon catheters
- IVUS catheters
- Diagnostic catheters
- PTCA guiding catheters
- PTCA guide wires
- EPDs

The exhibit below displays the share of revenue garnered by each device in the Japanese IC market in 2004.

**Exhibit 1.68** IC Market Revenue Shares, by Device, Japan, 2004 (Graphical Format)



Source: Millennium Research Group.

## Procedure Volumes

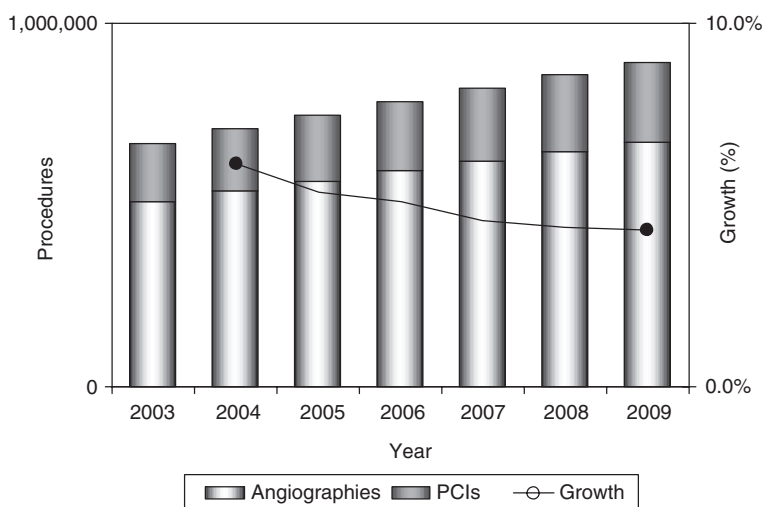
Procedure volumes in the Japanese IC market will see a moderate increase over the forecast period, while the ratio of angiographies and angioplasties is expected to remain stable. The exhibit below depicts PCI procedures against angiography procedures and overall growth.

IC treatment is available to all Japanese citizens. Rather than being localized in certain regions, PTCA procedure volumes are dispersed throughout the country with comparatively few large centers. As a result, the experience of Japanese doctors in performing these procedures is accumulated at a slower rate when compared to the US. Also due to this dispersion, the cost of conducting interventional procedures in Japan is relatively high as sales reps must visit a greater number of hospitals, increasing the costs passed on the final sales price of equipment. Costs are also higher because manufacturers must provide a range of sales support services to hospitals via multiple distribution channels. Given procedural dispersion, the level of treatment

## 1.9 Japanese Markets for Interventional Cardiology

provided by hospitals in Japan varies greatly when compared to the US. For example, less than 20% of Japanese medical institutions perform 400 PTCA procedures a year. Consequently, Japanese hospitals tend to place a high volume of smaller equipment orders, making it difficult for manufacturers to offer bulk discount prices.

**Exhibit 1.69** IC Procedures, by Type, Japan, 2003–2009 (Graphical Format)



Source: Millennium Research Group.

## Market Drivers and Limiters

**Exhibit 1.70** Drivers of the IC Device Market, Japan

Market Driver	Explanation
Growing patient population	Patients that were previously ineligible for PCI procedures are now candidates for PCIs with the introduction of DES. Advanced stent designs, as well as DES, will increase the potential to treat difficult cases, such as patients with multiple lesions.
Introduction of DES	DES has expanded the number of patients eligible for PCI with stent significantly due to its proven clinical efficacy.
Use of IVUS	With more frequent use of IVUS, operators may be able to avoid gaps between stents and match the length of the balloon as closely as possible with that of the stent to avoid injury outside the stent. The improved patient outcomes will increase the preference for PCI treatment.
Product introductions	The introduction of improved BMS stent designs, such as the Express2, will drive sales; the Express2 has been recognized for its superior deliverability. The approval of new PTCA balloon catheters featuring advanced technologies will justify price premiums.
Procedure complexity	Japanese physicians perform a high volume of complex PCIs, such as atherectomy, that require advanced accessory devices. Their added features justify premium prices to standard accessory devices.

Source: Millennium Research Group.

**Exhibit 1.71** Limiters of the IC Device Market, Japan

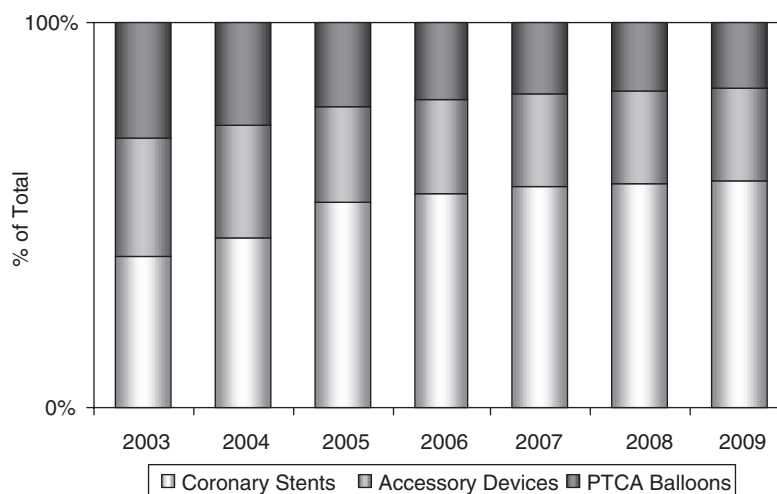
<i>Market Limiter</i>	<i>Explanation</i>
Decline in ASP	With the introduction of DES and the consequent decline in BMS usage, competitors have had to struggle to remain viable in the BMS market, primarily by slashing ASPs.
Decline in reimbursement	The MHLW's changes to PTCA balloon catheter reimbursements will spur an adjustment in physician practices and a decline in the ASP.

Source: Millennium Research Group.

## Interventional Cardiology Market

Revenues in the Japanese IC market will be driven largely by growth in the coronary stent market, which was valued in excess of \$400 million in 2004. Rolled out to market in 2004, DES is sold at a premium over BMS and provides opportunities to treat patient subsets that previously experienced suboptimal results after PCIs with BMS. Furthermore, Japanese physicians are recognized by the speed with which they adopt new products and technologies, which is expected to further fuel the DES market into the future. Growth in coronary stent revenues will be limited by the trend towards tightening of reimbursement guidelines set by the MHLW.

In the past, the PTCA balloon catheter market generated the greatest share of IC market revenues in Japan. Over the forecast period, however, this market segment will decline steadily at an estimated -3% due to expected changes in reimbursement that will result in the erosion of PTCA balloon ASPs. Additional

**Exhibit 1.72** IC Market, as a % of Total, by Device, Japan, 2003–2009 (Graphical Format)

Source: Millennium Research Group.

## 1.9 Japanese Markets for Interventional Cardiology

factors, such as the further penetration of stents that will result in an increase in direct stenting and a decline in plain old balloon angioplasty procedures, are linked to the continued decline in PTCA balloon catheter revenues.

Growth in the accessory device market will be driven by increases in angiography and PCI procedure volumes. The primary limiter of growth will be price pressures associated with intensified competition, commoditization, and restricted reimbursement. The exception is, however, the IVUS catheter market, which is valued in excess of \$100 million in 2004. Because reimbursement coverage is provided by the MHLW for use of IVUS catheters in PCI procedures, there is a resulting high rate of penetration of IVUS in Japan. Conversely, use of IVUS catheters in diagnostic produces is extremely uncommon in Japan because reimbursement is no longer provided for the application of the device in such cases. The exhibit below displays the segmentation of the market by device from 2003 through 2009.

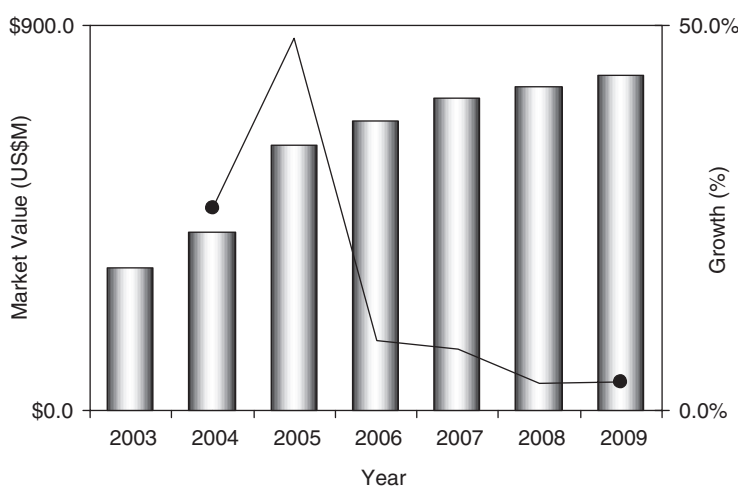
**Accessory devices include:**

IVUS catheters, diagnostic catheters, guide wires, guiding catheters, and EPDs.

## Coronary Stent Market

In 2004, the Japanese coronary stent market was valued in excess of \$400 million, a considerable increase over 2003. Growing at a moderate CAGR, by 2009 the market will be valued in excess of \$750 million. The market was significantly expanded in 2004 as a result of the introduction and quick uptake of Cordis' CYPHER DES.

**Exhibit 1.73** Coronary Stent Market, Japan, 2003–2009 (Graphical Format)



Source: Millennium Research Group.

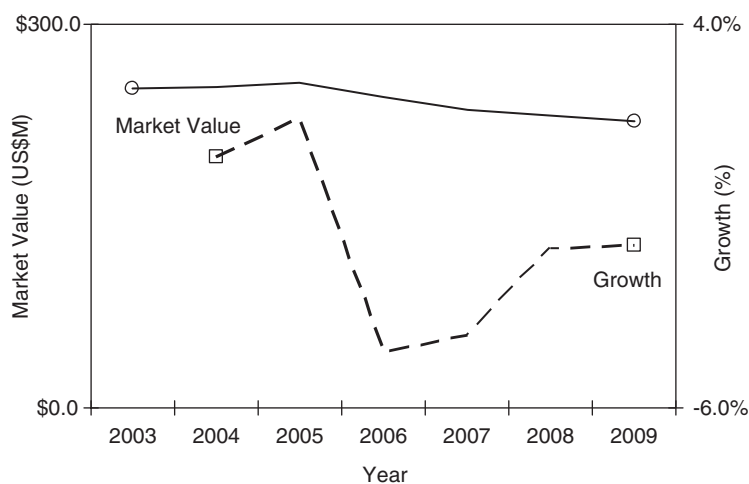
Throughout the forecast period, the market will be driven by increased DES penetration of PCI procedures; mass conversion to DES is expected in Japan not only due to the proven clinical success of the device, but also because of Japanese physicians' attitudes, which has always been that of rapid adoption of new products and technologies. The positive developments in this market will be slightly mitigated by dropping ASPs, a result of the MHLW tightening reimbursement rates.

## PTCA Balloon Catheter Market

In 2004, the Japanese PTCA balloon catheter market was valued at approximately \$250 million, a slight increase over 2003. This market will experience an overall decline in revenues through 2009 due to expected changes in reimbursement that will result in the erosion of balloon catheter ASPs. Additional factors will also serve to explain the rapid decrease in the PTCA balloon catheter market such as the increased uptake of stents, which will further result in more direct stenting and a decline in POBA procedures. Furthermore, PTCA balloon catheters are approaching commodity status in Japan, yielding increased vulnerability to price degradation.

The PTCA balloon market will experience marked decline between 2004 through 2007, which coincides with the 2004 introduction of Japan's first DES by Cordis, and the anticipated entry of Boston Scientific's DES in 2006.

**Exhibit 1.74** PTCA Balloon Catheter Market, Japan, 2003–2009 (Graphical Format)



Source: Millennium Research Group.

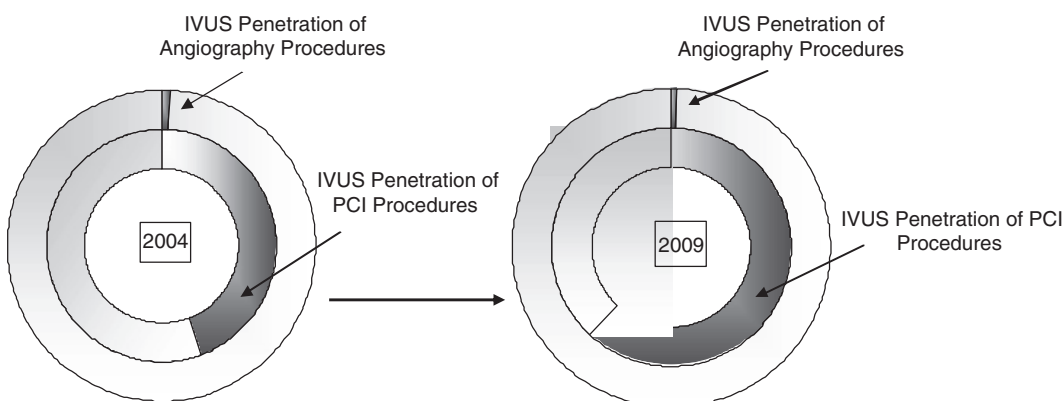


## Intravascular Ultrasound Catheter Market

The Japanese IVUS catheter market is the largest worldwide, valued at over \$100 million in 2004. The market is set to grow at a relatively low CAGR from 2005 through 2009, reaching revenues in excess of \$120 million. IVUS catheter penetration in PCI procedures is driven by reimbursement coverage provided by the MHLW. Conversely, the use of IVUS catheters in diagnostic angiographies is extremely uncommon in Japan because reimbursement is no longer provided for this use.

Another significant driver in the IVUS catheter market has been the introduction of DES. In Japan, IVUS is often used in “grand round” sessions, where national and regional centers of excellence call upon smaller clinics and hospitals to demonstrate treatments for difficult cases. Advanced techniques are also demonstrated, facilitated by the IVUS images to exhibit a physician’s capabilities. These sessions serve to promote the established centers as locations where physicians can send their more severe cases and serve to increase sales of IVUS catheters in Japan. With the introduction of DES in 2004, more grand rounds took place as a means of promoting DES, which co-promoted sales of IVUS catheters.

**Exhibit 1.75** IVUS Catheter Penetration, Japan, 2004 and 2009 (Graphical Format)



Source: Millennium Research Group.

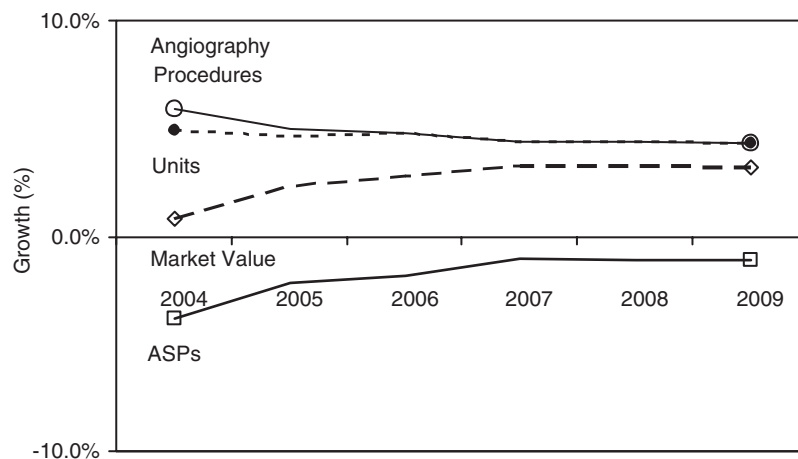
## Diagnostic Catheter Market

In 2004, the Japanese diagnostic catheter market was valued in excess of \$80 million, representing only a slight increase over 2003. Over the forecast period, the diagnostic catheter market will grow at a small CAGR yielding revenues slightly less than \$100 million by 2009. This growth will be driven primarily by

the aging Japanese population, which is at a heightened risk for coronary artery disease (CAD). This in turn will increase the volume of diagnostic angiography procedures. Changes in reimbursement prices and increasing competition amongst market players will serve to decrease ASPs over time, thus slightly limiting the market. Overall, however, these detracting market forces will have a limited impact, resulting in a relatively stable market through 2009.

Diagnostic catheter market growth is set to become one with diagnostic angiography procedure growth, as the number of units employed per angiography procedure stabilize through 2009.

**Exhibit 1.76** Diagnostic Catheter Market, Japan, 2004–2009 (Graphical Format)

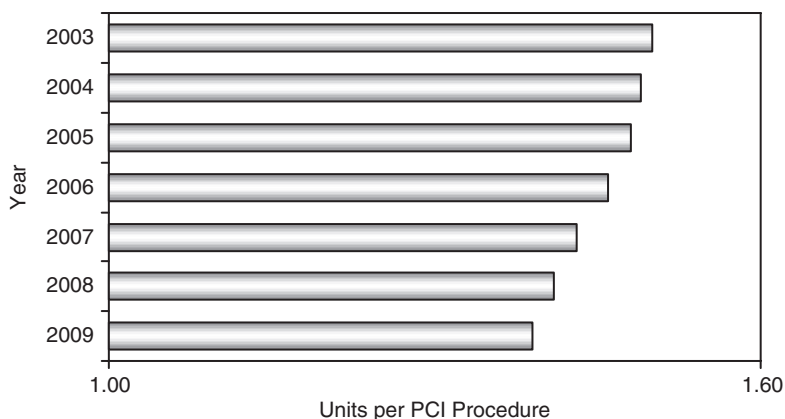


Source: Millennium Research Group.

## PTCA Guide Wire Market

Valued at over \$40 million in 2004, the Japanese PTCA guide wire market is set to remain relatively stable in growth from 2005 through 2009. Growth is expected to peak in 2006, propelled by the introduction of Cordis' DES system.

In Japan, as more inexperienced physicians attempt stent deployment, the need for extra caution and accuracy will come to the forefront. This notion has made the introduction and uptake of DES the primary driver of market growth in Japan. The high ratio of guide wires per procedure is, however, projected to decline consistently year over year through 2006, by which time there will be a more stark drop; it is expected that by this time physicians will have become well acquainted with best practices for DES deployment. Units per procedure are set

**Exhibit 1.77** PTCA Guide Wire Units per Procedure, Japan, 2003–2009 (Graphical Format)

Source: Millennium Research Group.

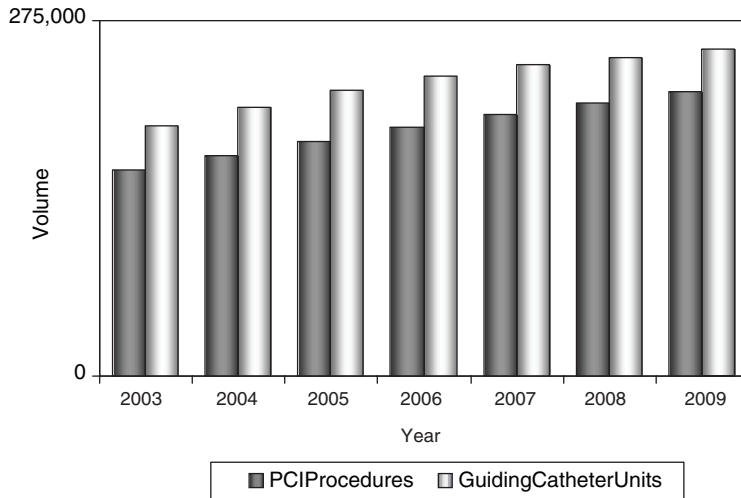
to stabilize by 2009. At this point, the direction of the guide wire market will primarily be dictated by PCI procedure volume growth. Mitigating growth within the forecast period, however, will be the downward pressure on ASPs exerted by the forces of competition and commoditization as well as unit usage limitations enforced by the MHLW.

## PTCA Guiding Catheter Market

In 2004, the Japanese PTCA guiding catheter market was valued at just below \$40 million, only a slight increase over 2003. Over the forecast period, the market will continue to increase at a very low CAGR. Though the primary driver of market growth will be the rise in PCI procedure volumes, market growth will be limited by increasing price pressures associated with swelling competition and commoditization. As displayed in the exhibit below, the volume usage of guiding catheters will mimic the volume of PCI procedures; the net effect, however, will be only a slight increase in market value due primarily to the adverse effects of dropping ASPs.

Further contributing to low market growth is the drop in units used per procedure. A significant impact on the market was forged with the introduction of DES in 2004. As physicians gain experience in DES deployment, the number of guiding catheters deployed per PCI is set to decrease, contributing further to a market stagnancy.

**Exhibit 1.78** PTCA Guiding Catheter Unit and PCI Procedure Volume, Japan, 2003–2009 (Graphical Format)

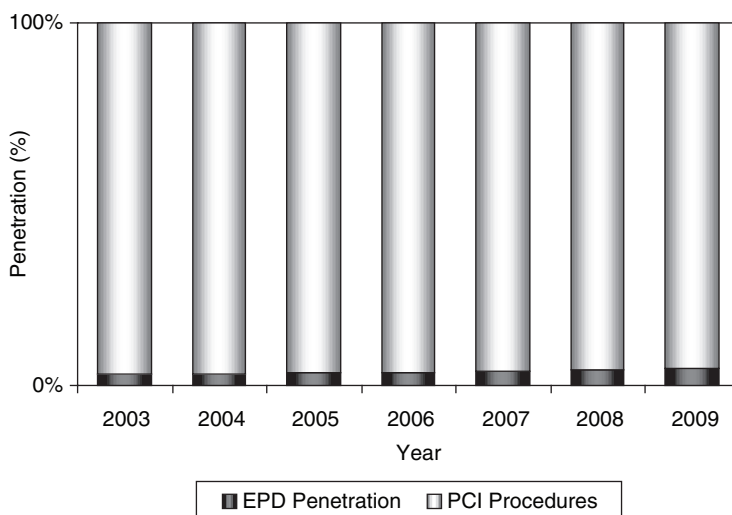


Source: Millennium Research Group.

## Embolic Protection Device Market

The 2004 Japanese EPD market was worth over \$6 million, only a slight increase over 2003. The market will experience positive growth through 2009 at a moderately

**Exhibit 1.79** EPD Penetration, Japan, 2003–2009 (Graphical Format)



Source Millennium Research Group.

### 1.9 Japanese Markets for Interventional Cardiology

high CAGR, mainly due to the introduction of DES, of which the employment is made optimal with EPDs in saphenous vein graft cases. The only competitor in the Japanese EPD market in 2004 was Medtronic, with its GuardWire occlusion balloon. Emerging competitors such as Boston Scientific and Guidant, who already compete in other global EPD markets, are expected to enter the market starting in 2006. Though the EPD market will expand due to new entrants, overall growth will be neutralized as ASPs drop sharply with new competition.

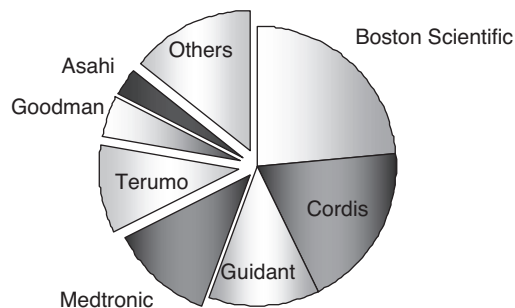
The exhibit below displays EPD penetration of PCI procedures, which is projected to remain relatively flat throughout the forecast period.

## Competitive Analysis

Competitors covered in this report (in order of market share) include the following:

Boston Scientific, Cordis, Guidant, Medtronic, Terumo, Goodman, Asahi Intecc, Kaneka, Volcano Therapeutics, Japan Lifeline, Fukuda Denshi, Abbott Vascular, Central Kogyo, Neich Medical, Japan Sherwood, Tokai Medical, Toray, Baxter, Japan Biosensors Inc., Zeon Medical, Nipro, Max Japan, Banri, Jimro, Kawasumi, Biotronik, B.Braun, Biotronik, Bard, Third Life, Microport, Zemex, Optim, Sun Bird, NuMed, Medical Maki, Nihon Kodan, Clinical Supply, and Cathex.

**Exhibit 1.80** Leading Competitors in the IC Market, Japan, 2004 (Graphical Format)



Source Millennium Research Group.

## 1.10 Asia Pacific Markets for Interventional Cardiology

### Market Overview

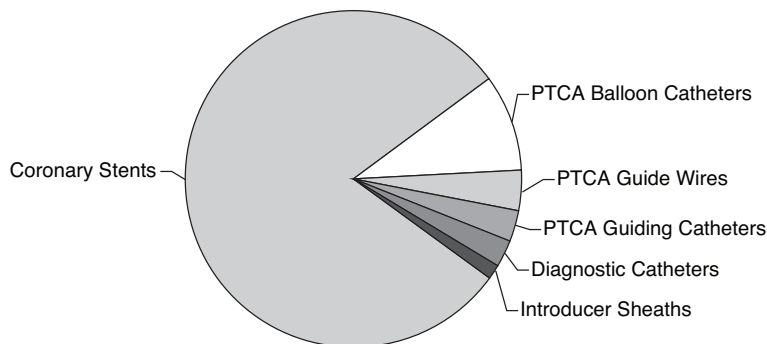
#### Markets covered in this report include:

- Coronary stents
- Percutaneous transluminal coronary angioplasty (PTCA) balloon catheters
- PTCA guide wires

In 2005, the Asia Pacific market for interventional cardiology (IC) devices was valued at nearly \$600 million, with coronary stents representing the highest-valued segment. Comprising Australia, China (excluding Hong Kong and Taiwan), India, and South Korea, the Asia Pacific market is fueled by the increasing incidence of coronary artery disease (CAD), rising angiography and percutaneous coronary intervention (PCI) procedure volumes, and the rapid uptake of drug-eluting stents (DES). The rapid economic progression is also resulting in better accessibility to interventional treatment, thereby creating tremendous opportunities for market growth. Asia Pacific is one of the fastest-emerging IC markets, and manufacturers are quickly investing more resources into this developing region.

Over the forecast period, the Asia Pacific IC device market will increase at a compound annual growth rate (CAGR) exceeding 10% and overshadow the limiting effects of average selling price (ASP) erosion and hospital budget constraints.

**Exhibit 1.81** IC Device Market, by Type, as a % of Total, Asia Pacific, 2005



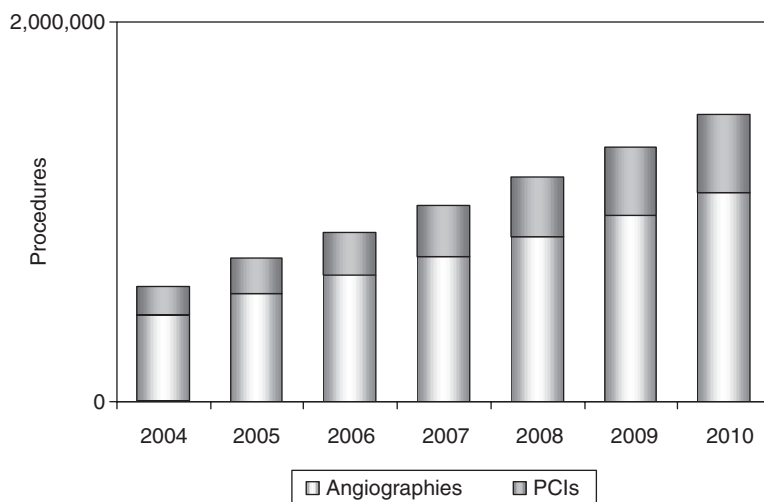
Source: Millennium Research Group.

## Procedures

In 2005, there were over 750,000 IC procedures in Asia Pacific, consisting of both diagnostic angiographies and PCIs. Over the forecast period, IC procedure volumes will continue to grow at a rapid pace due to the increasing incidence of CAD in the region. Along with a rapidly aging population, economic growth in Asia Pacific has led to more sedentary lifestyles that put individuals at greater risk for heart disease. This trend is particularly prevalent in the world's two most populous nations—China and India. The upswing in cardiovascular disease will therefore directly lead to more patients requiring diagnostic angiographies to detect the presence and severity of CAD.

In addition to demographic and socioeconomic drivers, IC procedures will be fueled by the adoption of DES. DES has sharply increased patient and hospital awareness of IC, leading to more demand for diagnoses and treatment. DES has also expanded the eligible patient base for PCI because more complex cases are able to be successfully stented. As DES becomes more affordable and widespread across Asia Pacific over the forecast period, PCI procedures will continue to rise. Overall, IC procedures will nearly double by 2010.

**Exhibit 1.82** IC Procedures, by Type, Asia Pacific, 2004–2010



Source: Millennium Research Group.

## Market Drivers and Limiters

**Exhibit 1.83** Drivers of the IC Device Market, Asia Pacific

<i>Market Driver</i>	<i>Explanation</i>
Procedure growth	<p>The incidence of CAD is on the rise in Asia Pacific as the rates of smoking, obesity, inactivity, and unhealthy diets continue to grow.</p> <p>Overall advancements in health care have resulted in an aging population that is more susceptible to cardiovascular disease.</p> <p>Growing patient awareness of heart disease and its methods of treatment will result in more demand for angiographies and PCIs over the forecast period.</p>
Greater DES penetration	<p>The high ASP of DES in combination with accelerating DES unit penetration will boost IC market revenues in Asia Pacific.</p> <p>Greater DES penetration also expands the patient population by converting CABG patients and treating more complex lesion types that are not strong candidates for BMS.</p> <p>Continued release of positive clinical and comparative trial results will enhance the profile of DES relative to BMS.</p>
Increasing competition	<p>The entrance of more IC device manufacturers, particularly in the DES market, will lead to more competitive pricing and progression in device technology.</p> <p>Manufacturers are becoming more proactive in their marketing and education towards physicians and hospitals. As a result, both product usage and awareness will continue to expand.</p>
Economic development	<p>The speedy rate of economic growth, particularly in China and India, will provide more capital for health care spending and investment.</p>

Source: Millennium Research Group.

**Exhibit 1.84** Limiters of the IC Device Market, Asia Pacific

<i>Market Limiter</i>	<i>Explanation</i>
Declining ASPs	<p>ASPs in all IC product groups are declining due to heightened competition. Moreover, many accessory devices are regarded by purchasers as commodities; therefore, price competition is intense and these products may be bundled and heavily discounted.</p>
Reimbursement	<p>DES and other IC devices are not reimbursed in China or India. When there is no reimbursement, the high costs to the hospital to implant a DES are often transferred to the patient, many of whom cannot afford it. In South Korea, coronary stents are not reimbursed in full and patients must cover a portion of the procedure cost.</p>
Health insurance	<p>A large proportion of the population in China and India do not possess any form of health insurance to cover the costs of PCI treatment. Even for those individuals who do have insurance, the remaining copayment is often still very large, particularly for DES procedures.</p>



<i>Market Limiter</i>	<i>Explanation</i>
Accessibility to treatment	In China, India, and South Korea, a disproportional percentage of total catheterization labs are located in the major city centers, resulting in poor access to treatment for rural residents. As a whole, the total number of catheterization labs in China and India is very low relative to population size and CAD prevalence. Although growing, the number of interventional cardiologists trained and certified to perform PCI is also underrepresented.
Budget restrictions	In Australia, despite heavy lobbying from hospital purchasing groups, tight budgets restrict the widespread use of DES in public facilities. Increased DES use will leave fewer funds available for other IC devices. As a result, purchasers will exert pressure on manufacturers to lower prices for balloons and accessory devices.
Reuse of accessory devices	In China, India, and, to a lesser extent, South Korea, sales of IC accessory devices are below actual potential because they are being reused by hospitals. The continuation of this trend will limit market revenues.

Source: Millennium Research Group.

## Coronary Stent Market

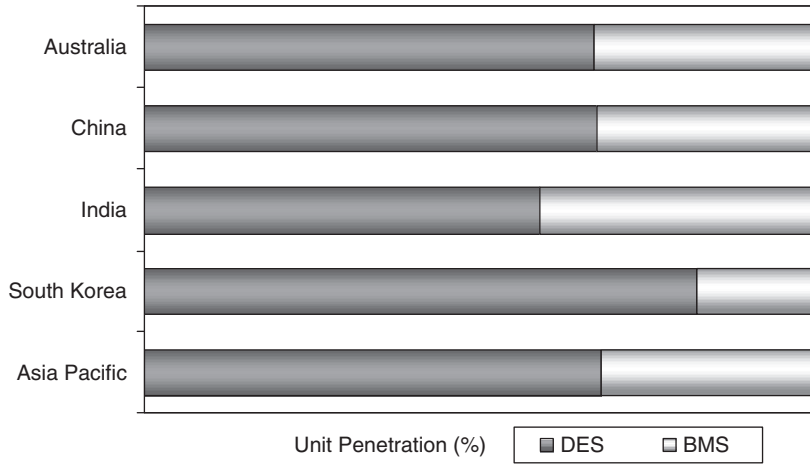
The coronary stent market, comprising DES and bare-metal stents (BMS), was the highest valued segment of the Asia Pacific IC device market, generating revenues exceeding \$450 million in 2005. Growth will predominantly occur as a result of the rapid adoption of DES, which are priced approximately three times greater than BMS. Despite the premium prices, clinical evidence supporting DES in the prevention of restenosis has been overwhelming. Moreover, the increased media attention placed on DES has spurred patient demand for the newer technology. As displayed in the exhibit below, DES represented the majority of total coronary stent units in 2005, with penetration highest in South Korea. With increasing PCIs, product enhancements, and more device approvals slated over the forecast period, the uptake of DES will be considerable in Asia Pacific.

The BMS segment will regress as a result of the conversion towards DES. Sales will largely be derived from budget-conscious hospitals and used to treat simple, de novo lesions or during mixed stent procedures. The BMS market declined by more than 20% over 2004 and will continue to drop at a CAGR around -10% over the forecast period. The BMS market will also be limited by decreasing ASPs, a trend that is common to the entire Asia Pacific coronary stent market.

## PTCA Balloon Catheter Market

Worth over \$50 million in 2005, the Asia Pacific PTCA balloon catheter market is driven by the rise in procedure volumes and the preference for predilation before the

**Exhibit 1.85** DES Unit Penetration, by Country, Asia Pacific, 2005

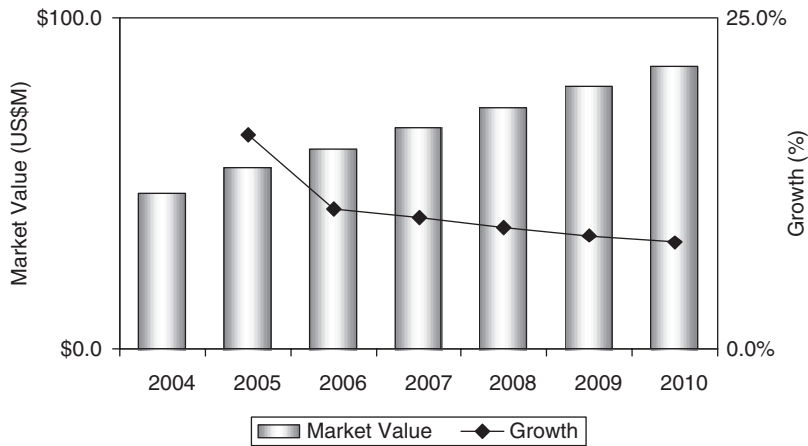


Source: Millennium Research Group.

placement of a stent. With more complex lesions now treated through PCI, there is an increased necessity for balloon predilatation, which is curbing the growth of direct stenting procedures. The adoption of varying compliance balloons and, to a lesser extent, cutting balloons, will also contribute to the rise in units and revenues.

Over the forecast period, price erosion will be the greatest limiter in the PTCA balloon catheter market. An influx of competitors has led to more competitive pricing and frequent practices of bundling and volume discounting. In addition to declining ASPs, the market sits below its potential value due to balloon reuse. Nevertheless, the PTCA balloon catheter market will grow at a CAGR exceeding 8%.

**Exhibit 1.86** PTCA Balloon Catheter Market, Asia Pacific, 2004–2010

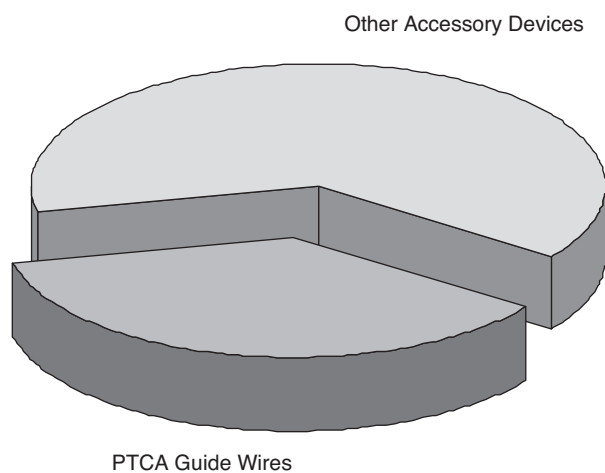


Source: Millennium Research Group.

## PTCA Guide Wire Market

In 2005, the Asia Pacific PTCA guide wire market was valued at over \$20 million. PTCA guide wires are required during every PCI; therefore, the rapid rise in procedures will drive unit and revenue growth over the forecast period. Guide wires were the highest valued accessory device segment in the market, owing to high prices and lower rates of reuse. In addition, market growth will result from the adoption of more premium-priced specialty guide wires, which ease the crossing of highly stenosed lesions such as chronic total occlusions. As is common with all other IC devices, price erosion will limit the positive effects of procedure and unit growth. Furthermore, the commoditization of workhorse wires will mitigate revenues generated in the market. By 2010, the PTCA guide wire market will be worth in excess of \$40 million.

**Exhibit 1.87** PTCA Guide Wire Market, as a % of Total, Asia Pacific, 2004–2010



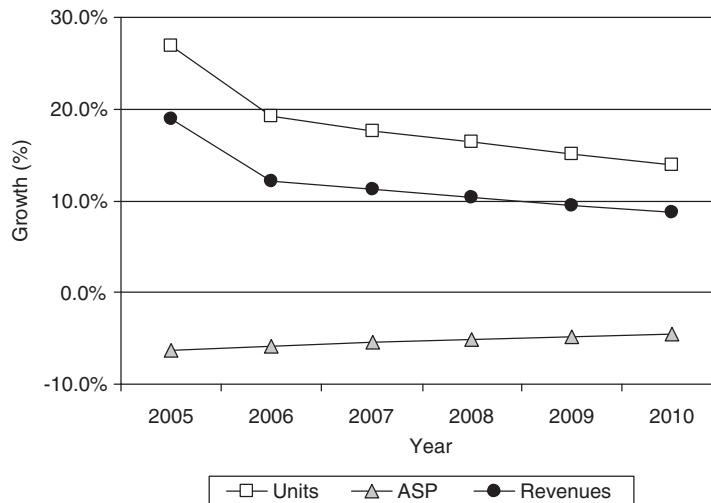
Source: Millennium Research Group.

## PTCA Guiding Catheter Market

The Asia Pacific PTCA guiding catheter market was worth over \$15 million in 2005. Similar to other IC accessory device markets, rising procedure volumes will be the greatest contributor to growth in the guiding catheter market. Consequently, unit growth will virtually mimic procedure growth. As DES becomes more widely adopted across Asia Pacific, the number of multivessel and complex cases that require several catheters will increase. The standardization of 6 French catheters will, however, minimize the amount of catheter exchanges needed during the procedure to accommodate varying IC device sizes.

Over the forecast period, guiding catheter ASPs will decline because of bundling and volume discounts. Moreover, guiding catheters are moving towards commoditization as technological innovation has slowed in recent years. The Asia Pacific PTCA guiding catheter market will increase at a CAGR of 10%.

**Exhibit 1.88** PTCA Guiding Catheter Market Growth, Asia Pacific, 2005–2010



Source: Millennium Research Group.

## Diagnostic Catheter Market

In 2005, the Asia Pacific diagnostic catheter market was worth close to \$15 million. With the number of angiographies quickly ascending in the region, demand for diagnostic catheters will also escalate over the forecast period. Unit sales will exceed a CAGR of 12%. The low cost of diagnostic catheters, in addition to frequent bundling by manufacturers, will further enhance unit volumes and drive the market.

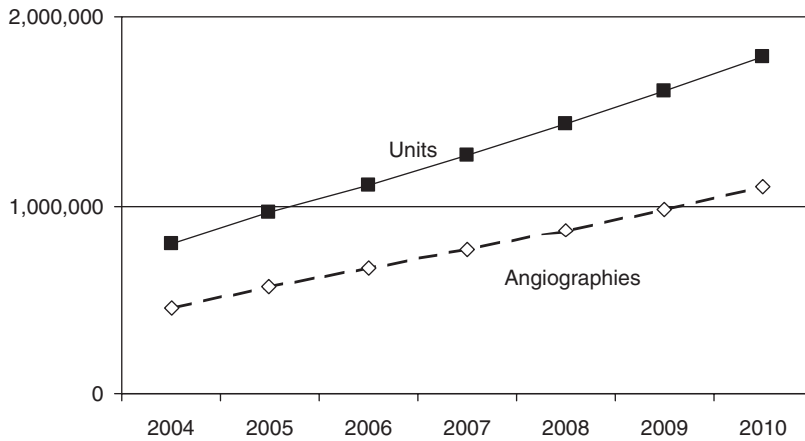
Device reuse will be a major limiter in the market. In 2005, diagnostic catheters were reused more often than any other type of IC accessory device. Furthermore, there is the potential for gradual adoption of newer imaging technologies, such as computed tomography scans and magnetic resonance imaging. Because these modalities do not necessitate the use of diagnostic catheters, their usage will mitigate market revenues.

## Introducer Sheath Market

The Asia Pacific market for introducer sheaths was valued in excess of \$8 million in 2005. Introducer sheaths allow other IC devices to be inserted into

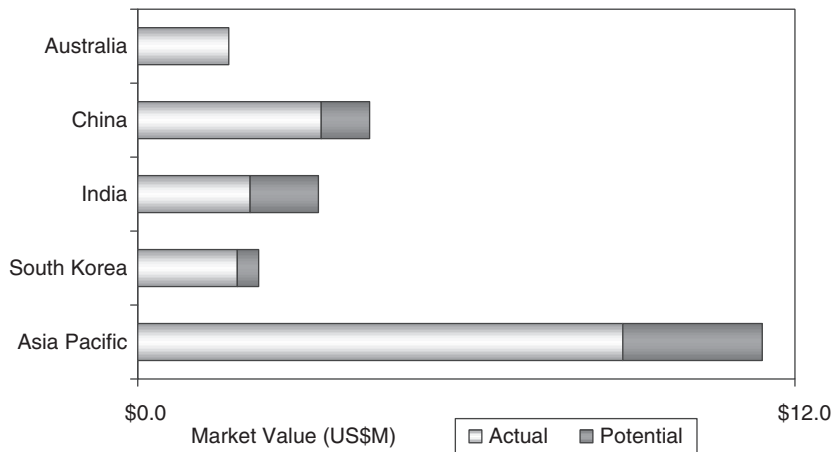
1.10 Asia Pacific Markets for Interventional Cardiology

**Exhibit 1.89** Diagnostic Catheter Market, Asia Pacific, 2004–2010



Source: Millennium Research Group.

**Exhibit 1.90** Introducer Sheath Market Reuse Analysis, by Country, Asia Pacific, 2005



Source: Millennium Research Group.

the body and are used in both diagnostic and interventional procedures. The market will therefore benefit from more patients being screened for CAD and receiving treatment due to the uptake in DES. Price erosion and sheath reuse will adversely affect market revenues over the forecast period. Introducer sheaths are widely considered to be commodity products, resulting in heavy discounting and bundling in order to promote higher margin IC devices. The Asia Pacific introducer sheath market will be worth over \$13 million by 2010.

## Competitive Analysis

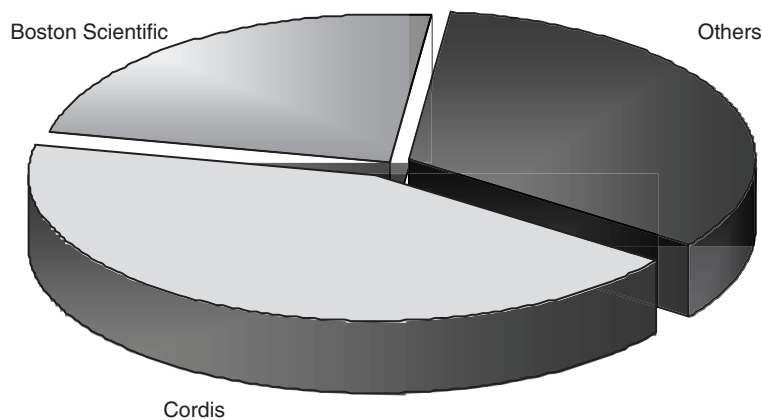
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In 2005, Cordis and Boston Scientific were the leading manufacturers in the Asia Pacific IC device market. The success of both companies was directly correlated to their strength in the lucrative DES segment of the coronary stent market. Other top competitors in the market were also leading manufacturers in the highly valued coronary stent market. Over the forecast period, companies will continue to launch new-generation devices, as well as consolidate a comprehensive portfolio of products to create a stronger image of an all-inclusive IC device provider. More local companies will also begin to emerge in Asia Pacific, leading to both greater price competition and product innovation.

In addition to Cordis and Boston Scientific, other manufacturers covered in this report include Abbott Vascular, AMG, Argon, Arrow, Atrium Medical, B. Braun, Beijing Lepu Medical, Biotronik, Cook, Goodman, Guidant, Hexacath, Invatec, Jung Sung Medical, Medtronic, Merit Medical, Microport Medical, Occam, OrbusNeich, Sahajanand Medical Technologies, Sorin Biomedica, St. Jude Medical, Terumo, Vascular Concepts, and Yin Yi.

**Exhibit 1.91** Leading Competitors in the IC Device Market, Asia Pacific, 2005

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Source: Millennium Research Group.

## 1.11 Latin American Markets for Interventional Cardiology

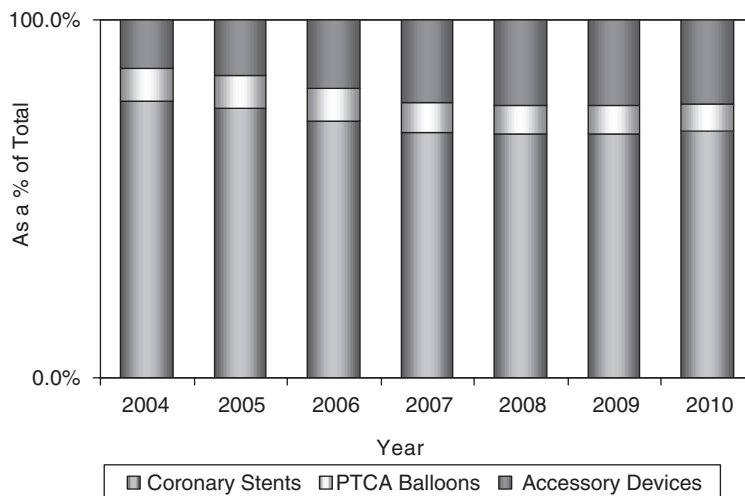
### Latin American Interventional Cardiology Device Market

Valued at over \$150 million in 2005, the Latin American market for interventional cardiology (IC) is one of the most rapidly growing markets in the world. From 2006 to 2010, the market will increase at a compound annual growth rate (CAGR) exceeding 7%. The continued uptake of drug-eluting stents (DES), changes in the Latin American regulatory environment, the aging Latin American population, and increased competition will serve to significantly drive the value of the IC market. Conversely, the market will be limited by rapidly declining average selling prices (ASPs), extensive accessory

**Accessory devices include:**

diagnostic catheters, percutaneous transluminal coronary angioplasty (PTCA) guide wires, PTCA guiding catheters, and introducer sheaths.

**Exhibit 1.92** IC Market, As a % of Total, by Device, Latin America, 2004–2010 (Graphical Format)



Source: Millennium Research Group.

device reuse, and the lack of DES reimbursement. The exhibit below displays the Latin American IC market from 2004 through 2010.

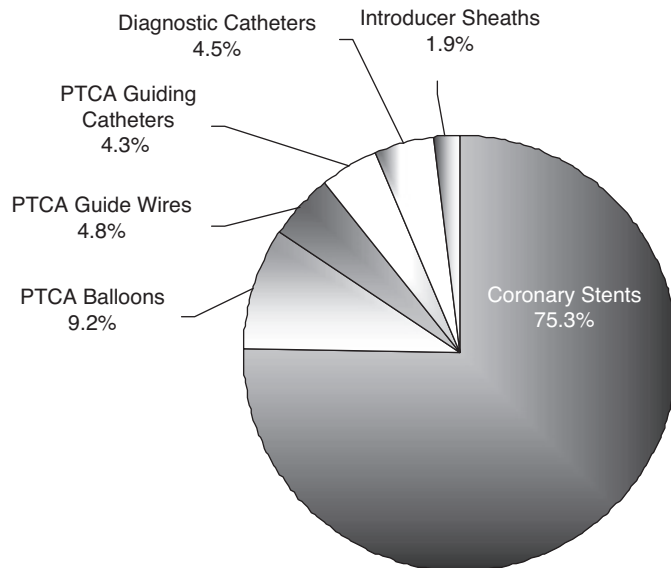
With regulatory bodies in Latin America expected to limit device reusage within the next 2 years, the market will experience an influx of revenues throughout the first half of the forecast period as purchasers are pushed to increase unit usage.

The IC market as covered in this report is comprised of the following devices:

- coronary stents: BMS and DES
- PTCA balloon catheters
- PTCA guide wires
- diagnostic catheters
- PTCA guiding catheters
- introducer sheaths

The exhibit below displays the breakdown of the Latin American IC market by device.

**Exhibit 1.93** IC Market, As a % of Total, Latin America, 2005 (Graphical Format)



Source: Millennium Research Group.

## Procedure Volumes

In 2005, over 300,000 IC procedures were performed in Latin America, a number that will exceed 400,000 by 2010. Procedure volumes are segmented into diagnostic angiographies and PCIs. PCI procedure volumes are growing at over twice

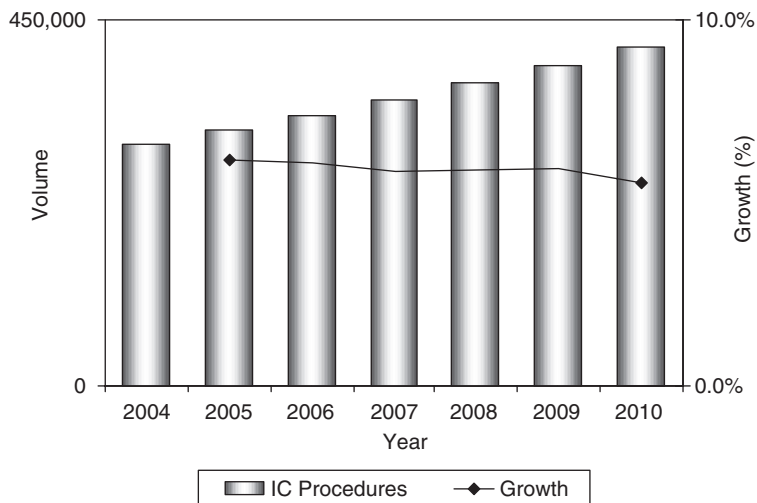


1.11 Latin American Markets for Interventional Cardiology

the rate of angiographies, driving overall growth of IC procedure volumes. Rapid PCI growth is attributed to the clinical efficacy of DES, which has expanded the patient population eligible for PCIs. Further contributing to PCI procedure volume growth into the forecast period are favorable changes in health care, offering reimbursement for DES, as well as the decline in DES pricing. Deeper DES penetration will also serve to limit the volume of angiography procedures because patients who are treated with DES rarely experience restenosis, a situation more common with BMS use, which may require another angiography.

Over 70% of all IC procedures in 2005 were angiographies, with total PCIs comprising the remaining portion. Because PCI procedures are growing at nearly twice the pace of angiographies through 2010, the proportion of angiographies is set to shift downwards through the forecast period.

**Exhibit 1.94** IC Procedure Volumes, Latin America, 2004–2010 (Graphical Format)



Source: Millennium Research Group.

## Market Drivers and Limiters

**Exhibit 1.95** Drivers of the IC Device Market, Latin America

Market Driver	Explanation
Growing patient population	As the Latin American population ages, there will be more patients requiring treatment for CAD.
Increasing DES penetration	DES has expanded the number of patients eligible for PCI with stent due to its proven clinical efficacy.

(Continued)

**Exhibit 1.95** (Continued)

<i>Market Driver</i>	<i>Explanation</i>
Discontinuation of device reuse	As regulatory bodies outlaw the practice of IC device reuse, the unit sales of accessory devices will grow, driving market revenues through the forecast period.
Increased competition	Without the need to go through long application processes, manufacturers of IC devices are able, with relative ease, to introduce their devices to market. Many competitors have entered this market without approval in any of the US, European or Japanese markets. These new competitors will increase competition, push down ASPs, and help advance technology.

Source: Millennium Research Group.

**Exhibit 1.96** Limiters of the IC Device Market, Latin America

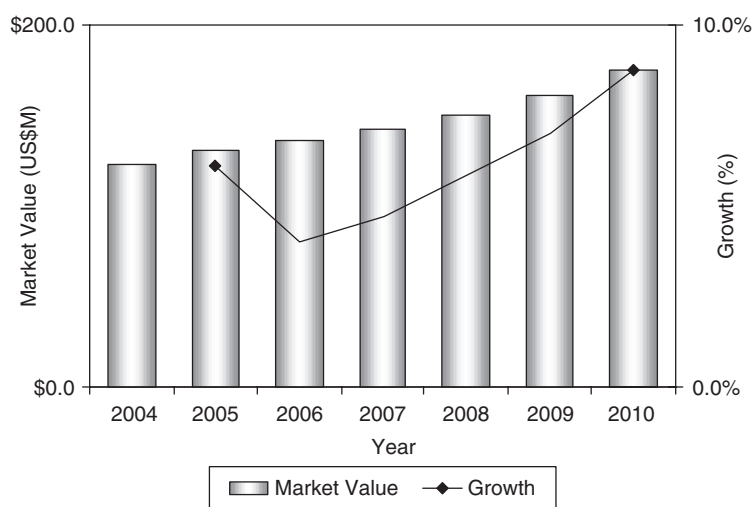
<i>Market Limiter</i>	<i>Explanation</i>
Device reuse	Currently, IC accessory devices in Latin America are reused anywhere between 2 and 5 times. This significantly impacts the market in that less units are sold than normal, shrinking the market revenue to a fraction of its actual potential.
Declining ASPs	With the introduction of DES and the consequent decline in BMS usage, competitors have had to struggle to remain viable in the BMS market, primarily by slashing ASPs.
Lack of reimbursement	Though reimbursement is available for most IC devices in Latin America, DES is currently not eligible in most countries. This fact limits DES use to mostly private institutions.

Source: Millennium Research Group.

## Coronary Stent Market

In 2005, the Latin American coronary stent market was valued at more than \$120 million and will grow to a value of over \$170 million by 2010. This market will be primarily driven by the increased uptake of DES that will expand the patient population eligible for PCI procedures. Further driving the coronary stent market is the relatively easy medical board approval of emergent technologies that is characteristic of Latin America. Mitigating market growth is the decline in both BMS use and ASPs. Further limiting this market are high DES prices combined with a lack of reimbursement in most countries. This will limit rapid DES uptake in public facilities across Latin America, which make up the mass majority of Latin America's medical centers.

Coronary stents are the only IC devices covered in this report that are not reused in Latin America; therefore, growth in this market is parallel to that of the patient population growth. As a result of strong growth, not plagued by reuse, coronary stents will sustain the Latin American IC market.

**Exhibit 1.97** Coronary Stent Market, Latin America, 2004–2010 (Graphical Format)

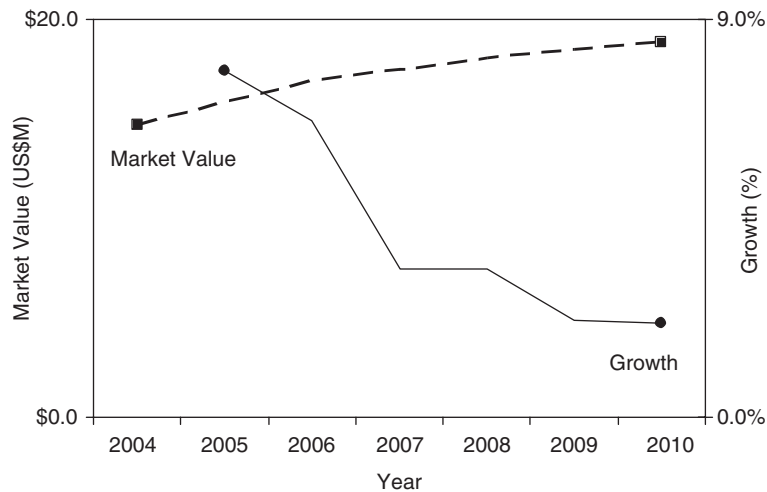
Source: Millennium Research Group.

## PTCA Balloon Catheter Market

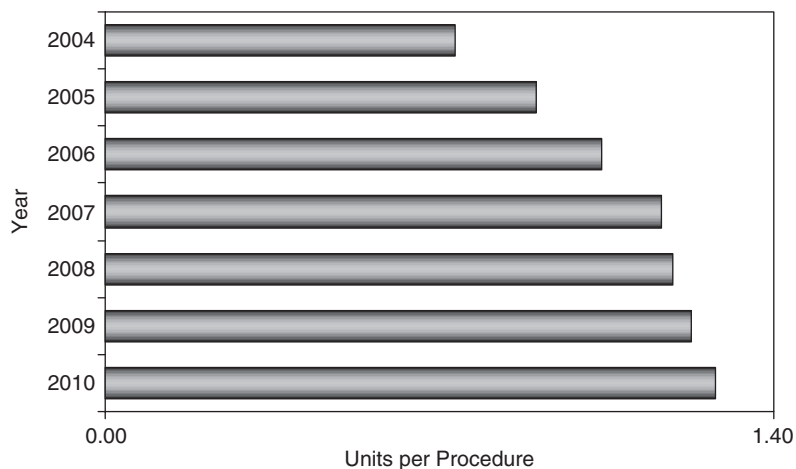
In 2005, the Latin American PTCA balloon catheter market was valued at over \$15 million, as shown in the exhibit below. This market will be primarily driven by rising procedure volumes. In particular, the growing population and the increased uptake of DES are expanding the eligible patient population for PCI procedures. Further driving the PTCA balloon catheter market is the relatively effortless medical board approval of emergent technologies that is characteristic of Latin America, as well as favorable reimbursement in all countries. Also contributing to revenue growth is the development of noncompliant balloons that are deemed more compatible with DES. Mitigating growth in the balloon catheter market is device reuse, which shrinks the market to a fraction of its potential size, and rapidly eroding ASPs estimated to decline notably through the forecast period.

## PTCA Guide Wire Market

The Latin American market for PTCA guide wires was valued at close to \$10 million in 2005. Market growth will decline in the first half of the forecast period after a sharp peak in 2005, marked by the overall increased usage of units per procedure. Units are forecast to increase steadily amongst all nations,

**Exhibit 1.98** PTCA Balloon Catheter Market, Latin America, 2004–2010 (Graphical Format)

Source: Millennium Research Group.

**Exhibit 1.99** PTCA Guide Wire Units per Procedure, Latin America, 2004–2010 (Graphical Format)

Source: Millennium Research Group.

particularly Brazil, where government regulations are set to outlaw all device reuse habits. The guide wire market will be primarily driven by rapidly growing PCI procedure volumes, which is a direct result of the rapid uptake of DES. Furthermore, the market will be driven by expected government restrictions on reusage. Mitigating growth within the forecast period will be the downward pressure on ASPs, which will result from manufacturers' counterbalancing attempts

## 1.11 Latin American Markets for Interventional Cardiology

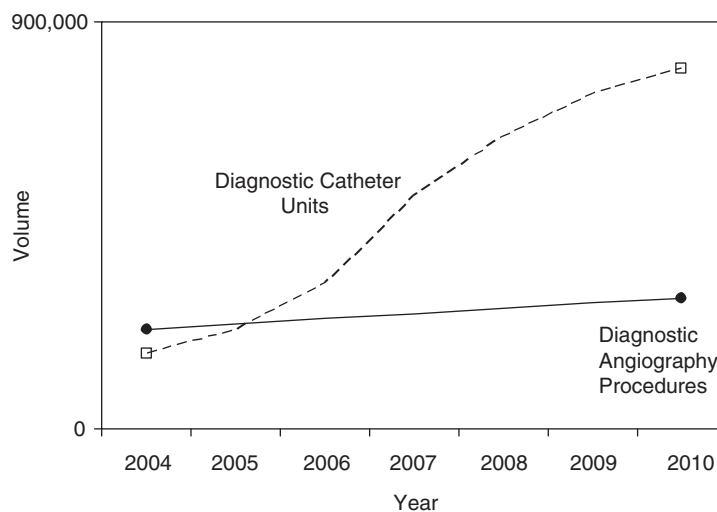
associated with high DES prices, as well as the forces of commoditization. Further limiting growth are prevalent device reuse practices that cut the guide wire market to a fraction of its potential.

## Diagnostic Catheter Market

In 2005, the Latin American diagnostic catheter market was valued at just under \$8 million, an over 30% increase from 2004. Diagnostic catheter revenues are expected to grow to a value in excess of \$20 million by 2010, representing a CAGR of over 20%. Growth in this market is directly correlated with diagnostic angiography growth because roughly 3 units are used per procedure. The diagnostic catheter market is therefore driven by angiography procedural growth, as well as expected government regulations restricting the common practice of reuse in Latin America. It is currently estimated that a single diagnostic catheter is reused anywhere between 2 and 5 times before being discarded, considerably limiting potential revenues.

Further limiting the market, though later into the forecast period, is the prospect of using computed tomography (CT) scan and magnetic resonance imaging (MRI) methods of diagnoses as replacements for diagnostic angiography procedures. These procedures would negate the use of diagnostic catheters altogether, making the devices completely obsolete. CT and MRI scans are not

**Exhibit 1.100** Diagnostic Catheter Market, Latin America, 2004–2010 (Graphical Format)



Source: Millennium Research Group.

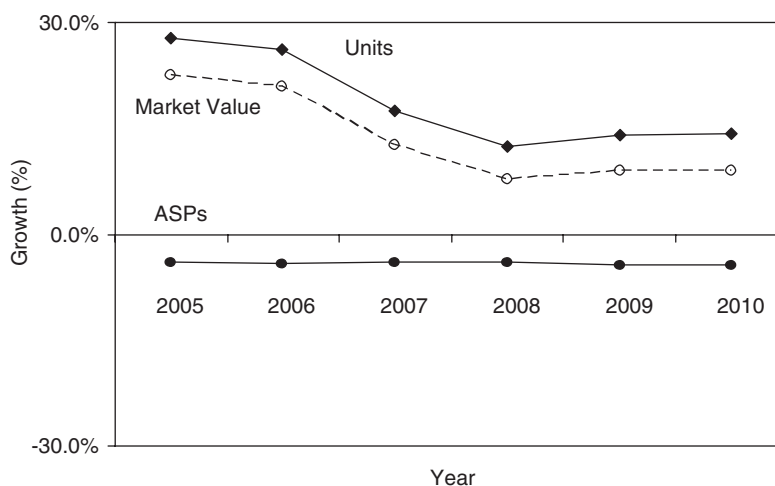
expected to completely take over diagnostic angiography procedures just yet because associated capital equipment costs are incredibly high and generated images produce greater than needed detail. A further issue inhibiting the rapid uptake of these scanning devices is the fact that these machines are not mobile; therefore, scanning acute, immobile patients becomes a problem.

## PTCA Guiding Catheter Market

In 2005, the Latin American PTCA guiding catheter market was valued at slightly less than \$8 million, an increase of more than 20% over 2004. The primary driver of the market growth will be the rise in PCI procedure volumes that comes as a direct result of the rapid uptake of DES. Further driving the market will be the almost complete eradication of device reuse by 2010, a common practice in Latin America that is expected to pour thousands more units into use annually. Units are forecast to increase steadily amongst all nations, particularly Brazil, where government regulations are set to outlaw reuse within the next 2 years.

Over the next 5 years, market growth will be slightly limited by increasing price pressures associated with commoditization as well as the current prevalence of device reuse. By 2010, the PTCA guiding catheter market will grow to a value just under \$13 million.

**Exhibit 1.101** PTCA Guiding Catheter Market Growth, Latin America, 2005–2010 (Graphical Format)

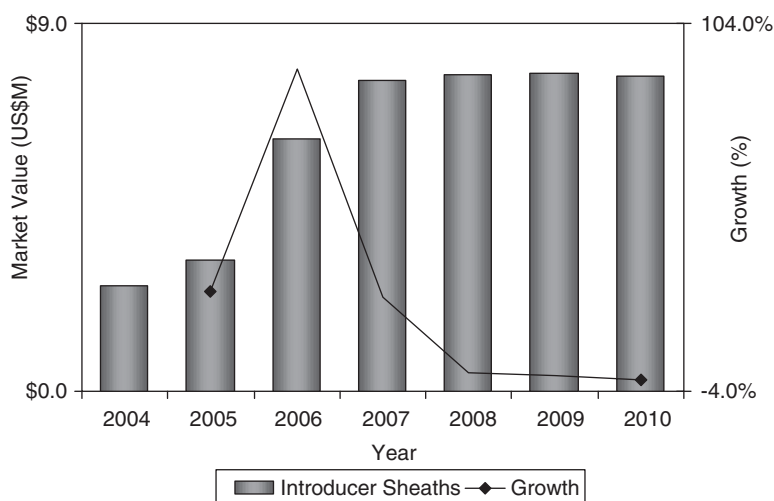


Source: Millennium Research Group.

## Introducer Sheath Market

The 2005 Latin America market for introducer sheaths was valued at just over \$3 million, a modest increase in revenues over 2004. This market is expected to grow to nearly \$8 million in revenues by 2010, experiencing the greatest growth in 2006 as device reuse across Latin America decreases significantly. Device reuse is linked directly to newly formed government restrictions as well as declining ASPs. The use of introducer sheaths will be driven by the increase in procedure volumes, particularly in percutaneous intervention procedures, over the forecast period. Angiography procedures are expected to grow because more patients will be screened for coronary artery disease, and PCI procedures will increase at an even greater rate because of the DES that have markedly expanded the market. Mitigating growth are continued device reusage as well as continually declining ASPs that have resulted from the lack of emerging technologies.

**Exhibit 1.102** Introducer Sheath Market, Latin America, 2005–2010 (Graphical Format)



Source: Millennium Research Group.

## Competitive Analysis

Competitors covered in this report (in order of market share) include the following:

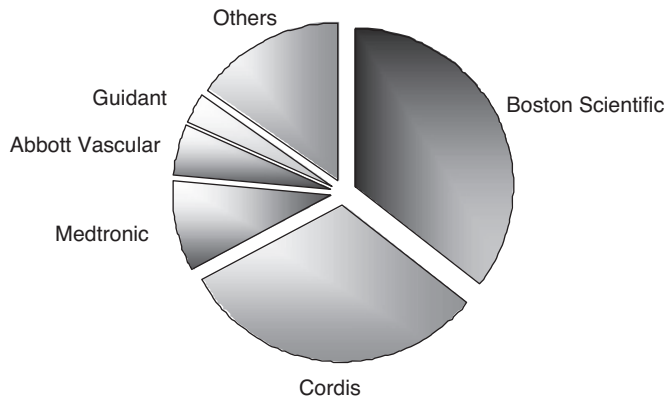
Boston Scientific, Cordis, Medtronic, Abbott Vascular, Guidant, Biotronik, St. Jude Medical, BBraun, Avantec, Scitech, Sahajanand Medical Technologies, Terumo, Blue Medial, Eucatech, Cook, Orbus,

### 1. CARDIOVASCULAR DEVICES

Merit Medical, Sorin Biomedica, Invatec, Hexacath, Translumina, Atrium Medical, Microport Medical, Arrow, Iberhospitex, Meomedical, Pan Medical, Clearstream, Medispes, Aachen Resonance, Lake Region, Bard Medical, In Situ Technologies, Minivasys, Med-X, and Velocimed.

The exhibit below displays some of the leading competitors in the Latin American IC market.

**Exhibit 1.103** Leading Competitors in the IC Market, Latin America, 2005 (Graphical Format)



Source: Millennium Research Group.



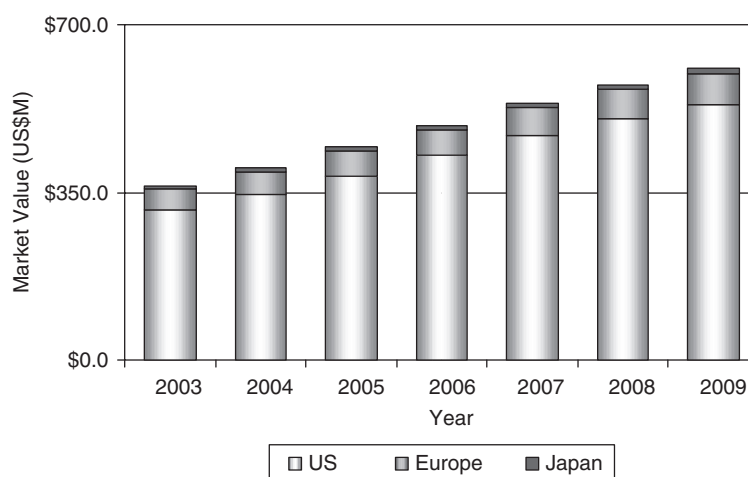
## 1.12 Global Markets for Vascular Closure Devices

### Global Markets for Vascular Closure Devices

The global vascular closure device (VCD) market is one of the fastest-growing accessory device markets worldwide. In 2004, the global VCD market was valued at just over \$400 million. The global market, comprised in this report of the US, Europe (France, Germany, Italy, and the UK), and Japan, will grow at a compound annual growth rate (CAGR) of approximately 8% over the next 5 years to be worth in excess of \$600 million by 2009.

VCDs are employed to seal the femoral artery access site following interventional cardiology and peripheral procedures. They are an alternative to the traditional method of manual compression, which is frequently deemed inconvenient and time consuming. VCDs represent an opportunity to ambulate the patient more quickly and safely. By discharging patients earlier, hospitals are able to make beds available to other patients and reduce both waiting lists and costs.

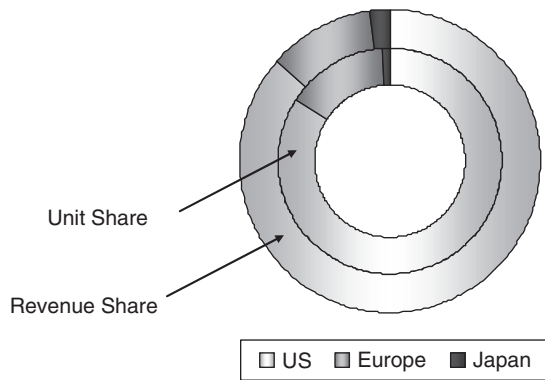
**Exhibit 1.104** VCD Market, by Region, Global (US\$), 2003–2009 (Graphical Format)



Source: Millennium Research Group.

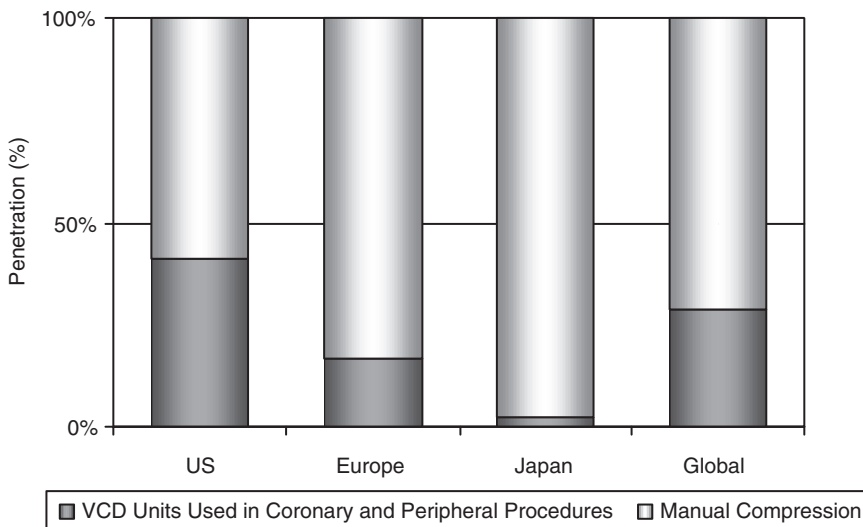
As displayed below, in 2004, the US captured an estimated 85% of revenue and unit share of the global market for VCDs. In the same vein, the US experienced not only the highest rate of growth at a CAGR of approximately 8.5%, but also the deepest penetration, with over 40% of all procedures including the use of a VCD. Generating the smallest percentage of revenues in the global market in 2004 was Japan; however, over 2003/2004, this market experienced intensive growth, in excess of 15%, due primarily to the entrance of a new competitor.

**Exhibit 1.105** VCD Market Shares, as a % of Total, by Region, Global, 2004 (Graphical Format)



Source: Millennium Research Group.

**Exhibit 1.106** VCD Penetration of Coronary and Peripheral Procedures, by Region, Global, 2004 (Graphical Format)



Source: Millennium Research Group.

## Market Drivers and Limiters

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### Market Drivers

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#### *Market Drivers*

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Shorter ambulation times

Positive cost-to-benefit ratio

High product efficacy

Positive clinical data

New VCD technologies

Improved patient comfort

Accumulated physician experience

DES clinical success

Intervention growth in coronary and peripheral procedures

Favorable labeling in the US

Interventional radiologist and vascular surgeon prevalence in peripheral market in Europe

Relative ease of CE Mark approval in Europe

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*Source:* Millennium Research Group.

### Market Limiters

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#### *Market Limiters*

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Device complications and poor ease-of-use

Concern of leaving foreign object behind in patient vessel

Alternative arterial access sites

Miniaturization of catheter sheath sizes

Downward pricing pressures

Revolving door effect and manual compression as a substitute

VCD usage risk associated with female anatomy

Manufacturer hesitation to enter market due to low returns in the US

Unfavorable reimbursement in Japan and Europe

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*Source:* Millennium Research Group.

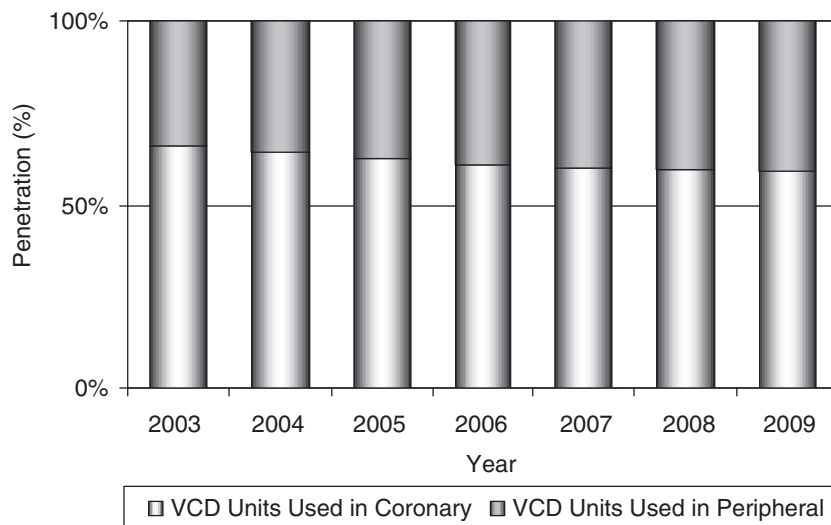
## Coronary versus Peripheral Procedures

Slightly less than 8,500,000 coronary and peripheral procedures were performed globally in 2004. Procedure volumes are growing at a CAGR of approximately 5% reaching a value in excess of 10,000,000 by 2009. In 2004, coronary and peripheral procedure volumes made up roughly 55% and 45% of procedure volumes, respectively, a figure which is not expected to change throughout the forecast period.

This procedure volume composition is not reflected in the VCD market in 2004, where the ratio of the number of units used in coronary indications versus peripheral indications was approximately 2:1. Moving through the forecast period, however, unit volume proportions are set to shift through 2009 towards a 50/50 split of VCDs used in peripheral and coronary procedures. The reason for the high rate of VCD usage in coronary indications is the smaller introducer sheath sizes as well as cardiologists' positive attitudes towards VCDs. Smaller introducer sheath sizes result in smaller arterial wounds, which are much easier to close when compared to wounds created in peripheral interventions.

In 2004, less than 25% of all peripheral procedures involved the use of VCDs. VCD technology awareness, unsuitability to some procedures (such as AAA stent-grafting), larger introducer sheaths, and a lack of clinical data have hindered adoption of VCDs in peripheral indications. Going forward, however, VCD penetration into peripheral procedures will increase sizably, fueled primarily by the miniaturization of sheath sizes as well as positive clinical data.

**Exhibit 1.107** VCD Units, as a % of Total, by Indication, Global, 2003–2009 (Graphical Format)



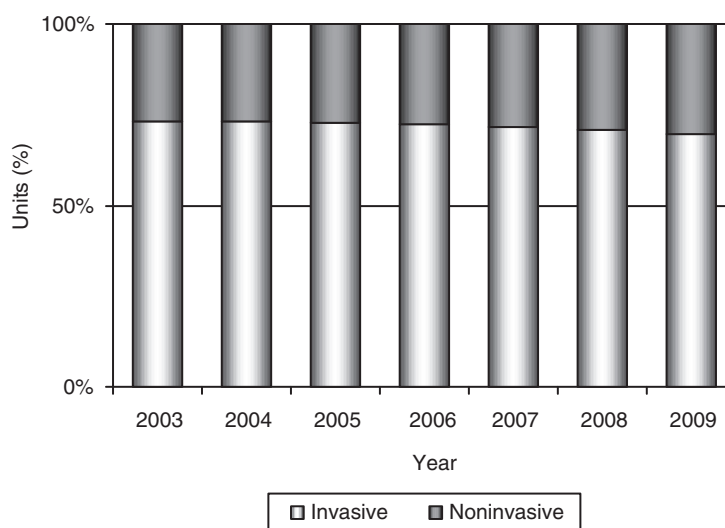
Source: Millennium Research Group.

## Invasive versus Noninvasive

The US VCD market is composed of invasive devices and noninvasive devices, with the key distinction being that invasive devices are inserted subcutaneously to close the femoral artery while noninvasive devices act at the epidermal level to induce a faster rate of thrombosis. Devices categorized as invasive are suturing mechanisms that instantly stitch together arterial openings, plug-based products that seal openings using varying substances, and, most recently, clip or staple based products. As displayed below, the VCD market is composed of approximately 75% invasive devices, with noninvasive devices making up the remaining 25%; these percentages are projected to shift by 2009 to around 70% and 30%, respectively.

Posing lower ASPs, easy to learn deployment techniques, and lack of complications, the noninvasive market is gaining momentum, growing at a CAGR of 15% through the forecast period, over 50% greater than growth for invasive devices. This is the reason why every major VCD manufacturer in the world will offer at least one type of noninvasive device by 2006. Invasive VCD market leaders like St. Jude and Abbott, which previously had no patch offerings, now offer the StasysPatch and Chito-Seal devices, respectively. Other examples include Medtronic, which entered the VCD market in 2002 through the acquisition of the Clo-Sur PAD from Scion CV, and Boston Scientific, which, through acquisition of Therus, is in the process of bringing its SoundSeal noninvasive VCD technology to market by 2006. With the entrance of the Big 4, there is no doubt

**Exhibit 1.108** VCD Units, as a % of Total, by Technology, Global, 2003–2009



Source: Millennium Research Group.

about the profitability of the noninvasive VCD market. The most attractive motivation for manufacturers will perhaps be, the low costs associated with bringing these noninvasive products to market.

## Leading Competitors

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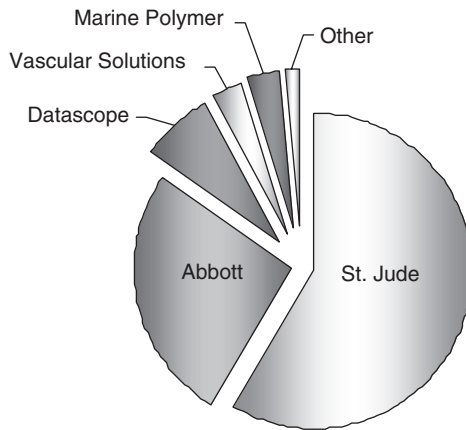
In 2004, St. Jude Medical, Abbott, Datascope, Vascular Solutions, Medtronic, and Marine Polymer Technologies were active in the global VCD market. Globally, St. Jude held the dominant position, having captured almost 60% of global VCD revenues, a—sharp increase from 2002 when that figure was roughly 40%. Their growing dominance of the global VCD market is attributed to the company's *Angio-Seal* device, which was introduced to the market in 2001. *Angio-Seal*'s success has been augmented by favorable labeling approved by the US FDA that states the device significantly reduces the time to patient ambulation and discharge following diagnostic procedures. Acknowledgment from a world-renowned national health board for clinical efficacy has assuredly bolstered St. Jude's position in the global market for VCDs. Also contributing to St. Jude's overall success is the *Angio-Seal*'s remarkable reception in Japan, which in just over 1 year, accounted for well over three-quarters of the Japanese VCD market. St. Jude's revenues are expected to continue growing as the *StasysPatch*, the company's first noninvasive device offering, enters all global markets through the forecast period.

Abbott was the second-leading producer of VCDs with its *Perclose A-T*, *ProStar XLs*, *Closer*, and *Chito-Seal* products. The company currently holds roughly 25% of the market, a drop of approximately 10% since 2002. Abbott revenues and market share are expected to increase as the company's new clip-mediated VCD, the *StarClose* (already available in Europe), enters all global markets in late 2005.

Datascope is the third-leading competitor in the global VCD market with its *VasoSeal* and *Safeguard* products. Though the company's market share dropped in 2004 to half of its value in 2002, it is likely that the company will once again enjoy a more substantial presence as the *X-Site* and newly developed *On-Site* devices (extravascular suture and collagen-based products respectively) are released globally in late 2005. The fourth-leading competitor, having gained impressive market share throughout 2004, is Marine Polymer Technologies. A market leader in the US noninvasive market, Marine Polymer gained noteworthy presence with its effective *Syvek* patch series. Vascular Solutions is the fifth-leading competitor in the global VCD market with its *D-Stat Patches* and *Duett* products. Having gained notoriety, the *Duett* is currently being phased out while the company further promotes its thrombin-based *D-Stat* patches, which have been proven through clinical trials to promote clotting.

1.12 Global Markets for Vascular Closure Devices

**Exhibit 1.109** Leading Competitors in the VCD Market, Global, 2004 (Graphical Format)



Source: Millennium Research Group.

Note: Other includes Medtronic, Boston Scientific/Sub-Q, and TZ Medical.

