

# Development of coronary vascular stents market in China and the success of domestic manufacturers

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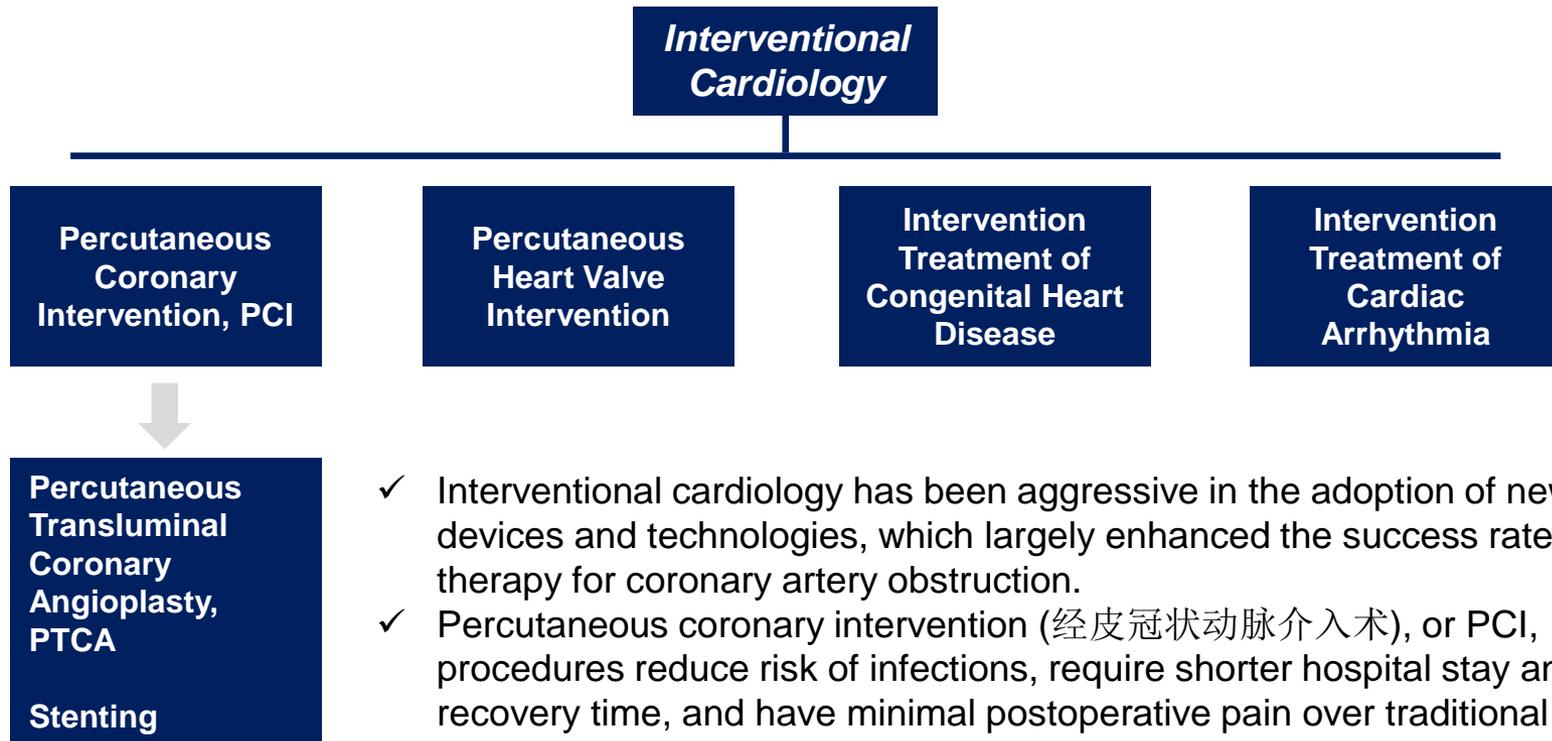
弗若斯特沙利文咨询有限公司

高级咨询顾问



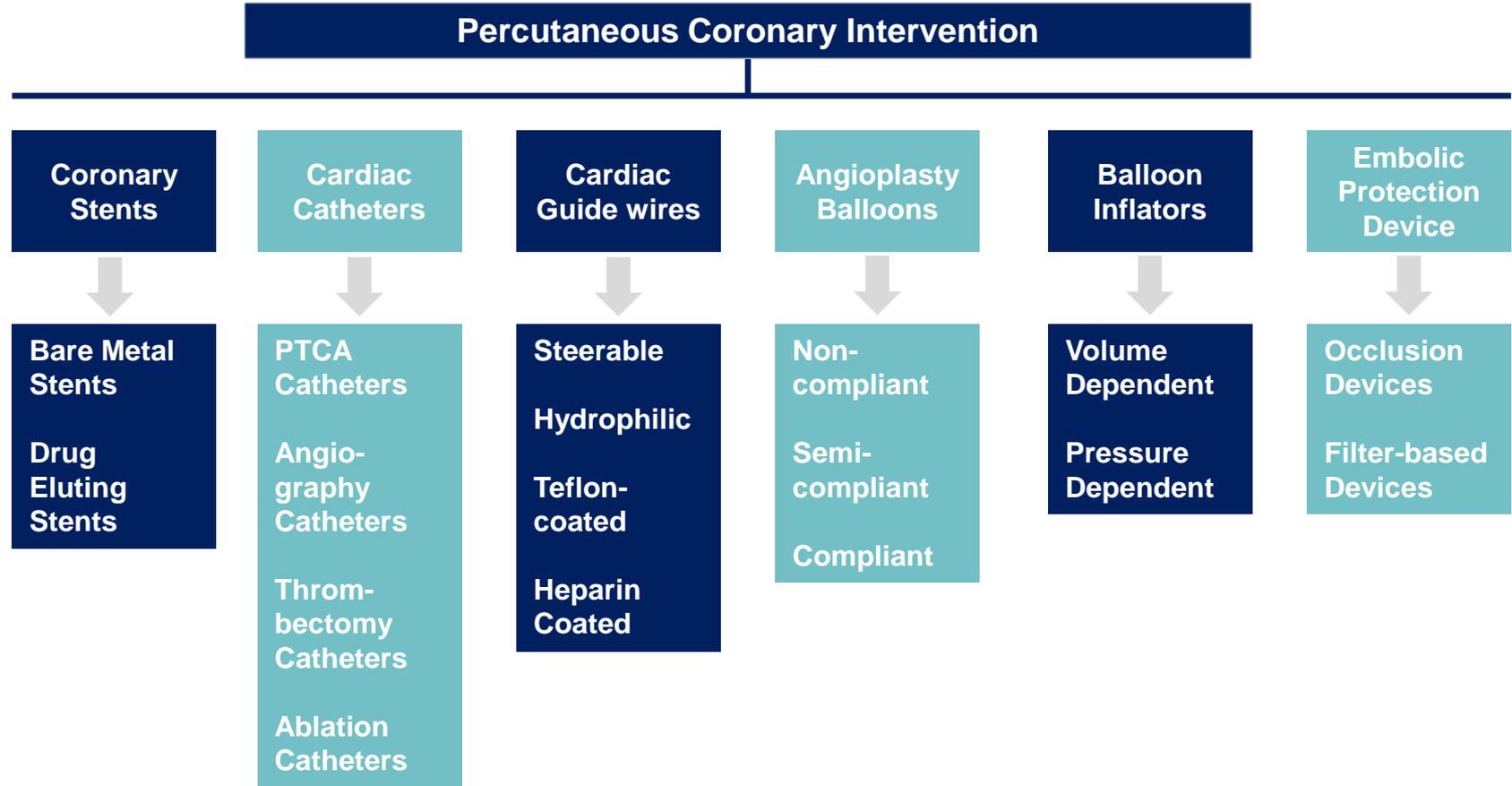
- 1 Market Overview
- 2 Drivers & Restraints
- 3 Regulation on Coronary Stents
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# Percutaneous coronary intervention is a predominant therapy for coronary artery obstruction



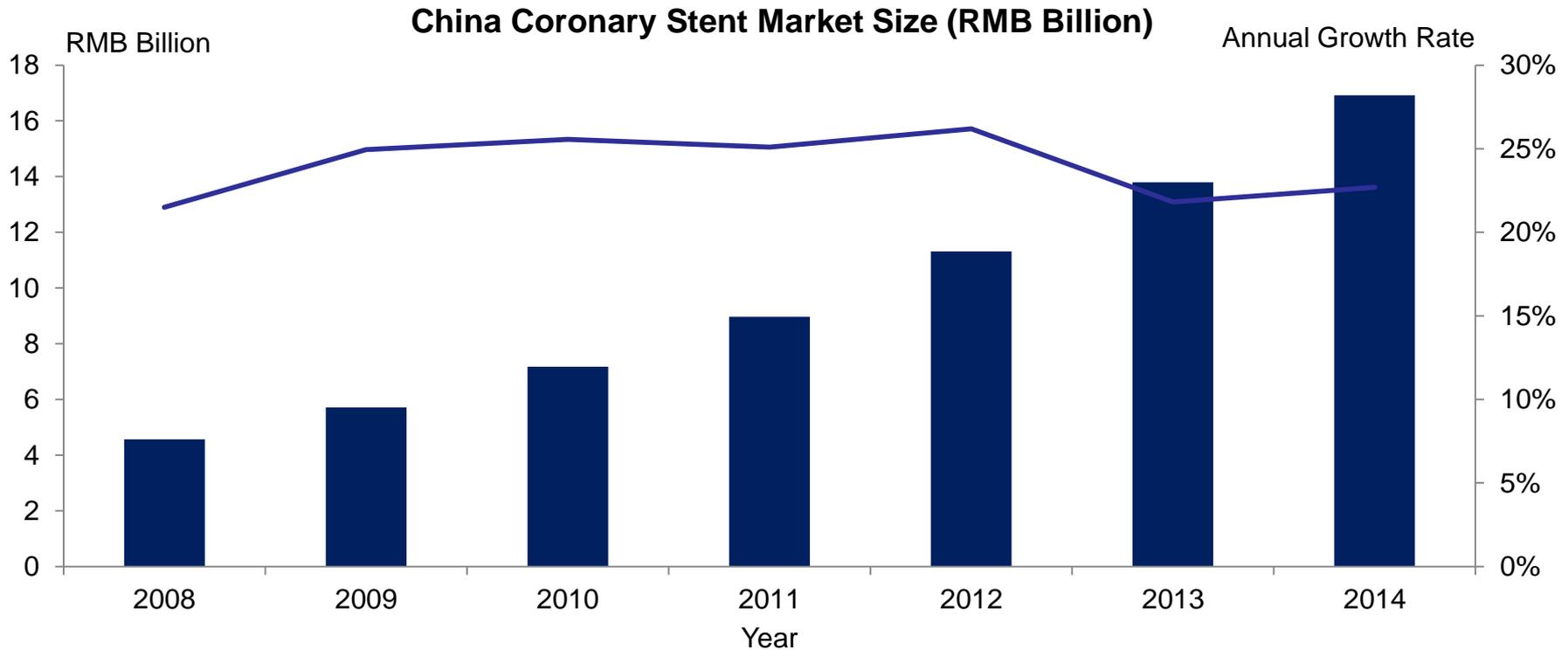
- ✓ Interventional cardiology has been aggressive in the adoption of new devices and technologies, which largely enhanced the success rate of this therapy for coronary artery obstruction.
- ✓ Percutaneous coronary intervention (经皮冠状动脉介入术), or PCI, procedures reduce risk of infections, require shorter hospital stay and recovery time, and have minimal postoperative pain over traditional bypass graft procedures. In China, the number of PCI performed every year is almost five to ten fold that of coronary artery bypass surgery (CABG).
- ✓ The launch of innovated devices including drug eluting stents drives the wide adoption of PCI in the treatment of coronary heart disease over traditional therapies.

# Coronary stent accounted for the largest share of PCI device market



- ✓ The coronary stent segment accounted for the by far the largest share of the total interventional cardiology and PCI devices market in terms of revenue.
- ✓ The introduction of drug eluting stents reshaped the entire PCI and even cardiology market in a few short years and generated massive revenues and profits for handful of leading players.

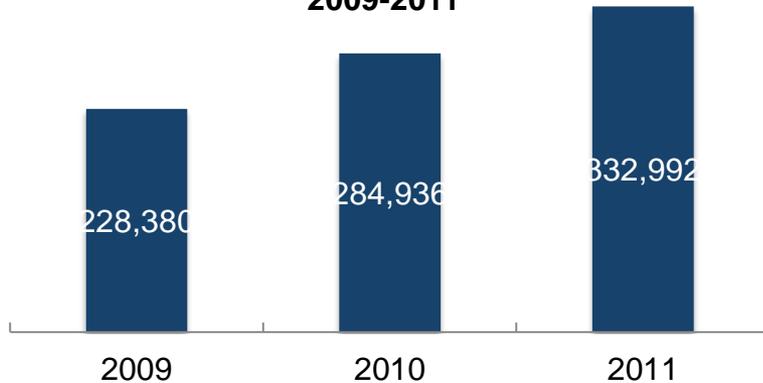
# Coronary stents market in China is experiencing a high growth rate with a CAGR over 20%



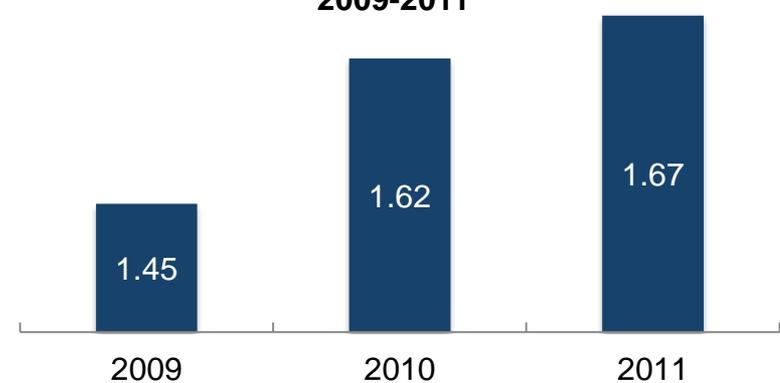
- ✓ In 2011, Chinese coronary stent market reached RMB9 billion and is expected to rise to RMB17 billion in 2014. The total sales revenue rising from coronary stents in China is expected to rise at a CAGR above 20% over the next few years. Despite price cuts, surging sales volume of coronary stents deriving from rising patients affordability and surgery capability of PCI sustains the double digit growth in the market size of coronary stents.

# Both the number of PCI procedures and average stents implanted has increased significantly

Number of PCI procedures in China  
2009-2011

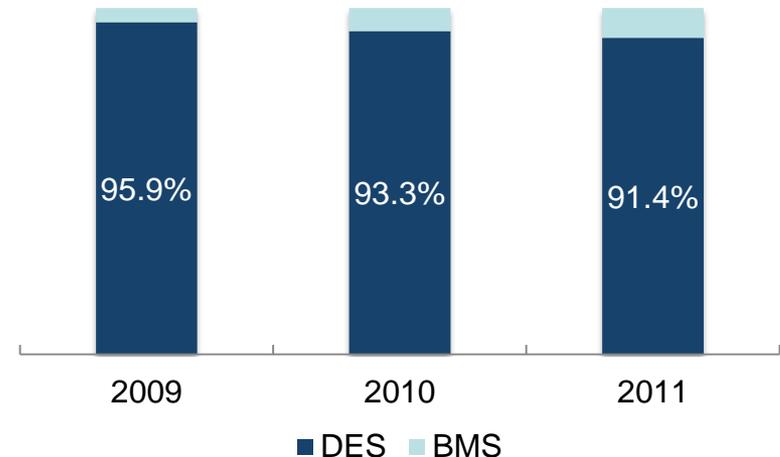


Average Number of Stents Implanted  
2009-2011



- ✓ Both the number of PCI procedures performed and average stents implanted in each case increased over the last 3 years.
- ✓ PCI procedures reached 332,992 in 2011, with a CAGR of **21%** during 2009 and 2011. However, the actual growth rate would be even higher given the fact that the number for six provinces are not included.
- ✓ The number of PCI procedures performed in China is expected to keep rising at a growth rate **over 20%** due to growing demand and increasing affordability.
- ✓ The percentage of DES implanted over BMS remained high over the last 3 years and the slight decrease in its share might be derived from the increase in patients with lower income.

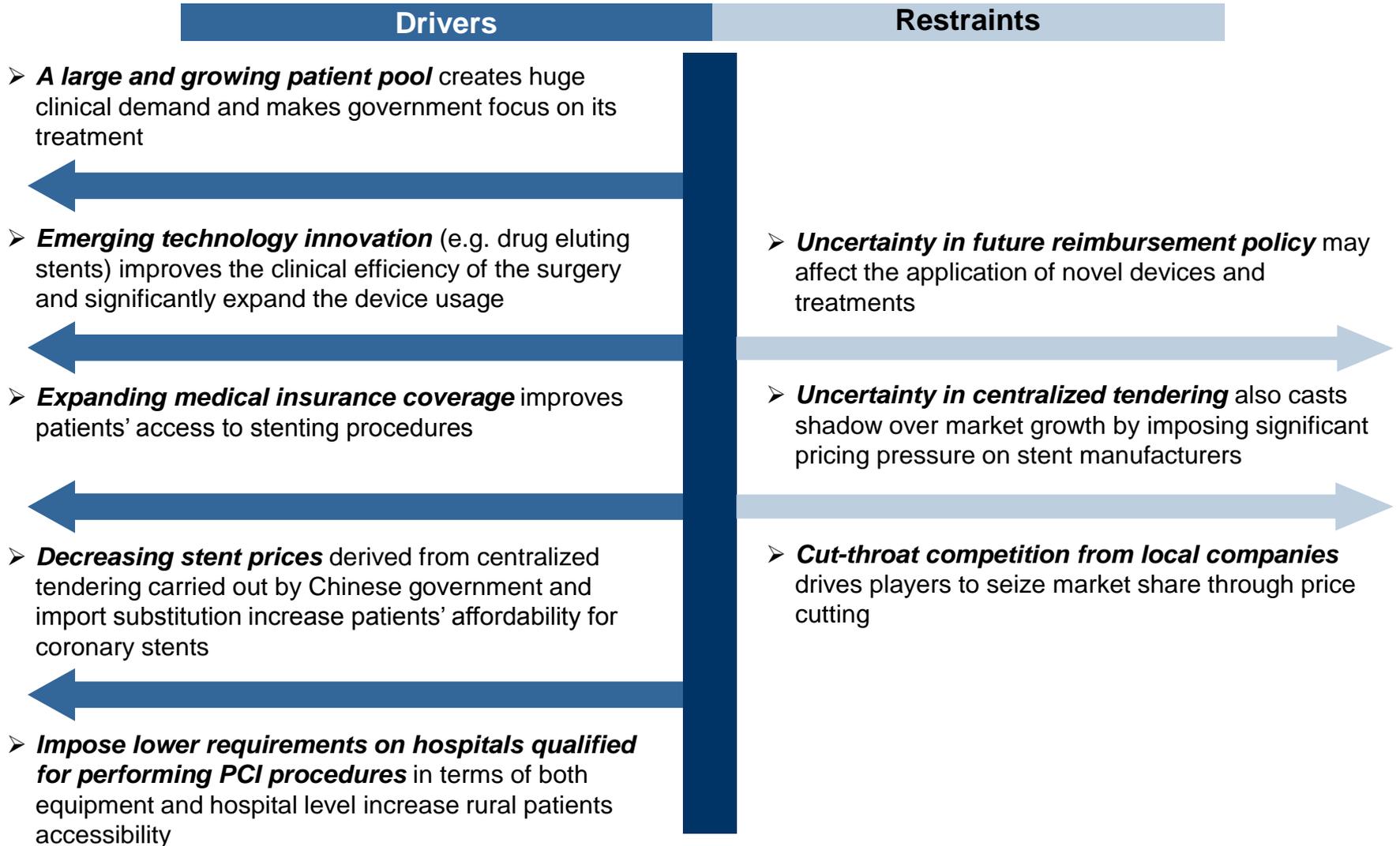
Share of DES over BMS  
2009-2011



Note: The number includes the PCI procedures performed in military hospitals. Six provinces have not yet reported their data, so the actual PCI number in 2011 would be higher.

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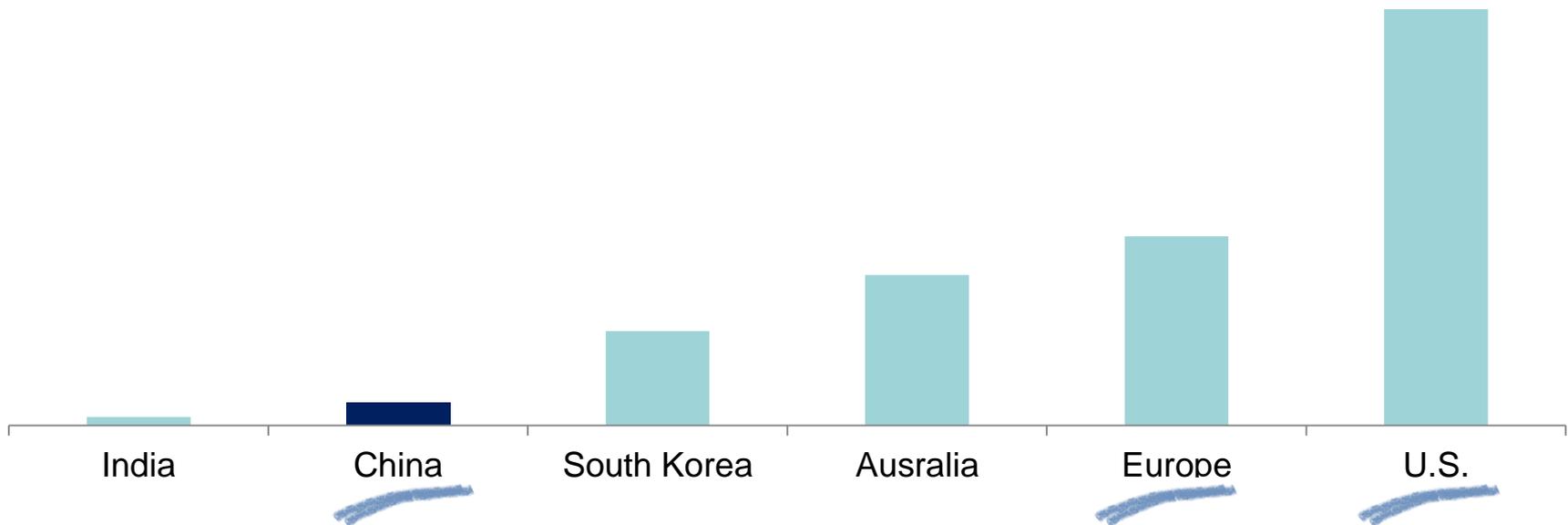
# Market Drivers and Restraints



# China has a large and growing patient pool for stent implanting

- ✓ China accounts for ~24% of world's aging population and is accelerating the growth at CAGR of 3.3% 10'-17'.
- ✓ According to Ministry of Health (MoH), over 230 million cases of cardiovascular disease were recorded in China in 2010 and heart disease accounted for ~19.7% of all deaths in 2008.

**PCI performed per million people, 2009**

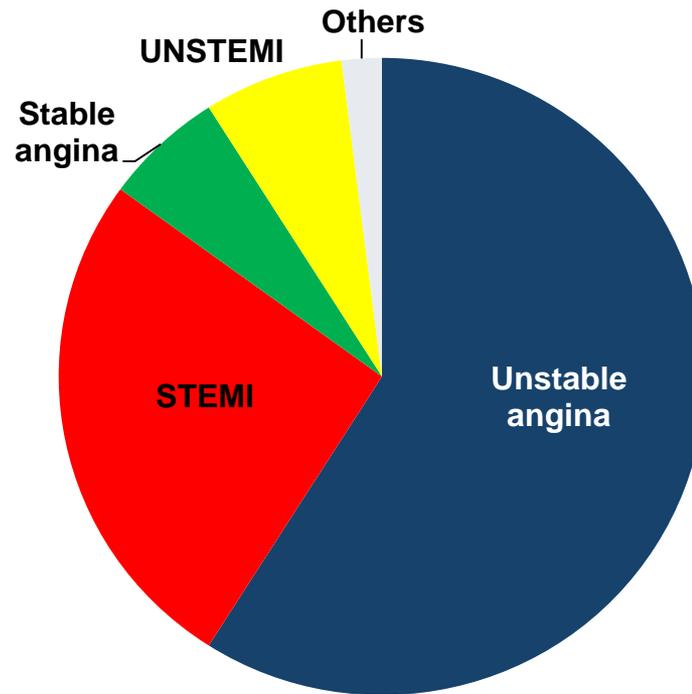


- ✓ In more developed countries, such as Europe and U.S., the number of PCI procedures performed annually is ten to twenty fold more than that in China. Since PCI is the predominant therapy for coronary heart disease, there is huge potential for the penetration of PCI procedures in China, driven by the large ageing population and rising incidence rate of cardiovascular disease.

# STEMI still counts for a small part of patients receiving PCI treatment

- ✓ The incidence rate of STEMI is 25 cases per 100,000 people, which means there are 600,000-700,000 new STEMI patients every year. Many STEMI patients live in rural area where the infrastructure of emergency interventional treatment is incomplete and the patients' awareness of interventional treatment is low. Thus only around 30% of STEMI patients receive PCI procedures and many of them are treated more than 12 hours after heart attack.

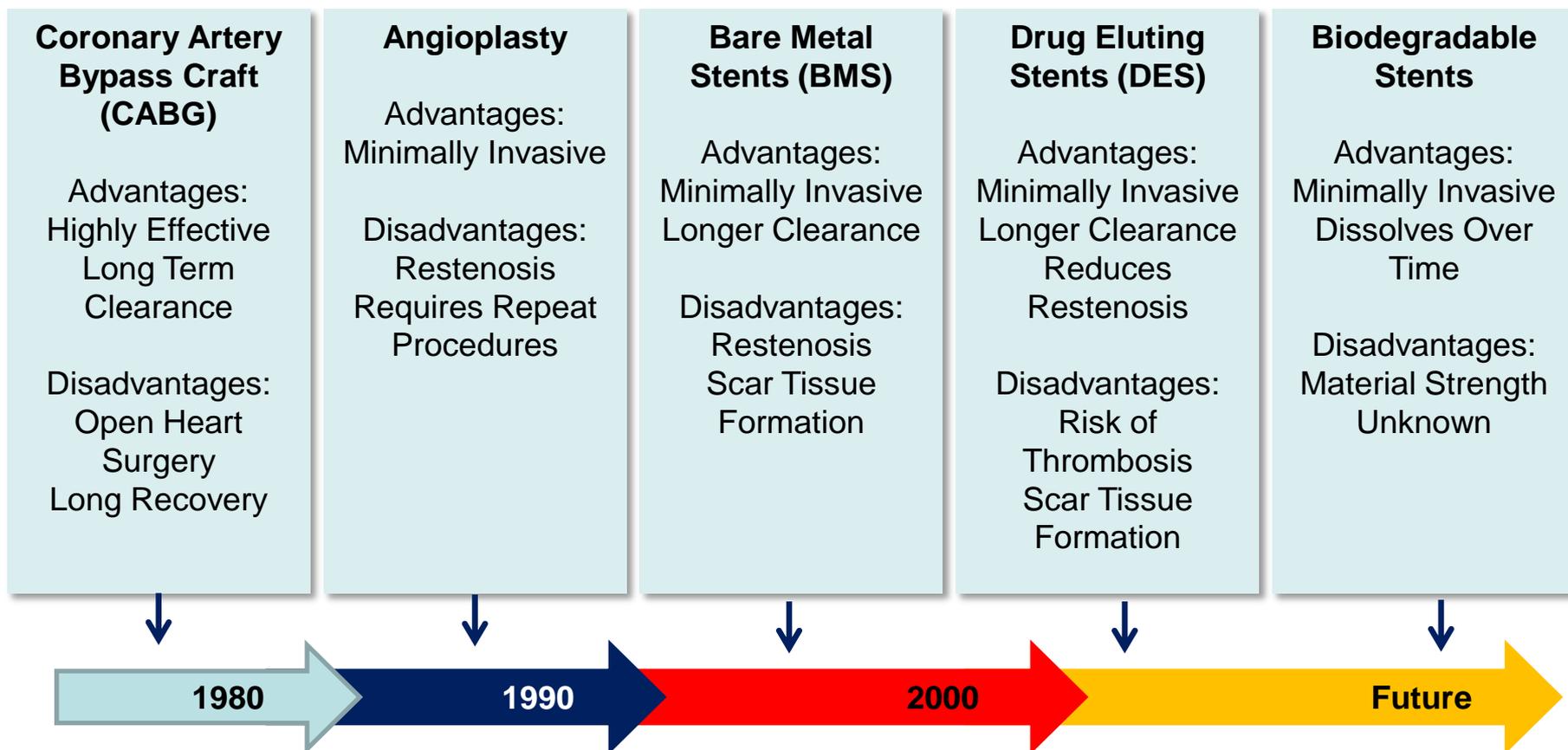
Break down of PCI patients by disease type in 2011



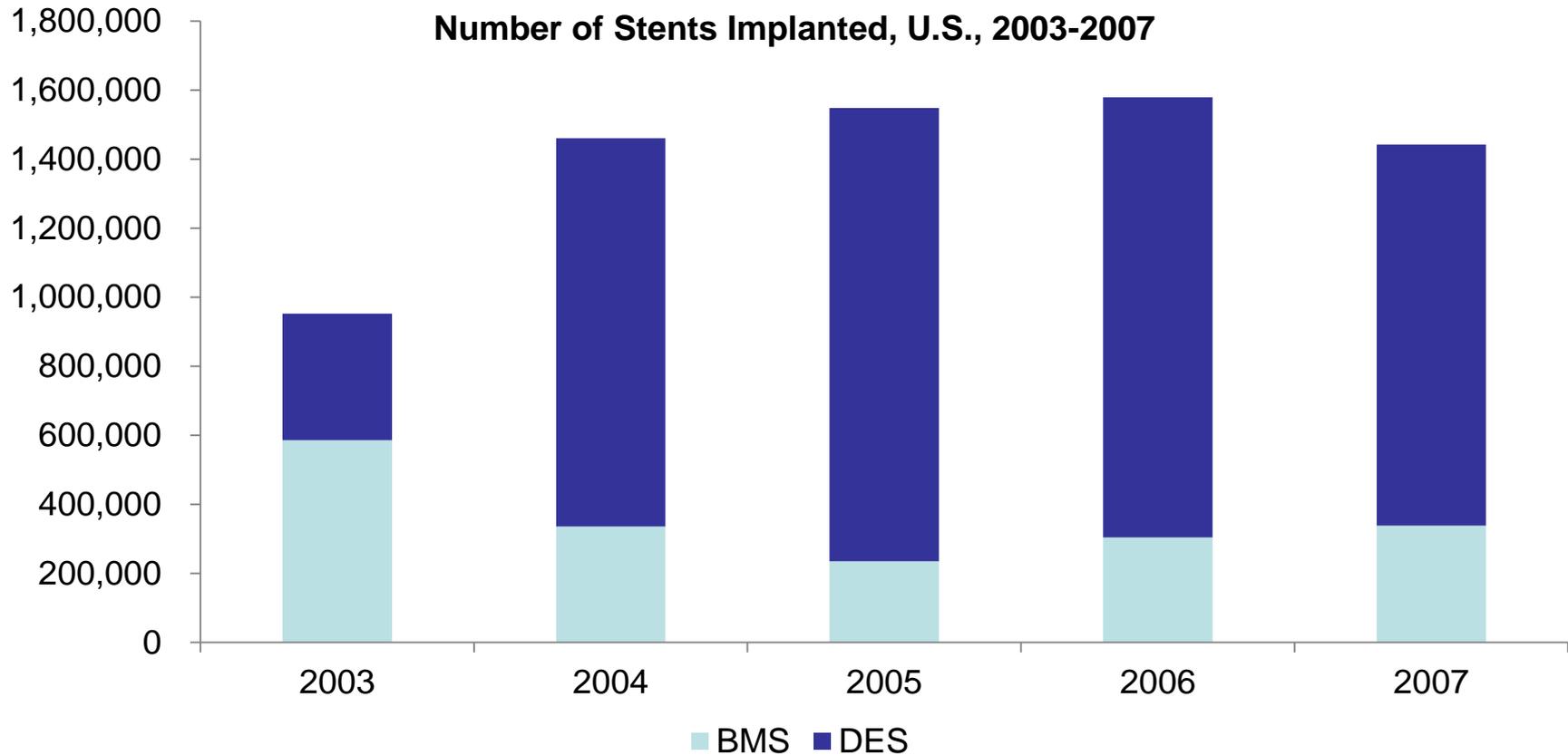
- ✓ Unstable angina patients represent over half of all PCI patients. This rate is much higher than that in developed countries (around 30%), due to China's more flexible diagnostic criteria for unstable angina.
- ✓ The situation is expected to improve in the future with more STEMI patients receiving PCI procedures.

# Proactive innovation in the treatment of coronary artery disease

## History of Coronary Artery Disease Care in U.S.

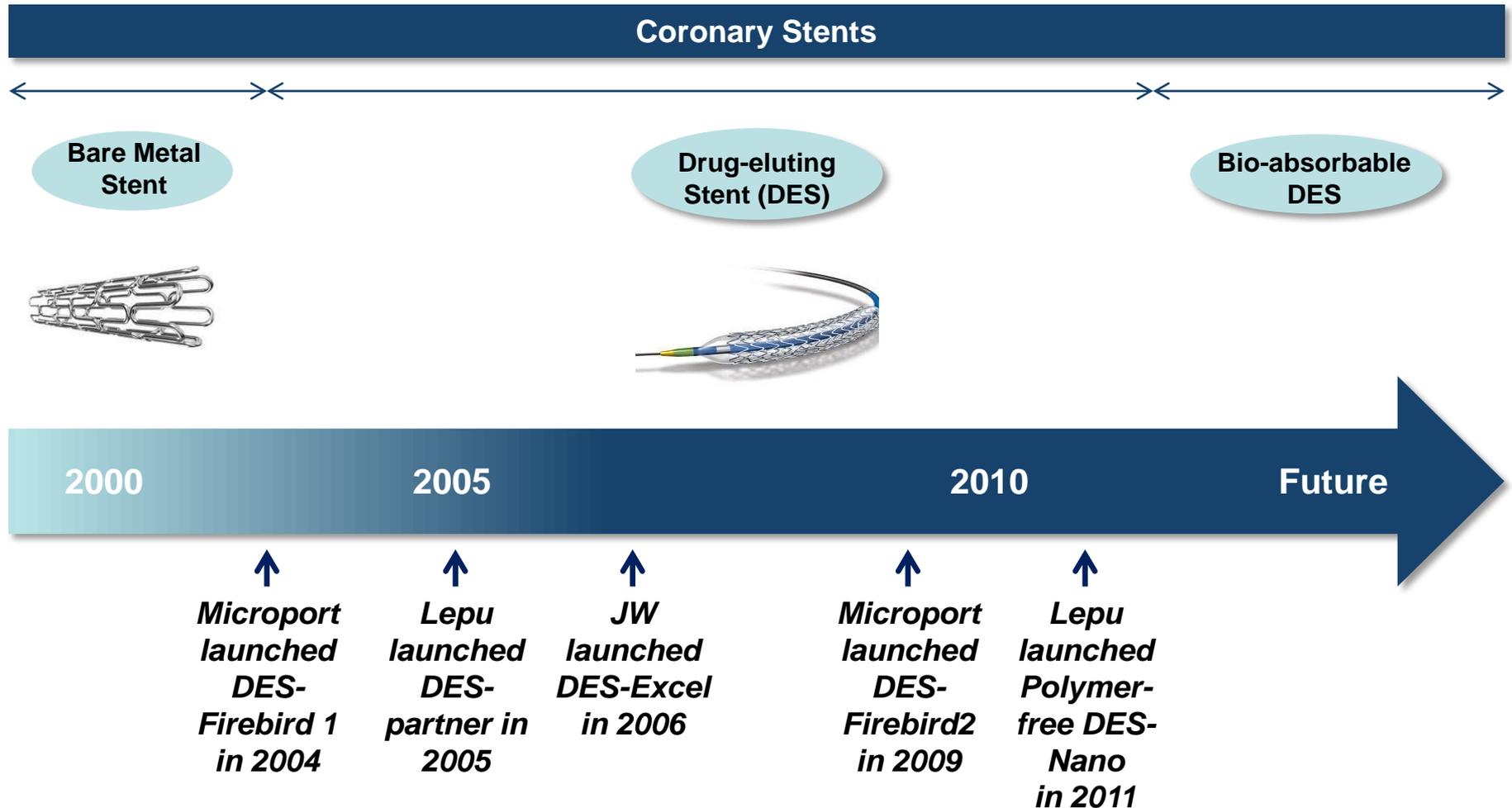


# Introduction of next generation products lead to significant market expansion



- ✓ Introduction of the next generation technology or devices leads to the sharp shrink of older methodology or devices and the expansion of market in a rapid pattern.
- ✓ Quick adoption of the new technology by cardiologists and patients drives manufacturers rapidly shift their marketing strategy from promoting the new technology to more of their brands over others.

# Introduction of coronary stents in Chinese market lead to the emerging of domestic manufacturers

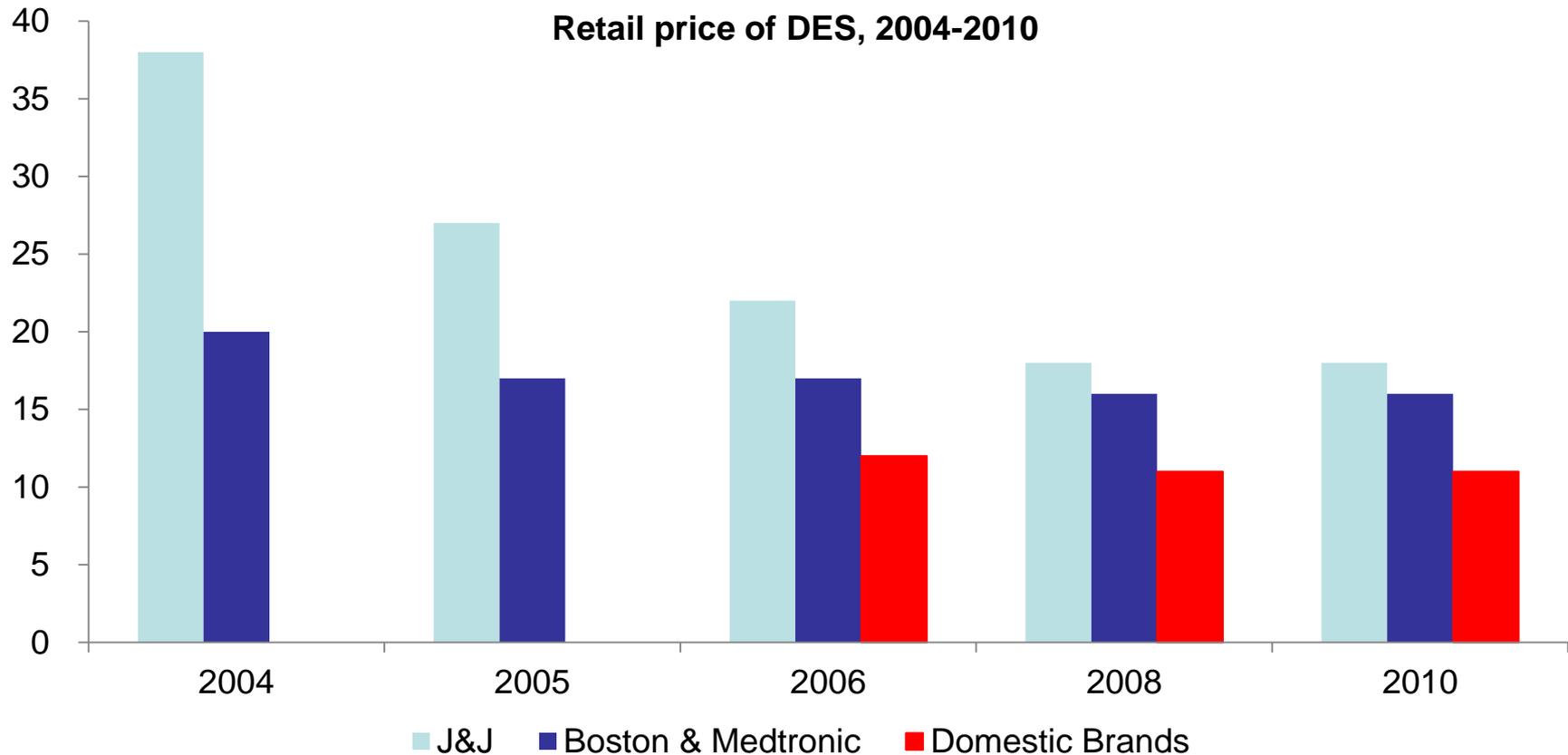


# Innovation in DES products

Generation	Feature	Products
Durable polymer	Permanent presence of polymers lead to inflammatory responses, local toxicity and mechanical complications	Microport's Firebird 2, Lepu's Partner, Abbott's Xience V, MDT's Resolute
Biodegradable polymer	Polymer that carries and controls the drug release during an proper period of time and after that erodes and vanishes from the vascular surface; Less thrombosis risk and potentially improve long-term outcomes.	JW' Excel, SinoMed's BUMA, Essen's Tivoli, Medfavour's NOYA, Kinhely's Helios, Microport's Firehawk
Polymer free	Modifications in the surface of the stent platform to carry the anti-proliferative drug and control their release; hence may lead to more rapid vessel healing and reduce the need for long term anti-platelet medications.	Yinyi's Yinyi, Lepu's Nano
Bio-absorbable	To be slowly metabolized by human body and completely absorbed over time; restore blood flow by propping a clogged vessel open and provide support until the blood vessel heals.	Abbott's Absorb Microport's Absorb

Source: KOL interview, Frost & Sullivan analysis

# Retail price of DES decline sharply in China due to centralized tendering and import substitution



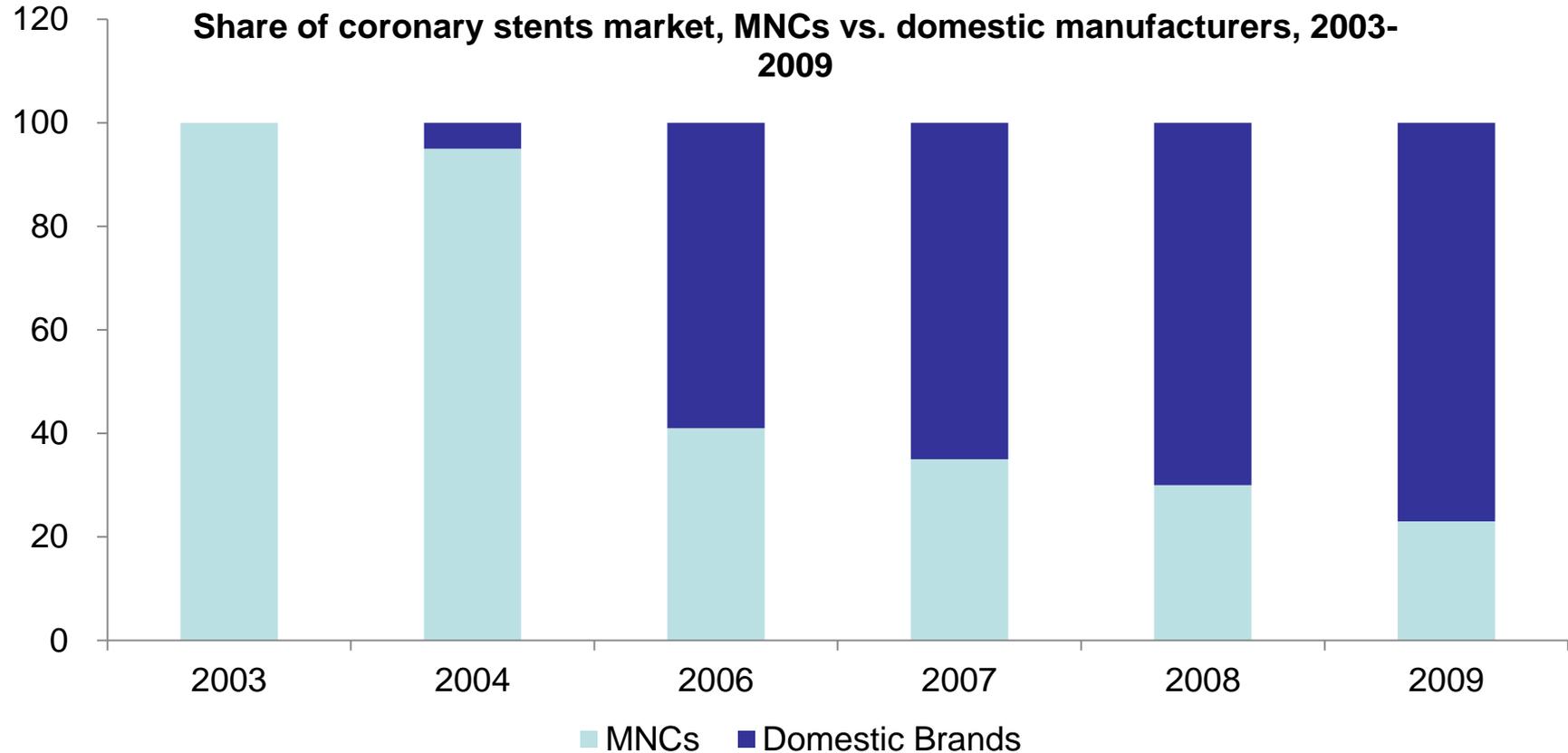
- ✓ DES has become more and more affordable to Chinese patients due to sharply decreasing retail prices and expanding medical insurance coverage.

# Centralized tendering had made great success in price cutting

Time	Key Event	% of price cuts (price hospitals charges to patients)	Local brands listed in the tender
<b>Beginning of 2005 and 3Q 2006</b>	Price cap were set by government in 8 provinces and municipalities. And hospitals and healthcare institutions in other provinces generally followed the prices in these eight provinces and municipalities.	29% for J&J, but 15% for Medtronic and Boston Scientific.	Firebird1, Partner, Excel
<b>3Q 2008</b>	First centralized tender was held by MOH to set the retail prices for all hospitals and healthcare institutions around China.	9% for domestic brands and 14% for foreign brands.	Firebird2, Partner, Excel, Yinyi
<b>4Q 2010</b>	In 2010, MOH announced no nationwide tender will be held this year due to budget reason, and tender will be conducted at provincial level.		
<b>3Q 2012</b>	Beijing tender for coronary stent was supposed to be held in October 2011, but this tendering has not yet been conducted. The result of Beijing tender will have influential impact on the tendering in other provinces.	10%~20% expected	Tivoli, BuMA, NOYA and Helios are expected to be listed in this round of tendering.

Source: Healthcare economist interview; Frost & Sullivan analysis

# Accelerated import substitution makes DES more affordable to Chinese patients



- ✓ Rapid import substitution by domestic DES manufacturers has dramatically cut down the retail price of DES and imposed great pricing pressure on MNCs.
- ✓ Meanwhile, since domestic brands enjoy more dominance in the market, intensive competition among domestic manufacturers has become another main factor to drive price cutting.

# Lower requirements on hospitals qualified for performing PCI makes stent implantation more accessible to rural patients

- ✓ Several modifications had been made to the newly released Administration Standard for Interventional Treatment on Cardiovascular Disease (2011 Ver.) to facilitate the penetration of cardiovascular intervention in lower level hospitals and rural area.
- ✓ The level of hospitals qualified for cardiovascular interventional treatment should be above county level Class 2 and no longer limited to Class 3. Besides, MRI and laminar air flow system are also no longer compulsory to obtain the qualification.
- ✓ However, requirements on the working and training experience of qualified surgeons are more demanding compared with the older version (2007 ver.).



卫生部医政司  
MINISTRY OF HEALTH OF THE PEOPLE'S REPUBLIC OF CHINA

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卫生部办公厅关于印发《心血管疾病介入诊疗技术管理规范（2011年版）》的通知

中华人民共和国卫生部      www.moh.gov.cn      2011-08-19 13:38:44

卫办医政发〔2011〕107号

各省、自治区、直辖市卫生厅局,新疆生产建设兵团卫生局:

为加强心血管疾病介入诊疗技术管理,规范心血管疾病介入诊疗行为,保证医疗质量和医疗安全,2007年7月,我部印发了《心血管疾病介入诊疗技术管理规范》(卫医发〔2007〕222号),在全国范围内开展心血管疾病介入诊疗技术准入和规范化管理工作。为贯彻落实深化医药卫生体制改革要求,满足农村地区心血管疾病诊疗需求,提高心血管疾病介入诊疗服务可及性,我部组织有关专家对《心血管疾病介入诊疗技术管理规范》进行了修订,形成了《心血管疾病介入诊疗技术管理规范(2011年版)》(以下简称《规范》)。现印发给你们,请遵照执行。



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卫生部关于印发《心血管疾病介入诊疗技术管理规范》的通知

卫医发〔2007〕222号

各省、自治区、直辖市卫生厅局,新疆生产建设兵团卫生局:

为加强心血管疾病介入诊疗技术管理,规范心血管疾病介入诊疗行为,保证医疗质量和医疗安全,我部组织制定了《心血管疾病介入诊疗技术管理规范》(以下简称《规范》)。现印发给你们,请遵照执行。

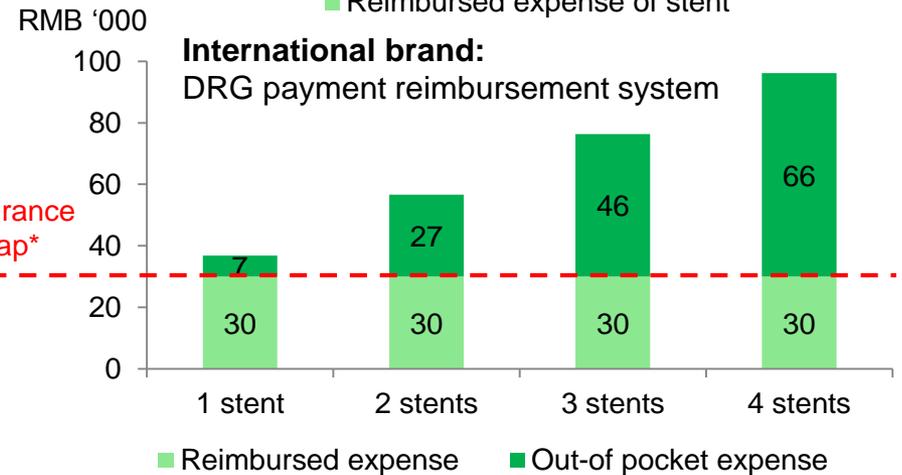
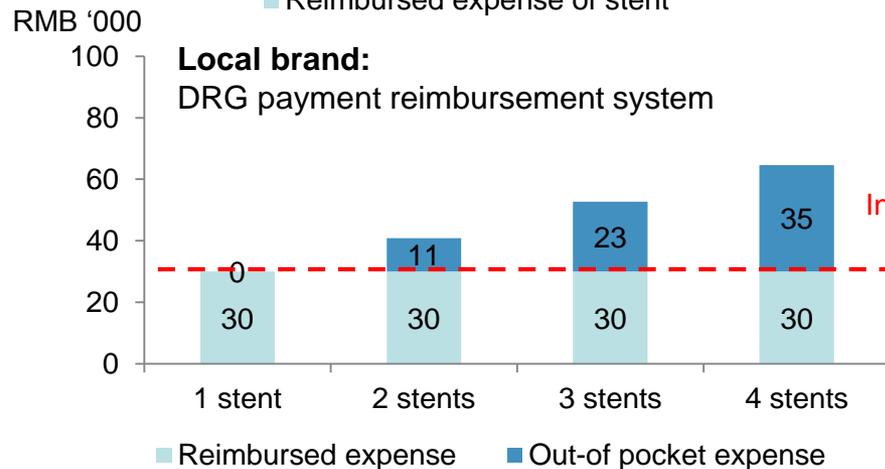
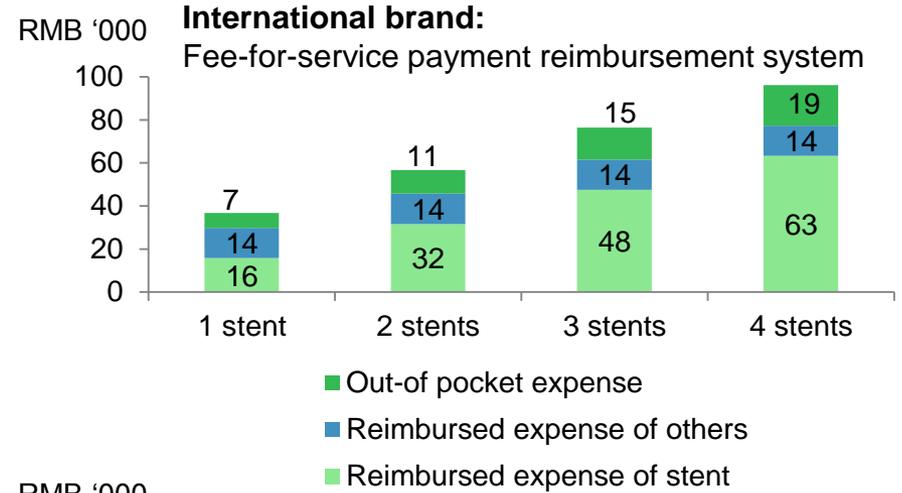
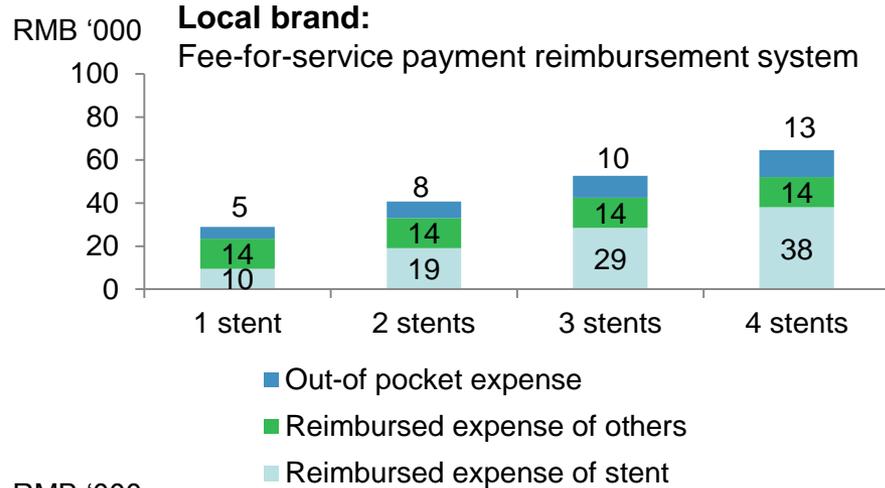
各省级卫生行政部门要按照《规范》要求,组织对医疗机构心血管疾病介入诊疗技术临床应用能力进行评价。凡通过能力评价的医疗机构,准予心血管疾病介入诊疗科目登记,在《医疗机构执业许可证》副本备注栏注明其原有的心血管内科、心脏大血管外科或者胸外科诊疗科目及其科目下心血管疾病介入诊疗项目。各省级卫生行政部门要及时将准予心血管疾病介入诊疗科目登记的医疗机构名单向社会公告。

# Reimbursement policy in most provinces favor domestic brands

In more than 60% provinces, the reimbursement policy apparently favors local brands against international brands.



# DRG policy may further impose pricing pressure on international brands



- ✓ Once the DRG policy is implemented and insurance cap is set, patients' out-of-pocket expenses increase dramatically with more than two stents implanted per PCI, imposing stringent control over the number of stents implanted.
- ✓ The insurance cap policy will have greater impact on international brands compared with local brands due to their high prices.

# Uncertainty in tendering policy and cut throat competition may affect market growth

## Uncertainty in centralized tendering

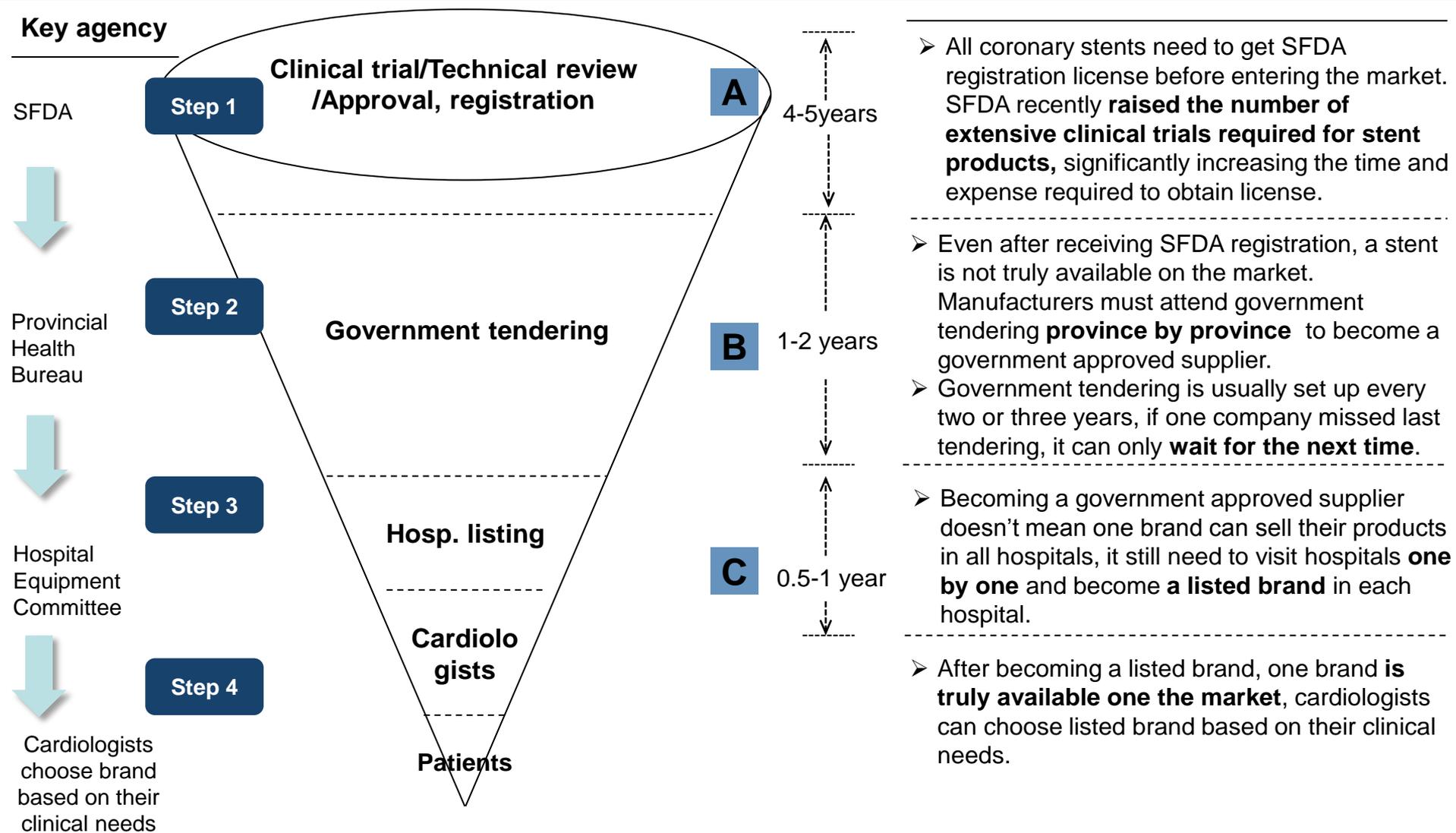
- ✓ Centralized purchasing of high value medical supplies conducted by MoH and NDRC has achieved great success in cutting the retail prices of DES, though receiving criticism for place much emphasis on lower price instead of product quality.
- ✓ Meanwhile, the magnitude of the price cutting may be limited due to the implementation of provincial tendering instead of centralized tendering.
- ✓ However, the swinging policy between centralized and decentralized tendering makes manufacturers find it hard to follow. And the postponed centralized tendering also forbids surgeons' and patients' access to innovated products and technologies.

## Cut throat competition among local manufacturers

- ✓ Top local players in China are well positioned to meet clinical demand from local surgeons and patients with more cost-effective products and better sales capacity compared with the MNCs.
- ✓ Since lack of significant technical leap in DES, products launched by most local players employed similar technical platform with slight modification, which leads to intensive competition in pricing.
- ✓ The newly emerging domestic brands(e.g. Tivoli, BuMA, NOYA and Helios) are expected to seize the market share from existing brands once they are listed as a stent supplier, mainly through aggressive promotion and more discount in prices.

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# Application process of coronary stents (1/5)

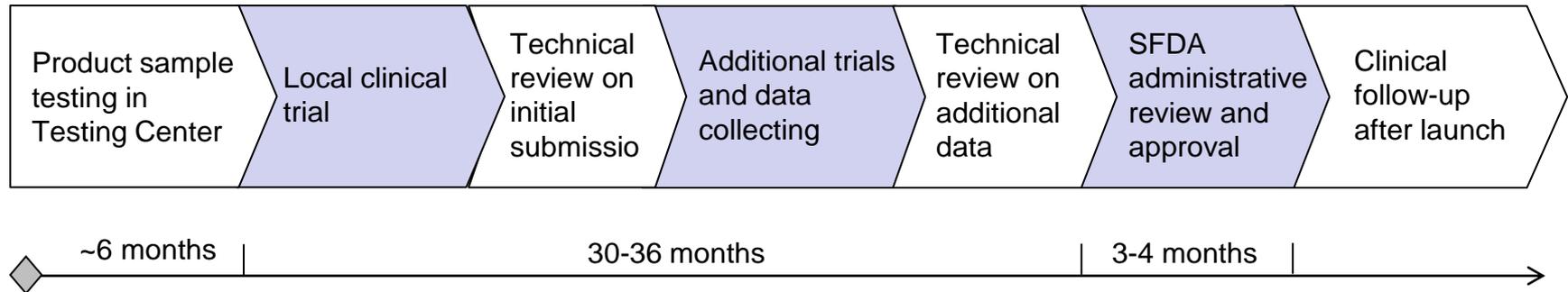


Source: Healthcare economist interview; SFDA; Frost & Sullivan analysis

# Application process of coronary stents (2/5)

## Step 1

### Timeline for coronary stent registration in China

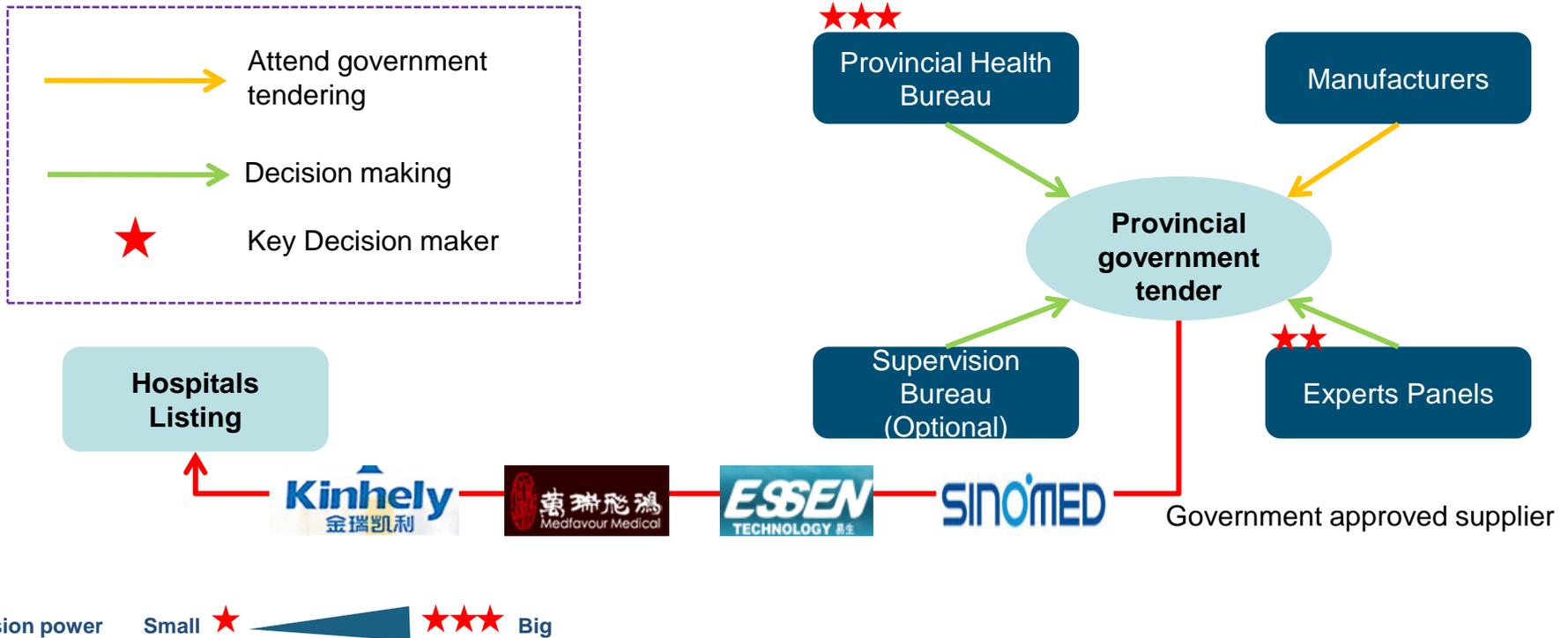


- ✓ The approval process has lengthened to 4-5 years since the government issued “The management standard and guidance of DES clinical trial” in 2010, which requires manufacturers to complete 1,000 clinical trials before registration and 2,000 cases of clinical follow-up after launch. It can now take three years to obtain SFDA approval from the commencement of clinical trials.
- ✓ While this extended approval process creates barriers to entry for new players to enter the market, it also significantly increases development costs for new products.

# Application process of coronary stents (3/5)

## Step 2

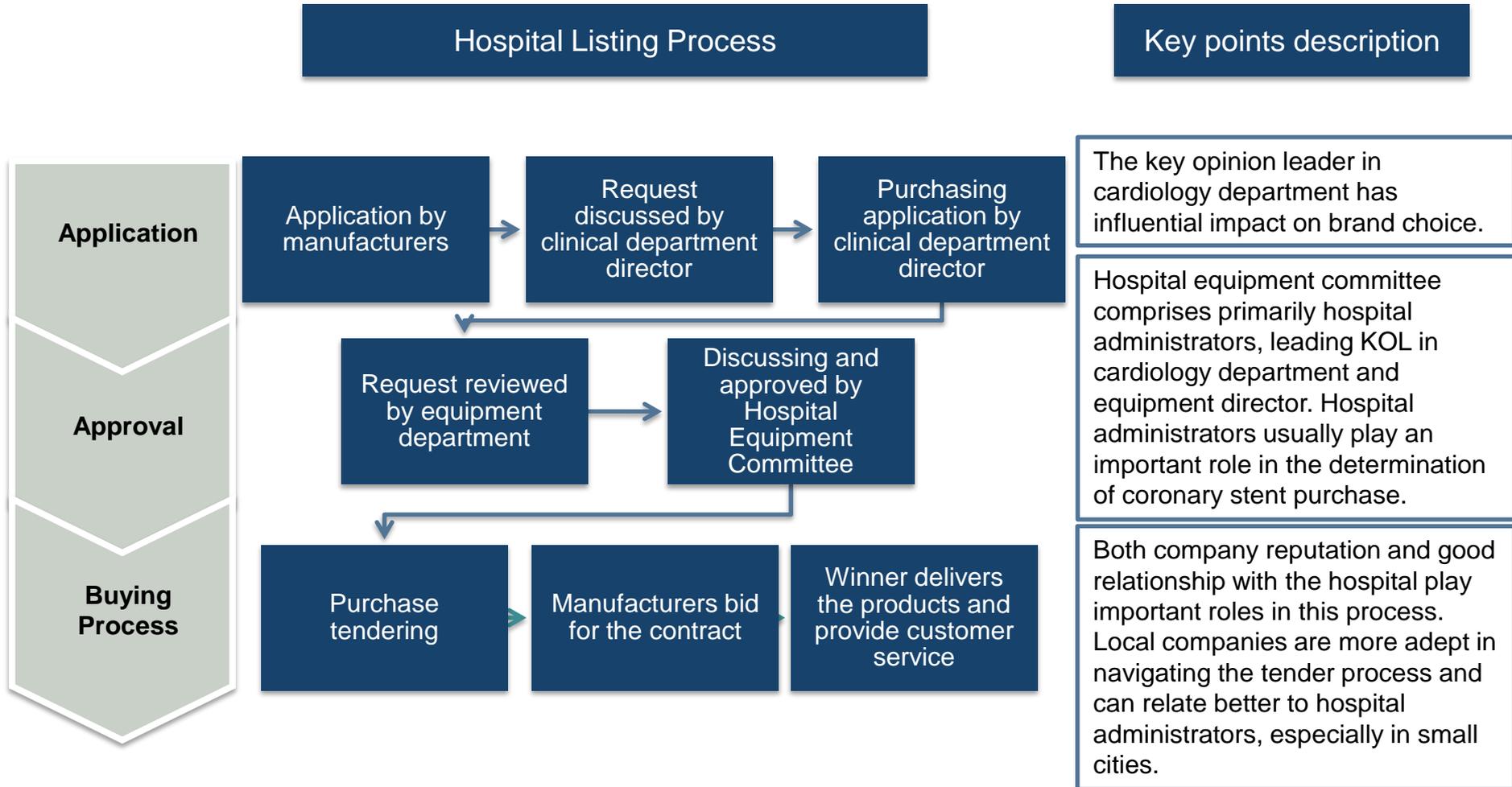
- ✓ Bids submitted by manufacturers or their distributors are reviewed by government-approved expert panels, experts are mainly leading cardiologists(KOLs) and healthcare economists.
- ✓ In addition to price, the panel reviews various other terms of the bid, such as product quality, brand, safety record and service provided.



Source: Healthcare economist interview, Frost & Sullivan analysis

# Application process of coronary stents (4/5)

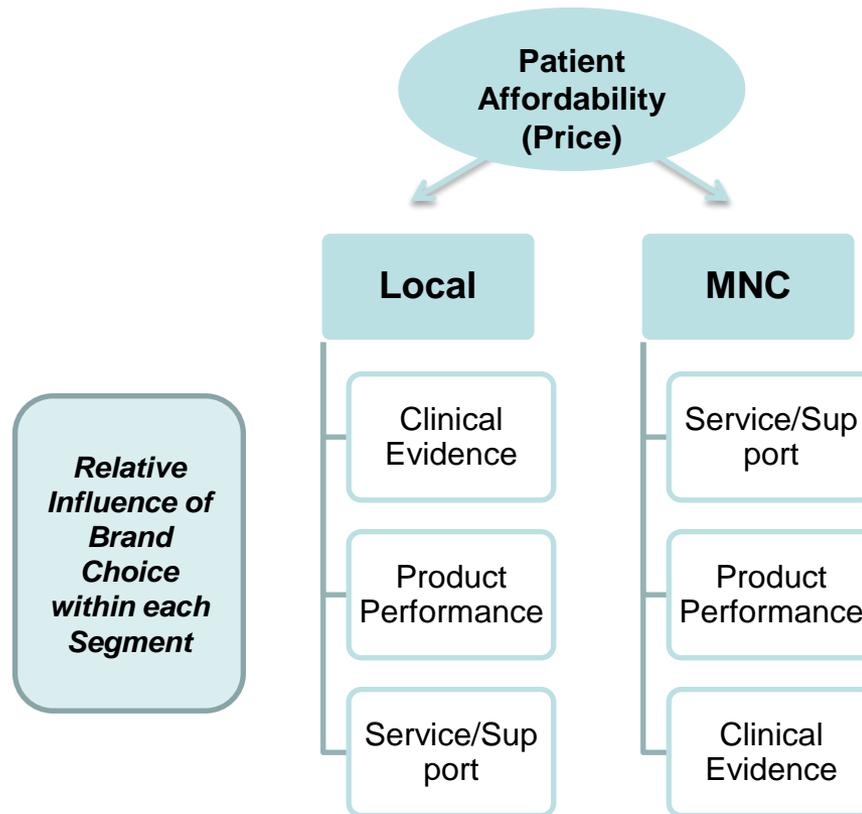
## Step 3



# Application process of coronary stents (5/5)

## Step 4

- ✓ Patient affordability is the key factor in cardiologists choice between local vs. MNC brand
- ✓ Within local brands, several factors influence choice of stent



# Healthcare institutions provide PCI treatment are under the monitor of provincial MoH

- ✓ According to the Administration Standard for Interventional Treatment on Cardiovascular Disease released by MoH, provincial MoH should be responsible for the assessment on the capability of healthcare institutions to process cardiovascular interventional treatment.
- ✓ For healthcare institutions qualified for cardiovascular interventional treatment, clinical information of each case received the treatment should be reported to provincial MoH through specific web site. And provincial MoH will have an eye on the application of interventional treatment in these healthcare institutions on timely basis according to these information.

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# KSF in Chinese coronary stent market (1/2)

## *Strong R&D capability to make significant leap in technology*

Launching a new device with only a marginal benefit over existing products on the market might only have a slight impact ensuring a firm gets adequate return on their investments.

However, instead of launching a me-too device, a product with a significant leap in technology would create a significant industry buzz and accelerate its product adoption. Firms need to make themselves aware of the features that will best serve the market six to seven years down the line. Furthermore, as the upcoming innovated technology in coronary stents makes older methodology shrink rapidly, catching up with the cutting edge technology is also necessary for firms to survive in this market.

Thus leading manufacturers usually possess rich pipelines composed of products under various stages (e.g. available on market; application for certification; under development) to ensure its long term presence in the market.

## *Addressing Optimal Clinical Need*

As upcoming DES products adopt slight modification and employ similar platform to those currently on the market, competition usually comes down to company's ability to address the widest range of clinical needs, simple ease of operation, and quality of communication with surgeons.

The quality practices of DES are highly stringent, due to the life saving potential of their products. In this industry one product failure or malfunction could be disastrous to a company's long term viability. When dealing with prosthetic implants, marketing one's self as the cheap alternative at the expense of quality is never effective.

# KSF in Chinese coronary stent market (2/2)

## *Reliable clinical data from both pre-launch and post-launch clinical trial*

While pre-launch clinical trials are a must for product approvals, post-launch clinical trials can be used to improve and enhance marketing initiatives and increase the credibility of the brand and the product.

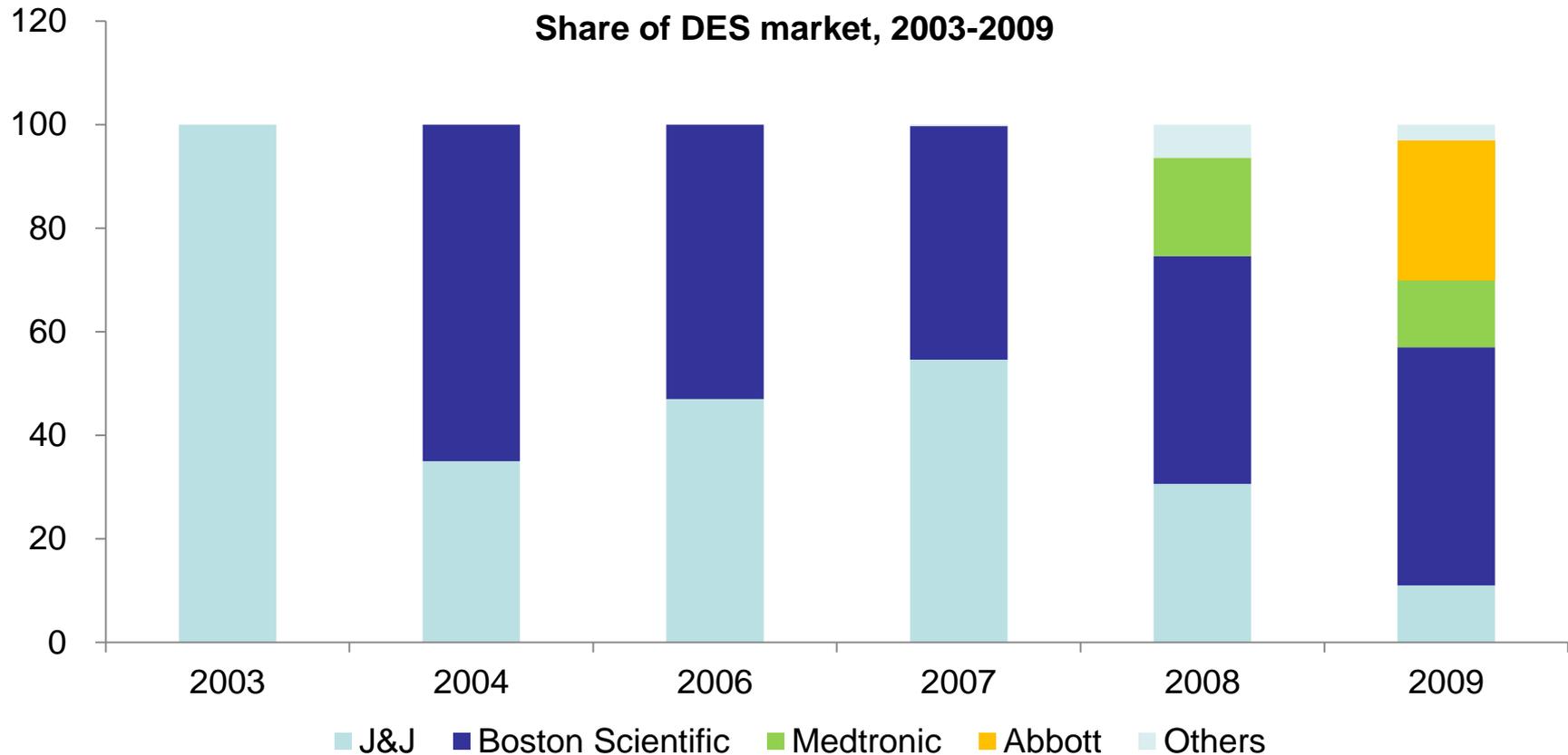
The avenues for success in the coronary stent market indicate a strong consumer demand for high quality devices with the most features. The broader the device capabilities, the more diverse range of disease states clinicians are able to address. Given that the coronary stent market only has a few players, and that most patients are aware of the devices available for their procedures, in the coming years direct to consumer advertising will become of greater importance. If advertisements for one's device detailed how the product consistently beat a competitor's device in head to head clinical trials, then it is possible that patients could influence their specialists' device selection process.

## *Strong and highly specialized sales force*

The technology involved in the market for coronary stents is typically highly complex. In addition, new product launches occur frequently within this market, requiring expert explanation. For companies to maintain their credibility, the sales and marketing personnel need to be highly aware of the clinical and technological issues involved and need to be able to work in partnership with physicians and surgeons. Chinese coronary stent market is a geographically widely expanded market with various clinical needs, regulation policies, and economic situation in various provinces, which lead to the need for a large crew of sales team to conduct fact-to-face communication with physicians and find their critical needs.

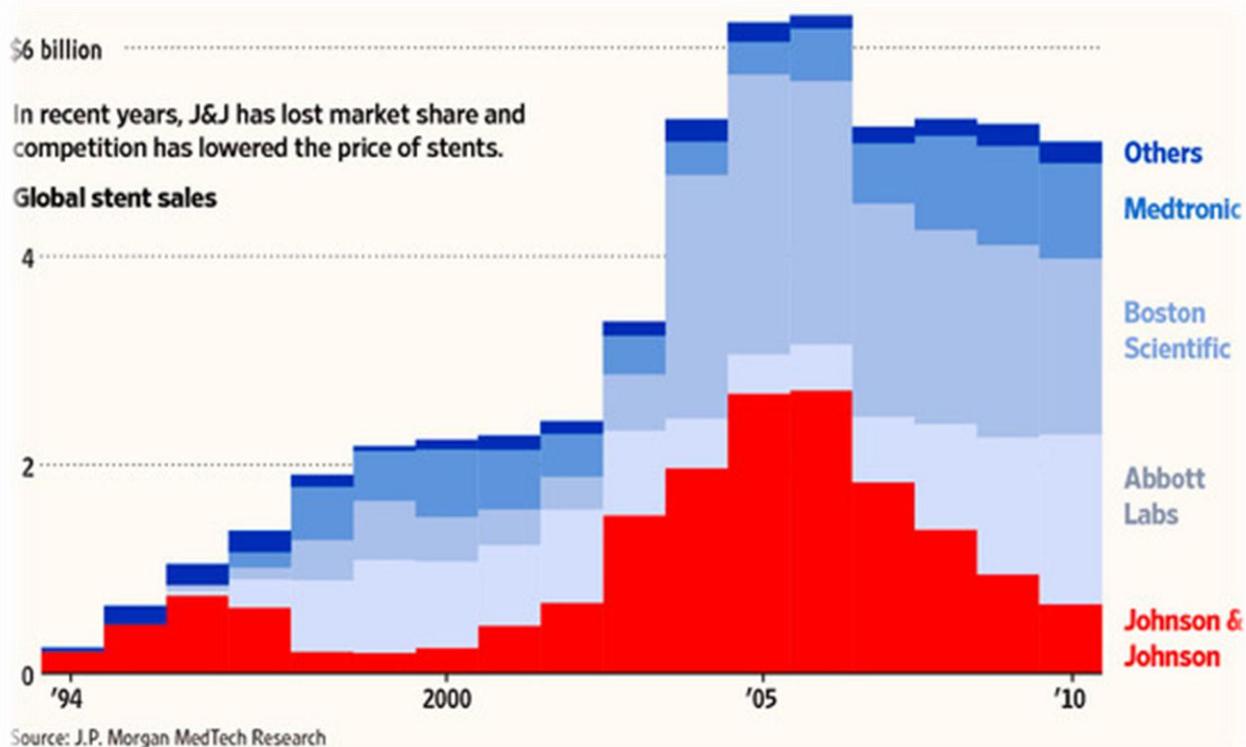
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# DES market is featured of cut throat competition with fast-paced new product introduction



- ✓ It seems nearly impossible for a company to keep leadership position in the highly competitive DES market with the entrance of new players and fast-paced new product introduction with stronger performance in clinical trials.
- ✓ New products with better performance in clinical trials tend to be accepted by the market rapidly and grab market share in short term.

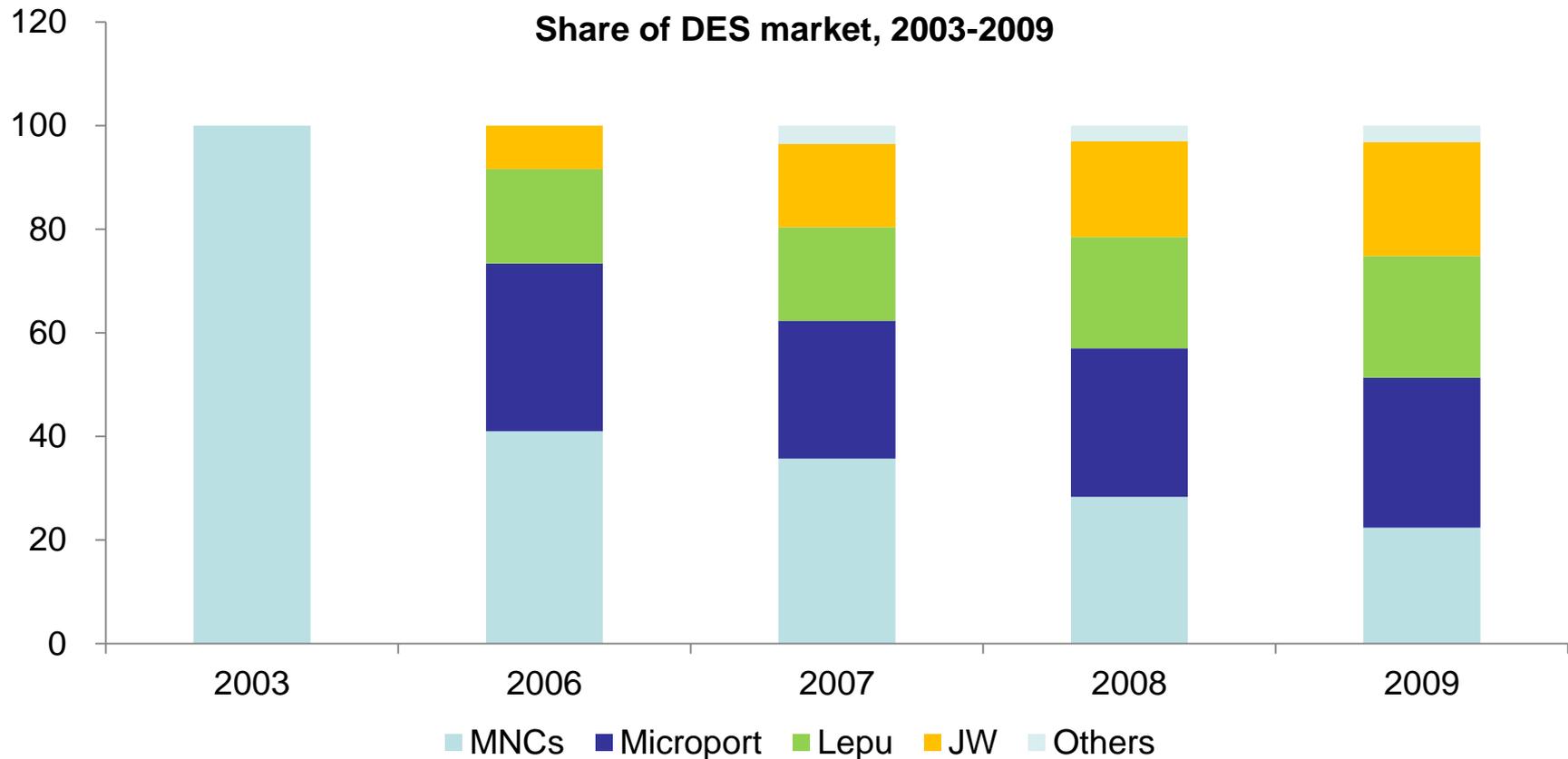
# End of J&J stent business carries lessons for medical device innovators



- ✓ J&J had left the coronary stent business through halting sales of its DES and discontinuing development of a next generation stent.
- ✓ J&J drug-eluting stent sales were \$627 million in 2010, down from a peak of \$2.6 billion in 2006.

- ✓ J&J created the global market for coronary stents.
- ✓ However, J&J failed to focus on constant innovation, choosing to rely on their major patent, which was thought broad enough to block any balloon expandable stent from the marketplace.
- ✓ As soon as Guidant gaining FDA approval for their initial coronary stent and launching a competitive device, J&J went from 95% to 25% of the U.S. market in 3 months.
- ✓ Although J&J was the first to DES market, they witnessed a sharp decline in market share from 2004 to mid 2005 reaching as low as 35% at one point when Boston Scientific launched its own DES.

# Domestic players has dominated the coronary stent market in China



- ✓ Despite accelerated import substitution, competition between domestic players is also becoming intensive. With relatively similar product performance and aggressive marketing strategy, the launch of new products could somehow affect the market share.
- ✓ Chinese physicians are more reluctant to change DES brand compared with their U.S. colleagues.

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# Overview of the two leading companies in Chinese coronary stent market

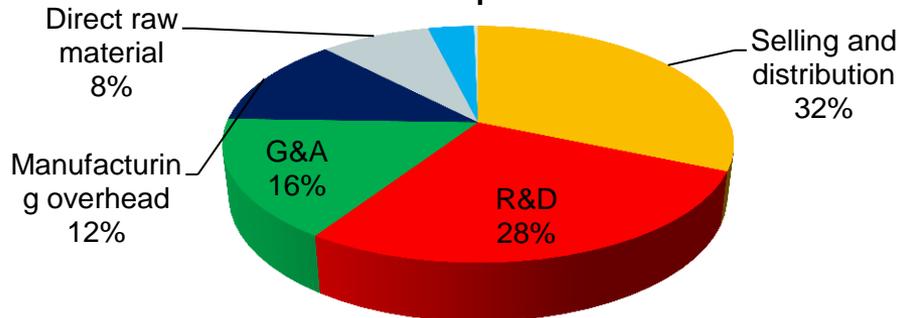


Revenue from coronary stents	RMB729.3 million	RMB663.4 million
GP ratio for coronary stents	90+%	93.4%
# of product certificates obtained	57	47
# of stent certificates obtained	4	4
R&D investment	RMB117.9 million	RMB66.2 million
R&D investment as % of total revenue	16.2%	7.2%
# of hospital customers	976	877
# of distributors	120+	160+

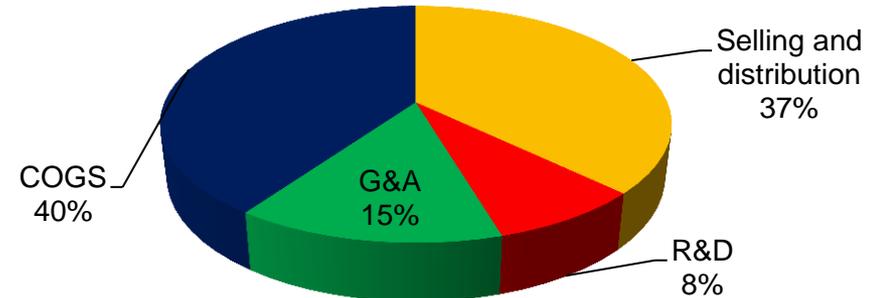
# Rich product portfolio and continuous new product introduction come from huge R&D investment

Company	Brand Name	Product	Launch Date
Microport	Mustang	Bare metal stents	11/2000
	Firebird	Drug eluting stents	7/2004
	Tango	Bare metal cobalt-chromium stents	9/2007
	Firebird2	Drug eluting cobalt-chromium stents	1/2009
	Firehawk	Third generation drug eluting stents	Beyond 2012
Lepu	Partner	Drug eluting stents	11/2005
	Nano	Polymer free drug eluting stents	11/2011
	Biguard	Drug eluting branched stents	Beyond 2012
	GuReater	Drug eluting cobalt-based stents	Beyond 2012
	-	Double drug eluting stents	Beyond 2012

Breakdown of cost structure and operating expense, Microport



Breakdown of cost structure and operating expense, Lepu

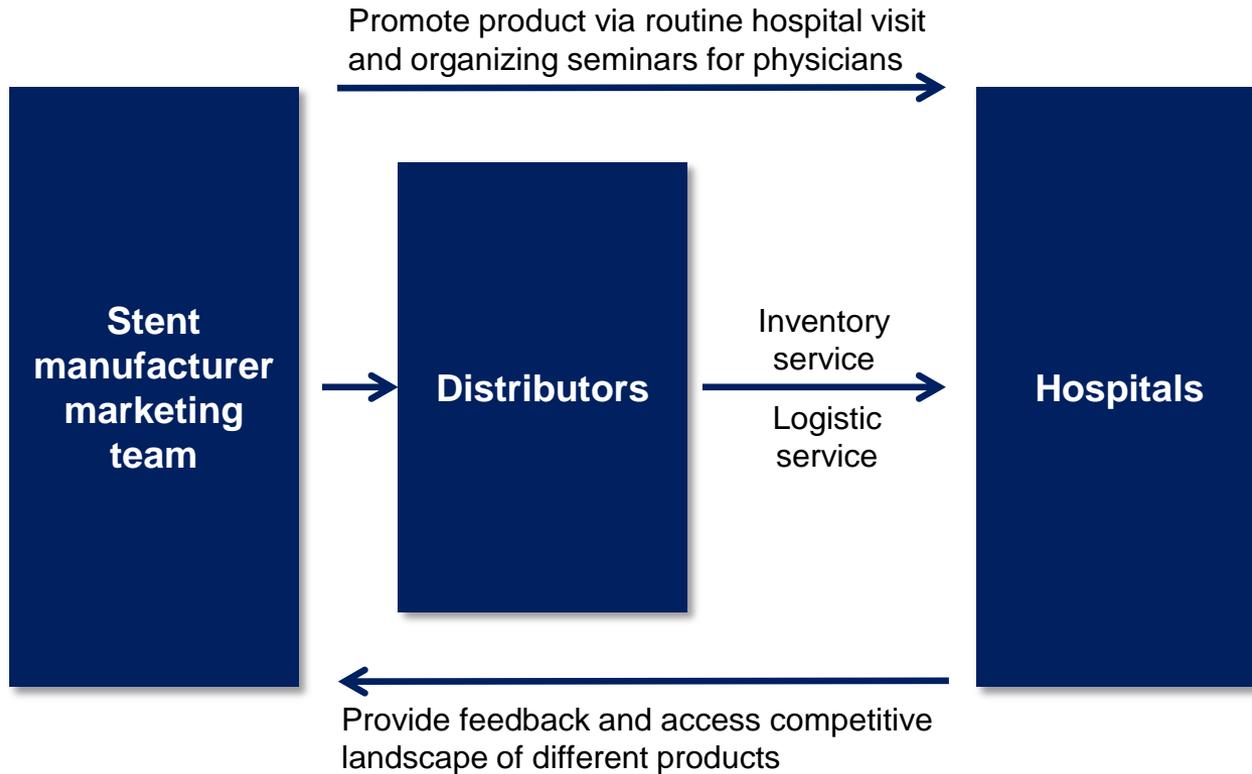


# Full range of product size to meet various clinical demands

Stent Length(mm)	8	10	12	13	14	15	16	18	19	20	21	22	23	24	25	26	28	29	30	33	35	36	38	
Firebird 2	×	×	×	√	×	×	×	√	×	×	×	×	√	×	×	×	×	√	×	√	×	×	×	
Partner	×	×	√	×	×	√	×	√	×	×	√	×	×	√	×	×	×	√	×	×	×	×	√	×
Nano	×	×	√	×	×	√	×	√	×	×	√	×	×	√	×	×	×	√	×	×	×	×	√	×
Excel	×	×	×	×	√	×	×	√	×	×	×	×	×	√	×	×	√	×	×	√	×	√	×	×
Yinyi	√	√	√	×	×	√	×	√	×	×	√	×	√	×	×	√	√	×	×	×	×	×	×	×

Stent Diameter(mm)	2.50	2.75	3.00	3.25	3.50	3.75	4.00
Firebird 2	√	√	√	×	√	×	√
Partner	√	√	√	×	√	×	√
Nano	√	√	√	×	√	×	√
Excel	√	√	√	×	√	×	√
Yinyi	√	√	√	√	√	√	√

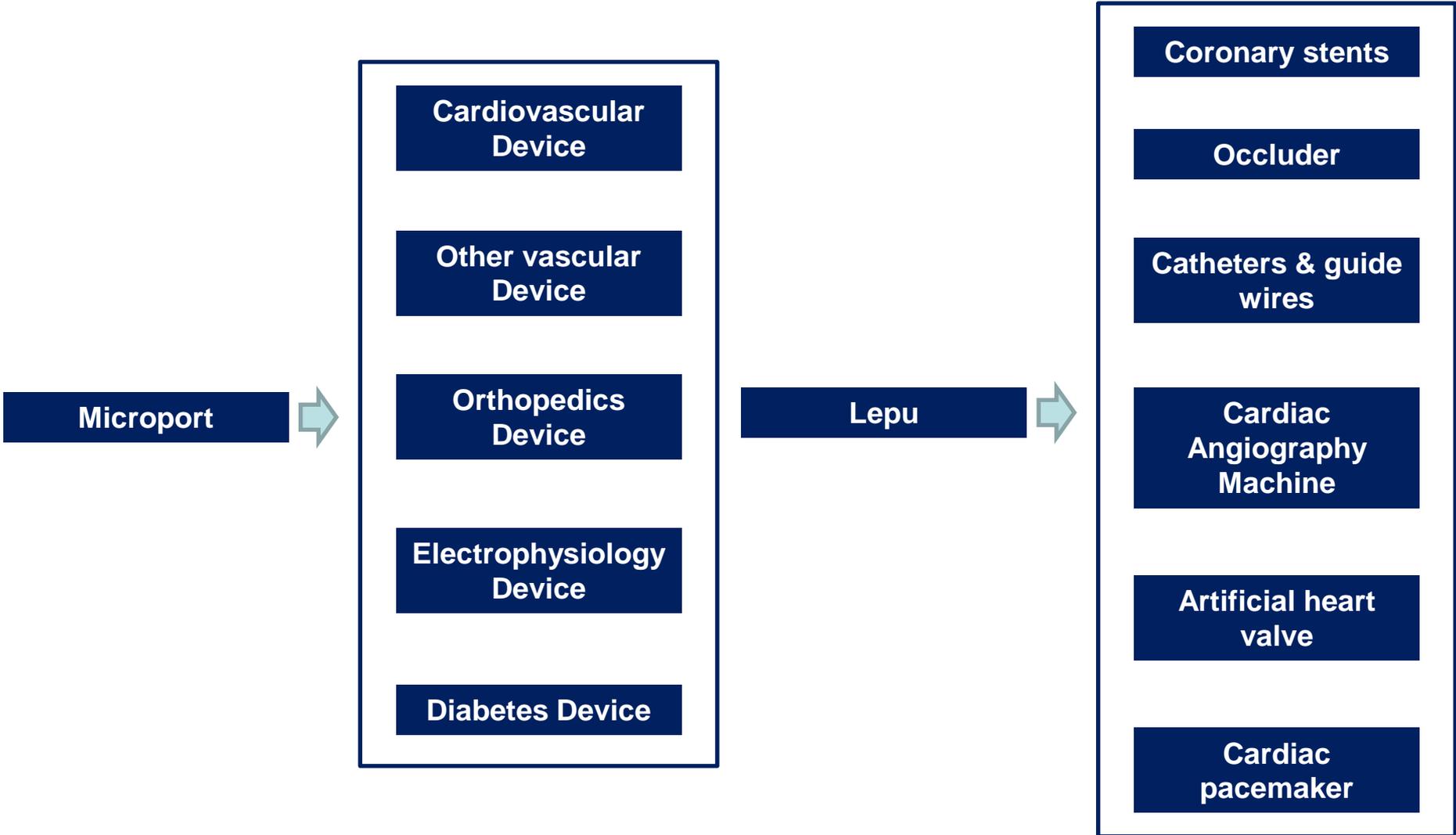
# Domestic players own stronger sales force and employ more flexible strategies



- ✓ Domestic players usually apply more flexible and aggressive marketing strategy compared with their MNC peers.
- ✓ More sales staff are recruited to conduct face-to-face promotion to physicians instead of simply contact regional distributors.
- ✓ Shift their focus of marketing from tier 1 cities to tier 2 and tier 3 cities, where the market is still far from saturation and with less competition.
- ✓ Close cooperation with leading KOLs or clinical training centers. Flying doctors and clinical training centers have significant influence over low level hospitals' brand selection.

Company	Microport	Lepu
Sales force staff	130+	190+
Distributors	120+	160+
Covered hospitals	976	877

# Implementation of portfolio diversification strategy to diminish the risk of being dependent on single product



***Thank You!***