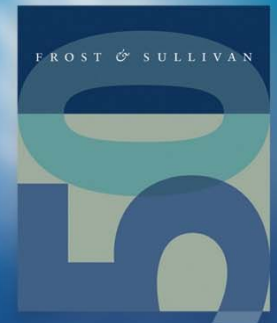


Overview of China medical device industry and analysis of implant product market

Frost Sullivan

Aaron Zhong



1

China medical device industry overview

2

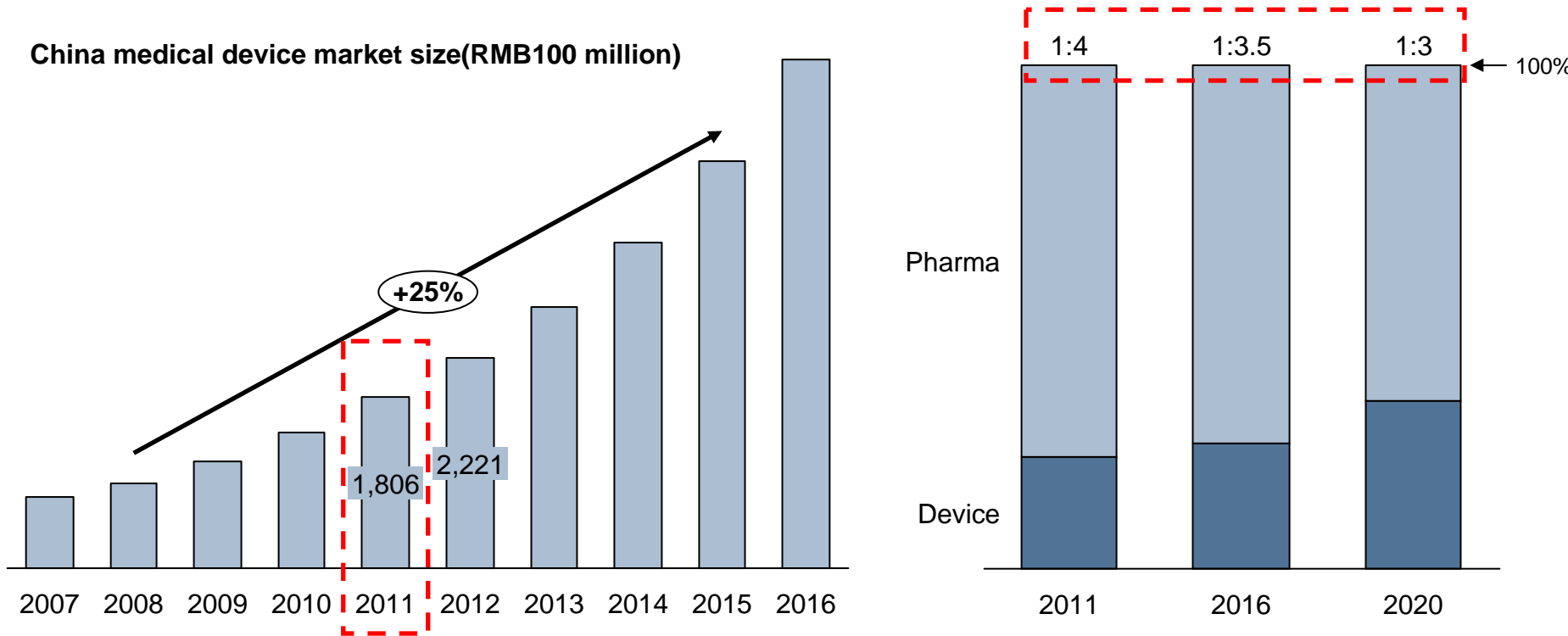
China implant product market analysis

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About Frost Sullivan



Historical and forecast of China medical device market

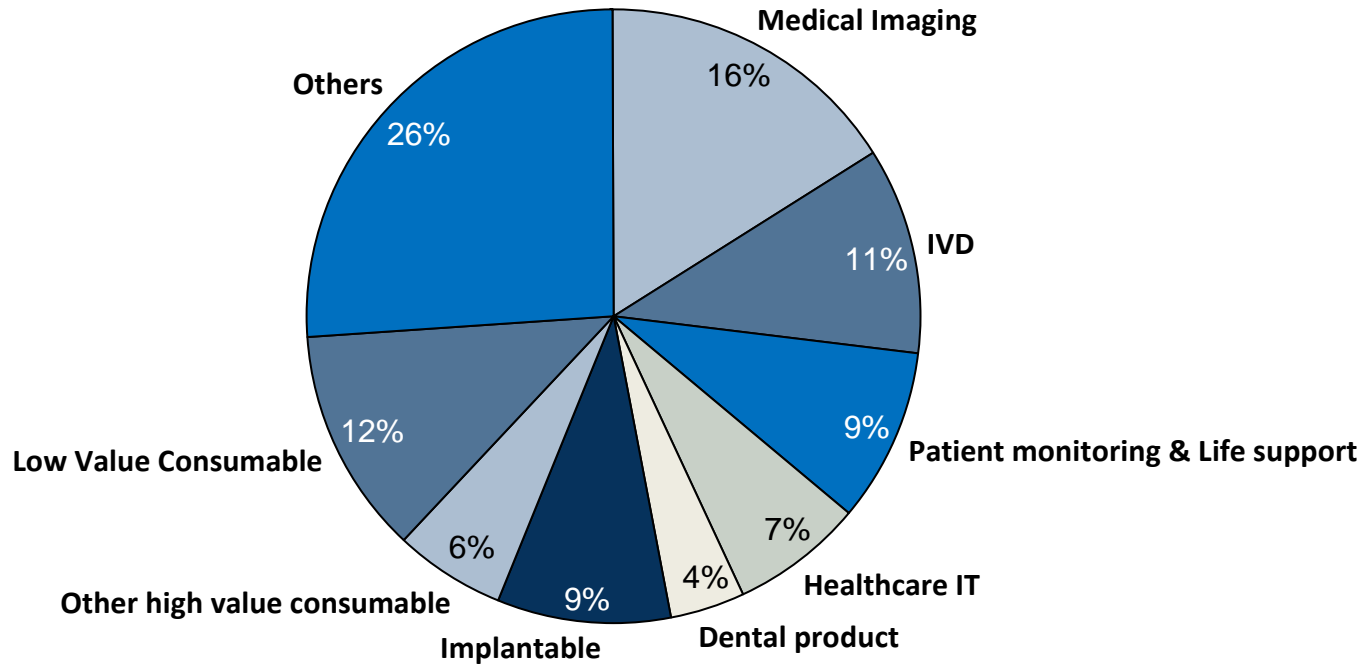


➤ Medical device sector in China is a RMB180bn market and is expected to grow at 25% CAGR in the next five years. It is growing faster than pharmaceutical market. The ratio of market size of device to pharma is expected to grow from 1:4 in 2011 to 1:3 in 2020.






































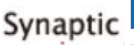







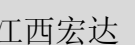
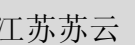
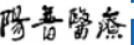









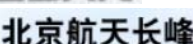









Breakdown of China medical device market

- Medical imaging is the largest segment which accounts for 16%. IVD and high value consumable segments are growing faster than other segments, especially the reagent and implant markets.

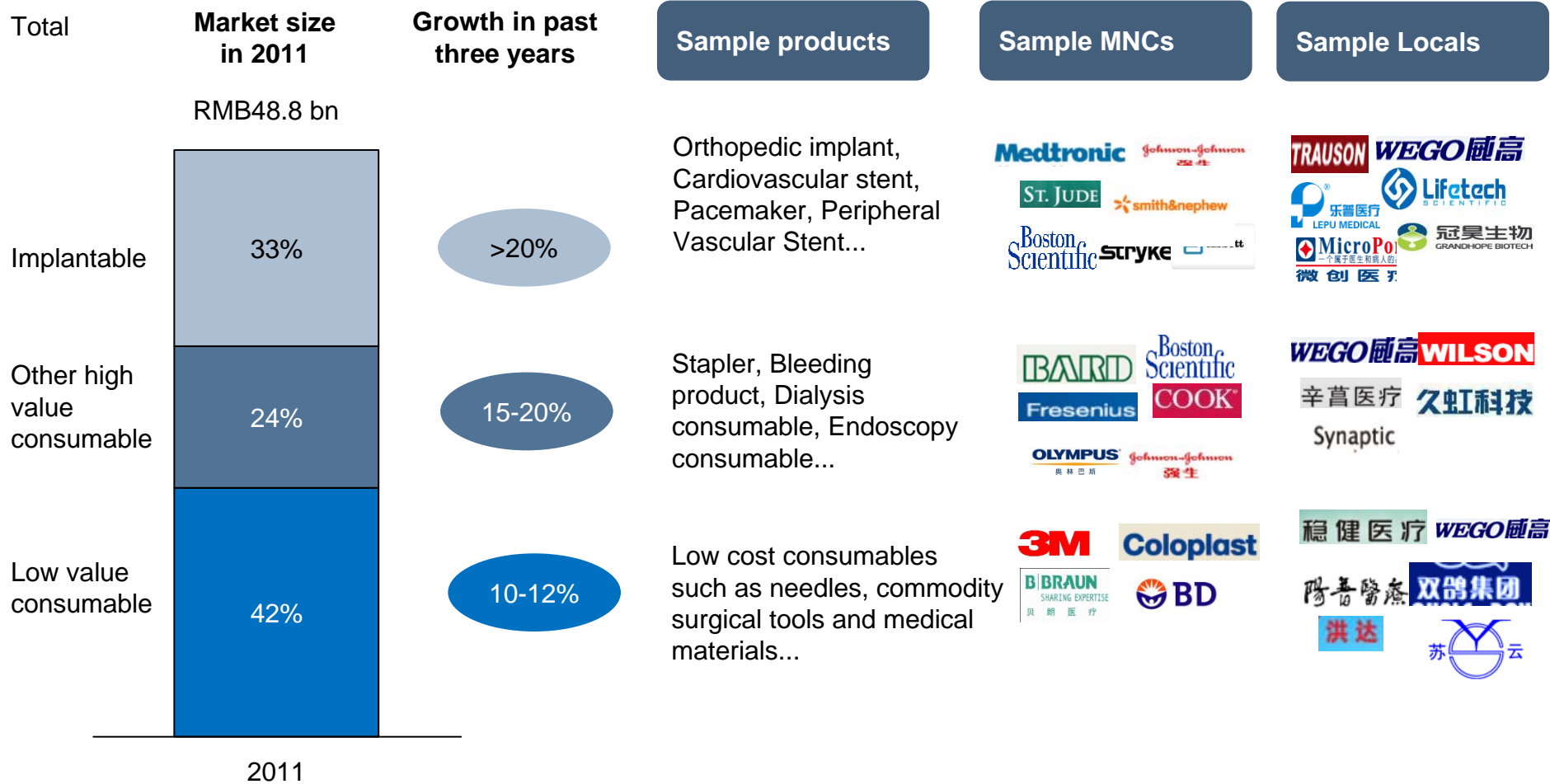
Breakdown of China medical device market in 2011



Sample MNC and local companies

Segment	Sample products	Sample MNCs	Sample Locals
Medical imaging	Ultrasound, CT, MRI, X-Ray, Nuclear imaging, DSA...	    	  
IVD	Immunoassay, Clinical Chemistry, Molecular Diagnostics, Hematology...	    	     
Implantable	Orthopedic implant, Cardiovascular stent, Pacemaker, Peripheral Vascular Stent...	     	   
Other high value consumable	Stapler, Bleeding product, Dialysis consumable, Endoscopy consumable...	     	    
Low Value Consumables	Low cost consumables such as needles, commodity surgical tools and medical materials...	   	   
Patient monitoring & Life support	Patient monitor, anesthesia machine, Ventilator, Operation Bed/Light & Ceiling Pendant ...	    	    
Healthcare IT	Hardware, HIS, PACS, LIS, EMR, Inpatient station...	   	    

Medical consumable sector



The uniqueness of China medical device market

1

Complicated market access issues

- Higher new product registration barrier
- Complex tendering and distribution process, which is significantly varied among provinces and cities, and even among hospitals within a city

2

Fragmented market environment

- Market concentration is low in the less-sophisticated product categories
- Intensified competition in the mid-low range segment

3

Lack of big leading company among local players

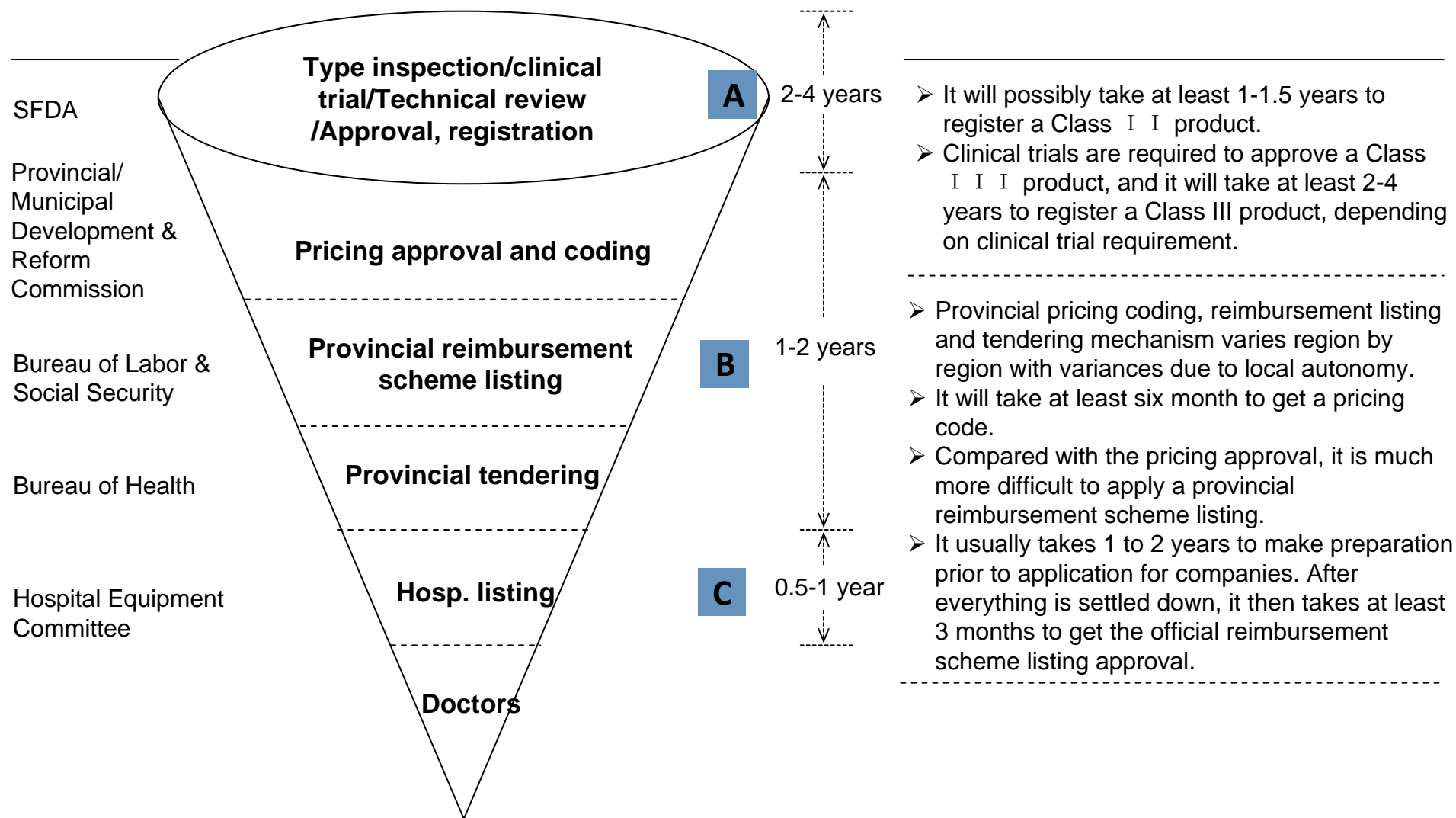
- Unlike the big device MNCs such as JNJ and Medtronic, most local players only cover 1-2 product categories
- The sales revenue of most local players are less than RMB50 million

4

Strong import substitution

- There is strong trend of import substitution with the increasing innovation capability of locals and governmental policy encouragement
- Leading local players are now turning to the high-end and technological sophisticated products where MNC take the majority of share

Tremendous time and efforts are required to sell the products into hospitals because of the prolonged and complex market access



- It will possibly take at least 1-1.5 years to register a Class I I product.
- Clinical trials are required to approve a Class I I I product, and it will take at least 2-4 years to register a Class III product, depending on clinical trial requirement.

- Provincial pricing coding, reimbursement listing and tendering mechanism varies region by region with variances due to local autonomy.
- It will take at least six month to get a pricing code.
- Compared with the pricing approval, it is much more difficult to apply a provincial reimbursement scheme listing.
- It usually takes 1 to 2 years to make preparation prior to application for companies. After everything is settled down, it then takes at least 3 months to get the official reimbursement scheme listing approval.

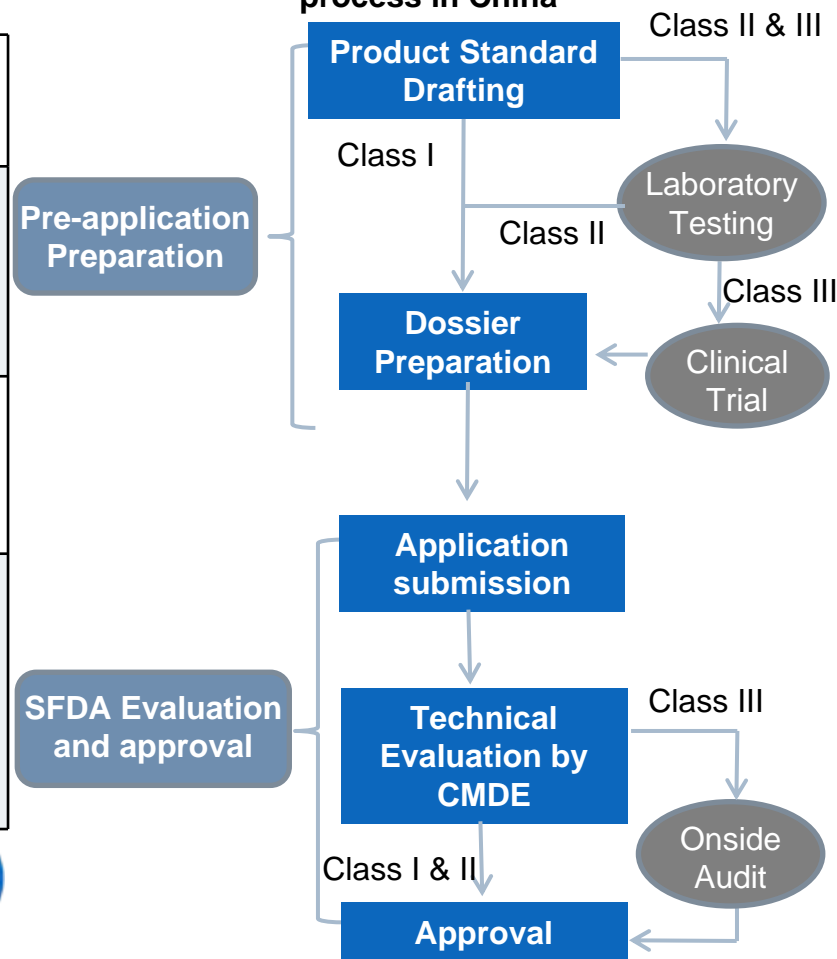
The process of new product registration exemplifies the difficulty of market access in China

A Product registration by product classification in China

Product Classification	Description	Safety Risk	Regulatory Approval Body	Time for registration process
III	Devices that are implanted into the human body to sustain and support life	High	State Food and Drug Administration (SFDA)	Minimal 3-4 years
II	Devices that have direct contact with the human body	Medium	Provincial level drug administrators	1.5-2years
I	Devices that can be proved safe and effective through traditional and routine tests	Low	City level drug administrators	1years

Certificate renewal is also required every four years

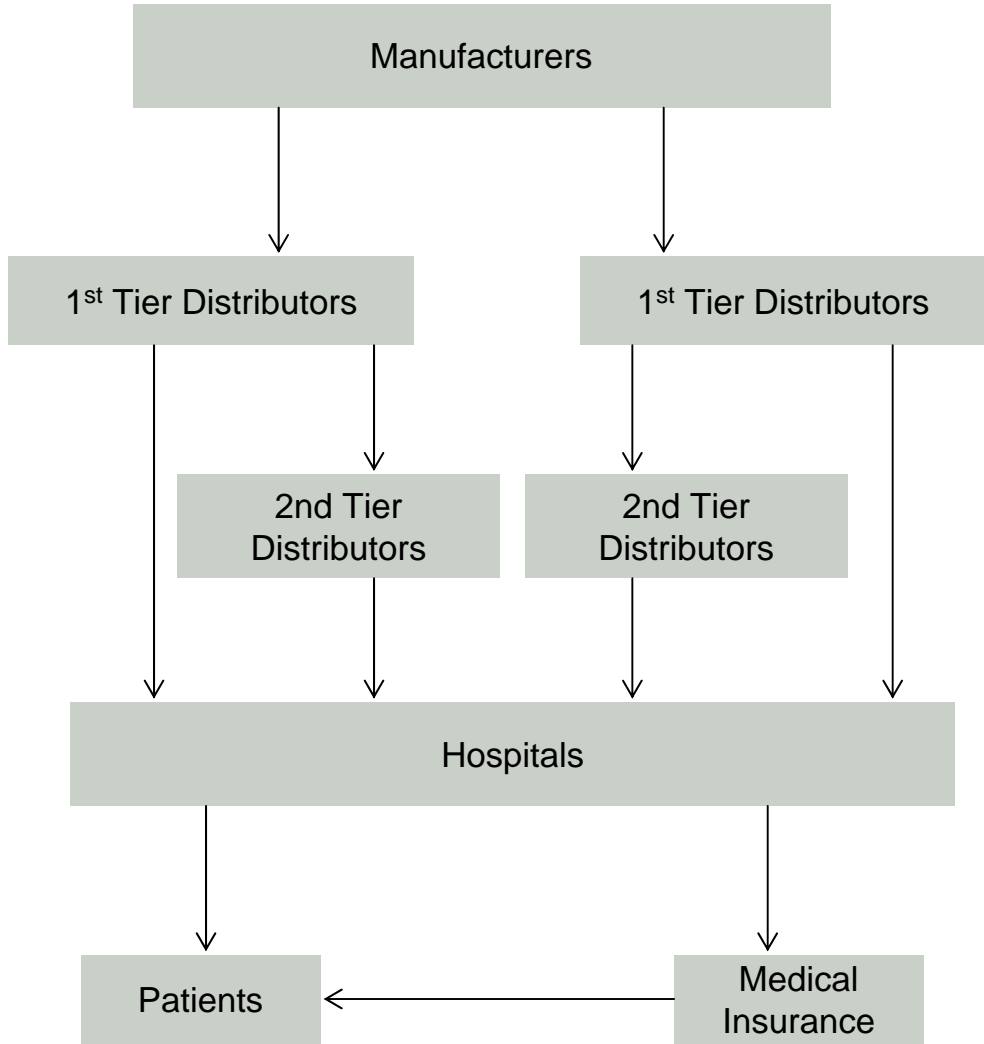
Typical R&D/product registration process in China



CMDE: Center of Medical Device Evaluation, a subsidiary of SFDA

The medical products distribution system is another source of complexity

B



Most medical product manufacturers choose distributor channel mode. Distributors are usually divided into two tiers covering different areas.

1st tier distributors are in charge of the provincial pricing, reimbursement listing and tendering. Apart from the provincial level affairs, they are also responsible for the hospital tendering in the cities/areas where they have strong relationships with hospitals.

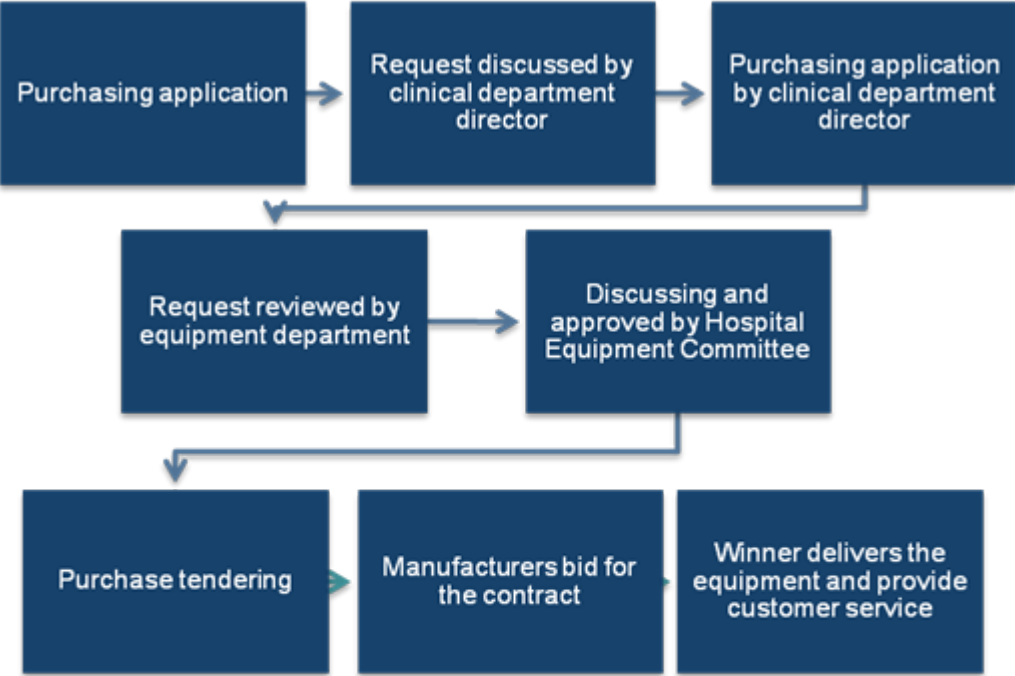
2nd tier distributors are responsible for cities where 1st tier distributors do not have capability to cover.

It also takes tremendous time and efforts to sell the products into hospitals

C

Hospital Purchasing Procedure

Key points description



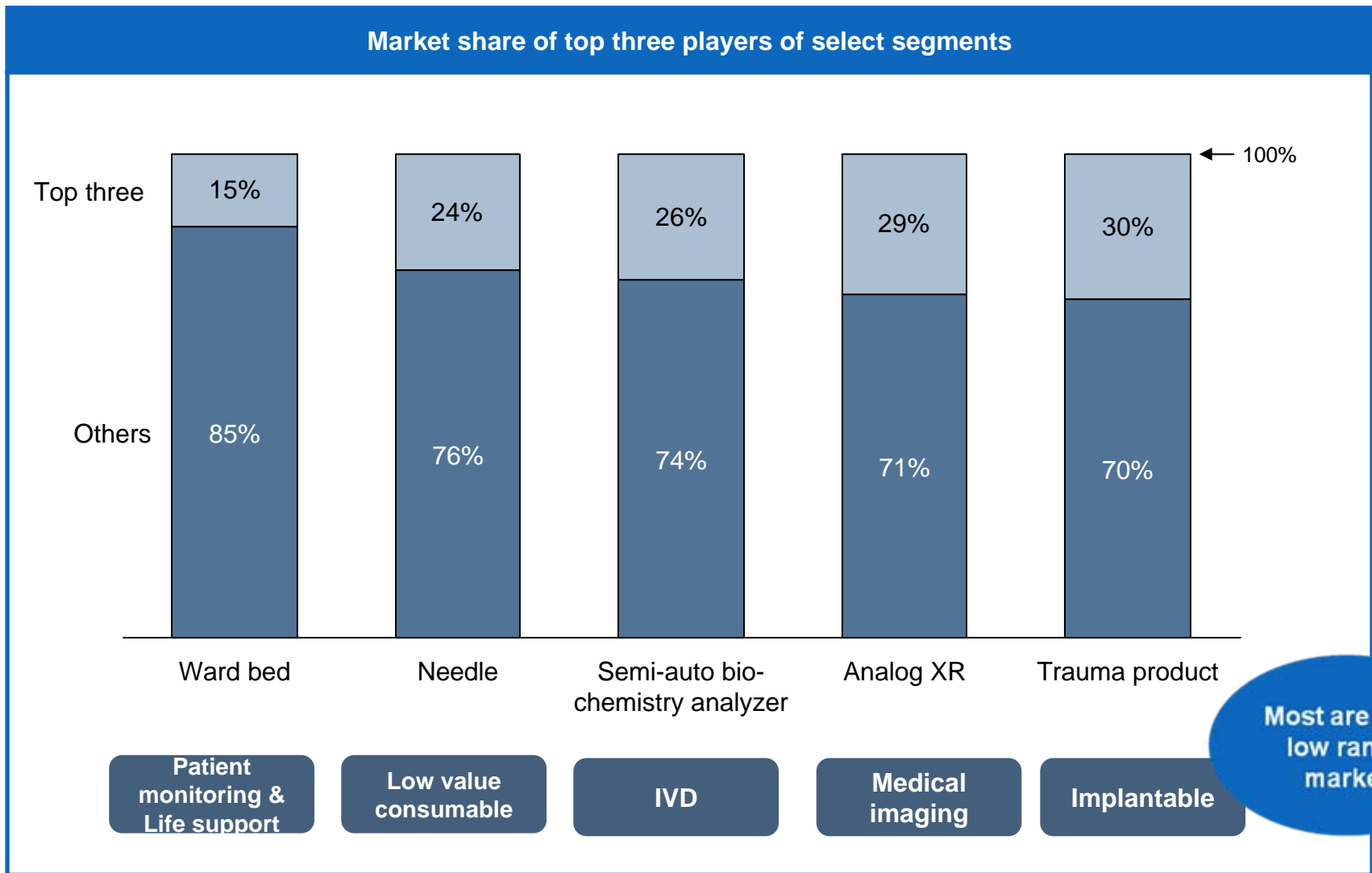
The key opinion leader in clinical department has influential impact on brand choice, esp. the non-vascular stent.

The equipment department directors play an extremely important role in the determination of low-value consumable purchase. In some hospitals, clinical departments do not have rights to apply for consumable procurement, which is firmly controlled solely by equipment department directors.

Both company reputation and good relationship with the hospital play important roles in this process. Hospitals tend to select the brands they have already used before,

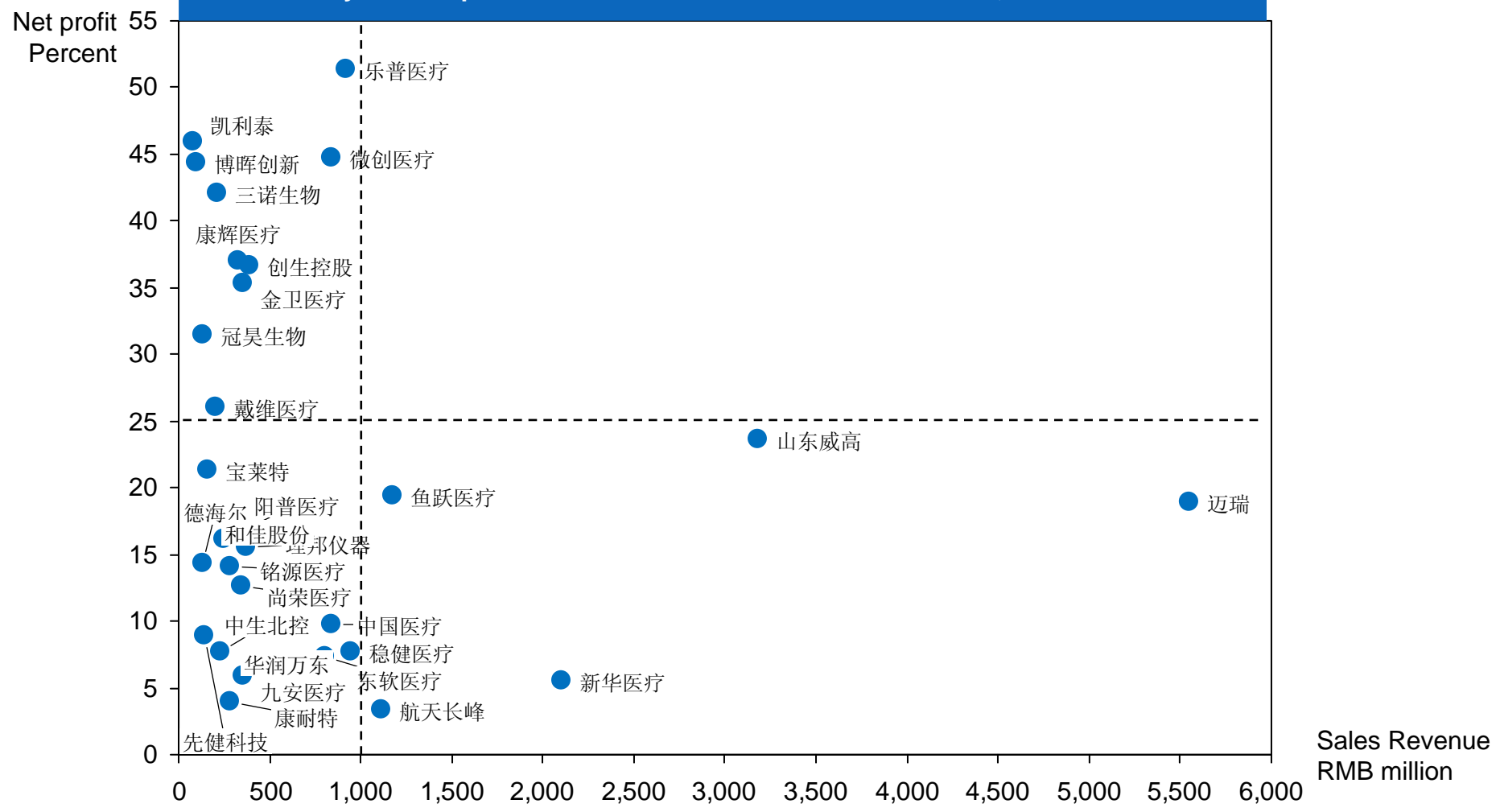
Doctors play important role in the brand choice and patients usually comply with doctors' advice due to the high professionalism in endoscopy area.

Examples of segments where the market concentration is low

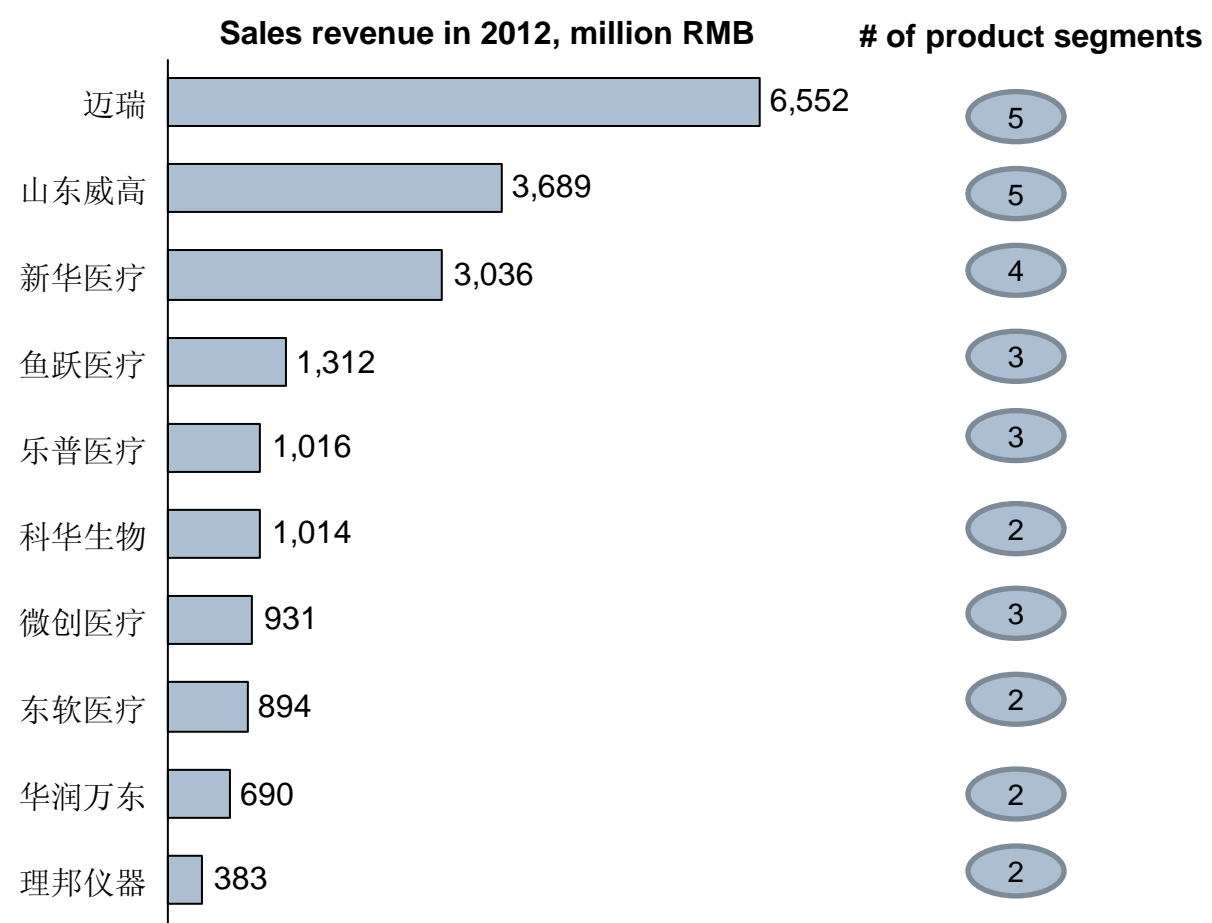


Overview of the top 30 listed local companies

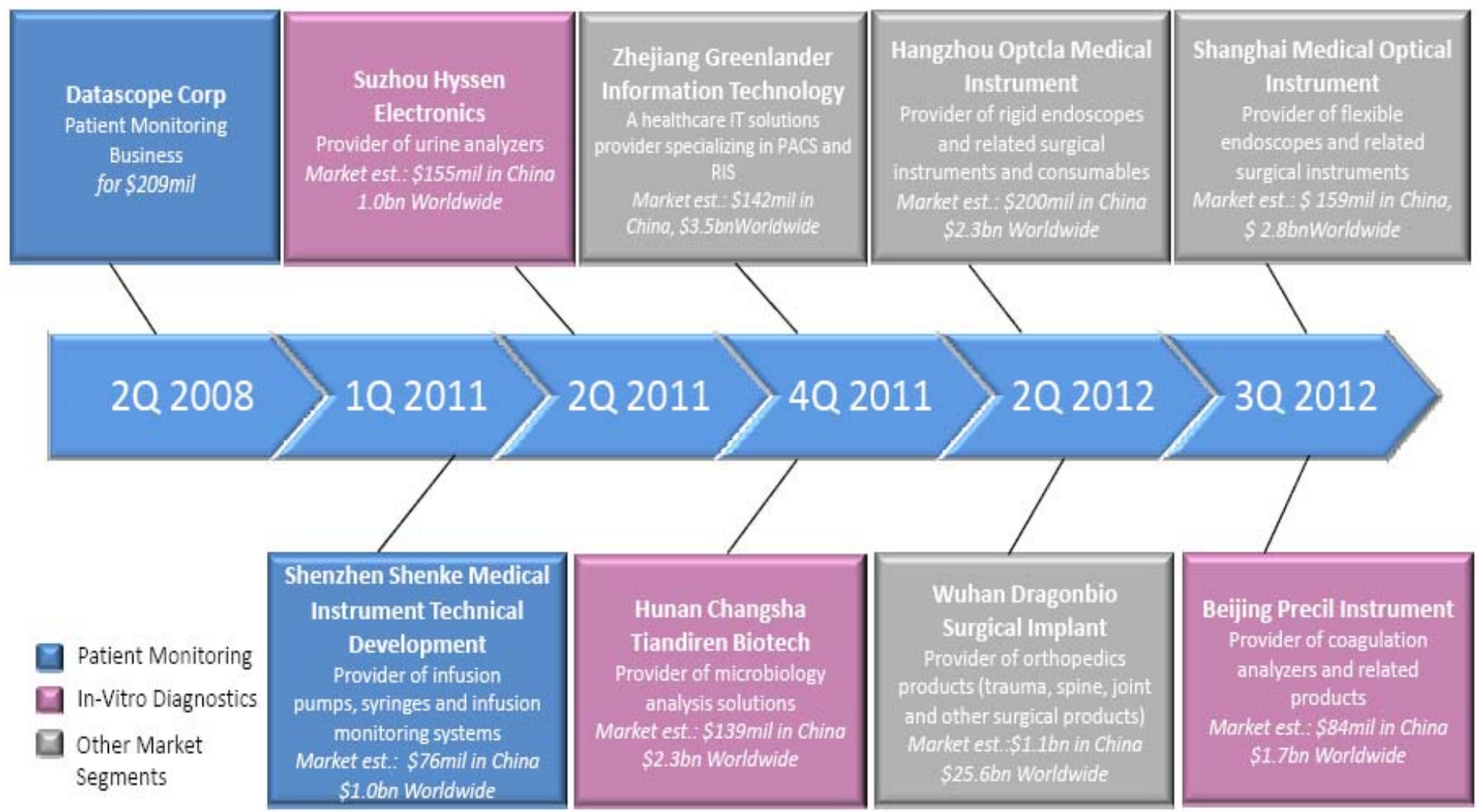
Only six companies have sales revenue more than RMB1,000 million.



Overview of the top 30 listed local companies

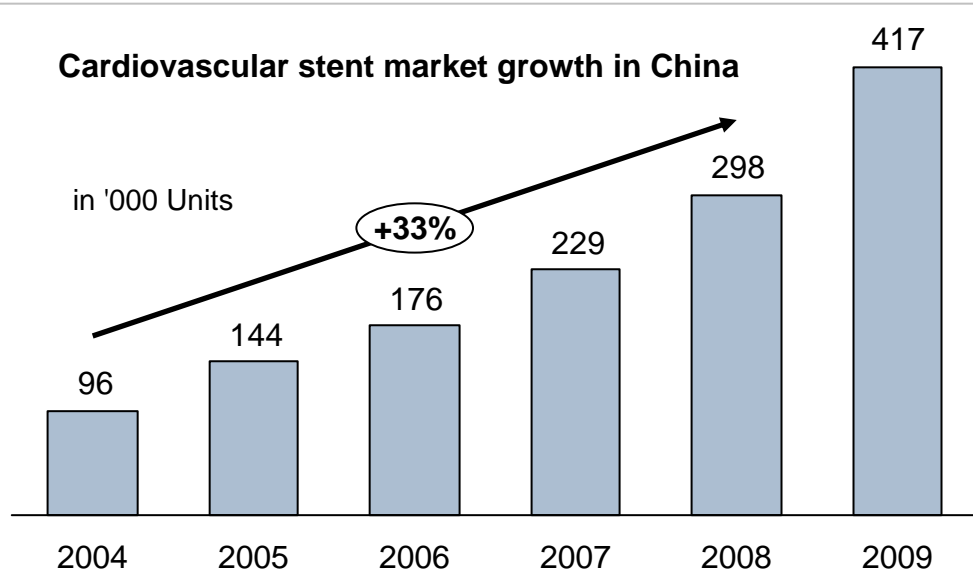


Mindray M&A road map

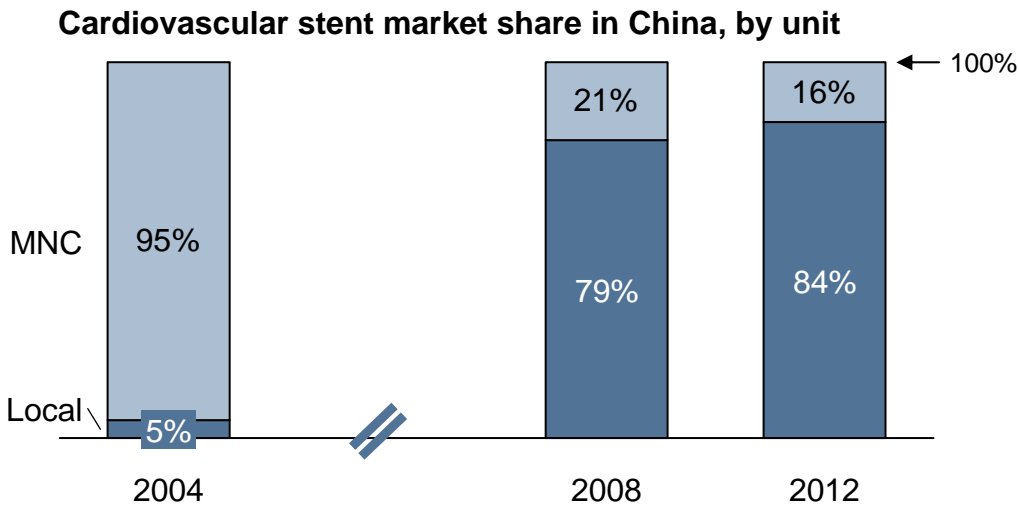


Examples of medical products sub-segments where local players have built leadership positions

➤ China cardiovascular stents market used to be a very small market in 2004 and has witnessed very strong growth driven by the increasing adoption of PCI (minimally invasive operation for coronary) and large demand from increasing patients with cardiovascular disease.



➤ There is strong trend of import substitution. Top three local firms in China are well positioned to meet the local demand with value products and better local knowhow compared with the MNCs. Therefore they successfully gained market share from MNCs during the period and benefited most from the market growth.



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China medical device industry overview

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China implant product market analysis

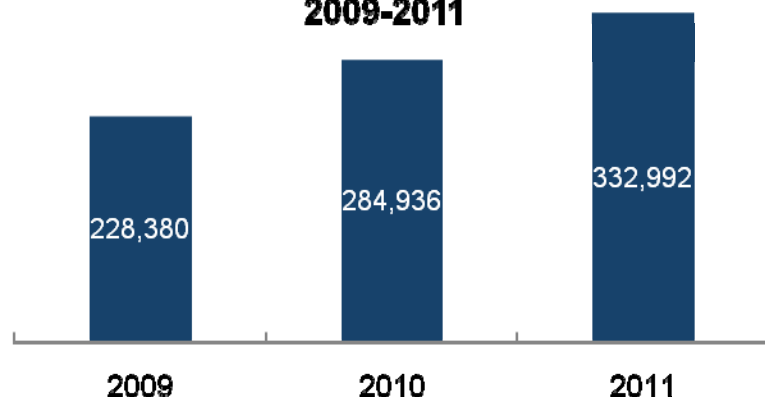
- **Cardiovascular stent**
- Orthopedic implant

3

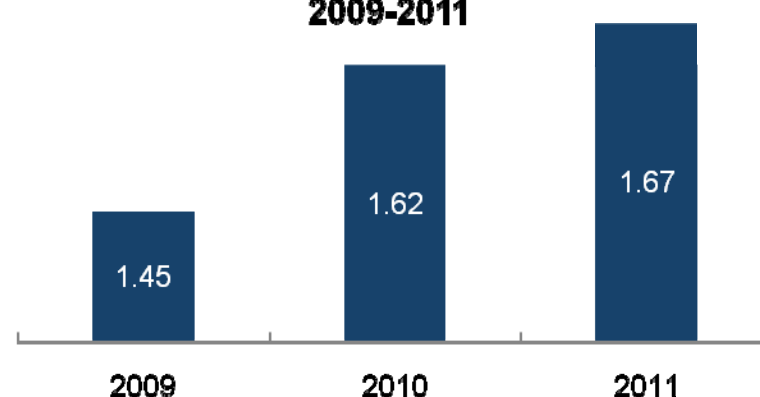
About Frost Sullivan

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

**Number of PCI procedures In China
2009-2011**

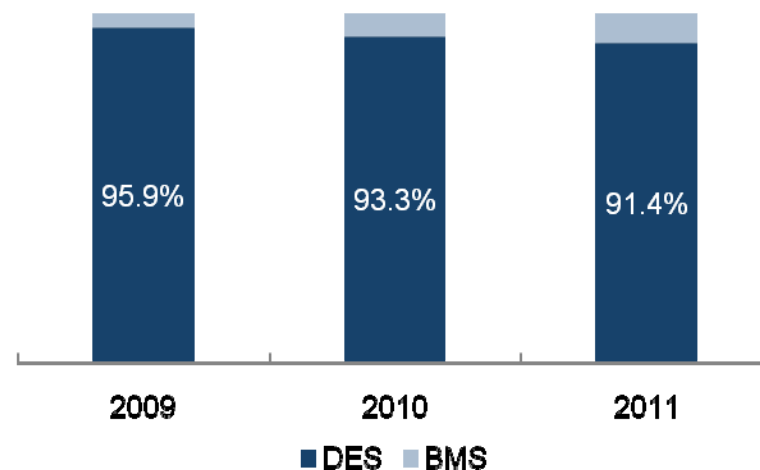


**Average Number of Stents Implanted
2009-2011**

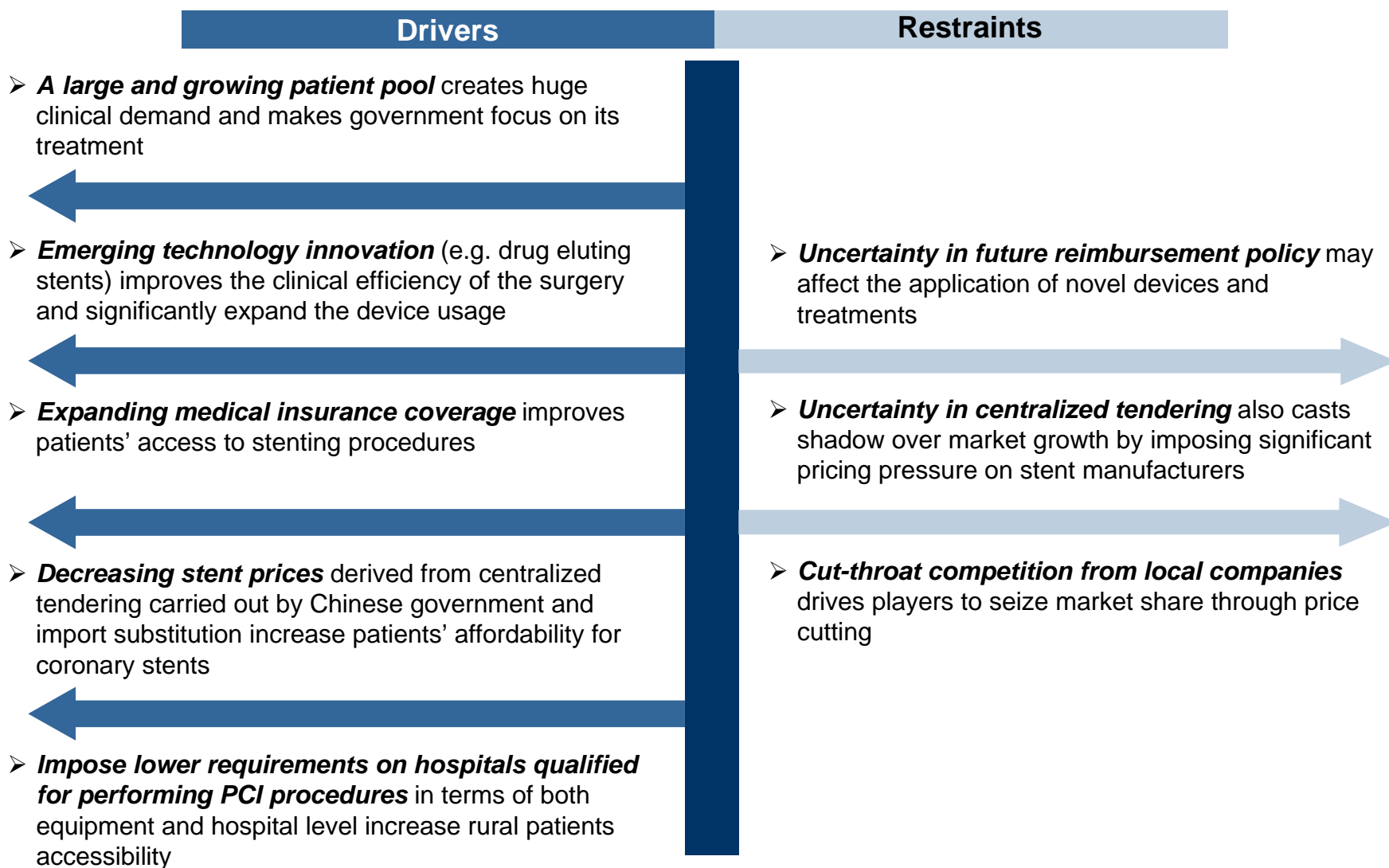


- Both the number of PCI procedures performed and average stents implanted in each case increased over the last 3 years.
- PCI procedures reached 332,992 in 2011, with a CAGR of **21%** during 2009 and 2011.
- The number of PCI procedures performed in China is expected to keep rising at a growth rate **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.

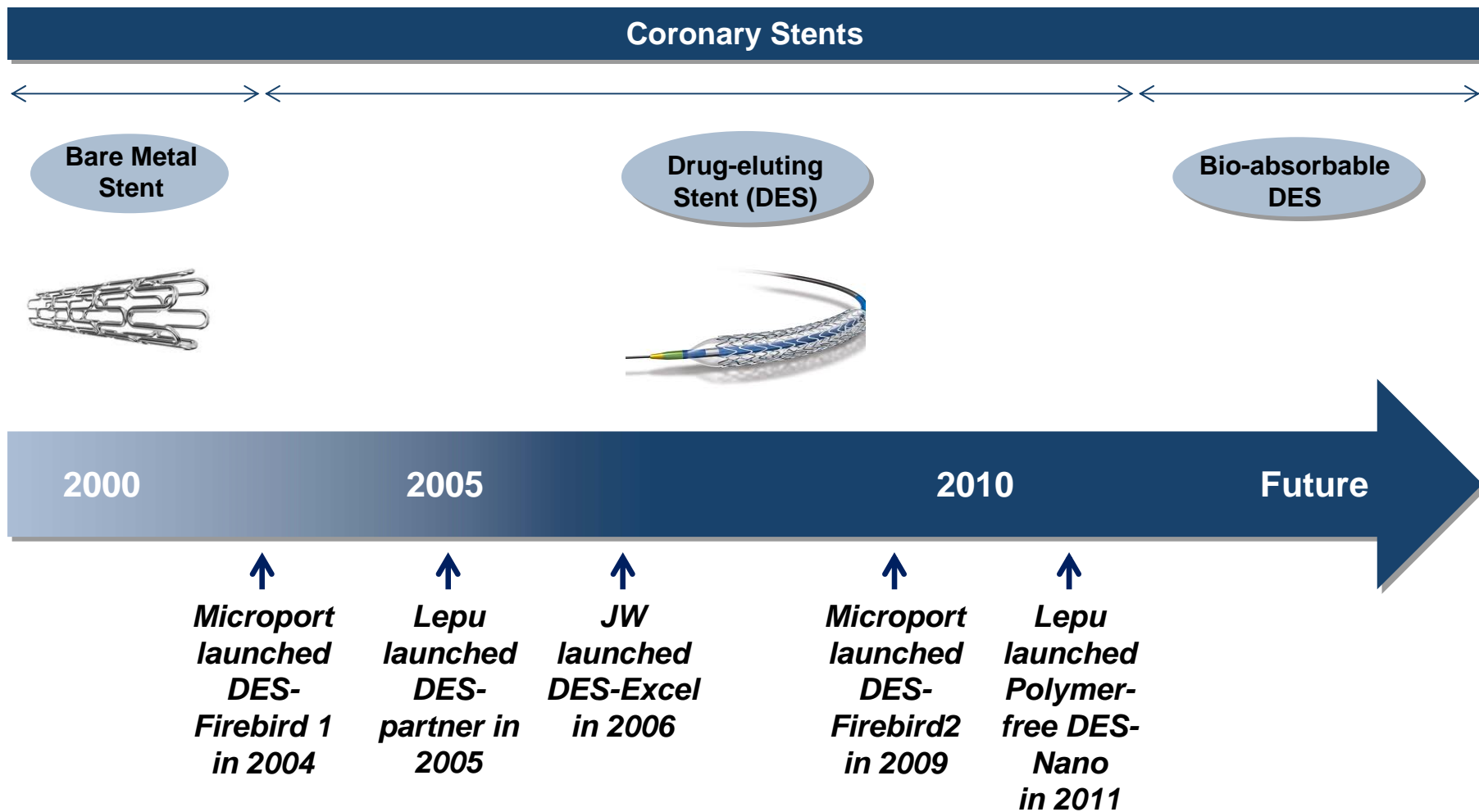
**Share of DES over BMS
2009-2011**



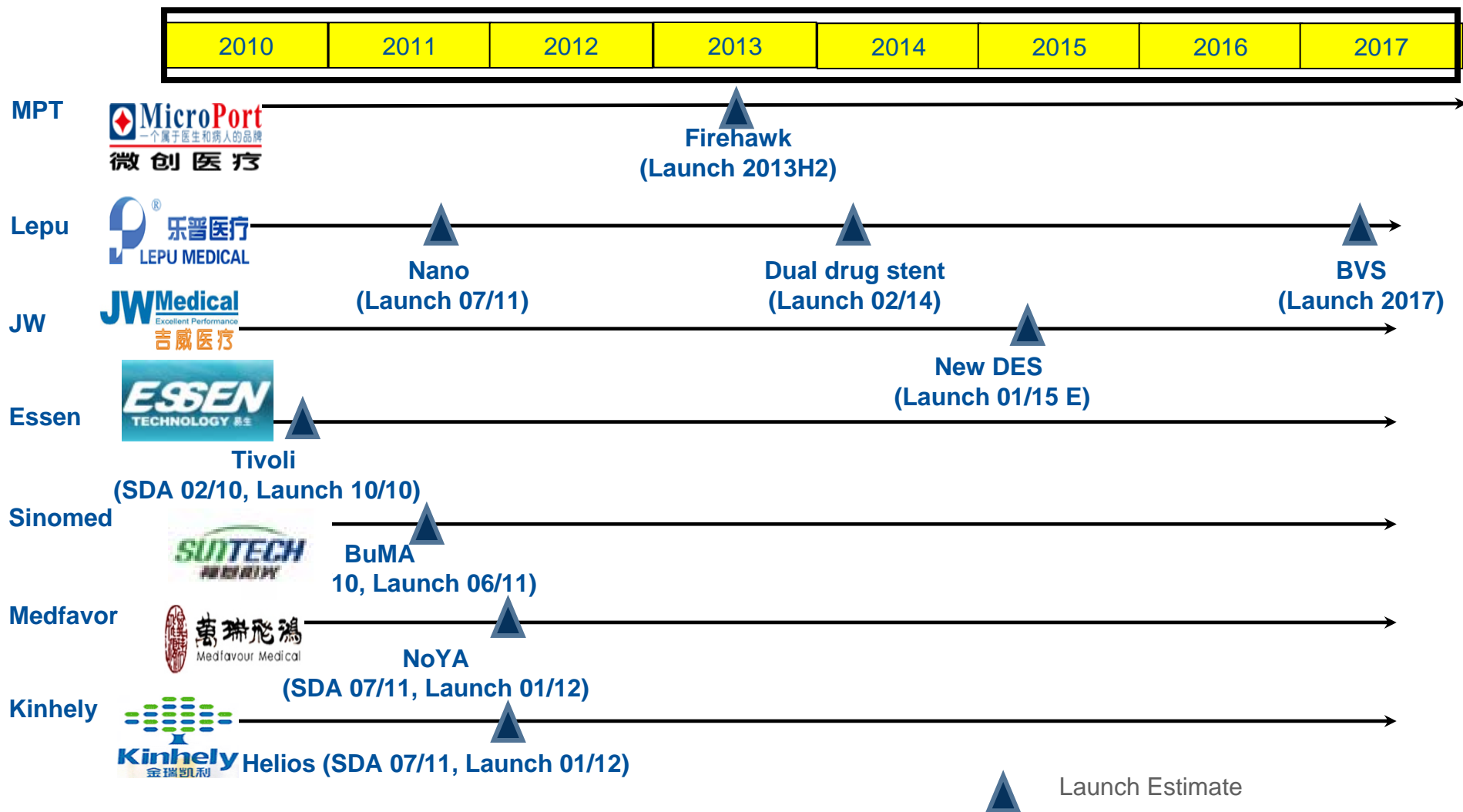
Market Drivers and Restraints



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



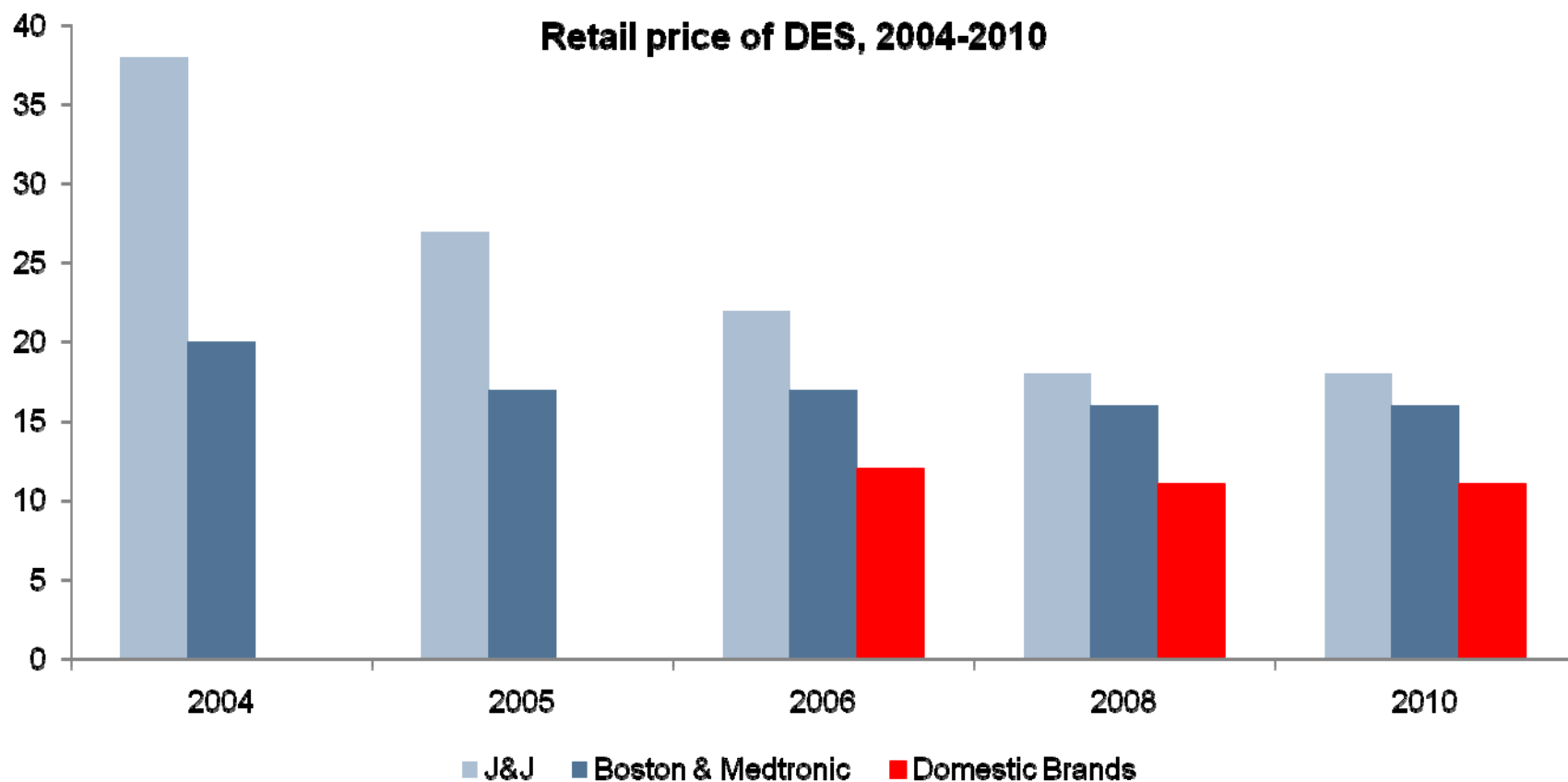
China Local DES approval time



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

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



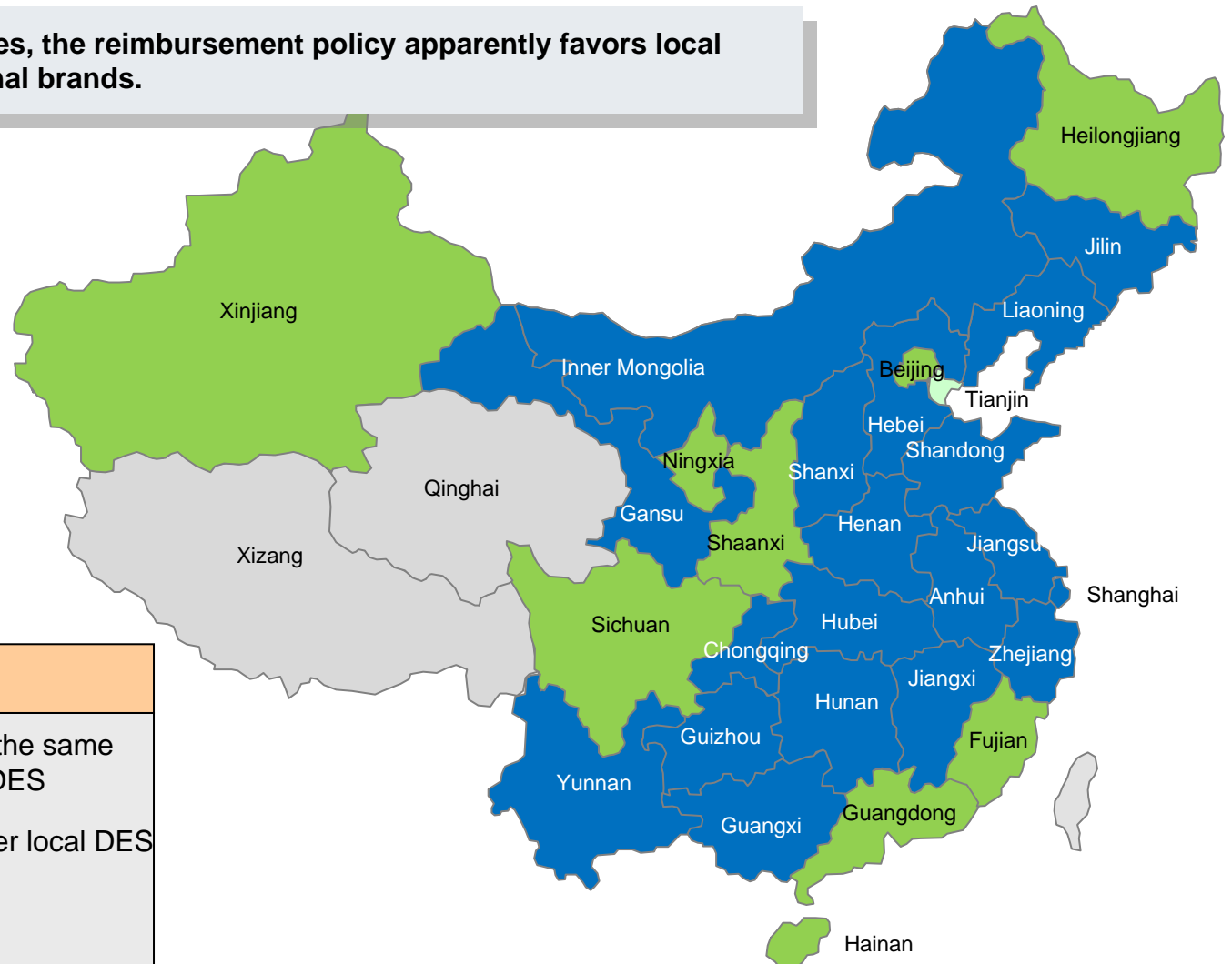
- DES has become more and more affordable to Chinese patients due to sharply decreasing retail prices and expanding medical insurance coverage.

Centralized tendering had made great success in price cutting

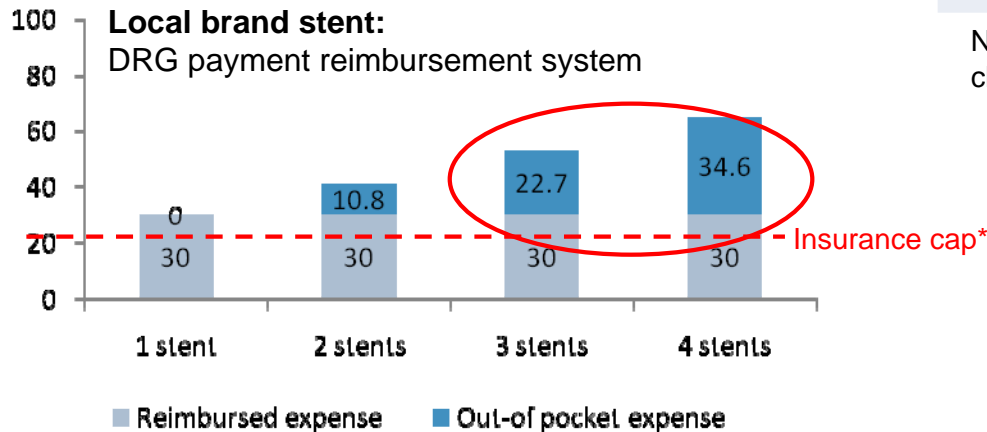
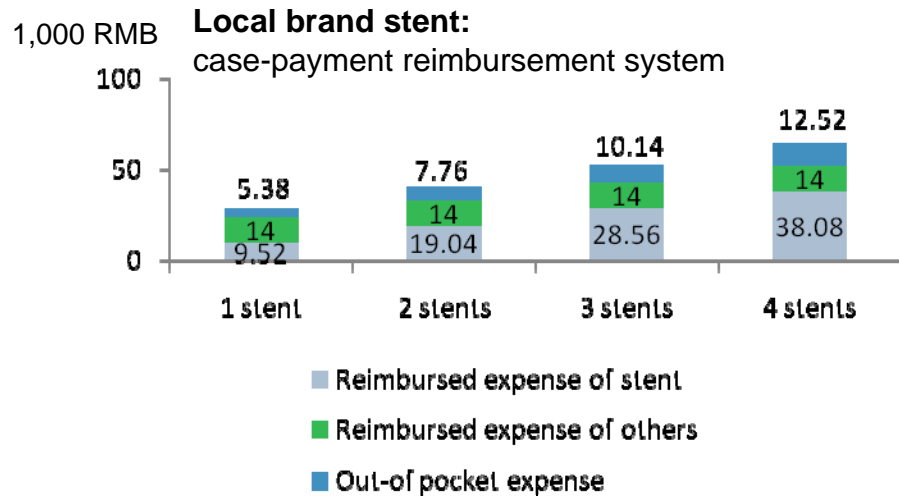
Time	Key Event	% of price cuts (price hospitals charges to patients)	Local brands listed in the tender
Beginning of 2005 and 3Q 2006	Price cap were set by government in 8 provinces and municipalities. And hospitals and healthcare institutions in other provinces generally followed the prices in these eight provinces and municipalities.	29% for J&J, but 15% for Medtronic and Boston Scientific.	Firebird1, Partner, Excel
3Q 2008	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
4Q 2010	In 2010, MOH announced no nationwide tender will be held this year due to budget reason, and tender will be conducted at provincial level.		
3Q 2012	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.

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



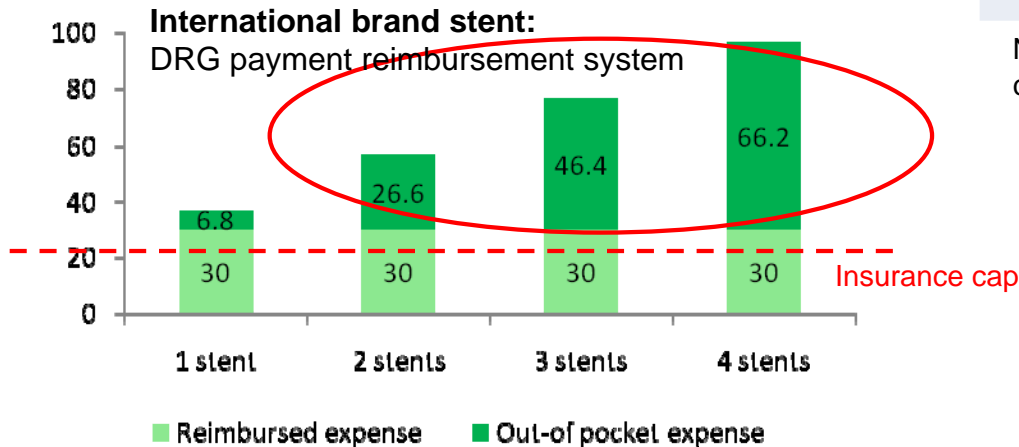
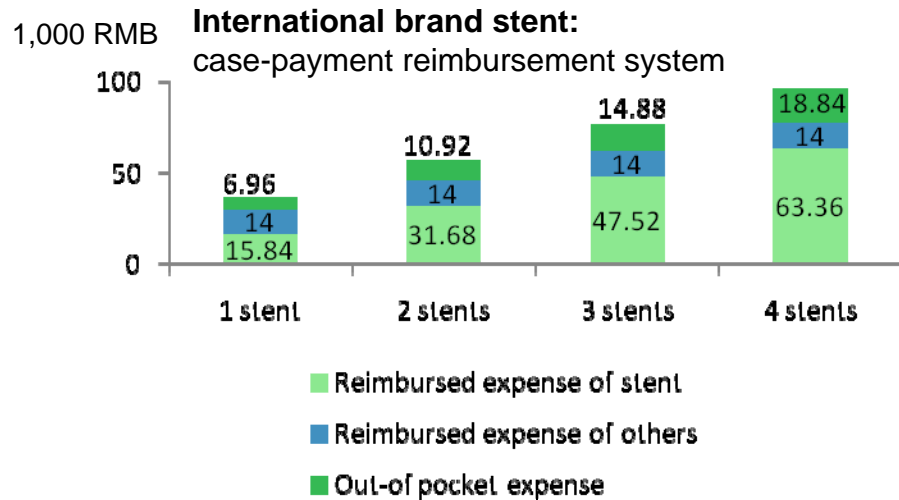
Local brand	1,000 RMB	Coverage
One stent cost	10.8	
After hospital mark-up @ 10%	11.9	
# of stent per PCI	1	
Total stent cost	11.9	80%
Other PCI materials cost	10	80%
Service fee	2	100%
Drug cost	5	80%
Total cost	28.9	
Reimbursed expense of stent	9.52	
Reimbursed expense of others	14	
Out-of-pocket expenses	5.38	

Note: Suppose the change of PCI cost is only correlated to the change of the number of stent per procedure.

➤ Once the government implements DRG policy and sets the insurance cap, patients' out-of-pocket expenses increase dramatically if more than two stents are implanted per PCI, imposing stringent control to the number of stent per PCI.

*Note: The diagnosis related group (DRG) payment policy will set an insurance cap per PCI procedure. The insurance cap is supposed to be 30,000RMB.

DRG policy may further impose pricing pressure on international brands



International brand	1,000 RMB	Coverage
One stent cost	18	
After hospital mark-up @ 10%	19.8	
# of stent per PCI	1	
Total stent cost	19.8	80%
Other PCI materials cost	10	80%
Service fee	2	100%
Drug cost	5	80%
Total cost	36.8	
Reimbursed expense of stent	15.84	
Reimbursed expense of others	14	
Out-of pocket expense	6.96	

Note: Suppose the change of PCI cost is only correlated to the change of the number of stent per procedure.

➤ The insurance cap policy will have greater impact on international brand stents due to their high prices.

➤ The out-of-pocket fee will rise sharply once more than one stent is used.

*Note: The diagnosis related group (DRG) payment policy will set an insurance cap per PCI procedure. The insurance cap is supposed to be 30,000RMB.

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.

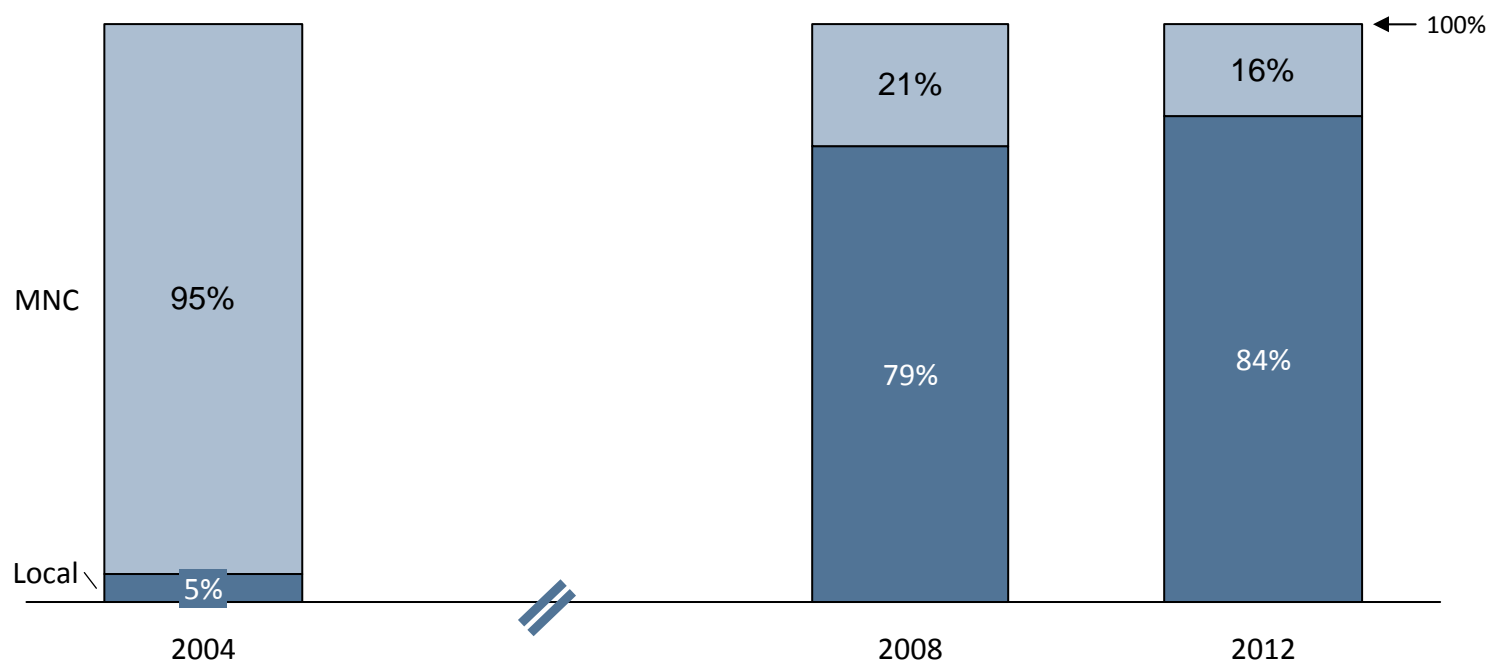
The avenues for success in the coronary stent market indicate a strong consumer demand for high quality devices with the most features. The broader the device capabilities, the more diverse range of disease states clinicians are able to address. Given that the coronary stent market only has a few players, 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.

Accelerated import substitution makes DES more affordable to Chinese patients

Cardiovascular stent market share in China, by unit



- 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.

1

China medical device industry overview

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China implant product market analysis

- Cardiovascular stent
- **Orthopedic implant**

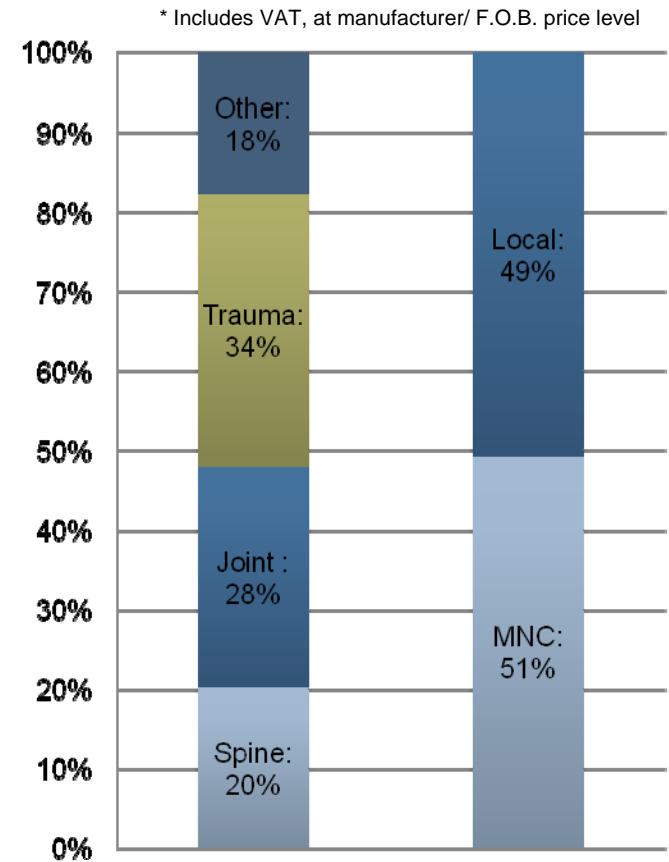
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About Frost Sullivan

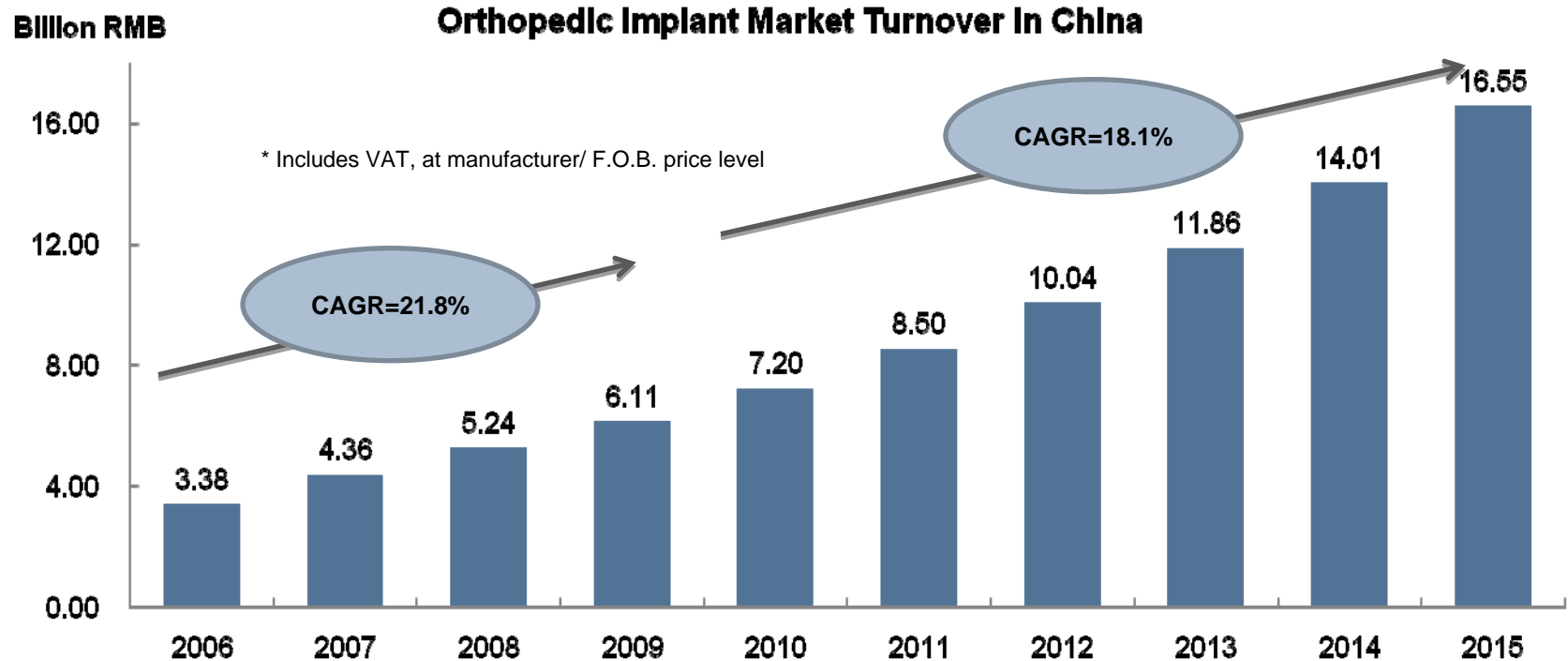
China Orthopedic Market Overview

- China's orthopedic implant market is expected to maintain the highest growth rate in the world, as a result of a large patient population, high fracture incidences, development of surgical facilities and improvement in patients affordability.
- Orthopedic implants are defined as Class III medical devices with highest risk for patients, and face a strict supervision by the China State Food and Drug Administration (SFDA).
- In China, orthopedic implant market can be categorized into trauma, spine, joint and other niche surgical materials. Trauma surgeries are widely adopted by large and middle-scale hospitals in both urban and rural areas, while spine and joint surgeries are concentrated in large urban hospitals.
- In China, doctors can identify import or local brands clearly, but most of them have a weak awareness of certain brands, even for leading brands, according to Frost & Sullivan interviews. Local and MNC brands had approximately 50/50 market share in 2009, based on the turnover in manufacturer/ F.O.B. price.

Snapshot of China Orthopedic Market



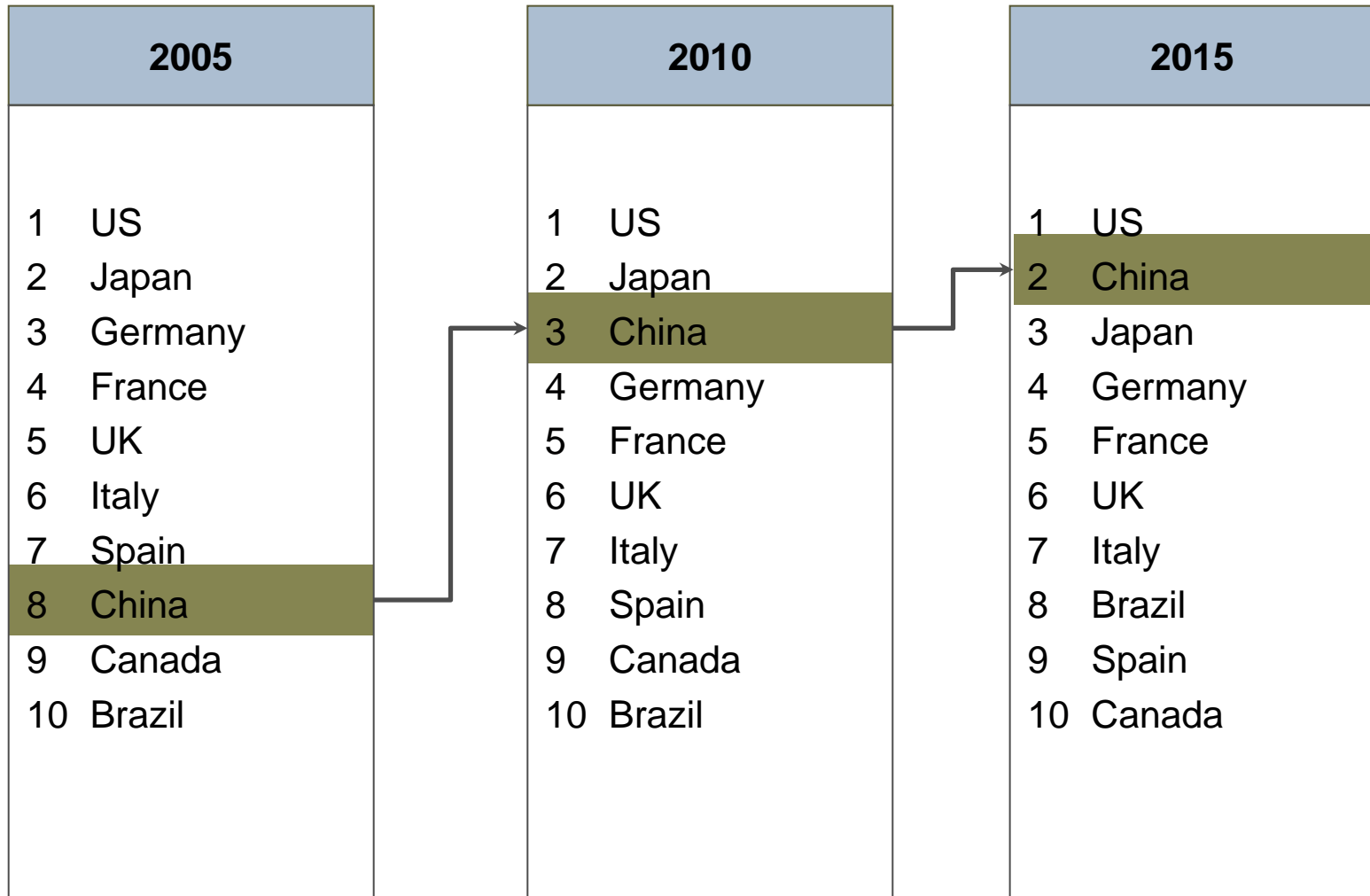
China Orthopedic Implant Market Dynamic (2006-2015)



* Includes VAT, at manufacturer/ F.O.B. price level

- China's orthopedic implant market reached RMB 6.11 billion in 2009, grew from 5.24 billion in 2008. In the next years, this market is expected to continue to grow at a 18.1% CAGR in next five years, and predicted by Frost & Sullivan to surpass Japan market in 2014 and 2015.

Chinese Orthopedic Market Ranking in Global Market



Major Factors to Drive Market

High Medical Needs

Aging population

Senior citizens over 60 have accounted for over 10% in Chinese population since 2005, according to official statistics data. These aging population will be a major reason for the high prevalence of fractures by osteoporosis, degenerative diseases, and arthritis, increasing the number of orthopedic surgeries in the next several years.

Economic Growth

Steady economic growth helps increase the number of car ownership, which can become a major cause for injuries in traffic accidents and trauma surgeries. In addition, urbanization trend causes more work injury accidents, increasing needs for trauma surgeries.

Surgical Facilities Development

Health Reform

In 2009, the Chinese government announced a huge healthcare reform plan and 850 billion RMB investment to develop healthcare infrastructure. According to this governmental program, each county in China should own a standard hospital network to meet basic medical needs, and greatly improve local surgery capacity including common orthopedic surgeries.

Development in Large Cities

Some large cities published their medical development plans in recent years, aiming to build regional clinical centers even Asia clinical center, such as in Shanghai. Under these plans, some state-of-the-art hospitals will be developed treat those most complicated diseases, which also include orthopedic surgeries.

Medical Insurance Improvements

Health Reform

In China's official health reform plan, 3 public medical insurance system have been established to provide a universal coverage for both urban and rural residents. This will help Chinese citizens to substantially improve the affordability of medical surgery.

Private insurance

Patients who have trauma fixation surgery may benefit from other insurance in China, such as unforeseen accident insurance and collision insurance. A development of Chinese insurance industry will help to improve the affordability of trauma fixation surgery and access to some orthopedic surgeries.

Trauma Patient Flow in China

	2008	2014	2020	Key drivers for growth
Injury by accidents	<ul style="list-style-type: none"> • 4.1% of total population • ~55M 	<ul style="list-style-type: none"> • 4.6% of total population • ~64M 	<ul style="list-style-type: none"> • 5.2% of total population • ~75M 	<ul style="list-style-type: none"> • Increasing car ownership • Aging population • Mass infrastructure construction • Improvement on healthcare access and affordability • Increase in hospital and development of healthcare network • Increase in hospital wards and beds • Improvement of surgeons training and awareness • Improvement of hospital facilities
Seeking Treatment	<ul style="list-style-type: none"> • 62% of total injuries • ~34M 	<ul style="list-style-type: none"> • 73% of total injuries • ~47M 	<ul style="list-style-type: none"> • 88% of total injuries • ~66M 	
Hospitalization	<ul style="list-style-type: none"> • 31% of total visits • ~10M 	<ul style="list-style-type: none"> • 36% of total visits • ~17M 	<ul style="list-style-type: none"> • 44% of total visits • ~29M 	
Surgical Candidates	<ul style="list-style-type: none"> • 32% of inpatients • 3.4M 	<ul style="list-style-type: none"> • 34% of inpatients • 5.7M 	<ul style="list-style-type: none"> • 34% of inpatients • 9.5M 	
Surgical Patients	<ul style="list-style-type: none"> • 45% of total candidates • 1.5M 	<ul style="list-style-type: none"> • 58% of total candidates • 3.3M 	<ul style="list-style-type: none"> • 75% of total candidates • 7.1M 	

Source: Literature, Frost & Sullivan primary research and estimate

Spine Patient Flow in China

	2008	2014	2020	Key drivers for growth
Disease Prevalence	<ul style="list-style-type: none"> • 1.3% of total population • ~17M 	<ul style="list-style-type: none"> • 1.7% of total population • ~25M 	<ul style="list-style-type: none"> • 2.7% of total population • ~38M 	<ul style="list-style-type: none"> • Aging society • Changing lifestyle • Spine trauma due to accidents • Improvement of healthcare access and affordability • Development of hospital increase and healthcare network • Increase of hospital wards and beds • Surgeons training and awareness rising • Improvement of hospital facilities
Seeking Treatment	<ul style="list-style-type: none"> • 30% of total patients • ~5.2M 	<ul style="list-style-type: none"> • 40% of total patients • ~10M 	<ul style="list-style-type: none"> • 54% of total patients • ~21M 	
Surgical Candidates	<ul style="list-style-type: none"> • 22% of total visits • ~1.1M 	<ul style="list-style-type: none"> • 23% of total visits • ~2.3M 	<ul style="list-style-type: none"> • 24% of total visits • ~5M 	
Surgical Patients	<ul style="list-style-type: none"> • 28% of total candidates • 0.3M 	<ul style="list-style-type: none"> • 36% of total candidates • 0.84M 	<ul style="list-style-type: none"> • 49% of total candidates • 2.4M 	
Implant users	<ul style="list-style-type: none"> • 56% of total surgeries • 0.17M 	<ul style="list-style-type: none"> • 57% of total surgeries • 0.48M 	<ul style="list-style-type: none"> • 57% of total surgeries • 1.37M 	

Source: Literature, Frost & Sullivan primary research and estimate

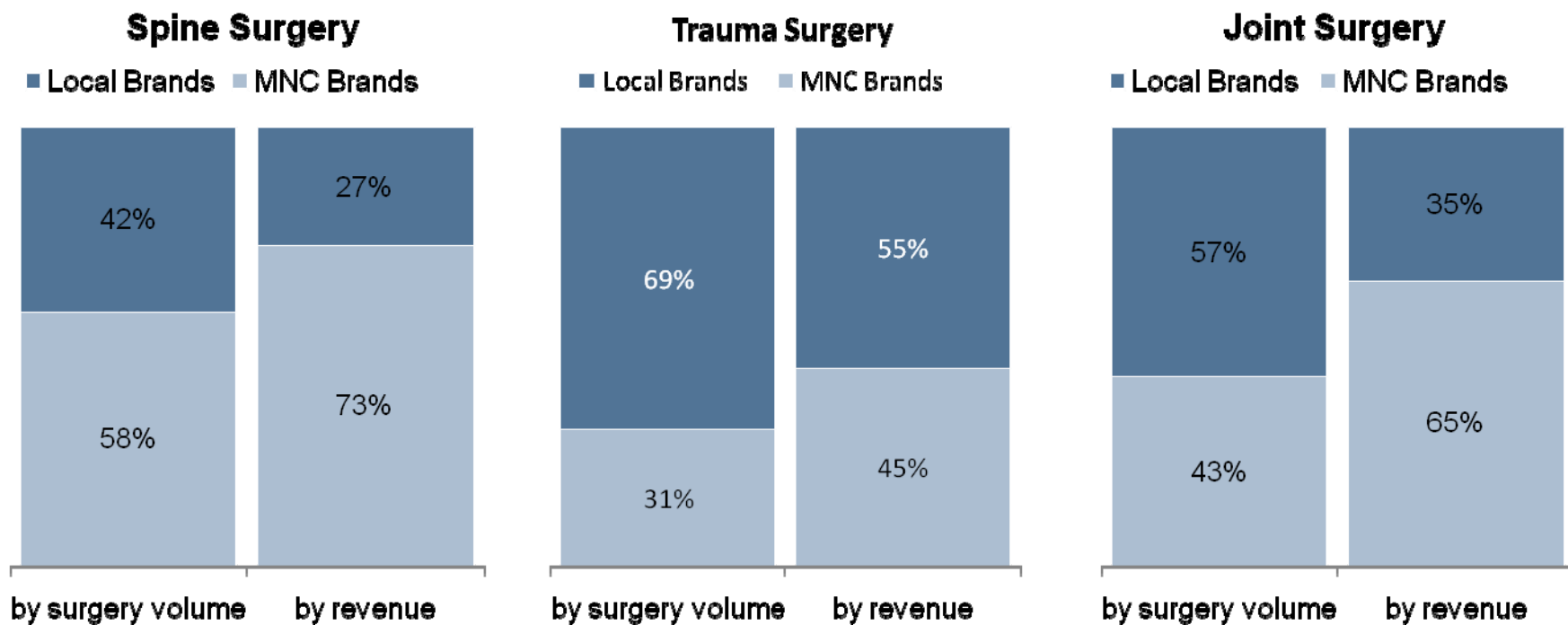
Joint Patient Flow in China

	2008	2014	2020	Key drivers for growth
Disease Prevalence	<ul style="list-style-type: none"> • 2.3% of total population • ~30M 	<ul style="list-style-type: none"> • 2.9% of total population • ~41M 	<ul style="list-style-type: none"> • 3.8% of total population • ~55M 	<ul style="list-style-type: none"> • Aging society • Prevalence of arthritis • Joint trauma due to accidents • Improvement of healthcare access and affordability • Development of hospital increase and healthcare network • Increase of hospital wards and beds • Improved surgeons training • Hospital facilities improvement
Seeking Treatment	<ul style="list-style-type: none"> • 40% of total patients • ~12M 	<ul style="list-style-type: none"> • 46% of total patients • ~19M 	<ul style="list-style-type: none"> • 55% of total patients • ~30M 	
In-patients	<ul style="list-style-type: none"> • 22% of total visits • ~4M 	<ul style="list-style-type: none"> • 37% of total visits • ~7M 	<ul style="list-style-type: none"> • 40% of total visits • ~12M 	
Surgical Candidates	<ul style="list-style-type: none"> • 13% of total inpatients • ~ 0.5M 	<ul style="list-style-type: none"> • 14% of total inpatients • ~ 1M 	<ul style="list-style-type: none"> • 17% of total inpatients • ~ 2M 	
Surgical Patients	<ul style="list-style-type: none"> • 22% of total candidates • ~ 0.11M 	<ul style="list-style-type: none"> • 23% of total candidates • ~ 0.23M 	<ul style="list-style-type: none"> • 25% of total candidates • ~ 0.5M 	

Source: Literature, Frost & Sullivan primary research and estimate

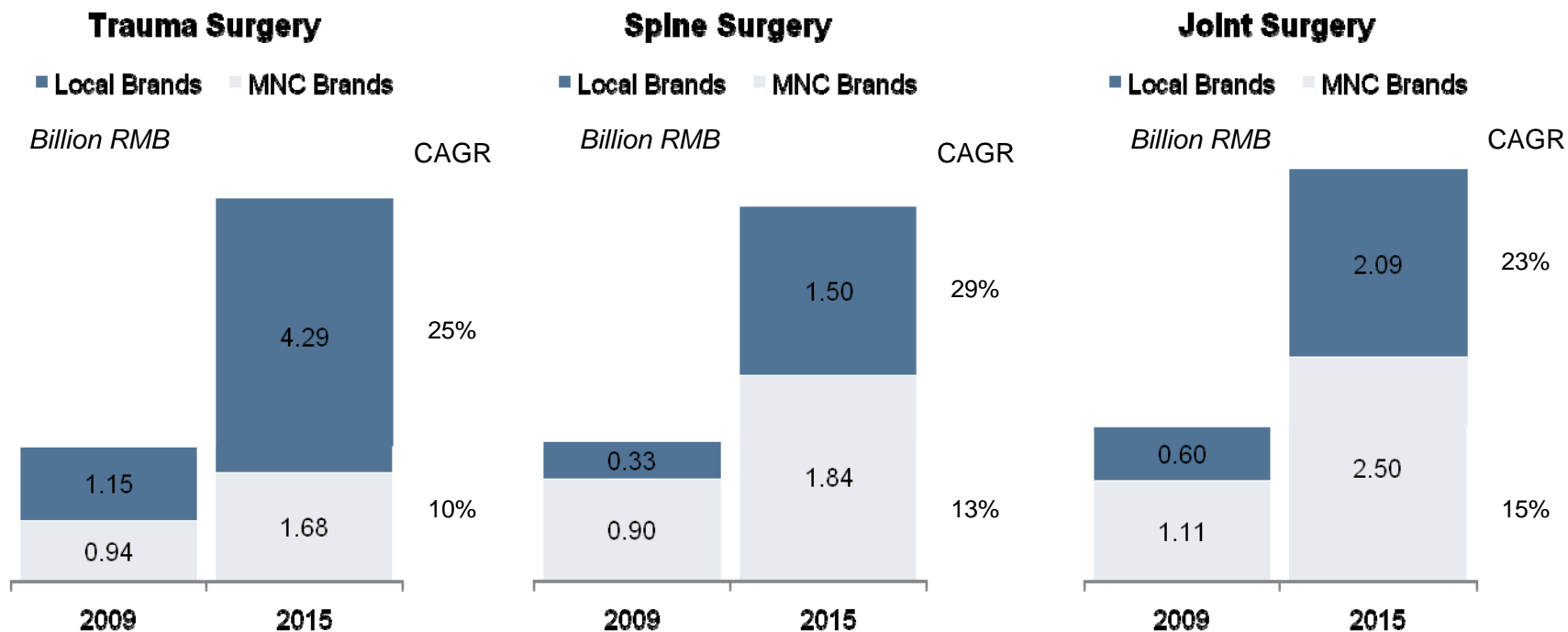
Market Share (MNC vs. Local)

- Orthopedists define spine surgery as difficult surgery compared to other orthopedic surgeries, especially patients who have neck surgeries are exposed to high risk of paralysis. As a result, more patients will choose MNC brands to avoid such risks, as they believe that MNC brands represent state-of-the-art technology.
- For common low risk surgeries, more doctors and patients typically adapt local brands due to affordability and favorable reimbursement provision.



Market Growth Trend by Segments (MNC vs. Local)

- In each market segment, Local brands performed a faster growth than that of MNC in the next several years.
- Local brands are expected to consolidate its advantage in trauma implant market, and reduce gap in other two market segments, which also represent large market potential.



*All these price includes VAT, at manufacturer/ F.O.B. price level

Key Drivers to Shift More MNC Share to Local Peers

With the opportunities from healthcare reform and development of leading local players, China 's domestic companies will gain more market share in the next several years.

Market Dynamic

- More surgical facilities will be built in district and county level hospitals during the implementation of healthcare reform
- More doctors have been training in these hospitals to improve surgical skills, as well as flying doctors are now permitted to perform operations in county hospitals.
- Universal public medical insurance still plays a key role to guard patients' affordability, which favors local brands significantly.

- More patients are seeking surgeries locally and adopting local brands there, instead of going to largest hospitals, especially under emerging situations for trauma fixation surgeries.

Market Player Performance

- The Chinese central and local governments continues to adopt new policies to accelerate growth of local companies.
- Innovation by leading local players will develop more customized products dedicated for Chinese market needs
- Leading local players have built their in-house sales teams and hired veterans from MNC, improving their sales force effectiveness substantially.

- Leading local brands have more opportunities to penetrate the largest hospitals in China, and increase its market share.

1

China medical device industry overview

2

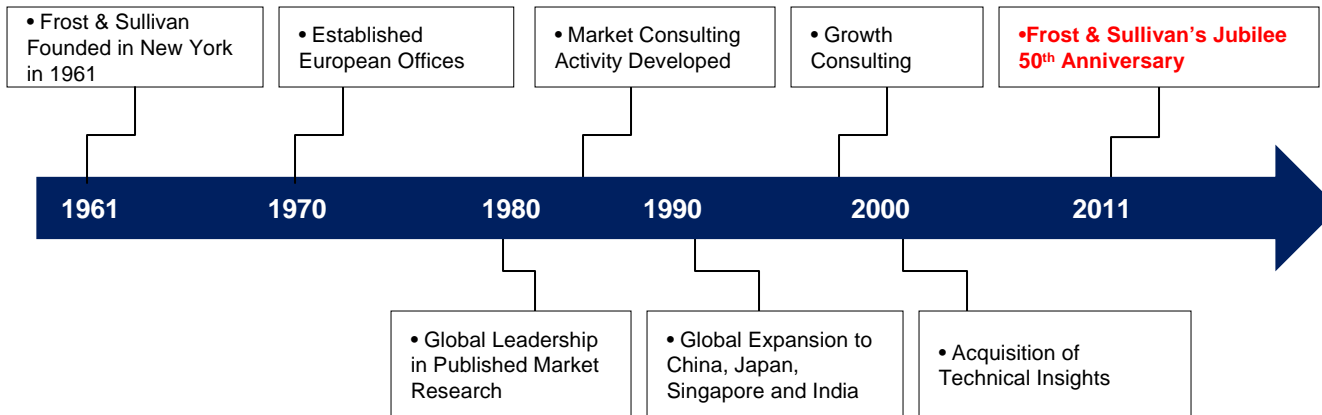
China implant products market analysis

- Cardiovascular stent
- Orthopedic implant

3

About Frost Sullivan

Global Coverage and History



China operations have 120 staff, split between Beijing, Shanghai, and Shenzhen



Beijing

40 People

- HC Team
- ICT Team



Shanghai

70 People

- HC Team
- Industrial Team



Shenzhen

10 People

- HC Team
- Financial Team

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