*This section contains information relating to our markets. Certain facts, statistics and data presented in this section and elsewhere in this document have been derived, in part, from various publicly available government and official sources, industry statistics and publications. We also commissioned an independent industry consultant, China Insights Consultancy ("**CIC**"), to prepare an industry research report ("**CIC Report**") upon which this Industry Overview section is based. Unless otherwise indicated, all historical and forecast statistical information, including trends, sales, market share and growth, is from the CIC Report.*

OVERVIEW OF VASCULAR DISEASES AND VASCULAR INTERVENTIONAL DEVICES

Overview

Clinically, diseases that share vascular pathology as a common pathological feature and seriously endanger vital organs, such as the heart, brain, and limbs, are collectively referred to as vascular diseases. According to the CIC Report, vascular diseases are the leading cause of death in China and globally, accounting for approximately 50% and 30% of deaths, respectively. Under the dual pressure of population aging and the persistent prevalence of risk factors such as hypertension, diabetes, dyslipidemia, and chronic kidney diseases, the burden of vascular diseases is expected to continue rising.

According to the World Health Organization and global leading medical centers, types of vascular diseases include, among others, (i) coronary artery disease, (ii) neurovascular diseases such as intracranial atherosclerotic stenosis, acute ischemic stroke, intracranial aneurysm and hemorrhagic stroke, and (iii) peripheral artery disease, the three of which cumulatively represent over 90% of prevalent vascular diseases.

Treatment Methods

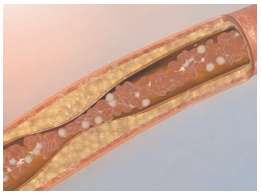
Pharmacotherapy, vascular intervention and surgery are the three types of methods commonly used in the treatment of vascular diseases. While pharmacotherapy remains the basis of medical management and surgery is typically performed in selected patients with complex or extensive disease, vascular intervention is a minimally invasive specialty increasingly adopted. The procedure utilizes medical imaging guidance to diagnose and treat diseases through vascular access. It employs various catheters and devices to target lesions within the vascular system. As vascular diseases share pathological changes in blood vessels as a common feature, nearly all of them can be treated using the vascular intervention technique. Comparing with traditional treatment methods of medication and surgery, vascular intervention demonstrates the following advantages:

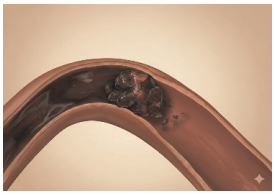
- **Minimally invasive and rapid recovery**: vascular intervention utilizes small percutaneous access instead of large incisions, significantly reducing trauma, pain, and hospital stay.

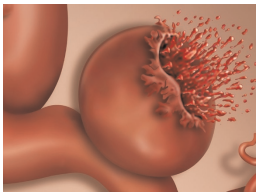
- **High efficacy with broad applicability**: vascular intervention provides a highly successful and safer alternative to open surgery, particularly beneficial for high-risk or inoperable patients.

Vascular Interventions and Interventional Devices

According to the CIC Report, vascular interventions and relevant interventional devices can be generally categorized into three types based on addressable vascular diseases, namely, stenosis, thrombosis, and anomaly. The following table sets forth examples of indications and commonly used devices with regard to each type:







Type	Stenosis	Thrombosis	Anomaly
Indications	Coronary artery disease, intracranial atherosclerotic stenosis, peripheral artery disease	Acute ischemic stroke	Aneurysm, arteriovenous malformation
Description	Abnormal narrowing of blood vessels due to, commonly, plaque buildup (atherosclerosis)	Intravascular occlusion caused by formation of a blood clot (thrombus), obstructing blood flow	Abnormal dilation or development of blood vessel, enduring risk of rupture and bleeding
Main Interventions and Therapeutic Devices	**Stenting** • Drug eluting stent • Bare metal stent • Covered stent • Bioresorbable stent **Balloon Angioplasty** • Plain balloon catheter • Drug coated balloon catheter	**Mechanical Thrombectomy** • Aspiration catheter and pump • Stent retriever	**Embolization** • Embolization coil • Coil-assist stent **Revascularization** • Flow diverter • Intrasaccular flow disruptor
Main Auxiliary Devices	• Guide catheter (distal access, conventional access) • Supportive and auxiliary catheter (coaxial guide catheter, extension catheter) • Microcatheter (coil delivery, stent delivery, flow diverter delivery) • Force focused balloon (cutting balloon, scoring balloon, knob balloon)		

Source: China Insights Consultancy

From the perspective of shared arterial characteristics, stents are the most primary therapeutic devices and stenting serves as standard of care in most vascular diseases. They are designed to restore normal blood flow and avoid the other critical consequences of vessel narrowing. Contemporary endovascular stents are the product of an iterative design and development process that leverages evolving concepts in vascular biology and engineering. In many respects, the stent is the paradigmatic example of a medically motivated and clinically verified device. Furthermore, auxiliary devices, such as access catheters, delivery catheters, and balloon catheters, maximize treatment efficacy, optimize perioperative safety, and broaden applicable indications. Thus, for leading vascular interventional device manufacturers committed to providing solutions that help reduce surgical risks and deliver long-term clinical benefits, developing well-matched auxiliary interventional devices is equally crucial.

OVERVIEW OF CORONARY ARTERY DISEASES AND CORONARY ARTERY INTERVENTIONAL DEVICE MARKET

Overview of Coronary Artery Diseases (CAD)

CAD, as the most common type of heart disease and the main cause of morbidity and death worldwide, is primarily caused by a buildup of plaque inside the arterial wall of coronary arteries, where atherosclerosis represents the leading pathophysiological pathway responsible. CAD can have long, stable periods known as chronic coronary artery disease, but can also become unstable at any time known as acute coronary syndromes.

According to the CIC Report, the prevalence of CAD, measured in population numbers, has grown steadily on a global scale from 249.9 million in 2020 to 270.8 million in 2025, and is expected to reach 315.4 million in 2035, representing CAGRs of 1.6% and 1.5%, respectively. In China, the prevalence of CAD has grown from 17.0 million in 2020 to 21.5 million in 2025, and is expected to reach 32.2 million in 2035, representing CAGRs of 4.8% and 4.1%, respectively. In the U.S, the prevalence of CAD has grown from 20.1 million in 2020 to 23.2 million in 2025, and is expected to reach 29.8 million in 2035, representing CAGRs of 2.9% and 2.5%, respectively. In Europe, the prevalence of CAD has grown from 34.4 million in 2020 to 38.8 million in 2025, and is expected to reach 48.4 million in 2035, representing CAGRs of 2.5% and 2.2%, respectively.

Treatment of CAD and Introduction to Percutaneous Coronary Intervention (PCI)

PCI emerged as a catheter-based minimally invasive revascularization strategy for CAD, and has become widely adopted owing to its proven efficacy, shorter procedure time, lower procedural trauma, faster recovery, and lower immediate procedural risk. A standard PCI procedure generally includes the following steps and relevant devices:

Steps	Lesion access	Preoperative assessment	Lesion preparation	Lesion treatment	Lesion optimization	Postoperative assessment
Description	• Access is established via radial or femoral artery to create a stable delivery route for guidewire and catheter entry	• Angiography is performed to assess the lesion site • Intravascular imaging and functional assessment techniques are selectively used in complex lesions to further determine surgical strategies	• Lesion preparation is performed to optimize procedural success, especially in complex cases • Semi-compliant balloons are used for pre-dilation in common cases. Non-compliant balloons, specialty balloons or atherectomy devices are used for fibrotic and calcified lesions	• POBA-only if adequate, but, in most cases, stents are needed to provide a scaffold to prevent recoil and dissection and locally deliver anti-proliferative drugs to reduce restenosis • Depending on lesion characteristics and patient conditions, different treatment strategy (stent-only, stent with DCB, DCB-only) is then performed	• Lesion optimization is performed to ensure stent expansion and apposition, reducing restenosis and thrombosis risk	• To confirm the therapeutic effect and check for complications, with the use of intravascular imaging and functional assessment techniques if necessary
PCI device	• Puncture needle and introducer sheath set, etc.	• Angiography catheter and wire	• Guide catheter and wire, guide extension catheter, microcatheter, etc. • Semi/Non-compliant balloon, Knob balloon • Cutting/Scoring balloon • IVL, RA, OA, ELCA	• DES, BMS, BRS • DCB	• Non-compliant balloon • Knob balloon	

Source: Guidelines for percutaneous coronary intervention (2025); Expert consensus on management of severely calcified coronary lesions with active devices; China Insights Consultancy

Over the past decades, PCI has progressed from plain old balloon angioplasty (POBA) to stent-based therapies, including bare-metal stents (BMS) and currently more adopted drug-eluting stents (DES). Across this technological progression, restenosis rates have declined markedly, from 30%–60% in the POBA era to 20%–30% in the BMS era. Building on these advances, DES has further reduced restenosis rates to generally below 10% through continued refinements in strut thickness, metallic platform design and manufacturing, and the use of more biocompatible or biodegradable polymer coatings. Consequently, DES has become a mainstay of PCI across a broad spectrum of coronary syndromes. Nevertheless, there are key clinical challenges remaining: (i) dependence on long-term dual antiplatelet therapy (DAPT) and the associated bleeding risk; and (ii) long-term safety concerns, particularly chronic inflammation and neoatherosclerosis induced by the permanent presence of non-resorbable metallic stents.

Given that restoring endothelial function limits inflammation and controls neointimal proliferation, an effective DES must balance neointimal growth triggered by the vessel injury of stenting with adequate re-endothelialization. The latest generation of DES increasingly emphasizes optimized drug-release kinetics and pro-healing surface interfaces. The essence of optimized drug-release kinetics is that they are designed to be synchronous with the smooth muscle cell proliferation process. Furthermore, after the outer drug and polymer degrade completely, the pro-healing surface interface acts to prevent corrosion and heavy metal ion release from the underlying stent, providing an optimal substrate for rapid endothelialization to accelerate healing. Accordingly, the DES innovation is expected to emphasize clinical adaptability, with priorities including compatibility with abbreviated antiplatelet therapy, broader applicability across diverse patient populations, and a lower risk of adverse events over extended follow-up.

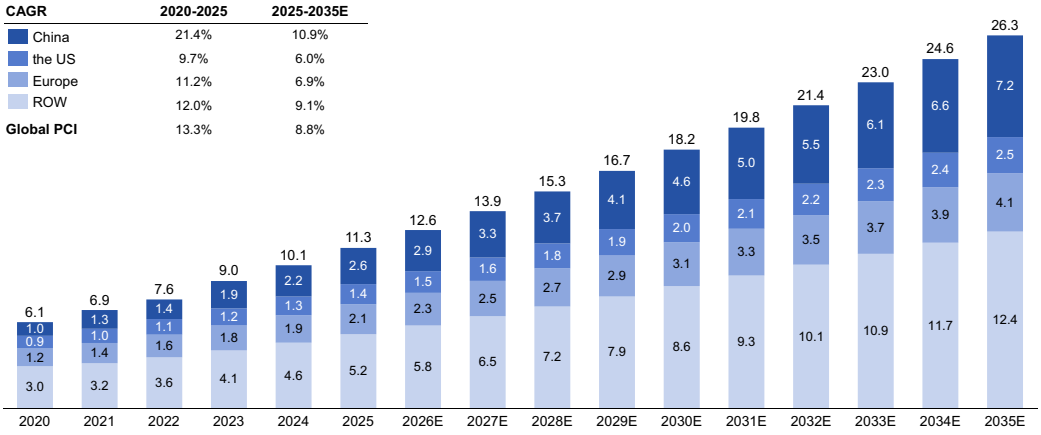
Beyond therapeutic devices, advances in lesion preparation have significantly improved the management of challenging lesions, particularly when integrated with intravascular imaging and physiological assessment. These strategies are particularly valuable in the treatment of heavily calcified lesions, fibrotic stenoses, and other anatomically complex lesions where adequate plaque modification is essential for optimal device delivery and stent expansion. Increasing introduction of devices including force-focused balloons, such as cutting balloons, scoring balloons, and knob balloons, and intravascular lithotripsy (IVL) has broadened the portfolio.

PCI MARKET OVERVIEW

According to the CIC Report, the volume of PCI differs among countries due to different penetration rate of PCI procedures and local treatment guidelines. The following chart sets forth the global PCI procedure volume from 2020 to 2025 and the estimated volume from 2026 to 2035:

Global PCI Procedure Volume, 2020-2035E

Million cases



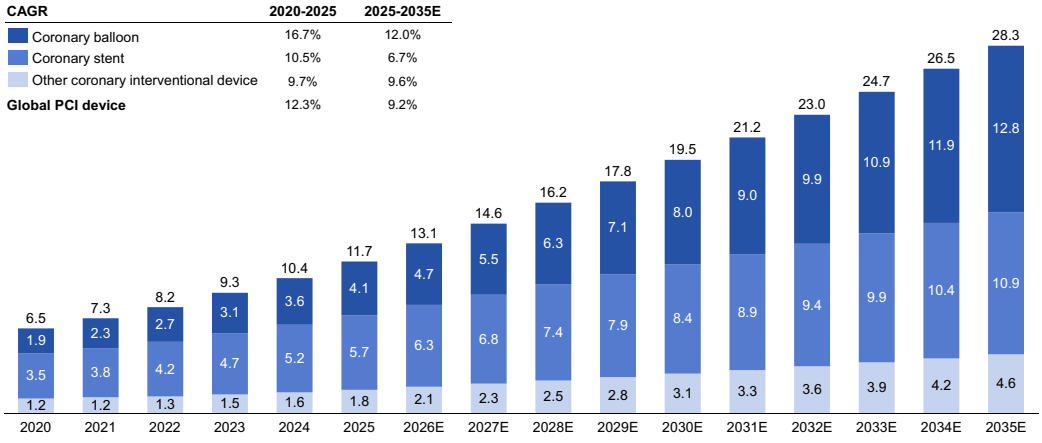
Source: NMPA; FDA; EUDAMED; National Center for Cardiovascular Quality Improvement; CCIF; European Society of Cardiology; Japanese Association of Cardiovascular Intervention and Therapeutics; NCDR; JACC: Asia. 2025 Jun, 5 (6) 701 -717.; China Insights Consultancy

While the future growth of PCI volume is in line with historical trends, the market size of PCI devices is also showing continuous growth globally. According to the CIC Report, the global market size by sales value grew from US$6.5 billion in 2020 to US$11.7 billion in 2025, and is expected to reach US$28.3 billion in 2035, representing CAGRs of 12.3% and 9.2%, respectively. In China, the market size by sales value was RMB9.0 billion in 2025, and is expected to reach RMB32.5 billion in 2035, representing a CAGR of 13.7%.

PCI devices primarily include broad categories of balloons and stents. Balloons generally include standard balloons, force focused balloons, drug-coated balloons and IVL. Stents generally include BMS, DES, and bioresorbable scaffolds (BRS). The following charts set forth market sizes of PCI devices in terms of sales value globally and in China, categorized by device types:

Global Market Size of PCI Device, in Terms of Sales Value, 2020-2035E

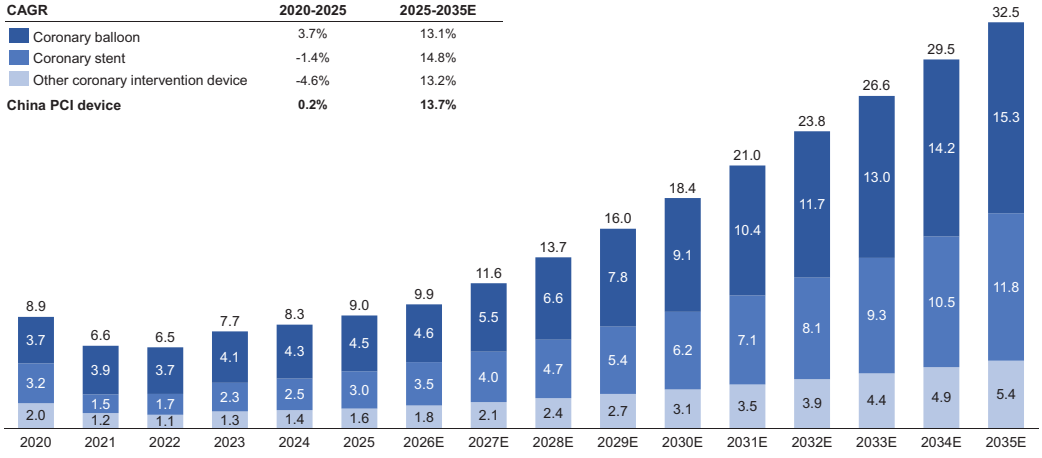
Billion USD



Source: NMPA; FDA; EUDAMED; National Center for Cardiovascular Quality Improvement; CCIF; European Society of Cardiology; Japanese Association of Cardiovascular Intervention and Therapeutics; NCDR; JACC: Asia. 2025 Jun, 5 (6) 701 -717.; Expert Interviews; China Insights Consultancy

Market Size of PCI Device in China in Terms of Sales Value, 2020-2035E

Billion RMB



Source: NMPA; National Center for Cardiovascular Quality Improvement; CCIF; European Society of Cardiology; Japanese Association of Cardiovascular Intervention and Therapeutics; NCDR; JACC: Asia. 2025 Jun, 5 (6) 701 -717.; Expert Interviews; China Insights Consultancy

Competitive Landscape

Competitive Landscape of Coronary Stent

BMS, DES and BRS are three types of coronary stent. Unlike BMS, DES is coated with drug that is slowly released into the artery wall. The drug helps to prevent the excessive growth of smooth muscle cells, which can lead to re-narrowing of the artery, a condition known as restenosis. While BMS remains

in limited use in some regions due to cost considerations and accessibility, DES has firmly established itself as the dominant technology in major markets such as China, Europe and the U.S. In the meantime, DES innovation continues with thinner struts, biodegradable polymers, and surface treatment technology to improve long-term outcomes including target lesion failure, stent thrombosis, and bleeding risk.

As of the Latest Practicable Date, there were 42 NMPA-approved coronary DES products in China, 27 of which from 15 companies were included in the latest list of China's national centralized volume-based procurement program (VBP). As of the Latest Practicable Date, our HT Supreme™ DES was the first and only domestically developed coronary DES to receive conditional premarket approval ("**PMA**") from the U.S. FDA. The following table sets forth the coronary DES market participants and details of their products included in China's national VBP as of the Latest Practicable Date:

					Long-term DAPT			Short-term DAPT		
Company	Product	First Approval	National VBP	Listed Price in China (RMB)	TLF	Definite/ Probable ST	Study	Definite/ Probable ST	Bleeding events	Study
SinoMed	BuMA®	NMPA 2010	N	2,850	6.4% (1-year)	0.5% (1-year)	PANDA III	N/A	N/A	N/A
	HT Supreme™	CE 2019 NMPA 2020 FDA 2025 (conditional)	Y	949	5.4% (1-year) 11.7% (5-year)	0.7% (1-year) 2.6% (5-year)	PIONEER III	0.2% (12-month)	1.5% (12-month, BARC 3-5)	PIONEER IV All comers 1-month DAPT
	HT Infinity®	NMPA 2022	Y	839						
	Buma Supreme	NMPA 2026	Y	798						
MicroPort	FireBird 2	NMPA 2008	Y	848	2.56% (1-year)	0.55% (1-year)	FOCUS	N/A	N/A	N/A
	Firebird Pro+	NMPA 2022	Y	939						
	Firehawk	NMPA 2014 CE 2015	Y	946	6.1% (1-year)	1.3% (1-year)	TARGET All Comers	0.25% (18-month)	5.87% (18-month, BARC 2-5)	TARGET DAPT PCI population excluding STEMI 3-month DAPT
	Firehawk Pro	NMPA 2022	N	12,000	17.1% (5-year)	2.8% (5-year)				
	FireCondor/ Firehawk Liberty	NMPA 2019 CE 2019	N	2,850						
Medtronic	Endeavor Resolute	CE 2007 FDA 2008 NMPA 2009	N	N/A	7.9% (1-year) 15.0% (5-year)	0.9% (1-year) 1.9% (5-year)	TWENTE	N/A	N/A	N/A
	Resolute Integrity	CE 2010 FDA 2012 NMPA 2016	Y	848	6.0% (1-year) 12.0% (5-year)	1.0% (1-year) 1.5% (5-year)	DUTCH PEERS	N/A	N/A	N/A
	Resolute Onyx	CE 2014 FDA 2017 NMPA 2022	Y	949	3.9% (1-year) 10.4% (5-year)	0.1% (1-year) 1.0% (5-year)	BIONYX All Comers	1.3% (12-month)	4.9% (12-month, BARC 3-5)	Onyx ONE HBR 1-month DAPT
	Onyx TruStar/ Onyx Frontier	CE 2022 FDA 2022 NMPA 2025	N	N/A						
Boston Scientific	Promus PREMIER	FDA 2013 CE 2013 NMPA 2015	N	846	3.5% (1-year) 9.1% (5-year)	0.4% (1-year) 0.8% (5-year)	PLATINUM	N/A	N/A	N/A
	SYNERGY	CE 2012 FDA 2015 NMPA 2017	Y	896	6.7% (1-year) 14.3% (5-year)	0.4% (1-year) 0.7% (5-year)	EVOLVE II	0.3% (3-15 months)	6.26% (3-15 months, BARC 2-5)	EVOLVE Short DAPT HBR 3-month DAPT
	SYNERGY XD	CE 2020 FDA 2020 NMPA 2024	N	2,850						
Abbott Medical	Xience Xpedition	CE 2012 FDA 2012 NMPA 2017	N	N/A	4.2% (1-year) 12.7% (5-year)	0.3% (1-year) 1.4% (5-year)	SPIRIT III/ IV	0.3% (1-6 months)	2.2% (1-6 months, BARC 3-5)	XIENCE 28 HBR 1-month DAPT
	Xience Xpedition 48	CE 2013 NMPA 2019	Y	848						
	Xience Alpine	FDA 2014 CE 2015 NMPA 2016	Y	947						
	XIENCE Sierra	CE 2017 FDA 2018 NMPA 2019	N	2,850						

					Long-term DAPT			Short-term DAPT		
Company	Product	First Approval	National VBP	Listed Price in China (RMB)	TLF	Definite/ Probable ST	Study	Definite/ Probable ST	Bleeding events	Study
	XIENCE Skypoint	CE 2021 FDA 2021 NMPA 2024	N	2,850						
	XIENCE Skypoint 48	CE 2021 FDA 2023 NMPA 2024	N	2,850						
Mixin Medtech/ Micell	MiStent	CE 2013 NMPA 2020	Y	949	5.8% (1-year)	0.7% (1-year)	DESSOLVE III	N/A	N/A	N/A
Kinhely	Helios	NMPA 2011	Y	949	N/A	0.33% (1-year)	HELIOS registry	N/A	N/A	N/A
Medfavour	NOYA	NMPA 2012 CE 2020	Y	848	N/A	N/A	N/A	N/A	N/A	N/A
Lepu Medical	Partner	NMPA 2005 CE 2012	Y	848	N/A	N/A	N/A	N/A	N/A	N/A
	Nano plus	NMPA 2011 CE 2020	Y	848	N/A	0.4% (1-year)	NANO	N/A	N/A	N/A
	GuReater	NMPA 2013 CE 2020	Y	848	N/A	N/A	N/A	N/A	N/A	N/A
	CoCr DES	NMPA 2026	Y	949	N/A	N/A	N/A	N/A	N/A	N/A
JW Medical/ Biosensors	BioFreedom	CE 2013 NMPA 2021 FDA 2022	N	2,850	5.0% (1-year) 14.1% (5-year)	1.0% (1-year) 1.8% (5-year)	SORT OUT IX	2% (390-day)	7.2% (390-day, BARC 3-5)	LEADERS FREE HBR 1-month DAPT
	Excrossal	NMPA 2017	Y	847	6.1% (1-year) 10.6% (5-year)	0.4% (1-year) 1.0% (5-year)	CREDIT II/ III	N/A	N/A	N/A
	Expansal	NMPA 2022	Y	946	N/A	N/A	N/A	N/A	N/A	N/A
	CoCr DES	NMPA 2025	Y	947	N/A	N/A	N/A	N/A	N/A	N/A
Essen Tech	Tivoli	NMPA 2010	Y	848	6.3% (1-year) 11.4% (5-year)	0.4% (1-year) 1.2% (5-year)	I-LOVE-IT 2	1.6% (5-year)	2.2% (5-year, BARC 3-5)	I-LOVE-IT 2 all comers 6-month DAPT
	Co-based DES	NMPA 2025	Y	946	N/A	N/A	N/A	N/A	N/A	N/A
BIOTRONIK	Orsiro	CE 2011 FDA 2019 NMPA 2019	N	2,850	6.2% (1-year) 12.3% (5-year)	0.5% (1-year) 0.7% (5-year)	BIOFLOW V	0.8% (12-month)	3.5% (12-month, BARC 3-5)	BIOFLOW-DAPT HBR 1-month DAPT
	Orsiro Mission	CE 2020 FDA 2021 NMPA 2024	Y	949						
Amsinomed	AVI Plus	NMPA 2012	Y	848	N/A	N/A	N/A	N/A	N/A	N/A
Rientech	Cordimax	NMPA 2012	Y	756	3.5% (1-year) 7.5% (5-year)	0.2% (1-year) 0.7% (5-year)	Randomized Controlled Trial	N/A	N/A	N/A
Zhongke Yian	Yian Core	CE 2021 NMPA 2025	Y	848	N/A	N/A	N/A	N/A	N/A	N/A

Note:

(1) "National VBP" and "Listed Price in China (RMB)" refer to the proposed status subject to implementation upon the second-round continuation procurement of the National VBP.

(2) "N/A" indicates that the relevant data were publicly unavailable or not directly comparable.

(3) Our BuMA® was included in the demand list for the second-round continuation procurement of the National VBP.

Source: NMPA; FDA; Literature Review; China Insights Consultancy

In terms of sales volume of coronary DES in China in 2025, we ranked fourth with a market share of 10.4%, according to the CIC Report. The following table sets forth the detail of market share information:

Market Share of Coronary DES in Terms of Sales Volume in China in 2025

Company	Market share	Background
Company A	27.6%	Company A, headquartered in Shanghai, China, is a global medical technology company engaged in the development, manufacturing and commercialization of medical devices across multiple therapeutic areas, with a focus on interventional and implantable technologies. It has been listed on The Stock Exchange of Hong Kong Limited.
Company B	18.7%	Company B, headquartered in Shandong, China, is a medical device company with a broad portfolio across consumables and higher-value medical devices. Its ultimate controlling parent company has been listed on the Shenzhen Stock Exchange.
Company C	12.8%	Company C, headquartered in Beijing, China, is a medical device and healthcare company with operations in cardiovascular and related medical device segments, covering R&D, manufacturing, and commercialization. It has been listed on the Shenzhen Stock Exchange.
SinoMed	**10.4%**	**/**
Company D	9.7%	Company D, headquartered in Marlborough, Massachusetts, the U.S., is a global medical device company that develops and manufactures technologies for a wide range of interventional medical specialties. It has been listed on the New York Stock Exchange.

Source: Company Annual Reports; Expert Interviews; China Insights Consultancy

Coronary BRS are temporary scaffolds that provide arterial support and later dissolve. They are designed to overcome the limitations of permanently caged DES, which may impair vasomotion and cause long-term concerns, such as delayed endothelialization and chronic inflammation. The ideal BRS should initially provide sufficient radial strength and framing support to prevent elastic recoil and maintain luminal patency. Moreover, the struts should be thin enough to minimize thrombogenicity, and the scaffold should deliver antiproliferative drugs with optimized release kinetics. Over the mid- to long-term, it should exhibit a controlled degradation profile and ultimately be fully absorbed to restore the vessel's natural structure and function.

BRS are transitioning from R&D to commercialization, although no product has yet achieved the level of robust clinical validation and routine adoption. A broad range of BRS design strategies are currently under investigation worldwide. Existing bioresorbable scaffold platforms can be broadly divided into two material classes: bioresorbable polymers and bioresorbable metals.

Polymeric BRS, exemplified by Abbott's PLLA-based Absorb BVS, were among the earliest scaffold platforms developed. Early polymeric BRS faced limitations in clinical application due to overly thick struts, uneven degradation, and an increased risk of thrombosis. To address these challenges, current strategies to optimize polymeric BRS focus on improving mechanical performance and resorption time through material composition, structural design and processing techniques.

Due to potentially favorable mechanical strength and biocompatibility, bioresorbable metals have attracted considerable attention. Magnesium-alloy-based alloys exhibit favorable biocompatibility and substantial resistance to platelet adhesion and aggregation, owing to their electrochemical characteristics. Therefore, magnesium-alloy-based BRS were the first to be developed for clinical investigation, as exemplified by Biotronik's AMS-1 scaffold. However, early magnesium-alloy-based BRS were reported to exhibit relatively weaker mechanical properties and rapid degradation rates. Currently, developers of

magnesium-alloy-based BRS continue to optimize magnesium alloy scaffolds through alloy composition adjustments, surface modification, and forging processes. In addition, research interest has expanded to other biodegradable metallic materials such as iron- and zinc-based alloys as design directions.

As of the Latest Practicable Date, there were only two magnesium-alloy based coronary BRS commercialized globally, with approximately six under first-in-man (FIM) or preclinical stage development in China. The details are set forth below:

Magnesium-alloy Based Coronary BRS Approved or under Development Globally

Company	Product Name	Approval Year/Status	Strut Thickness (μm)	Resorption time (months)	Drug Eluting
SinoMed	**N/A**	**Preclinical**	**110**	**6~9**	**Sirolimus**
Biotronik	Magmaris	2016, CE (No longer commercially available)	150	9~12	Sirolimus
Biotronik	Freesolve	2024, CE	99-147	12~24	Sirolimus
JMDT (Kaneka)	N/A	FIM in Japan (Study started in 2023.1)	100	12~26	Sirolimus
Tianyi Bio	N/A	Preclinical	N/A	N/A	N/A
Fengyuan Medical	N/A	Preclinical	N/A	N/A	N/A
Zhong Ke Yi 'an	N/A	Preclinical	N/A	N/A	N/A
Amsino Medical	N/A	Preclinical	N/A	N/A	N/A

Source: NMPA; FDA; EUDAMED; ChiCTR; ClinicalTrials.gov; Company Website; China Insights and Consultancy

Competitive Landscape of Coronary Force Focused Balloons (FFB)

Conventional balloon angioplasty often leads to uneven force distribution on the vessel wall, resulting in disordered intimal/plaque dissection. When used for moderate to severe coronary calcified lesions, it demonstrates low success rates and high complication rates. With advancements in percutaneous transluminal angioplasty and related devices, coronary FFB, primarily including cutting, scoring, and knob balloons have been developed by incorporating additional elements onto the balloon surface. These innovations provide expanded options for adjunctive or primary treatment of vascular stenosis. According to the CIC Report, the global market size of FFB grew from US$0.6 billion in 2020 to US$1.3 billion in 2025, and is expected to reach US$3.9 billion in 2035, representing CAGRs of 17.3% and 11.4%, respectively. In China, the market size of FFB grew from RMB0.6 billion in 2020 to RMB1.8 billion in 2025, and is expected to reach RMB4.6 billion in 2035, representing CAGRs of 25.1% and 10.1%, respectively.

Scoring balloons are specialized devices that convert radial expansion into controlled, localized scoring of plaque, moving beyond simple compression. Their evolution reflects a shift from "blunt compression" to "precise micro-cutting." Early wire-scoring balloons used external wires for focused stress but offered unpredictable force and limited efficacy against calcified lesions. Subsequent non-slip element balloons employed polymer spines for safety and grip, though with constrained modification capability. The current paradigm is the directional scoring balloon, which integrates triangular nitinol wires. This design delivers strong radial scoring while maintaining axial flexibility, enabling a transition from "random tearing" to "uniform, controlled micro-cutting." The latest spiral-arranged variants provide comprehensive plaque coverage and distribute stress evenly, effectively fracturing resistant

plaque for optimal lumen gain while minimizing flow-limiting dissection risk. With regard to different types of FFB devices, the market size of coronary scoring balloons in China have demonstrated steady growth from 2020 to 2025 with a CAGR of 11.6%, increasing from RMB0.4 billion in 2020 to RMB0.6 billion in 2025. Representing one of the most meaningful increments comparing to other types of FFB devices with a CAGR of 10.7% from 2025 to 2035, the market size of coronary scoring balloons in China is expected to further increase to RMB1.7 billion in 2035.

As of the Latest Practicable Date, there were 19 NMPA-approved coronary scoring balloon products in China. TRADENT™ was the first coronary scoring balloon approved by the NMPA that featured spiral nitinol scoring element, representing the latest design. The following table sets forth the the approved coronary scoring balloon products in China:

Company	Product Name	First Approval Date	Scoring Element Material	Number of Scoring Elements	Scoring Element Arrangement	Listed Price in China (RMB)
SinoMed	**TRADENT™**	**2023-09-12**	**Nitinol**	**3**	**Spiral**	**2,000~4,500**
OrbusNeich	ScoreFlex	2009-08-27	Stainless steel	2	Longitudinal	2,157~3,900
Goodman	NSE	2012-11-19	Nylon	3	Longitudinal	2,697~4,500
OrbusNeich	ScoreFlex NC	2021-06-15	Nitinol	2	Longitudinal	8,300
DK Medtech	DK Score	2022-09-05	Nitinol	3	Longitudinal	2,000~5,500
Brosmed	Wedge NC	2023-03-23	Nitinol	1	Longitudinal	2,168~5,000
Philips	AngioSculpt	2023-11-16	Nitinol	3	Spiral	12,380
DK Medtech	DK Score Pro	2023-12-19	Nitinol	3	Longitudinal	2,000~5,800
Yeapro	TrifinScore	2024-03-04	Nitinol	3	Spiral	2,200~4,400
MicroPort	Fire falcon	2024-11-21	Nylon	3	Longitudinal	1,900~5,700
Int Medical	Scoring balloon	2024-12-26	Nylon	3	Longitudinal	2,000~2,982
Mixin Medtech	Seledora	2025-03-14	Nylon	3	Longitudinal	2,200~5,600
Lepu Medical	Vessridge	2025-03-31	Nylon	3	Longitudinal	2,200~4,480
APT Medical	CONQUEROR Ridge	2025-05-27	Nylon	3	Longitudinal	2,982
You De Bang	Scoring balloon	2025-07-18	Nylon	3	Longitudinal	2,200~4,380
JW Medical	Xing Hen	2025-12-10	Nitinol	4	Spiral	2,149~6,500
Angiotec	Scoring balloon	2025-12-23	Nylon	3	Longitudinal	5,500
Sonosemi	CyliScore C14	2026-01-07	Nitinol	2	Longitudinal	6,500
OrbusNeich	Scoreflex TRIO	2026-05-09	Nitinol	3	Longitudinal	N/A

Source: NMPA; Provincial Medical Device Procurement Platform; Company Websites; China Insights Consultancy

Major Entry Barriers

- ***High R&D and technical barriers***: The development of interventional devices requires advanced R&D capabilities, involving intricate design, engineering, and validation processes. Manufacturers must enhance their understanding of coronary diseases to innovate more sophisticated devices.

- ***Stringent regulatory approval requirements***: PCI devices, as Class III cardiovascular or high-risk implantable devices, face stringent domestic and international regulatory oversight compared to devices for other anatomical areas.

- ***End-User recognition***: Cardiologists and hospitals must be convinced of a product's safety and clinical value before incorporating it into routine clinical practice. In particular, adoption decisions are often influenced by the real-world performance data, or endorsements from leading medical institutions and key opinion leaders.

- ***Hospital access and procurement barriers*:** Tendering and VBP mechanisms tend to favor established manufacturers with scale advantages and entrenched hospital relationships. To gain market entry, new entrants must differentiate themselves through innovative products or well-executed channel strategies.

Growth Drivers and Future Trends

- ***Aging population and rising CAD burden***: The rising prevalence of CAD, driven by population aging and increasing comorbidities such as diabetes, obesity, and hypertension, is expanding the eligible PCI patient pool. However, PCI procedure penetration rates remain relatively low in current markets

- ***Internationalization of domestic products***: Large-scale multicenter clinical trials have propelled leading domestic companies from technology adopters to globally competitive innovators. At the same time, domestic companies are accelerating their internationalization strategies by strengthening global marketing efforts to gradually establish globally recognized brands.

- ***Rising demand for PCI operations***: CAD patients are more willing to choose PCI operations due to its low trauma and reliability compared to traditional methods of treatment. Physicians also prefer PCI operations due to its lower risk compared to other methods of surgical treatment.

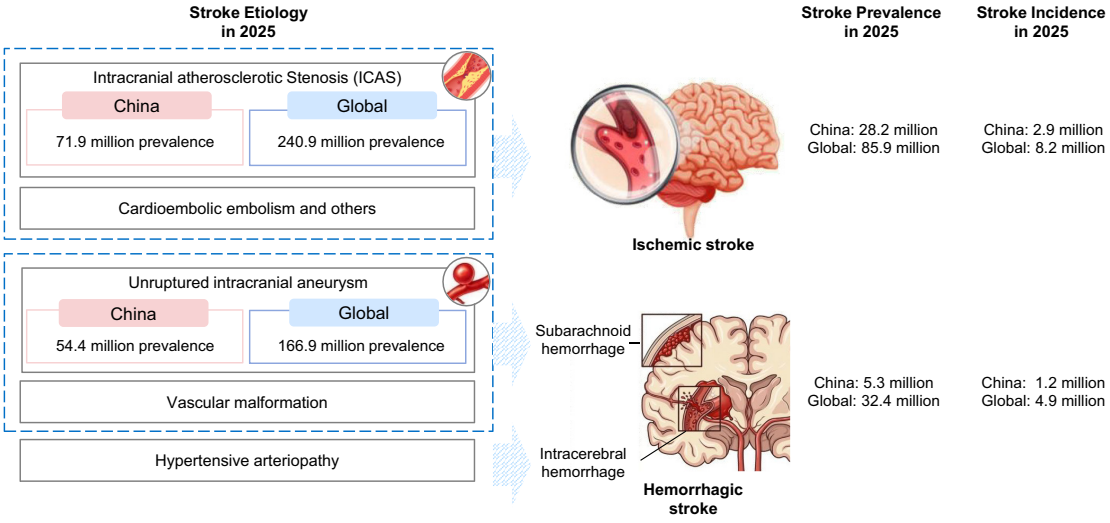
- ***Continuous product development***: As development and innovation accelerates, devices treating CAD are expected to increase in quality and prominence, and achieve better penetration rate in the global market, enhancing room for market expansion.

OVERVIEW OF NEUROVASCULAR DISEASES AND NEUROVASCULAR INTERVENTIONAL DEVICE MARKET

Overview of Neurovascular Diseases

The neurovascular system is a functional whole composed of the vascular network and neural tissue of the central nervous system (brain and spinal cord). It is responsible for delivering oxygen and nutrients to the brain and spinal cord, removing metabolic waste, and regulating local blood flow through neurovascular coupling mechanisms to ensure normal nerve function. Lesions in this system are a core cause of serious diseases such as stroke and vascular cognitive impairment.

Neurovascular diseases refer to transient or permanent neurological dysfunction caused by lesions in one or more cerebral blood vessels for various reasons, primarily classified into ischemic and hemorrhagic neurovascular diseases. Restrictions in blood flow may occur from vessel narrowing (stenosis), clot formation (thrombosis), blockage (embolism) or blood vessel rupture (hemorrhage). Neurovascular diseases are among the leading causes of death worldwide, with stroke being the single disease with the highest disability rate. The following diagram illustrates the classification and progression of specific neurovascular diseases:



Source: Lancet Neurol. 2021 Oct;20(10):795–820; The Lancet Public Health, 6, e897-e906; The Lancet Neurology, 24, 945-957; Brain Circ. 2025 Dec 15;11(4):251–260.; China Insights Consultancy

Introduction to Neurovascular Intervention and Market Overview

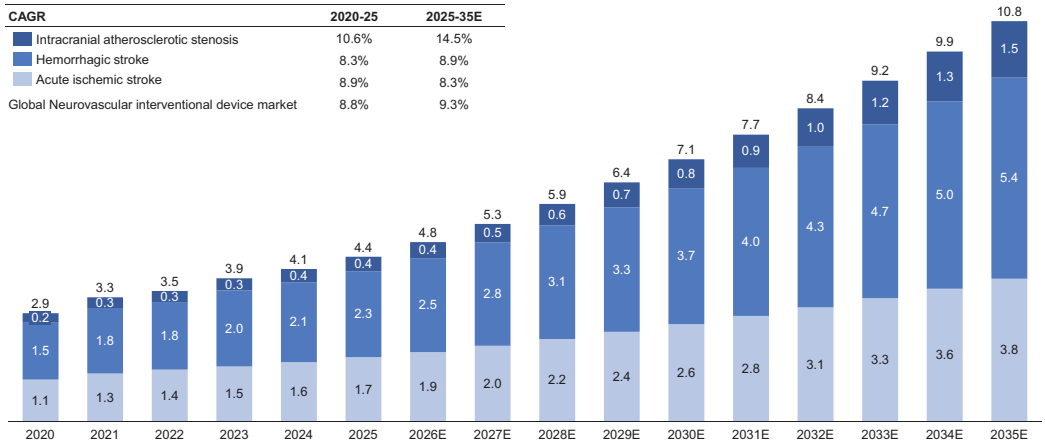
Neurovascular intervention is increasingly becoming the mainstream alternative to traditional craniotomy and medication for conditions such as intracranial atherosclerotic stenosis (ICAS), aneurysm-related hemorrhagic stroke, and acute ischemic stroke (AIS), owing to its significant advantages of being minimally invasive, enabling rapid recovery, and having a low complication rate. The number of neurovascular interventional procedures performed globally and in China has demonstrated stable growth, measured by surgeries performed on three major neurovascular diseases, namely, ICAS, hemorrhagic stroke and AIS. Globally, the number of procedures performed was 0.4 million in 2020 and 0.8 million in 2025, and is expected to reach 3.1 million in 2035, representing CAGRs of 16.0% and 14.0%, respectively. In China, the number of procedures performed was 152.9 thousand in 2020 and 384.4 thousand in 2025, and is expected to reach 1.8 million in 2035, representing CAGRs of 20.3% and 16.7%, respectively.

With regard to each major neurovascular disease, the number of interventional procedures performed also demonstrated meaningful growth globally and in China. Globally, the number of interventional procedures performed on ICAS, hemorrhagic stroke and AIS grew with CAGRs of 18.4%, 15.9% and 15.5% from 2020 to 2025, respectively, and is expected to grow with CAGRs of 18.6%, 13.3% and 12.7% from 2025 to 2035, respectively. In China, the number of interventional procedures performed on ICAS, hemorrhagic stroke and AIS stroke grew with CAGRs of 20.2%, 18.7% and 22.6% from 2020 to 2025, respectively, and is expected to grow with CAGRs of 19.5%, 14.9% and 17.1% from 2025 to 2035, respectively.

In line with the growth of the number of neurovascular interventional procedures, the size of the neurovascular interventional device market, measured in terms of sales value, also demonstrates rapid growth both in China and globally. The following charts sets forth the size of neurovascular interventional device markets in China and globally:

Global Market Size of Neurovascular Interventional Device, 2020-2035E

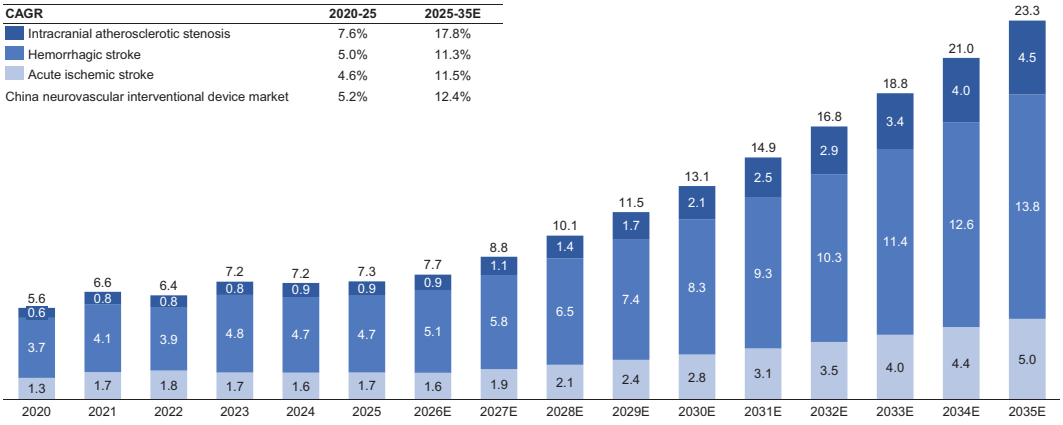
Billion USD



Source: NMPA; FDA; EUDAMED; ChiCTR; ClinicalTrials.gov; European Stroke Organisation guidelines on treatment of patients with intracranial atherosclerotic disease; Stroke: Vascular and Interventional Neurology, December, 2025, Vol. 5, No. S1; Company Website; China Insights and Consultancy

Market Size of Neurovascular Interventional Device in China, 2020-2035E

Billion RMB



Source: NMPA; China Stroke Prevention and Control Report; Provincial Medical Device Procurement Platform; Company Annual Reports; Expert Interviews; China Insights Consultancy

Competitive Landscape

We are a major developer and manufacturer of neurovascular interventional device in the Chinese Mainland market. In terms of sales revenue of neurovascular interventional device in China in 2025, we ranked sixth among domestic players with a market share of 3.0%. The following diagram sets forth the detail of market share information:

Market Share of Neurovascular Interventional Device in China in Terms of Sales Revenue in 2025

Company	Background	Market share	Sales Revenue in China in 2025 (million RMB)
Company E	Company E, headquartered in Shanghai, China, has established a comprehensive product portfolio that covers all three major areas of neurovascular disease, namely hemorrhagic stroke, cerebral atherosclerotic stenosis, and acute ischemic stroke. It has been listed on The Stock Exchange of Hong Kong Limited	8.4%	~607
Company F	Company F, headquartered in Zhejiang, China, focuses on innovative research and development, manufacturing, and sales of medical devices in the fields of peripheral and neurovascular intervention. It has been listed on The Stock Exchange of Hong Kong Limited.	8.0%	~578
Company G	Company G, headquartered in Jiangsu, China, focuses on the innovation, research and development, and production of high-end medical devices for structural heart and cerebrovascular interventions. It has been listed on The Stock Exchange of Hong Kong Limited.	5.8%	~423
Company H	Company H, headquartered in Shanghai, China, is a medical device company focusing on neurovascular interventional solutions, with a product pipeline covering acute ischemic stroke, hemorrhagic stroke, and neurovascular stenosis treatment. It has been listed on The Stock Exchange of Hong Kong Limited.	5.4%	~391
Company I	Company I, headquartered in Beijing, is a commercial-stage medical device company specializing in innovative neurointerventional and access devices for the diagnosis and treatment of hemorrhagic and ischemic stroke.	3.4%	~248
SinoMed	/	**3.0%**	**~216**
Imported Companies		62.4%	

Source: Company Annual Reports; Expert Interviews; China Insights Consultancy

Competitive Landscape of Intracranial Atherosclerotic Stenosis Interventional Device

Intracranial atherosclerotic stenosis (ICAS) is a condition characterized by the narrowing or blockage of arteries within the brain due to the deposition and accumulation of atheromatous plaques in the arterial walls. ICAS is a progressive pathological process that causes progressive stenosis and cerebral hypoperfusion and is recognized as one of the leading causes of stroke worldwide. According to the Chinese Intracranial Atherosclerosis Study, 46.6% of patients had intracranial atherosclerotic stenosis. The study also revealed that stroke patients with ICAS tend to have more severe symptoms and longer hospital stays.

Treatment of ICAS is often used as secondary prevention of stroke. Though interventional therapy is still under development, it has a higher recommendation level and level of evidence in patients with severe ICAS, and presents increasing adoption with strengthened clinical evidence. Two most common types of treatment procedures are:

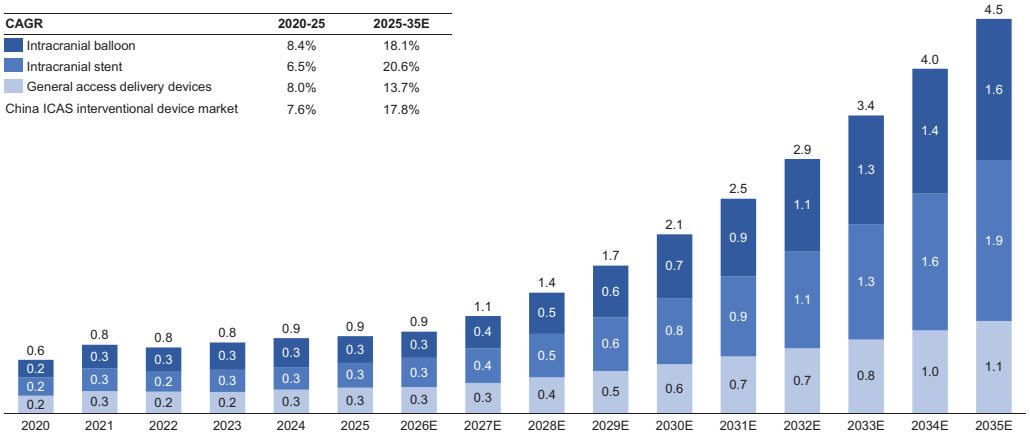
- ***Balloon angioplasty***: A procedure that guides a deflated balloon-tipped catheter to the stenotic site, inflates the balloon to dilate the lumen, compresses plaques against the vessel wall, and restores distal blood flow.

- ***Stenting***: The core function is to relieve stenosis of blood vessels by expanding the stent, thereby preventing ischemic stroke. The drug eluting can further inhibit intimal hyperplasia, reduce restenosis, and actively promote vascular healing through the medication they carry.

According to the CIC Report, the number of ICAS interventional procedures performed in China grew from 30.5 thousand in 2020 to 76.6 thousand in 2025, and is expect to reach 453.2 thousand in 2035, representing CAGRs of 20.2% and 19.5%, respectively. The market size, measured by sales value, of ICAS interventional devices is experiencing rapid growth in China, as demonstrated in the following chart:

Market Size of ICAS Interventional Device in China, 2020-2035E

Billion RMB



Note: Intracranial balloon includes PTA balloon and DCB.

Source: NMPA; ChiCTR; ClinicalTrials.gov; China Stroke Prevention and Control Report; 2022 Chinese Expert Consensus on Endovascular Treatment of Symptomatic Intracranial Atherosclerotic Stenosis; Provincial Medical Device Procurement Platform; Company Websites; Company Annual Report; China Insights Consultancy

As of the Latest Practicable Date, there were three NMPA-approved intracranial stents in China. Approved by the NMPA, NOVA NEO™ was the world's first and only intracranial DES approved. The following table sets forth details of approved intracranial stents in China:

Company	Product	Stent Platform	Coating	Expansion Method	NMPA First Approval	Ischemic stroke in territory of qualifying artery beyond 31 days through 1 year	1-year ISR	Listed Price in China (RMB)
SinoMed	**NOVA NEO™**	**316L Stainless Steel**	**Base coating: Poly(butyl methacrylate) Drug Coating: Sirolimus with a PLGA matrix**	**Balloon-expandable**	**2021-07-29**	**0.8%**	**9.5% (stenosis ≥50%)**	**41,000**
Microport	Apollo	316L Stainless Steel	BMS	Balloon-expandable	2004-11-19	6.9%	30.2% (stenosis ≥50%)	11,500
Stryker	Wingspan	Nitinol	BMS	Self-expanding	2006-11-04	5.8% (SAMMPRIS) 5.4% (WOVEN)	9.6% (SAMMPRIS, symptomatic ISR) 17.6% (WOVEN, stenosis ≥70%)	16,400

Source: NMPA; Literature Review; Provincial Medical Device Procurement Platform; China Insights Consultancy

In terms of sales volume of intracranial stent indicated for ICAS in China in 2025, we ranked first with a market share of 41.0%. The details are set forth below:

Market Share of Intracranial Stent Indicated for ICAS in Terms of Sales Volume in China in 2025

Company	Market share	Background
SinoMed	**41.0%**	**/**
Company E	38.9%	Company E, headquartered in Shanghai, China, has established a comprehensive product portfolio that covers all three major areas of neurovascular disease, namely hemorrhagic stroke, cerebral atherosclerotic stenosis, and acute ischemic stroke. It has been listed on The Stock Exchange of Hong Kong Limited
Company J	20.1%	Company J, headquartered in Michigan, the U.S., is a global medical technology company with a dedicated neurovascular business offering a broad portfolio covering ischemic and hemorrhagic stroke products. It is listed on the New York Stock Exchange.

Source: Company Annual Reports; Expert Interviews; China Insights Consultancy

Neurovascular vessels are characterized by small diameters and complex anatomical structures. Self-expanding stents are better able to conform to tortuous vascular pathways and enable safe and precise deployment, representing a key technological direction for improving interventional treatment outcomes in complex lesions.

As of the Latest Practicable Date, two intracranial stents indicated for ICAS in China had completed confirmatory clinical trials. As of the same date, COMETIU® was the world's first product to receive FDA Breakthrough Device designation for the treatment of ICAS, and China's first neurovascular interventional device to obtain such designation. The details are set forth below:

Company	Product	Expansion Method	Coating	ISR	Device and Technical Success Rates	NMPA Status
SinoMed	**COMETIU®**	**Self-expanding**	**Sirolimus**	**1.71% (6-month) 1.87% (>1-year)**	**100%**	**Confirmatory trial completed**
HeartCare	Intracranial DES	Self-expanding	Sirolimus	3.09% (6-month)	98.97%	Registration accepted

Source: ChiCTR; ClinicalTrials.gov; Neuroradiology, July, 2024, Vol.66, No.11; Company Websites; China Insights Consultancy

As of the Latest Practicable Date, there were more than 60 NMPA-approved intracranial percutaneous transluminal angioplasty (PTA) balloons in China. Neuro RX® was the first rapid-exchange intracranial PTA balloon approved by the NMPA. Neuro LPS® was the world's first low-pressure rapid-exchange intracranial PTA balloon. The following table sets forth the first ten intracranial PTA balloons in China to receive approval from the NMPA:

Company	Type	Product	First Approval Date	Nominal Pressure (atm)	Diameter (mm)	Length (mm)	Listed Price in China (RMB)
SinoMed	**Rapid-Exchange**	**Neuro RX®**	**2016-12-19**	**6**	**1.5~4**	**6~25**	**1,200**
		Neuro LPS®	**2020-06-19**	**3**	**1.5~4**	**8~20**	**1,200**
Stryker	Over-the-Wire	Gateway	2006-10-31	6	1.5~4	9~20	3,600
Achieva	Rapid-Exchange	SacSpeed	2020-08-12	6	1.5~4.5	6~25	800
Precision	Rapid-Exchange	Balloonfish	2020-11-09	6	1.5~4	7~20	1,200
HeMo	Rapid-Exchange	FocuStar	2020-12-11	4	1.5~4	9~20	780
Zylox-Tonbridge	Rapid-Exchange	Intracranial PTA Balloon Catheter	2021-03-24	6	1~5	6~30	1,200
Enid	Rapid-Exchange	Intracranial PTA Balloon Catheter	2021-03-24	N/A	N/A	N/A	780
Weiming	Rapid-Exchange	Intracranial PTA Balloon Catheter	2021-04-30	6	1~5	6~30	1,200
NeuroCare	Rapid-Exchange	Diveroad	2021-06-21	N/A	1.5~4	6~30	1,200

Source: NMPA; Company Websites; Provincial Medical Device Procurement Platform; China Insights Consultancy

In terms of sales volume of intracranial PTA balloon in China in 2025, we ranked first with a market share of 21.2%. The following diagram sets forth the detail of market share information:

Market Share of Intracranial PTA Balloon in Terms of Sales Volume in China in 2025

Company	Market Share	Description
SinoMed	**21.2%**	/
Company J	19.4%	Company J, headquartered in Michigan, the U.S., is a global medical technology company with a dedicated neurovascular business offering a broad portfolio covering ischemic and hemorrhagic stroke products and services. It is listed on the New York Stock Exchange.
Company F.	14.9%	Company F, headquartered in Zhejiang, China, focuses on innovative research and development, manufacturing, and sales of medical devices in the fields of peripheral and neurovascular intervention. It has been listed on The Stock Exchange of Hong Kong Limited.
Company G	11.2%	Company G, headquartered in Jiangsu, China, focuses on the innovation, research and development, and production of high-end medical devices for structural heart and cerebrovascular interventions. It has been listed on The Stock Exchange of Hong Kong Limited.
Company H	10.5%	Company H, headquartered in Shanghai, China, is a medical device company focusing on neurovascular interventional solutions, with a product pipeline covering acute ischemic stroke, hemorrhagic stroke, and neurovascular stenosis treatment. It has been listed on The Stock Exchange of Hong Kong Limited.

Source: Company Annual Reports; Expert Interviews; China Insights Consultancy

Competitive Landscape of Hemorrhagic Stroke Interventional Device

A hemorrhagic stroke occurs when bleeding disrupts brain function, either within the brain or between the brain and skull. It is classified into two types based on the bleeding site and cause, namely, intracerebral hemorrhage (bleeding occurs inside the brain) and subarachnoid hemorrhage (bleeding occurs between the brain and the membranes).

With regard to subarachnoid hemorrhage, rupture of intracranial aneurysm is the most common cause, accounting for approximately 85% of the cases. An intracranial aneurysm is a localized dilation or bulging of the wall of a blood vessel in the brain, usually occurring at a weak point in the vessel wall. Due to vessel wall thinning or damage, localized arterial dilation forms a balloon-like structure. This lesion can occur in any cerebral artery, but is most common in the anterior cerebral artery, anterior communicating artery, and middle cerebral artery. The size and shape of an aneurysm vary from person to person; it can be spherical, sac-like, or conical. Although most aneurysms do not cause immediate symptoms, their rupture can have fatal consequences.

Neurosurgical clipping and endovascular treatment are the standard therapies for exclusion of ruptured and unruptured intracranial aneurysms from the intracranial vascular circulation to prevent bleeding. With regard to endovascular treatment, commonly performed procedures include:

- ***Coil or balloon-assisted embolization***: fills the aneurysm with coils to promote thrombus formation to achieve aneurysm occlusion.

- ***Stent-assisted coil embolization***: for wide-necked or complex aneurysms, with the stent providing support to prevent coil displacement.

- ***Flow diversion***: used to treat large, unruptured internal carotid artery aneurysms with wide necks.

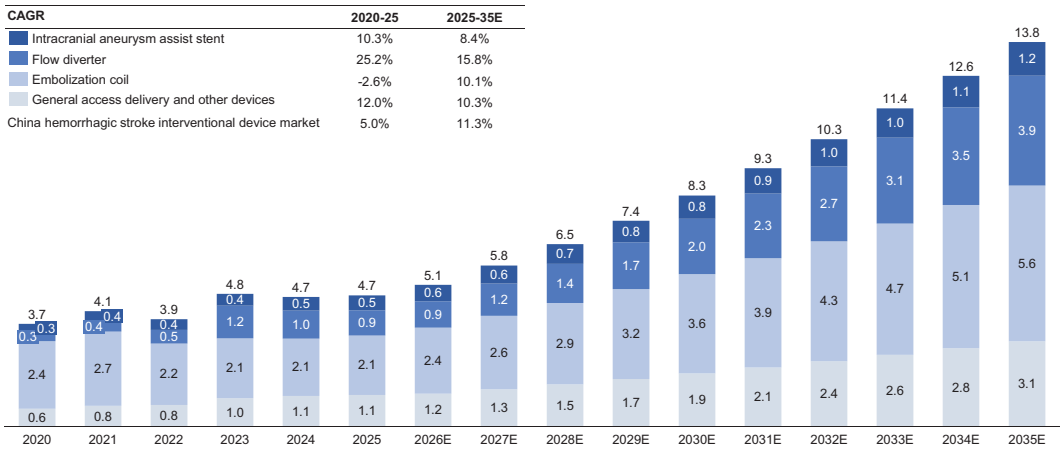
- ***Intrasaccular flow disruption***: used for selected bifurcation aneurysms, but long-term effectiveness requires further study.

According to the CIC Report, the number of hemorrhagic stroke interventional procedures performed in China grew from 74.9 thousand in 2020 to 176.3 thousand in 2025, and is expect to reach 708.3 thousand in 2035, representing CAGRs of 18.7% and 14.9%, respectively.

The market size, measured by sales value, of hemorrhagic stroke interventional devices is experiencing rapid growth in China, as demonstrated in the following chart:

Market Size of Hemorrhagic Stroke Interventional Device in China, 2020-2035E

Billion RMB



Source: NMPA; China Stroke Prevention and Control Report; Chinese Neurosurgical Journal, August, 2025, Vol. 11, No. 8; Provincial Medical Device Procurement Platform; Expert Interviews; China Insights Consultancy

Flow diverter represents a transformative advancement in the endovascular treatment of neurovascular aneurysms, offering several key advantages over traditional techniques such as coil embolization. The benefits lie in its hemodynamic mechanism and scaffolding for endothelial cell growth, making it particularly effective for complex and challenging aneurysms. As of the Latest Practicable Date, 24 flow diverters had been approved by the NMPA, seven of which were products with antithrombotic coatings. AUCURA™ was the first flow diverter compatible with 0.017" microcatheters and featuring advanced antithrombotic coating in China. The following table sets forth the details of all NMPA approved flow diverters with antithrombotic coatings:

Company	Product	First Approval Date	Stent Braiding Material	Microcatheter System	Coating	Complete Occlusion Rate after Surgery	Incidence of Ischemic Neurovascular Events	Listed Price in China (RMB)
SinoMed	**AUCURA™**	**2025-05-27**	**DFT metal wire (Cobalt-chromium-nickel-platinum)**	**0.017" 0.021" 0.027"**	**Hydrophilic Polymer (Poly-NTMA)**	**95.49% (1 year) 86.13% (6 months)**	**1.4% (1 year)**	**62,250**
Medtronic	Pipeline Flex	2023-03-13	Platinum-tungsten 35NLT alloy (nickel-titanium)	0.027"	Phosphorylcholine	77.2% (1 year) 70.8% (6 months)	2.9% (1 year)	67,000
HeartCare	RuYi	2025-02-08	Cobalt-chromium Platinum-tungsten	0.021" 0.027"	Phosphorylcholine	N/A	N/A	62,250
MicroVention	FRED X	2025-07-01	Nickel-titanium	0.021" 0.027"	Hydrophilic Polymer (PMEA)	63.5% (1 year)	N/A	N/A
Medtronic	Pipeline Vantage	2025-07-31	DFT metal wire (Cobalt-chromium-nickel-platinum)	0.021"	Phosphorylcholine	81.7% (6 months)	N/A	62,000
Skynor	SkyVega	2025-11-05	Nickel-titanium Platinum-tungsten	N/A	Phosphorylcholine	N/A	N/A	N/A
Ricoton	Manovra	2026-02-13	DFT metal wire (cobalt-chromium-platinum)	0.017" 0.021" 0.027" 0.030"	Phosphorylcholine	N/A	N/A	N/A

Note: *"N/A" indicates that the relevant data were publicly unavailable or not directly comparable.*
Source: *NMPA; Literature Review; Company Website; Provincial Medical Device Procurement Platform; China Insights Consultancy*

Stent-assisted coiling is used to treat wide-neck or complex intracranial aneurysms. The stent provides scaffolding across the aneurysm neck to prevent coil prolapse into the parent artery and improve the stability and efficacy of coil embolization. However, implanted stents may induce thrombus formation, which is associated with potential post-procedural complications. Surface-modified stent coatings can form a stable hydration layer that prevents protein and cell adhesion and inhibits activation of the coagulation cascade, thereby reducing the risk of device-related thrombosis. Our SECURA™ intracranial coated stent system is under registration stage in China, and is expected to be the first domestically-developed intracranial aneurysm coiling assisted stent with an antithrombotic coating approved in China.

Competitive Landscape of Acute Ischemic Stroke Interventional Device

Acute ischemic stroke (AIS), also known as cerebral infarction, is an acute neurovascular disease characterized by high incidence, disability, recurrence and mortality rates. It is caused by ischemia, hypoxia, necrosis and softening of local brain tissue due to cerebral circulation disorders, which leads to sudden local neurological deficit. Typical symptoms of AIS include (i) sudden numbness or weakness of the face, arm or leg, especially involving one side of the body, (ii) sudden confusion, trouble speaking or understanding, (iii) loss of vision in one or both eyes, (iv) walking problems, dizziness, loss of balance or coordination, and (v) sudden and severe headache with no known cause.

Endovascular treatment of AIS primarily comprises the following procedures:

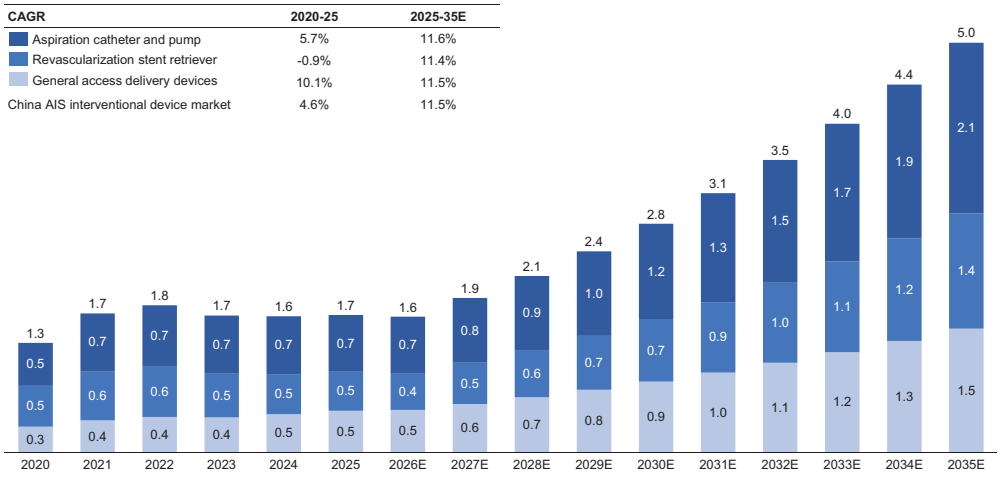
- ***Stent-retriever thrombectomy***: A procedure where a stent-like device retrieves and removes a clot from a blocked cerebral artery.
- ***Aspiration thrombectomy***: A procedure that uses a specialized catheter to directly suction and remove the blood clot from a blocked brain artery, rapidly restoring blood flow.
- ***Combined stent-retriever and aspiration thrombectomy***: A hybrid approach that combines both techniques to optimize clot removal and improve reperfusion.

Due to their minimally invasive nature and comparable efficacy, AIS interventional procedures are generally the preferred treatment choice. According to the CIC Report, the number of AIS interventional procedures performed in China grew from 47.5 thousand in 2020 to 131.6 thousand in 2025, and is expect to reach 639.5 thousand in 2035, representing CAGRs of 22.6% and 17.1%,, respectively.

The market size, measured by sales value, of AIS interventional devices is experiencing rapid growth in China, as demonstrated in the following chart:

Market Size of AIS Interventional Device in China, 2020-2035E

Billion RMB



Source: NMPA; China Stroke Prevention and Control Report; Provincial Medical Device Procurement Platform; Expert Interviews; China Insights Consultancy

As of the Latest Practicable Date, 38 stent retrievers and 44 aspiration catheters had been approved by the NMPA, including our revascularization device GHUNTER® and aspiration catheter Apachi®. GHUNTER® has received CE MDR certification in 2026, among a few domestically developed stent retrievers received CE marking.

Competitive Landscape of Access and Delivery Devices in Neurovascular Intervention

Access devices play a critical role in neurovascular interventional procedures by establishing a stable and secure vascular pathway. According to the distal reach and support capability, access devices mainly comprise long sheaths, guiding catheters, distal access catheters, support catheters, intermediate catheters and microcatheters. Among them, proximal access systems primarily provide procedural support, navigability, and deliverability for subsequent therapeutic interventions. Microcatheters function as the distal navigational interface between the proximal access system and the target lesion, enabling precise traversal through small and tortuous intracranial vessels and facilitating the controlled delivery of therapeutic devices. Additionally, occlusion balloon catheters are used to temporarily block blood flow for vessel control, prevent distal clot migration during procedures, or improve stent-graft apposition to the vessel wall. As of the Latest Practicable Date, more than 100 distal access catheters and long sheaths, 15 conventional guiding catheters, more than 45 support catheters, more than 150 microcatheters, and more than 50 occlusion balloon catheters had been approved, including our NOVARAILR® distal access catheter, OPTIMUS™ long sheath, Rayline® and AURALINE® micro catheter, COVESTAR® balloon guided catheter and APEX TRA® radial access catheter, APEX TRA GC® guiding catheter and APEX TRA SYSTEM® radial access catheter system.

In recent years, after achieving widespread adoption and clinical maturity in coronary interventions, the transradial approach has begun to drive a paradigm shift in neurovascular interventional procedures. With advantages such as immediate post-procedural ambulation, a low incidence of access-site complications, and improved patient comfort, transradial access is increasingly emerging as a preferred access strategy. Our APEX TRA® is the first radial-specific distal access guiding catheter commercialized in China

Major Entry Barriers

- ***Product development and manufacturing capabilities*:** Developing neurovascular interventional devices requires expertise in materials, mechanical engineering, product design, and manufacturing. The manufacturing process is complex, particularly for advanced devices, requiring skilled technicians, automated facilities, and economies of scale, creating high entry barriers.

- ***Product portfolio and solutions*:** Different procedures require diverse types and specifications of neurovascular interventional devices. A comprehensive supplier addresses compatibility concerns by offering one-stop, tailored solutions. This creates synergies in R&D, manufacturing, and commercialization, along with economies of scale that raise barriers for new entrants.

- ***Regulatory approval barriers***: High-risk neurovascular interventional devices are subject to stringent global regulatory oversight. Manufacturers must generate robust clinical evidence and implement comprehensive quality management systems, while navigating lengthy approval processes, which create high compliance and clinical data barriers to entry.

Growth Drivers and Future Trends

- ***Persisting incidence of stroke and increasing prevalence of stroke-related chronic conditions***: The patient population with ICAS and intracranial aneurysms continues to expand and is also trending younger.

- ***Proactive strategy for stroke prevention***: China is shifting its neurovascular strategy from passive treatment to proactive prevention, with increasing focus on the early detection and treatment of underlying core pathogenic factors.

- ***Continuous technological innovation***: Through the continuous refinement of treatment strategies and interventional devices, the field of neurovascular intervention is steadily entering a new stage characterized by greater safety and efficacy.

- ***Improved accessibility of neurovascular intervention:*** Many medical institutions are actively advancing the development of stroke centers to improve the timeliness of treatment. Neurovascular intervention is increasingly being extended to primary care settings and underserved markets.

OVERVIEW OF PERIPHERAL ARTERY DISEASES (PAD) AND PERIPHERAL INTERVENTIONAL MEDICAL DEVICES MARKET

PAD is characterized by arterial obstruction supplying the lower extremities, primarily caused by atherosclerosis and thrombosis. Based on arterial location, PAD mainly includes lower extremity PAD and renal artery stenosis, with over 80% of atherosclerotic obstructions occur in lower-extremity arteries. According to the CIC Report, the number of PAD patient increased from 299.9 million in 2020 to 325.9 million in 2025 globally, and is estimated to further increase to 372.7 million in 2035, representing CAGRs of 1.7% and 1.4%, respectively. In China, the number of PAD patient increased from 46.4 million in 2020 to 50.8 million in 2025, and is estimated to further increase to 59.0 million in 2035, representing CAGRs of 1.8% and 1.5%, respectively.

Treatment methods for peripheral artery disease include conservative therapy and surgical intervention. Surgical intervention aims to restore direct pulsatile blood flow to the distal limb and can be performed through endovascular interventions, where balloon angioplasty, stenting and atherectomy are commonly employed, or open surgical repair, such as endarterectomy or bypass grafting. Clinical guidelines provide graded recommendations for the choice of minimally invasive vascular intervention procedures and generally strongly support the therapy in appropriate patients.

Within the specific context of the below-the-knee (BTK) segment, however, the efficacy of these traditional modalities is challenged by a hostile biomechanical environment. This region is characterized by repetitive flexion, torsion, compression, and extension during daily activities. These stresses, compounded by complex pathologies such as long-segment occlusions and severe calcification, render permanent metallic implants highly susceptible to mechanical fatigue and restenosis. Bioresorbable scaffolds are expected to address these limitations by offering transient radial support followed by complete resorption, thereby representing a transformative solution for future BTK interventions.

OVERVIEW OF VALVULAR HEART DISEASES AND VALVULAR HEART DISEASE INTERVENTIONAL MEDICAL DEVICES MARKET

Valvular heart diseases refer to conditions in which the heart valves are damaged, resulting in altered blood flow and potentially serious complications such as stroke, heart failure, or death. Mitral regurgitation (MR) is one of the most common valvular heart diseases. In this condition, the mitral valve fails to close tightly, leading blood to flow backward during ventricular contraction. According to the CIC Report, the global prevalence of moderate-to-severe MR has increased from 26.9 million in 2020 to 31.3 million in 2025, and is estimated to further increase to 40.6 million in 2035, representing CAGRs

of 3.1% and 2.6%, respectively. In China, the prevalence of moderate-to-severe MR increased from 9.4 million in 2020 to 11.6 million in 2025 and is estimated to further increase to 15.4 million in 2035, representing CAGRs of 4.1% and 2.9%, respectively.

The transcatheter treatment for MR mainly involves two approaches: transcatheter mitral valve repair (TMVr) and transcatheter mitral valve replacement (TMVR). Although TMVr, represented by edge-to-edge repair, is currently more clinical validated and adopted, the procedure faces limitations in indications and high risk of residual MR, which is associated with poor outcomes. As such, there is a growing interest in TMVR devices to overcome the limitations of TMVr. TMVR is a procedure to replace a heart valve and implants a manufactured valve or one made from biological heart tissue. Considering the complexity and heterogeneity of mitral valve disease, TMVR could offer a more universal concept for treating mitral valve disease, with a more predictable decrease in MR severity.

SOURCE OF INFORMATION AND RESEARCH METHODOLOGY

We engaged CIC for preparing an independent industry report in respect of the global and China vascular interventional device market. The information from CIC disclosed in this document is extracted from the CIC Report, a report commissioned by us for a fee of RMB583,000, and is disclosed with the consent of CIC. The CIC Report has been prepared by CIC independently without any influence from us or other interested parties. CIC is an independent global consulting firm founded in 2014 in Shanghai. Its services include, among others, industry consulting, market strategic consulting and corporate training. CIC conducted (i) primary research, which involved discussing the status of the industry with certain leading industry participants, and interviews with industry experts on a best-effort basis to collect information in aiding in-depth analysis; and (ii) secondary research, which involved reviewing government statistics, industry association publication, company reports, independent research reports and data based on its own research database.