The information and statistics set out in this section and other sections of this document were extracted from the report prepared by CIC, which was commissioned by us, and from various official governmental publications and other publicly available publications. We engaged CIC to prepare the CIC Report, an independent industry report, in connection with the [**REDACTED**]. *The information from official government sources has not been independently verified by us, the Joint Sponsors, the* [**REDACTED**]*, the* [**REDACTED**]*, the* [**REDACTED**]*, the* [**REDACTED**]*, the* [**REDACTED**] *or any of our or their respective directors, senior management, representatives, advisers or any other person involved in the* [**REDACTED**] *and no representation is given as to its accuracy.*

ABOUT CHINA INSIGHTS INDUSTRY CONSULTANCY LIMITED

We commissioned China Insights Industry Consultancy Limited, an independent third party, to prepare a report on the global endovascular interventional instrument market in December 2022, which is cited in this document. The total fee we paid for the report prepared by China Insights Industry Consultancy Limited was RMB1,070,000. China Insights Industry Consultancy Limited, founded in Hong Kong, provides professional services including, among others, industry consulting, commercial due diligence and strategic consulting.

During the preparation of the CIC Report, China Insights Industry Consultancy Limited performed both primary and secondary researches, and obtained knowledge, statistics, information on and industry insights into the global endovascular interventional instrument market. Primary research involved interviewing key industry experts and leading industry participants. Secondary research involved analyzing data from various publicly available data sources, such as the government derived information, annual reports and industry association statistics. The CIC Report was compiled based on the following assumptions: (1) the overall social, economic, and political environment in the global economy is expected to remain stable during the forecast period; (2) relevant key drivers are likely to drive the continued growth of the global endovascular interventional instrument market throughout the forecast period; and (3) there is no extreme force majeure or unforeseen industry regulations in which the industry may be affected in either a dramatic or fundamental way. All forecasts in relation to market size are based on the general economic conditions as of the Latest Practicable Date, which would be adjusted if the COVID-19 outbreak persists or escalates and has an unpredicted negative impact on the general economy. The assumptions adopted in the CIC Report in relation to the COVID-19 pandemic include (i) surgeries in different regions experienced an obvious but short-term drop in 2020 compared to in 2019 due to the quarantine and temporarily shut down of hospitals pursuant to which all surgeries were suspended, (ii) the volume of surgery recovered and increased in 2021 and thereafter, as there was no material change in prevalence and prices of surgeries charged by the hospitals, which was based on the samples collected from hospitals and expert interview by China Insights Industry Consultancy Limited.

China Insights Industry Consultancy Limited has exercised due care in collecting and reviewing the information so collected and believes that the basic assumptions are factual and correct and the interpretations are reasonable. China Insights Industry Consultancy Limited has independently analyzed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected.

OVERVIEW OF CARDIOVASCULAR DISEASES

According to the World Health Organization, cardiovascular diseases (CVDs) are a group of disorders of the heart and blood vessels, which primarily include, among others:

- coronary artery disease – a disease of the blood vessels supplying the heart muscle;
- peripheral arterial disease – a disease of blood vessels supplying the arms and legs; and
- cerebrovascular disease – a disease of the blood vessels supplying the brain.

In addition, CVDs are one of the leading causes of death worldwide. According to the CIC Report, peripheral arterial diseases are the most common types of CVDs. In 2021, coronary artery disease, peripheral artery disease and cerebrovascular disease, accounted for approximately 29.9%, 51.1% and 18.3% of CVDs globally, respectively.

OVERVIEW OF PERCUTANEOUS CORONARY INTERVENTION PROCEDURAL INSTRUMENT MARKET

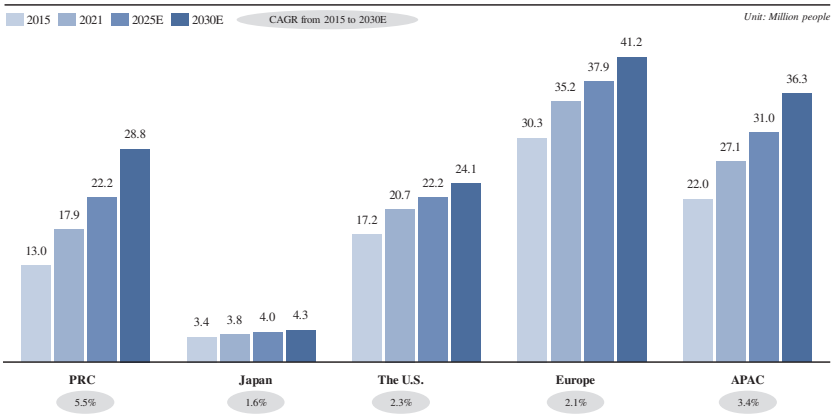
Overview of coronary artery disease

Coronary artery disease (CAD), as the most common type of heart disease, is primarily caused by a buildup of plaque in the walls of coronary arteries, namely the arteries that supply blood to the heart. Atherosclerosis serves as the most usual cause of CAD, in which the buildup of plaque inside the arterial wall gradually reduces the interior lumen of the artery, blocking the blood flow partially or completely. Other less usual causes include coronary artery spasm and coronary artery dissection.

According to the CIC Report, the prevalence of CAD has grown steadily on a global scale. In the PRC, the CAD prevalence has grown from 13.0 million in 2015 to 17.9 million in 2021, and is expected to continue growing to 28.8 million in 2030. In Japan, the CAD prevalence has grown from 3.4 million in 2015 to 3.8 million in 2021, and is expected to continue growing to 4.3 million in 2030. In the U.S., the CAD prevalence has grown from 17.2 million in 2015 to 20.7 million in 2021, and is expected to continue growing to 24.1 million in 2030. In Europe, the CAD prevalence has grown from 30.3 million in 2015 to 35.2 million in 2021, and is expected to continue growing to 41.2 million in 2030. In APAC region, the CAD prevalence has grown from 22.0 million in 2015 to 27.2 million in 2021, and is expected to continue growing to 36.3 million in 2030.

The following chart shows the global prevalence data of CAD by region:

Global prevalence of CAD, by region, 2015 vs. 2021 vs. 2025E vs. 2030E



Source: China Insights Industry Consultancy Limited, American Heart Association, Journal of American College of Cardiology, Centers for Disease Control and Prevention, Census Bureau, European Society of Cardiology, Europe Association of PCI, Chinese Circulation Journal, National Healthcare Security Administration, World Heart Federation, Ministry of Health, Labour and Welfare (Japan) and other literature review and expert interviews

Medical treatment for CADs

Medical treatment for CAD depends on their symptoms, cardiac function, and presence of other disorders. There are three primary methods of treating CAD, namely:

1. ***Medical therapy***: medical therapy is the most basic form of treating CAD out of the three methods of treatment. It involves the administration of medication aimed at managing CAD patients' symptoms. All CAD patients in stable condition require medical therapy to prevent disease progression and recurrent cardiovascular events. Recommended therapy includes antiplatelet drugs to prevent blood clot formation, and statins to lower LDL cholesterol. Where medical therapy is ineffective, PCI or CABG may be adopted instead.

2. ***Percutaneous coronary intervention (PCI)***: PCI is a minimally invasive procedure which involves the use of interventional instruments (e.g. catheters) to insert small structures such as balloons and stents into blood vessels to facilitate their dilation. This procedure does not require open-heart surgery, and is short in duration (around one hour, after which the patient may be discharged). PCI therefore has advantages of small trauma, quick recovery after operation, few complications, low risk, and low cost.

3. ***Coronary artery bypass grafting (CABG)***: CABG is an invasive surgical procedure which involves taking a blood vessel from another part of the body (i.e. the graft), and attaching it to the coronary artery above and below the narrowed or blocked area. This procedure diverts blood around the narrowed or blocked parts of the coronary arteries. This procedure is carried out under a general anesthetic, and

usually takes around three to six hours. Patients who have undergone CABG will usually be required to stay in hospital for at least seven days after the bypass surgery. The risks of CABG include stroke and myocardial infarction. However, CABG would be the preferred treatment for patients with diabetes, or with multivessel diseases.

Since PCI carries lower risk and costs, but still enjoys a similar treatment success rate compared to CABG, it is often the preferred form of treating CAD. In a PCI procedure, a semi-compliant balloon is used to pre-expand the blood vessel, following which either a stent or drug-coated balloon will be inserted into the blood vessel for clearing the blockage.

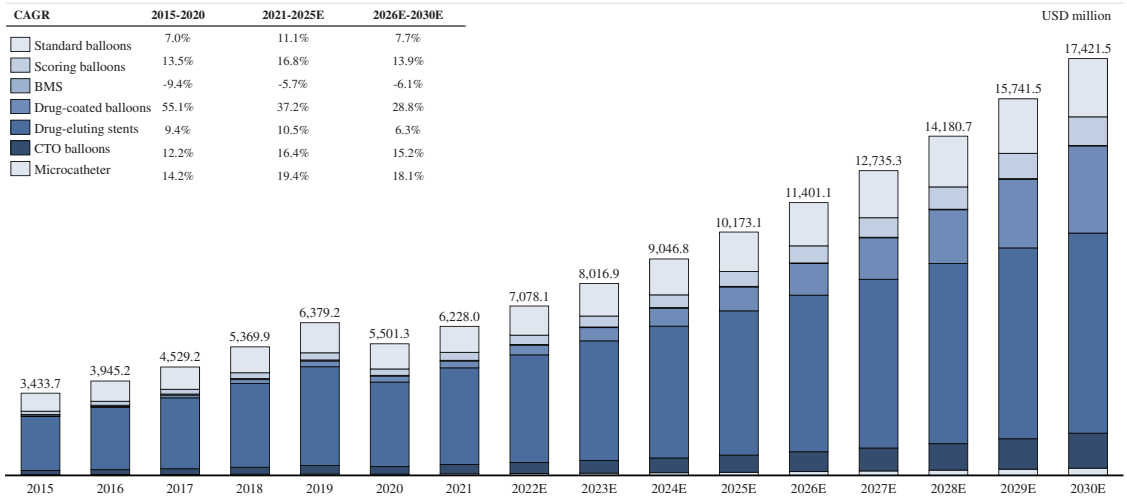
PCI market overview

According to the CIC Report, the volume of PCI differs between countries due to different penetration rate of PCI procedure or local treatment guideline. "Volume" of PCI refers to the number of PCI surgeries performed in a specific region in a given year, while "Penetration Rate" of PCI refers to the percentage of patients that can be treated with PCI surgeries actually proceeded with PCI surgeries in a specific region at a specific time. The calculation of PCI volume is based on prevalence multiplied by PCI penetration. The historical data of prevalence and PCI surgery volume are mainly from American Heart Association, European Society of Cardiology, Chinese Circulation Journal and sample hospital physicians interviews. The future penetration rate growth is in line with the historical trends. In the PRC, PCI volume had grown from 567,600 in 2015 to 1.2 million in 2021, and is expected to continue growing to 3.1 million in 2030; PCI penetration rate had grown from 4.4% in 2015 to 6.7% in 2021, and is expected to continue growing to 10.8% in 2030. In Japan, PCI volume had grown from 212,000 in 2015 to 272,800 in 2021, and is expected to continue growing to 572,300 in 2030; PCI penetration rate had grown from 6.2% in 2015 to 7.2% in 2021, and is expected to continue growing to 13.3% in 2030. In the U.S., PCI volume had grown from 592,700 in 2015 to 1.0 million in 2021, and is expected to continue growing to 3.5 million in 2030; PCI penetration rate had grown from 3.5% in 2015 to 5.0% in 2021, and is expected to continue growing to 14.6% in 2030. In Europe, PCI volume had grown from 890,000 in 2015 to 1.4 million in 2021, and is expected to continue growing to 3.8 million in 2030; PCI penetration rate had grown from 2.9% in 2015 to 4.1% in 2021, and is expected to continue growing to 9.1% in 2030. In APAC region, PCI volume had grown from 1.1 million in 2015 to 2.0 million in 2021, and is expected to continue growing to 6.0 million in 2030; PCI penetration rate had grown from 5.0% in 2015 to 7.4% in 2021, and is expected to continue growing to 16.6% in 2030.

According to the CIC Report, the market size of PCI procedural instruments is also showing continuous growth globally. In the PRC, the market size by sales value was US$765.5 million in 2015 and US$1,270.4 million in 2021, and is expected to reach US$3,751.2 million in 2030. In APAC region, the market size by sales value was US$733.4 million in 2015 and US$1,266.1 million in 2021, and is expected to reach US$2,985.3 million in 2030. In Europe, the market size by sales value was US$582.7 million in 2015 and US$892.6 million in 2021, and is expected to reach US$2,010.9 million in 2030. In the U.S., the market size by sales value was US$400.4 million in 2015 and US$672.9 million in 2021, and is expected to reach US$1,907.4 million in 2030. In Japan, the market size by sales value was US$394.5 million in 2015 and US$484.6 million in 2021, and is expected to reach US$824.1 million in 2030.

PCI procedural instruments primarily include standard balloons, scoring balloons, CTO balloons, drug-coated balloons, bare metal stents, drug-eluting stents, and microcatheters. The following chart shows the global market size of PCI interventional procedural instrument:

Global market size of PCI procedural instrument market, in terms of sales value*, 2015-2030E



Source: China Insights Industry Consultancy Limited, expert interviews and public information

Being the key instrument used for PCI procedures, balloon showed steady growth and is expected to take up the majority of the PCI procedural instrument market by 2030, according to CIC Report. In the PRC, balloon volume had grown from 874,100 in 2015 to 2.1 million in 2021, and is expected to continue growing to 6.4 million in 2030. In Japan, balloon volume had grown from 338,100 in 2015 to 450,400 in 2021, and is expected to continue growing to 1.1 million in 2030. In the U.S., balloon volume had grown from 918,600 in 2015 to 1.6 million in 2021, and is expected to continue growing to 6.2 million in 2030. In Europe, balloon volume had grown from 1.4 million in 2015 to 2.2 million in 2021, and is expected to continue growing to 6.3 million in 2030. In APAC region, balloon volume had grown from 1.7 million in 2015 to 3.2 million in 2021, and is expected to continue growing to 11.3 million in 2030.

Competitive landscape

We are a major PCI balloon developer and manufacturer selling our PCI balloons in over 70 countries and regions around the world. In terms of sales volume of PCI balloons in 2021, we ranked No. 2 in Japan market, No. 4 in the Europe market and No. 6 in both the PRC and U.S. markets. We achieved market share in PCI balloon market in terms of sales volume in 2021 in the Japan, Europe, the PRC and the U.S. of 20%, 11%, 8% and 3%, respectively. Our ability to lead the market is primarily due to the following reasons: (i) our track record of high product quality has been well-recognized by hospitals and physicians and are widely adopted in PCI procedures; (ii) we constantly improve and modify our products to accommodate the evolving needs of physicians and patients, and provide physicians with more customized

options and convenience; and (iii) we have benefited from favorable PRC policies that encourage the development and purchase of domestically-produced medical devices and price control of pharmaceutical products. For instance, there are local policies in Shanghai, Jiangsu, Zhejiang and Anhui with respect to a favorable reimbursement percentage by medical insurance for domestically-produced high-value medical consumables such as coronary interventional medical devices. The key PCI market players in the PRC include Medtronic, Abbott, Terumo, Boston Scientific and Lepu. The key PCI market players in Japan include Terumo, Nipro, Japan Lifeline and Abbott. The key PCI market players in the U.S. include Abbott, Boston Scientific, Medtronic, Cordis and B.Braun. The key PCI market players in Europe include Medtronic, Abbott, Boston Scientific and B.Braun. The following tables set forth the competitive landscape of PCI balloons in the PRC, Japan, the U.S. and Europe markets in terms of sales volume in 2021.

Market share of PCI balloon in terms of sales volume in 2021 by different countries/regions

PRC		Japan		U.S.		Europe	
Company A (the U.S.)	~20%	Company C (Japan)	30%-35%	Company B (the U.S.)	~30%	Company A (the U.S.)	~30%
Company B (the U.S.)	15%~18%	**OrbusNeich (Hong Kong, China)**	**20%**	Company D (the U.S.)	~28%	Company B (the U.S.)	~25%
Company C (Japan)	15%~18%	Company F (Japan)	~15%	Company A (the U.S.)	~22%	Company D (the U.S.)	~23%
Company D (the U.S.)	10%-15%	Company G (Japan)	~10%	Company J (the U.S.)	~10%	**OrbusNeich (Hong Kong, China)**	**11%**
Company E (PRC)	~8%	Company B (the U.S.)	<5%	Company H (Europe)	<5%	Company H (Europe)	~10%
OrbusNeich (Hong Kong, China)	**8%**			**OrbusNeich (Hong Kong, China)**	**3%**		

Note: countries/regions in bracket denote the places of headquarter of respective market players. For the background, principal business and principal places of operations/network coverage of the above top market players, please refer to "– Overview of Percutaneous Transluminal Angioplasty Procedural Instrument Market – Competitive Landscape" in this section for details.

Significant market share of OrbusNeich of PCI balloon in terms of sale volume in 2021 in other countries/regions					
Hong Kong	~52%	Pakistan	~59%	Russia	~26%
Singapore	~57%	Indonesia	~38%	Switzerland	~26%
Malaysia	~41%	Italy	~20%	Czech Republic	~33%
Taiwan	~40%	Slovakia	~40%	The Netherlands	~25%

Source: China Insights Industry Consultancy Limited, expert interviews and public information

In terms of sales volume of PCI stents in 2021, the top five market players in each of Japan and Europe accounted for collectively approximately 91% and 94% of the market share, respectively, and our market share was approximately 2% and 0.3% in Japan and Europe, the major regions where we sell PCI stents, respectively.

Growth drivers and future trends

There are four primary growth drivers and future trends that can be seen of the global coronary artery interventional instrument market:

1. ***Increasing CAD prevalence***: CAD prevalence increases with an aging population, and also amongst the younger population that engage in unhealthy consumption habits such as smoking and alcohol consumption, and increased stress levels.

2. ***Favorable government policies***: given the importance of the coronary artery interventional instrument market for CAD treatment, governments are paying more attention to this market, and are introducing favorable policies to develop this area, which in turn encourages further investments to leverage on such policies. Manufacturers are expected to continuously invest in research and development in constant improvement of their products. For instance, the Reform Plan for the Control of High-value Medical Consumables (治理高值醫用耗材改革方案) encourages the research, development and manufacturing of medical consumables. In addition, policies in Shenzhen such as the Shenzhen Dedicated Funds Support Policy on the Development of Strategic Emerging Industries (深圳市戰略性新興產業發展專項資金扶持政策) and the Shenzhen Technology Research and Development Funds Administration Measures (深圳市科技研發資金管理辦法) provide the basis for the government grant to support of R&D investment.

3. ***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. Doctors also prefer PCI due to its lower risk compared to other methods of surgical treatment.

4. ***Continuous product development***: as development and innovation of medical devices accelerates, medical devices treating CAD are expected to increase in quality and prominence, and achieve better penetration in the global market. As such, the continuous development and innovation of medical devices also enhances room for market expansion.

Threats and Challenges

The major threats and challenges of the global coronary/peripheral artery interventional instrument market primarily include:

Product upgrade and substitution: The coronary/peripheral artery interventional instrument products continue to go through upgrades and substitutions. Companies would continuously research, innovate and develop new generations of products with better surgical results, and as a result, older generation products would gradually become obsolete. For example, after the development of drug eluting stents, the market share of bare metal stents shrunk drastically. The drug eluting stents also compete with dual therapy stents or absorbable

stents. Therefore, the nature of the importance of continuous product upgrade and substitution poses can pose significant threat challenge on PCI/PTA instrument companies, and it is important for them to continuously upgrade their products.

Government regulatory risk: The medical device industry is heavily influenced by the regulations or policies promulgated by the government, which primarily include:

Strict approval regulations: Medical devices are required to go through stringent approval processes. Companies must obtain relative licenses and certificates to produce and sell medical devices and register again if they become invalid after expiry. Strict access systems and complex regulations are major challenges for medical device companies.

Government pricing-related policies: In many countries, government would control prices of medical devices through regulatory means in order to maintain costs of government medical insurances. The centralized procurement policies promulgated by the PRC government under which the purchases of the medical devices included in the centralized procurement scope by the public hospitals should be made through the public bidding or tender processes on the centralized procurement platform established by the respective local governments, often lead to a substantial decrease in the profitability of medical device products manufacturers. Other countries, such as Japan and the U.S., also have policies which would influence the profit margin of medical device products.

COVID-19 pandemic: The COVID-19 pandemic imposes negative effect on the whole medical health industry. Due to the pandemic, many hospitals enforce strict policies on hospital visits and limit the number of patients going to hospitals so that the resources being reallocated to treat COVID patients. Furthermore, the pandemic hit the global economy heavily, and the public's affordability of advanced medical services are impaired. Therefore, the pandemic heavily influences the global health expenditure, which as a result becomes a challenge for medical device companies to make a profit.

Low public awareness: The public awareness of peripheral artery diseases is generally lower than that of cerebral artery diseases or coronary artery diseases. The low public awareness results in low surgical penetration rate. For example, in 2021, the surgical penetration rate of PTA intervention is 0.6% in the PRC, far lower than that of PCI intervention, which is 6.7%, although it is expected to grow to 1.4% in 2030 as a result of various factors including patients awareness of peripheral artery disease, the education from physician conferences or companies and government reimbursement policies. Increased awareness and education of the public about the seriousness of PAD diseases can overcome this challenge.

Major Entry Barriers

The major entry barriers for new participants of the global coronary/peripheral artery interventional instrument market primarily include:

Intensive technology and continuous product innovation: Multi-disciplinary expertise in material and mechanical engineering, product design and manufacturing are necessary in the development of coronary/peripheral artery interventional instruments. In addition, coronary/peripheral artery is very important and complex, which implies a higher level of sophistication of means related to the surgical instruments. New entrants may generally find it difficult to recruit the necessary professionals and acquire the technologies in a short term. On the other hand, continuous product innovation is also important for medical device companies to maintain profitability. The key to success in the medical technology industry has been continuous innovation and a dedication to research and development. A key driver for this continuous innovation is the short lifecycles within the sector. Once a breakthrough technology has been established, improvements are made continuously. The value-based innovations of the medical device industry have proven to not only improve the lives of millions of patients, but also play an important role in making healthcare systems more efficient, which has become a priority for all governments.

Also, the global PCI/PTA market players often challenge the intellectual property of their competitors. Therefore, robust intellectual property protection is important to survive, the building up of which may be costly and time consuming.

Commercialization capability: It is important for medical device manufacturers to develop its global commercialization capabilities and utilize the distributorship sales model to access the global coronary/peripheral artery interventional instrument market. It requires market players to have the ability of mass production at a high quality standard that meets various regulatory bodies' requirements across the globe. In addition, establishing local sales offices with the relevant industry and cultural knowledge to manage direct sales and distributors can be difficult. Identifying suitable distributors in the development of a strong distribution network can also be time consuming. Moreover, gaining brand reputation and awareness plays an important part in product commercialization, which partly means to acquire recognition from target stakeholders such as hospitals and physicians. However, it typically takes years of efforts for a brand to establish solid relationships with physicians and hospitals, especially with KOLs and top-tier hospitals.

Heavy capital investment: Participation in the global PCI/PTA intervention instrument market requires heavy capital investment. Costs of research and development of coronary/peripheral artery interventional instrument products, enhancement of product quality and performance, brand promotion and marketing channel construction, establishing factories which enable mass production at a strict quality standard all require significant capital expenditure and investments. Particularly, a large amount of capital is necessary if the players hope to survive and continuously expand in this industry. Financial pressure is an inevitable challenge for most of the medical device startups in their initial years before they can break even, and it can take substantial time to achieve profitability. Attracting sufficient investments and utilizing the funds effectively and efficiently are practically hard to fulfill, presenting a huge barrier especially for new entrants in the market.

OVERVIEW OF PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY PROCEDURAL INSTRUMENT MARKET

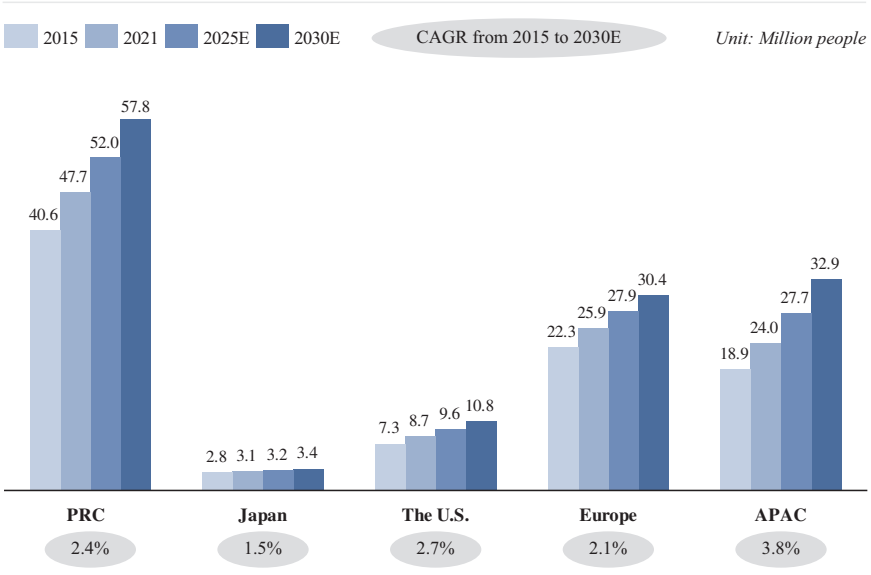
Overview of peripheral artery disease

Peripheral artery disease (PAD) is a common type of vascular diseases, primarily caused by atherosclerosis in the arteries in the limbs. In turn, this causes restricted blood flow to the arms, legs, kidneys, and stomach. Severe cases of PAD can lead to critical limb ischaemia, ulceration, gangrene and may result in amputation of the limbs. PAD is age-related, with its prevalence increasing significantly with age. While PAD can impact various parts of a human body, the PTA procedural instruments developed and manufactured by us primarily focus on treating the lower limb PAD as the main division and accounted for more than 60% of PAD according to epidemiology.

According to the CIC Report, the lower limb PAD prevalence has grown steadily on a global scale. In the PRC, the lower limb PAD prevalence had grown from 40.6 million in 2015 to 47.7 million in 2021, and is expected to continue growing to 57.8 million in 2030. In Japan, the lower limb PAD prevalence had grown from 2.8 million in 2015 to 3.1 million in 2021, and is expected to continue growing to 3.4 million in 2030. In the U.S., the lower limb PAD prevalence had grown from 7.3 million in 2015 to 8.7 million in 2021, and is expected to continue growing to 10.8 million in 2030. In Europe, the lower limb PAD prevalence had grown from 22.3 million in 2015 to 25.9 million in 2021, and is expected to continue growing to 30.4 million in 2030. In APAC region, the lower limb PAD prevalence had grown from 18.9 million in 2015 to 24.0 million in 2021, and is expected to continue growing to 32.9 million in 2030.

Peripheral artery disease is age-related, with its prevalence increasing significantly with advancing age. Currently, the prevalence in high-income countries is higher than that in low-to-middle-income countries. The following chart shows the global prevalence data of the lower limb PAD prevalence by region:

Global prevalence of PAD (lower limb), by region, 2015 vs. 2021 vs. 2025E vs. 2030E



Source: The Lancent; ESC guidelines on the diagnosis and treatment of PAD; China Insights Industry Consultancy Limited

Medical treatment for peripheral arterial disease

Similar with CADs, the three primary methods of treating PADs are medical treatment, surgical treatment and interventional treatment. Surgical treatment methods include aorto-(bi)femoral bypass, open surgery, and extra-anatomical bypass. Interventional treatment methods include endovascular therapy, primary stent implantation, drug-eluting balloons and drug-eluting stents. Percutaneous transluminal angioplasty (PTA) is a medical treatment procedure that can open up a blocked blood vessel using a catheter and a balloon, which inflates to open the blood vessel in order to restore normal blood flow. Sometimes, interventional and surgical methods may be adopted together to treat PAD. The treatment type and method depends on the type and extent of lesion being suffered by the PAD patient.

Market overview

According to the CIC Report, while the volume and penetration rate of peripheral PTA differs between countries, it is showing continuous growth globally. "Volume" of PTA refers to the number of PTA surgeries performed in a specific region in a given year, while "Penetration rate" of PTA refers to the percentage of patients that can be treated with PTA surgeries actually proceeded with PTA surgeries in a specific region at a specific time. The calculation of PTA volume is based on prevalence multiplied by PTA penetration. The

historical data of prevalence and PTA surgery volume are mainly from American Heart Association, European Society of Cardiology, Chinese Circulation Journal and sample hospital physicians interviews. The future penetration rate growth is in line with the historical trends. In the PRC, peripheral PTA volume had grown from 162,400 in 2015 to 273,100 in 2021, and is expected to continue growing to 823,200 in 2030; peripheral PTA penetration rate had grown from 0.4% in 2015 to 0.6% in 2021, and is expected to continue growing to 1.4% in 2030. In Japan, peripheral PTA volume had grown from 52,200 in 2015 to 95,100 in 2021, and is expected to continue growing to 217,000 in 2030; peripheral PTA penetration rate had grown from 1.9% in 2015 to 3.1% in 2021, and is expected to continue growing to 6.3% in 2030. In the U.S., peripheral PTA volume had grown from 34,500 in 2015 to 60,800 in 2021, and is expected to continue growing to 198,100 in 2030; peripheral PTA penetration rate had grown from 0.5% in 2015 to 0.7% in 2021, and is expected to continue growing to 1.8% in 2030. In Europe, peripheral PTA volume had grown from 96,900 in 2015 to 160,700 in 2021, and is expected to continue growing to 415,400 in 2030; peripheral PTA penetration rate had grown from 0.4% in 2015 to 0.6% in 2021, and is expected to continue growing to 1.4% in 2030. In APAC region, peripheral PTA volume had grown from 79,200 in 2015 to 160,000 in 2021, and is expected to continue growing to 437,200 in 2030; peripheral PTA penetration rate had grown from 0.4% in 2015 to 0.7% in 2021, and is expected to continue growing to 1.3% in 2030.

Further, according to the CIC Report, the market size of PTA procedural instruments is also showing continuous growth globally. In the PRC, the market size by sales value was US$166.0 million in 2015 and US$280.9 million in 2021, and is expected to reach US$976.6 million in 2030. In Japan, the market size by sales value was US$89.7 million in 2015 and US$161.1 million in 2021, and is expected to reach US$320.4 million in 2030. In the U.S., the market size by sales value was US$21.7 million in 2015 and US$36.3 million in 2021, and is expected to reach US$91.3 million in 2030. In Europe, the market size by sales value was US$61.0 million in 2015 and US$94.8 million in 2021, and is expected to reach US$194.7 million in 2030. In APAC region, the market size by sales value was US$50.0 million in 2015 and US$93.2 million in 2021, and is expected to reach US$205.3 million in 2030.

Competitive landscape

We are a major PTA balloon developer and manufacturer in the Japan and U.S. markets. In terms of sales volume of PTA balloons in 2021, we ranked No. 3 in the Japan market and No. 4 in the U.S. market. We achieved market share in PTA balloon market in terms of sales volume in 2021 in Japan and the U.S. of 13% and 12%, respectively. Our ability to lead the market is primarily due to the following reasons: (i) our track record of high product quality has been well-recognized by hospitals and physicians and widely adopted in PTA procedures and (ii) we constantly improve and modify our products to accommodate the evolving needs to the physicians and patients, and provide physicians with more customized options and convenience. In addition, we had a 1% market share in terms of sales volume in 2021 in the Europe PTA balloon market. We also actively seek opportunities in the PRC PTA balloon market. The key PTA market players in the PRC include Medtronic, Boston Scientific, Merit, Cordis and Acotec. The key PTA market players in Japan include Terumo, Asahi, Boston Scientific and Medtronic. The key PTA market players in the U.S. include Medtronic, Cordis,

Boston Scientific and Biosensors. The key PTA market players in Europe include Medtronic, Boston Scientific, Abbott, BD and B.Braun. The following table sets forth the top five players of peripheral balloons in the PRC, Japan, the U.S. and Europe markets in terms of sales volume in 2021.

Market share of PTA balloon in terms of sales volume in 2021 by different countries/regions

PRC*		Japan		U.S.		Europe	
Company A (the U.S.)	~30%	Company C (Japan)	~30%	Company A (the U.S.)	~30%	Company A (the U.S.)	~30%
Company D (the U.S.)	~20%	Company K (Japan)	~20%	Company J (the U.S.)	~15%	Company D (the U.S.)	~25%
Company I (the U.S.)	~16%	**OrbusNeich (Hong Kong, China)**	**13%**	Company D (the U.S.)	~15%	Company B (the U.S.)	~20%
Company J (the U.S.)	~15%	Company D (the U.S.)	~10%	**OrbusNeich (Hong Kong, China)**	**12%**	Company M (the U.S.)	~12%
Company N (PRC)	~13%	Company A (the U.S.)	~10%	Company L (Europe)	~8%	Company H (the U.S.)	<10%
						OrbusNeich (Hong Kong, China)	**1% ranked 6-10**

Note: countries/regions in bracket denote the places of headquarter of respective market players

Source: China Insights Industry Consultancy Limited, expert interviews and public information

* We did not commence sales of PTA balloons in the PRC in 2021.

The table below sets forth the background, principal business and principal places of operations/network coverage of the top market players in the PCI/PTA instrument markets:

Competitor	Background and principal business	Principal place of operations/network coverage	Business scale(number of employees)
Company A	Company A is a New York Stock Exchange listed medical device company that generates revenues from four business segments: cardiac and vascular, minimally invasive therapies, restorative therapies, and diabetes.	Global	Over 100,000
Company B	Company B is a New York Stock Exchange listed company primarily focuses on product lines including cardiac rhythm management, electrophysiology, heart failure, vascular and structural heart devices for the treatment of cardiovascular diseases, and diabetes care products for diabetes patients, as well as neuromodulation devices for the management of chronic pain and movement disorders.	Global	Over 100,000

Competitor	Background and principal business	Principal place of operations/network coverage	Business scale(number of employees)
Company C	Company C is a Tokyo Stock Exchange listed manufacturer of medical supplies which focuses on the cardiac and vascular segment and is engaged in the manufacture of catheter system and cardiopulmonary system products, the import of the cardiopulmonary systems and artificial blood vessels, as well as the sale of products mainly to hospitals and clinics nationwide through agents.	Global	Over 25,000
Company D	Company D is a New York Stock Exchange listed company offers medical device products covering interventional cardiology, peripheral interventions, cardiac rhythm management, electrophysiology, endoscopy, urology and pelvic health, neuromodulation, and specialty pharmaceuticals.	Global	Over 40,000
Company E	Company E is a PRC-based Shenzhen Stock Exchange listed company principally engaged in the research, development, production and sale of cardiovascular related medical equipment, medicines and health products, as well as in the provision of related medical services.	The PRC	Over 10,000
Company F	Company F is a Tokyo Stock Exchange listed company has three segments: the medical-related segment involves in the sale of injections and infusions, artificial organs, high function and dialysis related medical equipment, and diabetes, generics and kits related medicine products.	Mainly Japan and Asian countries	Over 35,000
Company G	Company G is a Tokyo Stock Exchange lised company mainly engaged in the production of cardiac rhythm devices, electrophysiological (EP) and ablations, surgical products and intervention products.	Japan	501-1,000
Company H	Company H is a private medical device manufacturer which supplies products ranging from catheters to surgical instruments.	Mainly Europe, North America and Asia-Pacific	Over 60,000

Competitor	Background and principal business	Principal place of operations/network coverage	Business scale(number of employees)
Company I	Company I is a NASDAQ Stock Exchange listed company designs, develops, manufactures and markets medical products for interventional and diagnostic procedures in the cardiovascular and endoscopy segments.	Mainly the U.S.	5,001-10,000
Company J	Company J is a private U.S. based medical device manufacturer focusing on interventional vascular medicine and neuroscience.	Global	Over 3,500
Company K	Company K is a Tokyo Stock Exchange listed company engaged in the development, manufacturing and sale of medical devices of ultra-fine stainless steel wire ropes, terminal processed products, etc.	Mainly Japan and the PRC	5,001-10,000
Company L	Company L is a private company operates globally, offering interventional devices and solutions for patients living with coronary artery diseases.	Mainly Europe, the PRC and Japan	0-500
Company M	Company M is a New York Stock Exchange listed company focuses on developing innovative surgical, endovascular interventions that not only meet clinical needs but also deliver value to health systems and improve patients' lives.	Global	Over 60,000
Company N	Company N is a PRC-based Hong Kong Stock Exchange listed interventional medical device company and its products are mainly used for vascular interventional treatment.	The PRC	0-500

Growth drivers and future trends

There are four primary growth drivers and future trends that can be seen of the global peripheral artery interventional instrument market:

1. ***Increasing PAD prevalence***: PAD prevalence is directly related to increasing age, particularly among those aged over 40 years old in the population. PAD prevalence is expected to increase in line with the global trend of aging population.

2. ***Growing popularity of early diagnosis***: with technological and medical advancements, the ability of early diagnosis for peripheral vascular diseases will continue to improve. Rising concern for healthcare especially in developing countries, coupled with the growing popularity of early diagnosis and GDP growth, is expected to have a positive impact on the growth of the peripheral arterial disease treatment market.

3. ***Continuous product upgrades and innovation***: constant improvement and innovation of PAD treatment medical devices is expected to drive the development of this industry in the global market.

4. ***Rising demand for PTA operations***: PAD patients are expected to prefer minimally invasive surgery owing to shorter recovery time, lesser scaring and lower risk of post-surgery complications. This is expected to drive the demand for the PTA market.

Threats and Challenges

For the major threats and challenges of the global peripheral artery interventional instrument market, please refer to "– Overview of Percutaneous Coronary Intervention Procedural Instrument Market – Threats and Challenges".

Major Entry Barriers

For the major entry barriers of the global peripheral artery interventional instrument market, please refer to "– Overview of Percutaneous Coronary Intervention Procedural Instrument Market – Major Entry Barriers".

OVERVIEW OF NEURO INTERVENTIONAL INSTRUMENT MARKET

Overview of intracranial vascular disease

Intracranial vascular disease is the most common life-threatening neurological event, including all disorders in which an area of the brain is temporarily or permanently affected by ischemia or bleeding and one or more of the cerebral blood vessels are involved in the pathological process. Restrictions in blood flow may occur from vessel narrowing (stenosis), clot formation (thrombosis), blockage (embolism) or blood vessel rupture (hemorrhage).

Treatment for Intracranial Vascular Diseases

There are three primary methods of treating intracranial vascular diseases, namely:

1. ***Intravenous thrombolysis (IVT)***: intravenous thrombolysis is a method using thrombolytic drugs to treat thrombosis. In the situation of ischemic stroke, this term specifically refers to degradation of fibrin, dissolving blood clots by activating plasminogen.

2. ***Neuro-interventional procedures***: minimally invasive procedures, including thrombectomy, aneurysm embolization and balloon/stent angioplasty, that are used to treat problems affecting the blood vessels with the help of radiology and advanced image-guidance technology. It is a cutting-edge method as a catheter-based approach is applied on intracranial vascular diseases. A neuro-interventional procedure allows a longer time window for treatment and comparable drug effect when compared to IVT, while it allows minimal damage, recovery cycle and side effects when compared to open surgery.

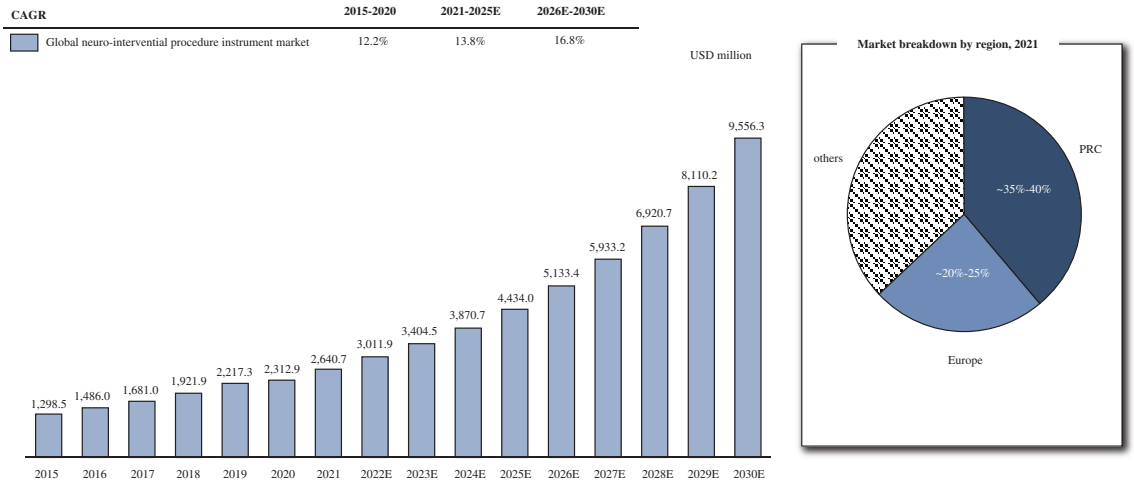
3. ***Open surgery***: the traditional type of surgery in which an incision is made using a scalpel. By opening the skull, surgeons can find the diseased vessels visually and do operations on them directly.

Stent retrieving thrombectomy serves as the first-line neuro-interventional treatment for acute ischemic stroke, while aspiration thrombectomy is experiencing fast development in recent years with great efficacy, according to the CIC Report. Neuro artery stenting serves as an important treatment for intracranial stenosis, and drug-eluting balloon as well as drug-eluting stenting are anticipated to experience fast development in the future.

Market overview

According to the CIC Report, the global neuro-interventional instrument market in terms of sale value has grown from US$1,298.5 million in 2015 to US$2,640.7 million in 2021, and is expected to continue growing to US$4,434.0 million in 2025, representing a CAGR of 13.8% from 2021 to 2025, and further grow to US$9,556.3 million in 2030, representing a CAGR of 16.8% from 2026 to 2030. In 2021, each of the PRC and Europe represented approximately 35%-40% and 20%-25% of the global neuro-interventional instrument market, respectively.

Global market size of Neuro interventional instrument market, in terms of sales value*, 2015-2030E



Source: China Insights Industry Consultancy Limited, expert interviews and public information

Growth drivers and future trends

In view of the above, there are four primary growth drivers and future trends that can be seen of the global neuro-interventional instrument market:

1. ***Increasing prevalence of stroke***: stroke is an age-related disease with an increasing prevalence for the elderly group. Considering the trend of aging population globally, it is expected that an increasing number of patients will suffer from stroke in the future.

2. ***Increasing number and penetration of neuro-interventional procedures***: with more innovative neuro-interventional procedures developed for various indications, doctors and patients will have a wider range of choices, resulting in an increasing number of neuro-interventional procedures. Despite the currently limited number of physicians capable of performing the procedures, more physicians will be trained to meet the large patient demand, allowing the neuro-interventional procedures to become a common clinical practice.

3. ***Continuous product improvement and innovation***: neuro-interventional procedure devices are typically high-end medical instruments, representing technological advances, transforming the way of clinical care with innovation. For example, smaller incisions could reduce surgical trauma and shorten recovery time for patients. The emergence and iteration of neuro-interventional medical devices will promote the development of global neuro-interventional medical device market.

4. ***Advances in imaging techniques may improve access to vascular interventional therapy***: in recent years, with the development of imaging technology and its increasing application in clinical practice, the intravascular environment can be better seen and the detection rate of vascular diseases (such as unruptured intracranial aneurysms, intermittent claudication, and threatening limb ischemia) can be improved. In addition, technological innovations such as ischemic penumbra have provided the basis for early stroke screening and prevention, resulting in the discovery of more eligible patients at high risk of stroke and the expansion of the patient population. As the use of AI algorithms increases, back-end automation of imaging systems and analytics software will accelerate in the coming years and help doctors achieve more efficient diagnoses.

Threats and Challenges

The major threats and challenges of the global neuro-interventional instrument market primarily include:

Uncertainties in macro-control: In certain countries, such as the PRC, the government regards precision medical products as a key development area and considers it to be a national development strategy. For example, the Chinese government's policies in the medical field related to people's livelihood and health are very strong, which may have a great impact on the income and profit of the investors. It is not ruled out that the government will introduce restrictive policies for the industry due to economic factors, political factors, macro-control and other factors. If the government's policies and regulations on the management of medical institutions are strict and not biased, it will cause policy risks.

Lack of core competitiveness: Although the R&D investment of enterprises in neuro intervention industry is increasing year by year, the R&D investment of new enterprises is far less than that of large multinational corporations due to the limited operating income of the new enterprises. The low R&D investment may have negative impact on the quality of products and the core competitiveness of the new enterprise.

Major Entry barriers

The major entry barriers for new participants of the global neuro-interventional instrument market primarily include:

Product portfolio and solutions: Different procedures require various types and specifications of neuro-interventional medical devices. New entrants may not be able to compete with other market players in terms of synergies for R&D, manufacturing and commercialization capabilities and economies of scale, and therefore cannot offer a comprehensive product portfolio to meet the various needs.

Registration and regulatory requirements: In certain countries, such as the PRC, Class III neuro-interventional medical devices generally require product registration testing and clinical trials if they are not exempted from clinical trials under the catalog published by the NMPA. Rigorous registration standards on safety and efficacy are implemented to regulate the development and commercialization of these medical devices. Furthermore, the product development and registration process may take up to five years and neuro-interventional medical device manufacturers need to obtain manufacturing licenses and to maintain strict compliance with GMP requirements and other various regulations in the PRC. As a result, registration and regulatory requirements in relevant jurisdictions would become entry barriers for new entrants in the market.

Heavy capital investment: Participation in the global neuro-intervention instrument market requires heavy capital investment. Costs of research and development of neuro-interventional instrument products, enhancement of product quality and performance, brand promotion and marketing channel construction, establishing factories which enable mass production at a strict quality standard all require significant capital expenditure and investments. Particularly, a large amount of capital is necessary if the players hope to survive and continuously expand in this industry. Financial pressure is an inevitable challenge for most of the medical device startups in their initial years before they can break even, and it can take substantial time to achieve profitability. Attracting sufficient investments and utilizing the funds effectively and efficiently are practically hard to fulfill, presenting a huge barrier especially for new entrants in the market.

OVERVIEW OF STRUCTURAL HEART DISEASE INTERVENTIONAL PROCEDURAL INSTRUMENT MARKET

Overview of structural heart disease

Structural heart disease refers to physical and physiological changes to the heart caused by anatomical abnormalities of the heart tissues or valves. Many structural heart diseases are present at birth (i.e. congenital), whilst others develop later in life. Types of structural heart disease include valvular heart disease (stenosis or regurgitation of the heart valves), congenital heart disease, heart failure, cardiomyopathy and ventricular abnormalities. Regional variation in the prevalence of valvular heart disease is apparent. For example, screening studies in populations of older individuals have demonstrated a prevalence of moderate or severe tricuspid regurgitation of 2.7% in the UK and 1.1% in the PRC.

1. Tricuspid valve disease

Prevalence of tricuspid regurgitation and tricuspid stenosis in the PRC, Japan and the APAC region has been steadily increasing, and is expected to continue to increase. Tricuspid regurgitation prevalence in the PRC was 9.5 million in 2015, rising to 11.7 million in 2021, and is expected to increase to 15.2 million in 2030; tricuspid stenosis prevalence in the PRC was 0.2 million in 2015, rising to 0.3 million in 2021, and is expected to maintain at 0.3 million in 2030. Tricuspid regurgitation prevalence in Japan was 0.6 million in 2015, rising to 0.7 million in 2021, and is expected to increase to 0.8 million in 2030; tricuspid stenosis prevalence in Japan was 0.4 million in 2015, rising to 0.5 million in 2021, and is expected to maintain at 0.5 million in 2030. Tricuspid regurgitation prevalence in APAC region was 4.4 million in 2015, rising to 5.2 million in 2021, and is expected to increase to 6.6 million in 2030; tricuspid stenosis prevalence in APAC region was 3.1 million in 2015, rising to 3.7 million in 2021, and is expected to increase to 4.6 million in 2030.

2. Mitral valve disease

Prevalence of mitral regurgitation and mitral stenosis in the PRC, Japan and the APAC region has been steadily increasing, and is expected to continue to increase. Mitral regurgitation prevalence in the PRC was 8.6 million in 2015, rising to 10.5 million in 2021, and is expected to increase to 13.5 million in 2030; mitral stenosis prevalence in the PRC was 0.6 million in 2015, rising to 0.8 million in 2021, and is expected to increase to 1.0 million in 2030. Mitral regurgitation prevalence in Japan was 2.2 million in 2015, rising to 2.4 million in 2021, and is expected to increase to 2.6 million in 2030; mitral stenosis prevalence in Japan was 0.1 million in 2015, maintained at 0.1 million in 2021, and is expected to increase to 0.2 million in 2030. Mitral regurgitation prevalence in APAC region was 14.9 million in 2015, rising to 17.8 million in 2021, and is expected to increase to 22.5 million in 2030; mitral stenosis prevalence in APAC region was 0.9 million in 2015, rising to 1.1 million in 2021, and is expected to increase to 1.3 million in 2030.

3. Aortic valve disease

Prevalence of aortic regurgitation and aortic stenosis in the PRC, Japan and the APAC region has been steadily increasing, and is expected to continue to increase. Aortic regurgitation prevalence in the PRC was 11.4 million in 2015, rising to 14.0 million in 2021, and is expected to increase to 18.0 million in 2030; aortic stenosis prevalence in the PRC was 0.5 million in 2015, rising to 0.6 million in 2021, and is expected to increase to 0.8 million in 2030. Aortic regurgitation prevalence in Japan was 0.6 million in 2015, rising to 0.7 million in 2021, and is expected to increase to 0.8 million in 2030; aortic stenosis prevalence in Japan was 0.5 million in 2015, rising to 0.6 million in 2021, and is expected to maintain at 0.6 million in 2030. Aortic regurgitation prevalence in APAC region was 4.4 million in 2015, rising to 5.2 million in 2021, and is expected to increase to 6.6 million in 2030; aortic stenosis prevalence in APAC region was 3.5 million in 2015, rising to 4.2 million in 2021, and is expected to increase to 5.3 million in 2030.

Treatment for Structural Heart Disease

There are three primary methods of treating structural heart diseases, namely:

1. ***Medication therapy***: drugs such as inhibitors, antibiotics, anticoagulants, beta-blockers, diuretics and vasodilators are administered to increase the heart's pumping ability, control irregular heartbeats, relieve cardiovascular discomfort and prevent blood clots. It is suitable for patients with very mild heart disease, or where surgery is unsuitable.

2. ***Transcatheter intervention***: minimally invasive procedures that involve the implantation of medical devices in the patient's blood vessels, such as transcatheter tricuspid valve replacement (TTVR), transcatheter mitral valve replacement (TMVR), transcatheter aortic valve replacement (TAVR), transcatheter mitral valve implantation (TMVI), percutaneous pulmonary valve implantation (PPVI), and transcatheter edge-to-edge mitral valve repair (TEER). It is suitable for high-risk patients with valvular or congenital heart diseases.

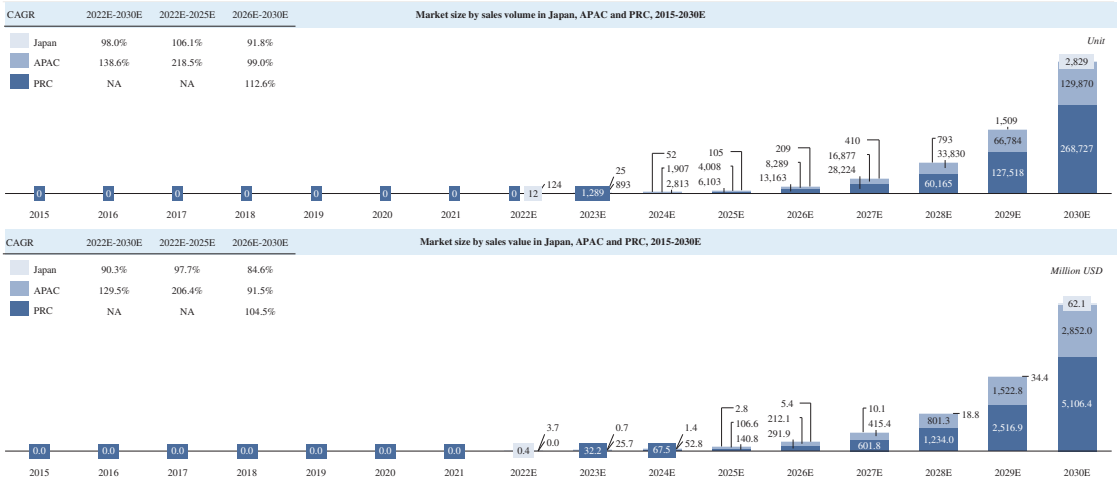
3. ***Open-heart surgery***: an invasive procedure where surgery will be conducted under general anesthetic, and patients will be placed on a cardiopulmonary bypass machine, which will temporarily act as the patient's heart and lungs whilst surgery is being performed. This method is suitable for patients with more advanced stage of heart disease with severe symptoms.

Valve Replacement Market overview

1. Transcatheter Tricuspid Valve Replacement (TTVR)

According to the CIC Report, it is expected that the first tricuspid replacement interventional surgical device in the PRC will be launched in 2023, reaching an expected sales volume of 1,289 units that year, growing exponentially to 6,103 by 2025 and 268,727 by 2030, representing a CAGR of 112.6% from 2026 to 2030, translating to US$32.2 million in terms of market size by sales value in the PRC in 2023, and rising to US$140.8 million by 2025 and US$5,106.4 million by 2030. According to the CIC Report, it is expected that the first tricuspid replacement interventional surgical device in Japan will be launched in 2022, reaching an expected sales volume of 12 units that year, growing exponentially to 105 units by 2025 and 2,829 units by 2030, representing a CAGR of 106.1% from 2022 to 2025 and 91.8% from 2026 to 2030, translating to US$0.4 million in terms of market size by sales value in Japan in 2022, and rising to US$2.8 million by 2025 and US$62.1 million by 2030. According to the CIC Report, it is expected that the first tricuspid replacement interventional surgical device in APAC region will be launched in 2022, reaching an expected sales volume of 124 units that year, growing exponentially to 4,008 by 2025 and 129,870 by 2030, representing a CAGR of 218.5% from 2022 to 2025 and 99.0% from 2026 to 2030, translating to US$3.7 million in terms of market size by sales value in APAC region in 2022, and rising to US$106.6 million by 2025 and US$2,852.0 million by 2030.

Japan, APAC and PRC market size of transcatheter tricuspid valve replacement surgical device



Source: China Insights Industry Consultancy Limited, expert interviews and public information

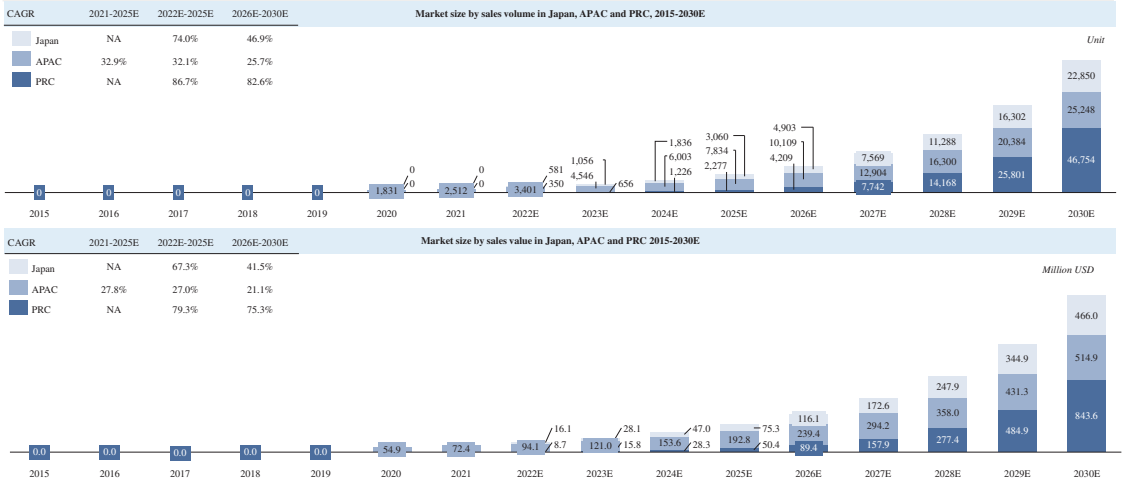
TricValve® Transcatheter Bicaval Valves is a system of two self-expanding biological valves for the treatment of patients with hemodynamically relevant tricuspid insufficiency and caval reflux. The prostheses are implanted percutaneously into the inferior and superior vena cava without disturbing the native tricuspid valve. It is especially intended for use for patients at extreme risk or who are inoperable for open surgical therapy. TricValve® Transcatheter

Bicaval Valves System is a method to address tricuspid regurgitation and caval reflux without disturbing the natural tricuspid valve. TricValve® Transcatheter Bicaval Valves System is the only CAVAL valve implantation available and has received CE Mark. As of the Latest Practicable Date, there is no other TTVR product approved for commercialization globally.

2. Transcatheter Mitral Valve Replacement (TMVR)

According to the CIC Report, the first mitral valve replacement interventional surgical device in the PRC is expected to be launched in 2022, reaching a sales volume of 350 units that year, and is expected to grow exponentially to 2,277 units by 2025 and 46,754 units by 2030, representing a CAGR of 86.7% from 2022 to 2025 and 82.6% from 2026 to 2030, translating to US$8.7 million in terms of market size by sales value in the PRC in 2022, rising to US$50.4 million by 2025 and US$843.6 million by 2030. According to the CIC Report, the first mitral valve replacement interventional surgical device in Japan is expected to be launched in 2022, reaching a sales volume of 581 units that year, and is expected to grow exponentially to 3,060 units by 2025 and 22,850 units by 2030, representing a CAGR of 74.0% from 2022 to 2025 and 46.9% from 2026 to 2030, translating to US$16.1 million in terms of market size by sales value in Japan in 2022, rising to US$75.3 million by 2025 and US$466.0 million by 2030. According to the CIC Report, the first mitral valve replacement interventional surgical device in APAC region was launched in 2020, reaching a sales volume of 1,831 units that year, and is expected to grow exponentially to 7,834 units by 2025 and 25,248 units by 2030, representing a CAGR of 32.9% from 2021 to 2025 and 25.7% from 2026 to 2030, translating to US$54.9 million in terms of market size by sales value in APAC region in 2020, rising to US$192.8 million by 2025 and US$514.9 million by 2030.

Japan, APAC and PRC market size of transcatheter mitral valve replacement surgical device

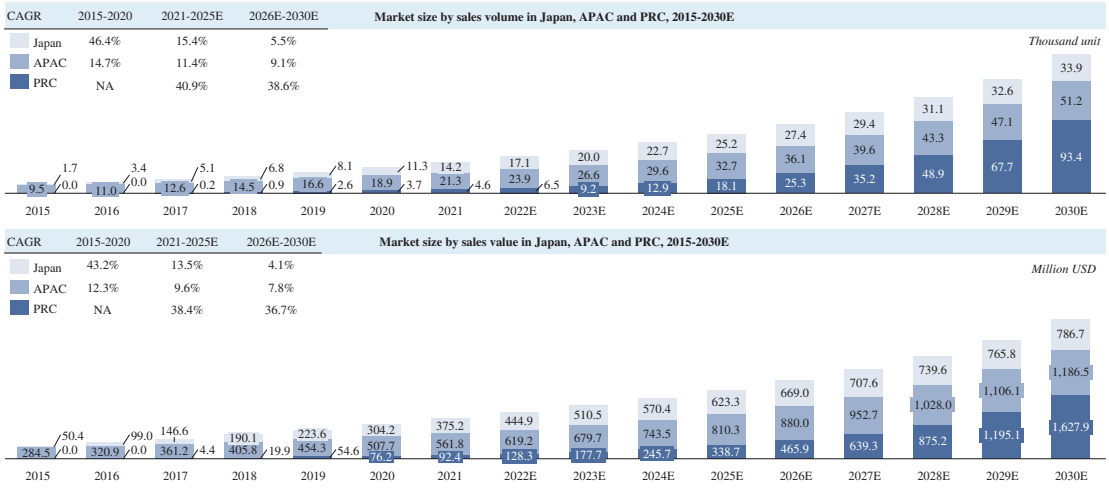


Source: China Insights Industry Consultancy Limited, expert interviews and public information

3. Transcatheter Aortic Valve Replacement (TAVR)

According to the CIC Report, the aortic replacement interventional surgical device market in the PRC has grown steadily from 200 units in 2017 to 4,600 in 2021, and is expected to reach 93,400 by 2030, translating to US$4.4 million in terms of market size by sales value in the PRC in 2017, rising to US$92.4 million in 2021 and further to US$1,627.9 million by 2030. The aortic replacement interventional surgical device market in Japan has grown steadily from 1,700 units in 2015 to 14,200 in 2021, and is expected to reach 33,900 by 2030, translating to US$50.4 million in terms of market size by sales value in Japan in 2015, rising to US$375.2 million in 2021 and further to US$786.7 million by 2030. According to the CIC Report, the aortic replacement interventional surgical device market in APAC region has grown steadily from 9,484 units in 2015 to 21,300 in 2021, and is expected to reach 51,200 by 2030, translating to US$284.5 million in terms of market size by sales value in APAC region in 2015, rising to US$561.8 million in 2021 and further to US$1,186.5 million by 2030.

Japan, APAC and PRC market size of transcatheter aortic valve replacement surgical device



Source: China Insights Industry Consultancy Limited, expert interviews and public information

Growth drivers and future trends

In view of the above, there are three primary growth drivers and future trends that can be seen of the structural heart interventional surgery market:

1. ***Aging population with high prevalence of cardiac disease***: structural heart disease prevalence is directly related with increasing age, and in particular, valvular diseases have high mortality rate. The aging population is expected to drive demand for interventional surgery.

2. ***Improvement of bio-valve technology***: with technological and medical advancements in bio-valve technology and more market education, the market share of bio-valve devices in the PRC is expected to increase gradually.

3. ***Emerging interventional procedure*** : constant improvement and innovation of structural heart interventional treatment medical devices is expected to drive the development of this industry in the global market.

Threats and Challenges

The major threats and challenges of the global structural heart disease interventional instrument market primarily include:

Patient acceptance and pricing: The risk awareness of structural heart disease is still in an early stages to the public, and it may be difficult for patients to accept even the world's leading technology products immediately. The pricing of the commercialized heart valve products is considered expensive to most of the patients, and therefore how to adjust the price to a widely accepted range becomes a challenge to the industry.

Lifetime rejection reaction: Patients who went through transcatheter valve replacement surgeries usually would experience rejection reactions, and are required to take anti-rejection medications throughout lifetime. The improvement of valve designs and materials can reduce the rejection reactions. Thus, it is a challenge for companies to design and produce artificial valve products with reduced rejection reactions.

Major Entry barriers

The major entry barriers for new participants of the global structural heart disease interventional instrument market primarily include:

Intensive technology and continuous product innovation: Multi-disciplinary expertise in material and mechanical engineering, product design and manufacturing are highly demanded in structure heart interventional instrument industry. The complexity of heart and heart valve required highly sophisticated and precision interventional instruments. Difficulty to New entrants may generally find it difficult to hire professionals and acquire the technologies in a short term.

Heavy capital investment: Costs of R&D on structural heart interventional instrument are heavy, which are mainly for the enhancement of product quality and performance, payment to the professional developers and laboratory in the long term, brand promotion and marketing channel construction all need fund to a significant extent. If a manufacturer hopes to survive and subsequently expand in this industry, financial pressure is an inevitable challenge for most of them especially in the initial years before finally breaking even. Attracting sufficient investments and arranging the funds effectively and efficiently are practically hard to fulfill for new entrants.

PRICE TRENDS OF MAJOR RAW MATERIALS AND PRICE TREND

Major Raw Materials

The key raw materials used in producing our balloon and stent products are medical grade stainless steel, polyester and nylon. Fluctuations in prices of these raw materials may be affected by the cost structure, product pricing and profitability of balloon and stent market players.

The average price of medical grade stainless steel in the PRC was approximately RMB15.2 per kilogram, RMB15.6 per kilogram, RMB15.1 per kilogram, RMB14.3 per kilogram and RMB14.9 per kilogram in 2017, 2018, 2019, 2020 and 2021, respectively. Over the past five years, the average price of medical grade stainless steel in the PRC has been fluctuating, yet the price is demonstrating a growing trend overall. The average price of medical grade stainless steel is expected to increase to RMB16.6 per kilogram in 2025.

The average price of polyester in the PRC was approximately RMB7.9 per kilogram, RMB9.2 per kilogram, RMB7.6 per kilogram, RMB5.4 per kilogram and RMB5.6 per kilogram in 2017, 2018, 2019, 2020 and 2021, respectively. Over the past five years, the average price of polyester in the PRC has been fluctuating, yet it demonstrates a gradual downward trend overall. The average price of polyester is expected to decrease to RMB4.2 per kilogram in 2025.

The average price of nylon in the PRC was approximately RMB17.8 per kilogram, RMB18.1 per kilogram, RMB14.1 per kilogram, RMB11.6 per kilogram and RMB13.1 per kilogram in 2017, 2018, 2019, 2020 and 2021, respectively. Over the past five years, the average price of nylon in the PRC has been fluctuating, but exhibits a gradual downward trend. The average price of nylon is expected to decrease to RMB10.2 per kilogram in 2025.

PRICE TREND OF BALLOONS AND STENTS

According to CIC Report, the average price of same model of standard PCI balloons is generally expected to decrease over time at approximately 2% per annum after its commercialization and product launch. In light of advances in technology and more medical device manufacturers entering into this market, the price of same model balloon will demonstrate a gradual downward trend in the future and new or more advanced generation of products will enjoy a higher average selling price.

According to CIC Report, the average price of same model of standard PTA balloons is generally expected to decrease over time at approximately 2% per annum after its commercialization and product launch.

The average price of same model of drug eluting stent is generally expected to decrease over time at approximately 2% per annum after its commercialization and product launch. In light of advances in technology and more medical device manufacturers entering into this market, the price of same model stent will demonstrate a gradual downward trend in the future and new or more advanced generation of products will enjoy a higher average selling price.