

Global Market Study of Ablation Therapy

Independent Market Research Report

Confidential For



Frost & Sullivan
September 2022

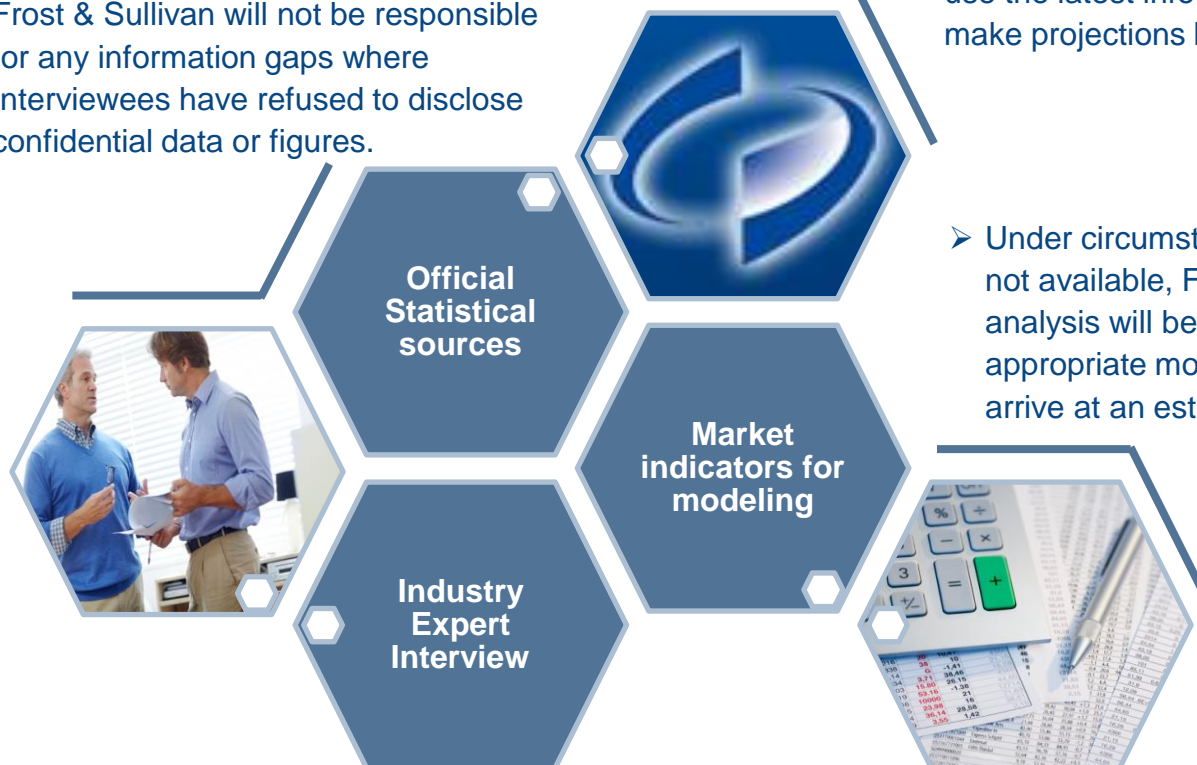


Limitations

■ Source of Information

- Interviews with industry experts and competitors will be conducted on a best-effort basis to collect information for in-depth analysis for this report.
- Frost & Sullivan will not be responsible for any information gaps where interviewees have refused to disclose confidential data or figures.

- The study took 2021 as the base year for analysis and 2022-2026 for forecast. However, some of the figures of 2021 may not be available at the moment from public statistical sources. Frost & Sullivan will use the latest information available (e.g. 2020) or make projections based on historical trends.

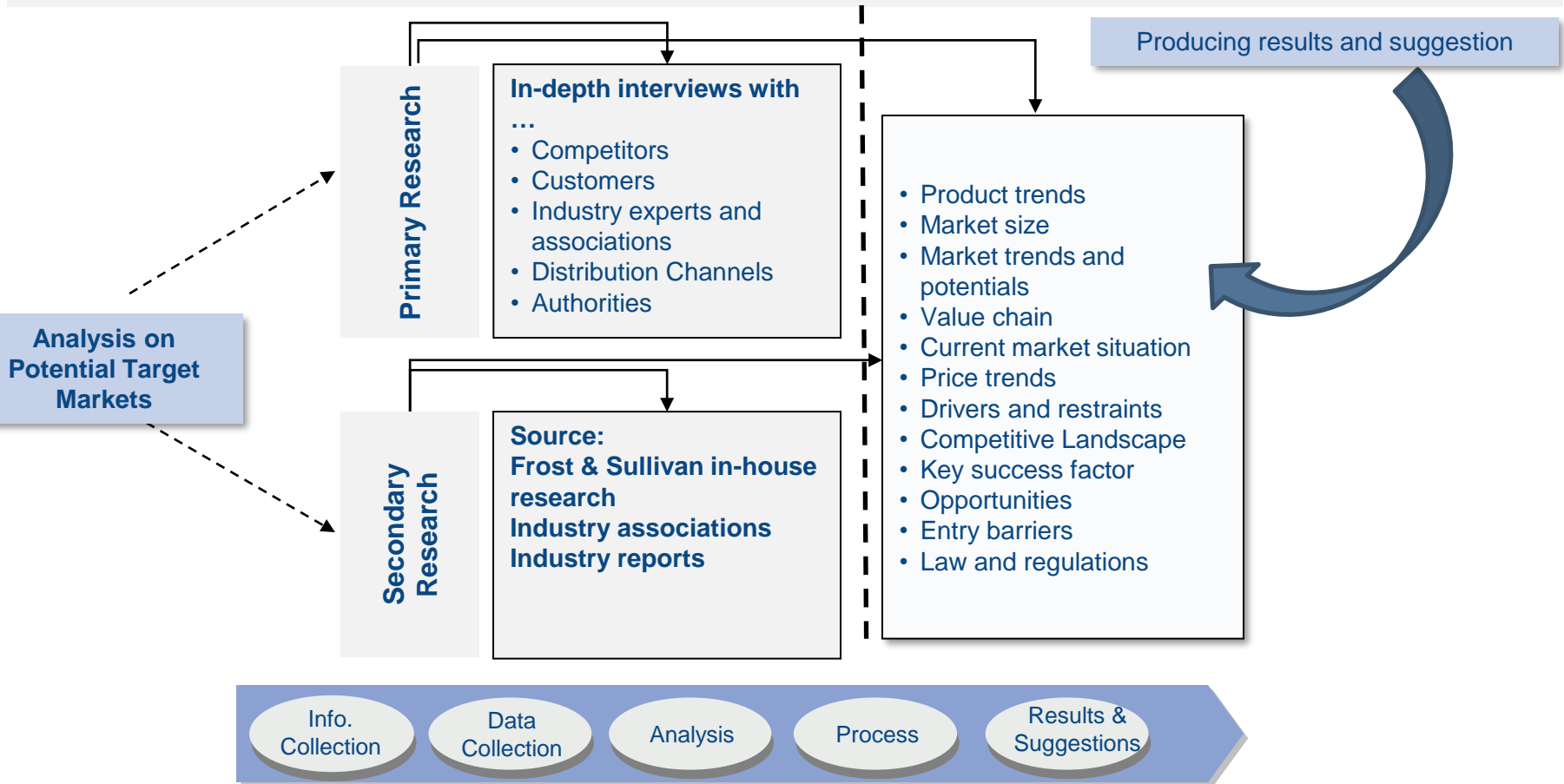


- Under circumstances where information is not available, Frost & Sullivan in-house analysis will be leveraged using appropriate models and indicators to arrive at an estimate.

- Sources of information and data will be clearly stated in the bottom right hand corner on each slide for reference.

Methodology

The methodology used by Frost & Sullivan in gathering the relevant market data in compiling the Frost & Sullivan Report included secondary research and primary interviews. Secondary research involves information integration of data and publication from publicly available resources, including official data and announcements from PRC government agencies, and market research on industry and enterprise player information issued by our chief competitors. Primary interviews were conducted with relevant institutions to obtain objective and factual data and prospective predictions.



Glossary

MWA: Microwave Ablation 微波消融

RFA: Radiofrequency Ablation 射频消融

CRA: Cryoablation 冷冻消融

LSA: Laser Ablation 激光消融

HIFU: high intensity focused ultrasound 高强度聚焦超声

IARC: International Agency For Research On Cancer 世界卫生组织国际癌症研究机构

CMA: Chinese Medical Association 中华医学会

CMDA: Chinese Medical Doctor Association 中国医师协会

HR: Hepatic Resection 肝切除术

OEM: Original Equipment Manufacturer 原始设备制造商，代工生产的一种

ODM: Original Design Manufacturer 原始设计制造商，代工生产的一种

R&D: Research and Development 研发

ALT: Alanine Transaminase 谷丙转氨酶，反映肝实质损害的指标之一

AST: Aspartate Aminotransferase 谷草转氨酶，反映肝实质损害的指标之一

AFP: α -fetoprotein 甲胎蛋白，肝功能检测指标之一

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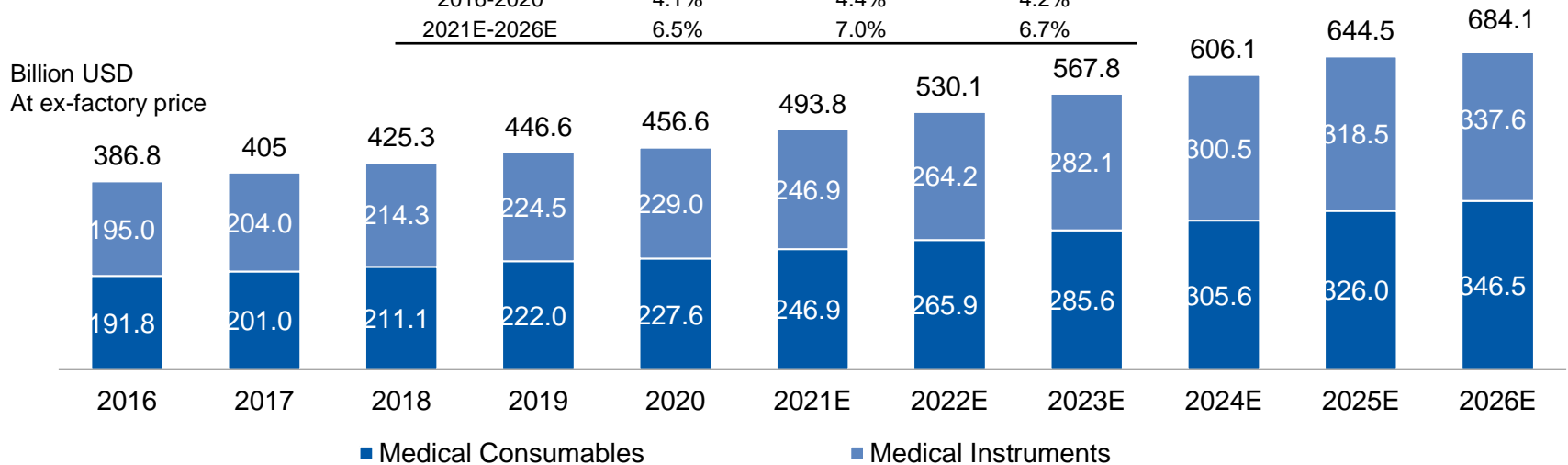
Market Size of Global Medical Device Market

- Due to the global aging problem and the increasing prevalence of chronic diseases, the growing clinical demand for medical devices has promoted the sustainable development of the global medical device market. The global medical device market has increased incrementally from USD386.8 billion in 2016 to USD456.6 billion in 2020, representing a CAGR of 4.2% due to the global medical device imbalance development and the gap of economic development in the emerging countries. Driven by the demand generated by illnesses associated with the aging global population and increasing healthcare expenditure, global medical device market is expected to reach USD684.1 billion in 2026, representing a CAGR of 6.7%.
- The global medical device market can be categorized into medical instruments and medical consumables, in which the medical consumables market is growing at a faster pace than the other.



Market Size of Global Medical Device Market, 2016-2026E

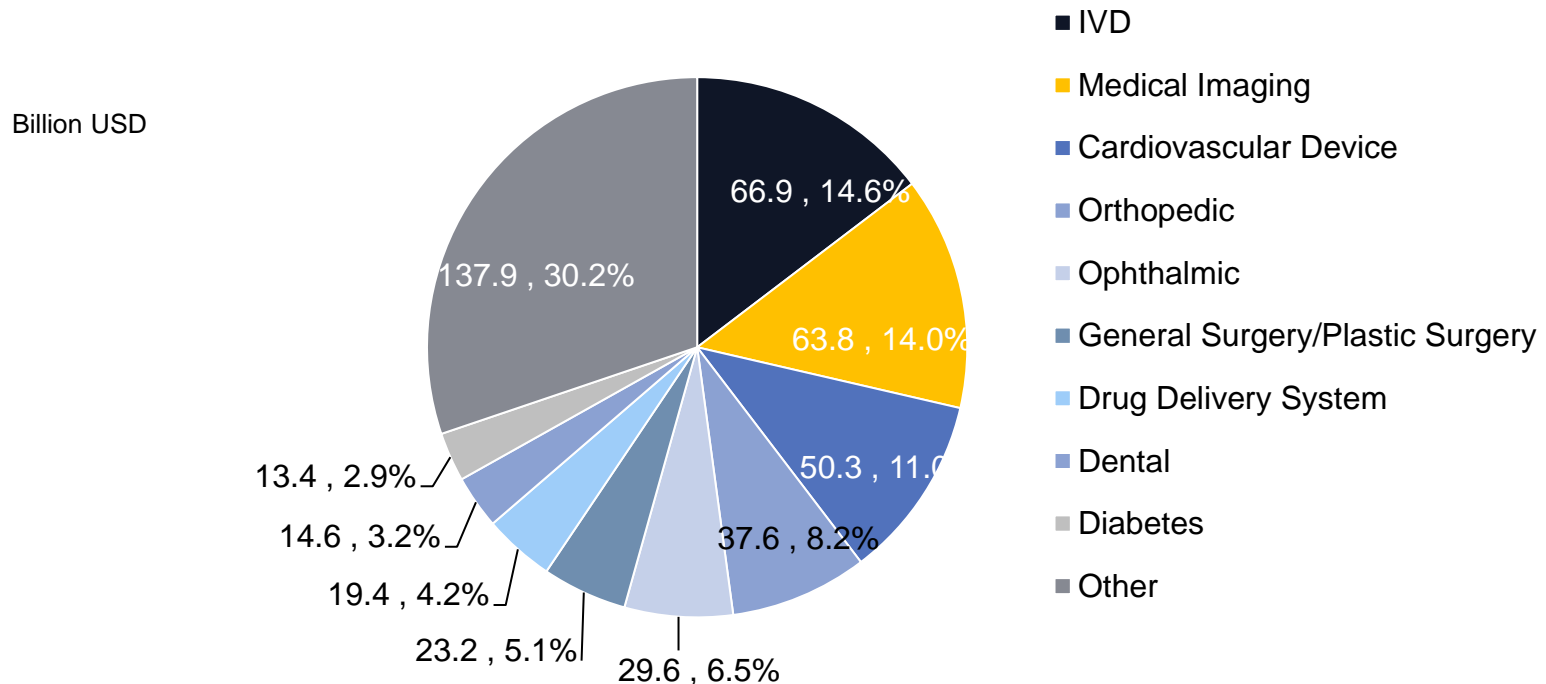
Period	CAGR		Total
	Medical Instruments	Medical Consumables	
2016-2020	4.1%	4.4%	4.2%
2021E-2026E	6.5%	7.0%	6.7%



Breakdown of Global Medical Device Market

- Increasing expenditure on healthcare and expansion of healthcare infrastructure, especially in emerging nations are anticipated to drive the future growth. The rising incidence of chronic diseases such as diabetes, cancer, heart diseases is fueling the demand for various medical devices. This further increases demand for medical devices and encourages several companies to introduce innovative technologies in this field. With the rising prevalence of chronic diseases, the need for preventive healthcare will increase exponentially. In vitro diagnostic (IVD), medical imaging and cardiovascular device are the top 3 segments of global medical device market by revenue, with a total share of 39.6% in global medical device market.

Breakdown of Global Medical Device Market, 2020

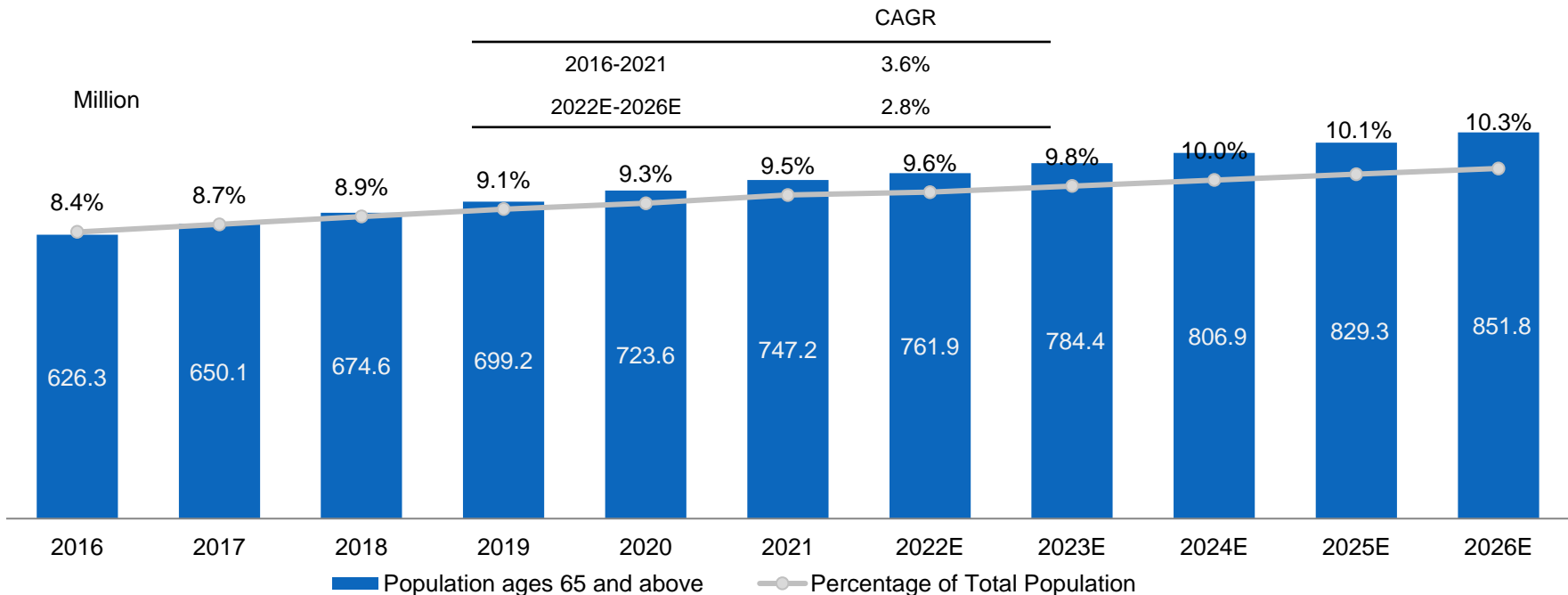


Growth Drivers of Global Medical Devices Market

Global Aging Population Trend

- The world's aging population is experiencing growth in terms of both number and proportion. There were 747.2 million people aged over 65 years old in 2021, accounting for 9.5% of the world's population. The population over 65 years old grows at a CAGR of 3.6% during the period of 2016 to 2021.
- Declining fertility and increasing longevity are the key drivers of population aging globally. It is estimated that the number of people aged over 65 in the world will reach 851.8 million in 2026, accounting for 10.3% of the total population, with a CAGR of 2.8% from 2022 to 2026.

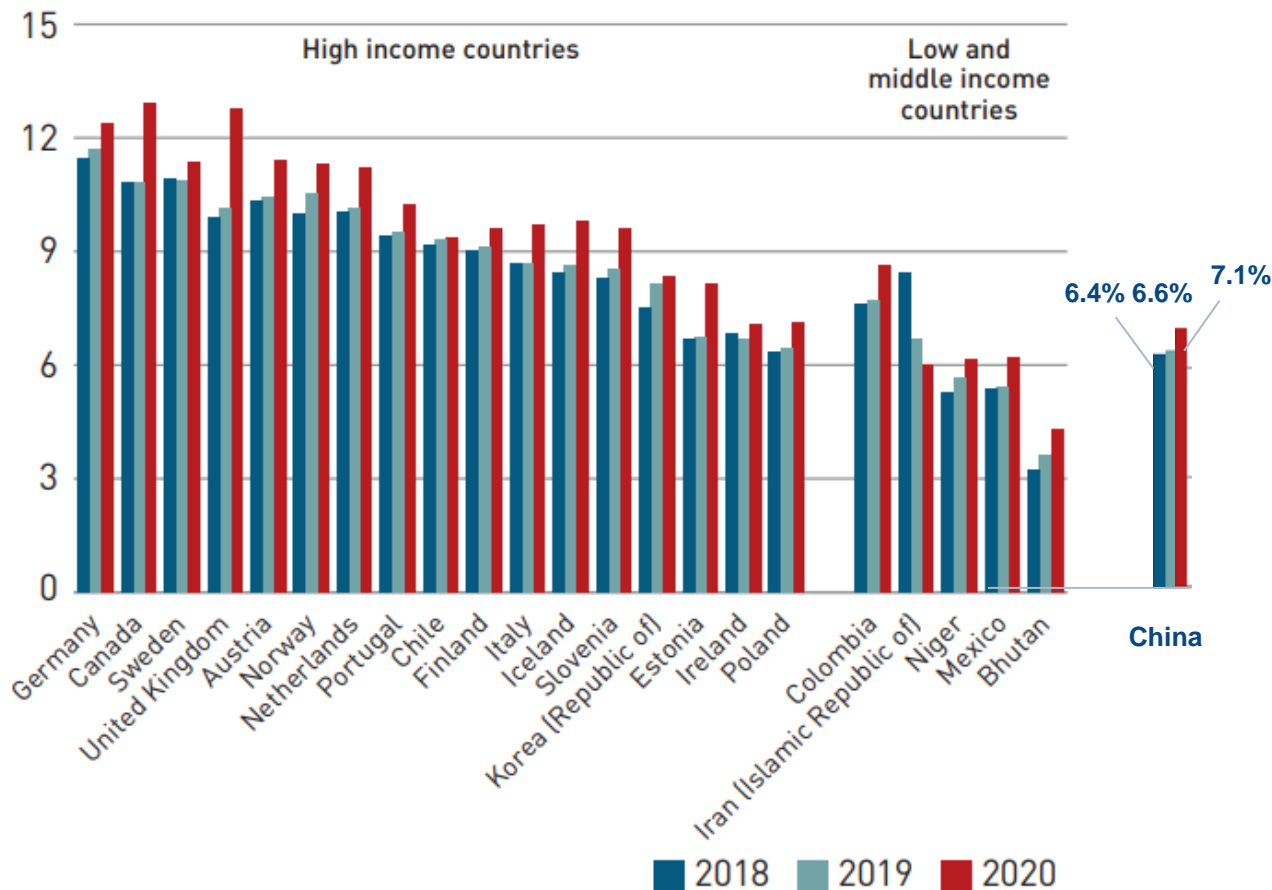
Global Aging Population, 2016-2026E



Growth Drivers of Global Medical Devices Market

Increasing Healthcare Spending

Health spending (% of GDP)



Key Implication

In high income countries, the United Kingdom had the largest increase in health spending as share of GDP (from 10.2% in 2019 to 12.8% of GDP in 2020). The Germany and Canada also recorded high share of GDP over 12% in 2020.

The health spending of China as share of GDP increased from 6.4% in 2018 to 7.1% in 2020.

Growth Drivers of Medical Device Market



Increasing Market Demand

- Nowadays, with the number of elderly people growing rapidly, the problem of aging population has swept the world. It is estimated that by 2050, the proportion of the population over 65 years old will be twice as that of the current population, reaching nearly 17%. As the prevalence of chronic diseases is strongly associated with the aging, so is the demand for medical devices and treatments. The aging population and longer life expectancy have a positive impact on the sustainable growth of the medical device industry.



Increasing Healthcare Investment

- Under the leadership of emerging technologies, global capital investment in the medical device industry has reached 2.9 billion USD, where most of the investment concentrates on the high-value medical devices. Besides, the direct investment into the medical device industry, increasing investments in the healthcare infrastructures and specialized hospitals indirectly drive the development of the medical device market..



Continuous Technology Innovation

- Technology innovation in medical device market can address the unmet clinical needs and therefore create much more market opportunities. For example, the innovative biodegradable biliary and pancreatic stent can benefit patients from low risk of complication and low expense without repeated procedures. Such technology innovations are believed to create enormous potential demand in the market since there is a large patient pool globally.



Impact: weak to strong

Future Trends of Medical Device Market



Rapid Growth of Gastrointestinal Segment

- The gastrointestinal device is one of the largest segments in global medical device market. A majority of malignancies will impact gastrointestinal and pulmonary, which has triggered the increasing prevalence of gastrointestinal disease. The gastrointestinal area has become a hotspot in the global capital investment and the gastrointestinal medical device market is expected to continue with rapid growth momentum. .



Domination of High-tech Medical Device

- With the development of technology, the high-tech segment of the medical device will demonstrate continuous growth in the future. Devices that add value by improving efficacy while reducing cost through complication reductions and through the elimination of removal procedures will surely command a higher premium than conventional medical devices, and the over all clinical cost will be reduced significantly.



Intellectual Property Protection

- The new technology developed by the medical device companies leads to increase efficiency, lower cost and delivery faster and more accurate results for the medical service institution and patients. In the next decades, it is estimated that medical device industry will introduce a vast of innovative technology, and the process of usage of medical device will changes fundamentally.



Integration of Service and Intelligent Data

- Medical device companies have traditionally adopted manufacturing and products selling to provide value. In the future, companies will not only focus on the role as the manufacturers, but also as the providers of comprehensive solution plans by combining the products with service and intelligent data. This integration will lead to a new trend of product upgrade alongside with the reformation of the value chain of medical devices.



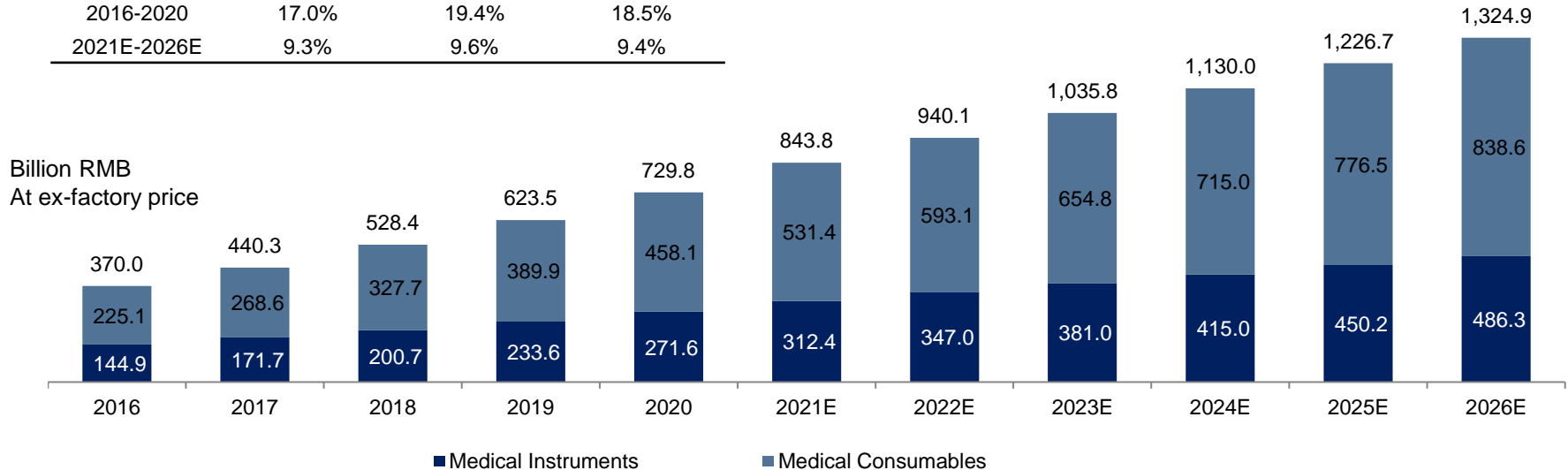
Impact: weak to strong

Market Size of Medical Device Market in China

- Driven by the increasing prevalence of various diseases and strong government initiative to promote local brands, the medical device market in China in terms of sales revenue has gained a rapid growth, increasing from RMB370 billion in 2016 to RMB729.8 billion in 2020, representing a CAGR of 18.5%. The medical device market in China is expected to continue to grow due to increasing clinical needs and continuous innovation on medical devices, which is expected to reach RMB1,324.9 billion in 2026, with a CAGR of 9.4% from 2021 to 2026.
- In the meantime, as sub-segments of medical device market, the medical instruments and medical consumables markets have witnessed a growing trend since 2016, and are expected to reach RMB486.3 billion and RMB838.6 billion in 2026 at a CAGR of 9.3% and 9.6% from 2021 to 2026, respectively.

Market Size of Medical Device Market, China, 2016-2026E

Period	CAGR		Total
	Medical Instruments	Medical Consumables	
2016-2020	17.0%	19.4%	18.5%
2021E-2026E	9.3%	9.6%	9.4%

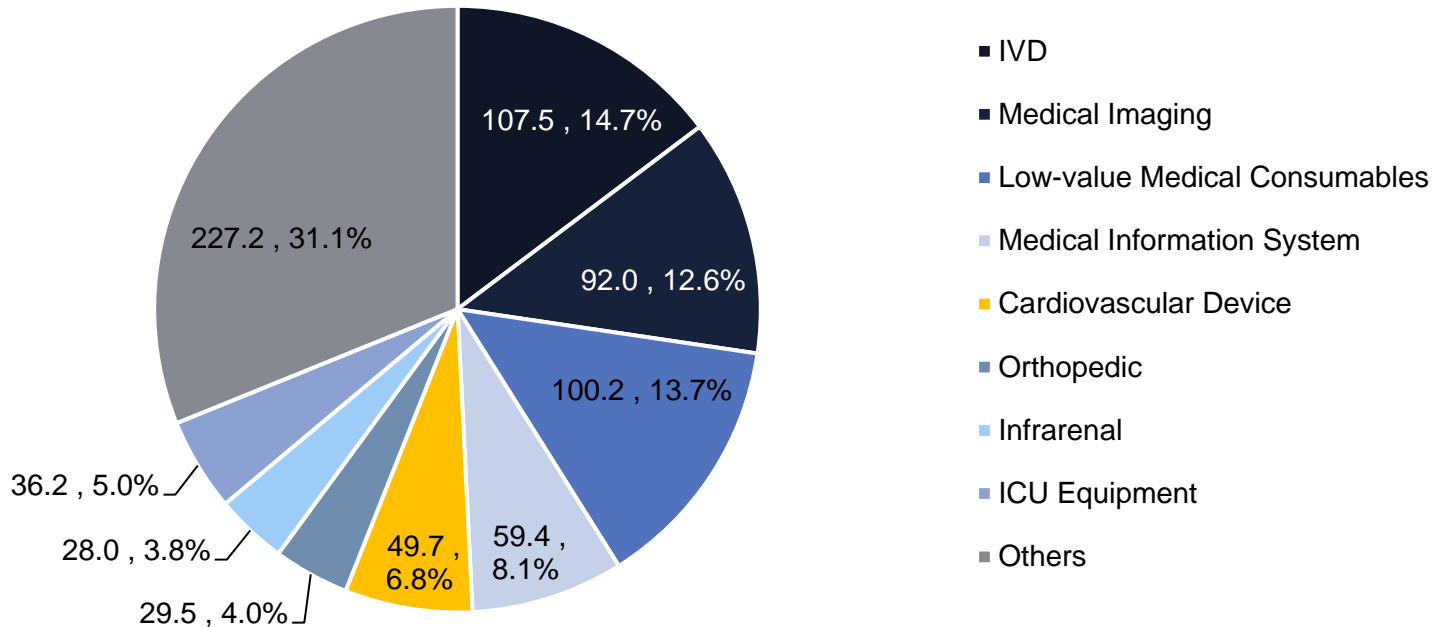


Breakdown of Medical Device Market in China 2020

- In the past, most medical devices produced by Chinese manufacturers were low-cost, high-volume items, while international manufacturers would supply hospitals and other healthcare facilities with high-end equipment. This dynamic is now rapidly changing. The Chinese government has launched a number of policies such as “Made in China 2025” initiative to boost the development of domestically made high-performance medical devices.
- In vitro diagnostic (IVD), low-value medical consumables and medical imaging, and were top 3 segments in China medical device market in 2020 by revenue, with a share of about 14.7%, 13.7% and 12.6%, respectively.

Breakdown of China Medical Device Market, 2020

Billion RMB



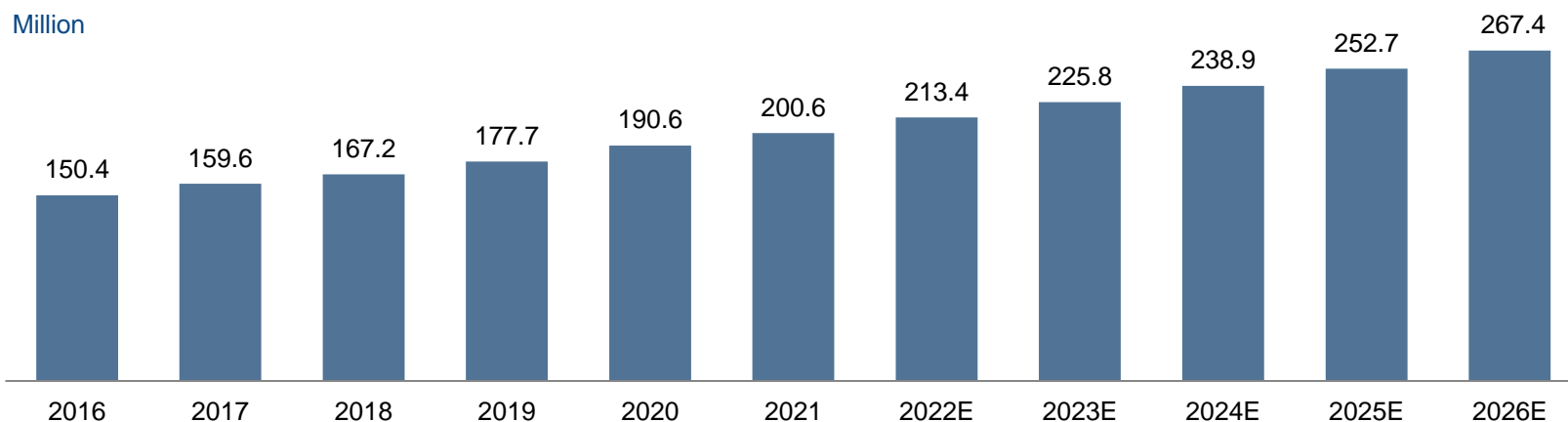
Growth Drivers of Medical Devices Market in China

Accelerating Aging Population and Trend in China

- At present, the fertility rate is gradually declining in China, and the life expectancy and the mortality rate are gradually approaching the level of developed countries. With the decline of fertility, birth rate, mortality and life expectancy, China has entered an aging society. From 2016 to 2021, the population is aging rapidly in China with people aged above 65 grew at a CAGR of 5.9% over the period. According to the data of the National Bureau of Statistics, the population over 65 years old reached 200.6 million in 2021, accounting for 14.2% of the total population.
- As the population of baby boom in the mid-20th century gradually enters the aging stage, the rapid aging of China's population will continue. Although the family planning policy is fully liberalized, the high living cost in the 1st and 2nd tier cities will inhibit the desire to have children, and has little moderating effect on the aging population. By 2026, the aging population is expected to reach 267.4 million, accounting for 18% of the total population, representing a CAGR of 5.8% from 2022 to 2026. The immune and metabolic system of the aged group has declined, and the healthcare expenses related to various diseases are increasing. The increasing aging population structure will promote the growing demand for medical care in China.

China Aging Population Trend, 2016-2026E

Period	CAGR
2016-2021	5.9%
2022E-2026E	5.8%



Growth Drivers of Medical Devices Market in China

Increasing Patient Pool and Death Toll of Major Chronic Diseases

- Same as EU and U.S., the prevalence of chronic diseases in China is also growing. Furthermore, due to the massive population, the patient pool of major chronic diseases in China is nearly third or twice as the number in the U.S. or EU. Noteworthy, China has an exceedingly high prevalence rate of digestive diseases compared to other countries, which can partly attributed to the unique eating habit of Chinese. There are 494 millions patient with digestive diseases in China in 2018.
- Death toll of chronic diseases is also rising. There are 4,544.9 thousand patients die of cardiovascular diseases and 2724.8 thousands patients die of cancer. More advanced therapies, drugs and medical devices are eagerly needed to satisfy the unmet demand.

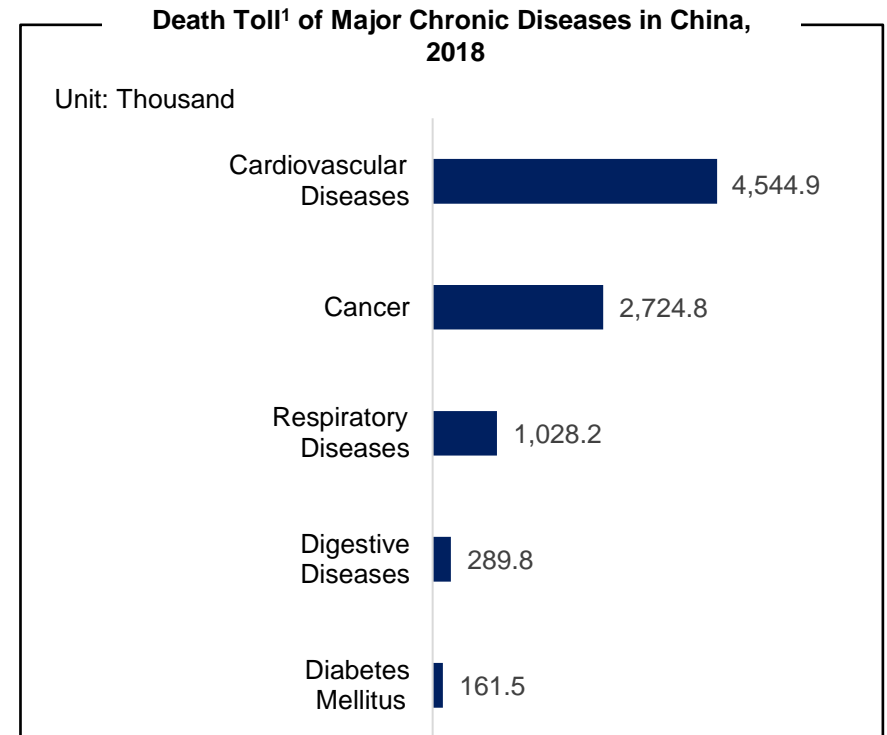
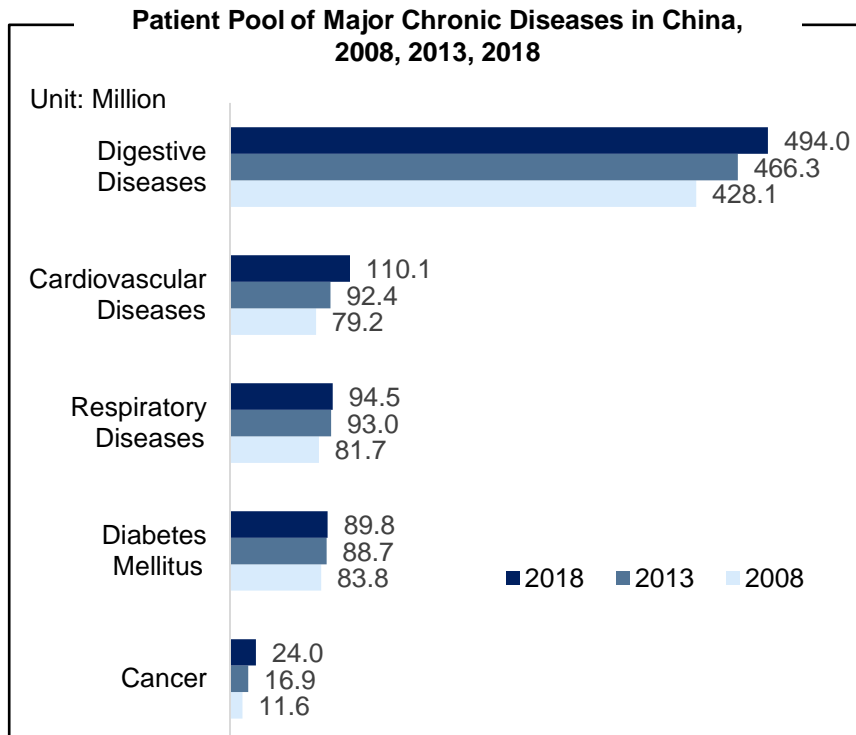


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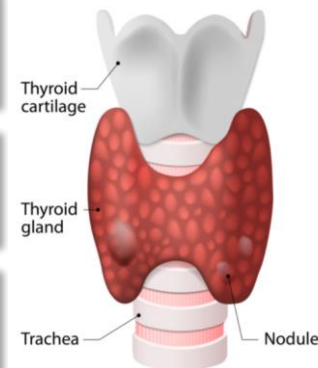
4 Competitive Analysis of Microwave Ablation Market in China

Etiology and Risk Factors of Thyroid Cancer and Thyroid Nodules

■ **Iodine deficiency:** Lack of iodine in diet can sometimes cause the thyroid gland to develop thyroid nodules. Excessive iodine intake is also one of the causes of thyroid nodules.

■ **Overgrowth of normal thyroid tissue:** An overgrowth of normal thyroid tissue is sometimes referred to as a thyroid adenoma. It's noncancerous, but may lead to hyperthyroidism.

■ **Chronic inflammation of the thyroid:** Hashimoto's disease, a thyroid disorder, can cause thyroid inflammation and result in enlarged nodules.



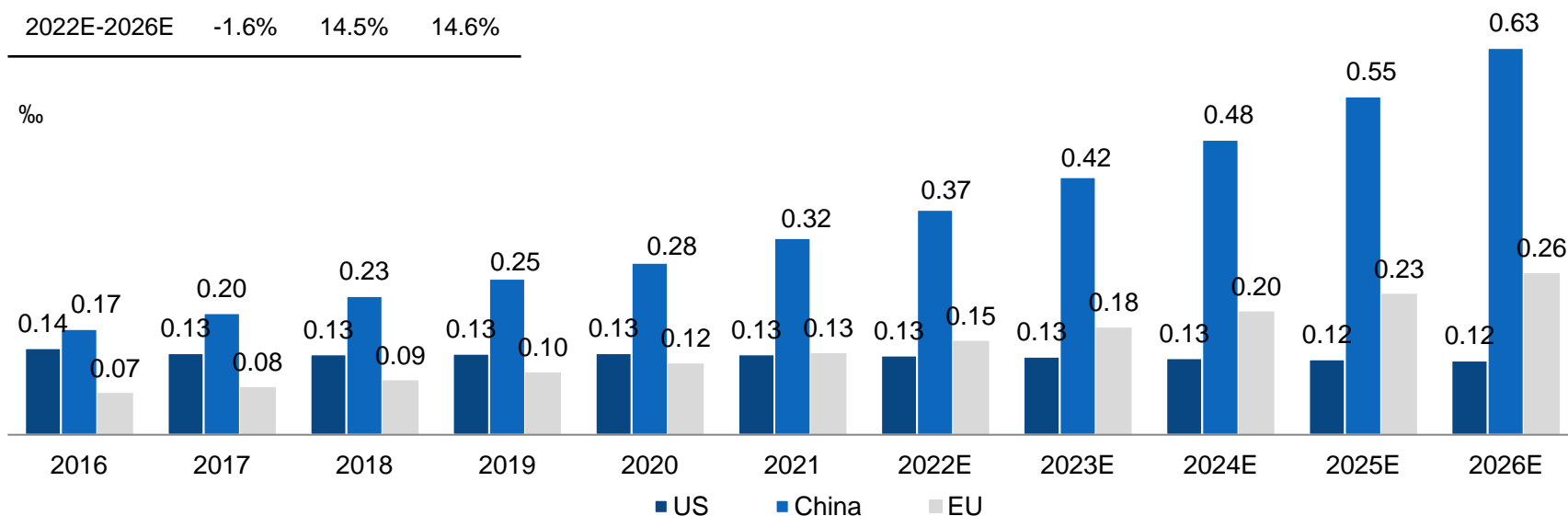
Etiology	Main risk factors
<p>Thyroid Cancer</p> <ul style="list-style-type: none"> ■ The exact cause of thyroid cancer is still difficult to determine. ■ Certain factors may increase the risk of thyroid cancer, such as a family history of thyroid or other endocrine cancer and having a history of radiation exposure from medical therapy or nuclear fallout. 	<ul style="list-style-type: none"> ■ Radiation exposure: Head and Neck's exposure to radiation in childhood may increase the risk of thyroid cancer. ■ Genetic conditions: A family history of medullary thyroid cancer, goiters, precancerous, polyps, multiple endocrine neoplasia type 2A syndrome and multiple endocrine neoplasia type 2B syndrome can also increase the risk. ■ Gender: Women are three times more likely to develop thyroid cancer. ■ Thyroid nodules or cysts: Fluid-filled cavities (cysts) in thyroid most commonly result from degenerating thyroid adenomas. Often, solid components are mixed with fluid in thyroid cysts. Cysts are usually noncancerous, but occasionally contain cancerous solid components.

Incidence Rates of Thyroid Cancer by Region, 2016-2026E

- Affected by changes in live environment and diagnosis techniques, the number of diagnosed thyroid cancer in China and Europe has been increasing rapidly in recent years. The incidence rates of thyroid cancer in China increased from 0.17 ‰ in 2016 to 0.32 ‰ in 2021. The incidence of thyroid cancer in Europe increased from 0.07 ‰ in 2016 to 0.13 ‰ in 2021.
- Due to the reduction of overdiagnosis, the incidence rates of thyroid cancer in the United States has continued to decline, from 0.14 ‰ in 2016 to 0.13 ‰ in 2021.

Incidence Rates of Thyroid Cancer, 2016-2026E

CAGR	U.S.	China	EU
2016-2021	-1.5%	13.2%	14.3%
2022E-2026E	-1.6%	14.5%	14.6%



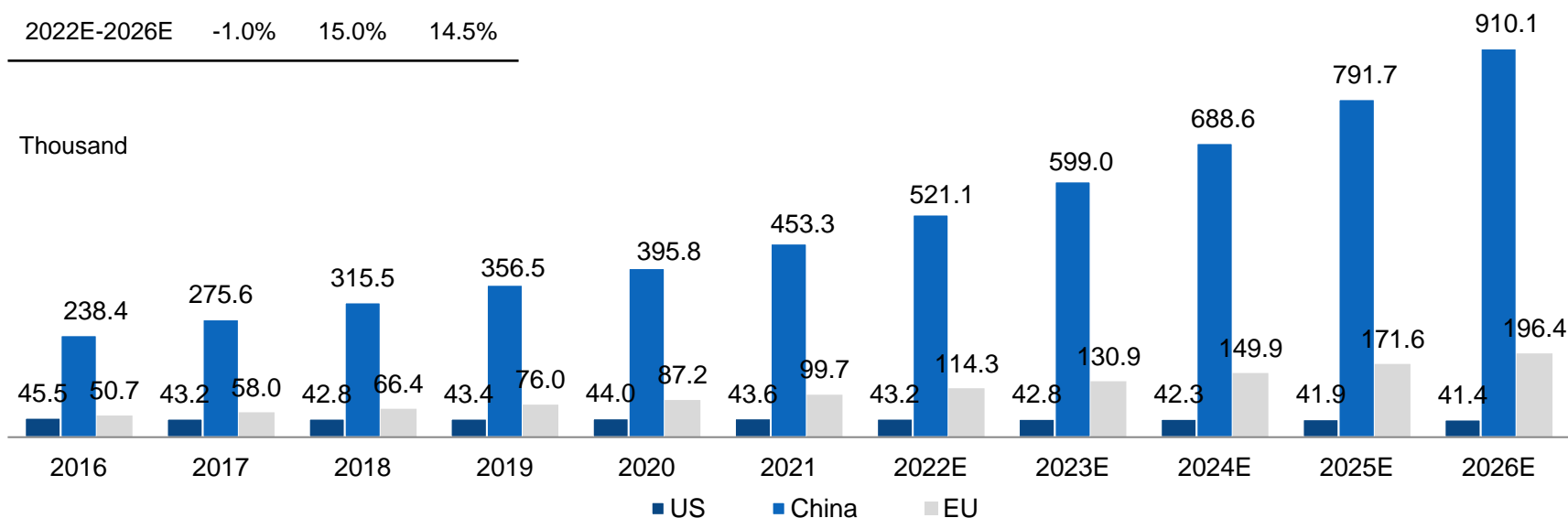
Source: International Agency for Research on Cancer, National Cancer Registry, Frost & Sullivan Analysis

Estimated New Thyroid Cancer Cases by Region, 2016-2026E

- The incidence of thyroid cancer in China and Europe has been increasing rapidly in recent years. The number of new thyroid cancer patients in China increased from 238.4 thousand in 2016 to 453.3 thousand in 2021. The number of new cases of thyroid cancer in Europe increased from 50.7 thousand in 2016 to 99.7 thousand in 2021.
- During the same period, the number of new thyroid cancer cases in the United States decreased from 45.5 thousand in 2016 to 43.6 thousand in 2021 due to the reduction in overdiagnosis.

Estimated Number of New Thyroid Cancer Cases, 2016-2026E

CAGR	U.S.	China	EU
2016-2021	-0.9%	13.7%	14.5%
2022E-2026E	-1.0%	15.0%	14.5%

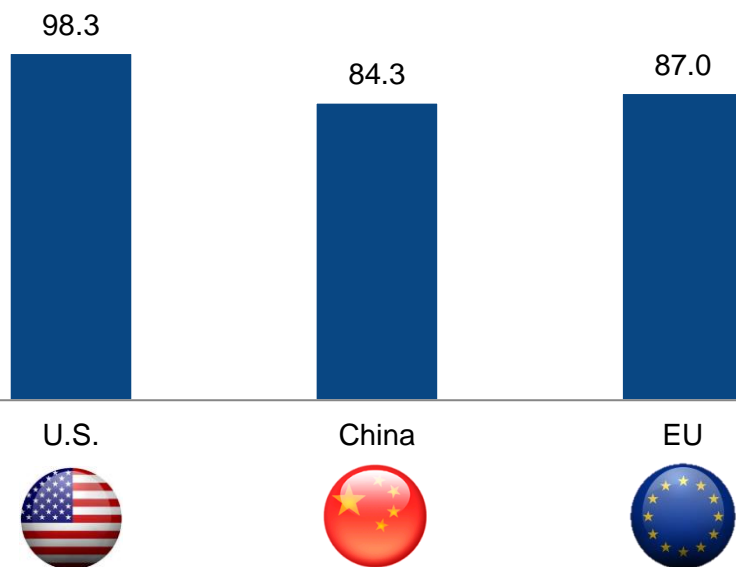


5-Year Survival Rate of Thyroid Cancer by Region

- According to the survey data in China (2012-2015), U.S. (2011-2017) and Europe (2013-2018), the current 5-year survival rate for thyroid cancer in China is 84.3%, while it's 87.0% in Europe and 98.3% in the U.S.
- The 5-year survival rate of thyroid cancer in China is lower than that in developed countries. The main reasons are: high metastatic rate of differentiated thyroid cancer lymph nodes, insufficient postoperative follow-up management and less emphasis on the treatment of small tumour.

5-Year Survival Rate of Thyroid Cancer, by Region

%



High metastatic rate of differentiated thyroid cancer lymph nodes

- Compared to developed countries in Europe and the U.S., the clearance rate of lymph node (淋巴结清扫率) in thyroid cancer treatment is higher in China, leading to more patients diagnosed with lymph node metastasis. Thyroid cancer was not included in regular medical screening until recent years. Compared to people who have regular body check-ups and screenings for thyroid cancer, patients with thyroid cancer in China are not found at early stage, which can lead to lymph node metastasis.

Poor postoperative follow-up management

- Both doctors and patients do not pay enough attention to the education of postoperative treatment. China is a country with vast territory, therefore there are great differences in the levels of education between urban and rural areas, convenience in transportation, making it difficult to enforce follow-up of patients. Many hospitals and other health institutions do not manage patients for the whole process, which makes it difficult for some patients to get professional recovery guidance after surgery.

Little attention to thyroid microcarcinoma

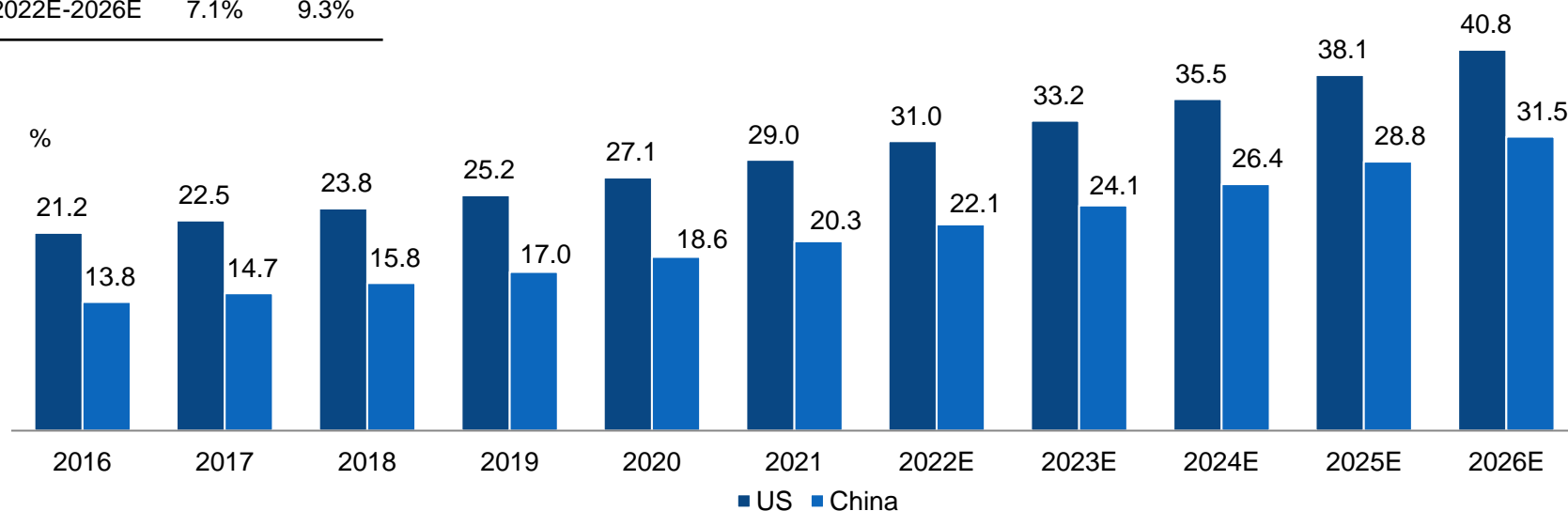
- Compared with other cancers, differentiated thyroid cancer has a better prognosis and longer survival time, causing the importance of treatment of thyroid cancer being neglected. Papillary carcinoma less than 10 mm is easily mistaken as "low-risk" in clinical practice, but it is cancer. Microcarcinoma has all the characteristics of tumours larger than 10 mm, such as lymph node metastasis, brain metastasis, lung infiltration and even death.

Incidence Rates of Thyroid Nodules by Region, 2016-2026E

- Globally, the incidence range of thyroid nodule is from as low of 40,000 per 100,000 people to as high of 71,000 per 100,000 people with an average of 50,000 per 100,000 people. As a result of thyroid radiography examination during routine physical screening in recent years, the incidence of thyroid nodules in China increased from 13.8% in 2016 to 20.3% in 2021.
- The U.S. leads the world in early screening of thyroid diseases. The incidence rate of thyroid nodules in the U.S. continue to increase, from 21.2% in 2016 to 29.0% in 2021.

Incidence Rates of Thyroid Nodules, 2016-2026E

CAGR	U.S.	China
2016-2021	6.5%	8.0%
2022E-2026E	7.1%	9.3%

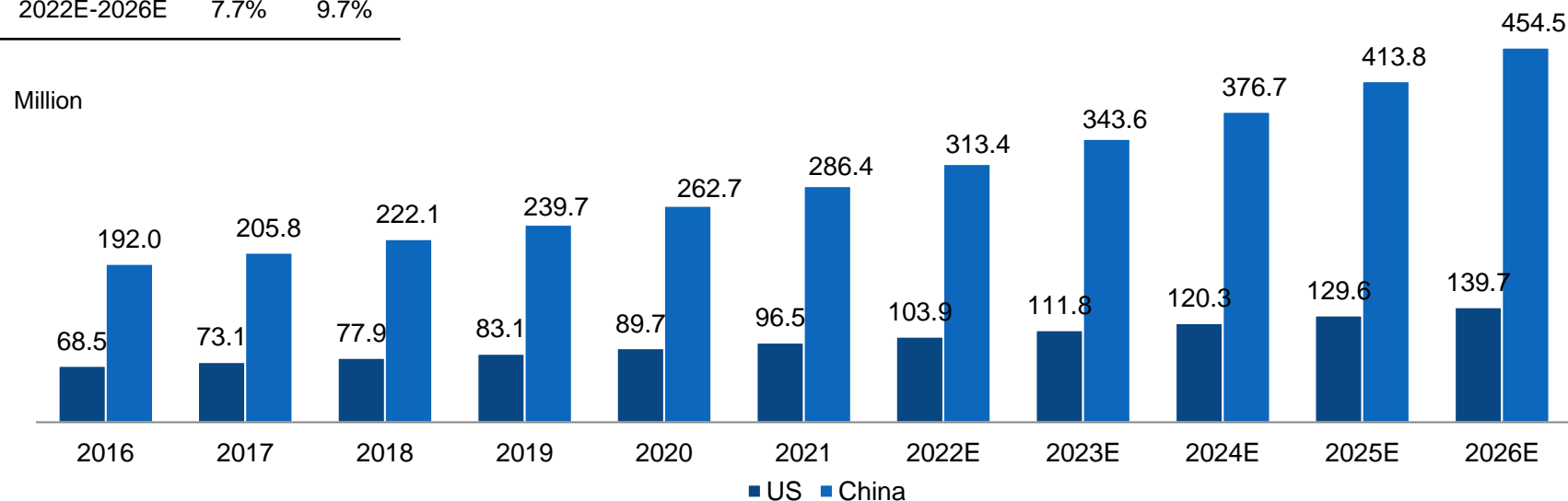


Estimated New Thyroid Nodules Cases by Region, 2016-2026E

- Thyroid nodules are one of the most common diseases in clinical practice. In recent years, the increasing awareness to health, popularization of high-frequency color doppler ultrasound and the improvement of ultrasound physicians' understanding of thyroid diseases are the main reasons for increasing diagnosis rate of thyroid nodules.
- The number of new thyroid nodules patients in China increased from 192.0 million in 2016 to 286.4 million in 2021. The number of new cases of thyroid nodules in U.S. increased from 68.5 million in 2016 to 96.5 million in 2021.

Estimated New Thyroid Nodule Cases, 2016-2026E

CAGR	U.S.	China
2016-2021	7.1%	8.3%
2022E-2026E	7.7%	9.7%



Definition, Etiology and Risk Factors of Breast Cancer and Lumps

Breast Cancer

Breast cancer is a disease in which breast epithelial cells grow out of control under the action of a variety of carcinogenic factors. The early stage of breast cancer often have the symptoms of breast lumps, nipple discharge, axillary lymphadenopathy and etc. In the late stage, cancer cells may metastasize, and multiple organ diseases may occur, which can directly threaten the life of the patient.

Breast lump

The lump is a localized swelling, protuberance, bulge or bump in the breast that is different from the breast tissue around it or the breast tissue in the same area of the other breast. It is divided into breast hyperplasia (or breast cysts) and breast neoplastic diseases, including benign breast tumour (such as breast fibroma, lobulated tumour, etc.) and breast cancer .

Etiology		Main Risk Factors	
Breast Cancer	In most cases, breast cancer and lumps occur in women.	Exposure to estrogen	<ul style="list-style-type: none"> Increased or extended exposure of estrogen in the body is closely related to the onset of breast cancer. Factors include early menarche age (<12 years old), late menopause age (>55 years old), late infertility and first childbearing age (>30 years old), short breastfeeding time, postmenopausal estrogen replacement therapy, and etc.
	The cause of breast cancer and lumps are still unclear.	Genetic factors	<ul style="list-style-type: none"> People with a history of breast cancer among first-degree relatives (such as parents, children, and siblings) have 2-3 times higher risk than that of the general population. Some genetic mutations can also increase the risk of breast cancer.
Breast Lumps	However, some high-risk factors related to the onset of breast cancer and lumps have been discovered.	Physical factors	<ul style="list-style-type: none"> Chest radiation therapy during childhood is also a pathogenic factor for breast cancer.
		Lifestyle	<ul style="list-style-type: none"> Overnutrition, obesity, high-fat diet, excessive alcohol consumption, etc.

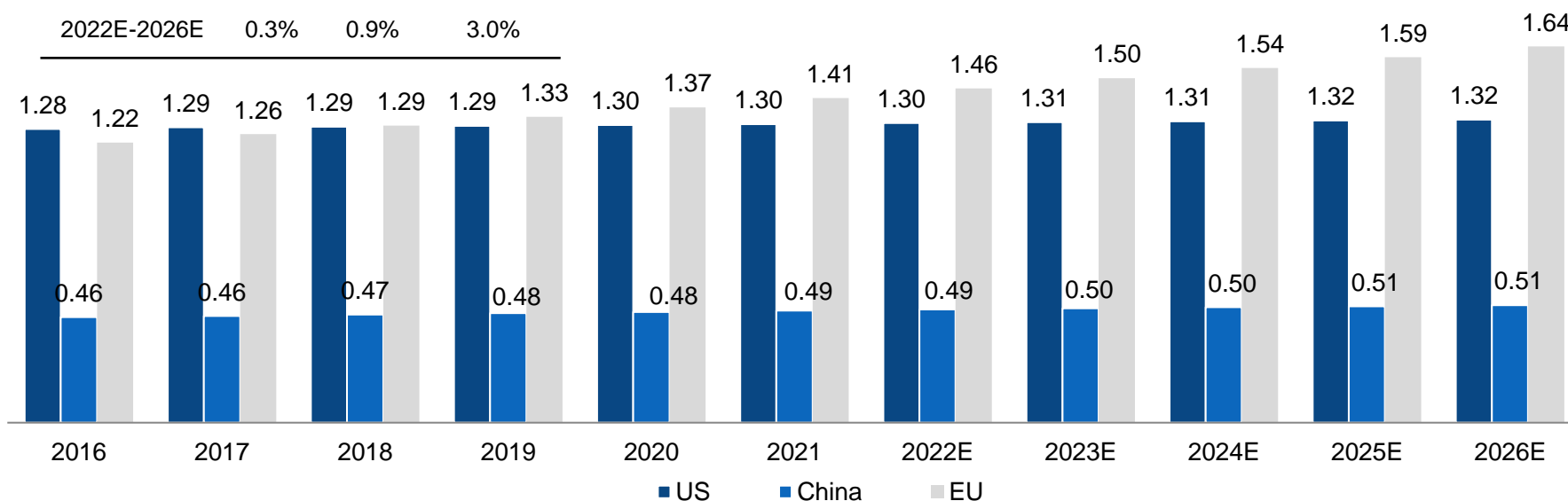
Incidence Rates for Breast Cancer by Region, 2016-2026E

- White women are more likely to have breast cancer, therefore the overall incidence of breast cancer in the United States and Europe is relatively higher. The incidence of breast cancer in the United States has increased from 1.28 ‰ female in 2016 to 1.30 ‰ female in 2021. The incidence of breast cancer in Europe has increased from 1.22 ‰ female in 2016 to 1.41 ‰ female in 2021.
- In contrast, the percentage of breast cancer among Asian women is lower than women in the U.S. and Europe. The incidence of breast cancer in China has increased from 0.46 ‰ female in 2016 to 0.49 ‰ female in 2021, and is expected to reach 0.51 ‰ female in 2026.

Incidence Rates for Breast Cancer, 2016-2026E

‰ female

CAGR	U.S.	China	EU
2016-2021	0.3%	1.2%	3.0%
2022E-2026E	0.3%	0.9%	3.0%

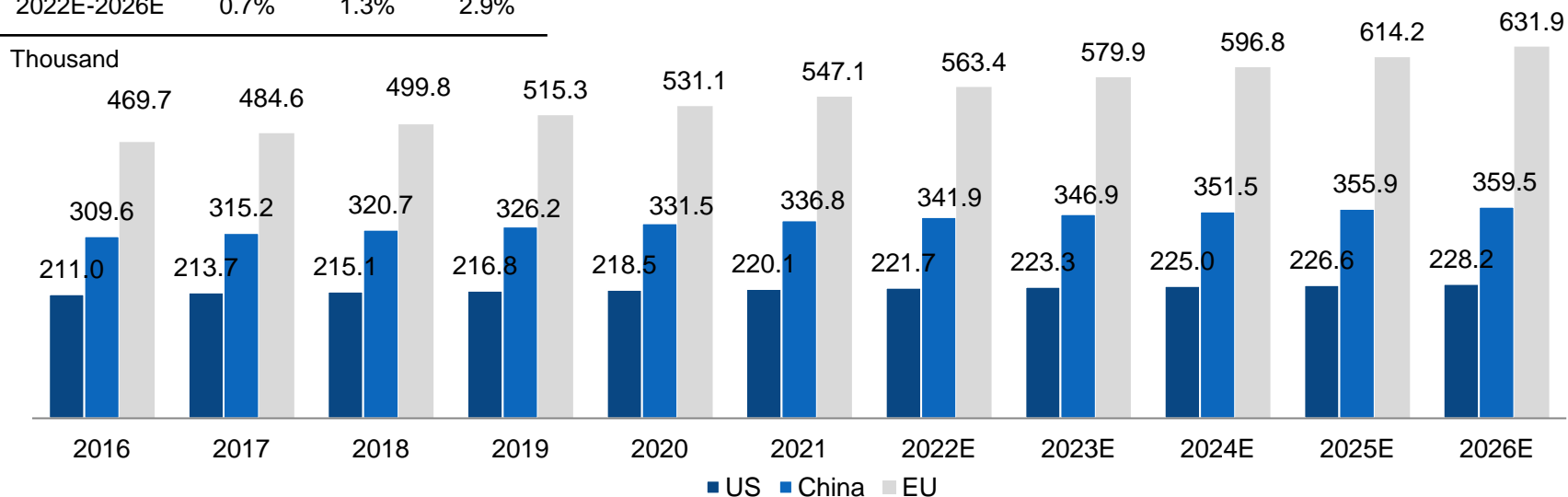


Estimated New Breast Cancer Cases by Region, 2016-2026E

- Breast cancer is often called the "pink killer", and its incidence ranks the first top among female malignant tumours. Male breast cancer is relatively rare.
- The number of new breast cancer patients in the United States has increased from 211.0 thousand in 2016 to 220.1 thousand in 2021. The number of new breast cancer patients in Europe has increased from 469.7 thousand in 2016 to 547.1 thousand in 2021.
- In recent years, the incidence of breast cancer in China continued to increase and has become a disease that endangers the health of women. The number of new breast cancer patients in China has increased from 309.6 thousand in 2016 to 336.8 thousand in 2021.

Estimated New Breast Cancer Cases, 2016-2026E

CAGR	U.S.	China	EU
2016-2021	0.8%	1.7%	3.1%
2022E-2026E	0.7%	1.3%	2.9%

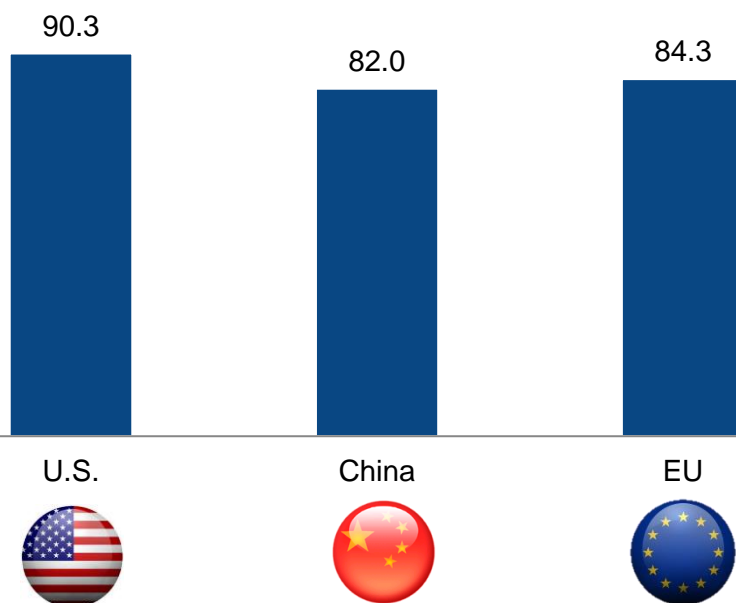


5-Year Survival Rate of Breast Cancer by Region

- According to the survey data of China (2012-2015), the U.S. (2011-2017) and Europe (2013-2018), the current 5-year survival rate of breast cancer in China is 82.0%, 84.3% in Europe and 90.3% in the U.S.
- The 5-year survival rate of breast cancer in China is lower than in the United States, which is primarily attributed to the lack of effective early screening, the gap in treatment quality, and the choices of different treatment methods.

5-Year Survival Rate of Thyroid Cancer by Region

%



Early Screening

- In the United States, early screening and diagnosis of cancer has become a routine and the coverage rate of early breast cancer screening is as high as 81.1%. However, in China, early screening for cancer has not yet been popularized and early mammography screening only accounts for 22.5% of people received early mammography screening. According to *Guidelines for Breast Cancer and Treatment*, early screening should also be combined with ultrasound, but the only 11.6% patients continued with additional ultrasound examination.
- Late diagnosis also limit patients' choices of treatment method. In China, many patients missed the best timing for breast-conserving surgery when they are diagnosed, leaving them with the riskier option of mastectomy surgery.

Treatment Quality

- Due to the gap in medical science and technology, the treatment quality of breast cancer in China is lower than in the United States. The United States pays attention to multidisciplinary treatment (MDT). Multiple departments including medical oncology, surgery, radiology and imaging departments working together to help patients achieve the ideal treatment outcome as soon as possible. In the process of breast-conserving surgery, American doctors usually perform the surgery in an integrated operating room, which can greatly reduce the probability of breast cancer patients needing another one after initial surgery, and can reduce the postoperative recurrence rate of breast cancer patients by 33%.
- However, China is still at the early stage of MDT due to the limitation of the traditional system of diagnosis and treatment by individual departments, still developing evidence-based medicine science and current economic level.

Treatment Options

- Because of the effective of early screening, MDT and other factors, about 64% of patients in the United States receive breast-conserving surgery while only it is only 5% in China. Compared to total mastectomy, breast-conserving surgery not only reduces postoperative psychosexual disorders and surgical risks, but also achieves almost the same or even higher survival rate as breast resection.

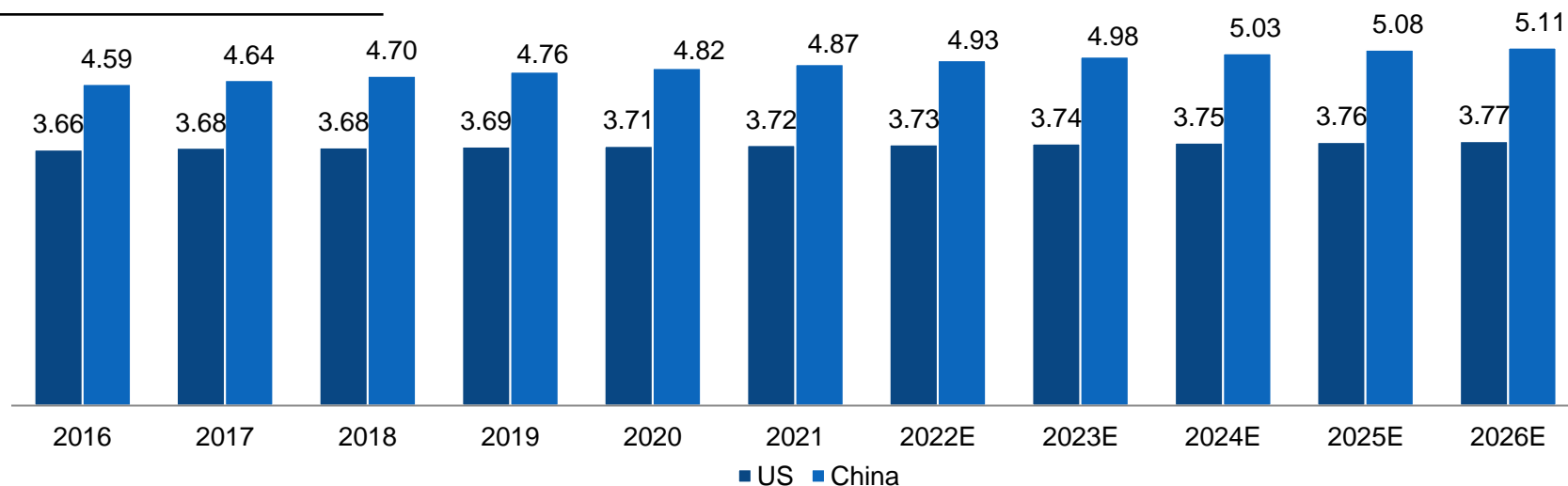
Incidence Rates for Breast Lump by Region, 2016-2026E

- In recent years, the prevalence of breast continued to increase. Due to the lack of timely and effective treatment for some breast lumps, the incidence of breast cancer in women has been rising globally. The number of diagnosed breast lumps in China has been increasing rapidly in recent years.
- The incidence of breast lumps in China increased from 4.59 ‰ female in 2016 to 4.87 ‰ female in 2021. And the incidence of breast lumps in the United States continued to increase, from 3.66 ‰ female in 2016 to 3.72 ‰ female in 2021.

Incidence Rates of Breast Lump, 2016-2026E

‰ female

CAGR	U.S.	China
2016-2021	0.3%	1.2%
2022E-2026E	0.3%	0.9%



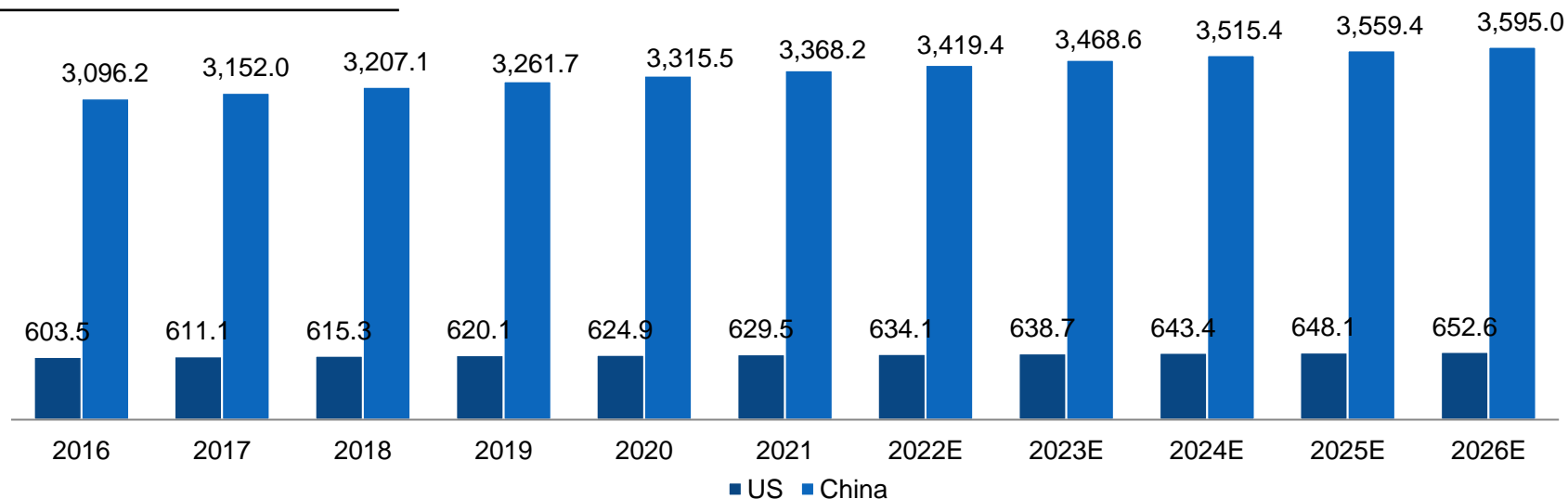
Estimated New Breast Lump Cases by Region, 2016-2026E

- Affected by factors such as stress and lifestyle, the incidence of breast lumps in women worldwide has been increasing in recent years. The incidence of breast lumps in China and U.S. has been increasing rapidly in recent years. The number of new breast lumps patients in China increased from 3.10 million female in 2016 to 3.37 million female in 2021. The number of new cases of breast lumps in U.S. increased from 0.60 million female in 2016 to 0.63 million female in 2021.
- In China, breast lumps are less likely to become cancerous than in the U.S.

Estimated New Breast Lump Cases, 2016-2026E

Thousand Female

CAGR	U.S.	China
2016-2021	0.8%	1.7%
2022E-2026E	0.7%	1.3%



Definition, Etiology and Risk Factors of Liver Cancer

Liver Cancer

- Liver cancer is a cancer that begins in liver cells and develop into a malignant tumour.
- Liver cancer can be divided into primary liver cancer and secondary liver cancer based on the cause. Secondary liver cancer based on the origin of cancer (primary starts in liver, secondary was spread from elsewhere to liver).

Classification	Etiology	Main risk factors	
Primary liver cancer: Malignant tumours of hepatocytes or intrahepatic bile duct epithelial cells	Hepatitis B Virus (HBV) Hepatitis C Virus (HCV)	Common factors of liver cancer. About 90% of hepatocellular carcinoma patients in China have a history of HBV infection. HBV infection leads to chronic hepatitis, which gradually develops into liver cirrhosis and then into liver cancer.	
	Liver Cirrhosis	Viral hepatitis and non-alcoholic steatohepatitis can easily lead to liver cirrhosis, and later develop into liver cancer.	
	No definite answer yet, but commonly agreed to be a complex process caused by multiple factors through multiple steps.	Food Pollution	<ul style="list-style-type: none"> • Some molds, especially <i>Aspergillus flavus</i> (aflatoxin B1, AFB1) possessed by <i>Aspergillus flavus</i> are highly toxic to the liver, causing degeneration and necrosis of liver cells, leading to liver cancer. • In addition, consuming food containing nitrosamines or lack of micronutrient is also an significant risk factor of liver cancer.
		Water Pollution	Drinking water contaminated by philomycid is another significant factor in increasing the probability of liver cancer.
	Alcohol Consumption	Excessive alcohol consumption may lead to fatty liver disease, alcoholic hepatitis and cirrhosis, which can ultimately lead to liver cancer.	
	Genetic Factors	Liver cancer has noticeable familial clustering and genetic predisposition characteristics.	
	Other Diseases	Diseases such as diabetes, oesophageal varices, liver cirrhosis, obesity, fatty liver disease and hereditary hemochromatosis could increase the risk of liver cancer.	
Secondary liver cancer: Malignant tumours of other organs have spread or metastasized to the liver	<ul style="list-style-type: none"> • After the tumour in other body parts grow to a certain extent, it releases cancer cells into the circulatory system, which may enter into liver and cause liver cancer. • Cancer cells with a higher malignancy will release growth factors to promote the proliferation of their own tumour cells, gradually forming independent tumour cell clumps. 		

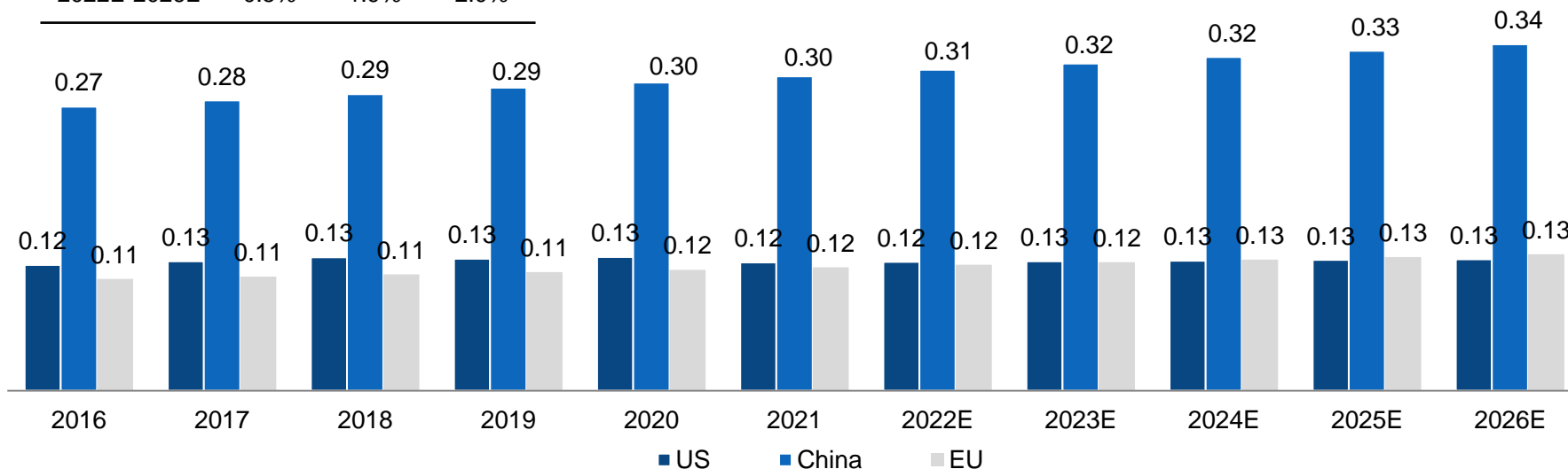
Incidence Rates of Liver Cancer by Region, 2016-2026E

- The global incidence of liver cancer continues to increase, which is closely related to the gradually deteriorating environment and unhealthy daily diet.
- China is the country with the largest incidence of liver cancer in the world. The incidence of liver cancer in China has increased from 0.27‰ in 2016 to 0.30‰ in 2021.
- The overall incidence of liver cancer in the United States and Europe is relatively low. The incidence of liver cancer in the United States increased from 0.12‰ in 2016 to 0.12‰ in 2021. The incidence of liver cancer in Europe has increased from 0.11‰ in 2016 to 0.12‰ in 2021.

Incidence Rates for Liver Cancer, 2016-2026E

‰

CAGR	U.S.	China	EU
2016-2021	0.4%	2.2%	2.0%
2022E-2026E	0.5%	1.9%	2.0%



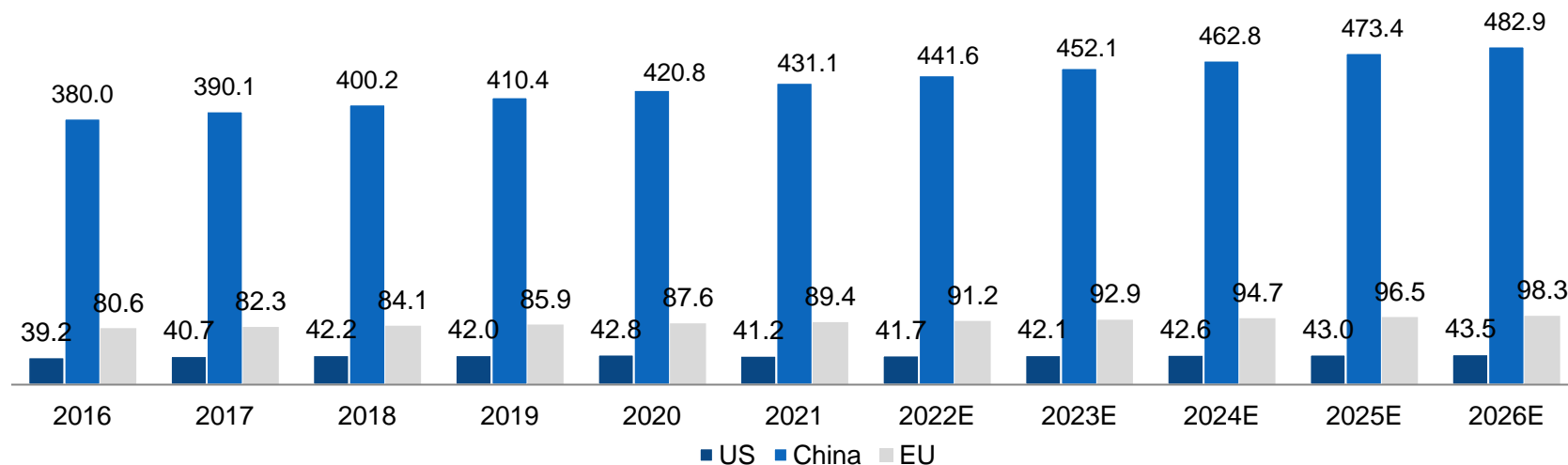
Estimated New Liver Cancer Cases by Region, 2016-2026E

- As a country with most liver cancer cases, China's new liver cancer patients has increased from 380.0 thousand in 2016 to 431.1 thousand in 2021.
- The number of new liver cancer cases in the United States has increased from 39.2 thousand in 2016 to 41.2 thousand in 2021. The number of new liver cancer patients in Europe has increased from 80.6 thousand in 2016 to 89.4 thousand in 2021.

Estimated New Liver Cancer Cases, 2016-2026E

Thousand

CAGR	U.S.	China	EU
2016-2021	1.0%	2.6%	2.1%
2022E-2026E	1.1%	2.3%	1.9%

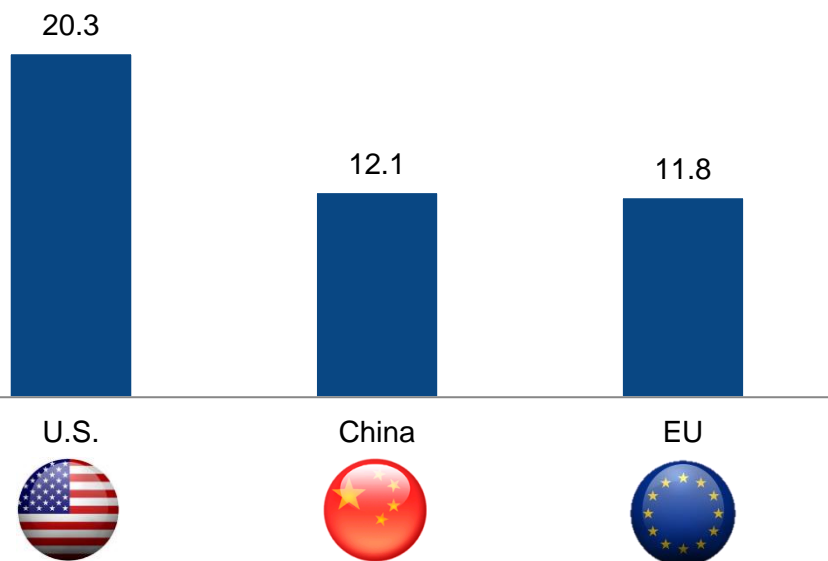


5-Year Survival Rate of Liver Cancer by Region

- According to the survey data in China (2012-2015), the United States (2011-2017) and Europe (2013-2018), the current 5-year survival rate of HCC (Hepatocellular carcinoma) in China is 12.1%, slightly higher than the 11.8% survival rate in Europe and much lower than the 20.3% survival rate in the United States.
- The five-year survival rate of HCC patients in China is much lower than that in the United States. Basic cancer treatments for cancer in China are quite different from those in the United States, especially in the subdivision of liver cancer.

5-Year Survival Rate of Liver Cancer by Region

%



Differences in the Quality of Fundamental Cancer Treatment

- In the U.S., early screening and diagnosis of cancer has become a routine. However, in China, early screening for cancer has not yet been popularized, and there is a lack of technical support for early screening and diagnosis.
- MDT is a popular and well-practiced approach to cancer treatment in the United States. However, in China, MDT is still developing.

Still Developing Treatment Method for Liver Cancer

- **Liver Transplantation:** The U.S. mainly relies on the Milan standard and University of California, San Francisco (UCSF) standard. In contrast, there is still no unified standard in China. Many institutions and scholars have suggested different standards, including Hangzhou Standard, Shanghai Fudan Standard, Huaxi Standard and Sanya Consensus. Although these standards expanded the scope of application of liver transplantation for HCC and benefited more HCC, there was no significant result in improving survival rate.
- **Interventional Therapy:** China uses transcatheter arterial chemoembolization (TACE), or interventional therapy. However, in addition to TACE, U.S. also have transcatheter arterial embolization (TAE) and drug-loaded microsphere embolization (DEB-TACE) treatment providing more possibilities for the treatment of liver cancer.
- **Medication:** While fewer medication of targeted therapy and immunotherapy have been introduced to China, the U.S. benefited from a wider selection of medications to improve treatment outcomes.

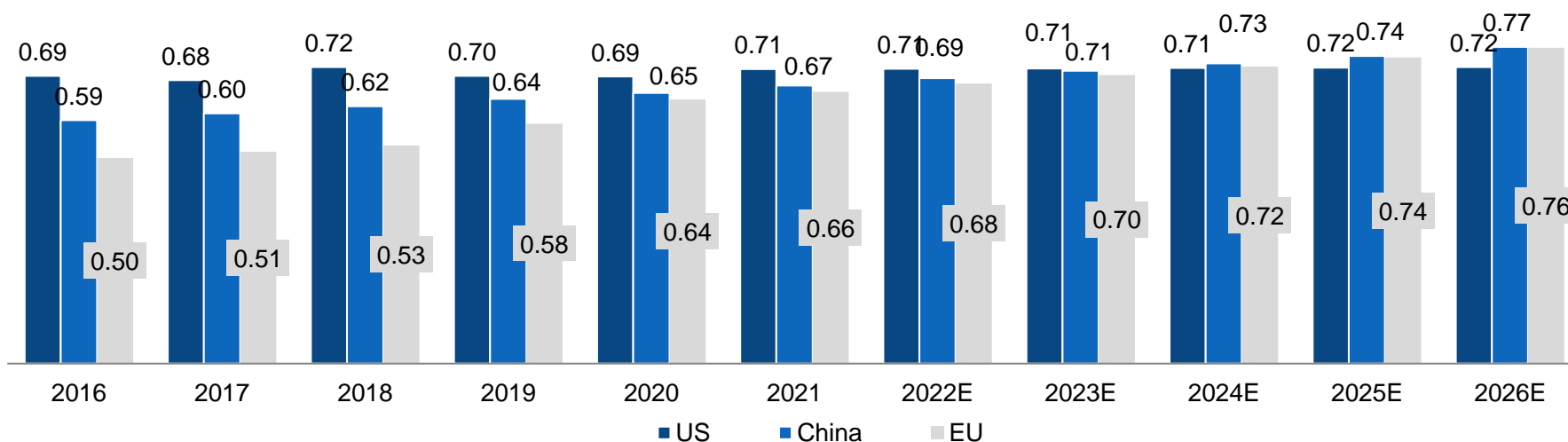
Incidence Rates of Lung Cancer by Region, 2016-2026E

- Due to smoking and air pollution, the incidence of lung cancer in China continued to increase, from 0.59‰ in 2016 to 0.67‰ in 2021.
- In recent years, anti-smoking campaigns have led to a slight decline in the incidence of lung cancer in the U.S., but the overall incidence of lung cancer in the U.S. increased from 0.69‰ in 2016 to 0.71‰ in 2021.
- The incidence of lung cancer in Europe increased from 0.50‰ in 2016 to 0.66‰ in 2021.

Incidence Rates of Lung Cancer, 2016-2026E

‰

CAGR	U.S.	China	EU
2016-2021	0.5%	2.7%	5.7%
2022E-2026E	0.1%	2.6%	3.1%



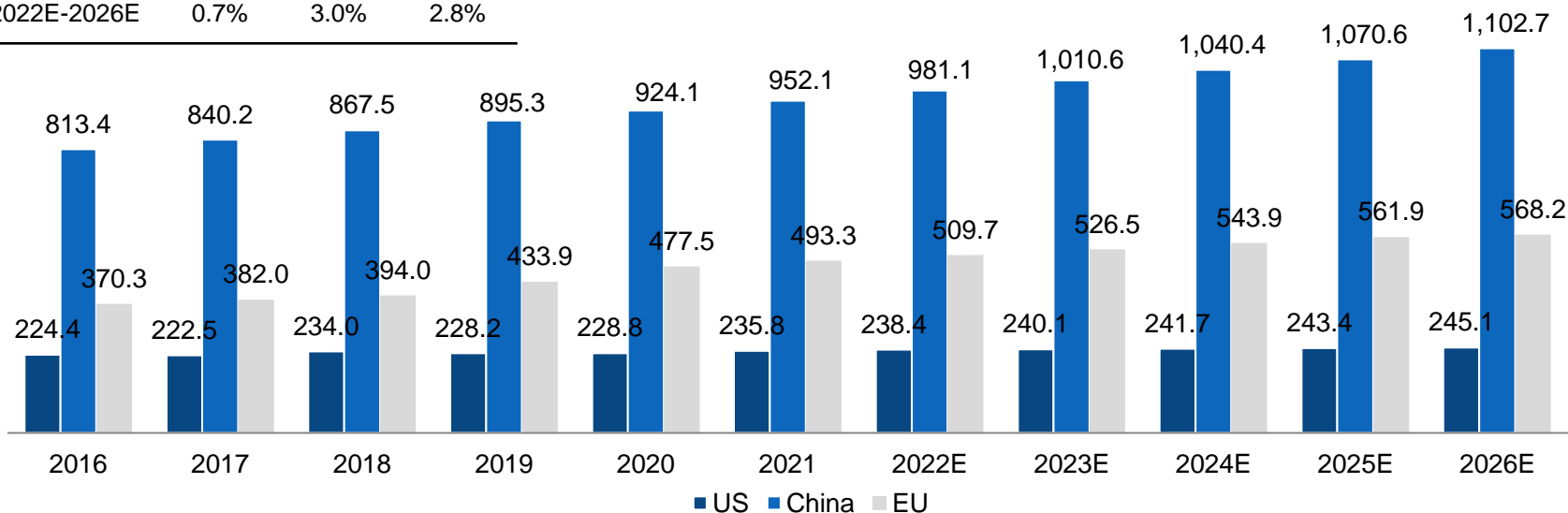
Estimated New Lung Cancer Cases by Region, 2016-2026E

- In terms of morbidities and deaths, lung cancer is the well-deserved "king of cancer." Although the combined application of surgery, chemotherapy, target therapy and immunotherapy has significantly improved the survival rate of lung cancer, the prognosis of lung cancer patients is still relatively insufficient compared with other cancers.
- The number of new lung cancer patients in China has increased from 813.4 thousand in 2016 to 952.1 thousand in 2021.
- The number of new lung cancer patients in the United States has increased from 224.4 thousand in 2016 to 235.8 thousand in 2021. The number of new lung cancer patients in Europe has increased from 370.3 thousand in 2016 to 477.5 thousand in 2021.

Estimated New Lung Cancer Cases, 2016-2026E

Thousand

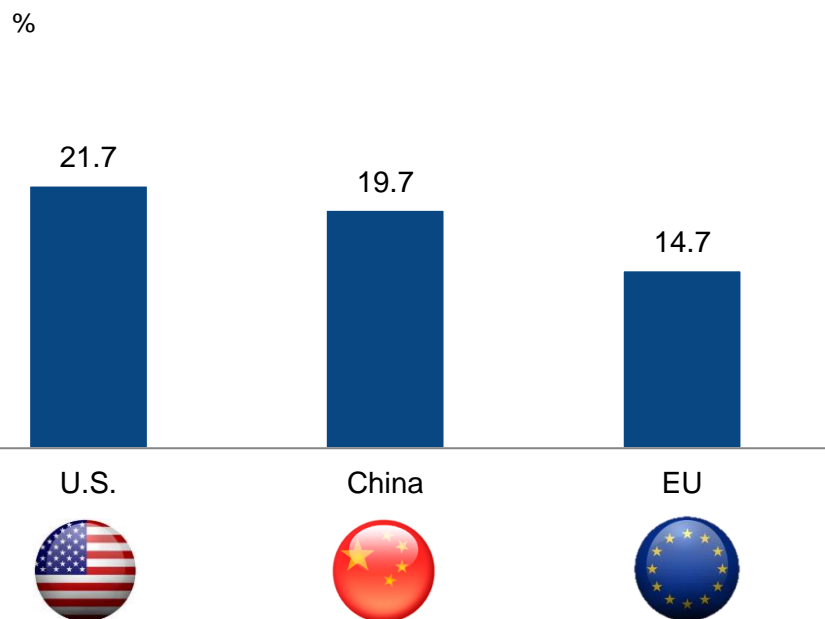
CAGR	U.S.	China	EU
2016-2021	1.0%	3.2%	5.9%
2022E-2026E	0.7%	3.0%	2.8%



5-Year Survival Rate of Lung Cancer, by Region

- According to survey data in China (2012-2015), the United States (2011-2017) and Europe (2013-2018), the current 5-year survival rate of lung cancer in China is 19.7%, which is higher than the overall European survival rate of 14.7% and lower than 21.7% in the United States. The global 5-year survival rate of lung cancer is less than 20%. It is recognized as a low survival rate mainly due to factors such as late diagnosis and smoking.
- In addition to the two significant factors of late diagnosis and smoking, the patient's age, health status, and type of lung cancer will also affect the 5-year survival rate of lung cancer. In addition, research in Europe pointed out that women of all ages have a higher survival rate than men.

5-Year Survival Rate of Lung Cancer by Region



Slower Early Lung Cancer Screening Globally

The best timing for lung cancer treatment is when the cancer cells have not yet metastasized and spread. However, most lung diseases do not have obvious symptoms at that time. The symptoms of lung cancer usually occur when cancer cells have spread to other parts of the body, especially in bones, brain, liver, adrenal glands, and pleura. In the U.S., only 16% of lung cancer cases were diagnosed at an early stage. Early lung cancer screening in other parts of the world is still in the early stage of development.

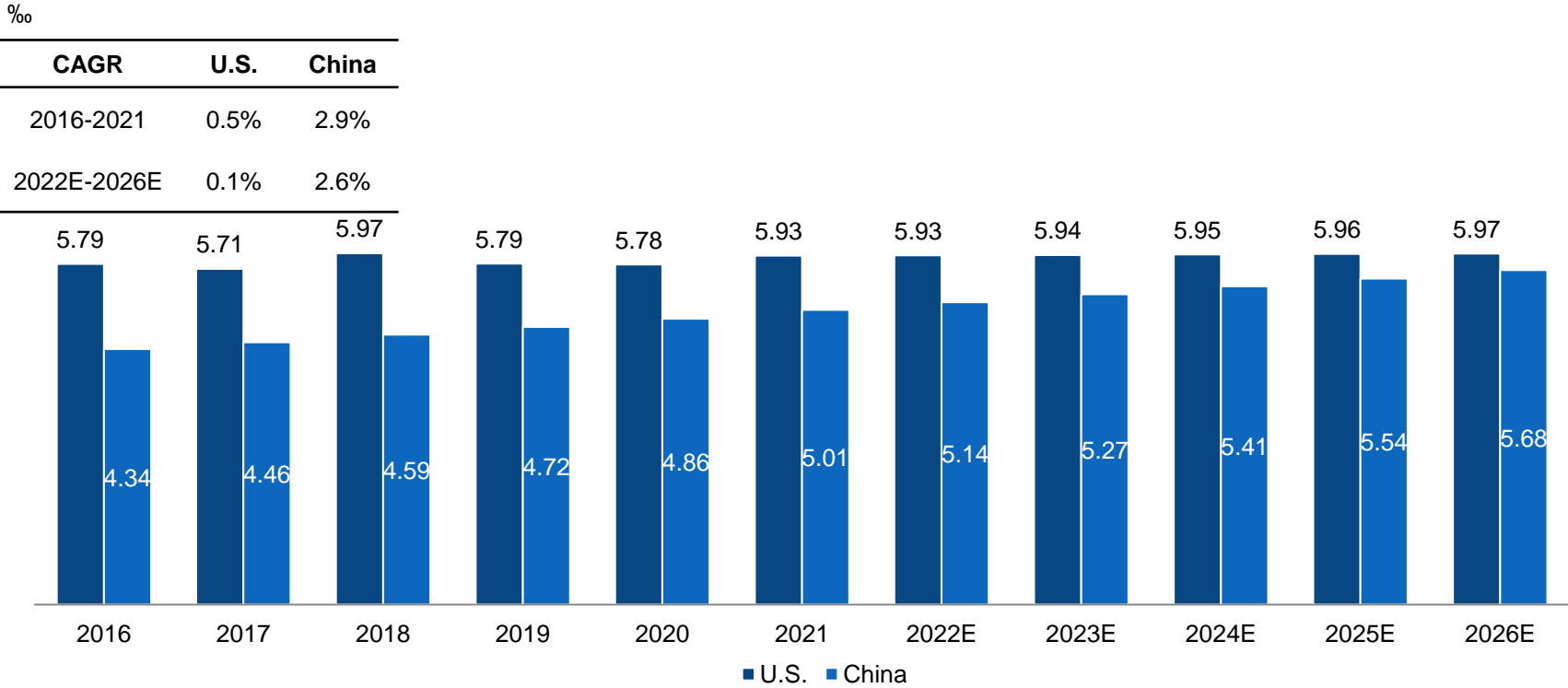
Smoking

Studies confirmed that continuing to smoke after the diagnosis of lung cancer will reduce the survival rate. On the other hand, smoking cessation has been shown to increase the chance of surviving early stage non-small cell lung cancer and may also increase the survival rate of small cell lung cancer. In a study of lung cancer patients, the survival rate of patients who quit smoking within 3 months after diagnosis reached almost 62%. For those who continue to smoke, the 1-year survival rate after diagnosis is only 41%. In recent years, smoking cessation activities contribute to the declining lung cancer mortality rate in the U.S.

Incidence rates of Pulmonary Nodules by Region, 2016-2026E

- Due to factors such as smoking and air pollution, the number of diagnosed pulmonary nodules in China has been increasing rapidly in recent years. The incidence of pulmonary nodules in China increased from 4.34‰ in 2016 to 5.01‰ in 2021.
- Due to higher coverage of lung screening in the United States, the number of pulmonary nodules diagnosed has increased significantly, the incidence rate of pulmonary nodules in the United States has increased from 5.79‰ in 2016 to 5.93‰ in 2021.

Incidence Rates of Pulmonary Nodules, 2016-2026E



Source: Frost & Sullivan Analysis

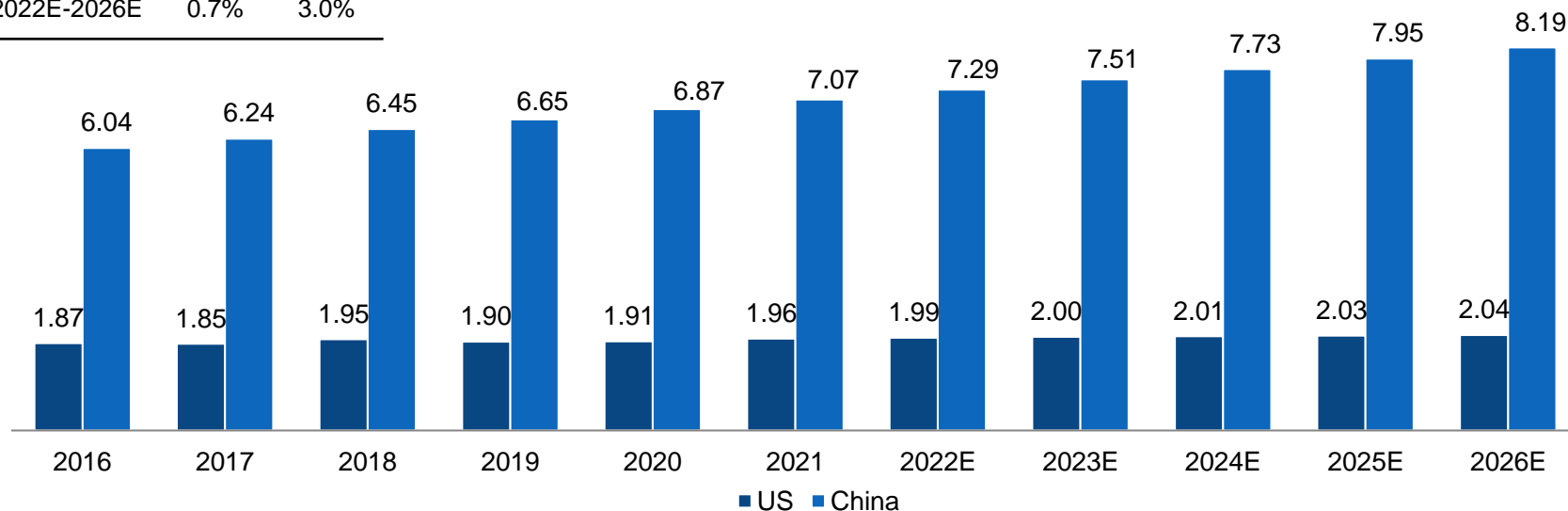
Estimated New Pulmonary Nodules Cases by Region, 2016-2026E

- The incidence of pulmonary nodules in both China and the U.S. have seen an upward trend in recent years. The number of new pulmonary nodules patients in China increased from 6.04 million in 2016 to 7.07 million in 2021. During the same period, the number of new cases pulmonary nodules in U.S. increased from 1.87 million in 2016 to 1.96 million in 2021.
- With the development of radiography, the number of patients diagnosed with pulmonary nodules is increasing year by year. Due to the possibility of cancerous transformation of some nodules and the high mortality rate of lung cancer, an increasing number of people start to pay attention to pulmonary nodules.

Estimated New Pulmonary Nodules Cases, 2016-2026E

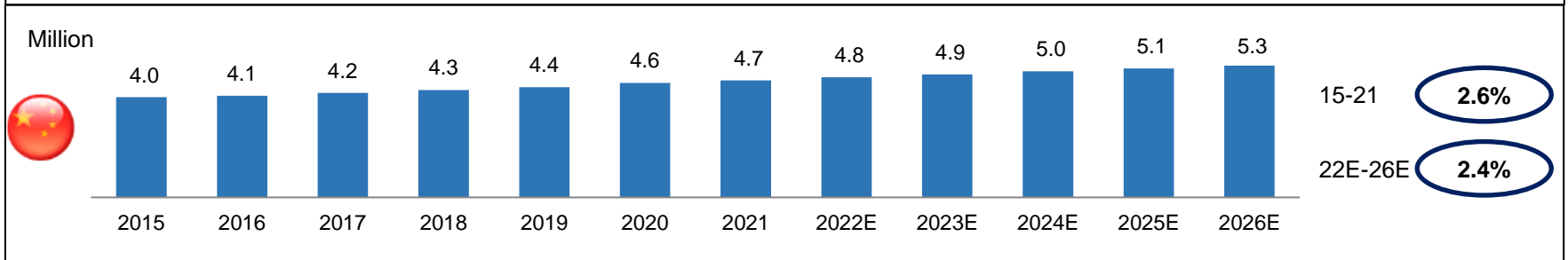
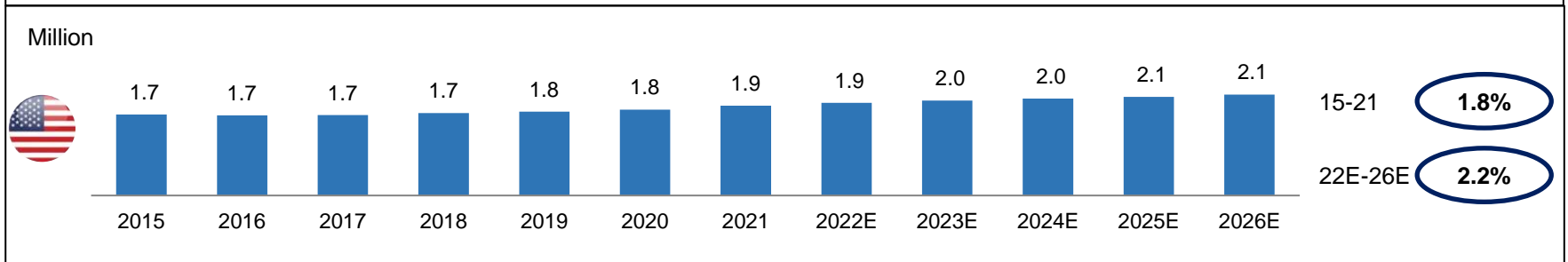
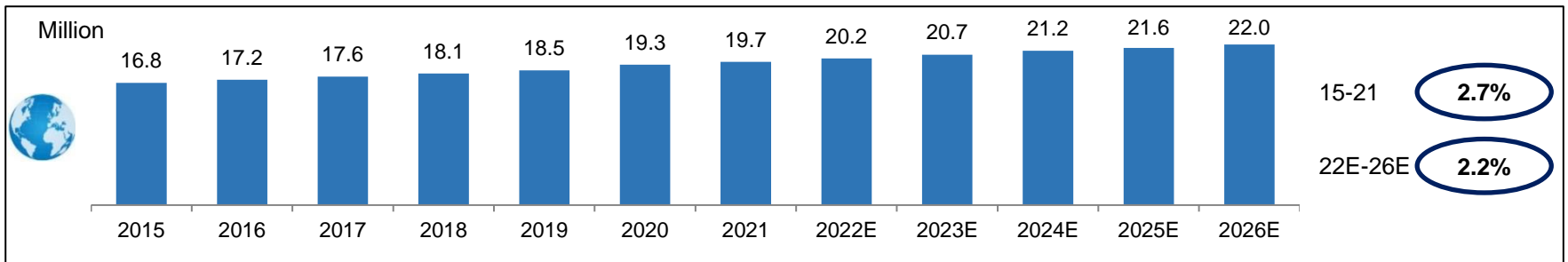
Million

CAGR	U.S.	China
2016-2021	1.0%	3.2%
2022E-2026E	0.7%	3.0%



New Cases of Cancer Patients Worldwide, in US, and China 2015-2025E

• In recent years, there has been a high incidence rate of cancer worldwide, with the annual number of new cases increasing from 16.8 million in 2015 to 19.7 million in 2021. The future compound annual growth rate of new cases in China is higher than the global average, and the number of new cases in China is expected to reach 5.3 million by 2026, accounting for 24.1% of the global number.

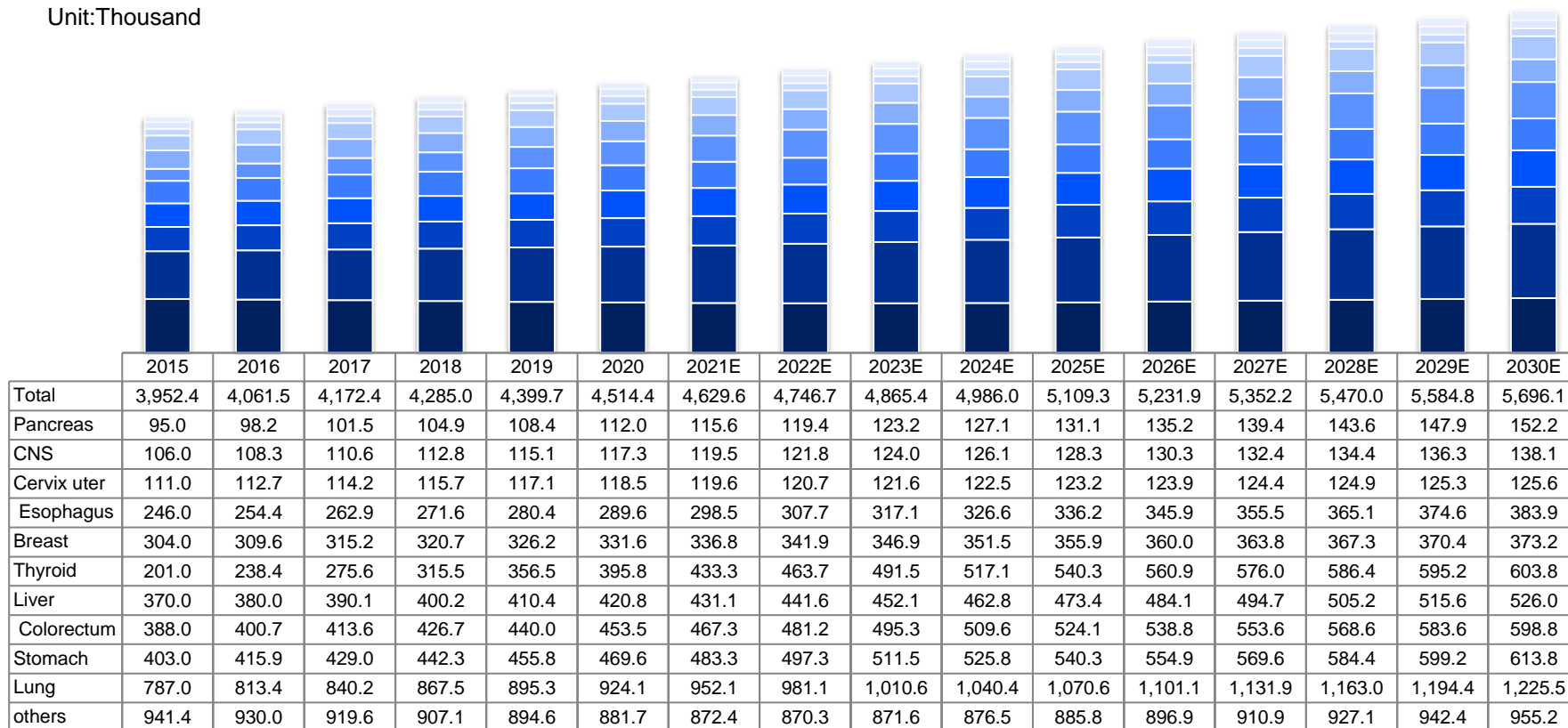


Top 10 Cancer in China 2015-2030E

- The overall number of new cancer cases in China is on the rise, and the number of new cancer cases will increase year by year. In terms of the number of new cases in 2020, lung, liver, stomach, colorectal and thyroid cancer were among the top five cancers with high incidence. These five types of cancer together account for more than 50 percent of the total number of new cancer cases in China.

New Cases of Top 10 Cancers in China, 2015-2030E

Unit: Thousand



Overview of Tumour Treatment

- Tumours are divided into benign tumours and malignant tumours, of which, malignant tumours are cancerous. Some types of benign tumours such as thyroid nodules, breast lumps and pulmonary nodules may transform into malignancies through a process known as cancer progression. Therefore, early detection and treatment of benign tumours plays an important role in cancer prevention. Currently, tumour treatment options primarily include surgery, radiotherapy, interventional radiology, chemotherapy, targeted therapy and immunotherapy. The type of tumour treatment depends on the specific conditions of the patient, such as the size and feature of the tumour, the desired effect, and the acceptable cost. The doctors will give patients professional suggestions on tumour treatment.

Surgery

Surgery is a clinical procedure in which a surgeon removes the cancer from an oncology patient with the aid of tools. It is effective for solid tumours with clear periphery at fixed positions or tumours at early stage. When the tumours have spread or systemic metastases have occurred, surgical treatment may not be suitable any more. Surgery typically costs RMB10,000 to RMB50,000 per procedure.

Radiotherapy

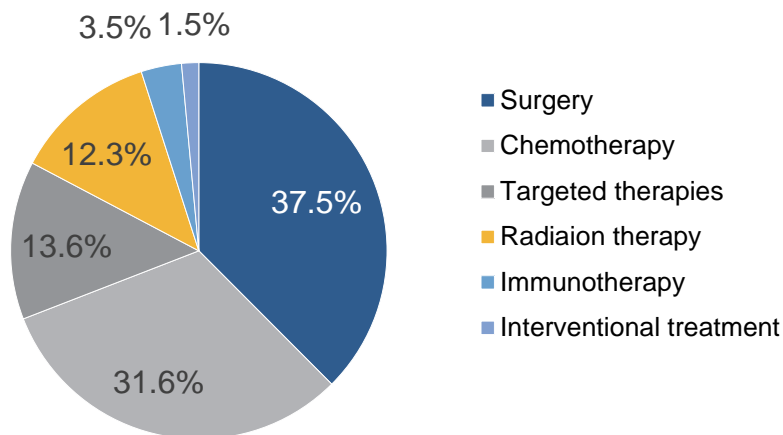
Radiotherapy uses high energy to kill malignant cancer cells or other benign tumour cells. Since the discovery of X-ray in 1895, radiotherapy has developed rapidly across the world, and it is now considered applicable to various types of cancer, including solid tumours and hematologic tumours. Radiotherapy typically costs RMB10,000 to RMB30,000 per course of treatment.

Interventional Treatment

Interventional Treatment is a clinical procedure of minimally invasive treatment which utilises puncture needles, catheters and other interventional devices under the guidance of digital subtraction angiography (DSA), CT, ultrasound and MRI equipment. Interventional radiology can be used to treat various types of solid tumours. Non-vascular interventional treatment is usually applied in tumor interventional treatment, including percutaneous biopsy, MWA, RFA ablation, argon-helium knife, etc. The cost of interventional treatment usually ranges from RMB10,000 to RMB40,000 per procedure.

Overview of Tumour Treatment (cont.)

Market Share of Tumour Treatment Option, 2021



Note: The market share of tumour treatment options is calculated based on treatment expenditure and number of patients who are treated.

Chemotherapy

Chemotherapy uses one or more pharmaceuticals to kill cancer cells and control their growth. Similar to radiotherapy, chemotherapy applies to various types of cancer, either alone or in combination with other treatment options. Chemotherapy typically costs RMB50 to RMB300 per day.

Targeted Therapy

Targeted Therapy typically uses small-molecule drugs or monoclonal antibodies to prevent the proliferation and spread of cancer cells by targeting the specific genes, proteins or tissue environments which contribute to the proliferation and spread of such cancer cells. Targeted therapy is applicable to various types of cancer with detectable targets. Targeted therapy typically costs RMB400 to RMB800 per day.

Immunotherapy

Immunotherapy uses biological agents to treat cancer by inducing, enhancing or restraining the immunoreactions of oncology patients, and it is considered suitable for various types of cancer, including solid tumours and hematologic cancer. Immunotherapy typically costs RMB500 to RMB1,500 per day.

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1 Analysis of Medical Device Market





2 Analysis of Related Disease Market

3 **Analysis of Tumour Ablation Therapy Market in China**

4 Competitive Analysis of Microwave Ablation Market in China

MWA, Radiofrequency Ablation(RFA), Cryoablation (CA) and Laser Ablation (LA) are major ablation techniques

- Tumour ablation therapy is a technique guided by ultrasound, computed tomography (CT), Magnetic Resonance Imaging (MRI) and other imaging techniques while using energy ablation (including MWA), chemical ablation, or other minimally invasive procedures to target the tumour, causing acute cellular necrosis with very high temperature to ultimately achieve inactivation of tumour. Tumour ablation technique is primarily applied in the treatment of both malignant and benign tumours. Based on different techniques, tumour ablation devices can be divided into microwave ablation devices, radiofrequency ablation devices, cryoablation devices, and other ablation devices such as high intensity focused ultrasound (HIFU) devices, nano knife devices, and etc.
- By comparison, MWA has the advantage in rapid heating and short operation time. Generally, it can be applied to tumours from 2cm to 5cm, thus has a wider applicable range of tumour size.

	 MWA	 RFA	 CRA	 LSA
Principle	<ul style="list-style-type: none"> • Microwave create heat for ablation 	<ul style="list-style-type: none"> • High-frequency electrical currents create heat for ablation 	<ul style="list-style-type: none"> • Utilize the gas throttling effect or argon/helium 	<ul style="list-style-type: none"> • He-Ne laser or excimer laser technology for ablation
Advantages	<ul style="list-style-type: none"> • Applicable for tumours from 2cm to 5cm. Multiple needles can be used based on the volume of tumour for simultaneous treatment, resulting in wider ablation range. • More efficient in coagulating blood vessels. • High heating speed, high intratumoural temperature and short operation time. 	<ul style="list-style-type: none"> • Applicable for tumours from 2cm to 5cm, can be performed under percutaneous puncture, open surgery and laparoscopy. • Wide range of applicable diseases. • Good conformity ability and applicable to tumours close to the major vessels and vital organs. 	<ul style="list-style-type: none"> • Less pain during operation • Easy to locate the range and border of tumours during operation, therefore has wide treatment range and smaller damage to surrounding tissues. • Good conformity ability and applicable to tumours close to the major vessels and vital organs. 	<ul style="list-style-type: none"> • The laser fiber bundle is small and flexible, and the energy output is precisely controllable
Disadvantages	<ul style="list-style-type: none"> • Not suitable for tumours close to major vessels or vital organs. 	<ul style="list-style-type: none"> • Low ablation frequency, poor penetration, slow heating rate, low intratumoural temperature and longer operation time than MWA. • Affected by tissue carbonization effect • Affected by blood perfusion 	<ul style="list-style-type: none"> • Freezing range too large, longer operation time, risk of causing complications such as ultra-low temperature, freezing shock and nerve damage. • Cryoablation consumes patient's platelets, therefore not amenable for people with poor coagulation function. 	<ul style="list-style-type: none"> • Longer operation time than MWA. • Not suitable for large nodules or tumours

Market Size of Ablation Industry

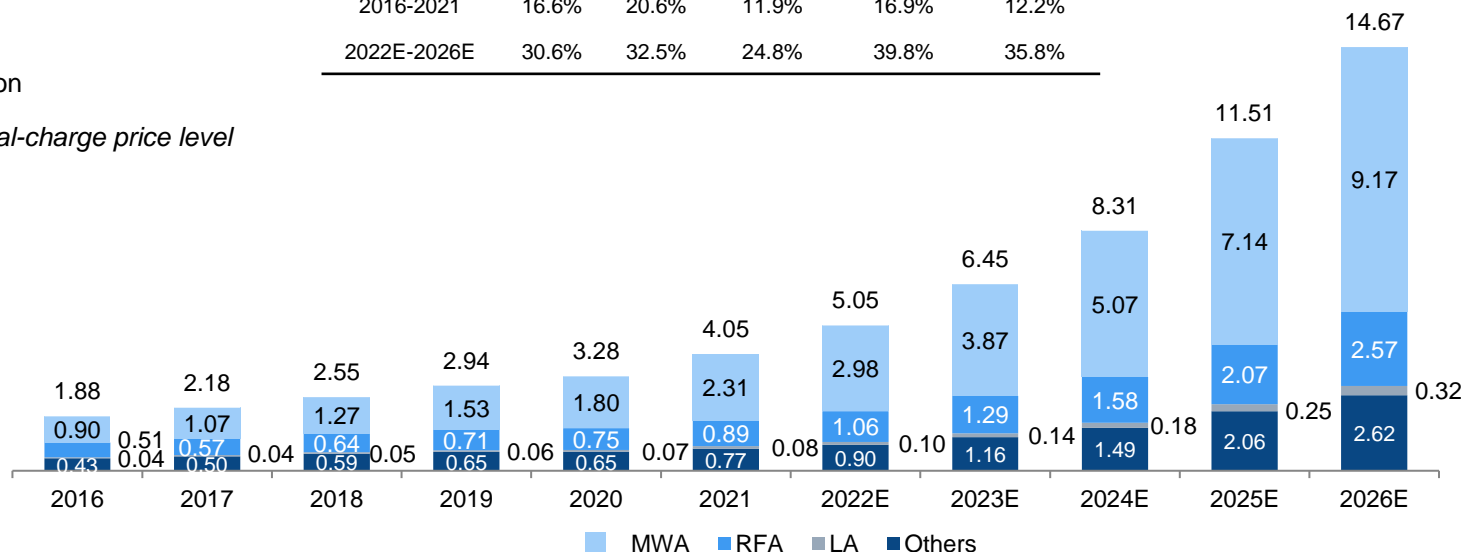
- Given the increasing number of cancer patients, the promotion of ablation technique in hospitals, the rising adoption of minimally invasive operation that has the advantages of short operation time and fast postoperative recovery, the ablation therapy has gradually become one of the most common treatments for tumour. From 2016 to 2021, the market size of China's tumour ablation industry in terms of hospital-charge price has increased from RMB1.88 billion to RMB4.05 billion with a CAGR of 16.6%. MWA is the largest sector of tumour ablation therapy market in China, contributed to 57% of the overall ablation market, with a sales revenue of RMB2.31 billion in 2021. With the further popularization of ablation therapy and the increasing coverage of such kind of treatment in medical insurance in different geographic regions (such as Shanghai, Fujian and Guangdong), the market size of the tumour ablation industry in China will continue to grow and is expected to reach RMB14.67 billion in 2026 with a CAGR of 30.6%.

Market Size of China's Ablation Industry, 2016-2026E

CAGR	Total	MWA	RFA	LA	Others
2016-2021	16.6%	20.6%	11.9%	16.9%	12.2%
2022E-2026E	30.6%	32.5%	24.8%	39.8%	35.8%

RMB Billion

At hospital-charge price level



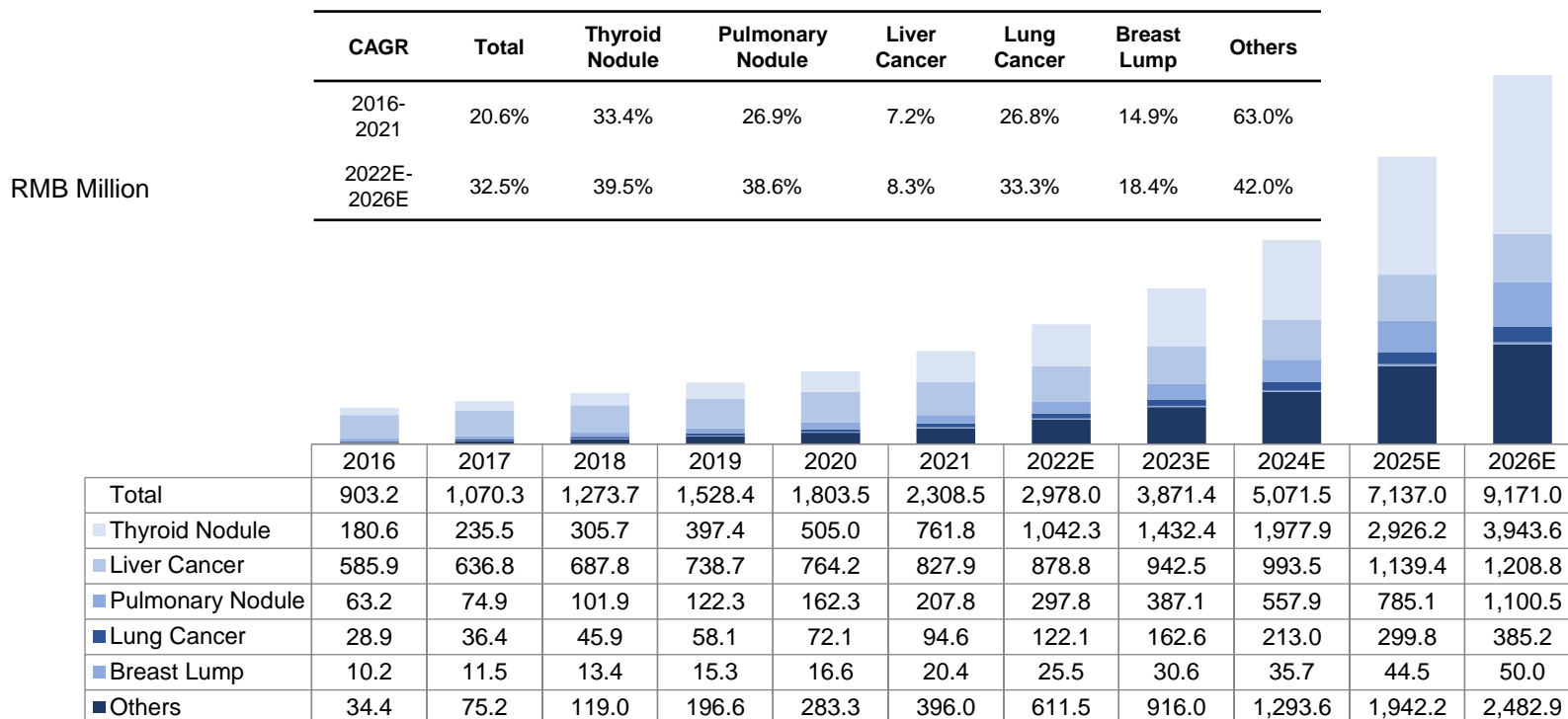
Note: Other tumour ablation methods including CRA, nano knife ablation, high intensity focused ultrasound ablation (HIFU) and etc., contributed to 19% of the overall tumour ablation therapy market in 2021.

Source: Expert interviews, Frost & Sullivan analysis

Market Size of MWA Industry

- From 2016–2021, the sales revenue of MWA market in China has increased from RMB903.2 million to RMB2,308.5 million, with a CAGR of 20.6%. With the increasing adoption of minimally invasive operation, the promotion of MWA therapy in different hospitals and the expansion of applicable diseases of MWA therapy, MWA market in China will maintain an upward trend in the future. It is estimated that MWA market in China will reach RMB9,171.0 million in 2026, with a CAGR of 32.5% since 2022. The sales revenue of MWA market for thyroid nodule and liver cancer reached RMB761.8 million and RMB827.9 million respectively in 2021 and is expected to increase to RMB3,943.6 million and RMB1,208.8 million respectively in 2026.

Market Size of MWA Industry in China by Segment 2016-2026E



Note: Others include thyroid cancer, breast cancer, varicose veins and prostate cancer etc., contributed to 17.15% of the overall MWA market in 2021.

Source: Expert interviews, Frost & Sullivan analysis

Number of MWA Procedures (1/2)

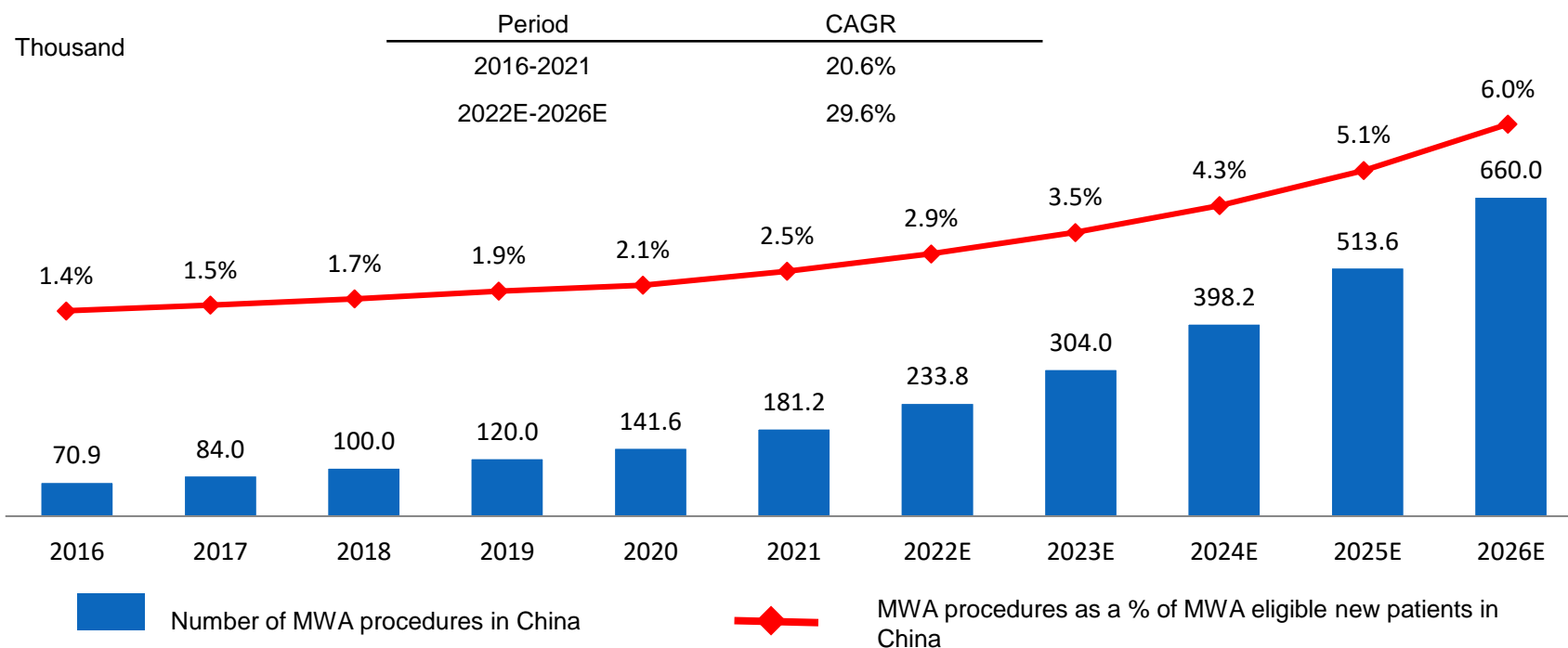
- MWA therapy can be applied to a wide range of diseases, including thyroid nodule and cancer, breast lump, liver cancer, pulmonary nodule and lung cancer.
- The patients eligible for MWA are patients:
 - (i) in a single-tumour case, with a tumour no larger than 5cm in diameter; or in a multiple-tumour case, with no more than three tumours and each tumour no larger than 3cm in diameter;
 - (ii) absence of vascular invasion, distant metastases, and lymph node involvement;
 - (iii) with no contraindication for MWA, for example, no severe organ dysfunction of the liver, kidney, heart, lung and brain, and standard or near-normal coagulation function;and
 - (iv) not a surgical candidate at the time of the procedure.
- MWA therapy is not applicable to patients with tumours near major blood vessels or vital organs. In addition, patients with the following conditions are not considered clinically eligible for MWA:
 - (i) liver failure, such as massive ascites, hepatic encephalopathy, and who are delirious etc.;
 - (ii) severe coagulation dysfunction (such as prothrombin time >30s, prothrombin activity <40%, and BPC <30×10⁹/L);
 - (iii) tumour volume exceeding 70% of liver volume or high extrahepatic tumour burden (including BCLC stage D liver cell carcinoma);
 - (iv) active inflammatory or infectious lesions in any organ;
 - (v) acute or severe chronic renal failure, heart/lung insufficiency; and
 - (vi) tumour near the diaphragm, gastrointestinal tract, gallbladder, pancreas, hilar liver and major bile ducts or blood vessels.

- (1) Glassberg M B, Ghosh S, Clymer J W, et al. (2019). Microwave ablation compared with radiofrequency ablation for treatment of hepatocellular carcinoma and liver metastases: a systematic review and meta-analysis. *OncoTargets and Therapy*.
- (2) BPC: Blood platelets count which is a test that measures the number of platelets in a person's blood.
- (3) BCLC: Barcelona clinic liver cancer (BCLC) staging uses a set of criteria to guide the management of patients with hepatocellular carcinoma (HCC). The classification system sorts patients into four categories.

Number of MWA Procedures (2/2)

- Due to the rising number of tumour patients, expanding indications of MWA therapy, together with the increasing number of hospitals able to perform MWA procedures, the number of MWA procedures in China increased from 70,900 in 2016 to 181,200 in 2021 with a CAGR of 20.6%, and is expected to grow at a CAGR of 29.6% from 2022 to 2026. Patients generally choose the method of treatment based on doctors' recommendations. In China, MWA is still in the stage of rapid development and product promotion. Hospitals in many regions have not applied the MWA technology, and doctors in those regions have not received relevant education and training to grasp the practical skill and technique on the operation of MWA. Therefore, more time is needed for market cultivation, promotion through academic conferences, and surgical training for clinicians in order to popularise MWA procedures. Also, the patients diagnosed for tumour may delay in their treatment especially when the tumours are diagnosed benign (i.e.non-cancerous). Along with the rising recognition of MWA by more doctors, the penetration rate of MWA is expected to increase. The penetration rate of MWA procedures, measured by the number of MWA procedures as a percentage of the number of new patients eligible for MWA procedures, increased from 1.4% in 2016 to 2.5% in 2021, and is expected to further increase to 6.0% in 2026.

Number of MWA Procedures and Penetration Rate in China, 2016-2026E



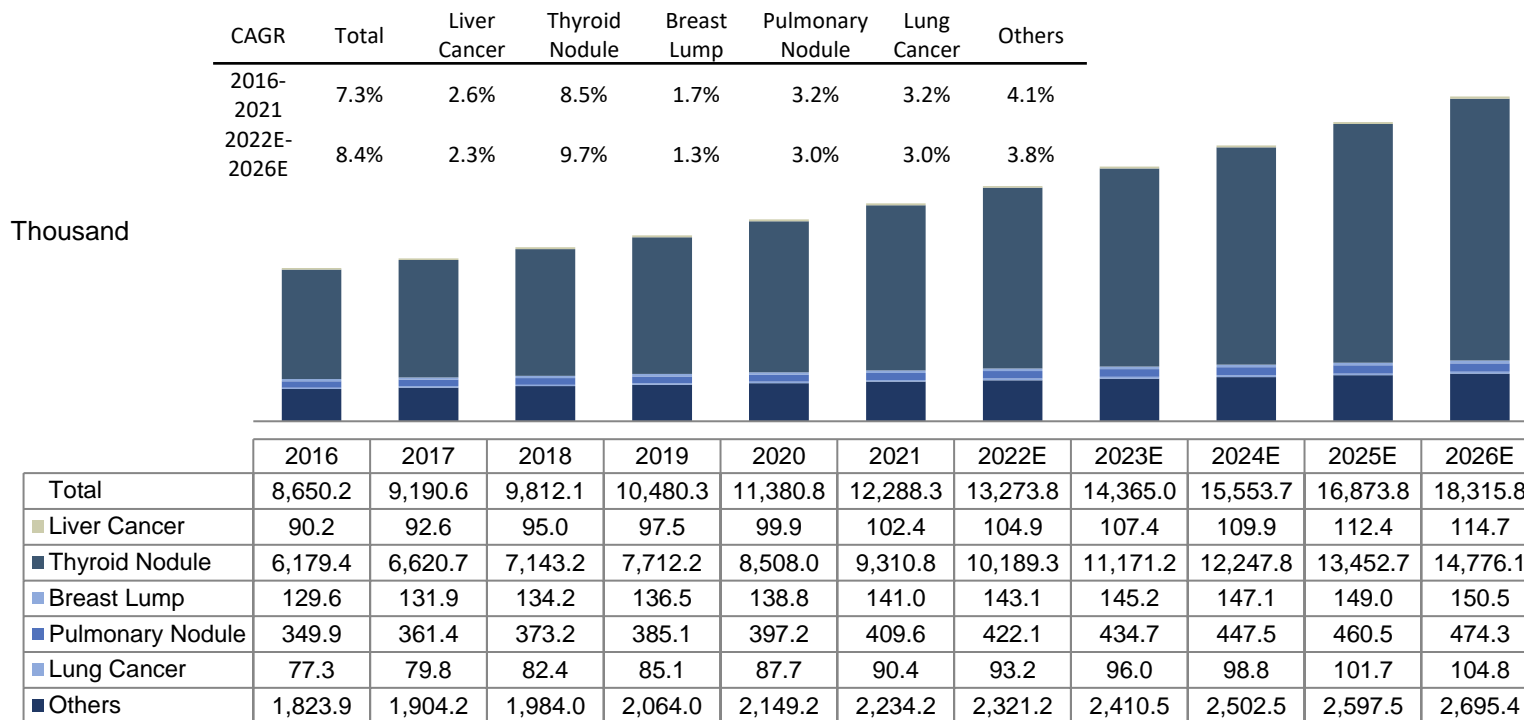
Note: The number of MWA procedures conducted in terms of the number of patients newly diagnosed for such diseases and eligible for MWA therapy.

Source: Expert interviews, Frost & Sullivan analysis

Number of New Patients Eligible for Ablation Therapy

- The patients eligible for MWA are patients: (i) (in a single-tumour case) with no larger than 5cm in diameter or in a multiply-tumour case, with no more than three tumours, among which, no tumour is larger than 3cm in diameter; (ii) absence of vascular invasion, distant metastases, and lymph node involvement; (iii) with no contraindication for MWA, for example, no severe organ dysfunction of the liver, kidney, heart, lung and brain, and standard or near-normal coagulation function; and (iv) who is not a surgical candidate at the time of the procedure.
- MWA is not applicable to patients with tumours near major blood vessels or vital organs. In addition, patients with the following conditions are not considered clinically eligible for MWA. (i) liver failure, such as massive ascites, hepatic encephalopathy, and who are delirious etc.; (ii) severe coagulation dysfunction (prothrombin time >30s, prothrombin activity <40%, and BPC <30 × 10⁹/L); (iii) tumour volume exceeding 70% of liver volume or high extrahepatic tumour burden (including BCLC stage D liver cell carcinoma); (iv) active inflammatory or infectious lesions in any organ; (v) acute or severe chronic renal failure, heart/lung insufficiency; (vi) tumour near the diaphragm, gastrointestinal tract, gallbladder, pancreas, hilar liver and major bile ducts or blood vessels.

Number of New Patients Eligible for Ablation Therapy, 2016-2026E



Note: The number of new patients eligible for ablation therapy refers to the number of patients newly diagnosed for such diseases in that year who opt for treatment and are eligible for ablation therapy. Source: Expert interviews, Frost & Sullivan Analysis

Analysis of MWA Market In China

Analysis of Market Drivers

Growing Number of tumour Patients Promotes the Market Expansion

We have seen an increasing trend of new patients with tumours. Given MWA therapy is minimally invasive and has the advantage of fast recovery and fewer complications, the penetration rate of MWA therapy is increasing. Applicable diseases for MWA therapy will continue to expand, therefore the demand for MWA therapy will gradually increase, further facilitating the growth of MWA medical devices market.

Numerous tumour Ablation Training Programs Will Enhance the Popularisation of MWA Technique.

Open surgery, chemotherapy and radiation therapy are relatively expensive, posing heavy burden on national medical insurance. Comparatively, ablation therapy has satisfactory clinical outcome with relatively low fees, relieving the burden partially. Led by National Health Commission and other relevant associations, MWA training programs are organized in different level of hospitals to promote the popularisation of MWA techniques.

Policies Support Innovation and Development of Medical Device Industry

In recent years, NMPA has adopted policy measures to promote innovation and development to optimise the review and approval of medical devices, improve work quality and efficiency and promote industrial innovation and advancement. In November 2018, NMPA published “Special Examination and Approval Procedures for Innovative Medical Products” to grant priority to eligible innovative medical devices and encourage research and innovation of medical devices. In March 2020, the State Council published “Regulation on Supervision and Administration of Medical Devices” to strengthen the supervision of development, production, management and application of medical devices in the PRC, and optimise the examination and review procedures for approval. In March 2020, NMPA and the Standardisation Administration of the PRC issued the “Opinions on Further Promoting the High-quality Development of Standardisation of Medical Devices” , stating that by 2025, an advanced

standard system of medical device that is in line with international standards will play the leading role for the nation in the transition from a big manufacturer of medical device to a powerful one. These policies will propel the innovation and R&D of the MWA industry as well as provide a healthy environment for market growth.

Medical Insurance Coverage of MWA Will Gradually Expand in Various Regions.

Due to differences in the level of economic development, medical insurance policies and tumour prevalence across different regions, there are large differences in the cost, insurance coverage and reimbursement ratios of MWA therapy in China. Currently, MWA therapy has been included in medical insurance coverage in some regions, such as Shanghai, Fujian and Guangdong. In addition, the high cost of traditional surgery causes heavy burden to Chinese medical insurance companies. The cost of MWA surgery, in contrast, is relatively low, which led it become a favorable treatment by Chinese government as well as Chinese medical insurance companies. In the foreseeable future, it is expected more and more regions in China will include MWA in their medical insurance.

Clinical Application (1/3)

- **Clinical studies of MWA of thyroid nodules show that the probability of major complications caused by MWA is extremely low.** Minor complications such as hoarseness can be recovered without further treatment in approximately 2 months after operation.

	Research Title	Sample Size	Time Period	Treating Hospital	Clinical Application Outcome
Benign Thyroid Nodule	<i>Clinical Analysis of 106 Color Doppler Ultrasound-guided Microwave Ablation for Benign Thyroid Nodules</i>	106 patients with benign thyroid nodules. (25 male and 81 female)	2018.10 – 2019.02	Shandong General Hospital of Armed Force	<ul style="list-style-type: none"> • Re-examination after 6 months showed that nodule reduction rate $\geq 25\%$ for all cases, with 7 complete removal. • Postoperative complications can be relieved without special treatment after 1 day to 2 months.
	<i>Clinical Analysis of Ultrasound-guided Microwave Ablation for Thyroid Adenoma</i>	74 patients with thyroid adenoma	2014.07 – 2016.07	Bayi Hospital Affiliated to Nanjing University of Chinese Medicine Vascular Surgery Department	<ul style="list-style-type: none"> • The probability of temporary nerve damage caused by MWA of thyroid nodules is 0 to 3.6%. • In contrast, the probability of temporary nerve damage caused by surgery is 2.3% to 9.8%. The probability of permanent damage is 1.1% to 2%.
	<i>To Study the Therapeutic Effect of Thyroid Cystic Nodule with Microwave Ablation and Lauromacrogol Injection</i>	62 patients with thyroid cystic nodules	2015.01 – 2018.05	General Hospital of Eastern Theater Command	<ul style="list-style-type: none"> • Ultrasound-guided percutaneous puncturing aspiration and MWA therapy is better than lauromacrogol injection in the treatment of thyroid cystic nodules.
	<i>Observation of the Recent Efficacy of Ultrasound-guided Percutaneous Microwave Ablation in the Treatment of Oppressive Solid Thyroid Nodules</i>	146 patients with benign solid thyroid nodules (average largest diameter $\geq 3\text{cm}$)	2016.01 – 2018.01	Affiliated Hospital of Jiangsu University Medical Ultrasound Department	<ul style="list-style-type: none"> • The percentage of major complication is 0. • Does not require replacement treatment with levothyroxine tablets. • Avoid damage to normal thyroid tissue and preserve patients' thyroid function to the greatest extent.

Clinical Application (2/3)

- Clinical studies on MWA of breast cancer show that at 12 months post-operation, the average volume of ablated lesions was reduced by 80.5%. Compared to traditional surgical treatment, MWA has shorter operation time, shorter average hospital stay and lower intraoperative blood loss.
- Clinical studies on MWA of benign breast lumps show that MWA have little impact on appearance. 100% of patients have no obvious MWA needle scars and satisfaction rate of appearance is 98.3%.

	Research Title	Sample Size	Time Period	Treating Hospital	Clinical Application Outcome
Thyroid Cancer	<i>Meta-Analysis of the Safety and Short-term Efficacy of Microwave Ablation and Traditional Open Surgery in the Treatment of Papillary Thyroid Microcarcinomas</i>	1307 patients with papillary thyroid microcarcinomas (PTMC)	2018 - 2020	-	<ul style="list-style-type: none"> • Comparing to traditional open surgery, MWA has shorter operation time and average hospital stay, as well as less intraoperative blood loss.
	<i>The study of Clinical Effect of Ultrasound-Guided Microwave Ablation in the Treatment of Thyroid Cancer</i>	996 patients with PTMC	2018 - 2020	-	<ul style="list-style-type: none"> • Postoperative complication rate for MWA is 4.39%, which is much lower than 20.20% of traditional open surgery.
	<i>The study of Clinical Effect of Ultrasound-Guided Microwave Ablation in the Treatment of Thyroid Cancer</i>	68 patients with thyroid cancer, including 42 male and 26 female.	2018.01 - 2019.01	Xiangdong Hospital affiliated to Hunan Normal University	<ul style="list-style-type: none"> • The percentage of major postoperative complication is 0; minor complication percentage is 13.2% and self-recovered after 2-4 days. • The average volume of ablated lesions was reduced by 80.5% at 12 months post-operation follow up.
Benign Breast Lump	<i>Clinical Application of Ultrasound-Guided Percutaneous Microwave Ablation for Benign Breast Lesions: A Prospective Study</i>	314 women aged 17 to 69 years old with 725 benign breast lesions.	2014.11 – 2018.11	-	<ul style="list-style-type: none"> • The frequency of palpable mass decreased from 29.8% to 7.4%. • The percentage of patients who felt breast pain decreased from 18.8% to 7.4%. • The percentage of patients with nipple discharge decreased from 13.4% to 3.9%. • 97.8% complete ablation after first round.

Clinical Application (3/3)

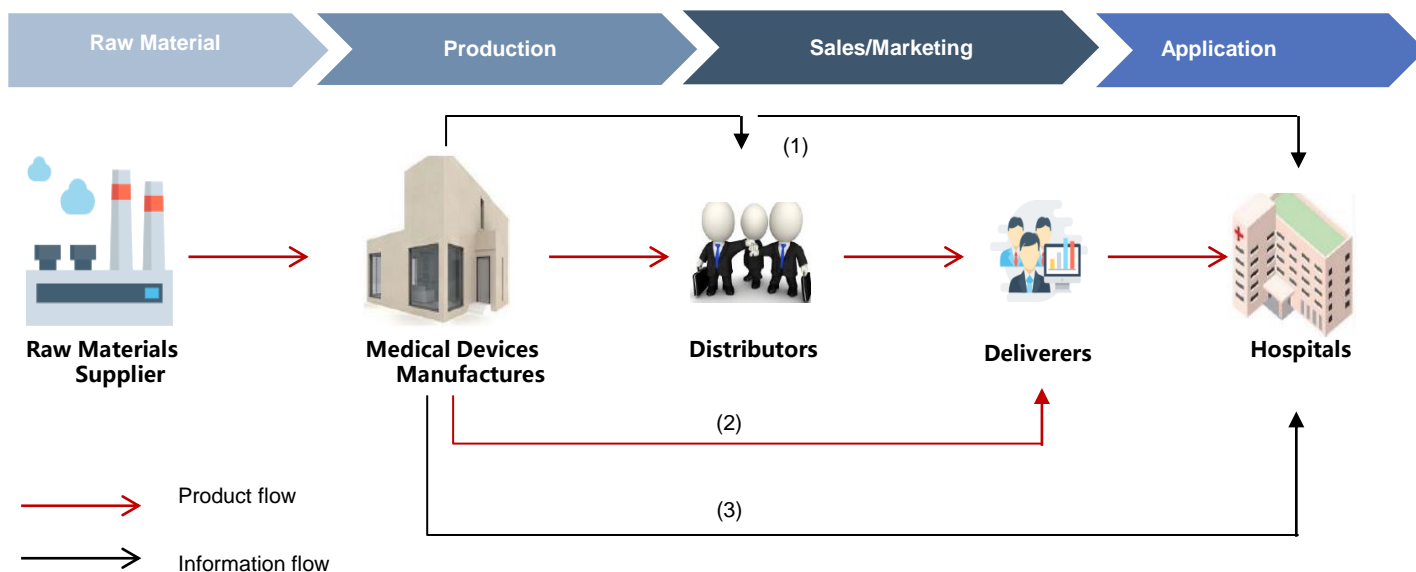
- Clinical studies on MWA for liver cancer shows that the primary treatment for liver cancer is hepatic artery chemoembolization. Combining hepatic artery chemoembolization with MWA has a better therapeutic outcome than hepatic artery chemoembolization alone.
- Clinical studies on MWA for lung cancer show that minimally invasive ablation combining with chemotherapy is better than either of them alone. MWA combining with chemotherapy and cryoablation combining with chemotherapy are similar in efficacy and is likely to be better than RFA combining with chemotherapy.

	Research Title	Sample Size	Time Period	Treating Hospital	Clinical Application Outcome
Benign Breast Nodule	<i>The Clinical Effect of Microwave Ablation in the Treatment of 235 Cases of Benign Breast tumours</i>	235 cases with 632 benign breast tumours	2017.09 – 2019.10	Department of Breast Surgery, Zhengxing Hospital, Zhangzhou, Fujian	<ul style="list-style-type: none"> • All patients were followed up for 3-24 months after ablation. In all cases, the ablation is complete with no bleeding, infection and without further ablation. All patients have no obvious ablation needle scar. Satisfaction rate of appearance reached 98.3%.
Liver Cancer	<i>Clinical Study on Application of Transcatheter Arterial Chemoembolization (TACE) with Microwave Ablation in the Treatment of Liver Cancer</i>	91 patients with liver cancer (55 male and 36 female)	2018.05 – 2020.05	Zhengzhou Yihe Hospital	<ul style="list-style-type: none"> • In recent years, the primary treatment of liver cancer is TACE, but the clinical outcome is not satisfactory when employed alone. Combining with MWA, the levels of AST, ALT and AFP were significantly lower than using TACE alone. The therapeutic outcome is satisfying.
Lung Cancer	<i>Clinical Outcome and Value Assessment of Computed Tomography-Guided Percutaneous Microwave Ablation in the Treatment of Surrounding Lung Cancer</i>	140 patients with surrounding lung cancer (69 male and 71 female)	2017.01 – 2018.01	Xiaogan Hospital Affiliated to Wuhan University of Science and Technology	<ul style="list-style-type: none"> • Total effective rate of MWA (meaning total or partial remission) was 77.14%, which was much higher than 44.28% of gemcitabine plus cisplatin chemotherapy.
	<i>Comparison of Clinical Efficacy of Local Minimally Invasive Ablation for Primary Lung Cancer: A Network Meta-Analysis</i>	28 studies which includes 2336 patients	2016.01 – 2020.07	-	<ul style="list-style-type: none"> • Minimally invasive MWA combined with chemotherapy was better than chemotherapy or MWA alone. • Therapeutic outcome of CA combined with chemotherapy and MWA combined with chemotherapy were similar, and both of them might be superior to RFA combined chemotherapy.

Source: Frost & Sullivan Analysis

Analysis of Value Chain of MWA

- The value chain of the MWA industry in China consists of supply of raw materials, production, sales and product application. Usually, the MWA medical devices manufacturers conduct their sales through various channels, namely (i) sales to distributors, (ii) sales to hospitals through deliverers, and/or (iii) direct sales to hospitals. For distribution model, distributors are responsible for sales channel development, customer maintenance, on-selling MWA medical devices to hospitals and providing hospitals with services such as preoperative consultation. For delivery model, deliverers usually have extensive network with hospitals and help MWA medical devices manufacturers to sell their products to hospitals. Some hospitals prefer procuring medical products from deliverers which are on their panel list only. For direct sales model, some MWA medical device manufacturers build their own marketing teams. Direct sales from the MWA medical device manufacturers to hospitals can reduce intermediate channels in product sales, reducing costs and increasing gross profit margins.



Notes:

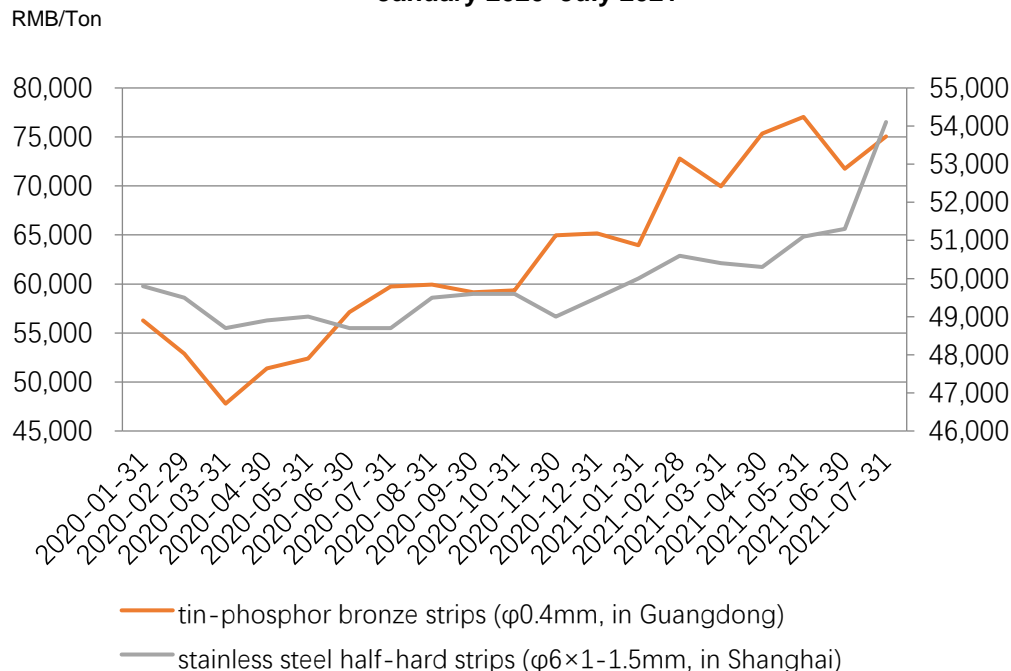
- (1) Distribution model: distributors on-sell MWA medical devices to hospitals.
- (2) Delivery model: deliverers usually have extensive network with hospitals and help MWA medical devices manufacturers to sell their products to hospitals.
- (3) Direct sales model: MWA medical devices manufacturers directly sell their products to hospitals.

Analysis of Value Chain of MWA

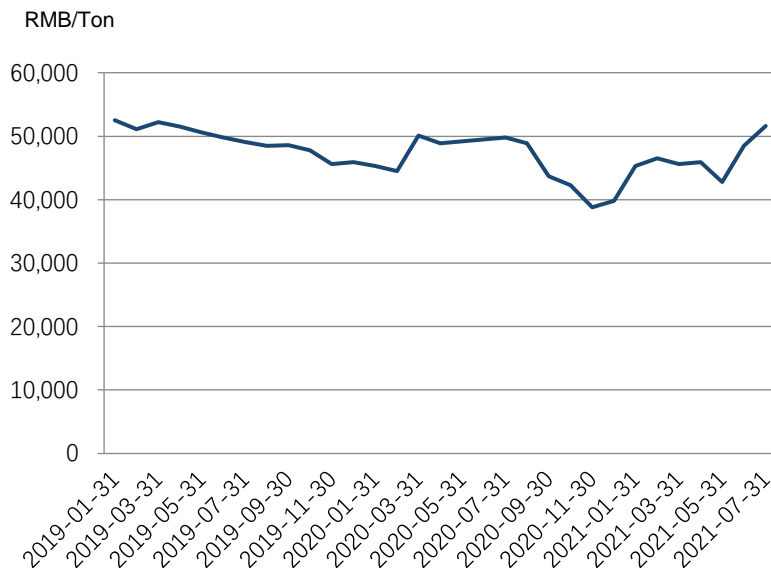
- A MWA needle is mainly composed of the needle tube which is made of stainless steel tube and the tip (針尖) which is made of tin phosphor bronze.
- Global economy is greatly affected by the impact of COVID-19. Major countries in the world have adopted quantitative easing policies, which has led to more serious over-issues in the global currency market. The prices of commodities such as stainless steel and tin-phosphorus bronze have shown an upward trend since the beginning of 2021. Under such circumstances, in the short term, prices of such commodities will remain high in the future.

- Polytetrafluoroethylene is used to coat the tip and shaft of the MWA needle. Its price is affected by both demand and supply. Electricity and gas restriction, with the impact of cold waves and haze, have caused short-term stop of on production by enterprises, resulting in short supply and price increases. With changes in demand on downstream market such as construction, medical care and automobiles, the price of chemical materials such as polytetrafluoroethylene would fluctuate accordingly.

Price History of Tin Phosphor Bronze Strip and 304 Stainless Steel Strip, January 2020–July 2021



Price History of Polytetrafluoroethylene (Disperse Resin), January 2019–July 2021



Comparative Research of MWA Application on Different Diseases

Research on the Application of MWA in Sample Diseases

China	U.S.	South Korea
Papillary Thyroid Microcarcinoma	Oncolytic Neoplasm or Chromophobe Renal Cell Cancer	Early-Stage Non-Small-Cell Lung Cancer
<p>A retrospective analysis of the medical records of 311 patients with T1aNOMO PTMC from January 2013 to September 2018. 168 patients received MWA therapy and 143 patients received open surgery.[1]</p> <p>% of open surgery: 54.0% % of MWA: 46.0%</p>	<p>Clinical and pathologic data were collected for consecutive patients with a histologic diagnosis of oncocytoma, oncolytic neoplasm, or chromophobe renal cell cancer (chRCC) from 2003 to 2016.[2]</p> <p>% of surgery:39.2% % of thermal ablation: 8.2% % of active surveillance: 52.6%</p>	<p>Treatment plans for 10,923 patients with age≥66 and with stage IA-IB NSCLC. [3]</p> <p>Treatment Lobectomy: 59% Sublobar resection: 11.7% Conventional radiation: 14.8% Observation:12.6% SABR: 1.1%</p>
		Liver Cirrhosis in Hepatocellular Carcinoma
		<p>264 cirrhotic patients out of 905 cases were consecutively evaluated for hepatocellular carcinoma. Performed 59 hepatic resections and 205 thermal ablations through a laparoscopic approach .[4]</p> <p>% of liver resection: 22.3% % of thermal ablation: 77.7%</p>
		Solitary Colorectal Liver Metastases
		<p>67 consecutive patients with solitary colorectal liver metastases were treated by either hepatic resection (HR) or RFA. 42 patients underwent HR and 25 patients underwent RFA.[5]</p> <p>% of HR: 62.7% % of RFA: 37.3%</p>

Comparative study of different treatment methods based on literature review: The penetration rate of MWA is higher in China while the penetration rate of ablation therapy is lower in the U.S. RFA is more widely used in South Korea. Analysis based on interviews with doctors and MWA sales expert: The U.S. and Europe have relatively lower penetration rate of MWA. RFA is preferred.

[1]: Li, Jianming, et al. "A comparative study of short-term efficacy and safety for thyroid micropapillary carcinoma patients after microwave ablation or surgery." *International Journal of Hyperthermia* 36.1 (2019): 639-645.

[2]: Miller, Brady L., et al. "Comparative analysis of surgery, thermal ablation, and active surveillance for renal Oncolytic neoplasms." *Urology* 112 (2018): 92-97.

[3]: Shirvani, Shervin Mohajer, et al. "Comparative effectiveness of five treatment strategies for early-stage non-small cell lung cancer in the elderly." (2012): 7062-7062.

[4]: Santambrogio, Roberto, et al. "Surgical resection vs. ablative therapies through a laparoscopic approach for hepatocellular carcinoma: a comparative study." *Journal of Gastrointestinal Surgery* 22.4 (2018): 650-660.

[5]: Hur, Hyuk, et al. "Comparative study of resection and radiofrequency ablation in the treatment of solitary colorectal liver metastases." *The American journal of surgery* 197.6 (2009): 728-736.

Numerous Tumour Ablation Training Programs Organized, Promoting the Popularization of MWA Technique (1/2)

- Open surgery, chemotherapy and radiation therapy are relatively expensive, posing heavy burden on national medical insurance. Comparatively, ablation therapy has satisfactory clinical outcome with relatively low fees, relieving the burden partially. Therefore Chinese government and other related departments strongly support the promotion of MWA techniques by organizing tumour ablation training. Chinese Medical Association (CMA) tumour Ablation Standardized Treatment Training, Chinese Medical Doctor Association (CMDA) tumour Ablation Standardized Treatment Training Program are the standardized, systematic and authoritative tumour ablation therapy training programs. These programs equip doctors with the operation of MWA, promoting the popularization of MWA techniques and therefore help the expansion of MWA market.

CMA tumour Ablation Standardized Treatment Training Program 中华医学会-肿瘤消融规范化治疗培训班

CMDA tumour Ablation Standardized Treatment Training Program 中国医师协会-肿瘤消融治疗技术规范培训项目

Standard

- Professional course material and courseware
- Systematic training process
- Standardized test
- Issue *Chinese Medical Association tumour Ablation Standardized Treatment Training Program Certificate* for qualified students

Standard

- On-site closed and centralized training
- Systematic assessment process including training, tests, 4-month practical practice at a designated base and etc.
- Students who pass the clinical practice assessment will be issued *tumour Ablation Treatment Training Certificate* by CMDA

Applicant Requirement (Maximum 180 members/term)

- Employed in secondary hospital and above
- Engaged in the diagnosis and treatment of solid tumours such as liver, thyroid, kidney, adrenal gland, lung, uterus, etc. and have at least 2 years of relevant work experience
- Have the knowledge of organ perforation of related organs.

Applicant Requirement (Maximum 200 members/term)

- Employed at Secondary Hospital Grade A and above
- Employed at department of medical services, oncology, hepatobiliary surgery, interventional therapy, radiology, ultrasound, thoracic surgery, respiratory, obstetrics and gynecology, urology, gastroenterology, hepatology, orthopedics, nephrology or pain management
- Practicing physician with attending physician or above level and have 3 years of relevant work experience of diagnostic imaging or relevant clinical experience

Curriculum

- Introduction to liver tumour diagnosis and ablation therapy
- RFA standard and individual treatment and operation
- MWA operation
- CT-Guided ablation technique
- Ablation therapy complications and preventions
- Liver cancer ablation with TACE/surgery/chemotherapy/immunotherapy comprehensive therapy.

Curriculum

- Principle, application and common devices of MWA, RFA and Argon-Helium Knife ablation.
- Ablation Therapy of live and lung tumour, prostate cancer, thyroid nodule, hyperplasia, adenomas and etc.
- Sample case discussion and on-site surgeries.

Numerous tumour Ablation Training Programs Organized, Promoting the Popularization of MWA Technique (2/2)

- The prerequisite for training programs organized by CMA and CMDA is doctors in relevant tumour diagnosis department and from secondary hospital and above. Some tertiary hospital organize such training programs as well. The curriculum include theoretical lecture, mock surgery, surgery shadowing and etc., facilitating the promotion of MWA therapy.
- Led by National Health Commission and other relevant associations, many tertiary hospitals also organize MWA training programs to promote the development of MWA, having positive influences on the globalization of Chinese MWA technique.

	Program Date	Program Size	Program Detail
The First Affiliated Hospital of Anhui Medical University	2020.12.22-23	15 Hospitals (in-province and out-of-province) participated	MWA and Closure of Vein Walls of Lower Extremity Training Program: Focus on standardized treatment of intravenous MWA surgery to promote MWA as a treatment plan and standardize surgical procedures.
Hebei Cancer Hospital	2020.10.31-11.02	Approximately 300 ultrasound physicians participated	Hebei Province MWA and “Early Diagnosis, Early Action ”of Breast Cancer Training Program: The training conducted 8 real-time surgery demonstrations, which lasted three and half hours, demonstrating the accuracy, short duration and efficiency of interventional operation under ultrasound guidance.
The Third Hospital of Nanchang	2019.04.13-14	Approximately 100 doctors and scholars	National Health Commission Special Training Program for Thyroid and Breast Ablation: Invited over 10 prestigious experts to conduct lectures and surgery demonstration. Members who pass the standardized test will be issued a certificate from National Health Commission.
The First Affiliated Hospital of Zhejiang University School of Medicine	2018.05.21-25	Doctors from 11 countries participated. 12 members only per term.	Hosted by World Congress on Interventional Oncology and undertaken by The First Affiliated Hospital of Zhejiang University School of Medicine, it is a “ The Belt and Road Initiative ” international training program.

Policies Support the Innovation and Development of Medical Device Industry

- In recent years, National Medical Products Administration has adopted policy measures to promote innovation and development to optimize the review and approval of medical devices, improve work quality and efficiency and promote industrial innovation and advancement. Currently, China's medical device industry presents two good trends: First, the entire industry continues to maintain rapid growth. Second, innovation and development are progressing at a high speed, especially in clinical application. A large number of high-end medical devices have achieved localization, replacing imported products.

2020.03



National Medical Products Administration and Standardization Administration issued "To propose the standardization and high quality development of medical devices"

Policy demands that by 2025, to construct the standard that comply with the research and development, production, trading, use, supervision and management needs of Chinese medical devices. This full-circle scientifically advanced standard should also be in line with international standards but with distinctive Chinese features.

2020.03



State Council amended and issued "Regulation on Supervision and Administration of Medical Devices"

Proposed specific guidelines to any entities in China that engaged in the research and development, manufacture, trading and use, or supervision and administration. Simplified and optimized the review and approval process; detailed and completed the responsibility of the quality and safety of the entire medical device life cycle of medical device; increased the punishment for violation of laws and regulations.

2018.11



National Medical Products Administration amended issued "Special Examination and Approval Procedures for Innovative Medical Products"

Proposed that early intervention, specific personnel responsibility, and scientific review for qualified innovative medical devices. Under the premise of not reducing the standards and procedures, the innovative medical devices should be given priority to ensure the safety and effectiveness of medical devices. Encourage research and innovation of medical devices.

2018.01



Former China Food and Drug Administration issued "Guidelines for Overseas Medical Devices Clinical Trial Data Acceptance."

Proposed the ethical, legal and scientific principles for accepting overseas clinical trial data and open up the path for Chinese medical devices to accept overseas clinical trial data, which can effectively avoid or reduce repetitive clinical trials and can accelerate the launch of tumour ablation devices in China.

In the Long Term, Volume-Based Procurement and Medical Insurance Negotiation will facilitate the innovation and development of MWA

- The purchase target of state-organized centralized drug procurement (hereinafter referred to as “volume-based procurement”) are mature generic medicines medicine and medical devices. Volume-based procurement will suppress the profit of homogeneous products. However, products with core technology and higher professional barriers are less likely to be procured as volume-based or suppressed in price.
- “Medical Insurance Negotiation” refers to the negotiation between relevant state agencies and pharmaceutical companies in terms of price and purchase volume to decide whether to include the relevant products of the company in medical insurance. Entering the medical insurance catalog through Medical Insurance Negotiation can achieve “price-for-volume”, helping companies increase sales of pharmaceutical products, thereby increasing market share while reducing corporate sales expenses and forcing companies to reinforce innovation.
- In the short-term, volume-based procurement and medical insurance negotiations will suppress product prices and reduce corporate short-term profits; in the long term, they can reduce corporate sales expenses, promote corporate innovation, popularize high-quality medical technology and accelerate the domestic substitution of high-end innovation of medicine and medical devices.

《国务院办公厅关于推动药品集中带量采购工作常态化制度化开展的意见》 Guidelines of General Council of State Council on Promoting Volume-Based Procurement of Medicine Jan, 2020

Coverage	Detail
<p>Product Coverage :</p> <ul style="list-style-type: none"> • Medicines with large consuming amounts and high purchasing price in basic medical insurance catalog <p>Company Coverage</p> <ul style="list-style-type: none"> • Marketing Authorization holders have obtained the medicine registration certificate of medicines within the volume-base procurement • Meet the requirements of volume-based procurement in terms of quality, production capacity, supply stability, etc. <p>Medical Institution Coverage</p> <ul style="list-style-type: none"> • All public medical institutions (including military medical institutions) 	<ul style="list-style-type: none"> • The base amount of medicine purchase is verified according to the demand reported by medical institutions and combined with previous year’s use, clinical usage status and medical technology progress. • Determine the number of companies that can be selected according to the market competition pattern and supply capacity, reflecting the scale effect and effective competition. • Strictly enforce the quality standards for shortlisted medicine and strengthen the main responsibility of selected companies to ensure quality.

《中共中央、国务院关于深化医疗保障制度改革的意见》 Guidelines of Central Committee of the Communist Party of China and State Council on Deepening Reform of Medical Security System Feb, 2020年

- Based on medical insurance payment, establish a provincial-level bidding procurement platform to integrate bidding, procurement, transaction, settlement and supervision, promoting the construction of a regional and national alliance procurement mechanism to form a fully competitive, pricing reasonable and regulated supply guarantee system. Deepen the reform of volume-based procurement system for medicine and medical consumables to establish a market-led price formation mechanism.

《国家医疗保障局关于国家组织冠脉支架集中带量采购和使用配套措施的意见》 Guidelines of National Medical Security Administration on Volume-Based Procurement of Coronary Stents Dec, 2020

- Combine the characteristic of the production, purchase, distribution and use of coronary stents and connect with existing medical insurance, medication prices and bidding and procurement policies. Make full use of supporting measures such as online registration platform, medical insurance fund prepayment, medical insurance payment and incentives and restrictions for medical institutions to promote the smooth implementation of volume-base procurement of coronary stents.
- The first nation-wide volume-based procurement of medical equipment.

Application of Two-Invoice System Can Shorten Medical Device Distribution

- Currently, the Two-Invoice system is mainly implemented in medication industry. In medical device industry, it has not been implemented nationally. Only some public hospitals in Anhui, Shanxi, Qinghai, Fujian, etc. have trial runs on expensive medical consumables. In the future, each province will promote Two-Invoice system based on government's guideline and its own unique circumstances.
- Before the application of Two-Invoice system, the marketing, hospital exploit and after-sales services for medical companies were mainly done by distributors. After the implementation, distribution companies only provide delivery services while marketing services need to be outsourced to third-party service organizations, which will increase the cost of sales of medical device companies.
- In summary, the implementation of Two-Invoice system will help reduce the distribution process of medicine, medical devices and other relevant products and standardize medicine and medical device market.

《印发关于在公立医疗机构药品采购中推行“两票制”的实施意见（试行）的通知》
"Notice the Implementation Opinions (Trial) on the Implementation of the
"Two Invoice System" in the Drug Purchase of Public Medical Institutions"
Jan, 2017

《关于巩固破除以药补医成果持续深化公立医院综合改革的通知》
Notice on Consolidating and Breaking the Achievements of Replenishing
Medicine with Medicines and Continuously Deepening the
Comprehensive Reform of Public Hospitals
Dec, 2016

Coverage

Two-Invoice system: A pharmaceutical manufacturing company issues only one invoice to a distribution company; the distribution company only issues one invoice to a medical institution.

Range: The Two-Invoice system is gradually implemented in the procurement of public medical institutions while other medical institutions are encouraged to adopt this policy in the procurement of medicines. Pilot provinces and public hospitals in reform pilot cities should take the lead in implementing the Two-Invoice system to encourage other regions.

Significance

- Deepen the reform of the medical and health system and promote the healthy development of pharmaceutical industry.
- Standardize the structure of medication distribution, reduce distribution process, and reduce falsely expensive medicine prices.
- Purify the distribution environment, prohibit payment-invoice laundering and strengthen the supervision and management of pharmaceutical market.
- Ensure the safety of medication for urban and rural residents and maintain people's health.

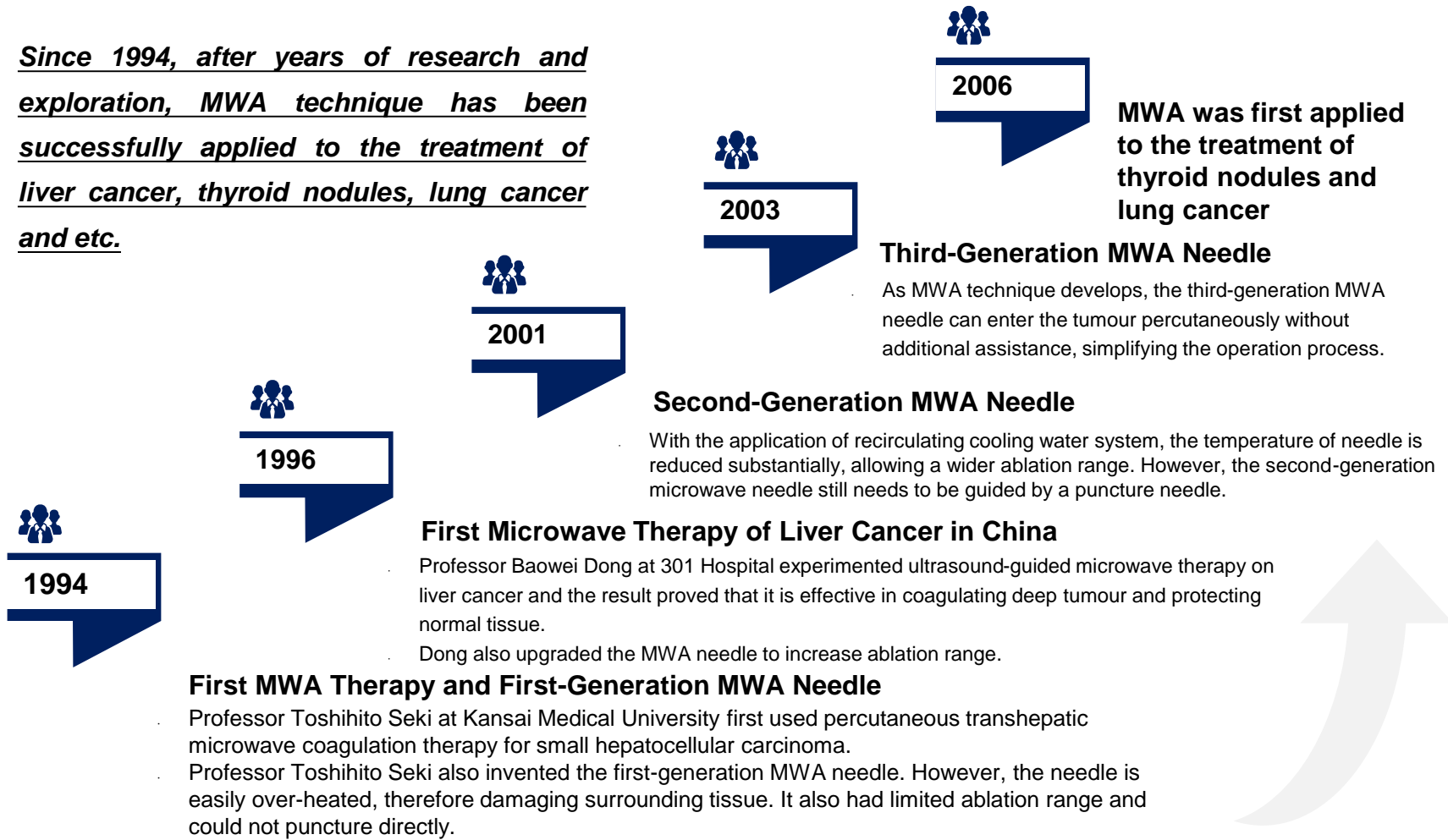
- **Price Reform:** For the same high-value consumables with similar prices and little difference in quantity, explore the implementation of packaged charges for medical services and set a unified medical service price.
- **Two Invoice System:** Implement volume-based procurement of high-value medical consumables and gradually implement the two invoice system for the purchase and sale of high-value consumables.

《安徽省食品药品监督管理局等五部门关于印发安徽省公立医疗机构医用耗材采购“两票制”实施意见（试行）的通知》
Guidelines of Five Departments including Anhui FDA on the Implementation
(Trial) of the "Two Invoice System" for Procurement of Medical Consumables
by Public Medical Institutions in Anhui
Nov, 2017

- **Two-Invoice System:** Since 2017/12/01, Two Invoice system for the procurement of medical consumables has been implemented in public medical institutions above secondary level in Anhui Province
- **Classification Range:** Ten categories of high-value consumables, including vascular intervention, non-vascular intervention, orthopedic implantation, neurosurgery, electrophysiology, pacemaker, extracorporeal distribution and blood purification. Ophthalmic materials, stomatology and other

History of China MWA Industry (1/2)

Since 1994, after years of research and exploration, MWA technique has been successfully applied to the treatment of liver cancer, thyroid nodules, lung cancer and etc.



History of China MWA Industry (2/2)

Since 2009, China's MWA technique has gradually been standardized and systematically developed.



2009

Develop Toward Standardization

- In June, the Ministry of Health released the first third-class medical technology catalogs that allowed clinical applications, including tumour ablation treatment techniques approved by provincial health administrative department.
- In November, the Ministry of Health issued the "Regulations for the Management of tumour Ablation Therapy Technique", marking China's tumour ablation therapy technique has entered a new stage of standardized and systematic development.



2010

Practice of MWA Technique

- In March, the Ministry of Health, together with Mei'en Biology and Fuzhong High-Tech Co.Ltd launched the "Clinical Research on Intratumour Immune Targeted Radiotherapy Combined with MWA Technique for the Treatment of Lung Cancer" in Shanghai on March 6, 2010. There were more than 110 participants including first-class hospitals with relevant qualifications.
- In September, Shanghai 10th People's Hospital successfully implemented the first MWA operation as a special research project of the Ministry of Health and ablated a tumour with a diameter of 6cm in just 8 minutes.
- In September, Chinese Medical Doctor Association Ultrasound Intervention and tumour Ablation Therapy Cooperative Committee was established in Shanghai.
- In November, China Cancer Minimally Invasive Therapy Technology Innovation Strategic Alliance was established in Beijing.



2011

Guidelines for Diagnosis and Treatment of Primary Liver Cancer (2011 Edition)

- The Ministry of Health organized experts to formulate the Guideline, stating that "MWA is a commonly used thermal ablation method in our country, which can inactivate tumours in one time.



2012

Organize tumour Ablation Training Programs

- Chinese Medical Association began to hold training programs on standardized treatment of liver tumours
- In August, the Chinese Medical Doctor Association launched the "National Training on the Application of Technical Specifications for tumour Ablation Therapy" project to conduct classified and staged training for clinical practitioners who have developed tumour ablation therapy technologies.



2019

The Medical and Hospital Administration of National Health Commission released **Guidelines for Diagnosis and Treatment of Primary Liver Cancer (2019 Edition)**

Trends of China MWA Market



Multi-Disciplinary Treatment

Open surgery, radiotherapy and chemotherapy all have their limitations in the treatment of malignant tumours, such as large incision, long recovery time, high cost and more complications. Multi-disciplinary treatment refers to a combination of two or more treatment methods, such as open surgery and ablation therapy. Studies have found that its outcome is better than a single surgery or ablation alone. In the future, multi-disciplinary treatment will have more and more applications in the treatment of tumours. MWA, as a widely used technique with satisfying outcome, is favored in the multi-disciplinary treatment.



MWA Intelligence

MWA therapy requires a doctor's operating proficiency and instrument mastery, as well as precise positioning during the operation. Therefore, the success rate depends on the doctor's operating experience. With the development of MWA intelligence, doctors can use robots and optical surgical navigation technology to accurately locate tumour lesion, improve surgical accuracy and reduce the dependence on personal experience. For example, certain companies are developing MWA operation robots, wireless remote-control MWA devices, and etc. Intelligence applications such as MWA robot systems are key research directions in the future. AI surgical robots can (i) improve surgical efficiency and reduce surgical risks through precise navigation and treatment; (ii) perform various tumour treatments and inspection operations; and (iii) provide digital platform for preoperative management and postoperative rehabilitation. The penetration rate of robot-assisted MWA procedures is estimated to reach 2.0% in 2026, and is expected to increase to 18.7% in 2030.



Market Penetration

Training programmes organised by Chinese Medical Association (CMA) and Chinese Medical Doctor Association (CMDA) only allow doctors in the relevant tumour diagnosis department of Grade II hospitals or above to participate. Some tertiary hospitals organise such training programmes as well. With the continuous development and widespread promotion of MWA technology, some lower-tier hospitals started to organise MWA training programmes as well. Through these training activities, MWA therapy will gradually become more popular in China and the application of MWA devices in lower-tier medical institutions will become more common.

Medical Insurance Coverage of MWA Will Gradually Expand in Various Regions

- Due to differences in the level of economic development, medical insurance policies and tumour prevalence in various regions, there are large differences in the cost, insurance coverage and reimbursement ratios of MWA therapy. Currently, MWA therapy has been included in medical insurance coverage in some areas, such as Shanghai, Fujian and Guangdong. In addition, the high cost of traditional surgery makes China's medical insurance burden heavy. The cost of ablation surgery, in contrast, is relatively low, which led it become a favorable treatment by Chinese government. In the foreseeable future, more and more regions in China will include MWA in their medical insurance.

Shanghai

In April 2021, Shanghai Healthcare Security Administration include RFA, MWA and CA therapy for tumour in medical insurance.

Treatment	Payment Category	Deductible
tumour Ablation Technique (CA)	Second (乙)	20%
tumour Ablation Technique (RFA, MWA)	First (甲)	/

In December 2020, Shanghai Healthcare Security Administration include tumour ablation (cryo and thermal) in medical insurance.

Treatment	Exclusion	Highest Fee
tumour Ablation Technique (Cryo and Thermal)	One-Time Cryoprobe	¥ 3,000 per time (Cancer Hospital Only)

Fujian Province

In April 2021, Fujian HealthCare Security Administration include RFA, MWA and CA treatment for tumour in medical insurance,

Treatment	Fee	Deductible
Percutaneous tumour Ablation (RFA, MWA, CA)	If fee of ablation kit does not exceed ¥ 8000, operation fee is ¥ 3,600-4,000.	20%
	If fee of ablation kit exceed ¥ 8000, operation fee is only 50%, around ¥ 1,800-2,000.	/

Guangdong Province

Medical Insurance in Guangzhou covers ablation therapy. The reimbursement rates differ in diseases. For example, the reimbursement for liver cancer ablation is between ¥ 25,000 to 36,000, for lung cancer is around ¥ 20,000,

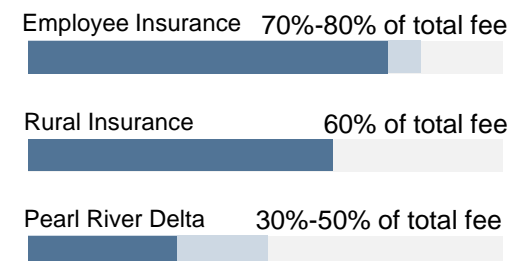


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- 2 Analysis of Related Disease Market
- 3 Analysis of Tumour Ablation Therapy Market in China
- 4 Competitive Analysis of Microwave Ablation Market in China**

Competitive Analysis

- MWA medical devices industry in China is featured with high market concentration with top 4 manufacturers accounting for about 90.6% in 2021 in terms of sales revenue of MWA medical devices and our Group ranks the third in the MWA medical device market in the PRC in terms of sales revenue in 2021. The following table sets forth the ranking of top 4 MWA players in China market and their respective market shares in terms of sales revenue of MWA medical devices:

TOP Four Manufacturers in China's MWA Market, 2021

Ranking	Domestic Companies	Nature of the Company	Sales revenue of MWA medical devices(RMB Million)	Market share by sales revenue of MWA medical devices (%)
1	Company A	PRC	344.9	36.9%
2	Company B	PRC	213.2	22.8%
3	Our Group	PRC	157.2	16.8%
4	Company C	PRC	131.2	14.0%
Ranking	Overseas Companies	Nature of the Company	Sales revenue of MWA medical devices(RMB Million)	Market share by sales revenue of MWA medical devices (%)
6	Company D	Foreign	26.8	2.9%

Competitive Analysis

- At present, MWA is developing rapidly in the field of treatment of thyroid nodules. It has the advantages of short operation time, small incision, quick recovery, no effect on appearance, and low complication rate. Better Medical ranks the first in the MWA market in terms of sales revenue and sales volume of MWA needles for the treatment of thyroid nodules and breast lumps in China in 2021 with a market share of 39.9% and 45.4% respectively.

Top 4 Players in China's MWA Market for MWA needles for the treatment of thyroid nodules and breast lumps, 2021

Ranking	Name	Sales Revenue of MWA needles for the treatment of thyroid nodules and breast lumps (Unit: million)	Market share by sales revenue (%)
1	Our Group	101.8	39.9%
2	Company A	90.9	35.6%
3	Company C	35.9	14.1%
4	Company B	24.3	9.5%

Ranking	Name	Sales Volume of MWA needles for the treatment of thyroid nodules and breast lumps (Unit:thousand)	Market share by sales volume (%)
1	Our Group	30.7	45.4%
2	Company C	18.5	27.4%
3	Company A	14.0	20.7%
4	Company B	3.8	5.6%

Competitive Analysis

- Company A is a non-listed company headquartered in Nanjing with RMB86 million registered capital, which was established in 2000, Company A is a leading manufacturer of medical devices in China, which covers microwave, high frequency and laser ablation systems with approximately 600 employees. The products are positioned at mid to high-end which are sold to domestic and overseas markets.
- Company B is a non-listed entity headquartered in Nanjing with RMB50,000 registered capital, which was established in 1988. Company B offers products including disposable water-cooled MWA needles and MWA therapeutic apparatus and has established in-depth cooperation with more than 100 hospitals in China in the field of MWA. Company B has approximately 80 employees.
- Company C is headquartered in Nanjing and was established in 1994 and has focused on the R&D, production, and sales of microwave medical devices with approximately 400 employees. Company C is a wholly-owned subsidiary of a company listed on the Shanghai Stock Exchange with market capitalisation of over RMB14 billion.
- Company D was established in 1949, headquartered in Minneapolis, Minnesota in the U.S., and is a global medical technology company dedicated to providing lifelong treatment solutions for patients with chronic diseases. Company D was listed on the NASDAQ and the NYSE with market capitalisation of over US\$120 billion. Company D has approximately 90,000 employees globally. Main products cover arrhythmia, heart failure, vascular disease, heart valve replacement, external cardiac support, minimally invasive cardiac surgery, malignant and non-malignant pain, diabetes, gastrointestinal diseases and other diseases.

Enter Barriers of MWA Medical Device Market in the PRC

- MWA medical devices market in China has high entry barriers due to its high standard in R&D and technical innovation, substantial investment cost and long commercialization process. The demand for effective branding and resourceful sales channels also creates barriers for new entrants in the market.

R&D and technical barriers

R&D professionals and mature core technology build a high entry barrier for MWA medical devices market in China. The R&D process of MWA medical devices often requires the cooperation between enterprises, universities, research institutions and hospitals. Currently, MWA medical device enterprises have relatively mature technology and have specialised technological advantages. It is a complicated, difficult and time-consuming process for new entrants to break through the technical barriers or to develop new competitive technologies.

Long commercialisation process

The commercialisation of Class II and Class III medical devices is a long and investment-intensive process. Since medical devices are closely related to people's safety such as MWA medical devices, the Chinese government has developed strict regulations in product registration, production licensing, and the filing of medical devices, which make the commercialisation process more time-consuming.

Branding and sales channel barriers

Hospitals are more likely to purchase devices from a MWA medical device manufacturer that has developed good reputation in the industry, which makes the branding of the company crucial. Existing MWA medical device manufacturers sell products to Grade II and Grade III hospitals in China through direct sales and re-selling model, and their products have accumulated a good reputation. As for new entrants, in addition to competitive technology, they also need more resourceful sales channels to expand the market.

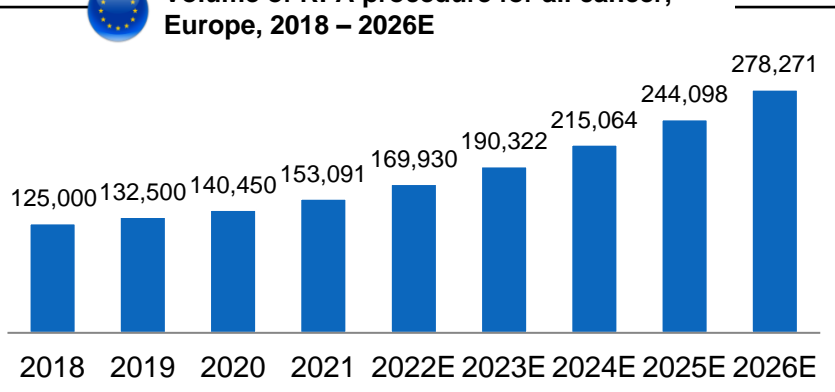
Analysis of Overseas MWA Market

Market Size of Ablation Procedure Market - Europe

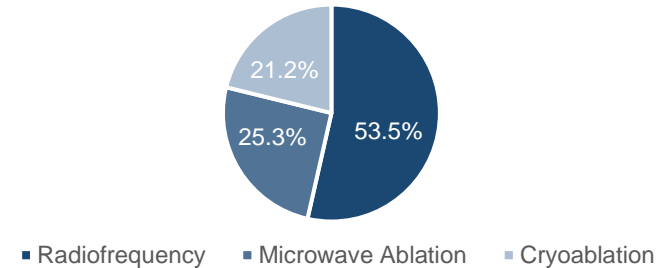
- In 2021, the European radiofrequency ablation market had the highest volume, expected to be around 153,091 at a CAGR of 7.0%, accounting for 53.5% of the total ablation market, followed by Microwave ablation and cryoablation.



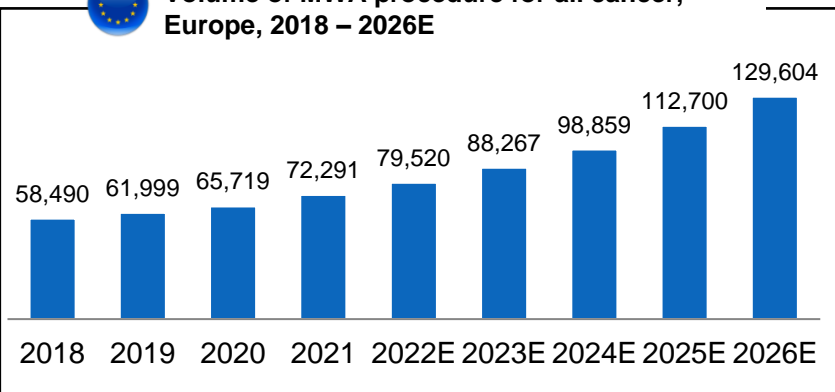
Volume of RFA procedure for all cancer, Europe, 2018 – 2026E



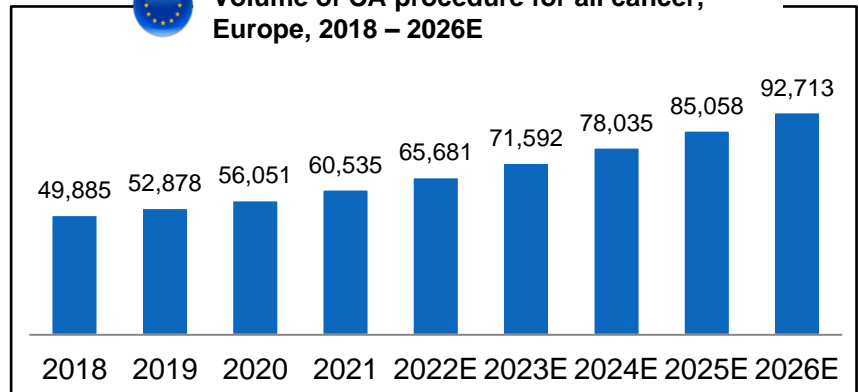
Ablation procedure volume split for all cancer, Europe, 2021



Volume of MWA procedure for all cancer, Europe, 2018 – 2026E

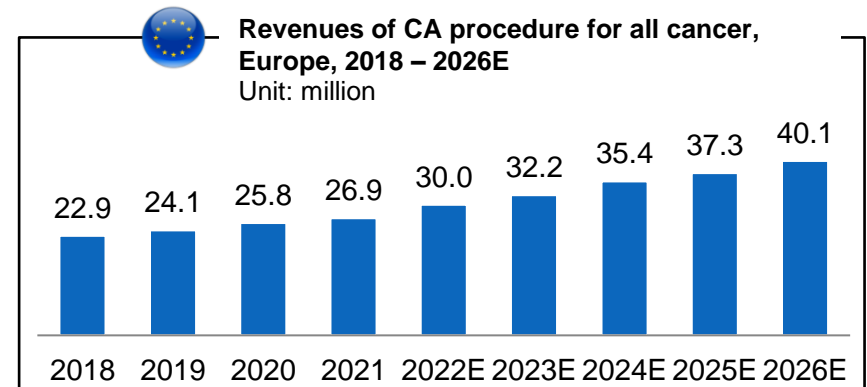
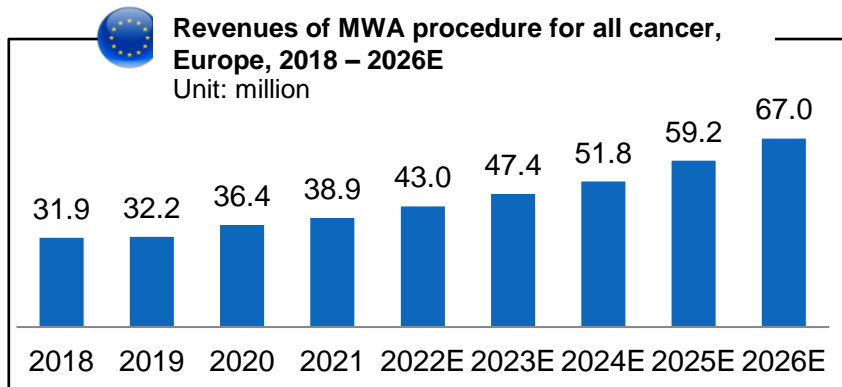
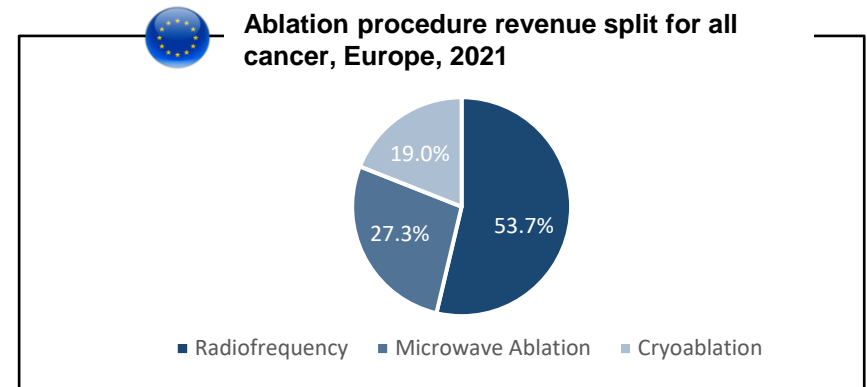
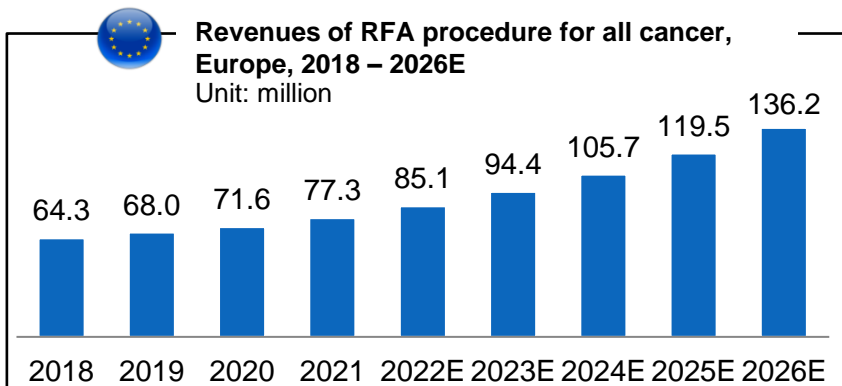


Volume of CA procedure for all cancer, Europe, 2018 – 2026E



Market Size of Ablation Procedure Market - Europe

- From the perspective of revenue, in 2021, the European radiofrequency ablation market also had the highest revenue of the total ablation market, and cryoablation was the least.
- European ablation market will keep on growing with the driven factors as follow: growth in demand for minimally invasive cancer procedures; Increasing prevalence of cancer; New expansion technological advancement; Expanding number of hospitals, surgical and ablation centers; Increasing awareness about tumor ablation methods over traditional treatments and surgical methods.

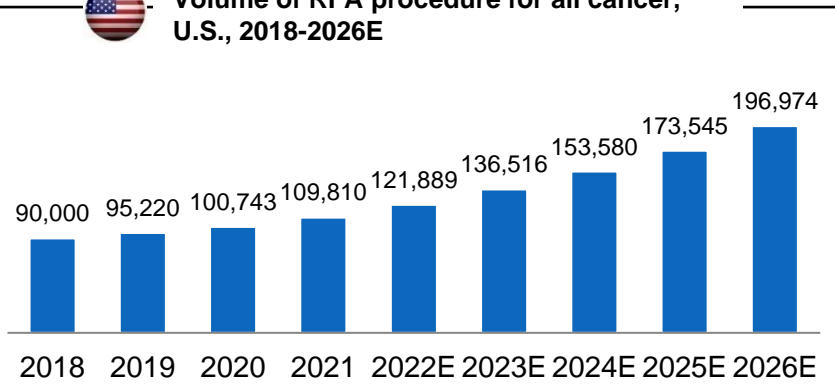


Market Size of Ablation Procedure Market – U.S.

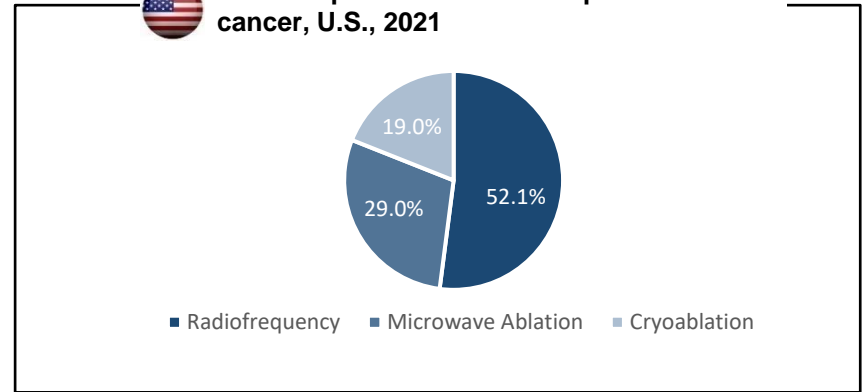
- In 2021, the radiofrequency ablation market had the highest volume of the total U.S. ablation market, reaching by 109,810, with CAGR 6.9%.



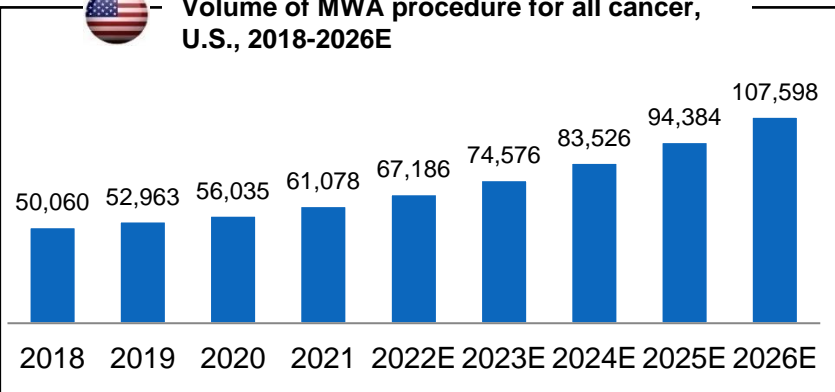
Volume of RFA procedure for all cancer, U.S., 2018-2026E



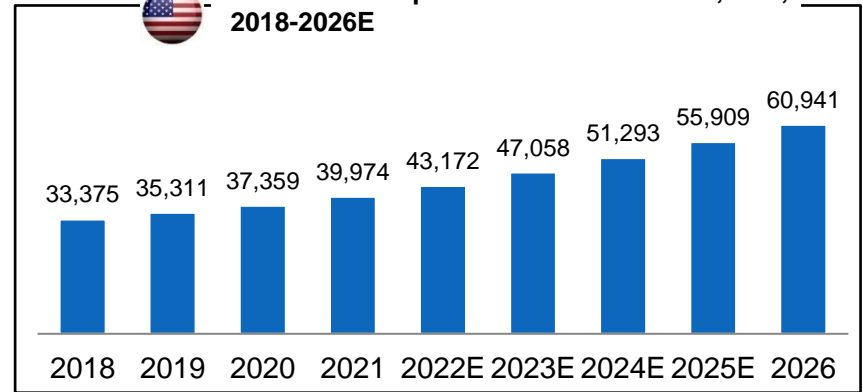
Ablation procedure volume split for all cancer, U.S., 2021



Volume of MWA procedure for all cancer, U.S., 2018-2026E



Volume of CA procedure for all cancer, U.S., 2018-2026E

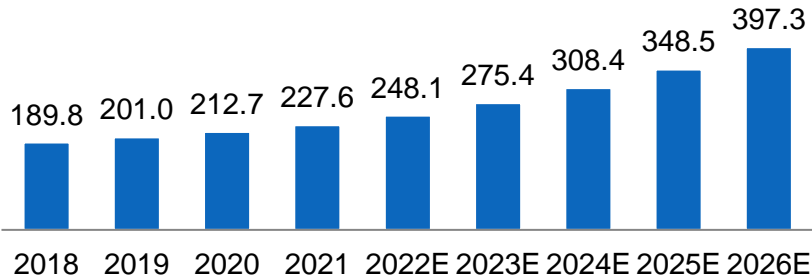


Market Size of Ablation Procedure Market – U.S.

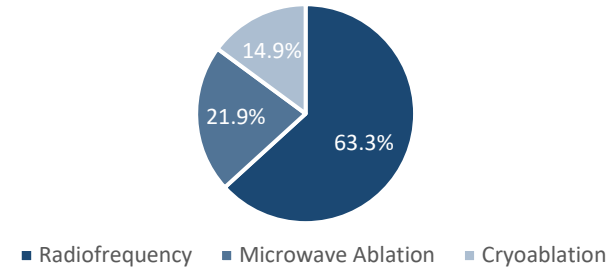
- From the perspective of revenue, in 2021, the radiofrequency ablation market also had the highest revenue, accounting for 63.3% of the total ablation market.
- The United States market accounts for major contribution of global ablation market. High disposable income and various reimbursement policies in the country will enable patients to opt for ablation procedures. Furthermore, growing influence for minimally invasive medical devices will aid the market size expansion. Moreover, rising prevalence of cancer will foster the regional market demand. Pertaining to the adoption rate, the market for ablation products is likely to grow exponentially in forthcoming years.



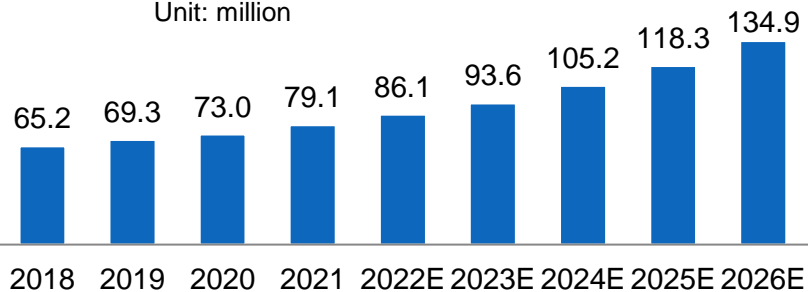
Revenues of RFA procedure for all cancer, U.S., 2018 – 2026E
Unit: million



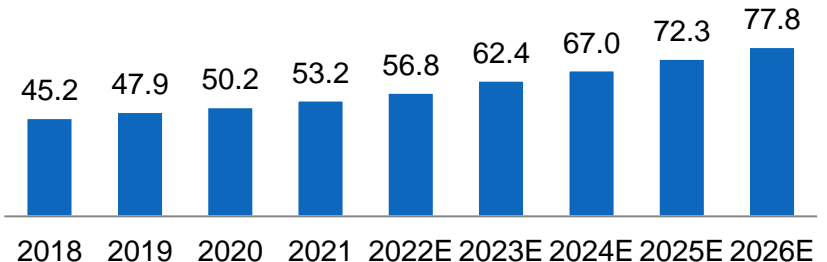
Ablation procedure revenue split for all cancer, U.S., 2021



Revenues of MWA procedure for all cancer, U.S., 2018 – 2026E
Unit: million



Revenues of CA procedure for all cancer, U.S., 2018 – 2026E
Unit: million



Comparison between overseas tumour ablation therapy market and the tumour ablation therapy market in China (1/2)

- MWA was the largest sector of tumour ablation therapy market in China in 2021, contributing to 57.0% of the overall tumour ablation therapy market, followed by RFA which contributed to 22.0% of the overall tumour ablation therapy market.
- RFA was the largest sector of tumour ablation therapy market in the U.S. and Europe in 2021, contributing to 63.3% and 53.7% of the overall tumour ablation therapy market, respectively; followed by MWA which contributed to 21.9% and 27.3% of the overall tumour ablation therapy market in the U.S. and Europe, respectively.
- MWA has the largest market share of tumour ablation therapy market in China mainly because, after years of research and exploration of MWA by Chinese scholars, MWA technology has developed rapidly in the PRC. Comparing to RFA, MWA generally has a shorter operation time and it can simultaneously treat multiple lesions. According to “Radiofrequency ablation versus microwave ablation for early stage hepatocellular carcinoma: A PRISMA-compliant systematic review and meta-analysis” published in *Medicine* in 2020, the median ablation time was shorter in the MWA group (12 minutes) compared with the RFA group (29 minutes). In addition, research has shown that MWA treatment has similar safety and efficacy as compared to RFA(1). The indications of MWA therapy in the PRC market have gradually expanded from liver tumour to other indications (such as thyroid nodules, breast lumps, pulmonary nodules, varicose vein, bone tumours, uterine fibroid, prostate cancer), which leads to the rise in market share of MWA therapy in the PRC. Another reason for the rise in market share of MWA therapy in the PRC is that the MWA medical device manufacturers have put considerable effort in promoting MWA products in the past years through academic conferences, and conducting surgical training for medical practitioners to popularise MWA therapy in the PRC. On the other hand, the product promotion of RFA medical device manufacturers in the PRC is not as strong as that of MWA medical device manufacturers.

Comparison between overseas tumour ablation therapy market and the tumour ablation therapy market in China (2/2)

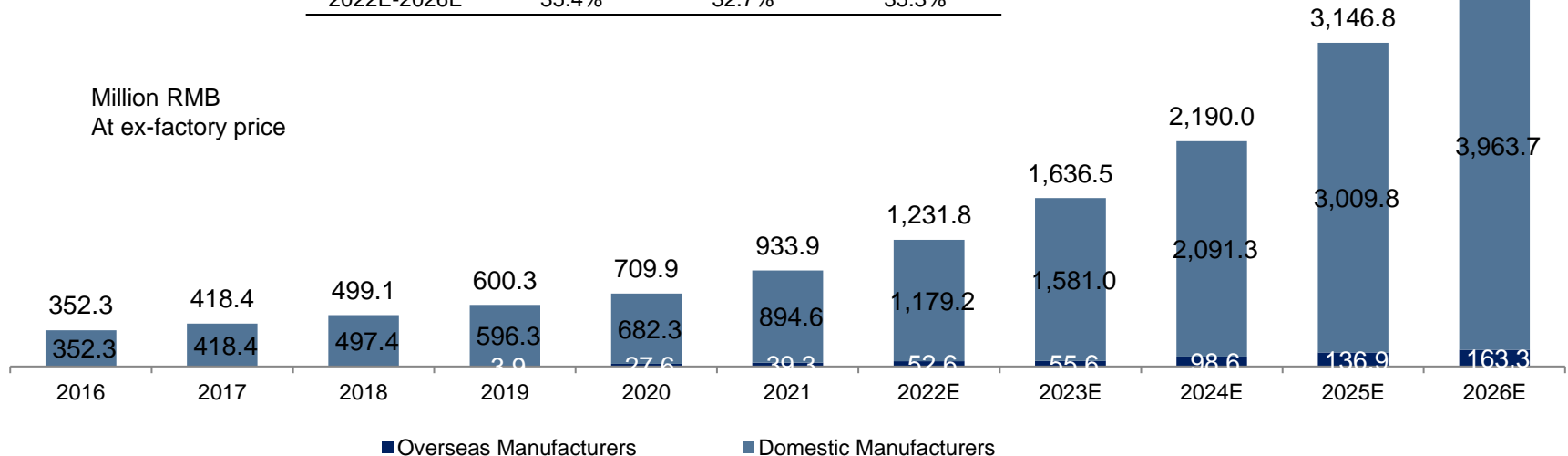
- RFA is the most widely adopted thermal ablation treatment which has the largest market share of tumour ablation therapy market in the U.S. and Europe mainly because (i) the study on application of RFA technology in the U.S. and Europe has a longer history as compared to MWA and earlier research has shown that RFA is a safer tumour ablation treatment with lower complication rate than MWA; and (ii) RFA has a proven record of satisfactory therapeutic effect in tumour ablation due to its features safety and low complication rate. Thus, RFA has become a more established and recognised treatment modality in the U.S. and Europe. Meanwhile, MWA has a relatively short application history in the U.S. and Europe with less research and clinical data, and has been primarily used in the treatment of liver cancer and lung cancer only. In addition, MWA has not been promoted strongly in the U.S. and European markets. Moreover, MWA treatment may cause over-ablation when coagulate the tumour tissue due to the production and transmission of intense heat. Therefore, some MWA medical devices nowadays are equipped with a cooling system where cooling saline runs through the MWA needles except its tip which has direct contact with the tumour. The circulation of cooling saline can prevent or reduce damage to other parts of the patient's body. While recent research has shown that MWA treatment can achieve similar therapeutic effect(1), due to user stickiness, medical practitioners in the U.S. and Europe who generally have more clinical experience in performing RFA therapy still tend to advise their patients to receive treatment options that they are more familiar with to reduce the risk of error in operation. Hence, the market share of MWA was relatively smaller than that of RFA in the U.S. and Europe from 2018 to 2021.

Supplementary for Verification

- MWA needles are one category of high-value medical consumables which are sold at high prices. In addition, the direct sales model of MWA medical devices industry in China is more profitable for manufacturers.
- The market players of MWA medical devices industry in China include both local companies and overseas companies. The following chart sets forth the historical and forecast industry revenue split between domestic and overseas market players. Compared with domestic manufacturers, the foreign manufacturers, Medtronic and Johnson & Johnson, entered the market late. Medtronic launched its MWA products in 2018 and Johnson & Johnson entered the market in 2020. In addition, the prices of their MWA needles are higher than the prices of domestic products.

Market Size of MWA Market, China, 2016-2026E

Period	CAGR		Total
	Domestic Manufacturers	Overseas Manufacturers	
2016-2021	20.5%	/	21.5%
2022E-2026E	35.4%	32.7%	35.3%



Source: Expert interviews, Frost & Sullivan analysis

Supplementary for Verification

- Varicose veins are the most common disease of the venous system. Varicose veins develop gradually in the early stage, and symptoms such as sinking, soreness, fatigue, and swelling of the superficial veins of the calf will appear. High-risk groups are teachers, surgeons, nurses, hairstylists, counter ladies, chefs, restaurant waiters, and other occupations that need to stand for a long time.
- The cancer progression rate among persons with pulmonary nodules, thyroid nodules and breast lumps are 5.5%, 5.0% and 7.0%, respectively.
- It takes generally 24–36 months for Class II medical devices and 48–60 months for Class III medical devices to complete the R&D process.
- The national medical insurance programme in China would generally reimburse patients for a higher percentage of the product cost if they use a medical device manufactured by a Chinese domestic company as opposed to an imported device.
- Hospitals in China which have procured the Group's MWA medical devices during the Track record period have all resumed full services.
- Company elected not to maintain certain types of insurances, such as litigation insurance and business interruption insurance. This practice is in line with the industry practice in the PRC.
- The MWA medical device industry in the PRC is litigious with respect to patents and other intellectual property. Companies operating in our industry routinely seek patent protection for their product designs, and many principal competitors have large patent portfolios.
- The “two-invoice system” refers to the system that requires one invoice to be issued from pharmaceutical manufacturers to pharmaceutical distributions companies and the other invoice to be issued from pharmaceutical distributions companies to medical institutions. As at the Latest Practicable Date, the “two-invoice system” is mainly applicable to the fields of high value medical consumables in most provinces in China. Qinghai Province and Shaanxi Province have formulated rules and regulations to implement the “two-invoice system” in the field of all medical consumables.
- In recent years, NMPA has adopted policy measures to promote innovation and development to optimise the review and approval of medical devices, improve work quality and efficiency and promote industrial innovation and advancement. In November 2018, NMPA published “Special Examination and Approval Procedures for Innovative Medical Products” 《創新醫療器械特別審查程序》 to grant priority to eligible innovative medical devices and encourage research and innovation of medical devices. In March 2020, the State Council published “Regulation on Supervision and Administration of Medical Devices” (《醫療器械監督管理條例》) to strengthen the supervision of development, production, management and application of medical devices in the PRC, and optimise the examination and review procedures for approval. In March 2020, NMPA and the Standardisation Administration of the PRC issued the “Opinions on Further Promoting the High-quality Development of Standardisation of Medical Devices” (關於進一步促進醫療器械標準化工作高質量發展的意見), stating that by 2025, an advanced standard system of medical device that is in line with international standards will play the leading role for the nation in the transition from a big manufacturer of medical device to a powerful one. These policies will propel the innovation and R&D of the MWA industry as well as provide a healthy environment for market growth.

Supplementary for Verification

- MWA is a minimally invasive treatment technique that denaturises and coagulates the protein of tumour cells with extreme heat generated by microwave energy. There are a total of [ten hospitals](#) in Guangdong Province that are listed as the top 100 hospitals in 2020 in the PRC issued by the Hospital Management Institute of Fudan University* (復旦大學醫院管理研究所).
- Better is the first company to have its proprietary MWA medical devices specifically indicated for thyroid nodules completed the relevant clinical trials in China and undergoing final approval by NMPA for Class III registration certificate for MWA medical devices.
- Conventional tumour treatments such as open surgery, chemotherapy and radiation therapy are relatively expensive, posing heavy burden medical insurance. Comparatively, MWA treatment has satisfactory clinical outcome with relatively low fees. Meanwhile, the MWA treatments can curb benign tumour from developing to malignant tumour. As large malignant tumour generally requires major surgery and incurs higher medical expenses, early MWA treatment of tumours can decrease medical expenses reimbursement by private insurance companies and government medical expenditure by reducing the number of patients having the need to undergo major and expensive surgery.
- MWA medical devices are currently covered by the national medical insurance in Guangdong Province and the reimbursement rate is up to 80% of the total fee for employee insurance and up to 60% of the total fee for rural insurance, which can further decrease the payers medical expenses reimbursement. It is expected that an increasing number of regions in China will include MWA in their medical insurance.
- Laser ablation has been used in clinical practice for several decades, but it has not been widely used in tumour therapy due to the lack of non-invasive temperature monitoring mechanism and accurate and effective heating method in the early stage. In recent years, with the development of fiber beam and the transformation of laser, laser ablation technology has been rapidly developed in the field of tumour treatment. Laser ablation can treat a number of brain lesions, including epilepsy, radiation necrosis, intractable brain edema, and tumours such as meningioma, ependymoma, primordial neuroectodermal tumours, chordoma, and hemangioblastoma. Compared with other stereotactic procedures, such as RFA, gamma knife, and focused ultrasound, laser ablation can achieve low-risk invasive damage of soft tissue lesions, with precise and controllable ablation range, small error, and almost no damage to normal structures surrounding the lesions. In the field of brain cancer, prostate cancer and other indications with high sensitivity to treatment accuracy, laser ablation is expected to gain a broader market growth. The incidence rates of cancers including prostate cancer and brain cancer have been increasing in recent years, and it is estimated that the number of new cases of brain cancer and prostate cancer will reach 128,300 and 129,100 respectively by 2025. For tumour treatment in the brain and prostate, precise control of the size and location of the lesion is required. The application of laser ablation is advantageous as the shape and size of the ablation lesions can be adjusted by the combination of multiple optical fibers. Compared with other ablation procedures, laser ablation has the advantages of precise and controllable ablation range, little error, and almost no damage to the structure surrounding the lesion. Therefore, we are of the view that there is a broad market for laser ablation products for prostate cancer and brain cancer;
- Intelligence applications such as MWA robot systems are key research directions in the future.

Supplementary for Verification

- As a hospital needs to procure a wide range of medical devices to provide comprehensive treatment options to all sorts of patients, some hospitals may prefer to procure from a deliverer who is able to provide various product mix selection instead of engaging separate medical device and pharmaceutical manufacturers for each medical device and/or pharmaceutical product for simple administration during their procurement process.
- Given (i) the advantages to hospitals and manufacturers by adopting the deliverer model; and (ii) a number of players in the medical devices industry have adopted the deliverer model in the PRC, Frost & Sullivan is of the view that sales through deliverers is an industry norm.
- Selling products to distributors is in line with the industry practice in China.
- Frost & Sullivan is of the view that the transactions with the overlapping deliverers/distributors and marketing services providers within the medical device industry are in line with the industry norms.
- Overlapping of customer and supplier is a common phenomenon in the medical device industry in the PRC.
- The credit period of public hospitals are normally longer, as the internal procedures of public hospitals regarding decision making and approval, and reconciliation and settlement typically take a longer period of time and thus would affect the collection of trade receivables of deliverers from hospitals and in turn affect the Group's collection of trade receivables from their deliverers.
- It is an industry norm for certain distributors/deliverers not to enter into framework agreement taking into account their scale of operation and their own business practices.
- It is common in the medical device industry in the PRC for medical device manufacturers or its marketing service providers to collaborate with KOLs without remuneration.
- Distributors/deliverers in China sometimes play multiple roles in the medical device industry, for example, medical device companies affiliated to Jointown Pharmaceutical Group (600998.SH), Sinopharm Group (01099.HK) and Baheal Medical Inc. (301015.SZ) not only provide wholesale distribution services for manufacturers as distributors/deliverers, but also provide marketing services for pharmaceutical/medical device manufacturers. These distributors/deliverers engage in multiple business in the medical device industry, as those businesses are likely to have synergy effect when carried out together due to their business nature. The distributors/deliverers could accumulate knowledge, network and experience in the medical device industry through both streams of business, which can have positive effect to the other businesses. On the other hand, medical device manufacturers in China sometimes engage distributors/deliverers as marketing services providers since the medical device manufacturers can take advantage of their network and experience in the medical device industry to promote the technologies and/or the products of the medical device manufacturers, while better allocating its internal resources in other areas, such as R&D and production. Based on the above, Frost & Sullivan is of the view that the transactions with the overlapping deliverers/distributors and marketing services providers within the medical device industry are in line with the industry norms.

Supplementary for Verification

According to Frost & Sullivan, there will be sufficient and sustainable demand for the Group's products due to the following reasons:

- (1) The cost of surgical treatment of tumour is high, which results in increasing pressure on medical insurance payment. By comparison, minimally invasive surgery costs less and can effectively reduce the pressure of medical insurance payment. Therefore, the government is more inclined to support minimally invasive treatments such as MWA;
- (2) From the perspective of patients, the number of patients with liver cancer, lung cancer, breast nodules, thyroid nodules and other tumours have shown an increasing trend, which represents the potential population size of MWA therapy keeps expanding. At the same time, compared with surgical surgery, MWA has the advantages of being minimally invasive, rapid recovery, fewer complications, and low treatment cost, which can reduce the financial pressure of patients. Therefore, as the number of patients who can receive MWA treatments increases, more patients will be willing to receive MWA treatments; and
- (3) MWA manufacturers, together with relevant associations, promote MWA devices to doctors in different hospitals and cities, which will propel the rising applications of MWA devices in various departments in hospitals.
- The key competing products of the Group's MWA needles for treatment of thyroid nodules and breast lump are manufactured by Nanjing ECO Microwave System Co., Ltd. (南京億高微波系統工程有限公司) ("ECO Medical"), the Group, Nanjing Viking Jiuzhou Medical Device R&D Center* (南京維京九洲醫療器械研發中心) ("Vison Medical") and Canyon Medical Technology Co., Ltd. (南京康友醫療科技有限公司) ("Canyon Medical"). Compared with those competitors, the Group is a pioneer in the MWA medical device market for treatment of thyroid nodules as it is the first company to have its proprietary MWA medical devices specifically indicated for thyroid nodules completed clinical trials in China and undergoing final approval by NMPA for Class III registration certificate for MWA medical devices. The Group ranked first among MWA medical device providers in the treatment for thyroid nodules and breast lumps in the PRC in terms of sales revenue in 2020. The Group has also established a stable relationship and close contact with hospitals and doctors which allows the Group to obtain feedback from doctors, upgrade its existing product offering and form new strategies to adjust to market demands.
- Canyon Medical is indicated as Company C among the top players in China's MWA market as disclosed on page 103-b of the Prospectus. As advised by Frost & Sullivan, it is the only domestic market player operating under a listed group among the top four market players.

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- The deliverer model is and will be adopted by an increasing number of medical device manufacturers, along with the traditional distributorship model.
- The listed market players in the medical device industry that adopt or will adopt the deliverer model and their major business.
- The rise of the deliverer model is mainly due to the implementation of the two-invoice system policy. As advised by Frost & Sullivan, in view of the implementation of the two-invoice system in the abovementioned provinces, the medical device manufacturers began to explore alternative sales model to take up the functions originally entrusted to the multiple layers of distributors, by taking up some functions themselves and/or engaging deliverers to take up the delivery function and marketing service providers to take up some of the marketing functions in promoting the medical devices or the underlying technology.
- The deliverer model has been adopted in the medical industry in China for more than 10 years. The deliverers could serve more than hundreds of medical device or pharmaceutical manufacturers at the same time, and bear customer default risks for each manufacturer. Therefore, deliverers bearing the customer default risks for the medical device or pharmaceutical manufacturers is a generally accepted and common feature under the deliverer model in the pharmaceutical and medical device industry in the PRC.
- Delivers bearing the customer default risks for the medical device or pharmaceutical manufacturers is a generally accepted and common feature under the sales through deliverer model in the pharmaceutical and medical device industry in the PRC.
- It is an industry norm for medical device manufacturers to set different prices for the same product sold to different distributors, depending on their abilities and the ancillary services they are expected or required to provide.
- IP co-ownership arrangement is also adopted by other medical device companies in the PRC (and by other MWA medical device manufacturers).
- Clinical evaluation on medical devices of the same type is a process of evaluating a medical device by comparing it with the existing clinical data of a Class III medical device of the same type, and it can be used to upgrade the registration of an existing Class II medical device to a Class III medical device. As clinical evaluation on medical devices of the same type will not involve clinical trial on human subjects, such process takes significantly less time and cost than the normal registration process of Class III medical devices.
- Based on the latest information available, other than some of the Group's competitors which have already obtained Class III registration certificates for their MWA therapeutic apparatus and MWA needles specifically indicated for liver cancer, none of the competitors of the Group have obtained Class III registration certificates for their MWA needles specifically indicated for thyroid nodules or other diseases which the Group has planned to expand its indication on its Class III medical registration certificate (including breast lumps, lung cancer, varicose vein, bone tumours and uterine fibroid). Accordingly, it is submitted that no competitive disadvantages would be posed to the Group.

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- Compared with other ablation methods, MWA has shorter operation time, less bleeding risk and less sensitivity to thermal deposition. In order to further reduce the influence of “thermal deposition effect” on ablation, the technology of microbubble ultrasonic cavitation to enhance the effect of MWA has been applied in early clinical studies. Studies have shown that ultrasound cavitation technology can effectively reduce the impact of thermal precipitation. We believe that acquiring or investing in relevant companies would enable us to combine ultrasound cavitation with MWA technology to improve the treatment effect of our MWA products; and companies that focus on the development of AI and are in possession of the relevant products and technologies which potentially enable us to develop AI robotic surgery assistance which provides precision in the MWA or other ablation clinical application. We consider that the high technical level and experience required from doctors hinder the popularisation of MWA products. AI surgical robots can (i) improve surgical efficiency and reduce surgical risks through precise navigation and treatment; (ii) perform various tumour treatments and inspection operations; and (iii) provide digital platform for preoperative management and postoperative rehabilitation. Therefore, we believe that the development and deployment of AI technology in the field of MWA will become the key breakthrough for us to improve our market competitiveness.
- During the Track Record Period, our sales volume in the first half of a year was generally lower than the sales volume in the second half of a year as our customers tend to procure more of our products in the second half of a year, which is common for MWA medical device manufacturers in the PRC.
- As the deliverers perform centralisation of the delivery arrangement between the hospital and various medical device and pharmaceutical manufacturers, delivery costs can also be reduced accordingly.
- It takes generally 48 to 60 months for Class III medical devices to complete the R&D process.

Supplementary for Verification

The following table sets out the efficacy data of the major tumour ablation therapies when they are applied to the treatment of liver cancer and thyroid nodule, respectively.

	MWA	RFA	CRA	LSA
Liver cancer	For tumours <3 cm in diameter: 5-year LTP: 8.3%, 5-year DFS: 12%; Complete ablation rate for tumors: 98.3%;	For tumours <3 cm in diameter: 5-year LTP: 21.2%, 5-year DFS: 19%; Complete ablation rate for tumors: 98.1%;	For tumours ≤4 cm in diameter: 3-year LTP: 7%; Complete ablation rate for tumors: 97.4%;	For tumours <3 cm in diameter: 1-year LTP (8.5% for patients in percutaneous ultrasonography guided laser ablation group; 15.0% for patients in endoscopic ultrasonography-guided laser ablation group); Complete ablation rate for tumors: 89.0%;
Thyroid Nodule	VRR of nodule: 1st month: 15.3%; 3rd month: 47.9%; 6th month: 67.8%; 12th month: 79.3%; 18th month: 91.7%	VRR of nodule: 1st month: 15.4%; 3rd month: 48.2%; 6th month: 68.1%; 12th month: 80.1%; 18th month: 89.2%	N/A	VRR of nodule: 91.7%*

Notes:

(1) LTP: local tumour progression; DFS: disease-free survival; VRR: volume reduction ratio; Complete ablation rate: percentage of the patient population whose tumour is completely eradicated after the ablation therapy.

(2) The different years of LTP are presented based on the best available information that can be obtained from the independent study of such ablation method.

(3) The LTP data are based on the best available information that can be obtained for each ablation method and no available information of DFS for CRA and LSA can be obtained.

* An independent study without comparison with other ablation methods