

INDUSTRY OVERVIEW

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OVERVIEW OF THE METABOLIC DISEASES

Metabolic diseases are a group of disorders in which the body’s normal mechanisms for converting food into energy and key nutrients at the cellular level are disrupted. When these pathways malfunction, cells cannot properly process or transport proteins, carbohydrates and lipids, leading to widespread biochemical imbalance. Clinically, this underlies major conditions such as obesity and overweight, MASH and T2DM.

Taken together, metabolic diseases have become one of the heaviest burdens on global healthcare systems. In 2021, diabetes alone was responsible for about 6.7 million deaths worldwide and 1.4 million deaths in China, with related medical expenditures reaching approximately US\$966 billion and US\$165 billion, respectively. Obesity and overweight, which are key drivers of diabetes and cardiovascular disease, affected around 3.1 billion people worldwide in 2020 and were associated with an estimated US\$2.0 trillion in healthcare costs. In China, the number of people with obesity or overweight rose rapidly from 570.7 million in 2020 to 655.4 million in 2025, and direct medical spending linked to these conditions was about RMB200 billion in 2021. MASH, which is closely intertwined with both diabetes and obesity/overweight, can progress to liver failure and hepatocellular carcinoma, further escalating costs. In the United States, the lifetime care cost for all MASH patients was estimated at US\$250.6 billion in 2023, while in China, MASH-related deaths are projected to increase from 25,580 in 2016 to 55,740 by 2030.

Most metabolic diseases currently lack curative therapies, and existing interventions mainly aim to control disease progression and alleviate symptoms. This is largely because metabolic disorders are highly complex, typically accompanied by multiple comorbidities and intertwined pathogenic pathways that demand an integrated management strategy. Many available treatments are designed to act on a single metabolic condition rather than the broader constellation of health problems experienced by patients. While some drug candidates can provide meaningful symptom relief, they may also be associated with significant long-term adverse effects, which further complicate the overall management of metabolic diseases.

OVERVIEW OF WEIGHT-LOSS MEDICAL DEVICE

The global obesity epidemic has catalyzed the emergence of a diverse spectrum of weight-loss medical devices, which complement or substitute traditional pharmacologic and surgical interventions. These devices aim to address the growing global burden of obesity and metabolic diseases by providing mechanical, physiological, or neurohormonal modulation to achieve sustainable weight loss and metabolic improvement.

Among these, endoscopic bariatric and metabolic therapies (EBMTs) represent an active area of research and development. Utilizing a fully incisionless, transoral approach, EBMTs bridge the therapeutic gap between pharmacotherapy and surgery. They offer a balance of clinical efficacy, reversibility, safety, and cost-effectiveness, making them particularly appealing for patients seeking minimally invasive yet durable

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outcomes. Clinical trials show that these therapies induce approximately 10 to 20% total body weight loss and one to two percentage-point reductions in HbA1c, while doing so through a single, incisionless gastrointestinal intervention that reshapes gastric capacity and nutrient flow without chronic systemic drug exposure, allowing rapid recovery, reversibility and a lower peri-procedural risk profile compared with surgical bariatric operations.

In parallel, GLP-1 RAs such as semaglutide and tirzepatide have reshaped the obesity-treatment landscape, delivering clinically meaningful weight loss and metabolic benefits. A real-world clinical study of semaglutide demonstrated an average TWL% of approximately 4–6% at 6–7 months, increasing to around 9–15% after 12 months of treatment. GLP-1 is an incretin hormone that stimulates glucose-dependent insulin secretion, suppresses glucagon release, delays gastric emptying, and promotes satiety. GLP-1 RAs such as semaglutide and tirzepatide mimic the physiologic effects of incretin hormones to enhance insulin secretion, delay gastric emptying, and promote satiety. However, despite the clinical successes of these drugs, their long-term use remains limited by high discontinuation rates, gastrointestinal intolerance, and rapid weight regain after treatment cessation. Importantly, GLP-1–based therapies primarily modulate appetite and energy balance rather than addressing the anatomical and mechanical determinants of satiety that underpin durable weight control, underscoring the need for complementary, durable and well-tolerated non-pharmacologic options.

While conventional bariatric surgery has demonstrated durable weight-loss outcomes, its invasive nature, perioperative risks and limited patient acceptance constrain its applicability to a broader obese population. These limitations highlight an ongoing unmet need for solutions that combine pharmacologic potency with the physiological durability of device-based interventions. Against this backdrop, EBMTs are emerging as the next-generation standard of care, capable of complementing GLP-1 therapies, providing alternatives for patients deriving limited benefit, and offering less invasive options for patients with obesity who are terrified by permanent physiological changes of and not suitable for surgery, including those in clinically critical or highly fragile condition. As the technological landscape evolves, these devices are set to play an increasingly integral role in a comprehensive, multi-modal approach to managing obesity and its related metabolic disorders.

Treatment Pathways for Overweight and Obesity under National Clinical Practice Guidelines

National clinical practice guidelines recommend a stepwise treatment pathway for overweight and obesity based on BMI level, obesity-related diseases and treatment response. Nutrition, exercise and psychological intervention serve as the basic management measures throughout the entire process for all patients. For patients with lower BMI levels and without obesity-related diseases, clinical nutrition therapy is generally recommended as the first-line intervention. As BMI increases, or when obesity-related diseases are present, pharmacotherapy such as GLP-1 receptor agonists and orlistat may be considered or recommended together with nutrition therapy. Within this pathway, metabolic and bariatric therapy is positioned as a more intensive intervention option for patients with higher BMI levels, obesity-related complications, or inadequate response to nutrition and drug therapy. In particular, it may be considered for patients with BMI of 27.5 to <32.5 kg/m² under certain clinical conditions, and is generally recommended for patients with BMI ≥32.5 kg/m², especially those requiring more substantial weight loss and metabolic improvement. Throughout the treatment process, patients’ conditions should be continuously monitored and assessed to support individualized treatment adjustment.

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Limitations of Pharmacologic and Bariatric Surgery Therapies for Weight-loss

The following table outlines the major limitations observed in current pharmacologic weight-loss treatments.

Category	Sub-Issues	Key Points / Data
I. Therapeutic Durability & Adherence Issues	Limited Durability and Rebound Weight Gain	<ul style="list-style-type: none"> In the STEP-1 extension, ~2/3 of prior weight loss was regained within 1 year after stopping semaglutide (−17.3% →−5.6%).
	High Discontinuation and Adherence Challenges	<ul style="list-style-type: none"> ~26% of patients discontinue GLP-1 therapy by three months, ~31% by six months, and ~68% by 12 months — mostly due to gastrointestinal (GI) side effects, cost, or access barriers.
II. Safety and Adverse Reactions	Gastrointestinal Adverse Effects	<ul style="list-style-type: none"> Common: nausea, vomiting, diarrhea, constipation. GI adverse events reported in 49% of semaglutide users vs 26% placebo (STEP-4).
	Loss of Lean Body Mass	<ul style="list-style-type: none"> 25–39% of total weight loss originates from lean tissue (DXA data). Muscle loss raises sarcopenia concerns, particularly in older adults. High lean mass loss increases frailty and fall risk in older or medically complex patients.
III. Systemic Safety Signals	Pancreatitis and Retinopathy Signals	<ul style="list-style-type: none"> Overall pancreatitis risk not statistically increased, but reported in case series. SUSTAIN-6: worsening diabetic retinopathy observed in rapid responders. Pharmacovigilance Risk Assessment Committee confirmed NAION as a rare adverse reaction to semaglutide. Denmark reported confirmed cases of irreversible vision loss.
	Thyroid Tumor Warning and Contraindications	<ul style="list-style-type: none"> Boxed warning for C-cell tumors (MTC/MEN2 contraindication).
IV. Other Clinical and Practical Limitations	Gallbladder and Biliary Disease Risk	<ul style="list-style-type: none"> GLP-1 agonists linked to increased gallstone and cholecystitis incidence.
	Cost and Accessibility Limitations	<ul style="list-style-type: none"> High out-of-pocket cost and limited insurance or Medicare coverage for obesity drugs.

Current pharmacologic weight-loss therapies, particularly GLP-1 RAs and related incretin-based agents, can induce substantial short-term weight reduction; however, their real-world use is constrained by multiple efficacy, safety and access limitations. Clinical studies have shown that the durability of effect is limited once treatment is stopped: patients regained roughly two thirds of previously lost weight within one year after discontinuing semaglutide, a GLP-1 RA, indicating that long-term maintenance generally requires ongoing therapy. In practice, adherence is challenging, around two thirds of patients discontinue GLP-1 treatment within 12 months, most commonly because of drug cost, gastrointestinal intolerance, or difficulties obtaining prescriptions and reimbursement.

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Tolerability and safety also pose important constraints. Gastrointestinal adverse events such as nausea, vomiting, diarrhea, and constipation are very common, with nearly half of treated patients experiencing GI side effects compared with about one-quarter of placebo recipients in pivotal trials. In addition, body-composition analyses suggest that approximately 25–39% of total weight loss comes from lean tissue, raising concerns about sarcopenia and functional decline, particularly in older adults. High lean mass loss may also increase frailty and fall risk in older or medically complex patients. Systemic safety signals, including case reports of pancreatitis, a higher incidence of gallbladder and biliary disease, and warnings about potential risks of thyroid C-cell tumors in susceptible individuals, necessitate careful patient selection and monitoring. In addition, the Pharmacovigilance Risk Assessment Committee has confirmed NAION as a rare adverse reaction to semaglutide, and Denmark reported confirmed cases of irreversible vision loss. Rapid improvements in glycemic control have also been associated with worsening diabetic retinopathy in some patients with pre-existing eye disease.

Beyond clinical considerations, pharmacologic weight-loss therapies face practical barriers related to cost and coverage. Many agents require long-term administration at relatively high prices, resulting in substantial out-of-pocket expenditure where obesity drugs are not broadly reimbursed. Limited insurance and public-payer coverage, particularly for chronic weight-management indications, restricts access and contributes to high discontinuation rates. Collectively, these limitations highlight the need for complementary, durable and well-tolerated weight-management modalities, including minimally invasive device-based interventions.

While traditional bariatric surgery has demonstrated well-established efficacy in patients with obesity, its invasive and largely irreversible nature, together with perioperative risks, limits its applicability across broader populations requiring weight loss and metabolic therapy. In contrast, EBMTs, characterized by minimal invasiveness, reversibility, and repeatability, are better suited for intervention in obesity and metabolic disorders and are well aligned with healthcare systems that emphasize tiered care delivery and long-term chronic disease management.

Endoscopic Bariatric and Metabolic Therapy

EBMTs are a group of minimally invasive, transoral, incisionless interventions that act within the stomach and proximal small intestine to induce weight loss and metabolic improvement. EBMT procedures function via well-established physiological pathways to reduce caloric intake, modulate incretin hormones, and improve insulin sensitivity. Using endoscopically delivered gastric bypass stent, balloons, suturing systems, liners, or other implants, these procedures reduce gastric capacity, delay gastric emptying, and isolate nutrient exposure in the proximal gut. In parallel, these procedures modulate metabolic gut hormones, such as GLP-1, PYY and ghrelin, to improve appetite control and glycemic regulation. Proximal gut nutrient isolation may also contribute to favorable metabolic responses in certain EBMT procedures. By simultaneously reducing caloric intake and enhancing metabolic control, EBMT aims to achieve more sustainable weight loss and durable improvements in cardio-metabolic health.

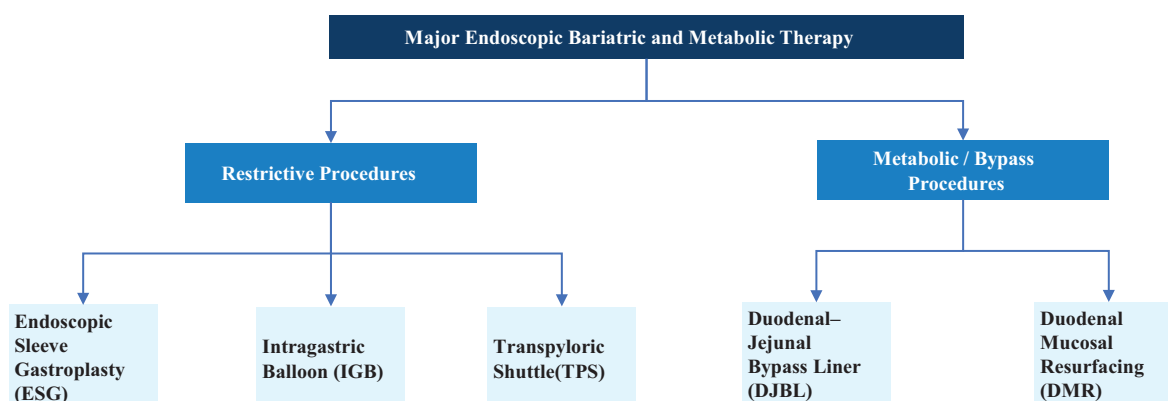
Compared with conventional bariatric surgery, EBMT offers several distinctive advantages. Procedures are entirely performed through natural orifices without external incisions, resulting in lower peri-operative risk, shorter recovery time and suitability for outpatient or day-case settings. Most devices are designed to be adjusted or removed endoscopically if needed, rather than being permanent. This reversibility allows clinicians to repeat, modify or escalate treatment over time as part of a stepwise obesity- management strategy. These therapies are also compatible with pharmacologic and digital programs, enabling combination or sequential treatment with GLP-1 RAs and structured lifestyle interventions for sustained weight control. EBMT procedures can be tailored to patient anatomy, BMI level and comorbid conditions, allowing gradual adjustment of intervention intensity and combination with lifestyle or pharmacologic therapies as needed.

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Milestones in the evolution of EBMTs includes the expansion of intragastric balloon systems in the 2010s, guideline recognition of balloons as a standard weight-loss option, regulatory approvals of endoscopic sleeve gastropasty platforms and aspiration devices, and more recent approvals of novel gastric bypass stents and duodenal-jejunal bypass liners in major markets, including China and Europe. EBMT is now primarily indicated for adults with severe or morbid obesity who have not achieved adequate results with diet, exercise, and pharmacotherapy; individuals with mild or moderate obesity and obesity-related metabolic diseases such as T2DM, hypertension, or MASH; and patients who are intolerant of or unresponsive to medication-based weight-loss therapy. In addition, the DMR product Revita has obtained CE marking certification in Europe. Compared with pharmacologic weight-loss therapy, EBMT can deliver greater weight loss without chronic systemic exposure, injection burden, high long-term drug costs, or the rapid weight regain often seen after treatment cessation. Compared with bariatric surgery, it avoids major abdominal surgery, prolonged hospitalization or irreversible anatomical alteration, offering a safer, reversible and more acceptable option for many patients. By combining high efficacy with a more favorable safety, tolerability and reversibility profile, EBMT achieves a risk–benefit balance that neither drugs nor surgery alone can offer.

Classification of Endoscopic Bariatric and Metabolic Therapies

The following diagram outlines the main categories of EBMT, grouped into restrictive and metabolic/ bypass procedures.



Source: Frost & Sullivan analysis

EBMT encompass a broad range of minimally invasive gastrointestinal interventions designed to achieve clinically meaningful weight loss and metabolic improvement. These procedures are performed entirely through natural orifices using flexible endoscopic platforms, avoiding surgical incisions. EBMT techniques function through well-established mechanisms including gastric volume restriction, delayed gastric emptying, modulation of incretin hormones, such as GLP-1 and PYY, alteration of duodenal nutrient flow, and mucosal metabolic remodeling. Collectively, these pathways result in reduced caloric intake, improved insulin sensitivity, and enhanced metabolic control.

Metabolic/bypass procedures focus more directly on alteration of duodenal nutrient flow and mucosal metabolic remodeling, and modifying nutrient exposure and mucosal signaling in the proximal small intestine to achieve metabolic benefits that may be partly independent of weight loss. Key examples include but are not limited to (i) the duodenal-jejunal bypass liner (DJBL), a flexible endoscopic liner deployed from the duodenum to the jejunum to mimic the effects of a surgical bypass by reducing contact between chyme and the intestinal wall; and (ii) duodenal mucosal resurfacing (DMR), which uses controlled thermal ablation of the duodenal mucosa followed by mucosal regeneration to modulate duodenal signaling and support improvements in glycaemic control and insulin sensitivity in selected patients.

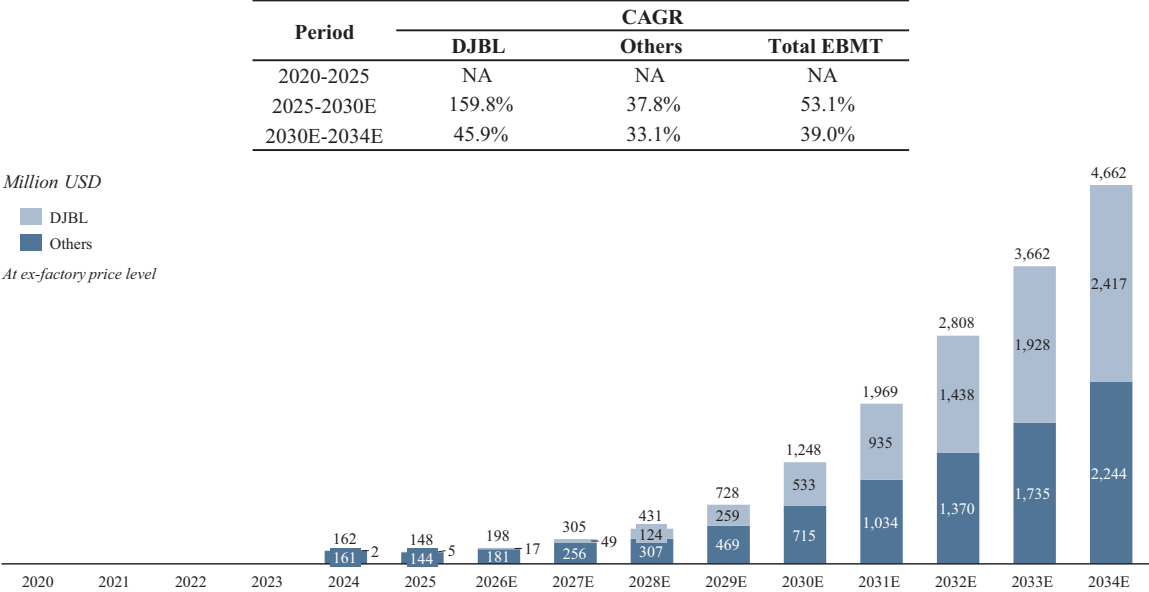
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EBMT is positioned between pharmacologic therapies and bariatric surgery, providing a reversible, scalable and patient-acceptable therapeutic continuum, and is increasingly recognized as an essential component of modern obesity and metabolic disease management.

Global EBMT Device Market Outlook

The following chart sets forth the global market size of EBMT medical devices, at ex-factory price level, for the period from 2020 to 2034.

Global Market Size of EBMT Medical Devices, 2020–2034E



Source: Frost & Sullivan Analysis

The global market for EBMT medical devices, including DJBL and other EBMT devices, is expected to experience a temporary decline from US\$162 million in 2024 to US\$148 million in 2025 at ex-factory price level, before entering a rapid growth phase. The market is projected to expand to approximately US\$728 million by 2029, approximately US\$1,248 million by 2030E, and further to approximately US\$4,662 million by 2034E. The total EBMT medical device market is expected to grow at a CAGR of 53.1% from 2025 to 2030E and 39.0% from 2030E to 2034E. DJBL and other EBMT devices are expected to grow at CAGRs of 159.8% and 37.8%, respectively, from 2025 to 2030E, and 45.9% and 33.1%, respectively, from 2030E to 2034E.

The temporary decline in 2025 mainly reflects the early-stage commercialization status of EBMT devices and the short-term impact of evolving obesity treatment paradigms. In particular, the broader global supply, improving accessibility and pricing optimization of GLP-1-based weight-loss drugs, such as semaglutide and tirzepatide, may divert part of the potential EBMT patient population toward pharmacological treatment in the near term, given the convenience and higher initial acceptance of drug therapy compared with endoscopic device-based interventions. In addition, certain representative global EBMT companies faced revenue pressure and a tighter financing environment in 2025, leading to cost-control measures, channel adjustments and reduced sales and marketing investments, which further slowed near-term commercialization. Meanwhile, although future treatment pathways may gradually evolve toward a complementary model between pharmacotherapy and EBMT devices, such as using drugs for initial weight reduction and device-based interventions for long-term weight maintenance and metabolic improvement, this combined treatment model remained at the stage of clinical exploration and evidence

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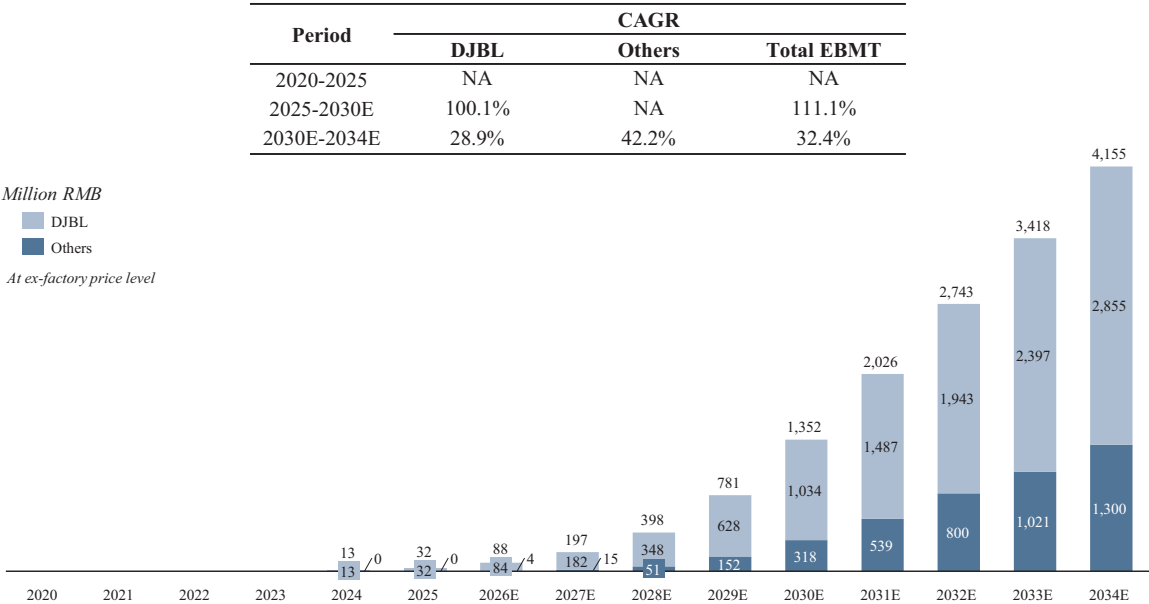
generation in 2025 and had not yet translated into broad clinical adoption. Looking forward, the global EBMT medical device market is expected to resume strong growth, supported by rising obesity and metabolic disease prevalence, broader clinical adoption, accelerating product approvals, continued evidence generation, improving outpatient treatment capacity, and the increasing recognition of EBMT devices as minimally invasive metabolic interventions that may complement pharmacotherapy and provide an alternative for patients who are not suitable for, or are unwilling to undergo, bariatric surgery.

The global market for DJBL medical devices remains at an early but rapid expansion stage. At ex-factory price level, the market size increased from US\$1.8 million in 2024 to US\$4.5 million in 2025, and is projected to expand to US\$259.3 million by 2029 and US\$533.1 million by 2030E. From 2025 to 2030E, the global DJBL medical device market is expected to grow at a CAGR of 159.8%, reflecting the early-stage launch and rapid clinical adoption of DJBL products. Growth momentum is expected to continue from 2030E to 2034E, with the market forecast to reach US\$2,417.5 million by 2034E, representing a CAGR of 45.9% during the period. This growth is expected to be supported by the rising prevalence of obesity and T2DM, increasing clinical acceptance of endoscopic metabolic therapy, gradual regulatory approvals in major markets, and the progressive incorporation of DJBL devices into multidisciplinary obesity and metabolic disease management pathways.

EBMT Device Market Outlook in China

The following chart sets forth the historical and projected market size of obesity medical devices in China, at ex-factory price level, for the period from 2020 to 2034.

Market Size of EBMT Medical Devices in China, 2020–2034E



Source: Frost & Sullivan Analysis

The market for EBMT medical devices in China, including DJBL and other EBMT devices, is expected to grow from RMB13 million in 2024 to RMB32 million in 2025 at ex-factory price level, before entering a rapid growth phase. The market is projected to expand to RMB781 million by 2029, RMB1,352 million by 2030E, and further to RMB4,155 million by 2034E. The total EBMT medical device market in China is expected to grow at a CAGR of 111.1% from 2025 to 2030E and 32.4% from 2030E to 2034E. DJBL and other EBMT devices are expected to grow at CAGRs of 100.1% and NA, respectively, from 2025 to 2030E, and 28.9% and 42.2%, respectively, from 2030E to 2034E.

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The market for DJBL medical devices in China remains at an early but rapid expansion stage. At ex-factory price level, the market size increased from RMB12.7 million in 2024 to RMB32.2 million in 2025, and is projected to expand to RMB628.3 million by 2029 and RMB1,033.5 million by 2030E. From 2025 to 2030E, the DJBL medical device market in China is expected to grow at a CAGR of 100.1%, reflecting the early-stage commercialization and rapid clinical adoption of DJBL products in China. Growth momentum is expected to continue from 2030E to 2034E, with the market forecast to reach RMB2,855.0 million by 2034E, representing a CAGR of 28.9% during the period. This growth is expected to be supported by the rising prevalence of obesity and T2DM in China, increasing clinical acceptance of endoscopic metabolic therapy, gradual expansion of domestic product approvals, growing outpatient endoscopic treatment capacity, and the progressive incorporation of DJBL devices into multidisciplinary obesity and metabolic disease management pathways.

Global Competitive Landscape of Approved EBMt

Fluid-filled intragastric balloon systems

Fluid-filled intragastric balloons are currently the most established segment of approved EBMt products. Systems such as Orbera, Spatz3, Medsil and LexBal are endoscopically placed in the stomach for several months to partially occupy gastric volume, enhance satiety and support short- to mid-term weight loss in adults with obesity who have failed diet and exercise programs. These devices have obtained FDA and/or CE approvals since 2008 to 2021 and are marketed across the US, Europe and other regions, with indications typically covering patients with class I–II obesity or BMI around 30–50 kg/m². Newer designs such as the Allurion (Elipse) swallowable capsule balloon further simplify placement by avoiding endoscopy in selected cases.

Product Name	Company	First Approval Year	Regulatory Agency	Approval Country/Region	Product Description	Indication
Orbera Intragastric Balloon System	Boston Scientific	2015	FDA+CE	USA/ Global	Liquid-filled gastric balloon designed for 6-month placement	BMI 30–50 kg/m ² ; adults with obesity who failed to lose weight through diet and exercise.
Spatz3 Adjustable Balloon System	Spatz FGIA Inc.	2021	FDA+CE	USA / EU / LATAM	Adjustable-volume liquid-filled balloon;	BMI 35–40 kg/m ² , or BMI 30–34.9 kg/m ² with ≥ 1 major obesity-related comorbidity; failed supervised weight-loss program.
Medsil Intragastric Balloon	Medsil (Medispar)	2008	CE	CE markets	Saline-filled silicone balloon; endoscopic placement/removal; 6-month dwell	BMI 30–40 kg/m ² ; adults with obesity (per manufacturer).
LexBal	Lexel	2015	CE	CE markets	Liquid-filled intragastric balloon; endoscopic placement/removal; up to 12-month dwell	BMI used for obesity/overweight management in adults under specialist supervision (centers typically treat BMI 30–40 kg/m ²).
Allurion (Elipse)	Allurion Technologies	2015	CE	EU / Middle East / APAC	Swallowable capsule balloon that self-inflates after ingestion, no endoscopy required	BMI ≥ 27 kg/m ² ; adults ≥ 18 years as adjunct to lifestyle and behavior modification programs.

The table above summarizes the main commercialized fluid-filled intragastric balloon systems, including their manufacturers, approval years, regulatory agencies, key markets and principal indications.

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Gas-filled, hybrid and special balloons

Gas-filled balloons and hybrid systems broaden the EBMT competitive landscape by offering different profiles of comfort, adjustability and dwell time. The Obalon Balloon System, a swallowable gas-filled capsule balloon requiring minimal endoscopic intervention, and the Heliosphere air-filled balloon provide non-surgical options for adults with overweight or obesity in the US and selected international markets. Hybrid devices such as End-Ball, which can be filled with air and/or liquid, and special designs such as the TransPyloric Shuttle (TPS), which delays gastric emptying through transpyloric positioning, target patients with BMI typically in the 27–40 kg/m² range and are positioned as outpatient weight-loss tools under specialist supervision.

The following table summarizes approved gas-filled, hybrid and special balloon products, together with their sponsors, regulatory status, geographic coverage and intended patient populations.

Product Type	Product Name	Company	First Approval Year	Regulatory Agency	Approval Country / Region	Product Description	Indication
Gas-filled balloon	Obalon Balloon System	Obalon Therapeutics	2014	FDA+CE	USA / Selected EU	Swallowable gas-filled capsule balloon; 3 capsules placed over 12 weeks	BMI 30–40 kg/m ² ; adults > 22 years who failed diet and exercise programs.
	Heliosphere Balloon	Helioscopic Medical Imaging	2014	CE	EU / Middle East / LATAM	Air-filled intragastric balloon for non-surgical obesity treatment	BMI ≥ 27 kg/m ² ; adults with obesity or overweight with difficult-to-control type 2 diabetes.
Hybrid (air + liquid) balloon	End-Ball	Endalis	2016	CE	EU / Asia (CE markets)	Endoscopic balloon that can be filled with air and/or liquid; ~700 mL; 6-month dwell	BMI 27–40 kg/m ² ; adults with overweight/obesity
Special balloon	TransPyloric Shuttle (TPS)	BAROnova	2019	FDA+CE	USA	Endoscopically placed transpyloric silicone device that delays gastric emptying; max 12-month dwell	BMI 35.0–40.0 kg/m ² , or BMI 30.0–34.9 kg/m ² with ≥1 obesity-related comorbidity; used with diet and behavior modification.

Non-balloon EBMT devices

Beyond balloon technologies, non-balloon EBMT devices focus on duodenal bypass and duodenal implants to address both weight and metabolic control. The gastric bypass stent system approved by the NMPA in China provides a temporary endoscopic bypass solution for obese patients who have not responded adequately to lifestyle or pharmacologic therapy. In European Union, the RESET duodenal-jejunal bypass liner (DJBL) is designed to mimic surgical Roux-en-Y gastric bypass effects for the management of obesity in adult patients with BMI ≥40 kg/m², or those with BMI ≥30 kg/m² accompanied by at least one cardiometabolic risk factor such as T2DM or dyslipidemia, while the Revita system employs endoscopic catheter-based DMR using hydrothermal ablation to remodel dysfunctional duodenal mucosa. As an incisionless procedure, Revita is designed as an adjunct to diet and exercise to improve glycemic control in inadequately controlled T2DM patients with preserved β-cell function and to reduce liver fat in T2DM patients with metabolic dysfunction-associated fatty liver disease (MAFLD). These products illustrate the evolution of treatment toward metabolic-focused, reversible EBMT solutions.

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The following table summarizes the principal commercialized non-balloon EBMT devices, including duodenal-jejunal bypass liners and duodenal implants, and sets out their core features and indications.

Product Type	Product Name	Company	First Approval Year	Regulatory Agency	Approval Country / Region	Product Description	Indication
Duodenal- Jejunal Bypass Liner	Gastric Bypass Stent System	Tangji Medical	2024	NMPA	China	Endoscopic stent delivery system for temporary gastrointestinal bypass; includes retrieval kit	For patients with inadequate response to lifestyle modification, non-invasive, or pharmacologic therapy, including: 1) Simple obesity with BMI ≥ 32.5 kg/m ² ; 2) BMI 30-32.5 kg/m ² with ≥ 2 metabolic syndrome components; 3) BMI 30-32.5 kg/m ² with obesity-related comorbidities.
	RESET	Morphic Medical	2025	CE marking	EU / UK	Endoscopically anchored polymer liner in proximal small intestine (≤ 9 months) to mimic RYGB effects	BMI ≥ 40 kg/m ² , or those with BMI ≥ 30 kg/m ² accompanied by at least one cardiometabolic risk factor such as type 2 diabetes or dyslipidemia.
DMR	Revita	Fractyl Health	2016	CE marking	EU / UK	Endoscopic catheter- based duodenal mucosal resurfacing (DMR) system using hydrothermal ablation to remodel dysfunctional duodenal mucosa (incisionless procedure).	As an adjunct to diet and exercise, for DMR to improve glycemic control in inadequately controlled T2D patients (with preserved β -cell function) and reduce liver fat in T2D patients with NAFLD.

Currently, no duodenal–jejunal bypass liner (DJBL) device has been approved by the U.S. FDA for commercial use, and such devices remain investigational in the United States. In Europe, certain DJBL products have previously obtained CE mark certification, and newer devices such as RESET® have recently received CE marking, allowing limited commercialization in the European Union.

Duodenal-Jejunal Bypass Liner Therapy

Although invasive bariatric surgery delivers substantial and well-documented benefits, its use remains concentrated in only a portion of eligible patients. Clinical selection criteria, the need for specialized centers, and the long-term implications of irreversible anatomical changes mean that many individuals continue to look for less invasive options. This situation has encouraged the development of reversible endoscopic therapies that aim to reproduce the key physiological benefits of metabolic surgery while reducing procedural burden and offering greater flexibility in patient management.

The duodenal-jejunal bypass liner (DJBL) represents an important and emerging technology, which is a reversible weight loss treatment modality invented with reference to the principles of a traditional bariatric therapy, Roux-en-Y Gastric Bypass. DJBL has the characteristics of obvious weight loss effects, reversibility, less invasive, and fewer adverse effects.

The system consists of a flexible, polymeric sleeve endoscopically anchored in the duodenal bulb and extending approximately 60 cm into the proximal jejunum. By creating a physical barrier between ingested nutrients and the mucosa of the upper small intestine, the liner prevents direct contact with bile and pancreatic secretions, thereby delaying digestion and absorption.

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Clinically, the DJBL is placed endoscopically under sedation and removed after 3-9 months, making it a fully reversible, incisionless, and repeatable intervention. Published studies report 10-20 % TWL and marked HbA1c reduction (~1-2%). Adverse events are generally mild and transient, including abdominal discomfort or nausea; more serious complications such as device migration or hepatic abscess are rare and manageable with timely removal.

DJBL therapy bridges the therapeutic gap between pharmacologic treatment and invasive bariatric surgery. It appeals to patients who are refractory to pharmacologic weight-loss therapy yet unwilling or unfit for permanent surgical alteration. The device’s reversibility, scalability, and metabolic potency position it as a cornerstone technology within the evolving ecosystem of endoscopic bariatric interventions.



Source: Literature review, Frost & Sullivan analysis

Indication of Duodenal-Jejunal Bypass Liner Therapy Mentioned in Guidelines in China

	Indication		
Guideline for Diagnosis and Treatment of Obesity (2024 edition)	(1) BMI ≥ 32.5 kg/m ² , or BMI ≥ 27.5 kg/m ² with T2DM, regardless of treatment response.	(2) BMI 27.5–32.5 kg/m ² , failed medical therapy or with obesity-related comorbidities.	(3) BMI 25.0–27.5 kg/m ² with T2DM: requires ethical review and patient consent.
The Expert Consensus on Digestive Endoscopic Treatment of Obesity in China	(1) BMI ≥ 27.5 kg/m ² : endoscopic bariatric therapy is acknowledged regardless of comorbidities, and regardless of prior failure of other intervention;	(2) BMI 25.0–27.5 kg/m ² + waist ≥ 90 cm (male) / ≥ 85 cm (female): endoscopic bariatric therapy after failure of lifestyle and medical treatment;	(3) BMI 25.0–27.5 kg/m ² + ≥ 1 obesity-related disease: therapy acknowledged if expected weight loss can improve related conditions after failure of lifestyle and medical treatment.
The Expert opinion on Endoscopic Duodenal-Jejunal Bypass Liner Implantation for Weight Loss (2025 Edition)	(1) BMI ≥ 28 kg/m ² or 24–28 kg/m ² (18–65 yrs): consider;	(2) BMI meets criteria (<18 or >65 yrs): requires MDT review and informed consent;	(3) BMI meets criteria with severe comorbidities: proceed cautiously after MDT discussion.
Gastric Bypass Stent System Registration Technical Review Report (NMPA)	(1) BMI ≥ 32.5 kg/m ² — obese patients not responding to non-surgical therapy;	(2) BMI 30–32.5 kg/m ² — patients with at least two metabolic syndrome components;	(3) BMI 30–32.5 kg/m ² — patients with obesity-related comorbidities such as T2DM, hypertension, or dyslipidemia.

The clinical application of the DJBL is supported by a clearly defined framework of indications established in leading guidelines. Against this backdrop, DJBL offers a novel therapeutic option in China, addressing a previously unmet gap between pharmacotherapy and invasive bariatric surgery in the obesity treatment landscape, particularly for patients with moderate to severe obesity accompanied by metabolic comorbidities.

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Guideline for Diagnosis and Treatment of Obesity (2024 edition) issued by the NHC provides explicit direction for special patient populations. For instance, patients with a BMI meeting the standard threshold but who are outside the typical age range of 18-65 years, or those presenting with complex, severe comorbidities, are recommended to undergo a comprehensive Multi-Disciplinary Team (MDT) evaluation. This ensures careful risk-benefit analysis and reinforces the principle of personalized treatment planning, which is central to modern metabolic care. In addition, the NHC guideline indicates that interventional treatment options may be considered for patients with a BMI ≥ 32.5 kg/m², or a BMI ≥ 27.5 kg/m² with T2DM, regardless of prior failure of medical therapy, providing an evidence-based basis for the clinical use of gastric bypass stent systems without requiring exhaustion of pharmacological treatment.

According to the Expert Consensus on Digestive Endoscopic Treatment of Obesity in China, DJBL therapy is considered applicable for patients with a BMI ≥ 27.5 kg/m², regardless of the presence of comorbid conditions, and regardless of prior failure of other intervention. For individuals with BMI 25.0-27.5 kg/m², DJBL may be considered if they present with increased waist circumference (≥ 90 cm (male) or ≥ 85 cm (female)) and have failed to achieve adequate results through lifestyle modification and pharmacologic management.

The Gastric Bypass Stent System Registration Technical Review Report issued by the NMPA further refines the indication criteria, specifying eligibility for patients with BMI ≥ 32.5 kg/m², or for those with BMI 30-32.5 kg/m² accompanied by at least two metabolic syndrome components, or obesity-related comorbidities such as T2DM, hypertension, or dyslipidemia. These evidence-based thresholds establish a clear regulatory benchmark for patient selection and reinforce DJBL as a scientifically validated, device-based metabolic therapy.

Collectively, these guideline-based indications reflect growing clinical and regulatory consensus on the therapeutic value of DJBL. The structured patient-selection criteria not only enhance clinical outcomes but also support broader clinical adoption by aligning DJBL therapy with national regulatory standards and emerging international best practices.

Advantage of Duodenal-jejunal Bypass Liner Therapy

Mechanistic innovation

The DJBL employs a non-surgical metabolic bypass mechanism that mimics key physiological effects of Roux-en-Y gastric bypass through a combination of physical isolation, hormonal modulation, bile acid regulation and gut microbiota alteration. By deploying a flexible polymeric liner from the duodenal bulb to the proximal jejunum, the DJBL prevents direct contact between ingested food and the intestinal mucosa. In parallel, it separates bile and pancreatic secretions from the chyme, thereby delaying the digestion and absorption of fats and carbohydrates and reducing overall nutrient absorption. As nutrients pass through the duodenum and proximal jejunum without contacting the intestinal wall, stimulation of K cells and secretion of GIP are reduced. Meanwhile, the accelerated delivery of chyme to the distal small intestine stimulates L cells to secrete GLP-1, resulting in increased GLP-1 levels. These hormonal changes contribute to improved glycaemic control and weight reduction. Operating on principles comparable to Roux-en-Y gastric bypass, the DJBL has been shown to increase circulating bile acid levels in patients with obesity and T2DM. Elevated bile acids further promote GLP-1 secretion and support improvements in glucose metabolism. In addition, the DJBL alters the distribution of gut microbiota and their metabolic products, indirectly regulating host metabolism and contributing to improvements in insulin resistance and hepatic steatosis.

Minimally invasive and reversible

DJBL therapy exemplifies the upgrades in minimally invasive, incisionless interventions that redefine patient accessibility in obesity and diabetes management. As a fully reversible and repeatable system, DJBL

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can be removed or replaced as clinically indicated, offering a procedural flexibility unattainable in surgical bariatrics. The absence of external incisions and the outpatient nature of the procedure significantly reduce procedure-related risk, shorten recovery time, and allow most patients to be discharged on the same day. Compared with traditional bariatric surgery, DJBL thus provides an alternative with far lower procedural burden.

Strong clinical efficacy

Clinical data of DJBL demonstrates weight loss and glycemic control within 12 months post-implantation. Across multiple multicenter clinical studies, DJBL users have demonstrated 10-20% total body-weight loss with HbA1c and fasting glucose reduction. Recent data from China indicate that patients can achieve approximately 11–12% total weight loss within a 3-month implantation period, accompanied by significant reductions in BMI and waist circumference. Additionally, DJBL significantly reduces cardiovascular risk parameters, such as blood pressure and lipid levels, but these benefits also diminish post-retrieval. These outcomes approach those of surgical gastric bypass while maintaining a superior safety and recovery profile.

Broad patient applicability

The DJBL system demonstrates broad clinical applicability across overweight and moderate to severe obesity populations, offering a practical solution for individuals with BMI ≥ 25.0 kg/m² who have failed lifestyle or pharmacologic interventions. This population has traditionally occupied a treatment gap between pharmacotherapy and invasive surgery, often experiencing inadequate response to medications while being considered insufficiently obese for surgical approval. Our product is particularly suitable for patients with obesity-related metabolic comorbidities, individuals who are intolerant to pharmacotherapy, eligible surgical candidates who decline invasive procedures, as well as those experiencing weight regain following prior medication or surgeries such as sleeve gastrectomy.

Safety and cost advantages

DJBL delivers a balance of safety, controllability and economic efficiency compared with traditional bariatric surgery, with clinical data to date supporting a favorable and well-tolerated risk profile. From a health-economic perspective, DJBL’s short procedural time, outpatient setting, and low complication rate translate into significant cost savings for healthcare systems. These characteristics support its potential inclusion in reimbursement programs as a cost-effective metabolic therapy. The discontinuation of the ENDO Trial highlighted certain safety concerns associated with earlier DJBL designs and underscored the importance of device optimization and improved clinical management protocols for subsequent generations of endoscopic bariatric devices. Compared with earlier DJBL systems, newer-generation devices, including the Gastric Bypass Stent System developed by Tangji Medical, incorporate design improvements intended to enhance device stability and safety, such as optimized anchoring structures and retrieval mechanisms, which may help reduce the risk of device-related complications observed in earlier studies.

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Comparison of Major Obesity Treatment Modalities: EBMT vs Pharmacotherapy vs Bariatric Surgery

Comparison Dimension	EBMT (e.g., <i>Intragastric Balloon</i> / DJBL)	Pharmacotherapy: Semaglutide 2.4 mg	Bariatric Surgery: Sleeve Gastrectomy (SG) / Roux-en-Y Gastric Bypass (RYGB)
Treatment modality	<ul style="list-style-type: none"> Minimally invasive endoscopic therapy; no gastric resection involved; gastric anatomy largely preserved; procedures may be repeatable or partially reversible 	<ul style="list-style-type: none"> Long-term pharmacological management of obesity; requires ongoing administration 	<ul style="list-style-type: none"> Invasive surgical procedures involving gastric resection or gastrointestinal reconstruction
Representative interventions	<ul style="list-style-type: none"> <i>Intragastric Balloon</i>, DJBL 	<ul style="list-style-type: none"> Once-weekly GLP-1 receptor agonist 	<ul style="list-style-type: none"> SG, RYGB
Typical weight loss	<ul style="list-style-type: none"> Clinical studies suggest approximately 10–20% TWL within 6–12 months, significantly higher than lifestyle intervention alone 	<ul style="list-style-type: none"> STEP-1 trial reported approximately 14.9% body weight reduction at 68 weeks 	<ul style="list-style-type: none"> Typically 25–30% TWL within 12 months, representing the largest weight-loss magnitude
Durability of effect	<ul style="list-style-type: none"> Weight-loss effects can be maintained with structured follow-up and lifestyle management 	<ul style="list-style-type: none"> Weight maintenance generally requires continuous treatment; in the STEP-1 extension, approximately two-thirds of prior weight loss was regained within one year after semaglutide discontinuation, High Discontinuation and Adherence Challenges, 68% of patients discontinue GLP-1 therapy by one year 	<ul style="list-style-type: none"> Generally demonstrates strong long-term durability of weight loss
Metabolic benefits	<ul style="list-style-type: none"> Improvements observed in metabolic comorbidities such as glycemic control, blood pressure, and sleep apnea 	<ul style="list-style-type: none"> Improvements observed in weight-related metabolic indicators 	<ul style="list-style-type: none"> Most pronounced improvements in metabolic diseases such as T2DM and hypertension
Invasiveness / reversibility	<ul style="list-style-type: none"> Less invasive than surgery; rapid recovery; some procedures are reversible or adjustable 	<ul style="list-style-type: none"> Non-invasive 	<ul style="list-style-type: none"> Most invasive and largely irreversible
Safety profile / common risks	<ul style="list-style-type: none"> Generally favorable safety profile; serious complications relatively uncommon 	<ul style="list-style-type: none"> Mainly gastrointestinal adverse events; with muscle loss; Pancreatitis and Retinopathy Signals; Thyroid Tumor Warning and Contraindications 	<ul style="list-style-type: none"> Perioperative complications, anesthesia risks, and potential long-term nutritional deficiencies
Key advantages	<ul style="list-style-type: none"> Provides a balanced option between efficacy and invasiveness, enabling meaningful weight loss with relatively low treatment burden 	<ul style="list-style-type: none"> Non-interventional and broadly scalable 	<ul style="list-style-type: none"> Largest magnitude of weight loss
Key limitations	<ul style="list-style-type: none"> Weight-loss magnitude typically lower than bariatric surgery 	<ul style="list-style-type: none"> High Discontinuation and Adherence Challenges; and with muscle loss. 	<ul style="list-style-type: none"> High invasiveness and longer recovery with ongoing nutritional management

Source: Frost & Sullivan analysis

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Comparative Positioning of GBS and Major Obesity Treatment Options

Comparison Dimension	GBS (Gastric Bypass Stent System)	Other DJBL Devices	Pharmacotherapy (GLP-1-based anti-obesity drugs)
Treatment modality	<ul style="list-style-type: none"> Endoscopically implanted temporary gastrointestinal bypass device; minimally invasive, removable and reversible; designed to partially mimic metabolic effects of gastric bypass 	<ul style="list-style-type: none"> Endoscopically implanted duodenal–jejunal bypass liner (DJBL); minimally invasive, removable and reversible 	<ul style="list-style-type: none"> Long-term pharmacologic management requiring continuous drug administration to maintain weight-loss effects
Representative products / procedures	<ul style="list-style-type: none"> Tangji Medical GBS 	<ul style="list-style-type: none"> RESET 	<ul style="list-style-type: none"> Semaglutide 2.4 mg and other GLP-1 receptor agonists
Typical weight-loss / metabolic outcomes	<ul style="list-style-type: none"> In the pivotal trial, 69.4% of test-group patients in the FAS and 76.2% in the PPS achieved >5% TWL at three months. Mean EWL% at three months reached 34.9% in the PPS. 	<ul style="list-style-type: none"> At 9 months, TWL approximately 11–14 kg, BMI reduction ~4–5 kg/m², HbA1c reduction ~1% 	<ul style="list-style-type: none"> STEP-1 trial showed mean weight reduction of ~14.9% at 68 weeks
Key advantages	<ul style="list-style-type: none"> Shorter procedure time and shorter indwelling time (three months), which may improve procedural efficiency and patient convenience 	<ul style="list-style-type: none"> Minimally invasive and reversible; designed to mimic metabolic effects of bypass surgery 	<ul style="list-style-type: none"> Non-interventional with high patient acceptance
Key limitations	<ul style="list-style-type: none"> Long-term real-world evidence continues to accumulate 	<ul style="list-style-type: none"> Longer indwelling time of up to nine months may increase device-related risks, including migration and liver abscess, particularly after prolonged implantation beyond six months. 	<ul style="list-style-type: none"> Requires long-term treatment; with high Discontinuation and Adherence Challenges; and with muscle loss.
Safety profile / common risks	<ul style="list-style-type: none"> Favorable short-term safety profile; no device migration or serious device-related complications observed in pivotal clinical trial; 100% successful removal within 90 days 	<ul style="list-style-type: none"> Possible abdominal discomfort, nausea, and rare device migration 	<ul style="list-style-type: none"> Mainly gastrointestinal adverse events; with muscle loss; Pancreatitis and Retinopathy Signals; Thyroid Tumor Warning and Contraindications
Patient-related costs	<ul style="list-style-type: none"> Typically a one-time or staged device and endoscopic procedure cost, potentially avoiding long-term pharmacotherapy expenses; generally ranging from RMB36,600-RMB39,100 	<ul style="list-style-type: none"> Usually one-time device cost plus implantation and removal procedures, approximately €8,000–€15,000 	<ul style="list-style-type: none"> Requires continuous medication; annual cost in China may reach approximately RMB 35,000, resulting in ongoing expenditure
Treatment positioning	<ul style="list-style-type: none"> GBS is an approved endoscopic option for patients with BMI >32.5 kg/m², and for BMI 30.0–32.5 kg/m² patients with metabolic syndrome components or obesity-related comorbidities. 	<ul style="list-style-type: none"> BMI ≥40 kg/m² or those with BMI ≥30 kg/m² accompanied by at least one cardiometabolic risk factor such as type 2 diabetes or dyslipidemia 	<ul style="list-style-type: none"> Used with lifestyle intervention for overweight or obese adults, including BMI 24.0–27.5 kg/m² with obesity-related comorbidities and BMI 27.5–32.5 kg/m² after inadequate response to lifestyle intervention.

Source: Frost & Sullivan analysis

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Growth Drivers of Weight-loss Devices Market

The growth of the weight-loss devices market is driven by the following key factors:

- ***Unmet Clinical Demands of Obesity and Its Co-morbidities.*** The global prevalence of overweight and obesity continues to rise. While lifestyle modification remains foundational, it typically yields modest and difficult-to-maintain outcomes. Pharmacotherapy’s real-world use is often limited by tolerability issues, long-term adherence challenges, and uneven access across patient groups. These therapeutic gaps create opportunities for minimally invasive, device-based solutions capable of achieving meaningful weight loss and metabolic improvement without systemic drug exposure.
- ***Low Acceptance of Invasive Bariatric Surgery.*** Conventional bariatric surgery delivers weight-loss and metabolic efficacy but requires major abdominal surgery, carries meaningful peri-operative and long-term complication risks, and results in permanent anatomical alterations. The growing adoption of short-stay or day-case interventions that modulate gastric emptying or nutrient flow illustrates a clear shift in clinical practice toward safer and more flexible treatment options between chronic pharmacotherapy and major surgery, creating a favorable environment for innovative endoscopic platforms such as gastric bypass stent systems.
- ***Supportive Policy and Payer Trends.*** China has designated a comprehensive three-year “Weight Management Year” campaign (2024–2026) to strengthen the national response to overweight and obesity as a public health priority. This multi-sector initiative aims to establish a supportive environment for weight management. As part of implementation efforts, the NHC has also issued guidance requiring that healthy weight management clinics be established in all tertiary general hospitals, children’s hospitals, and traditional Chinese medicine hospitals by mid-2025. Policy directives place particular emphasis on digital integration, precision and minimally invasive interventions, metabolic disease management, and the establishment of specialized weight-management clinics. In parallel, ongoing diagnosis-related group/diagnosis-intervention packet (DRG/DIP) and value-based payment reforms are designed to improve access to innovative, endoscopic and reversible weight-loss technologies.
- ***Technology and Evidence Tailwinds.*** Rapid technological advances in minimally invasive gastrointestinal device platforms, anchoring systems and biocompatible materials continue to enhance the safety, durability, and ease of placement or removal for device-based therapies. Emerging clinical evidence from randomized controlled trials and real-world studies increasingly supports minimally invasive, gastrointestinal device-based interventions as effective stand-alone options or as part of combination regimens with pharmacotherapy and lifestyle modification. Continued innovation is expected to expand patient eligibility, strengthen long-term outcomes, and solidify the clinical value of weight-management devices.

Future Trends of Weight-loss Devices Market

The weight-loss devices market is expected to evolve along four major trends:

- ***Evolving Clinical Focus.*** The clinical understanding of obesity is shifting from a primary focus on excess body weight to the broader concept of metabolic dysfunction. As reduction of cardio-metabolic risk becomes the central treatment objective, greater emphasis is placed on interventions that improve glycemic control, lipid profiles and liver health rather than weight alone. Minimally invasive, gastrointestinal device-based therapies are well aligned with this shift, offering reversible options that deliver both weight loss and metabolic benefits.

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- ***Integration with Digital Health.*** Digital health technologies enable continuous, end-to-end management before and after weight-loss interventions. The integration of endoscopic devices with app-based coaching and data-driven follow-up enhances long-term adherence, reduces relapse rates, and improves real-world outcomes.
- ***Combination and Sequencing with Medicines.*** Early clinical studies and emerging real-world experience suggest that reversible gastrointestinal device-based interventions can be used in combination or sequence with anti-obesity pharmacotherapy, and may provide greater or more durable weight loss than either approach alone in selected patients. Devices can induce rapid initial weight loss and glycemic improvement, reducing the need for high-dose or prolonged drug use, while pharmacologic agents can help sustain device-initiated results and extend treatment durability. Tailored approaches, such as combining gastric bypass stent system with GLP-1 or amylin analogs, offer measurable metabolic synergy and reduce discontinuation risk. These integrated regimens are expected to generate payer-relevant, real-world outcomes over three to 12-month time horizons.
- ***Outcomes, Economics, and Reimbursement Readiness.*** Health technology assessments are placing increasing emphasis on composite clinical endpoints, such as TWL% and EWL% combined with metabolic biomarkers such as HbA1c and alanine aminotransferase, an enzyme found mostly in the liver, high levels of which can indicate liver damage, as credible measures of value. The outpatient, minimally invasive nature of these therapies supports faster recovery, lower use of inpatient resources and the potential for DRG/DIP-related savings. As payer pilots continue to evaluate total cost-effectiveness and long-term durability, coverage expansion and reimbursement for reversible weight-loss devices are expected to support broader coverage.

The Key Industry Challenges of the EBMT and DJBL Market

The EBMT and DJBL market faces the following key challenges:

- ***Regulatory and Clinical Evidence Requirements.*** Despite the growth potential of the EBMT market, including DJBL devices, regulatory approval for novel metabolic intervention devices remains complex and time-consuming. As EBMT technologies represent relatively new treatment approaches, regulatory authorities often require comprehensive clinical evidence to demonstrate long-term safety and efficacy before granting approval or expanding indications. In addition, the clinical evidence base for certain EBMT technologies remains relatively limited compared with established bariatric surgery procedures. Although multiple clinical studies have demonstrated the potential effectiveness of EBMT devices in weight loss and metabolic improvement, additional long-term and large-scale clinical data may still be required to further establish their clinical positioning and support broader adoption by physicians.
- ***Physician Adoption and Clinical Practice Integration.*** Physician awareness and adoption of EBMT technologies may take time to develop. Bariatric surgery and pharmacotherapy have been established treatment approaches for obesity management for many years, while the integration of new endoscopic metabolic therapies into clinical practice may require physician training, accumulation of procedural experience and updates to treatment guidelines. As a result, the pace of EBMT adoption may depend on the availability of trained physicians, hospital procedural capacity and the degree to which EBMT devices are incorporated into multidisciplinary obesity and metabolic disease management pathways.
- ***Reimbursement and Patient Affordability Constraints.*** Reimbursement coverage for EBMT procedures remains limited in many healthcare systems. In certain markets, obesity treatments are not fully covered by public healthcare insurance programs, which may affect patient affordability.

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and slow the adoption of device-based therapies. The pace of market development may therefore depend on payer recognition of the clinical and economic value of EBMT, including its potential role in reducing long-term obesity-related complications and healthcare costs.

- **Competition from Pharmacotherapy and Bariatric Surgery.** Competition from alternative obesity treatment options may also influence the development of the EBMT market. Pharmacological treatments, particularly GLP-1 receptor agonists and other emerging anti-obesity drugs, as well as established bariatric surgery procedures, may compete for the same patient population seeking weight management or metabolic interventions. While EBMT technologies, including DJBL devices, offer a minimally invasive treatment option positioned between pharmacotherapy and bariatric surgery, market development may still be affected by evolving treatment preferences, drug availability, patient acceptance and physician recommendations.

OBESITY AND OVERWEIGHT

Medically, obesity is a chronic metabolic disease caused by a variety of factors and characterized by excessive body fat accumulation. Fundamentally, the condition arises from an energy imbalance. Generally, obesity is the result of a combination of genetic factors, environment, personal diet and exercise choices. In the current epidemiological context, modern lifestyle changes, high-calorie diets, and lack of exercise are important factors contributing to the rapid growth of obese people. The WHO recognizes overweight and obesity as major global health challenges and key risk factors for noncommunicable diseases, such as cardiovascular disease, T2DM, and certain cancers.

Global Prevalence of Obesity and being Overweight

Obesity and being overweight are commonly assessed using anthropometric indicators such as BMI, waist circumference and waist-to-hip ratio. For adults, the World Health Organization (WHO) defines overweight as a BMI of at least 25 kg/m² and obesity as a BMI of at least 30 kg/m².

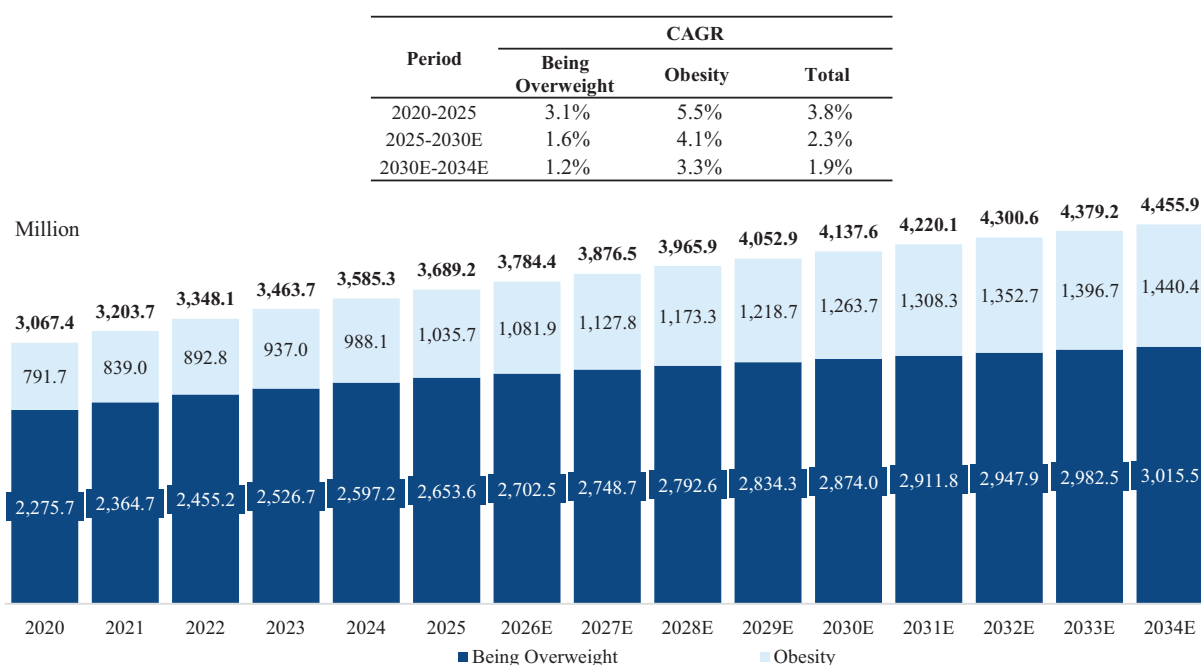
Globally, the burden of excess body weight is substantial and continues to rise. The number of patients who are overweight increased from 2,275.7 million in 2020 to 2,653.6 million in 2025, representing a CAGR of 3.1% over the same period, driven mainly by changes in dietary patterns and increasingly sedentary lifestyles. This population is projected to keep expanding, reaching 2,874.0 million in 2030, representing a CAGR of 1.6% from 2025 to 2030 and 3,015.5 million in 2034, representing a CAGR of 1.2% from 2030 to 2034.

The prevalence of obesity shows an even steeper upward trend. The number of patients with obesity worldwide grew from 791.7 million in 2020 to 1,035.7 million in 2025, corresponding to a CAGR of 5.5% over the same period. It is expected to increase further to 1,263.7 million in 2030, representing a CAGR of 4.1% from 2025 to 2030, and to reach 1,440.4 million in 2034, representing a CAGR of 3.3% from 2030 to 2034. Taken together, the total number of patients with overweight or obesity is forecast to rise from 3,067.4 million in 2020 to 4,455.9 million in 2034, underscoring the growing global demand for effective and scalable weight-management solutions.

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The following chart illustrates the historical and projected number of patients with overweight or obesity worldwide from 2020 to 2034, measured in millions.

Global Prevalence of Obesity and being Overweight, 2020-2034E



Source: Literature review, Frost & Sullivan analysis

Prevalence of Obesity and Being Overweight in China

Obesity and being overweight in China are primarily assessed using the Chinese adult diagnostic criteria, which define overweight as a BMI of at least 24 kg/m² and obesity as a BMI of at least 28 kg/m². Compared with WHO thresholds, these lower BMI cut-offs indicate a higher cardio-metabolic risk at a given BMI level in Chinese populations, and all prevalence figures below are calculated based on this basis.

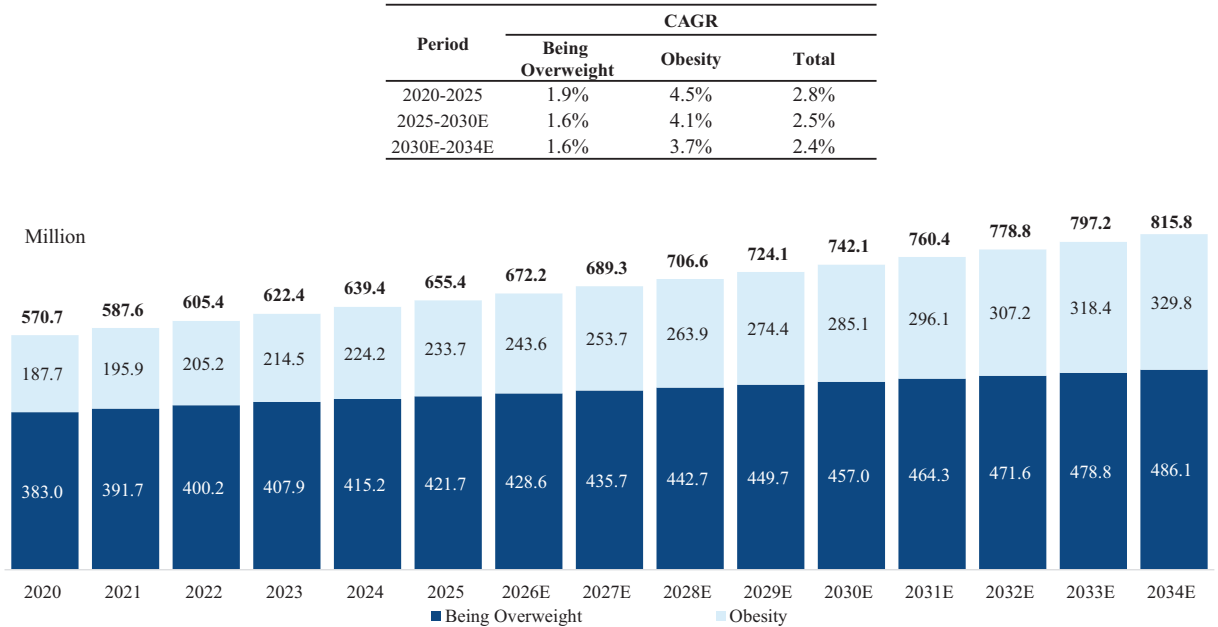
Under these criteria, the number of patients who are overweight in China increased from 383.0 million in 2020 to 421.7 million in 2025, representing a CAGR of 1.9% over the same period. This population is projected to continue rising to 457.0 million in 2030 and 486.1 million in 2034, representing a CAGR of 1.6% from 2025 to 2030, and a CAGR of 1.6% from 2030 to 2034. The steady growth of the overweight population is largely driven by shifts in dietary patterns toward higher-calorie foods and reduced physical activity associated with urbanization and lifestyle changes.

Obesity has expanded even more rapidly. The number of patients with obesity grew from 187.7 million in 2020 to 233.7 million in 2025, representing a CAGR of 4.5% over the same period, and is expected to reach 285.1 million in 2030 and 329.8 million in 2034, representing a CAGR of 4.1% from 2025 to 2030, and a CAGR of 3.7% from 2030 to 2034, respectively. As a result, the total number of patients with overweight or obesity in China is projected to increase from 570.7 million in 2020 to 815.8 million in 2034. This persistent upward trend, particularly in the obese segment, points to a large and expanding population at elevated cardio-metabolic risk, underscoring the need for more effective and scalable weight-management interventions.

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The following chart illustrates the historical and projected number of patients with overweight and obesity in China from 2020 to 2034, measured in millions under Chinese diagnostic criteria.

Prevalence of Obesity and being Overweight in China, 2020-2034E



Source: Literature review, Frost & Sullivan analysis

MASH COMPLICATED WITH OBESITY

MASH complicated with obesity represents the inflammatory and fibrotic end of the MAFLD spectrum in individuals with excess adiposity. Over time, these processes can progress from simple steatosis to MASH, fibrosis and ultimately cirrhosis and hepatocellular carcinoma. Clinically, MASH complicated with obesity is often silent for many years. As disease advances, patients may develop non-specific symptoms such as fatigue, weight loss, abdominal discomfort, nausea and cognitive changes, while signs of liver dysfunction emerge in advanced stages. Obesity, T2DM, dyslipidaemia, hypertriglyceridaemia and other components of metabolic syndrome are key risk factors, and many patients present with multiple cardio-metabolic comorbidities. Because MASH is a strong predictor of progression to cirrhosis and liver-related mortality, resolution of MASH rather than simple fat reduction has become the central therapeutic goal in clinical management and drug development.

The rising global prevalence of obesity has translated into a parallel increase in MASH complicated with obesity, including more patients progressing to advanced fibrosis and cirrhosis. Although lifestyle modification and weight loss remain the cornerstone of management, durable weight reduction is difficult to achieve in routine practice, and currently available pharmacotherapies often focus on metabolic comorbidities or complications rather than directly resolving liver inflammation and fibrosis. As a result, there is growing clinical interest in safe, effective, and sustainable weight-management and metabolic interventions, including both pharmacologic and device-based approaches, to address the substantial unmet need in MASH complicated with obesity.

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Prevalence of MASH in Obesity Patients Globally

MASH has become a major global public health concern, closely linked to the rising obesity epidemic. As the progressive, inflammatory and fibrotic form of metabolic liver disease. Among obesity patients, the burden of MASH is substantial and continues to grow. In 2020, an estimated 266.8 million obesity patients worldwide were living with MASH. This number increased to 349.0 million by 2025, 425.8 million by 2030 and 485.4 million by 2034, representing a CAGR of 5.5% from 2020 to 2025, a CAGR of 4.1% from 2025 to 2030, and a CAGR of 3.3% from 2030 to 2034. The steadily rising prevalence highlights the urgent need for earlier screening, preventive strategies and innovative therapies that address both obesity and metabolic liver disease. The following chart illustrates the historical and projected number of patients with obesity living with MASH worldwide from 2020 to 2034, measured in millions.

Global Prevalence of MASH in Obesity Patients, 2020-2034E

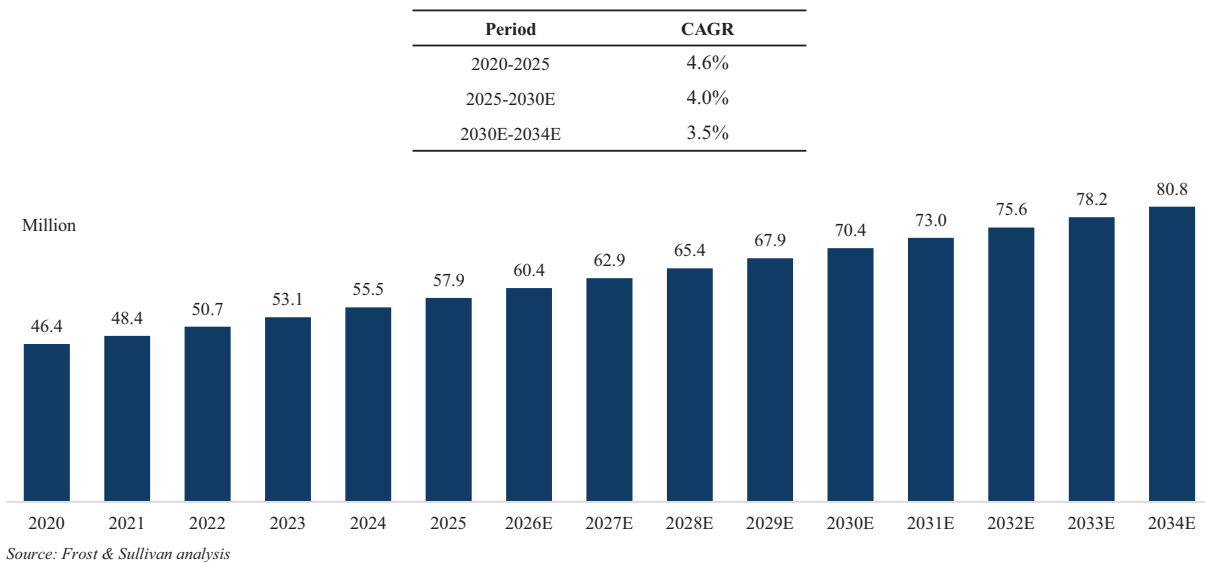


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Prevalence of MASH in Obesity Patients in China

In China, rising rates of obesity and steatotic liver disease are driving a growing burden of MASH in patients with obesity. MASH represents progression from simple steatosis to inflammatory and fibrotic liver disease and is strongly linked to T2DM, dyslipidaemia, and other cardio-metabolic comorbidities. The number of patients with obesity living with MASH in China is estimated to increase from 46.4 million in 2020 to 57.9 million in 2025, representing a CAGR of 4.6% over the same period. This population is projected to further rise to 70.4 million in 2030, representing a CAGR of 4.0% from 2025 to 2030, and 80.8 million in 2034, representing a CAGR of 3.5% from 2030 to 2034, indicating sustained but gradually moderating growth on top of an already high baseline prevalence. These trends highlight a substantial and expanding pool of Chinese patients with MASH complicated with obesity who require earlier identification and more effective treatment options targeting both weight and liver disease. The following chart illustrates the historical and projected number of patients with obesity living with MASH in China from 2020 to 2034, measured in millions.

China Prevalence of MASH in Obesity Patients, 2020-2034E



Global and China Competitive Landscape of EBMT Devices for treatment of MASH

Globally, no medical device has yet obtained regulatory approval with MASH as its primary treatment indication. Current interventional options for patients with MASH and obesity remain limited to lifestyle modification, pharmacologic therapy and bariatric surgery, and device-based approaches are still at the exploratory or clinical-research stage in major markets. Our product candidate GBS-SH, intended for MASH complicated with obesity has received Breakthrough Device Designation from the FDA as an innovative therapy. It is the first medical device from China to obtain such designation for the treatment of metabolic diseases, positioning the product at the forefront of the global EBMT landscape for MASH with obesity.

T2DM COMPLICATED WITH OBESITY

T2DM complicated with obesity represents a major subtype of acquired metabolic disease characterized by the coexistence and reciprocal interaction of excess adiposity and impaired glucose metabolism. In these patients, excess body weight or waist circumference aggravates insulin resistance, increases the likelihood of progressing from prediabetes to T2DM and makes blood glucose control more difficult.

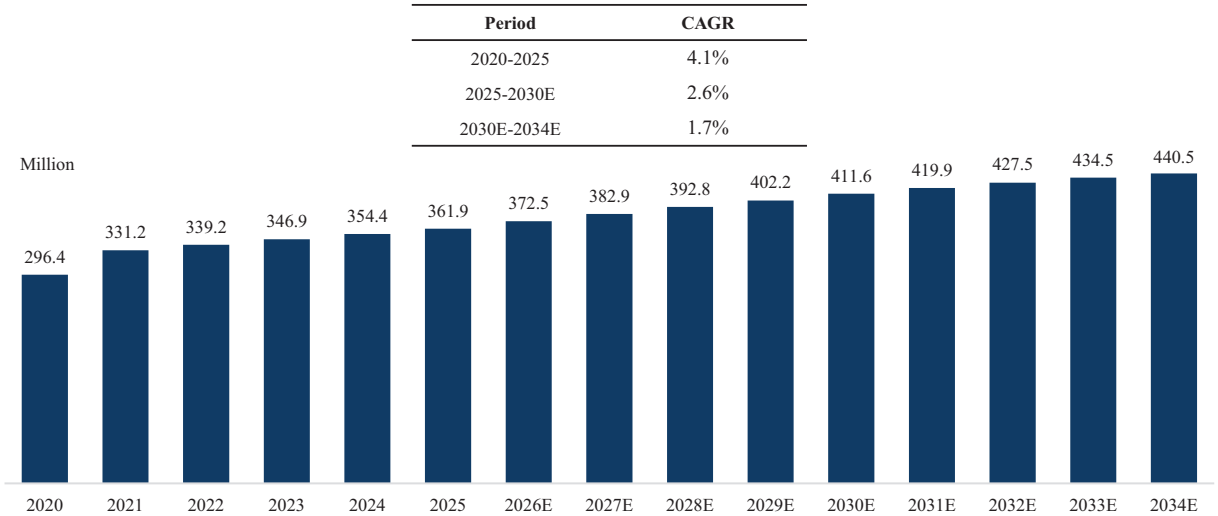
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From a clinical management perspective, T2DM complicated with obesity is addressed through an integrated approach encompassing lifestyle modification, pharmacologic therapy, and interventional procedures such as surgical bariatric operations and endoscopic bariatric and metabolic therapies. Lifestyle modification forms the foundation of care but is difficult to maintain over the long term in real-world settings. Conventional bariatric surgery offers substantial and durable metabolic benefits and can even induce remission of T2DM in selected obese patients, yet its invasive nature, surgical risks, and lifelong postoperative follow-up requirements limit broader adoption. Consequently, there remains a significant unmet clinical need for safe, effective, and durable weight-loss solutions that can complement or bridge pharmacologic therapy.

Prevalence of T2DM in Obesity Patients Globally

Globally, the number of patients with obesity living with T2DM is projected to rise from 296.4 million in 2020 to 361.9 million in 2025, representing a CAGR of 4.1% over the same period. This figure is expected to further increase to 411.6 million in 2030, representing a CAGR of 2.6% from 2025 to 2030, and to 440.5 million in 2034, representing a CAGR 1.7% from 2030 to 2034. Although growth is anticipated to moderate gradually over time, the absolute number of patients with T2DM complicated with obesity will continue to expand, underscoring the substantial and persistent global burden of this condition. The following chart illustrates the historical and projected number of patients with obesity living with T2DM worldwide from 2020 to 2034, measured in millions.

Global Prevalence of T2DM in Obesity Patients, 2020-2034E



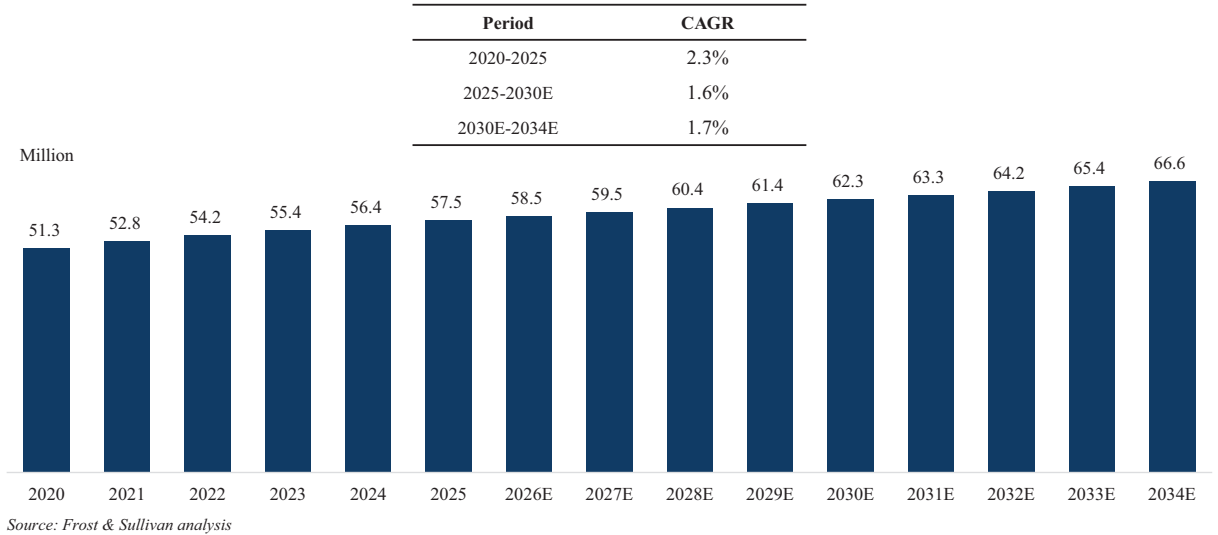
Source: Frost & Sullivan analysis

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Prevalence of T2DM in Obesity Patients in China

In China, excess body weight and central obesity are also key drivers of T2DM. At the same time, shifts toward energy-dense diets, population aging, increasingly sedentary lifestyles, and broader screening and diagnosis continue to drive the rising prevalence of T2DM complicated with obesity. Under these trends, the number of patients with obesity living with T2DM in China is projected to increase from 51.3 million in 2020 to 57.5 million in 2025, representing a CAGR of 2.3% over the same period. This figure is expected to reach 62.3 million in 2030, representing a CAGR of 1.6% from 2025 to 2030, and to 66.6 million in 2034, representing a CAGR of 1.7% from 2030 to 2034, indicating continued but gradually moderating growth on top of a high baseline prevalence. The following chart illustrates the historical and projected number of patients with obesity living with T2DM in China from 2020 to 2034, measured in millions.

China Prevalence of T2DM in Obesity Patients, 2020-2034E



Global and China Competitive Landscape of EBMT Devices for Treatment of T2DM Complicated with Obesity

On the global front, a representative EBMT product specifically targeting metabolic dysfunction in T2DM is the Revita system, which utilizes DMR. Revita is an endoscopically delivered, catheter-based system that employs hydrothermal ablation to remodel dysfunctional duodenal mucosa through an incisionless procedure. As an adjunct to diet and exercise, it is designed to improve glycemic control in inadequately controlled T2DM patients with preserved β -cell function and to reduce liver fat in T2DM patients with MAFLD. This innovative approach highlights the industry’s evolution toward procedure-based metabolic modulation. The following table summarizes the key attributes of Revita, including device type, regulatory status and diabetes-related indication.

Product Name	Company	Device Type	Stage / Approval	Diabetes-related Indication	Notes
Revita	Fractyl Health	DMR	CE Approved	T2DM patients (with preserved β -cell function) and reduce liver fat in T2DM patients with MAFLD	Endoscopic catheter-based DMR system using hydrothermal ablation to remodel dysfunctional duodenal mucosa (incisionless procedure).

INDUSTRY OVERVIEW

In China, diabetes-related EBMT devices remain at an earlier stage of development. We are developing a gastrointestinal bypass stent system intended to address metabolic disorders, including MASH and T2DM complicated with obesity, through endoscopic creation of a short-term intestinal bypass. While the device has already been approved for obesity treatment, additional indications in T2DM and MASH are being evaluated in clinical studies and, subject to successful trial results and regulatory review, could potentially obtain approval in the coming years. This pipeline underscores the emerging domestic innovation potential in EBMT solutions for patients with diabetes and obesity.

REPORT COMMISSIONED BY FROST & SULLIVAN

In connection with the [REDACTED], we have engaged Frost & Sullivan to conduct a detailed analysis and prepare an industry report on the major markets for which our product candidates are positioned. Frost & Sullivan is an independent global market research and consulting company that provides market research on a variety of industries including biotechnology. We have agreed to pay Frost & Sullivan a total fee of RMB730,000 for the preparation of the Frost & Sullivan Report, and we believe that such fees are consistent with the market rate. The payment of such amount was not contingent upon our successful [REDACTED] or on the results of the Frost & Sullivan Report. Except for the Frost & Sullivan Report, we did not commission any other industry report in connection with the [REDACTED].

The market size projections in the Frost & Sullivan Report were based on the following key assumptions: (i) the addressable market size is calculated as the product of target market population, disease prevalence rate, diagnosis rate, treatment rate, therapy penetration rate, and average annual treatment cost, with adjustments for patient compliance and disease-specific factors; (ii) future market trends incorporate considerations of evolving healthcare policies, competitive landscape developments, pipeline advancements, and changes in patient demographics; (iii) the overall healthcare environment and regulatory framework in the target jurisdictions are expected to remain stable during the forecast period; and (iv) there are no extreme disruptions such as force majeure events or fundamental changes to industry regulations that would dramatically alter market dynamics. The reliability of the Frost & Sullivan Report may be affected by the accuracy of the foregoing key assumptions.