NON-VASCULAR STENTS – GLOBAL ANALYSIS AND MARKET FORECASTS
The table presents the key metrics for non-vascular stents in the 10 major markets (10MM) covered in this report (US, France, Germany, Italy, Spain, UK, Japan, Brazil, China, and India) during the forecast period from 2011–2021.

Sales for Non-Vascular Stents

In 2013, the total non-vascular stents market was estimated at $488.6m across the 10MM covered in this report. By the end of the forecast period in 2021, non-vascular stents sales will grow to $694.9m at a Compound Annual Growth Rate (CAGR) of 4.5%.

The key drivers of this market during the forecast period are:

- Growing prevalence of diseases in the major markets covered in this report
- Growing elderly population worldwide and increased life expectancy
- Expanding use of stents in non-malignant applications, and the need for effective therapies that reduce the risk of complications
- Technological innovations in stent technology with regard to stent design and delivery systems
- Rising use of fully-covered, removable metal stents in gastrointestinal applications
- Movement towards the increase use of minimally-invasive techniques, augmented by rising patient demand and awareness

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<th>Non-Vascular Stents, Key Metrics in the 10 Major Markets, 2013–2021</th>
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<td>APAC</td>
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<td>(2013) Xlumena receives FDA approval for the AXIOS stent and delivery system for the treatment of pancreatic pseudocysts.</td>
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<td>(2014) FDA lowers the risk classification for pancreatic drainage stents to Class II devices.</td>
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<td>(2015) Clinical study to evaluate the SX ELLA Esophageal Biodegradable Stent System (DESTINY) in 66 patients will be completed.</td>
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<tr>
<td>(2015) Clinical study to evaluate colonic stenting with elective surgery versus emergency surgery for malignant colonic obstruction in 200 patients will be completed.</td>
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<tr>
<td>(2016) Clinical study to evaluate a fully-covered self-expanding biliary metal stent (WallFlex) for the treatment of benign biliary strictures in 164 patients across 11 countries will be completed</td>
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<td>Number of companies covered</td>
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<tr>
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<td>5EU</td>
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<td>Brazil</td>
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Source: GlobalData, based on primary research interviews with leading physicians in the 10 MM
5EU = France, Germany, Italy, Spain, and UK; APAC = Asia-Pacific (Japan, China, and India)
CE Mark = Conformité Européenne (European Conformity) Mark
Executive Summary

Of the 10MM covered in the report, the US currently has and will continue to have the largest share in the non-vascular stents market throughout the forecast period. Together, the US, the 5EU countries, and Japan will account for 76% of the non-vascular stents market in 2021. Collectively, the 5EU countries are forecast to have a 24% market share in the future. Among the emerging markets, China and India have captured significant market share due to their large patient population base, which is expected to further increase in the future. The emerging markets, including Brazil, China, and India, are expected to account for 24% of the market, closing in on the 5EU, and will serve as an outlet of expansion for stent manufacturers to increase their global presence.

Figure below illustrates the non-vascular stents revenue by major market at the beginning and end of the forecast period.

![Non-Vascular Stents Revenue ($m), by Major Market, 2013 and 2021](chart)

Source: GlobalData, based on primary research interviews and surveys with leading physicians in the 10MM
Executive Summary

Market Dynamics by Segment
The non-vascular stents market is a well-established one. This report covers the four segments within the overall non-vascular stents market in the 10MM from 2013–2021: enteral stents (esophageal, gastroduodenal, and colonic stents), pancreatic and biliary stents, airway stents, and urinary tract stents (ureteral, prostate, and urethral stents). The urinary tract stents market will display no significant increase during the forecast period due to the increasing difficulty in gaining patient acceptance of these devices, even though this market constituted approximately 50% of the total non-vascular stents market revenues in 2013. Meanwhile, the pancreatic and biliary stents market will show maximum growth, increasing at a CAGR of 7.1%, followed by enteral stents at a CAGR of 5.5%, during the forecast period.

Unmet Needs Remain a Challenge
While non-vascular stent technology has evolved over the years to address the challenges involved in treating patients, there are still several unmet needs and limitations with regard to the current devices. Over the years, a plethora of non-vascular stents has been developed, featuring innovative designs, structures, coatings, and delivery systems. While many research and development (R&D) efforts are focused on stents used in high-volume procedures, such as cardiovascular stents, there have not been many attempts made to improve non-vascular stents. For example, there is a need for improvements in stent technology aimed at reducing post-procedural complications, ensuring stents with high radial strength and flexibility and minimal foreshortening and fracture, and stents for specific indications and anatomies. Hence, there is a still a lot of room for improvement, and newer stent devices need to be developed to overcome these drawbacks and fuel growth within this market.

Future Looks Strong in the Emerging Markets
The future of the non-vascular stents market looks strong in the emerging markets, where Brazil, China, and India are seeing higher volumes of stenting procedures. This is due to the fact that China and India have the largest patient population base. With increasing household incomes and an increased demand for better-quality healthcare, these countries hold promise for the future growth of this market. Driven by this rising demand, the Asian domestic players are garnering greater attention in this market, and are directly competing with the multinational brands.

The other significant driver of the non-vascular stents market will be the changing perception of the use of these devices as a curative, rather than a palliative, treatment option, especially in the developed nations. Novel stent technologies in the non-vascular stents market aimed at addressing unmet needs, such as biodegradable stents, have been developed. Given that these stents degrade over a period of time, this technology offers several benefits, including saving time and resources associated with stent removal procedures and...
Executive Summary

improving the feasibility of future interventions. However, currently only one commercially available biodegradable stent is available in nations that accept the CE Mark. Also, the adoption of biodegradable stents has been slow in EU, which can be attributed to the lack of long-term clinical data and high selling prices. Overall, GlobalData expects moderate growth in this mature market.

What Do Physicians Think?
The physicians interviewed by GlobalData indicated that there is a lack of attention by stent manufacturers on the non-vascular segment of the market, in comparison with the cardiovascular segment.

“As I say, it [the non-vascular segment] is still perceived very much as a market of the dying cancer patient, which we are now — yes, that is established — but we’re using [non-vascular stents] for so many other things. But it is not perceived as a big market and a big money-spinner [maker]. And the Cooks of this world and the Medtronics are invested in aortic grafts and the [use of] drug-eluting stent[s] for vascular disease.”

Key Opinion Leader

“A lot of the development [of non-vascular stents] is driven by marketing, and not by clinical need. So, all of a sudden, you get a stent that has got loads of humps on it, and it looks very exciting, but what [need] does it actually address?”

Key Opinion Leader

However, the physicians believe that the ongoing innovations in biodegradable stent technology show promise.

“There are developments going on in [regard to the use of] different materials, different polymers, and we only have an uncovered biodegradable stent, which has a bit of a problem with mucosal granulation. That is, hopefully, going to be sorted [out] by the end of next year, when there will be a [stent with a] biodegradable membrane [available]. There’s all sorts of things happening in [the biodegradable stent] sector. And I think that’s where the future lies, really.”

Key Opinion Leader

The physicians also noted that significant unmet needs remain in this market.

“There’s only one type of biodegradable stent available, which we’re using continuously off-label for things it isn’t licensed for, because it does that [which we are attempting to do] very well.”

Key Opinion Leader

“Because if you — wherever you go — if you go to the esophagus, you have to address [stent] migration. If we go to the large and small bowel, we have to address [the need for] bio-resistant coverings. [Also,] we haven’t got removable stents for the colon because people haven’t thought that far [ahead].”

Key Opinion Leader
Executive Summary

“I've got — my seasoned [urinary] stone patients say to me, ‘You can do what you like, but don’t leave a stent in.’ They really do say that.”

Key Opinion Leader

In particular, the physicians are interested in solid clinical studies proving that there are positive outcomes for these products.

“We don't understand how [stents] work in the environment we put them in. It is entirely [a matter of,] ‘That looks good, and I think it's all right.' But there is no large-scale evidence, which would be actually quite easy [to obtain] if there was a bit of money put in.”

Key Opinion Leader
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Introduction

2 Introduction

Non-vascular stent technology has evolved over the years, such that these devices are routinely used in clinical practice for different indications. Although the current stent technologies provide mechanical support to the lumen of the organ in which they are used, both short- and long-term complications still occur, resulting in poor clinical outcomes and endangering patient safety. Based on the shortcomings of the current stents, a newer generation of devices boasting innovative structures, durable metal alloys, biodegradable stent platforms, and bioactive coatings is in development.

This report focuses on the four segments within the overall non-vascular stent market: enteral stents (esophageal, gastroduodenal, and colonic stents), pancreatic and biliary stents, airway stents, and urinary tract stents (ureteral, prostate, and urethral stents). It estimates the sales in the overall non-vascular stents market in the 10 major markets (10MM) (US, France, Germany, Italy, Spain, UK, Japan, Brazil, China, and India) from 2013–2021. The report provides an investigation of the unmet needs, future adoption trends, and Compound Annual Growth Rates (CAGRs) in each geographic region and market segment. GlobalData’s analysis indicates that while this market is mature, there is room for further technological development and increased adoption in order to address stenting procedure complications and overcome concerns regarding the current stent designs and materials. Future growth in this market is dependent on the ability of manufacturers to provide stents that show significant clinical improvement over the currently available products, and are minimally-invasive, while continuing to lower product prices. Also, with the markets in the Asia-Pacific (APAC) region being highly fragmented among the local players, there will be a continued battle for market share by the top five manufacturers, as they try to tap into the market through technological innovation and investment in establishing strong distribution networks. However, the major market opportunity lies within the emerging markets, such as India and China, which currently have a largely underserved patient population. The key to market growth in these regions will be the realignment of clinical practice to function in concert with the local distribution network, as well as acquisitions by larger foreign companies of the local market players.
Introduction

2.1 Catalyst

As the non-vascular stents market is more mature than the other stent markets, expanded indications for the use of these devices is the single most important factor that will drive growth in this market over the forecast period from 2013–2021. This report identifies the unmet needs in the non-vascular stents market with respect to both stent technology and delivery platforms, and also discusses the need for improvement in the design and development of these stents. Long-term clinical data confirming the efficacy of non-vascular stents will allow surgeons to continue to adopt new products. Additionally, the emergence of many local players, which are the main drivers of innovation in this market, will influence large manufacturers to focus on mergers and acquisitions (M&As). While austerity measures affect some segments of this market, it will be important for manufacturers to focus on cutting costs in order to maintain growth.

This report presents the current technologies and the drivers of the future growth of the overall non-vascular stents market in the 10 major markets (US, France, Germany, Italy, Spain, Japan, Brazil, China, and India), and also discusses the market dynamics and the adoption rates of various devices.

2.2 Related Reports

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