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3.5 Biodegradable Stents


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Elixir Reports Outstanding 1-year Results for Safety and Efficacy for 100% Bioresorbable DESolve® Novolimus Eluting Coronary Scaffold System
Elixir’s DESolve® Novolimus Eluting Biodegradable Coronary Scaffold System Certified by CE
Asian Heart Institute Conducts Angioplasty with New Generation Biodegradable Stent
Elixir Medical Finalizes the Enrollment for the DESolve Nx Pivotal Trial Carried Out for Fully Bioresorbable Coronary Scaffold System
REVA Medical Announces Interim Clinical Results
Biodegradable Stent Proven to be Safe for Long-Term Treatment of Coronary Artery Disease
Abbott Receives Japanese Approval for XIENCE PRIME™ Drug Eluting Stent
Abbott and St. Jude Medical Widens Alliance for Cardiovascular Products in the United States.
Reva Medical’s ReZolve™ Stent bring a New Revolution to Cardiology: Claims to Stop Heart Attacks before they occur with Resorbable Stents
Abbott begins Medical Trials for ESPRIT I for Treatment of Peripheral Artery Disease
Abbott Initiates Clinical Trial to Evaluate and compare Absorb™ Bioresorbable Vascular Scaffold and Metallic Drug Eluting Stent
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Abbott begins Clinical Trials for ABSORB™ BTK, to treat Below-the-Knee Limb Ischemia
Abbott Announces the Success of International Clinical Trial of ‘ABSORB’, a Bioresorbable Vascular Scaffold in Japan.
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What Befalls the Fate of Stents? Michigan Tech Scholars Mimic Blood Flow in the Lab
New, Biodegradable Heart Stent Prove Safe in Trials
Clinical Follow-up Results of Biodegradable Stents (EXCEL™) and Durable Polymer Stent (CYPHERTM) in Treating Coronary Artery Disease
Bio-Absorbable Stent for Treating CAD
Biodegradable Stents for the First Time in India:
MRI Could be Used for Routine Surveillance of Great Vessel Stents
A Randomized Comparison between Biodegradable Polymer Sirolimus-Eluting Stents and PARTNER Stents for Patients with Coronary Artery Diseases
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Biodegradable Polymer Technology is safe and Effective: A Study Conducted by Limus Eluted from a Durable Versus Erodible Stent Coating
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Better Patient Outcomes with Drug Eluting Stents
Cardiac Stent Patients with Diabetes May Benefit From Drug That Counteracts Effects of Leptin
Increased Number of Patients with Drug-Coated Cardiac Stents Survive and Avoid Expensive Follow-Up Procedures
Drug-Eluting Stents Give Improved Outcomes Compared to Bare-Metal Ones
Blending in: Dissolvable Stents Promise to Protect Arteries
Innovative Design Could Prevent Blood Clot Formation That Plagues Stents Presently
Study Shows Heart Drugs Equally Good at Preventing Heart Attacks, Death in the Case of Some Individuals
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RI Technologies brings an informative update on the Global Biodegradable Stents market. This study gives an insight into Global Stents and Biodegradable Stents market. The report also provides an overview of the Worldwide Bare Metal Stents and Drug Eluting Stents market. Market analytics for Biodegradable Stents by Application and by Biodegradable Material is provided in this niche report. The market is divided by Application into Coronary Arterial Stents, Peripheral Arterial Stents and Other; and by Biodegradable Material into Polymer and Metal. Global stents market is analyzed from 2010 -2020, while estimations and predictions for biodegradable stents market are provided from 2017-2022. Key market dynamics are provided for North America, Europe, Asia-Pacific, and Rest of World (RoW). Business profiles of 23 biodegradable stents companies are discussed in the report. Information related to recent product releases, product developments, partnerships, collaborations, and mergers and acquisitions is also covered in the report.

The Biodegradable Stents report is an ideal research tool providing strategic business intelligence to the corporate sector. This report may help strategists, investors, Stents companies, and biotechnology companies in--

- Gauging Competitive Intelligence
- Identifying Key Growth Areas and Opportunities
- Understanding Geographic Relevance to Product
- Knowing Regional Market Sizes and Growth Opportunities and Restraints
- Keeping Tab on Emerging Technologies
- Equity Analysis
- Tapping New Markets
2. REPORT SYNOPSIS

An occlusion in the coronary artery that supplies blood to the heart muscles can lead to heart attack. In order to keep the arterial lumen open, a minute tubular support is given at the time of performing balloon angioplasty. This tubular scaffold placed at the site of pathological artery is referred to as a stent. This stent is carried by the balloon which inflates the occluded part of the artery, and after proper positioning, the balloon is deflated leaving the stent adhering to the wall of the artery. Restenosis or narrowing of the blood vessel again may occur despite the presence of the stent in about one-fourth of the patients in whom balloon angioplasty has been performed. Anyhow, this procedure reduces the risk of restenosis considerably.

Stents can be differentiated as per their material composition, open-, thickness of struts, and their capability of eluting drugs for local delivery. Stent design of may also be precise for certain indications like small (<2.5 mm diameter) vessels or lesions which results in bifurcation of a main vessel and side branch.

Bare metal stents (BMS) brought major enhancements in the balloon angioplasty as it recorded the drop in angiographic restenosis rate to 20% to 30% and target lesion revascularization rate to 10% to 15%.

Clinical restenosis in PTCA generally cause in the first year after which recurrent ischemia is much likely to occur following new or progressive disease at any other area other than restenosis. BMS related in-stent restenosis is likely to occur off late, due to atherosclerotic process progression within neointima.

BMS resulted in improved short-term results like less residual stenosis, exclusion of dissection, and less chances of in-hospital CABG and myocardial infarction. BMS is thus considered to be better option as compared to nonstent interventions (PTCA and atherectomy) for most patients.

Types of Stents

Stents are commonly used for the treatment of coronary arteries, and under such cases bare-metal stent, the drug-eluting stent, or a covered stent (in rare case) is inserted. This device is used as insertion material in the blood vessel. Upon insertion, this device expands the blood vessel thereby preventing the blockage. Coronary stents are inserted during angioplasty, a percutaneous coronary intervention procedure. Intracoronary stents are available in various forms.

There are three key varieties of stent which are used in the recent and advanced surgical procedures.

Bare-Metal Stents

A stent is made up of metal mesh. Stent is placed as permanent device. Surgical intervention is required for the removal of stent.

The metal stents has following drawbacks;

- Predisposition that leads to late stent thrombosis
- Late vessel adaptive is prevented or expansive modeling is prevented
- Problems related to surgical revascularization
- Imaging related problems particularly with masculine CT
Drug Eluting Stents (DES)

Drug-eluting stents (DES) grew in popularity around five years back and doctors began using them for the treatment of ‘atherosclerotic’ coronary heart disease. The polymer covering on the initial models of drug-eluting stents (DES) such as Cypher™ and Taxus™ were not biodegradable. Virmani et al examined carefully autopsy specimens and indicated that ‘late stent thrombosis’ after implantation of stent might have occurred due to the polymer. Researchers carried out several studies in order to establish this hypothesis. Mauri et al, making use of a ‘hierarchical’ categorization of stent thrombosis, stated that frequency of explicit or possible stent thrombosis occurrences in the DES series were at much elevated level than the bare-metal stent (BMS) grouping during a four year checkup. The general agreement on this these days is to continue with use of clopidogrel for a minimum of one year, probably for a longer period in patients after they underwent drug-eluting stent implantation, in order to avert stent thrombosis. In spite of this, the updated version of 2005 Percutaneous Coronary Intervention (PCI) Guidelines of American College of Cardiologists (ACC) / American Heart Association (AHA) suggest that a dose of ‘clopidogrel’ 75 mg/ day should be administered for a minimum of one month after BMS implantation, for three months after ‘sirolimus-eluting’ insertion and for six months after ‘paclitaxel-eluting’ stent implantation

Biodegradable Stents

Biodegradable Stent degrades completely leaving behind the well-developed blood vessel. The smooth muscle cell proliferation inhibition causes the eluted drug to minimize the volume of neo-intimal tissue and, thus limits about half of the restenosis frequency. It inhibits endothelial cell proliferation, and results in slow process of re-endothelialisation

Bioresorbable polymeric stents have become popular alternative for metallic stents as these can remain in situ for a predetermined period of time, these keep the wall of the blood vessel intact and ultimately disintegrates to non-toxic substances. A major part of the problems related to the metal stents are solved with this stent. There is evidence to support the fact that the use of bioresorbable coronary stent reduces the necessity for a substitute part after half a year. The use of bioresorbable stents is advocated in such cases where removal surgery is difficult. For e.g. in case of treatment of tracheomalacia in newborns and infants. The bioresorbable stents can help to release drugs and proteins into the blood through an intermediary wall.

Initially it was firmly believed that a corrosion resistant stent made of stainless steel will be an ideal support for diseased artery. Several improved variations have been introduced in the fabrication of stent, and the latest is to make bioabsorbable stents. Non-corrodible metal stents went into oblivion with the discovery of biodegradable/bioabsorbable stents. The novel stents make the drugs like Plavix redundant. Since the novel stents are non-metallic the patients had no need to expose themselves to MRI unnecessarily. The modern trend is to make a stent non-permanent and dissolve completely after allowing sufficient time for wound repair and tissue regeneration in the artery. Further, the products of disintegrating stent should be absorbable, safe, and non-toxic. The stent fabrication involves incorporating the drugs that prevent restenosis. The drugs should be released into the body fluid slowly

Bioabsorbable stents are said to possess following advantages:

- Restoration of blood flow.
- Good healing process. Vessel healing is done in about three months’ time.
Absorption option of the stent, when no longer needed.

No permanent implant is seen after absorption

2.2 Segmentation

Exhibit 1. Segmentation of Biodegradable Stents Market by Type and Application (2010 - 2020)

<table>
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<th>Type</th>
<th>Application</th>
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*Other Applications Includes Urethral, Esophageal etc.

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Exhibit 2. Segmentation of Biodegradable Stents by Application and by Biodegradable Material (2017 - 2022)

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</table>

*Other Applications Includes Urethral, Esophageal etc.

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2.3 Stents - Global Market Analysis

Growing at a CAGR of xx.xx % for the period from 2010 - 2020, global Stents market is projected to reach about US$ xx.xx billion by 2020, from an estimated US$ xx.xx billion in 2014.

Every year more than 1 million coronary stent procedures are performed in the United States.


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CAGR% xx.xx

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2.4 Biodegradable Stents - Global Market Analysis

Global Biodegradable Stents market is projected at US$ xx.xx billion in 2017, and is further projected to reach US$ xx.xx billion by 2022, increasing at a very high CAGR of xx.xx % during the analysis period 2017-2022.


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3. MARKET DYNAMICS

3.2 Stents - Global Market Analysis


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### 3.5 Biodegradable Stents


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3.6 Biodegradable Stents – Analysis by Application

The global coronary biodegradable arterial stents market is expected to reach about US$ xx.xx billion in 2015, to represent the largest market with a share of xx.xx %. Growing at a very high CAGR of xx.xx %, during the analysis period, the market is projected to reach almost US$ xx.xx billion in 2020.

Peripheral Arterial Stents represents the second largest market with a value of US$ xx.xx million in 2015 and is anticipated to cross US$ xx.xx billion by 2020, increasing at a CAGR of xx.xx %


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<tr>
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<td>XX.xx</td>
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3.7 Biodegradable Stents – Analysis by Material


<table>
<thead>
<tr>
<th>Year/Application</th>
<th>Polymer</th>
<th>Metal</th>
<th>Total</th>
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<tbody>
<tr>
<td>2017</td>
<td>xx.xx</td>
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<tr>
<td>2022</td>
<td>xx.xx</td>
<td>xx.xx</td>
<td>xx.xx</td>
</tr>
<tr>
<td>CAGR%</td>
<td>xx.xx</td>
<td>xx.xx</td>
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3.8 Biodegradable Stents – Market Outlook

Bioresorbable polymeric stents have become a popular alternative for metallic stents as these can remain in situ for a predetermined period of time, these keep the wall of the blood vessel intact and ultimately disintegrates to non-toxic substances. A major part of the problems related to the metal stents are solved with this stent. There is evidence to support the fact that the use of bioresorbable coronary stent reduces the necessity for a substitute part after half a year. The use of bioresorbable stents is advocated in such cases where removal surgery is difficult. For e.g. in case of treatment of tracheomalacia in newborns and infants. The bioresorbable stents can help to release drugs and proteins into the blood through an intermediary wall.

Biodegradable stents have still a lot way to go before hitting the market. Several controversies and lack of confidence in the product looms large. Though Abbott has developed its product in the United States, the company is conducting trials in Europe, Australia and New Zealand. This is because of the stringent regulation of the FDA on new medical devices.

Global biodegradable stents market is projected at US$ xx.xx billion in 2015, and is further projected to reach US$ xx.xx billion by 2020, at a whopping CAGR xx.xx % during the analysis period 2015-2020.
4. COMPETITOR DYNAMICS

4.1 Major Companies Profiles

Abbott Vascular (USA)
Biotronik SE & Co. KG (Germany)
Kyoto Medical Planning Co., Ltd. (Japan)
Reva Medical, Inc. (USA)
UK Medical (UK)
Xenogenics Corporation (USA)

4.2 Major Activities/Product Launches

First implantation of Elixir Medical's DESolve® Novolimus Eluting Coronary Scaffold System in Europe
BIOTRONIK Reports Use of First–in–Human Use of Bioabsorbable Magnesium DREAMS Scaffold
Elixir Reports Outstanding 1-year Results for Safety and Efficacy for 100% Bioresorbable DESolve® Novolimus Eluting Coronary Scaffold System
Elixir’s DESolve® Novolimus Eluting Bioresorbable Coronary Scaffold System Certified by CE
Asian Heart Institute Conducts Angioplasty with New Generation Biodegradable Stent
Elixir Medical Finalizes the Enrollment for the DESolve Nx Pivotal Trial Carried Out for Fully Bioresorbable Coronary Scaffold System
5. PRODUCT TECHNOLOGY/RESEARCH

The advent of coronary stent in 1986 brought about one of the most sweeping changes in the methods followed in interventional cardiology since its introduction in 1977. In spite of several advantages in using a metallic ‘drug eluting stent (DES)’, the trend has been to move away from this type of stents because of certain constraints in its functioning and consequently, adoption of ‘biodegradable technology’ in making stents has evoked a lot of interest among specialists in cardiology. These biodegradable stents are produced from polymers or ‘metal alloys’ either with coating of drugs or without it. This material has the ability to ‘scaffold’ the artery to facilitate healing in the natural course and after that it gets biodegraded or decomposed. However, the advances in this technology have been rather tardy with many biodegradable stents are only at the clinical trials and many others at still in the preclinical level in the development process. In the meantime, efforts are being made simultaneously to look into the limitations in using normal metallic DES, seeking especially, to reverse the sullied reputation that DES stents could cause ‘thrombosis’. Consequently, stents with more biocompatible polymer and DES that do not contain any polymer have been made and are at present being examined in clinical trials.

Exhibit 28. Biodegradable Polymer Coated Drug Eluting Stents and Drugs Used

<table>
<thead>
<tr>
<th>Stent</th>
<th>Drug Used</th>
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<tr>
<td>ABLUMINUS Sirolimus eluting stent system</td>
<td>Sirolimus</td>
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<tr>
<td>Active</td>
<td>Paclitaxel</td>
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<td>ALEX</td>
<td>sirolimus</td>
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<td>BioMatrix</td>
<td>Biolimus A9™</td>
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<td>IRIST</td>
<td>Simvastatin</td>
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<td>&quot;I need to focus on strategic opportunities&quot;</td>
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<td>- Sales &amp; Marketing Professional</td>
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<td>&quot;Am I spending on the right content?&quot;</td>
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<td>&quot;I require easy methods to search and share reports and insights&quot;</td>
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<tr>
<td>- Market Research Professional</td>
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<table>
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</thead>
<tbody>
<tr>
<td>&quot;I need market research that helps us make strategic decisions, keep pace and lets us keep control too&quot;</td>
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<tr>
<td>- Company Head</td>
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</table>

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