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2 Introduction

2.1 Peripheral Vascular Stents Overview

Peripheral vascular stent is an expandable perforated tube that is inserted into a peripheral vessel to prevent blood flow constriction. Carotid artery stents, Iliac artery stents, Infrapop stents, Renal stents and Fem-pop stents are covered under this segment.

- **Carotid Artery Stents**
  A carotid artery stent is the tube that is inserted in the Carotid artery, to increase the flow of blood blocked by plaque. It is generally recommended for people who are unable to undergo an endarterectomy. Only Bare Metal Stents are considered because in most of the surgeries Bare Metal Stents are used for the carotid artery stenting. One unit refers to one Carotid Artery Stent.

- **Iliac Artery Stents**
  An Iliac artery stent is the tube that is inserted in the Iliac artery to increase the flow of blood in the narrowed iliac arteries. Iliac Artery Stents includes Iliac Artery Bare Metal Stents, Iliac Artery Drug Eluting Stents, Iliac Artery Covered Stents, Iliac Artery Bio-absorbable Stents. One unit refers to one Iliac Artery Bare Metal Stent, one Iliac Artery Drug Eluting Stent, one Iliac Artery Covered Stent and one Iliac Artery Bio-absorbable Stent.
  Iliac Artery Bare-metal stent is a stent without a coating. It is a mesh-like tube of thin wire.
  Iliac Artery Drug-Eluting stent is coated with a medicine or drug that helps further prevent the arteries from re-closing.
  Iliac Artery Covered Stent is a flexible tube used to repair or support a damaged section of an artery. These stents are made up of a metallic frame which is covered by durable fabric.
  Iliac Artery Bio-absorbable Stent is manufactured from a material that may dissolve or be absorbed in the body.

- **Fem-pop Stents**
  A Fem-pop Stent is a tiny, expandable metal coil that is inserted into the femoral and popliteal arteries located in thigh and knee during the femoropopliteal artery stenting procedures. Fem-pop Artery Stents includes Fem-pop Artery Bare Metal Stent, Fem-pop Artery Drug Eluting Stent, Fem-pop Artery Covered Stent and Fem-pop Artery Bio-absorbable Stent. One unit refers to one Fem-pop Artery Bare Metal Stent, one Fem-pop Artery Drug Eluting Stent, one Fem-pop Artery Covered Stent and one Fem-pop Artery Bio-absorbable Stent.
  Fem-pop Artery Bare-metal stent is a stent without a coating. It is a mesh-like tube of thin wire.
  Fem-pop Artery Drug-Eluting stent is coated with a medicine or drug that helps further prevent the arteries from re-closing.
  Fem-pop Artery Covered Stent is a flexible tube used to repair or support a damaged section of an artery. These stents are made up of a metallic frame which is covered by durable fabric.
  Fem-pop Artery Bio-absorbable Stent is manufactured from a material that may dissolve or be absorbed in the body.

- **Renal Stents**
  Renal stent is a tube that is inserted in the renal arteries to increase blood flow to kidneys. Only Bare Metal Stents are considered because in most of the surgeries Bare Metal Stents are used for the Renal Artery Stenting. One unit refers to one Renal Stent.
• **Infrapop Stents**

An Infrapop Stent is a tiny, expandable metal coil that is inserted to establish flow in the tibial, peroneal or pedal arteries. Infrapop Artery Stents includes Infrapop Artery Bare Metal Stents, Infrapop Artery Drug Eluting Stents, Infrapop Artery Covered Stents and Iliac Artery Bio-absorbable Stents. One unit refers to one Infrapop Artery Bare Metal Stent, one Infrapop Artery Drug Eluting Stent, one Infrapop Artery Covered Stent and one Iliac Artery Bio-absorbable Stent.

Infrapop Artery Bare-metal stent is a stent without a coating. It is a mesh-like tube of thin wire.

Infrapop Artery Drug-Eluting stent is coated with a medicine or drug that helps further prevent the arteries from re-closing.

Infrapop Artery Covered Stent is a flexible tube used to repair or support a damaged section of an artery. These stents are made up of a metallic frame which is covered by durable fabric.

Infrapop Artery Bio-absorbable Stent is manufactured from a material that may dissolve or be absorbed in the body.
3 Products under Development

3.1 Peripheral Vascular Stents - Pipeline Products by Stage of Development

![Pipeline Products by Stage of Development](chart)

**Figure 1: Peripheral Vascular Stents - Pipeline Products by Stage of Development**

**Source:** Primary and Secondary Research, GlobalData
As of April, 2015

**Table 1: Peripheral Vascular Stents - Pipeline Products by Stage of Development**

<table>
<thead>
<tr>
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<tr>
<td>Pre-Clinical</td>
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<tr>
<td>Clinical</td>
<td></td>
</tr>
<tr>
<td>Issued</td>
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<tr>
<td>In Approval Process</td>
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**Source:** Primary / Secondary Research, GlobalData
As of April, 2015
3.2 Peripheral Vascular Stents - Pipeline Products by Segment

Table 2: Peripheral Vascular Stents - Pipeline Products by Segment

<table>
<thead>
<tr>
<th>Category Name</th>
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<tr>
<td>Carotid Artery Stents</td>
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<tr>
<td>Iliac Artery Stents</td>
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<tr>
<td>Renal Stents</td>
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<td>Tracheobronchial Stent</td>
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<td>Fem-pop Stents</td>
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</table>

Source: Primary / Secondary Research, GlobalData

As of April, 2015
3.3 Peripheral Vascular Stents - Pipeline Products by Territory

![Figure 3: Peripheral Vascular Stents - Pipeline Products by Territory](chart)

Source: Primary and Secondary Research, GlobalData
As of April, 2015

<table>
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<tr>
<th>Territory</th>
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Source: Primary / Secondary Research, GlobalData
As of April, 2015
7 Appendix

The data and analysis within this report is driven by GlobalData. GlobalData gives you key information to drive sales, investment and deal making activity in your business. Our coverage includes 200,000 + reports on 185,000+ companies (including 150,000+ private) across 200+ countries and 29 industries. The key industries include Alternative Energy, Oil & Gas, Clean Technology, Technology and Telecommunication, Pharmaceutical and Healthcare, Power, Financial Services, Chemical and Metal & Mining.

7.1 Methodology

GlobalData company reports are based on a core set of research techniques which ensure the best possible level of quality and accuracy of data. The key sources used include:

- Company Websites
- Company Annual Reports
- SEC Filings
- Press Releases
- Proprietary Databases

Taxonomy:

GlobalData has developed an industry-leading four tier (market, category, segment, subsegment) medical devices taxonomy. The taxonomy is both comprehensive and constantly updated ensuring data quality. The report published is a category based report where the product taxonomy vary from category level to sub-segment level.

Origination:

GlobalData’s pipeline products and clinical trials data is built using information and data from a number of important sources based on both internal and external sources to develop a comprehensive and robust view of the medical devices market.

Secondary Research:

Extensive secondary research is done to gather data specific to the pipeline products and clinical trials. We track medical devices that are in development related to nearly 18 markets (ie, cardiovascular devices, dental devices etc) that we cover. GlobalData conducts extensive research to gather data specific to pipeline products (product status, current stage of development, product description, technology and estimation timelines of medical devices) and clinical trials. Hundreds of medical specific live news sources are monitored on a daily basis.

Primary Research:

Primary research is conducted to validate the product status, stage of development and estimated timelines. GlobalData’s pool of primary research candidates for the pipeline products enquiries includes marketing / product managers, R&D director, sales director and key person involving with regulatory process.
Updates:
All pipeline products are updated at least once in a quarter. Products are updated through secondary research sources such as live news, press releases, company websites, presentations, sec filings, transcripts etc.
GlobalData uses an in house template to estimate product approval date and product launch date in case if data is not obtained either through secondary or primary research. The template uses various parameters (pipeline territory (region), device class, stage of development, product source date) to analyze and estimate the product approval/launch date.
A wide range of factors are considered while estimating timelines for the medical devices.

Notes
• Financial information for the company is taken from the most recently published annual reports or SEC filings
• The number of products mentioned in various graphs can be inconsistent due to plotting of different fields
• Pipeline Products by Stage of Development Graph - Displays exact count of pipeline products
• Pipeline Products by Segment Graph - Products tagged directly to sector is not included but its sub-level tagging is shown
• Pipeline Products by Territory Graph - Displays count of all multiple territories tagged to pipeline products
• Pipeline Products by Regulatory Path Graph - Displays only count of territories for which Regulatory Path is defined
• Pipeline Products by Estimated Approval Date Graph - Displays count of all estimated approval dates tagged to multiple territories
• Only the below mentioned status of Clinical trials are included in the report specific to the pipeline products:
  Ongoing, Recruiting
  Ongoing, not Recruiting
  Ongoing, Recruiting by invitation
  Ongoing, not yet recruiting
• Recent Development section covers news posted during last six months
• GlobalData considers regulatory approved (Approved and Issued) products as pipeline in case products are yet to launch in the market.

Table 172: Glossary

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Name</td>
<td>Indicates product name</td>
</tr>
<tr>
<td>Developed By</td>
<td>Provides information of the company which develops the product</td>
</tr>
<tr>
<td>Product Description</td>
<td>Provides information on product (What is the condition, where it will be used, benefits, technical specifications etc)</td>
</tr>
<tr>
<td>Indication</td>
<td>Provides information on the therapeutic or diagnostic conditions where the product is used</td>
</tr>
<tr>
<td>Application</td>
<td>Indicates the procedure or intervention for which the selected product is used</td>
</tr>
<tr>
<td>Device Class</td>
<td>Provides product class information based on their design complexity, characteristics and risk factors i.e. Class I, II and III</td>
</tr>
<tr>
<td>Highest Stage of Development/Development stage</td>
<td>Provides information on the developmental status e.g. early development, pre-clinicals, clinical, in approval process</td>
</tr>
<tr>
<td>Territory</td>
<td>A geographic region where the product is currently in pipeline or will be commercially launched</td>
</tr>
<tr>
<td>Estimated Approval Date</td>
<td>Provides information on expected product approval date</td>
</tr>
<tr>
<td>Market Category/Equipment Type</td>
<td>Indicates the classification of a medical device based on therapy area and application</td>
</tr>
<tr>
<td>Regulatory Path</td>
<td>Regulatory process through which the product gets marketing</td>
</tr>
<tr>
<td>Technology</td>
<td>Indicates the core technology used in product</td>
</tr>
<tr>
<td>Function</td>
<td>Provides information about the mechanism of action of the device</td>
</tr>
<tr>
<td>Early Development</td>
<td>Defined when a product is in prototype or design stage of development</td>
</tr>
<tr>
<td>Pre Clinical</td>
<td>Defined when a product is tested in animals</td>
</tr>
<tr>
<td>Clinical</td>
<td>Defined when a product is tested in humans for the safety and efficacy of the device</td>
</tr>
<tr>
<td>In Approval Process</td>
<td>Defined when a product is filed for approval with regulatory body for approval of the product</td>
</tr>
<tr>
<td>Issued</td>
<td>Defined when a product receives regulatory approval from European Union</td>
</tr>
<tr>
<td>Approved</td>
<td>Defined when a product receives regulatory approval from a country other than Europe</td>
</tr>
<tr>
<td>Planned (Ongoing, not yet Recruiting)</td>
<td>The participants are not yet to be recruited or enrolled for the study</td>
</tr>
<tr>
<td>Ongoing, Recruiting</td>
<td>The participants are currently being recruited or enrolled for the study</td>
</tr>
<tr>
<td>Ongoing, not Recruiting</td>
<td>The study is still ongoing. The patients are being treated or examined or study results are being analyzed for its endpoints. But enrollment for the study stands completed</td>
</tr>
<tr>
<td>Ongoing, Recruiting by invitation</td>
<td>The participants are being (or will be) selected from a predetermined population (as decided in advance by the researchers)</td>
</tr>
<tr>
<td>Global (Pipeline territory)</td>
<td>If source does not indicate any specific country as pipeline region, then Global is added as the pipeline territory</td>
</tr>
</tbody>
</table>

Source: Primary / Secondary Research, GlobalData
As of April, 2015

7.2 About GlobalData

GlobalData is one of the world’s leading providers of company operational data and strategic analysis, providing detailed information on tens of thousands of companies globally. Our highly qualified team of Analysts, Researchers, and Solution Consultants use proprietary data sources and various tools and techniques to gather, analyze and represent the latest and the most reliable information essential for businesses to sustain a competitive edge. Data is continuously updated and revised by large teams of research experts, so that it always reflects the latest events and information. With a large dedicated research and analysis capability, GlobalData employs rigorous primary and secondary research techniques in developing unique data sets and research material for this series and its other reports. GlobalData offers comprehensive geographic coverage across world’s most important sectors, focusing particularly on energy and healthcare.

7.4 Disclaimer

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