Global Incontinence Care Products and Devices Market Assessment & Forecast: 2015-2019

Segments Assessed: Adult Diapers (Underwear & Briefs, Pads & Guards, Liners and Drip Collection), Catheters (Foley, Intermittent and Male External), Drainage Collection Bags, Urinary and Bowel Sphincters, Slings, Pessaries, Clamps and Nerve Stimulation Devices.

Geographies Assessed: North America, Europe, Asia-Pacific, Latin America, Middle-East and Africa.
About Us

Spearhead Acuity Business Research & Consulting (SA-BRC) is a premium Life Science business intelligence and data analytics firm. SA-BRC team offers a wide range of business intelligence services to multiple stakeholders such as Medical Device Manufacturers, Service Providers (Hospitals, Payers, etc.), Suppliers, Group Purchase Organizations, Distributors and all other individuals in the entire value chain of healthcare industry. Our research and consulting capabilities extend across several sub-domains within the sphere of Life Sciences such as Biotechnology, Healthcare IT, Medical Devices, Veterinary Sciences, Wellness Products and Pharmaceuticals.

Our skills and capabilities help in putting forth the most accurate perspective of the market. We track all major and minor events that create ripples and affect the life-science market in different ways. Our data modeling process includes the evaluation of impacting events and analyzing other invaluable sources (public & proprietary) of information and finally reporting results that will influence the decision making of the readers.

SA-BRC has helped start-ups and market leaders across the globe achieve their revenue goals strategically in multiple stages such as adoption, pre-launch research, regional analysis, social media analytics, competitive mapping, market entry and post marketing surveillance. We frequently build panels of experts for gathering data and invite participants of the healthcare industry to share their opinions and views on our reports. Our current network of industry experts span across all major life-science domains and take pride in keeping ourselves abreast with the latest happenings within the sphere of Life-Science.
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### Chapter 1  Preface

#### 1.1 Research Scope

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<th>Description</th>
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<tr>
<td>Chapter 1:</td>
<td>Research Scope</td>
<td>The preface provides a brief overview of the flow of the research report. The overview is further supplemented by a graphical representation of the segments analyzed in the report. This is followed by the postulations or assumptions considered for analysis of different segments.</td>
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<td>Chapter 1:</td>
<td>Research Methodology</td>
<td>Provides the methodology adopted by SA-BRC while estimating the current and future market in terms of value.</td>
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<td>Chapter 2:</td>
<td>Inferences &amp; Summary</td>
<td>The chapter lists down key (quantitative and qualitative) highlights and takeaways of the market as reported in the study.</td>
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<td>Chapter 3:</td>
<td>Drivers, Inhibitors &amp; Opportunities</td>
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</tr>
<tr>
<td>Chapter 4:</td>
<td>Market Estimations for Products in the Incontinence Care Products and Devices</td>
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</tr>
<tr>
<td>Chapter 6:</td>
<td>Recent Developments &amp; Competitive Strategies</td>
<td>Elaborates the market share of key players (2014), recent developments for the years 2013, 2014 &amp; 2015 and major competitive strategies adopted by companies in this area based on events for past 2 years.</td>
</tr>
</tbody>
</table>
1.1.1 Market Segmentation

FIG. 1 Market Segmentation: Incontinence Care Products and Devices

Incontinence Care Products & Devices Market Assessment: Forecast 2015 - 2019

Products
- Adult Diapers
  - Undergarments & Briefs
  - Liners & Drip Collectors
- Incontinence Slings
  - Male Incontinence Slings
  - Female Incontinence Slings
- Incontinence Catheters
  - Foley Catheters
  - Male External Catheters
- Incontinence Drainage Bags
  - Gellhorn Pessaries
- Incontinence Pessaries & Clamps
  - Ring Pessaries
  - Other Pessaries
  - Clamps
- Nerve Stimulation
  - Sacral Nerve Stimulation
- Artificial Sphincters
  - Electrical Nerve Stimulation
  - Artificial Urinary Sphincters
  - Artificial Bowel Sphincters

Demography
- North America
- Europe
- Asia-Pacific
- Latin America
- Middle-East
- Africa

Source: SA-BRC Analysis
1.1.2 Postulations

Certain assumptions were considered in order to estimate the complete forecast of the Incontinence Care Products and Devices Market. These have been detailed below:

- Market estimations are reported assuming that no major economical event (rise or fall) may occur during the forecast period. The estimations reported in the study provide the best possible outcome based on current market trends and certain foreseeable future market events.

- For estimating market of pessaries, only the three most commonly used types have been included in this report. The three types were chosen based on reviews and responses from urologists and gynecologists that have been prescribing them as treatment.

- For the purpose of market estimation, Liners and Drip Collection products have been assumed in a single segment. The assumption was considered since the market for drip collection products is negligible as compared to any other segment and cannot be separately analyzed under the global scope of the assessment.

- Market estimates have been calculated by considering average cost of products and devices in a particular region.

- Injections with bulking agents have not been covered in the scope of this report and will be a part of upcoming project on cosmetic injectable market.
## 1.2 Methodology of Research

### FIG. 2 Research Methodology: Global Incontinence Care Products and Devices Market Assessment

<table>
<thead>
<tr>
<th></th>
<th>Primary Research</th>
<th>Secondary/Desk Research</th>
</tr>
</thead>
</table>
| **Quantitative Research** | • Online-web (CATI/CAWI/CAPI)  
• Telephonic and video conference  
• Interviewee Location: Multiple respondents from each of 6 geographies  
• Interviewee Field Exp.: All interviewees were c-level, d-level, VP level and senior management  
• Target Information: validation of secondary findings; cross-verification of other primary interviews,  
• Organization – Research Institutes, Manufacturers, Distributors, Resellers | • Proprietary third party databases  
• In-house data repository  
• Company websites  
• Annual Reports/ SEC Filings  
• Investor presentations  
• Equity & Stock (Seeking Alpha, Zacks, Medical Buyer etc.) |
| **Qualitative Research** | • Scientist blogs  
• Online communities/Scientist Forums  
• Online chat with KOLs/experts  
• Focused Group Discussions  
• Target Information: Insights on market trends, market impact factors, marketing and awareness programs etc. | • Unicef.org, CDC, WHO, NHS, NIH  
• Pubmed, healthynewbornnetwork.org  
• MedIntensiva.org, news-medical.net  
• nonwovens-industry.com, mcknights.com  
• Medicalbuyer.com, arabhealthonline.com  
• Simonfoundation.org  
• Canadian Continence Foundation, National Association for Continence, American Urological Association  
• Up-to-date, sciencedirect, WileyOnline  
• TrendsinMensHealth.com |

Data triangulation was done for the information (quantitative/qualitative) collected through primary and secondary sources. Analysis also included evaluation of all major macro and microeconomic factors.

Post data triangulation process, the summary of our study was shared with KOLs and industry experts to suggest further insights to our analysis as well as validate the overall Incontinence Care Products and Devices Market.

Source: SA-BRC Analysis. **Websites mentioned in the above representation are few examples from our exhaustive list of references that cannot be compiled in entirety.
1.2.1 Companies covered in this report

**TABLE 1 List of companies covered in this report**

| S.No | Company Name                      | S.No | Company Name
<table>
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<th></th>
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<tbody>
<tr>
<td>1</td>
<td>Medtronic Inc</td>
<td>2</td>
<td>ColoPlast</td>
</tr>
<tr>
<td>3</td>
<td>Svenska Cellulosa Aktiebolaget (SCA)</td>
<td>4</td>
<td>Ontex</td>
</tr>
<tr>
<td>5</td>
<td>Kimberly Clark (K-C)</td>
<td>6</td>
<td>B.Braun</td>
</tr>
<tr>
<td>7</td>
<td>Endo (American Medical Systems)</td>
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<td>Johnson &amp; Johnson (Ethicon)</td>
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<td>Pelvalon Inc</td>
</tr>
<tr>
<td>11</td>
<td>UniCharm</td>
<td>12</td>
<td>StimGuard</td>
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</tbody>
</table>

Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis
Chapter 2 Précis

2.1 Market Inferences

Key highlights and insights to the global incontinence care products and devices market:

- The Incontinence Care Products and Devices Market was valued at US$ 9,861.3 million in 2014 and expected to grow to US$ 13,747.7 million by 2019 at a CAGR of 6.9% from 2015 to 2019.

- Sacral Nerve Stimulation devices are anticipated to grow the fastest with CAGR of 18.7% from 2015 to 2019. Increasing incidence of fecal and urinary incontinence in North America and Europe is a significant growth driver for this device segment. The rise in incidence subsequently has been estimated largely aided by the aging population in the developed regions.

- The adult diapers (pads, guards, briefs, liners, drip collection, etc) was the largest market segment by value in 2014 that generated sales of US$ 7,322.9 million representing 74.3% share of the total market.

- Artificial Sphincters and Incontinence Slings & Meshes were the slowest growing segments in the market. Severe setbacks to sling & mesh manufacturers due to side-effects and constant litigations by patients have severely curtailed the growth for the moment.

- North America continued to lead global incontinence care products and devices market with a share of 32.0% in 2014 that translated into revenues worth US$ 3,152.6 million.

- Middle-East is expected to be the most potential market with CAGR 8.7% for 2015-2019, whereas Africa is estimated to be the slowest of the six regions and is anticipated to grow at a CAGR of 2.4% from 2015 to 2019. Middle East and Asia-Pacific are estimated to be the most profitable regions in coming years.

- SCA was a leader in the Adult Diapers Market segment with a share of 37.3%. Medtronic Inc was estimated to be the unchallenged leader in the Sacral Nerve Stimulation market with a share of over 90%. Endo, Ethicon and Coloplast were the leading players in the Incontinence Slings & Meshes (TVM) market with shares worth 26.0%, 13.0% and 8.0% respectively.
The global adult diapers market was valued at US$ 7,322.9 million in 2014, representing the largest market segment in terms of revenues in the overall incontinence care and management products market. Rise in the elderly population with urinary and fecal incontinence problems, increased awareness of personal hygiene, large range of products both for men and women, development of innovative products that provide better comfort and hygiene, easy availability of products, innovative environment friendly products such as biodegradable, light and fluffless adult diapers are some of the factors that will drive the growth of global adult diapers market at a CAGR of 7.2% from 2015 to 2019.

![Pie charts showing market share by region in 2014 and 2019](chart.png)

Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis
Chapter 3  Market Dynamics

3.1  Market Drivers

3.1.1 Rising geriatric population

A rapidly rising geriatric population base is one of the major factors responsible for the rise in incidences of urinary incontinence. This will drive the demand for incontinence devices in elderly population. According to the estimations of the United Nations University (UNU), the percentage of the world’s population above the age of 65 years will increase from 7% in 2000 to 16% in 2050. A study conducted by WHO in 2005, also determined that urinary incontinence is a major consequence of ageing. Therefore, constant rise in the base of geriatric population will keep the impact of this driver at a high level throughout the forecast period.

FIG. 4  Global Aging Population 2014 (%)

Source: HelpAge International
3.1.2 Increasing awareness and acceptance of incontinence as a debilitating condition

Discomfort, stress and embarrassment in wearing incontinence products in social gatherings is a major concern for incontinence patients. Hence, acceptance level of incontinence care products is quite low especially among men. According to SCA group, only 20% of all men with incontinence use care products that are available in the market. Creating awareness through various initiatives by NGOs, WHO and other healthcare organizations will increase the acceptance for incontinence care products. Rising acceptance of incontinence will fuel the market growth with high impact during the forecast period.

3.1.3 Increasing demand for personalized products

Rising costs of hospital care and therapy is leading to amplification of demand for personalized incontinence care products such as urinary bag, briefs, underwear, guards and shields. Further development in the technology will increase the demand for incontinence care products with high level of compliance. New fabrics and non-woven material entering the market is reducing cases of allergies and helping patients keep their condition inconspicuous. This factor will have a high impact on the growth of the incontinence care market.

3.2 Market Inhibitors

3.2.1 Presence of substitutes

An incontinence patient may be addressed with any of the available treatment methods such as drug therapy, surgery, nerve stimulation, catheterization and use of devices, depending on the convenience and the clinical boundaries of the clinician. Medicines impede the growth for demand of the incontinence care devices. Also, availability of internal substitutes such as a brief for underwear; and intermittent self-catheterization for intermittent catheterization, impedes the overall market growth. Further development of such alternatives, catering to the demand for technologically advanced incontinence care products will restrain the growth for conventional treatment methods. This factor will have a medium impact on the growth of the incontinence care market.

3.2.2 Low cost manufacturers

Due to presence of wide array of products in the incontinence care market, small players are gaining interest in this market and are providing products at a lower price. Increased penetration of private label brands, at discounted prices, has led to decrease in the overall average price of a product. Such
a restrain, pulls the overall market size down, decreasing demand for the established expensive products and thus hinder the market growth.

3.3 Opportunities

3.3.1 Emerging economies and high birth rate countries

Asia-Pacific has a very large diabetic and obese population, and diabetes is considered as one of the major reasons for causing incontinence. Due to nerve damage, diabetics have an increased risk of over 70% to develop incontinence thus incontinence may be observed in all age groups. This brings to attention the true market potential for incontinence products in this region. Along with this, a very large aged population in countries such as Japan, China and South East Asia is considered as an unmet demand that is now being capitalized upon by Asian majors such as Uni-Charm and Daio Paper Corporation, Kao Corporation, Koyo Corp, Carmelton Company and several other private label companies. In 2014, Adult diapers sold more than child diapers illustrating new dimensions developing in the incontinence market. Increasing potential has been high enough to attract conventional baby diaper leaders and an apt illustration of this is the decision of P&G to enter the incontinence market in the year 2013.
Chapter 4 Incontinence Care Products and Devices Market – Global Market Size Assessment by Devices, Forecast: 2015 - 2019

4.1 Introduction

The inability to control the evacuative urination or defecation functions of the body is known as incontinence. Urinary and fecal incontinence involves the loss of control of bladder function and bowel or fecal evacuation. Some of the medical conditions such as excess urine formation, enlarged prostate, multiple sclerosis, spinal cord injury, Parkinson's disease, muscle damage, and loss of storage capacity in the rectum can cause urinary and fecal incontinence. A large population globally, including both the aged and adolescent, suffers from chronic urinary and fecal incontinence problems, due to which the global market for incontinence care and management products is lucrative for the manufacturers and distributors of various kinds of adult diapers. Incontinence is also a common effect of spinal cord injury (SCI), traumatic brain injury (TBI) and Post Traumatic Stress Disorders (PTSD)—injuries that predominantly affect young men, many of them military veterans.

The global Incontinence Care Products and Devices Market was valued at US$ 9,861.3 million in 2014 and expected to grow to US$ 13,747.7 million by 2019 at a CAGR of 6.9% from 2015 to 2019.

Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis
In the incontinence catheters market, the major types of urological catheters available in market are intermittent catheters and non-intermittent catheters. Urological catheters are available in many sizes, types (straight, Foley, coude tip) and materials (silicone, latex, Teflon). The key growth drivers for this market include the aging population worldwide, mainly in developed countries like the U.S., Japan and Western Europe, and the increased incidences of urological disorders that require catheterization. The better healthcare facilities and increasing awareness worldwide will also drive growth of this market. The technological advancements such as using antimicrobial coatings over catheters prevents formation of crusts and biofilms; using newer and safer materials to enhance pre and post catheterization experience, is expected to drive the sales of urological catheters in future. The European market is the largest regional market for incontinence catheters; with Germany being the largest contributor within the region. The North American market led by the U.S. follows the European market, and is picking up in terms of growth due to the favorable Medicare policies for reimbursement for incontinence catheters. The global market for neurostimulation devices, particularly those for treatment of urinary incontinence is set to spur in the given period of forecast. Neurostimulation devices are created to treat a variety of nerve disorders including Parkinson’s disease, urinary incontinence and chronic pain. Currently, a new era has come up wherein the major goal for the researchers is to understand the best indications to be treated by available neurostimulation modalities such as direct nerve stimulation, sacral nerve stimulation and Pudendal nerve stimulation.


The inability to control the evacuative urination or defecation functions of the body is known as incontinence. Urinary and fecal incontinence involves the loss of control of bladder function and bowel or fecal evacuation. Some of the medical conditions such as excess urine formation, enlarged prostate, multiple sclerosis, spinal cord injury, Parkinson’s disease, muscle damage, and loss of storage capacity in the rectum can cause urinary and fecal incontinence. A large population globally, including both the aged and adolescent, suffers from chronic urinary and fecal incontinence problems, due to which the global market for adult diapers is lucrative for the manufacturers and distributors of various kinds of adult diapers. The global adult diapers market was valued at US$ 7,322.9 million in 2014 and forecast to reach US$ 10,367.0 million by 2019 with a CAGR of 7.2 % from 2015 to 2019.

Increase in the aged population with urinary and fecal incontinence problems, increased awareness of personal hygiene, large range of products both for men and women, development of innovative products that provide better comfort and hygiene, easy availability of products, innovative
environment friendly products such as biodegradable, light and fluffless adult diapers are some of the factors that will drive the growth of global adult diapers market. However, factors such as nutritional supplements, high cost, side effects such as skin rashes; allergy can hinder the growth of this market to some extent.

Adult diapers are available in different types based on materials and absorbency required. Some patients require light incontinence protection for which thin pads and liners may be sufficient, however, in many instances the incontinence can by heavy and require thick absorbent layers and think briefs and underwear. Materials used for making pads include polyester, hydrogel absorbent with viscose rayon, polypylene or polyethylene coverstock, fluff wood pulp and others. Adult diapers are used for both urinary incontinence and fecal incontinence. Some varieties of adult diaper products include all-in-one cloth diaper, contoured cloth diaper, prefold adult cloth diaper, disposable underwear, adult underwear, beltless underwear, briefs with fastening, briefs with non-fastenable tabs, pad and pant systems and male drip collectors for light incontinence. Absorbency booster pads that are commonly worn inside adult diapers for extra absorbency usually lack elastic and waterproof outer barriers. When the main adult diaper is unable to absorb the urine these booster pads help in absorbing a few ounces of urine. These absorbency booster pads come in various lengths and widths.


<table>
<thead>
<tr>
<th>Segment</th>
<th>2014</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underwear &amp; Briefs</td>
<td>53.5%</td>
<td>51.8%</td>
</tr>
<tr>
<td>Pads &amp; Guards</td>
<td>26.9%</td>
<td>27.6%</td>
</tr>
<tr>
<td>Liners &amp; Drip Collection</td>
<td>19.6%</td>
<td>20.6%</td>
</tr>
</tbody>
</table>

Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis

Geographically, North America dominates the adult diapers market followed by Asia-Pacific due to its large pool of aging population suffering from adult incontinence problems. According to the National Association for Continence, more than 25 million Americans suffer from incontinence or other
bladder-control problems. Of this population, up to 50% are from nursing homes and facilities. Few of the leading companies involved in the manufacturing and distribution of adult diapers are Kao Corporation, Kimberly-Clark Corporation, Svenska Cellulosa Aktiebolaget (SCA) and Uni-Charm Corporation amongst others such as Ontex Global and The Boots Company PLC.


Adult underwear and briefs are disposable incontinence protection innerwear designed to be pulled over without the hassle of fasteners and adhesive tapes. They have absorbent lining with elastic around waist and legs to contain leaks. Some brands have underwear specifically designed for men or women, however, the most absorbent pull-ons are unisex models. For aged people, they are also worn instead of innerwear and can be left on overnight as well. As with most absorbents, the products are categorized for patients according to the level of incontinence ranging from light to heavy. However, underwear and briefs are typically used in cases of heavy incontinence throughout day and night.

In 2014, the global underwear and briefs market was valued at US$ 3,916.3 million and is estimated to grow to reach US$ 5,373.2 million by 2019 at a CAGR of 6.5% from 2015 to 2019. Key companies in this segment are Kimberly-Clark Corporation, Svenska Cellulosa Aktiebolaget (SCA), and Uni-Charm Corporation.
4.2.2 Pads & Guards Market, US$ Mn (2013 - 2019)

Pads and guards are similar to liners and are worn inside innerwear. The pads and guards are capable of being worn inside absorbent underwear and briefs as well for increased protection. Although pads can be worn by both male and females, guards are typically shaped for male anatomy and can be inserted in-front of the male genitalia. Prevail brand of guards are most popular for heavy incontinence and said to have the highest absorbency of up to 19 oz of fluid which is almost half a litre. Several other brands with high absorbency are available and available in pharmacies as well as supermarkets.

![FIG. 8 Incontinence Adult Diapers – Global Pads & Guards Market 2013 – 2019 (US$ Millions)](image)

Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis

In 2014, the global pads & guards market was valued at US$ 1,971.3 million and is estimated to grow to reach US$ 2,858.2 million by 2019 at a CAGR of 7.7% from 2015 to 2019. Due to increased activity of aged people as well as demand for greater discreetness, the market for liners, pads and guards is growing faster than conventional underwear and briefs.

4.2.3 Liners and Drip Collection Devices Market, US$ Mn (2013 - 2019)

Liners and Shields are thin absorbent products that are positioned inside a patient’s innerwear with the help of adhesive strip that attaches to the bottom of the innerwear. The liner has a moisture-proof backing with the highly absorbent core which provides excellent absorption capacity maintaining skin dryness and odor reduction.
Drip collection products are similar to guards, however they comprise a compartment or a pocket in order to completely surround the male genitals to absorb any moisture and dribble. It is composed of a padded sheath that is highly absorbent. The product is exclusively used by male patients and it is noted that several patients find them uncomfortable to wear, however these can be extremely effective in preventing urine leakage. In 2014, the global liners and drip collection products market was valued at US$ 1,435.3 million and is estimated to grow to reach US$ 2,135.6 million by 2019 at a CAGR of 8.3% from 2015 to 2019.

### 4.3 Incontinence Catheters Market, US$ Mn (2013 - 2019)

Urinary catheters also referred to as Foley catheters have been in use since 1934 for the drainage of bladder and collection of urine. It involves insertion of plastic or rubber tube into the urethra and then advancing the tube into the bladder. This report analyzes the market for three different types of products, namely, Foley catheters, intermittent catheters and male external catheters. It is sometimes used to inject medicinal liquids for treatment and diagnosis in the patient's urinary bladder. The major types of urological catheters available in market are intermittent or Robinson catheters and non-intermittent (include indwelling and condom) catheters. Urological catheters are available in many sizes, types (straight, Foley, coude tip) and materials (silicone, latex, Teflon).
4.3.1 Foley Catheters, US$ Mn (2013 - 2019)

Foley catheters are thin sterile flexible tubes that are the most common type of indwelling urinary catheters. The catheter is held in place by a balloon at the tip that is inflated with sterile water. The balloons typically come in two different sizes: 5 cm³ and 30 cm³. They are commonly made using silicone rubber, polyurethane, latex or natural rubber. Foley catheters are used not only for incontinence but also drainage in case of patients who are immobile or have reduced ambulation.
An indwelling urological catheter is used with a drainage bag and is left in the urinary bladder. It can be used for short time periods as well as for longer time depending on the patient’s condition and requirement. This type of catheter can be inserted through the urethra or through a small hole in the abdominal region. The global market for Foley catheters was valued at US$ 771.5 million in 2014. The market is expected to grow at a CAGR of 6.5% from 2015 to 2019 to reach US$ 1,056.1 million by 2019. The major driver of this market is the absence of multiple substitutes in this market, particularly in developing regions of the world. The major challenge restricting the growth of the market is the high incidence of CAUTI or catheters associated urinary infection. The market is thus expected to grow a shade slower than the market for Robinson catheters. Some of the leading products in this category are Rutner Universal Wedge Catheter and Uroradiometric Catheter Set from Cook Medical Inc., Duraflow 2 Hemodialysis catheters from AngioDynamics, Inc. and Specialty Latex Foley Catheters from Covidien.

### 4.3.2 Intermittent / Robinson Catheters, US$ Mn (2013 - 2019)

Intermittent catheters are thin flexible tubes that are primarily made of silicone, rubber, latex or plastic. Unlike Foley catheters that are indwelling, intermittent catheters are inserted to drain urine periodically directly into pans or into drainage bags. An intermittent urological catheter is used only when needed and is removed from the body when the flow of urine has stopped. Generally the intermittent catheter is used at least every six hours and before going to bed. The intermittent catheter is used to help protect the kidneys, prevent incontinence (urine leakage) and lessen the number of infections by promoting good drainage of the bladder, while lowering pressure inside the bladder.

![FIG. 12 Incontinence Care Products and Devices – Global Intermittent/Robinson Catheters Market 2013 – 2019 (US$ Millions)](image)

Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis
These devices provide greater independence to the patient and help reduce the incidence of CAUTI. These catheters also have two to six holes to facilitate drainage, especially in the presence of blood clots that may occlude one or more openings. The catheter is used in patients under a rehabilitation program where intermittent catheterization is routinely done to monitor improvement in the patient’s bladder function. Some of the leading players in this market are Rochester Medical Corporation, Teleflex, Inc, Dover catheters from Kendall-Covidien (now part of Medtronic Inc) and Bard latex intermittent catheters. Even intermittent catheters come with Coude tip, straight tip or closed system. The closed system intermittent system includes a self-contained drainage bag that collects the urine while protecting the catheter from infection-causing bacteria. In 2014 the intermittent/Robinson catheters market was valued at US$ 377.4 million and is expected to grow to US$ 529.7 million by 2019 at a CAGR of 7.0% from 2015 to 2019.


Male external catheters or condom catheters and some variants are also called Texas Style because they employ a three-piece construction technique. The catheter has a thin, latex sheath similar to a condom that can rolled over the penis and is attached to a silicone tube, where urine is drained into a bag or other collection device through a plastic catheter insert. These catheters are fully collapsible to prevent pooled urine a major cause of skin irritation and break-down. Products by companies such as Hollister have products can be used by people who have latex allergies since they are made of clear breathable silicone.

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</tr>
</thead>
<tbody>
<tr>
<td>Value (US$ Millions)</td>
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<td>77.3</td>
<td>81.7</td>
<td>86.4</td>
<td>91.4</td>
<td>96.6</td>
<td>102.1</td>
</tr>
</tbody>
</table>

Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis
In 2014 the male external catheters market was valued at US$ 77.3 million and is expected to grow to US$ 102.1 million by 2019 at a CAGR of 5.7% from 2015 to 2019. In terms of market players the segment is quite fragmented with key leading players being Rochester Medical, Mentor, UroCare, Coloplast, Hollister Medical and B Braun Melsungen AG.


Drainage collection bags are used for collecting urine through a catheter attached or inserted into the bladder. It is advised to change urine bags along with catheters at least once every month in order to reduce CAUTI. These bags are also used for collecting urine samples for conducting diagnostic tests. The drainage bags market is driven by growth factors such as aging global population, increasing awareness levels of consumers in accepting incontinence products and the availability of cost effective bags especially sourced from Chinese manufacturers. Coloplast is the market leader in the global urine collection bags market owing to its extensive product portfolio, e.g., Urisheathers, Peristeen as well as due to high market penetration of its new products, e.g. SpeediCath Compact Male, which is available in 11 countries worldwide. Several types of drainage bags are available that are very discreet and can be attached to the leg of the patient or hidden under the clothes in order that the person can continue daily tasks comfortably.

![FIG. 14 Incontinence Care Products and Devices – Global Urinary Drainage Bags Market 2013 – 2019 (US$ Millions)](Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis)

In 2014 the urinary incontinence drainage bags market was valued at US$ 261.3 million and is expected to grow to US$ 305.9 million by 2019 at a CAGR of 3.2% from 2015 to 2019.

Artificial Sphincter (AS) is a device used to treat urinary incontinence (UI) and made up of silicone rubber. This device has been in use since 1972 for the treatment of severe urinary incontinence; several technical evolutions led to significant improvement in the surgical and functional development of AS. The most advanced AS device AMS800 (AMS, Minnetoka, MN, USA) developed in 1987 is still used today with minor developments (e.g. antibiotic coating). In UI cases, it is generally accepted that AS is the gold standard of treatment and the oldest AS was manufactured and marketed by American Medical Systems 35 years ago. It is also estimated that currently more than 150,000 patients worldwide have been implanted with an AS, the majority with AMS800. The devices are used in case of damage to the sphincter muscles as well as combating nerve damage that results in loss of sphincter muscle control. Thus the device acts as a substitute for sacral nerve stimulation for many patients as well.

An artificial sphincter works in different ways based on its design. Although various designs are available in the market, mechanical construction mechanism is a common thread among them. Several designs are liquid inflatable or spring loaded and consist of an externally accessible control mechanism which helps the user to relieve constriction to allow concentration. The device has an inflatable cuff that fits around the urethra close to the point where it joins the bladder. A balloon regulates the pressure to the cuff, and a bulb controls inflation and deflation of the cuff. The balloon is surgically placed within the pelvic area, and the control pump is placed in the scrotum.
Other different brands of device available are FlowSecureTM manufactured by Sphinx Medical, Periurethral Constrictor by Silimed, ZSI 375 manufactured by Surgical Implants, Tape Mechanical Occlusive Device TMOD manufactured by GT Urological. According to the research carried out by First Department of Urology, Aristotle University of Thessaloniki, Greece it was observed that preparation and implantation of the ZSI 375 is technically uncomplicated and time saving with no serious adverse events associated with the device. Every device has advantages and disadvantages over other models. For e.g. TMOD has many advantages over AMS800 as it is a single piece device and doesn’t require assembly or preparation before operation which reduces time and cost, is non-hydraulic and requires no pressure-regulating balloon which decreases surgical complications.

Geographically, North America is the leading regional market for artificial sphincters. It was observed that 4,500 surgeries of implantation are carried out in the United States per year, as compared to 110 surgeries in Austria, 100 surgeries in South Korea and negligible number of surgeries carried out in other countries.

### 4.5.1 Artificial Urinary Sphincters Market, US$ Mn (2013 - 2019)

An artificial urinary sphincter is implanted to treat stress UI that occurs during normal daily activities such as walking, coughing, lifting objects, or exercising. The procedure may be ordered for men following prostate surgery, to help them reduce incontinence. Prior to implantation, other treatment methods such as bladder exercises are provided with surgery as the last option. Patients undergoing this procedure will be given either general or spinal anesthesia, and therefore will feel no pain during the procedure. The cuff of the device is placed around the urethra through an incision made in the scrotum/labia or lower belly.

<table>
<thead>
<tr>
<th>Year</th>
<th>US$ Millions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>35.4</td>
</tr>
<tr>
<td>2014</td>
<td>36.3</td>
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<td>2015</td>
<td>37.2</td>
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<tr>
<td>2016</td>
<td>38.2</td>
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<tr>
<td>2017</td>
<td>39.2</td>
</tr>
<tr>
<td>2018</td>
<td>40.2</td>
</tr>
<tr>
<td>2019</td>
<td>41.3</td>
</tr>
</tbody>
</table>

Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis
The market for urinary sphincters accounted for a share of 57.6% in 2014 of the total sphincters market that translated into revenues of US$ 36.3 million and is forecast to grow to US$ 41.3 million by 2019 growing flat at a CAGR of 2.6% from 2015 to 2019. Massive use of substitute treatment methods, foremost being adult diapers, has resulted in the decline of demand for opting surgical procedure to treat UI. This has resulted in the market growing slower than bowel sphincters segment. Major players in this segment are American Medical Systems, Sphinx Medical and Zephyr Medical among a few others.


The demographic changes have led to a significant increase in the incidence of incontinence. Fecal incontinence affects nearly 10% of people over 60 years of age, and about 2 million people in Europe have daily severe. Fecal incontinence is one of the most devastating of all physical disabilities, since it affects self-confidence and personal image, and leads to social isolation. The success of current treatments is moderate because of numerous complications including infections that often require device removal and more prominent is the use of adult underwear and diapers.

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</thead>
<tbody>
<tr>
<td>Sales (US$ Millions)</td>
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<td>26.7</td>
<td>27.5</td>
<td>28.4</td>
<td>29.2</td>
<td>30.1</td>
<td>31.0</td>
</tr>
</tbody>
</table>

The market for bowel sphincters accounted for a share of 42.4% in 2014 of the total sphincters market that translated into revenues of US$ 26.7 million and is forecast to grow to US$ 31.0 million by 2019 at a CAGR of 3.0% from 2015 to 2019. A significant level of innovation is taking place in this area and along with the involvement of key player American Medical Systems, Sphinx Medical and others; new device manufacturers such as Torax Medical have entered this naive yet potential market. Scientists and innovators from University of Bern and Basel have come together and are
developing prototypes artificial muscles based on hundred thousands of dielectric electrically activated polymers layers on the nanometer scale for the treatment of fecal incontinence. A study conducted to compare magnetic sphincter identical to Torax Medical with conventional pump based sphincter, concluded that in the short term, the magnetic anal sphincter is as effective as the artificial bowel sphincter in restoring continence and quality of life.


Sling procedure also known as suburethral fascial sling or pubovaginal sling is a kind of surgical treatment to help control urinary stress incontinence by creating a supporting hammock around the bladder neck and urethra using a sling material that may be strips of body’s tissue or synthetic material. Major sling materials used in the procedure include rectus fascia, Teflon and Gore-Tex. This procedure is performed when other options fail to treat the illness. The procedure is usually performed laparoscopically through a small incision near the vagina or abdomen/belly. High prevalence of the condition coupled with worldwide aging population and technical advances in this field are some major factors contributing in the growth of incontinence slings market. According to sources from the National Association For Continence (NAFC), indicate that worldwide around 200 million people are suffering from some forms of urinary incontinence. It further states that the condition is more common in women and anticipates that in the United States out of 25 million adult sufferers, 75% to 80% are women. This large pool of patient presents potential market for sling procedures.

FIG. 18 Incontinence Care Products and Devices – Global Slings & Meshes Market 2013 – 2019 (US$ Millions)

<table>
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<tr>
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<tbody>
<tr>
<td>Sales</td>
<td>307.8</td>
<td>316.4</td>
<td>325.2</td>
<td>334.4</td>
<td>343.7</td>
<td>353.3</td>
<td>363.2</td>
</tr>
</tbody>
</table>

Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis
In 2014, the global male and female slings & meshes market was valued at US$ 316.4 million and is forecast to reach US$ 363.2 million by 2019 at a CAGR of 2.8% from 2015 to 2019.


Urinary incontinence is a common post-operative complication in males after radical prostatectomy and transurethral resection of the prostate (TURP). The male sling procedure is meant to help men treat urinary incontinence due to sphincter weakness or bladder dysfunction. Minimally invasive nature of the male sling procedure is one of the major factors driving the growth of male sling procedure market. The AdVance Male Sling System developed by AMS is a new system being used widely in men owing to ease of operation, minimal invasive nature and fast recovery. Other male slings include ProACT by Uromedica, Inc., Remeex by Neomedic International and Argus by PROMEDON S.A.

The major factors driving the growth of this market include high prevalence of the illness, aging population and technical advances in the area of slings development. In addition, rising smoking population is also considered as a driver for this market as smoking is closely associated with the incidence of urinary incontinence. However, other surgical options for treating post-prostatectomy such as bulking agents and artificial urinary sphincter (AUS) may pose significant challenge before this market to grow.

Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis
In 2014, the global male slings market was valued at US$ 80.0 million and is forecast to reach US$ 94.6 million by 2019 at a CAGR of 3.4% from 2015 to 2019.

### 4.6.2 Female Incontinence Slings Market, US$ Mn (2013 - 2019)

Sling is a first-line surgical procedure for treating stress incontinence in women affected with intrinsic sphincter deficiency or urethral hypermobility. This procedure also proves to be useful in managing urge incontinence to some extent. The procedure involves an incision above the pubic bone where a layer of abdominal fascia is removed that is used as a sling later in the procedure. Some of the major factors identified to drive the demand for female incontinence sling procedure include the high prevalence of the incontinence among women coupled with advances in technology leading to minimally invasive and successful treatment. Various sources including website of Encyclopedia of Surgery, indicate that in a range of 10% to 30% women experience incontinence at some stage of their lifetimes. Continued advances in technology have led to the advent of innovative and safe sling product such as Tension-Free Vaginal Tape (TVT) by Johnson & Johnson that is being used widely worldwide.

**FIG. 20** Incontinence Care Products and Devices – Global Female Slings & Meshes Market 2013 – 2019 (US$ Millions)

![Graph showing the global female slings & meshes market 2013-2019](image)

Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis

Other prominent female incontinence sling brands available in the market are MiniArc (AMS) and Safyre (Promedon) and PELVILACE (Bard Medical). The advantages associated with these female sling products are likely to drive the market during the forecast period. However, the market has also witnessed product recall when U.S. FDA issued an order to all manufacturers for post market surveillance study. ProteGen (Boston Scientific) and ObTape (Mentor Corporation) were some among the recalled mesh products. In 2014, the global female slings & meshes market was valued at US$
236.3 million and is forecast to reach US$ 268.6 million by 2019 at a CAGR of 2.6% from 2015 to 2019.


Pelvic organ prolapse (POP) is the protrusion of pelvic organs into the vagina or outside the vaginal opening. This increasingly common problem has serious urinary, defecatory, sexual, social and psychological implications. POP may affect as much as 30% of the population of adult women, predominantly in the older age groups. As the population is aging, this will likely represent a major women’s health issue in coming years.

For many women, pelvic reconstructive surgery is a common treatment method, costing over US$ 1 billion each year even though a third of these procedures eventually fail. The major current alternative to surgery is the use of pessaries, intra-vaginal space occupying devices, which are considered to be an effective first line treatment approach by most specialists. However, limitations of currently available models discourage their more widespread acceptance: self-insertion and removal of existing pessaries can be difficult, especially for the elderly.

![FIG. 21 Incontinence Care Products and Devices – Global Pessaries Market 2013 – 2019 (US$ Millions)](image)

Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis

Pessary treatment of prolapse is one of the oldest remedies in medicine and is an important conservative treatment that is particularly valuable for the physically frail. Pessaries can be used for diagnosis and treatment of prolapse, for voiding dysfunction and urinary incontinence and for the management of incontinence or retention during pregnancy.
The use of pessaries is not a common method for treatment of urinary incontinence particularly in North America. However, there has been a considerable market for these devices in Europe and Asian countries. Furthermore, it is expected that the market for incontinence treatment pessaries is expected to grow steadily in the near future as it is the most cost effective treatment and safe option for treatment of pelvic organ prolapse and urinary incontinence.

### 4.7.1 Ring Pessaries Market, US$ Mn (2013 - 2019)

Ring Pessaries are commonly prescribed to women with prolapsed uterus and/or incontinence. A common ring pessary is shaped with a central void, although there are many types of ring pessaries, those with and without support, and those with a knob for concomitant stress urinary incontinence. Incontinence ring pessaries include a knob that fits behind the pubic symphysis, supporting the urethra during times of increased abdominal pressure to diminish stress incontinence.

![FIG. 22: Incontinence Care Products and Devices – Global Ring Pessaries Market 2013 – 2019 (US$ Millions)](source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis)

In 2014, the global ring pessaries market was valued at US$ 134.9 million and is forecast to reach US$ 163.4 million by 2019 at a CAGR of 3.9% from 2015 to 2019.

### 4.7.2 Gellhorn Pessaries Market, US$ Mn (2013 - 2019)

Gellhorn pessaries are the second most common type accounting for a share of 25.6% in 2014. There are two variants of Gellhorn pessary namely, short stemmed and long stemmed. These are used and prescribed based on comfort level of the female or purely based on physical examination of the woman. The Gellhorn pessary is chosen for more advanced stages of prolapsed. Research studies
indicate that Gellhorn pessary suffers from a disadvantage that it had to be refitted more frequently as compared to ring pessaries. The Gellhorn, which works well and is used often but is difficult to remove. While a manufacturer may recommend a certain pessary for a particular condition, many pessaries are appropriate for a variety of conditions. In 2014, the global Gellhorn pessaries market was valued at US$ 108.6 million and is forecast to reach US$ 129.5 million by 2019 at a CAGR of 3.6% from 2015 to 2019.

![FIG. 23 Incontinence Care Products and Devices – Global Gellhorn Pessaries Market 2013 – 2019 (US$ Millions)](image)

Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis

### 4.7.3 Other Pessaries Market, US$ Mn (2013 - 2019)

Other major pessary types include Doughnut/Donut pessary, Mar-Land, Dish pessary, Hodge pessary and Cube Pessary. Donut vaginal pessary is for 3rd degree prolapse as well as cystocele and rectocele along with incontinence. The Donut vaginal Pessary can be compressed for easy insertion. It is used for advanced prolapse cases since it fills a larger space. There are also several types that are inflatable and can be easily inserted and removed by the patient. The Hodge vaginal pessary is for 1st or 2nd degree prolapse, cystocele, stress incontinence and incompetent cervix. The Mar-Land vaginal pessary is for stress incontinence and minor degrees of prolapse. Many varieties of Doughnut pessaries cannot be autoclaved as they are inflatable.
In 2014, the global Other pessaries market was valued at US$ 81.6 million and is forecast to reach US$ 97.3 million by 2019 at a CAGR of 3.6% from 2015 to 2019.


Incontinence clamps are simplest mechanical devices used for treatment of minor urge and stress UI. Penile clamps can be very uncomfortable and also debilitating and cause depression among patients. The market for incontinence clamps is highly fragmented as there are several importers with affordable products that are commoditized in Europe and Asia-Pacific. A Cunningham Incontinence clamp is shaped like a pincer and is placed on the shaft of the penis. Other variants are the squeezer clip, Baumrucker clamp and the J-clamp.

Key players in this market are Personal Med, Greenwald Surgical, Bard, Life Control, Jackson Medical, UriClak and Post-T-Vac Medical. In 2014, the global clamps market was valued at US$ 99.0 million and is forecast to reach US$ 120.8 million by 2019 at a CAGR of 4.1% from 2015 to 2019. An emerging player in this area is The Dribblestop™ Male Urinary Incontinence Clamp which is a small external clamp that applies gentle pressure to the urethra and top of the penis to help control bladder leakage. Although the company claims that blood circulation is not affected and that can be worn comfortably day and night, SA-BRC reviews with patients has come up with no difference between using other clamps. Most patients suffer from similar problems and insist that clamps cannot be used over long durations as compared to diapers or other substitutes.

Nerve stimulation acts as a very competent solution to encouraging body’s natural mechanism to control incontinence. According to aggregated sources such as the NHS, CDC, bladder-control.co.uk and several others approximately 27 million people suffer from urinary and fecal incontinence, the larger portion being categorized under UI. There are approximately 8 million people in United Kingdom suffering from these conditions. Nerve stimulation devices provide gentle stimulation to the nerves near the sphincter muscles and stimulate the muscles to function naturally.
Sacral nerve neurostimulation is believed to be one of the most innovative methods for treatment and management of pelvic-perineal dysfunction. In the mid 1990’s there was large scale enthusiasm over the impressive results of sacral neuromodulation. However, the poor long-term results in the then patients led the researchers to question the effectiveness of this modality and thereby conduct further in-depth research. Thus, initiatives such as identification of predictive factors for the successive outcomes and improvement of patient selection, psychometric assessment has assisted in enabling the identification of patients with conversion-histrionic disturbance which show immediate result to neuromodulation therapy. Electrical stimulation is also used to a large extent as a primary treatment method along with exercises to control incontinence. How the results through electrical stimulation are achieved is not clearly understood, however it is believed that the stimulation may make the muscles contract, producing an effect similar to Kegel exercises, which strengthen the muscles by contracting them frequently. The stimulation may also encourage the growth of nerve cells that cause the muscles to contract. In 2014, the nerve stimulation devices market for incontinence was valued at US$ 247.5 million and is forecast to reach US$ 440.2 million by 2019 at a CAGR of 12.4% from 2015 to 2019.


Sacral Nerve Stimulation is provided through an implantable medical device that is surgically placed under the outer quadrant of buttock or sometimes in the abdomen or back. It typically involves the implantation of a programmable stimulator which delivers low amplitude electrical stimulation via a lead to the sacral nerve, usually accessed via the S3 foramen.

FIG. 27 Incontinence Care Products and Devices – Global Sacral Nerve Stimulation Devices Market 2013 – 2019 (US$ Millions)

Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis
Currently, researchers are trying to understand the best indications to be treated by available neurostimulation modalities such as direct nerve stimulation, sacral nerve stimulation and Pudendal nerve stimulation. In the future, adjustable stimulation based on particular nature and levels of dysfunction would be able to replace the need for continuous or on-demand neurostimulation. Clinical investigation on developing intelligent stimulation are being conducted worldwide, however none of them have yet been developed as a technology capable of being commercialized. In 2014, the sacral nerve stimulation devices market was valued at US$ 94.5 million and is forecast to reach US$ 222.7 million by 2019 at a CAGR of 18.7% from 2015 to 2019. Until recently, Medtronic Inc (US) was the only notable player operating in this segment and offering InterStim line of devices to patients with severe incontinence. In 2015, a new California based start-up Axonics Modulation Technologies, Inc has introduced their device which is anticipated to attract other implantable device manufacturers to this segment in coming years.


Electrical nerve stimulation or transcutaneous electrical nerve stimulation is delivered externally without implants. The system uses electrodes attached at the area of nerve damage and therapeutic doses of electric shocks are passed into the skin. There are two major types of delivering electrical nerve stimulation. Posterior/Percutaneous tibial nerve stimulation (PTNS) is done by inserting a very small electrode onto the skin of your lower leg. The electrode is connected to an electrical stimulator (pulse generator) outside your body. The stimulator sends pulses to the electrode, which stimulates the tibial nerve in your leg. That electrical current then affects the nerve in your lower back that controls bladder and pelvic floor function. PTNS is estimated to have effect on a large population with stress, urge or mixed incontinence.

A second method growing in popularity is Pelvic Floor Stimulation (PFS) is targeted for incontinence mainly in women. The device provides electrical stimulation therapy at home using a unit with a vaginal or anal electrode. These devices are used for both urge and stress incontinence. In 2014, the electrical nerve stimulation devices market was valued at US$ 153.0 million and is forecast to reach US$ 217.6 million by 2019 at a CAGR of 7.3% from 2015 to 2019.
The market of electrical nerve stimulation devices in incontinence is fragmented and unregulated particularly for PFS. Key players offering PTNS devices include Cogentix Medical (US), Advanced Uro-Solutions (Medtronic Inc) (US), DynaMD BiowavePENS (US), NeuroTrac TENS/PENS (Kr) and several others. Key players in the PFS market include TensCare (UK), Med-Fit (UK), Utah Medical Products Inc (US), Heise Medizintechnik (Ger), Win Health Medical (UK), Pelvicfloorexercise (Aus), Associated Medical and The TENS Company (US).

5.1  Introduction

Incontinence is the loss of control or involuntary evacuation of urine or feces that can occur due to multiple causes such as stress, nerve damage of sphincter, urge incontinence, overflow of bladder and pregnancy among some other types. The incontinence market consists of devices for prevention and treatment such as absorbent pads, urology catheters and bags, artificial sphincters, pessaries and clamps and devices that give therapeutic stimulation to nerves. Incontinence occurs in all ages and can affect a person at any point in their lives. That being said, there is still a large percentage of aged population is affected by this as compared to younger adults and children. The report attempts to evaluate and analyze the market for products and devices used in the treatment of incontinence over four major geographical regions namely, North America, Europe, Asia-Pacific and Rest of the World. The following pages will elucidate the several factors driving and restraining the growth of the incontinence products and devices market in these regions.


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<thead>
<tr>
<th>Region</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>CAGR %</th>
</tr>
</thead>
<tbody>
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<td>3,349.4</td>
<td>3,559.7</td>
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Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis

North America was the largest market in 2014 valued at US$ 3,152.6 million and is expected to grow to US$ 4,281.3 million by 2019 at a CAGR of 6.3% from 2015 to 2019. It accounted for a share of 32.0% of the global incontinence products market which was valued at US$ 9,861.8 million in 2014. Absorbent product brands such as Depend, Poise and Tena are leading the absorbents segment due
to extensive use by adults in North America. A major restraint for adult diapers is the feeling of embarrassment in using these products by adults. This scene is however changing with manufacturers changing their approach in selling absorbent products. Aged population is a major driver and the Asian market is teeming with opportunities for incontinence products due to a very large population of aged.


North American region held the majority share in the market of around 32.0% in 2014. United States and Canada has a moderate density of gynecologists and obstetricians. Improving reimbursement rates for several devices and products is encouraging the penetration of incontinence care products.


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Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis

The incontinence care products and devices market is expected to face several challenges in coming years due to the advent of pharmaceutical products to combat incontinence. The Canadian Urological association and Pfizer Canada are developing a new fellowship program offering support and funding for Canadian urological researchers. Astellas Pharma Canada introduced Myrbetriq, a drug for urge incontinence. The growth stems from a demand for treatment of incontinence which is observed to be on a rise in recent years as there are approximately 27 to 30 million people of all ages suffering from incontinence. Absorbents and adult diapers was the largest market with a value of US$ 2,275.9 million in 2014 and is expected to reach US$ 3,128.8 million by 2019 at a CAGR of 6.6% from 2015.
to 2019. Medtronic’s Sacral Nerve Stimulation and other electrical stimulation devices have shown consistent positive results in containing and treatment of incontinence. Since neurostimulation is a minimally invasive procedure, the product has great opportunities as a long term treatment for incontinence. Incontinence and prolapse treatment market for vaginal meshes or slings is expected to grow the slowest owing to the large percentage of post-operative failures. The segment faces a large number of litigations in which companies such as J&J and Boston Scientific continue to struggle. Key players in the North American incontinence care products and devices market are Kimberly Clark, SCA, Johnson & Johnson, American Medical Systems, Medtronic and Cooper Surgical.


European region encompasses the countries of United Kingdom, Germany, France, Italy and Spain which are the major economies of European Union. Along with this, the market also takes into account Nordic regions and Eastern Europe. Statistics show that close to 8 million people in U.K have suffered from urinary or fecal incontinence. Studies have indicated that over 38% women and 29% men have clinically significant symptoms of incontinence. The market for incontinence devices and products in Europe is growing the slowest as compared to other geographies. The most prominent type is stress UI which affects more than two thirds of all incontinence incidences. Incontinence occurring from pregnancy is the lowest in the region due to a confirmed drop in number of childbirths. Absorbent products such as adult pads and diapers were introduced in the 1970’s and since then have made a significant market in the region. There are several organizations tracking the incidence of incontinence such as the International Continence Society (ICS), Association for Continence Advice (ACA) and World Health Organization (WHO) who are also involved in the education of people in managing incontinence.

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Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis

There are several drug substitutes for managing incontinence and one of the recent approvals is the use of Botox in Europe. Botox is a strong toxin used in cosmetic procedures, which is a powerful muscle relaxant that allows greater capacity of fluids to be stored in the bladder. Approval of innovative technologies along with alternative therapies such as acupressure will compete with other invasive procedures and increase the demand for non-invasive cures. In 2014, the European incontinence care products and devices market was valued at US$ 2,485.4 million and is forecast to reach US$ 3,354.3 million by 2019 at a CAGR of 6.2% from 2015 to 2019.

Major revenue segments are the absorbent and diapers which was valued at US$ 1,798.5 million in 2014 and forecast to reach US$ 2,463.2 million by 2019. Pessaries are also preferred over other options for controlling incontinence. Foremost drivers for the market are aging population, increasing obesity and changing lifestyle. Key players are SCA, Kimberly Clark, Ontex Global, SRS Medical and Attends Healthcare (part of Domtar). There are several small innovative companies such as InTone that have introduced new device to stimulate and treat muscles responsible for loss of bladder control. The device has been approved by FDA and is already available in the market. Companies such as these are likely to gain largest ground due to the non-invasive nature of the devices.

Asia-Pacific is an emerging region for incontinence market. APAC market includes the countries in the Indian Subcontinent, China, Japan, Korea, South-East Asia and Australia. Japan, China and India are pegged to become the largest markets for incontinence as population grows older. Some reports and studies suggest that the market for adult absorbent products is larger than those for children owing to a higher percentage of geriatric population. Companies such as Simavita (AUS) have introduced smart electronic sensor “SIM” that is placed on an aged care resident's incontinence pad to detect urinary discharge. The data from the sensor is then analyzed using special computer software, enabling care takers to build an accurate profile of the resident's continence. Studies indicate that over 1 in every 10 aged people suffers from incontinence.


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Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis

The adult diapers and absorbents market is expected to be a strong contributor to the overall incontinence products market. There is a low level of awareness and adoption for surgical techniques such as artificial sphincters and neuromodulation of sacral nerves due to low acceptance in both medical community as well as patients. Although devices such as artificial sphincters have been approved in countries such as Japan in the last decade, their use has remained at a minimum, which indicates that slings and sphincters have been the slowest segments to grow in the overall incontinence market. Asia has been a strong player in alternative therapies such as reflexology, acupressure and acupuncture that have shown considerable clinical success amongst patients and
hence remain the primary options for treatment. Rise in medical tourism is also expected to supplement the growth of the market in the future. Surgical procedures such as artificial sphincters and slings are used only in extreme cases such as post prostatectomy that results in severe UI. Injectable bulking agents are also in use for treating incontinence for weak muscles.

Asia-Pacific is slated to become the largest market for incontinence products and will exceed Europe by the year 2018. The growth will be driven mainly by a significant percentage of aged population, increasing adoption of new innovative treatment devices and increasing awareness of incontinence products. Key players in the region are Kimberly Clark, Unicharm and SCA among a large number of local players. In terms of value Asia-Pacific accounts for a share of 26.4% of the global incontinence market, but in terms of volume, the region is an undisputed leader due to its mammoth population. A large number of patients who suffer from incontinence opt for cheaper absorbent products manufactured by local players to balance the level of purchase power. An expanding economy and increasing per capita income on hygiene products is expected to propel the market for these products in the coming years.

5.5 Latin America Incontinence Care Products & Devices Market, US$ Mn (2013 - 2019)

Latin America region includes countries of Brazil, Argentina, Chile, Mexico, and Caribbean among other smaller economies within the region. Currently South America produces about 300,000 metric tons of nonwovens annually, Mexico produces about 98,000 metric tons, and the Caribbean produces about 9000 metric tons, for regional production of about 400,000 metric tons, according to INDA estimates. Latin America is a leader in consumption of non-wovens although it ranks fourth largest in the adult diaper market. Kimberly Clark had been a leading supplier in the region with little interference from other global majors for almost a decade. However, Swedish SCA is expecting to challenge its position with the acquisition of Brazilian hygiene maker Pro Descart in a deal valued at $71 million on a debt-free basis. Companhia Providencia is Brazil’s largest nonwovens manufacturer with sales reported at US$ 326 million in 2010. Currently, 61% of the company’s sales are conducted in Brazil.

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Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis

Teleflex is estimated to be a leader in Latin American sales of catheters. The Latin American market is quite fragmented with a large percentage of imports and local manufacturing companies. The demand for costlier anti-bacterial catheters has been on the rise with global erosion in prices and is expected to become a standard in most medical facilities in the region. Medical tourism in Latin America is driving expensive procedures such as implantation of nerve stimulation devices and cuff-based artificial sphincters market.

5.6 Middle-East Incontinence Care Products & Devices Market, US$ Mn (2013 - 2019)

The middle-east region comprises Arab countries such as Saudi Arabia, Qatar, Oman, United Arab Emirates and non-Arab countries such as Iran, Iraq, Turkey, Israel and Jordan. Middle-East countries such as United Arab Emirates have invested heavily in building a strong healthcare infrastructure and due to vast purchasing potential. Middle-East has shown an increasing trend in establishing medical facilities in countries such as Dubai and United Arab Emirates. Several countries such as Dubai offer medical tourism opportunities for treating incontinence which includes surgical procedures such as the implantation of artificial sphincters, vaginal meshes and slings and bulking agents. Emirates Hospital is one such group that provides these procedures. Demand from Latin America and Middle-East will drive to growth of the market. There is a high level of research and development being carried out in Middle Eastern countries such as Israel and United Arab Emirates. Urology Research
Center affiliated to Tehran University of Medical Sciences (TUMS) on October 5, 2013 successfully used stem cells for the first time in the Middle-East for urinary incontinence treatment.


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Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis

According to a recent study on incontinence in UAE women, approximately 42% suffered from the condition with a mean age of 38. Nearly 80% of the patients complained of disrupted daily life; namely praying, social activities, physical activities, and intimacy. Higher rate of multiple pregnancies in the region is considered to be a significant factor responsible for the incidence of UI.

Kimberly Clark and SCA are the leading suppliers of adult diapers in Africa. The region has the highest infant mortality rates due to conflicts, malnutrition, disease and poverty. SA-BRC analysis concluded with zero distributors and manufacturers for artificial sphincters; however our panels of experts determine that procedures have been carried out by importing the devices through Middle-East and Asia-Pacific on case-to-case basis.


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<td>2.2</td>
<td>0.5</td>
</tr>
<tr>
<td>Artificial Sphincter</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>NA</td>
</tr>
<tr>
<td>Slings &amp; Meshes</td>
<td>3.0</td>
<td>3.0</td>
<td>3.1</td>
<td>3.1</td>
<td>3.2</td>
<td>3.3</td>
<td>3.3</td>
<td>1.7</td>
</tr>
<tr>
<td>Pessaries</td>
<td>3.4</td>
<td>3.5</td>
<td>3.5</td>
<td>3.6</td>
<td>3.6</td>
<td>3.6</td>
<td>3.7</td>
<td>1.1</td>
</tr>
<tr>
<td>Nerve Stimulation</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.5</td>
<td>0.5</td>
<td>0.5</td>
<td>4.0</td>
</tr>
<tr>
<td>Total</td>
<td>92.0</td>
<td>94.8</td>
<td>97.5</td>
<td>100.1</td>
<td>102.7</td>
<td>105.1</td>
<td>107.4</td>
<td>2.4</td>
</tr>
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</table>

Source: Proprietary data sources, KOL opinions, Primary Interviews, SA-BRC Analysis
Chapter 6  Key Players Analysis: Global Incontinence Care Products and Devices Market, 2014 (%)

6.1 Key Players Market Share: Global Incontinence Care Products and Devices Market, 2014 (%)

The global market for incontinence care and management products is highly fragmented with numerous small and large players. The market space is highly competitive particularly in consumer segments such as adult diapers. In 2014, SCA was a clear leader with significant revenues from operations that span across the globe from its most prominent brand Tena. It controlled a market share of 37.3% followed by Kimberly Clark which is a leader in North America. Kimberly Clark’s global share in adult incontinence diapers was 23.7% in 2014, led by its brands Depend and Poise.

UniCharm, an Asian major is expected to become a significant competitor to international brands illustrated by the company’s aggressive expansion in Asia.

In the artificial sphincters market, currently the AMS 800TM Urinary Control System from AMS (American Medical Systems) is the one of very few artificial urinary sphincters currently on the global market, thus showing its clear monopoly in the market in this segment of the incontinence care market. According to company sources, physicians worldwide have implanted the device in more than 94,000 men as a treatment for stress urinary incontinence due to prostatectomy over 30 years. SA-BRC estimates show that American Medical Systems (Endo) controlled 85.5% of the artificial...
sphincters market in 2014. Notable players controlling remainder of the market are Sphinx Medical, Zephyr, Torax Surgical and Brazilian company Silimed. In the global catheter and drainage collection market Coloplast led the way with a share of 38.7% followed by Bard with a share of 21.4%. Since Coloplast also operates in the TVM market, the controlling share of the company in the overall incontinence market is expected to be significant as compared to companies operating in a single segment.

The key player’s analysis of the other important product segments of the incontinence care and management products market has been described below with their respective market shares.

The sacral nerve stimulation market is young and Medtronic currently controls over 90.0% of the entire market with the acquisition of emerging companies such as NDI Medical, which has been producing alternative products for urinary incontinence. The electrical stimulation devices market is highly fragmented with a large number of private players thus SA-BRC was unable to substantiate leaders in this area.

For the incontinence slings or TVM market, Endo (American Medical Systems), Ethicon and Boston Scientific were the leading players in with shares of 26.0%, 13.0% and 8.0% respectively, and 53.0% of the market was comprised other manufacturers such as Coloplast and Cook Medical. The trans-vaginal mesh market has been plagued with series of litigations and suits resulting in pay-offs to patients in the tune of hundreds of millions. All companies have had their share of trouble with
this product due to which it continues to be the slowest growing product segment in the incontinence care products market.

6.2 Global Incontinence Care Products and Devices Market: Recent Developments 2013-2015

6.2.1 Mergers and Acquisitions

<table>
<thead>
<tr>
<th>S. No</th>
<th>DATE</th>
<th>PARTICULARS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mar-2015</td>
<td>Boston Scientific Announces Definitive Agreement To Acquire American Medical Systems' Urology Portfolio For Up To $1.65 Billion. Upon completion of the transaction, the AMS Men’s Health and Prostate Health businesses will become part of Boston Scientific Urology and Women’s Health. The acquisition encompasses the AMS product portfolio for treating urologic conditions, including benign prostatic hyperplasia (BPH), male stress urinary incontinence and erectile dysfunction.</td>
</tr>
<tr>
<td>2</td>
<td>Mar-2015</td>
<td>Uroplasty Inc, a manufacturer of neurostimulation devices for incontinence is now Congentix Medical. Uroplasty completed an all-stock merger it announced in December with a New York device maker called Vision-Sciences, Inc. Uroplasty shareholders end up owning 63 percent of the combined company, Cogentix, which starts its new fiscal year Wednesday.</td>
</tr>
<tr>
<td>3</td>
<td>Jan-2015</td>
<td>Medtronic acquired Covidien and assimilated its complete product portfolio. Covidien is a leader in Catheters and TVM segments thus making Medtronic an automatic leader in this segment. Along with this, having monopoly in the Sacral Neurostimulation market, Medtronic is now a force to reckon with in the Incontinence Care Market.</td>
</tr>
</tbody>
</table>

Source: Press Releases, Annual Reports and Reuters

6.2.2 Joint Ventures, Expansion and Collaborations

<table>
<thead>
<tr>
<th>S. No</th>
<th>DATE</th>
<th>PARTICULARS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Apr-2015</td>
<td>SoCal startup Axonics Modulation Technologies has raised $17.3 million, according to a new regulatory filing. The startup has developed implantable sacral neuromodulation devices that treat conditions like overactive bladder and fecal incontinence.</td>
</tr>
<tr>
<td>2</td>
<td>Jun-2013</td>
<td>Laborie Medical Technologies, Inc. (&quot;LABORIE&quot;), based in Toronto, Ontario, has completed its acquisition of BUCK Elektromedin GmbH and BUCKmeditec GmbH &amp; Co. Bad Rappenaeau, Germany based BUCK develops and distributes innovative and advanced biofeedback and electrical stimulation equipment, accessories and consumables for pelvic floor dysfunction in the treatment of urinary and fecal incontinence.</td>
</tr>
<tr>
<td>3</td>
<td>Sep-2013</td>
<td>C. R. Bard Inc. entered into a definitive agreement to acquire Rochester Medical Inc., a leading developer and supplier of silicone urinary incontinence and urine drainage products, for approximately USD 262 million. Rochester’s technology and distribution assets would provide a strong platform for combined portfolio to compete in global incontinence market.</td>
</tr>
</tbody>
</table>
B. Braun Melsungen announced that it has opened a new subsidiary in Canada named as B. Braun of Canada, Ltd. to establish its position in the Canadian market.

Source: Press Releases, Annual Reports and Reuters

### 6.2.3 New Product Launches and Approvals

<table>
<thead>
<tr>
<th>S. No</th>
<th>DATE</th>
<th>PARTICULARS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>May-2015</td>
<td>StimGuard Receives FDA IDE Approval to Launch a US Clinical Trial for a Revolutionary Wireless Device to Alleviate overactive Bladder Symptoms. The micro sized neurostimulator can be implanted non-surgically by using only a needle.</td>
</tr>
<tr>
<td>2</td>
<td>Apr-2015</td>
<td>ApexM Incontinence device has been cleared for over the counter sale by FDA. The device from InControl Medical treats female stress, urge and mixed urinary incontinence.</td>
</tr>
<tr>
<td>3</td>
<td>Apr-2015</td>
<td>The Eclipse System by Pelvalon Inc. has been approved for marketing by the FDA for treatment of fecal incontinence. The system includes an inflatable balloon, which is placed in the vagina. Upon inflation, the balloon exerts pressure through the vaginal wall onto the rectal area, thereby protecting against unwanted stool passage.</td>
</tr>
<tr>
<td>4</td>
<td>Dec-2014</td>
<td>New TENA Pants Normal is 20 percent thinner, more comfortable to wear. It is improved both for the user and the environment as it reduces the carbon dioxide emissions in the production.</td>
</tr>
<tr>
<td>5</td>
<td>Dec-2014</td>
<td>K-C test marketing pessary product under Poise Brand. Kimberly Clark has been test marketing pessary products in parts of United States and will vie for a sizable portion of the market in coming years.</td>
</tr>
<tr>
<td>6</td>
<td>Aug-2014</td>
<td>P&amp;G’s Always Brand, the Global Leader in Feminine Care, Launches Revolutionary New Always Discreet™ for Sensitive Bladders.</td>
</tr>
<tr>
<td>7</td>
<td>Jul-2013</td>
<td>AMS launched its MiniArc Pro single-incision sling system, for female stress urinary incontinence, in U.S.</td>
</tr>
</tbody>
</table>

Source: Press Releases, Annual Reports and Reuters
6.3 Competitive Landscape: Strategies

SA-BRC has analyzed commercial and research activities of over 25 players in the incontinence care market. The market is highly fragmented and commoditized for products such as adult diapers. New innovative technological developments in neurostimulation are expected to drive the competition further among electronic medical device manufacturers. Illustrated below are some of the major broadly elucidated strategies followed by manufacturers in this segment.

- Effective marketing strategy for removing embarrassment of the condition. The subject of adult incontinence has long been associated with the elderly, however, fecal and urinary incontinence can become a major social stigma for outgoing young people as well as working adults. P&G’s marketing has helped expand the market for adult diapers; however, it has resulted in growth and penetration of competitor products as well such as SCA Tena.

- Forward integration is another strategy companies from non-wovens can initiate. The fluff industry can compete within the adult diapers industry without a hindrance along with manufacturers competing in the baby diapers space. Repositioning and revaluing baby diapers with design changes to focus on adults are a cost effective sustenance model. This has been aptly illustrated by P&G that has entered the adult diapers market.

- Moderate M&A activity in the market indicates low potential in most product segments. However, recent mergers and acquisitions in the neuromodulation segment show the excellent potential of the market. Companies operating in the devices segment can adjust their focus to include one of the several new start-ups in neurostimulation for incontinence. That being said several companies such as Coloplast’s strategy is focused on organic growth and centered on increasing investments for globalizing urology care business, growth in Europe and developed markets and expansion and growth in emerging markets.

- Investment in emerging regions of the world. Increasing investment in healthcare, rising purchase power in Asia-Pacific, Latin America and Middle-East can be capitalized by being an initiator in these regions. Due to complexity in understanding and raising business in the emerging regions, the initiators will be in a strong position to command the market.
Chapter 7  Epilogue

Incontinence care market is challenged greatly by internal substitutes. There is a large variety of treatment methods available such as adult diapers, bulking injections, artificial sphincters, slings & meshes. Drugs such as Anticholinergic agents act on efferent nerves to counteract overactive bladder (OAB) after it occurs. To prevent the occurrence of OAB, therapies should be directed at blocking the afferent nerves that control the bladder. The market for bulking agents that has not been analyzed in this report due to predefined scope of research is expected to be an emerging mode of treatment. The healthcare industry is moving away from invasive surgeries progressively hence neurostimulation devices are considered the last option for patients with extreme incontinence issues. There is a great deal of collaborative activity within small players as well. Although it is estimated that over 25 million American’s suffer from Urinary Incontinence, with as many as 4 in every 5 affected being women, social norms remain the biggest factor in the reporting and delayed treatment of incontinence.

Within product segments, the adult diaper industry has been moving towards a fluff-less future with introduction of superabsorbent material. Aging population in most parts of the world has been by far the greatest stimulus to the market for adult incontinence care products in recent years. As a result, the potential global market for adult incontinence products is growing faster than the potential global markets for diapers and other types of hygiene absorbent products. Thus this is creating a market for other incontinence devices to expand as well. Increasing prostatectomy and BPH has led to urinary incontinence in men along with other conditions such as brain disorders. On the other hand almost every company that has entered the trans-vaginal meshes and slings market has been sued and is stuck in high value litigations. The market for TVM has greatly diminished in the last few years due to severe side-effects resulting from the operations.

SA-BRC estimates the current market to have greatest potential in the adult diapers, neurostimulation and bulking agents segment. The major challenge is that almost no treatment method is a lasting cure. Most popular methods available are avenues for controlling and care. Increasing number of pharmaceutical options are promoted effectively to patients and along with improving reimbursement standards, it is expected that the market will grow into a potential revenue generating sector within the end of the decade.
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**Contact**

**John Whitmore**
10685-B Hazelhurst Dr. #17411
Houston, TX 77043
United States
Contact Number: +1(832)-426-3701
Email: john@sa-brc.com, sales@sa-brc.com
Website: www.sa-brc.com