Insights Pack

Roots Analysis
BUSINESS RESEARCH & CONSULTING

Needlestick Safety Injection Devices Market, 2014 - 2024

2014

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EXECUTIVE SUMMARY

Safety injection devices market has already established a dominant position in the healthcare community	▪ With the increased awareness about accidental needlestick injuries and growing emphasis on occupational safety, the safety injection devices have emerged as one of the most popular and preferred delivery devices. ▪ These devices have been around for more than two decades. The first safety syringe, featuring a sliding safety shield, was introduced by Becton Dickinson in 1988 ▪ Since then, this category of medical devices has witnessed significant technological improvements and achieved an unrivalled place in the delivery systems for parental drugs and vaccines.
Not only these devices offer multiple benefits, they are also considered to be more economical in the long term	▪ The safety injection devices have several advantages over traditional drug delivery systems. Most importantly, the addition of safety feature provides optimal protection to the healthcare employees and patients, reducing the risk of accidental needlestick injuries. ▪ In addition, the use of safety syringes facilitates the ease of disposal. In case of a retractable syringe, the needle is locked into the barrel of the syringe and the entire assembly can be safely disposed of. The cost of disposal of a safety syringe is relatively much lower compared to a conventional syringe. ▪ The incorporation of safety mechanism results in a higher purchase price compared to conventional devices. However, they are known to offer long term economic advantage if the consequences of a needlestick injury and associated treatment expenses are taken into consideration.
The market landscape has changed gradually over the past few years; as the market matures further, new players are trying to carve out a niche for themselves taking advantages of the established	▪ For the past several years, a handful of companies have been dominating the safety injection devices market. The Needlestick Safety and Protection Act, 2000 has directed the entry of new manufacturers and spurred the uptake of the market. ▪ The market has now become fragmented, with over 39 companies

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supply chain and distribution network	competing at present. Becton Dickinson remains the ▪ market leader, followed by Covidien and Smiths Medical. ▪ In addition, Unilife and Revolutions Medical are some new players which have, in the recent past, introduced important safety devices with passive protection. ▪ The increasing number of partnerships is evident of the fact that the leading companies actively look up to these smaller companies for licensing the technology from latter and use their own global presence to make the technology widely available
The manufacturing sector is abuzz with development activity; advances in technology are leading to continuous improvements in the design and functionality of the devices	▪ The indispensable need for safety and the huge competition is driving more innovation and technological advancements in the design of these products. This, in turn, is likely to create immense opportunities for the manufacturers in the foreseeable future. ▪ One of the most viable examples is the emergence of needleless systems. Furthermore, the growing trend of self-medication and increase in the incidence of chronic diseases has boosted the sales of prefilled syringes with safety features.
At a 9.0 % of the growth rate, we forecast the market for safety syringes to rise to XX billion units by 2024.	▪ Wider customer adoption and declining prices will likely result in retractable syringes gaining an increased share of the pie. ▪ Non-retractable syringes will continue to witness moderate growth as well; however, some of the older devices will gradually phase out.
The overall opportunity is set to expand as regulatory bodies in emerging markets realize the benefits of safety injection devices	▪ While the use of safety devices has been mandated in the US; Europe and other international healthcare markets are also moving towards the mandatory use of devices with needlestick prevention features. ▪ In fact, some regional players are now well positioned to benefit from this evolving trend. Examples include Wenzhou Beipu Science & Technology in China and Formosa Medical Devices in Taiwan.
Notwithstanding the heightened activity, there are some challenges which must be addressed to realize the full market potential	▪ One of the biggest challenges in the market is the higher cost associated with the safety injection devices. It is one of the reasons for the slow rate of adoption in some healthcare units. ▪ Simultaneous development of alternative drug delivery devices such as infusion sets, auto-injectors and blunt fill needles also pose a credible threat to the future growth. ▪ Other challenges, which can be easily mitigated, include overcoming patients'/medical practitioners' reluctance to switch from conventional to safety syringes and lack of general awareness about healthcare safety.

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- Despite these challenges, the overall future outlook indeed remains promising; the price sensitive market will continue to seek improvements for the benefit of the end-users and the wider pharmaceutical industry.

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2

SWOT ANALYSIS

2.1. CHAPTER OVERVIEW

With the advent of the needlestick safety and prevention act and enforcement of other regulatory laws, the use of medical safety devices including safety syringes and safety needles have gained immense importance over the past few years. Their necessity in maintaining occupational health and safety can't be denied. Furthermore, the novel and innovative safety designs have several advantages for the patients, in particular for self-injecting end-users. At the same time, some of the safety products currently in the market may not be capable of completely eliminating needlestick injuries or prevent reuse of the device because of the human factors involved. However, the emergence of needleless systems and other technological advancements in the field of medical safety is bound to present several new opportunities in the market.

This chapter presents a closer look at the market highlighting key issues under a SWOT framework. Table 2.1 lists the strengths, weaknesses, opportunities and threats relevant to the industry. We have briefly discussed some of the factors in the following sections.

Table 2.1 **SWOT Analysis**

Strengths	Weaknesses
Offer several advantages over traditional injection devices; the most prominent one being enhanced safety resulting in reduced risk of occupational infection to the healthcare workers	Higher cost as compared to the conventional injection systems
Allows convenient disposal; needlestick injuries occurring during disposal and post disposal can be reduced to a great extent	In some cases, results in a different method of administration limiting the scope for wider adoption in the near-term
Regulatory laws enforcing proper use of the safety devices in healthcare settings	Activation of safety mechanism, at times, may result in patient discomfort including pain and tissue trauma
Rapidly growing injectable drugs market and the rising trend towards self-administration	Training programs are required; wrong method of usage can result in the increased likelihood of needlestick injuries.

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Long-term cost advantages with the use of safety injection devices	

Opportunities	Threats
Ongoing technological / design innovations such as pre-filled safety syringes and emergence of needleless systems	Presence of other alternative drug delivery devices including auto-injectors, blunt fill needles and safety blood collection and infusion sets.
Taking advantage of established supply chain / procurement processes of conventional syringes	History of device recalls in the industry
Upcoming opportunities offered not just by developed markets but also the emerging markets such as Brazil, Mexico	
Applications of safety syringes in affiliated areas such as dentistry	

Source: Roots Analysis

2.2. STRENGTHS

2.2.1. LONG-TERM COST ADVANTAGES WITH THE USE OF SAFETY DEVICES

In comparison to traditional syringes, safety syringes might seem expensive but if long-term consequences of a needlestick injury are considered, the safety devices are found to present cost advantages as compared to the conventional injection products. According to the CDC, the expenses involved in the treatment of the healthcare practitioners who sustain a needlestick injury can range from USD 500 to USD 3,000.[1] This results in a huge cost burden for the entire medical community and can be easily avoided by the use of appropriate safety devices.

It is important to mention that the use of safety syringes and needles eliminates the need to recap the needles which help reduce the needlestick injuries to a great extent; recapping the needles are reported to account for 25 - 30% of the needlestick injuries.[2]

2.2.2. CONVENIENT DISPOSAL

One of the major advantages that the use of a safety syringe provides is the ease of disposal. When a conventional syringe is used, the user is required to dispose of the device in a safe manner post administration. Since the human factor is involved, there may be wrong disposal practise which can be highly detrimental. According to International Health Care Worker Safety Center, improper disposal is a cause of 10% of the needlestick injuries.[3]

In case of a conventional syringe, the method that is commonly adopted is the disposal of uncapped needles into sealable sharps container. In such cases, the needles might be stuffed into the overfilled

[1] *Source*: http://www.bd.com/us/safety/about/
[2] *Source*: http://www.slideshare.net/doctorrao/needle-stick-injuries-11575403
[3] *Source*: http://www2.uwstout.edu/content/rs/2004/article05.pdf

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containers which can still be injurious. On the other hand, if a retractable syringe is used, the needle gets locked in the barrel of the syringe which can be safely disposed of. In addition, the process of disposal of a safety syringe is cost effective as compared to a traditional syringe. Since the retractable safety syringes require less space in sharps container, their use reduces the disposal costs further and also saves the additional time spent on changing the containers.

2.2.3. REGULATORY LAWS ENFORCE USE

Needlestick injuries have resulted in an increased number of occurrences of infection due to transmission of blood-borne pathogens. To address such safety issues, there has been an increasing demand for ready-to-use, single dose, disposable syringe systems with safety features. Now health care facilities are also opting for safety devices to protect their staff from occupational hazards. Strict regulations have been enacted by governments around the world to mandate use of safety-engineered devices. Several organizations including OSHA and FDA have displayed concern about the prevention of needlestick injuries and, as such, issued regulatory guidelines. Since the needlestick safety and prevention act was passed in the United States in 2001, more than 24 states have implemented needlestick prevention laws. OSHA has the authority to issue fines up to USD 7,000 per incident in case of serious violations of the Needlestick Safety and Prevention Act.[4] As the aspect of occupational safety gains more attention and the healthcare professions become more compliant with the regulations, the market is expected to witness entry of new manufacturers driving the uptake.

2.3. WEAKNESSES

2.3.1. HIGHER ONE-TIME COST

As is the case with most of the advanced and innovative products in the market, the cost of a safety syringe at present is relatively higher than a conventional syringe. In some cases, the price can be as high as USD 1.00. This makes them unlikely to be affordable by countries with small health budgets. Factors such as start-up costs of the facility, low manufacturing volume and addition of safety features / associated parts account for the majority of the cost associated with the safety devices. However, as the demand picks up and more manufacturers get involved in the market, the prices are expected to come down driving mass adoption.

2.3.2. OPERATING CHALLENGES

The design of the safety syringe and the incorporation of the safety mechanism can, at times, result in the change in the procedure of administration. This is the primary cause of resistance of use of these devices by the healthcare workers. The inclusion of an add-on device makes the device

[4] *Source*: http://www.starwellnessusa.com/Portals/0/brochure/service/homepage/Needlestick-Safety-Prevention-Act.pdf

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relatively bulky and the operation more cumbersome. In syringes with hinged or sliding needle covers, the activation process requires a grip change in order to operate the safety feature.

Often, the activation of the retraction or shielding mechanism requires additional steps to be performed; the manually activated devices require the application of additional force to set off the mechanism. Furthermore, in some cases, the operation and activation of the safety syringe might cause tissue trauma to the patients.

2.4. OPPORTUNITIES

2.4.1. DESIGN INNOVATIONS: NEEDLELESS SYSTEMS AND PRE-FILLED SYRINGES

The best way to prevent needlestick injuries and needle reuse is to avoid the use of needles that are the primary source of infection. This principle is utilized in the design of needleless injection systems that administer medications without needle connections. The needleless injection systems, instead of using a needle to penetrate the skin, make use of the pressure exerted by the injected liquid to puncture the skin. Though the concept of needle free injection systems exists since 1930s, it has taken on new significance recently due to the increasing awareness about occupational safety.

Besides needleless injection systems, there are some needleless connector systems that are used to enhance safety in the infusion systems. Similar to needleless injection systems, the needleless connector devices eliminate the needles in intravenous systems (IV) that are used to deliver fluids, medications and blood through veins. According to OSHA, interlocking parts are used in these devices instead of needles for connections. Needleless connectors eliminate the use of a needle by directly connecting the IV administration sets (also called infusion sets) to the catheters.

Furthermore, the prefilled syringe format is gaining huge attention owing to the key benefits associated with its use. Compared to the conventional needle and vial format, prefilled syringes are better suited to reduce and/or prevent needlestick injuries. This is primarily owing to the reduced interaction during drug preparation. They are ready-to-use, easily disposable and reduce risk of cross contamination. They can be combined easily with safety devices having a needle retraction system, thereby preventing needlestick injuries. Prefilled syringes with integrated safety features have also been recently developed. Use of prefilled syringes considerably reduces the risk of blood-borne pathogens transmission. The prefilled syringe manufacturers are developing innovative devices which address this safety concern. In 2011, Unilife Corporation introduced its Unifill ready-to-fill syringes, with an integrated safety feature. More companies will look to develop competing products in order to cater to the unmet need in the market.

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2.4.2. RISE OF EMERGING MARKETS

Following the passage of the anti-needlestick legislation, the US market for safety syringes has witnessed significant developments in terms of the introduction of new and innovative safety injection devices. Though at present, the emerging markets lag behind in terms of awareness and governmental legislations, the ongoing focus is likely to accelerate the pace of adoption of the safety devices in these regions. Increased focus on healthcare awareness and regulatory initiatives will be the primary drivers for the growth of this market in emerging economies. Once these growth strategies are implemented, these regions will indeed be a major contributor in increasing the demand for safety syringes in the years to come.

Realizing the unmet market needs and future growth prospects, the companies are looking forward to selling and marketing their products in emerging economies. For instance, Revolutions Medical is currently working to get the import license for distributing its RevVac safety syringe in international markets including Brazil and Mexico.

Becton Dickinson, one of the leading players in this market, reported a 10% increase in the international revenues from safety engineered devices, amounting to USD 917 million in 2013.[5]

2.4.3. CASE IN POINT: SAFETY DENTAL SYRINGES

The use and application of safety syringes is widely recognized in the field of dentistry.

Needlestick injuries are common in the clinical dental practise with a sizeable proportion occurring with the use of non-disposable local anaesthetic syringes, predominantly during the removal and disposal of the syringe. The use of non-disposable syringes involves the re-sheathing of needles in order to dismantle the syringe and the appropriate components are then autoclaved. Specifically, in the UK, up to 56% of the dental practises can cause at least one needlestick injury per year and 30% of these injuries carry a moderate or high risk of infection.[6]

Safety dental syringes help to reduce the risk of accidental needlestick injury to a dental health provider that can occur after the administration of local anaesthesia (LA). As mentioned earlier, the protective feature in the majority of safety dental syringes is a protective sheath that covers the needle after it is withdrawn from the patient's tissues. However, there are a number of challenges that are associated with the implementation and use of needle safety devices at dental settings. To begin with, additional design modifications are required in these devices to make them clinically

[5] *Source*: http://biz.yahoo.com/e/131127/bdx10-k.html
[6] *Source*: http://panadent.co.uk/products/insafe-needle-disposal-starter-packs/

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appropriate for use in patients' mouths. In addition, there are visualization restraints during administration that can further increase the chances of needlestick injuries.

Nevertheless, the need for safety and continuous innovations are driving the development of improved safety devices. Some of the examples of the safety injection devices used in dentistry include the Ultra Safety Plus XL Syringe by Septodont, SafetyWand by Milestone Scientific, RevVac safety syringe by Revolutions Medical and InSafe Dental Syringe by Astek Innovations Ltd.

Specifically, the InSafe Dental Syringe is one of the few reusable safety syringes that are used in dentistry. The device is available in 1.8 or 2.2 ml format and is compatible with all the standard needles. The needle is dismantled at the end of the administration procedure through a single handed technique. In order to remove the needle securely, insert and fix the syringe with locked sleeve into the sharps container. Twist and push to fully insert the needle. The next step is to withdraw the syringe back and the contaminated needle is subsequently disposed of in the sharps container. Hence, unlike other dental syringes, the re-sheathing of the needle is not required. The needle remains protected always by a sliding sleeve that securely locks in the forward and back positions. In addition, the sleeve lock activation can be visually confirmed. The cost per injection is approximately 12pence for needle and adapter.[7]

The device is available in the following three configurations:

1. Handle type: It includes the thumb ring handle and T-type handle designs.
2. Cartridge type: It includes the 2.2 ml and 1.8 ml cartridge designs.
3. Aspiration type: It includes the O-ring, harpoon, 3-point harpoon, self aspirating and standard models.

Some of the key advantages of the InSafe dental syringe include:

1. It does not require the change of the administration technique by the dentist.
2. It allows the cartridge to be changed without dismantling the device.
3. The device can be conveniently disposed in the InSafe sharps container.
4. It offers a wide range of interchangeable aspiration options and handle design.
5. The weight and feel of the syringe is similar to that of a conventional syringe.
6. The syringe is autoclavable and can be fully dismantled for sterilization.

[7]*Source*: http://panadent.co.uk/wp-content/uploads/2014/01/InSafe-FAQ-July-2014.pdf

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2.5. THREATS

2.5.1. HISTORY OF DEVICE RECALLS

Many of the current self-injector devices in the market have incurred recalls. As the patients start using these devices, usability, safety and other issues have surfaced. The developers of such devices should be aware of these precedents to avoid a similar fate for newer devices. Any device recall is associated with a massive cost burden which will significantly impact the device evolution in a negative way. These costs are related to investigation / inspection, loss of market share, product replacement, current pipeline assessment and loss of production / development time.

As an illustration, Table 2.2 and 2.3 provides a few instances when auto injectors and pre-filled syringes have been recalled due to performance, quality or safety issues.

Table 2.2 **Recall of Autoinjectors**

Name of auto-injector	Reason	Recalling Manufacturer	Month-Year	Who made this recall
Enbrel SureClick Auto injector	Lack of Assurance of Sterility: Syringe barrel flange that slightly deviated from the center line of the syringe barrel resulted in broken or cracked syringes	Amgen Manufacturing, Limited	September 14, 2009 and January 18, 2010	FDA
NeulastaSureClick Injection Device	Slow or incomplete delivery of the content.	Amgen Limited	October 2006	MHRA
Anapen 500mcg, 300mcg and Junior 150mcg	Problem with delivery time and delivery volume of the dosage following activation of the auto injector has been identified	Lincoln Medical Limited	May 2012	MHRA
Diazepam Injection	Impurities/Degradation Products: High out of Specification levels for carbostyril, a known degradation product of diazepam	Meridian Medical Technologies	June 2012	FDA
Twinject 0.3 mg Auto-Injector	High Force-To-Fire values for the 12 month pull performance testing of Twinject 2008 annual stability units	Sciele Pharma, Inc., Atlanta	September 2009	FDA

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Name of auto-injector	Reason	Recalling Manufacturer	Month-Year	Who made this recall
EpiPen Auto-Injector 0.3mg/dose and EpiPen Jr. Auto-Injector 0.15mg/dose	Leakage from the vial into the needle area	Meridian Medical Technologies Inc.	May 1998	FDA
Epinephrine injection, USP, auto-injector	Small number of sheaths covering the needle may have pinholes	Shionogi Pharma, Inc., Atlanta	October 2010	FDA
SimponiSmartject Autoinjector	Affected auto injectors deliver less than the full dose if used.	Centocor Ortho Biotech, Inc.	February 2011	-

Source: Roots Analysis

Table 2.3 **Prefilled Syringe Recalls, 2003-2014**[8]

Drug	Company	Month/ Year	Reason for Recall	Issue Categorization
Eprex	J&J	August 2003	Rubber plunger leachables in drug	Contamination / Leachables
Ephedrine Hydrochloride	Aurum Pharmaceuticals Ltd.	January 2006 (UK)	Packaging Issue	Packaging Issue
NeulastaSureClick Autoinjector	Amgen	October 2006	Uneven silicone oil coating	Glass-Related Issue
Prefilled Flush Syringes	AM2 PAT Inc./ Sierra Pre-Filled Inc.	December 2007	Contamination	Contamination / Leachables
Heparin Sodium	Covidien	March 2008	Contamination	Contamination / Leachables
Enbrel SureClick Autoinjector	Amgen	September 2009	Glass breakage due to deviation of flange from center line	Glass-Related Issue
Paediatric H1N1 vaccine	Sanofi Pasteur	December 2009	Potency of the vaccine dropped below pre-specified limit	Drug-Related Issue
Enbrel	Amgen	October 2010	Glass breakage	Glass-Related Issue
Prefilled Saline Flush Syringes	Excelsior Medical	October 2010	Sterilization issues	Sterilization Issue
Zarzio	Sandoz	January 2011	Glass breakage	Glass-Related Issue
InvegaSustenna (paliperidonepalmitate)	J&J	February 2011	Glass breakage	Glass-Related Issue
Humira Pen	Abbott Laboratories	March 2011	Contamination with glass pieces	Contamination / Leachables
Eprex	J&J	September 2011	Inconsistent potency in dosage	Drug-Related Issue
Medroxyprogesterone Acetate	Teva Pharmaceuticals	December 2011	Presence of silicone particles	Contamination / Leachables

[8] Updated till May 2014; List may not be exhaustive

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Drug	Company	Month/ Year	Reason for Recall	Issue Categorization
Enoxaparin Sodium	Sandoz	February 2012	Defect with stopper	Packaging Issue
Morphine Sulfate	Hospira	April 2012	Higher volume than prescribed	Packaging Issue
Hydromorphone	Hospira	August 2012	Higher volume than prescribed	Packaging Issue
Typhoid Vi Polysaccharide Vaccine (Typhim Vi)	Sanofi Pasteur	October 2012	Potency of the vaccine dropped below pre-specified limit	Drug-Related Issue
Isovue (iopamidol)	Bracco Diagnostics	December 2012	Presence of foreign particles	Contamination / Leachables
Monoject Flush Syringes	Covidien	August 2013	Packaging and sterilization issue	Packaging Issue; Sterilization Issue
Copaxone (glatiramer acetate)	Teva Pharmaceuticals	October 2013	Presence of foreign particles	Contamination / Leachables
Imitrex (sumatriptan)	GSK	November 2013	Packaging issue compromising the sterility of the drug	Packaging Issue

Source: Roots Analysis

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3

CONCLUSION

3.1. TRANSITION FROM CONVENTIONAL DEVICES TO SAFETY INJECTION DEVICES

Over the past few years, there has been an increasing awareness about the healthcare workers being exposed to the threat of acquiring deadly diseases such as HIV and Hepatitis B through accidental needlestick injuries. This has stimulated the demand for safety delivery systems in the medical field over conventional syringes and needles. The simultaneous stringency in regulations and healthcare initiatives by governmental bodies has further fuelled the transition to safety injection devices from the traditional methods of administration. Technology is playing an equivalent part in enhancing injectable drug safety and patient compliance with the introduction of passive retractable safety syringes and needle free injection systems.

The strength of the market is derived from the advantages that the use of safety injection devices offers over traditional methods of drug delivery; some of the key benefits include the ease of disposal and other long term cost savings. With the use of safety mandated in the US, other healthcare markets are slowly moving towards the adoption of safety injection systems.

3.2. TECHNOLOGICAL ADVANCEMENTS HAVE ENSURED THAT THESE DEVICES CONTINUE TO GAIN TRACTION FROM HEALTHCARE PRACTITIONERS AND PATIENTS ALIKE

Technological advances in the design and working principle, over the past few years, have had a major impact on the safety injection devices market. Though safety engineered syringes have been around for more than twenty years, it has only been in the recent past that the subject is gaining widespread attention.

The market is considerably mature and has the presence of around 70 safety injection devices. In addition to the old safety syringes with basic safety features, there are some newly launched innovative products with improved safety mechanisms that are making a significant impact on the competitive landscape. The design modifications that have happened over the years include the

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incorporation of the retraction mechanism and passive designs that are capable to provide optimal protection and are caregiver friendly. Some of the retractable syringes such as the RevVac safety syringe, developed by Revolutions Medical, feature vacuum based retraction mechanism, rather than the commonly employed spring based retraction. This has resulted in increasing the ease of use, lowering the defective rate and cost of manufacturing.

Other examples of design modifications include the needleless injection and connector systems that eliminate the use of a needle. This can significantly reduce the number of needlestick injuries. In addition, the incessant growth in the injectable drugs market and increasing trend of self-administration is likely to further push the demand for the prefilled syringes.

Table 3.1 outlines a representative sample set of safety syringes currently available in the market; it demonstrates the multitude of options which the end-user currently has at his disposal.

Table 3.1 **Safety Syringes: Analysis by Volume**

Syringe Volume (ml) →

S.No.	Name of the Syringe	0.5 ml	1 ml	3 ml	5 ml	10 ml	20 ml
1	BD Safety-Lok Syringe		✓	✓	✓	✓	
2	BakSnap Retractable Safety Syringe		✓	✓	✓	✓	✓
3	SureSafe Automatic Retractable Syringe	✓	✓	✓	✓	✓	
4	SafePro Plus Safety Syringe			✓	✓	✓	
5	Mysafety Syringe		✓	✓	✓		
6	Medigard Auto Retractable Syringe		✓	✓	✓	✓	
7	Q Stat Safety Syringe		✓	✓	✓	✓	
8	Vanish Point Syringe	✓	✓	✓	✓	✓	
9	RevVac Safety Syringe			✓			
10	Needle-Pro EDGE Safety Device		✓				
11	SOL-CARE Luer Lock Safety Syringe			✓	✓	✓	✓
12	SOL-CARE TB Safety Syringe with Fixed Needle	✓	✓				
13	SafeSnap Safety Syringe			✓	✓	✓	
14	SafeSnapReadyToFill syringe			✓	✓	✓	
15	UniqSafe Safety Syringe		✓	✓	✓	✓	

Source: Roots Analysis

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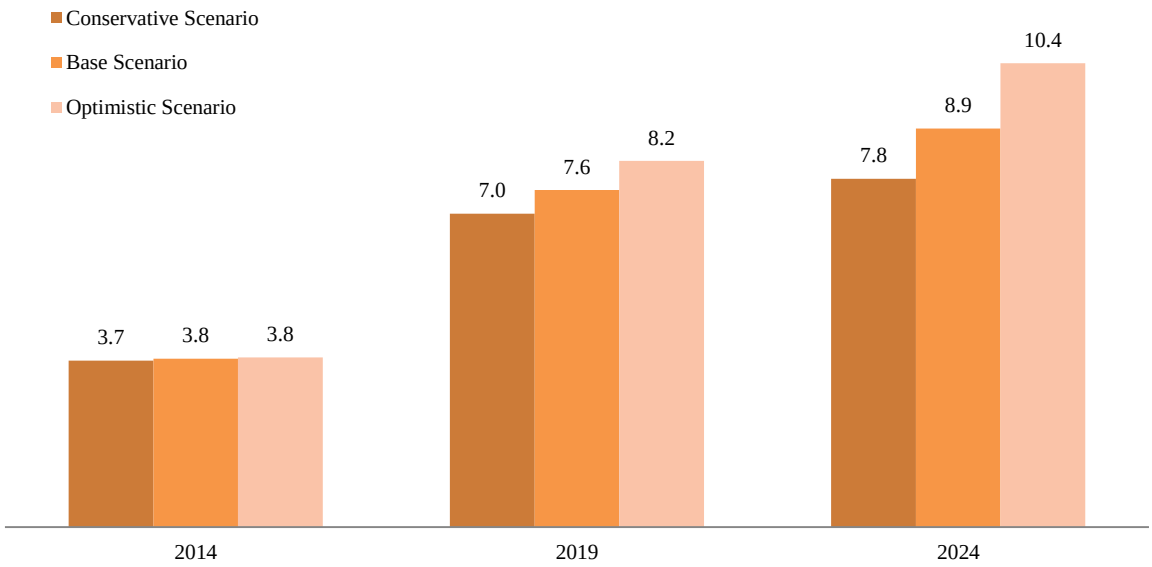
3.3. A MULTI-BILLION DOLLAR RAPIDLY GROWING MARKET

The market for safety syringes, which includes the retractable and non-retractable syringes, is estimated to be worth USD 3.8 Billion in 2014. With the improved regulatory landscape and continuous design innovations, we expect the market to witness strong growth in the years to come.

Figure 3.1 **Safety Syringes Market (USD Billion): Comparative Scenarios, 2014, 2019 and 2024**



Source: Roots Analysis

Figure 3.1 highlights the forecasted growth for the market of safety syringes. By the end of the coming decade, we expect the market to grow to USD 8.9 Billion (at an annualized growth rate of 9.0%) in our base scenario. Of note, the growth rate for the retractable syringes is likely to be higher than that for the non-retractable syringes over the ten year period. In terms of volume, we expect ~24 billion units to be sold annually by 2024.

The upside, driven by enforced regulations in emerging markets and ongoing technological developments, could be much higher. In our optimistic scenario, we have forecasted the market to be worth 26.5 billion units (equivalent to USD 10.4 billion) by 2024.

3.4. CONCLUDING REMARKS

Safety injection devices market, with the promise of providing safe drug delivery holds immense opportunities for the manufacturers in the future. As the stakeholders realize the potential of syringe and needle based safety devices to improve the quality of healthcare and, at the same time, control the long-term healthcare costs, their adoption is likely to increase. Additionally, the continuing

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advances in technology will ensure even higher compliance to the treatment regime. Needleless injection systems and prefilled syringes with safety features will continue to drive the uptake of this market.

At the same time, it is worth noting that the growing demand of non-invasive drug delivery systems and other alternative systems could cannibalize the sales of safety injection devices in the near future. Lack of regulatory guidelines in Asia Pacific could be one of the major reasons for the slow adoption of these devices in these regions. However, we believe that, despite all the challenges, the opportunities for achieving success in the market are aplenty.

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4

SAMPLE INSIGHTS

In this section, we have provided sample extracts of the insights captured in the main report.

Specifically, the following pages offer details on the following:

1. Safety Injection Devices: Market landscape
2. Safety Syringes: Distribution by Type of Safety Feature
3. Safety Syringes: Competitive Analysis
4. Safety Needles: Analysis by Price
5. Retractable Safety Syringes Market Forecast, 2014 - 2024

For more details on any of the above or if you'd like to access the full report, please write to us at sales@rootsanalysis.com

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4.1. SAFETY INJECTION DEVICES: MARKET LANDSCAPE

This section outlines the various types of safety injection devices available in the market. These devices have been categorized into the following three types, which have been discussed in detail in the subsequent chapters.

1. **Safety syringes:** These are the syringe based safety devices in which the safety mechanism is integrated or associated with the syringe. Examples of safety syringes include BD Safety-Lok syringe developed by Becton Dickinson and Monoject safety syringes manufactured by Covidien.
2. **Safety needles:** These are the needle based safety devices in which the safety feature is associated with the needle. Examples of safety needles include BD Autoshield Duo-Pen needle developed by Becton Dickinson and Magellan Hypodermic Safety Needles developed by Covidien.
3. **Other add-on safety needle tools:** These comprise the stand-alone needle protection devices which can be used with the needle systems that do not have an integral engineered or attached safety mechanism. The add-on safety needle tools include the tip caps or other needle protectors that are usually packaged individually and can be attached with the conventional injection device during use. Examples of add-on safety needle devices include Point-Lok Needle Protection Device developed by Smiths Medical and Monoject Safety Syringes Tip Caps by Covidien.

Sample Insights 1
For access to the full version, contact

Table 4.1 presents the list of safety injection devices available in the market along with their categorization into the above described three types.

Table 4.1 List of Safety Injection Devices

S.No	Name of the Device	Company	Category
1	BD Safety-Lok Syringe	Becton Dickinson	Safety syringe
2	BD Safety Glide Syringe for Insulin, TB and Allergy	Becton Dickinson	Safety syringe
3	BD Integra Syringe with Retracting PrecisionGlide Needle	Becton Dickinson	Safety syringe
4	BD Safety Glide Shielding Hypodermic Needle	Becton Dickinson	Safety needle
5	BD Eclipse	Becton Dickinson	Safety needle
6	BD AutoShield Duo Pen Needle	Becton Dickinson	Safety needle
7	BD AutoShield Pen Needle	Becton Dickinson	Safety needle
8	The BD UltraSafe PLUS Passive Needle Guard	Becton Dickinson	Other safety tools

Complete list of 72 safety syringes, safety needles and add-on safety tools presented on Page 36, 37 and 38

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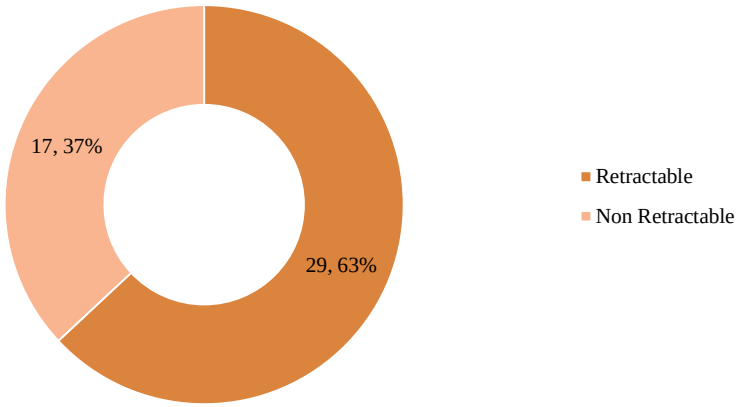
4.2. SAFETY SYRINGES: DISTRIBUTION BY TYPE OF SAFETY FEATURE

During our research, we identified 46 safety syringes. Figure 4.1 shows the distribution of safety syringes by the type of safety mechanism, i.e. into retractable and non-retractable syringes.

Figure 4.1 Safety Syringes: Distribution by Type



Source: Roots Analysis

Out of 46 safety syringes that were identified during the research, 29 were found to be retractable, accounting for 63% of the total safety syringe devices. 17 safety syringes (the remaining 37%) are non-retractable in which the safety feature involves covering the needle with a shield or protector. The data reflects the increased focus on retractable syringes which undeniably is due to the numerous benefits that they offer to the users including enhanced safety, less time required for operation and ease of use.

Sample Insights 2
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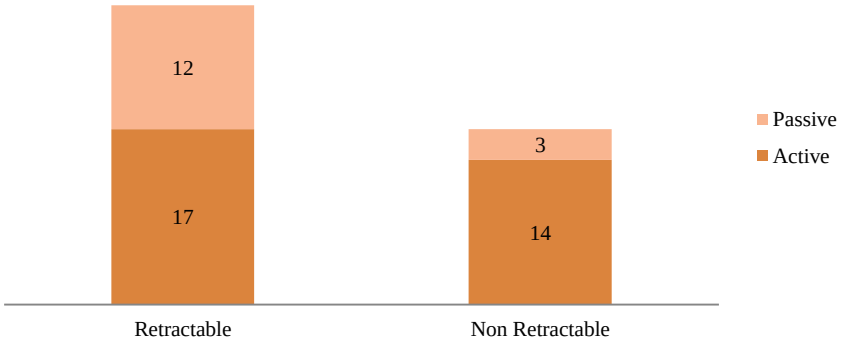
Figure 4.2 Safety Syringes: Distribution by Mode of Activation



Source: Roots Analysis

As can be observed from Figure 4.2, out of 29 retractable syringes, 17 are active (i.e. manually retractable) and 12 are passive, in which the needle is retracted automatically after administration. In case of non-retractable syringes, out of 17 syringes, 14 are active, which require manual operation to activate the safety feature.

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4.3. SAFETY SYRINGES: COMPETITIVE ANALYSIS

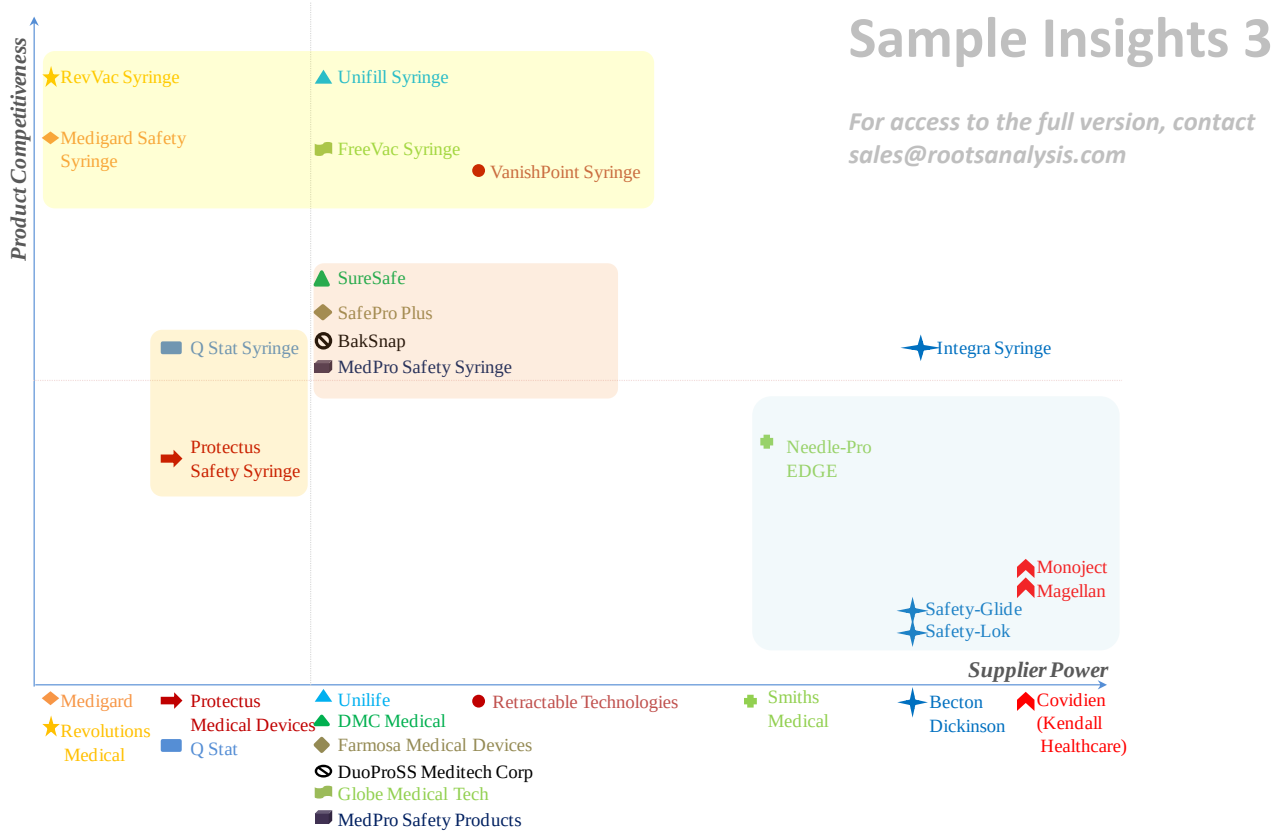
As mentioned earlier, we identified 46 safety syringes during our research. Out of these 46 safety syringes, 17 have been analysed on the following two parameters.

1. Product Competitiveness
2. Supplier Power

The primary purpose of this analysis is to assess these products which are influencing the present competitive landscape. It provides an approach to segregate the product portfolio while highlighting specific features for some of them. It is important to mention that, at no point, the discussion in this analysis should be construed as a firm recommendation that one device is better than the others.

Similarly, supplier power is indicative of the parameters that illustrate the comparative position of several device manufacturers in terms of their relative strength in commercialising these devices. These proxy parameters which have been taken into account to do this ranking include annual revenues, number of employees etc. Figure 4.3 analyses 17 safety syringes that are distributed on the basis of product competitiveness along Y axis and on the basis of supplier power along X axis.

Figure 4.3 **Safety Syringes: Product Competitiveness Analysis**



Supplier Power increases from left to right

Product Competitiveness increases from bottom to top

Source: Roots Analysis

Continued on page 63, 64 and 65

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4.4. SAFETY NEEDLES: ANALYSIS BY PRICE

Table 4.2 shows the prices of some of the safety needles arranged in descending order.

Table 4.2 Safety Needles: Purchase Price[9]

S.No	Name of the Device	Company	Active/Passive	Price/Piece
1	BD AutoShield Duo Pen Needle	Becton Dickinson	Passive	$1.00
2	Novo Nordisk NovoFine Autocover	Novo Nordisk A/S	Passive	$0.65
3	BD Safety Glide Shielding Hypodermic Needle	Becton Dickinson	Active	$0.41
4	Surguard3 Safety Hypodermic Needle	Terumo Medical Corp.	Active	$0.41
5	Magellan Hypodermic Safety Needles	Covidien (Kendall Healthcare)	Active	$0.37
6	BD Eclipse	Becton Dickinson	Active	$0.28
7	SurGuard2 Safety Needle	Terumo Medical Corporation	Active	$0.25

Source: Roots Analysis

Sample Insights 4

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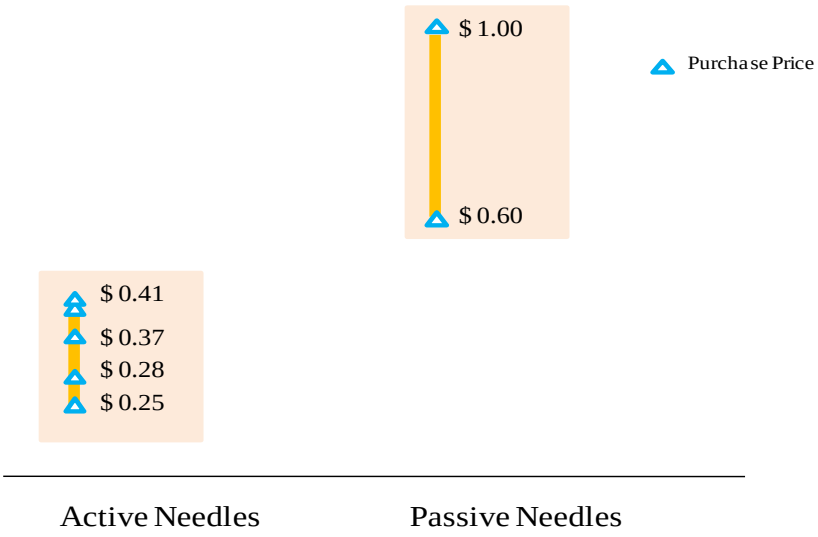
Similar to the safety syringes, the price of safety needles is also quite variable. In the sample dataset that we researched, prices ranged from USD 0.25 to USD 1.0. The table indicates that passive needles are more expensive than active needles owing to the obvious benefits such as automatic safety mechanism and consequent ease of use. One of the more expensive passive safety needle, developed by Becton Dickinson, is priced at USD 1.00. The pre-eminence of a passive safety technology also exists because most of the needlestick injuries occur in a few seconds after the syringe's withdrawal.[10] Figure 4.4 highlights this information in a pictorial representation.

Figure 4.4 Safety Needles: Analysis by Price



Source: Roots Analysis

[9] List may not be exhaustive
[10] *Source*: http://www.ondrugdelivery.com/publications/Prefilled%20Syringes%20Sep%202011/Safety%20Syringe.pdf

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4.5. RETRACTABLE SAFETY SYRINGES MARKET, 2014- 2024

Retractable Safety Syringes Market, 2014- 2024 Figure 4.5highlight our base scenario for the likely growth in number of retractable safety syringes in the short-mid term. We firmly believe that the technological advancements and benefits of retractable syringes including ease of use and enhanced safety over the non-retractable syringes are likely to push the demand for retractable syringes higher. In addition, the improved economic advantages and the caregiver- friendly operation features are some other key reasons that will spur the growth of this segment. As a result, retractable safety syringes are likely to gain higher market share in the future.

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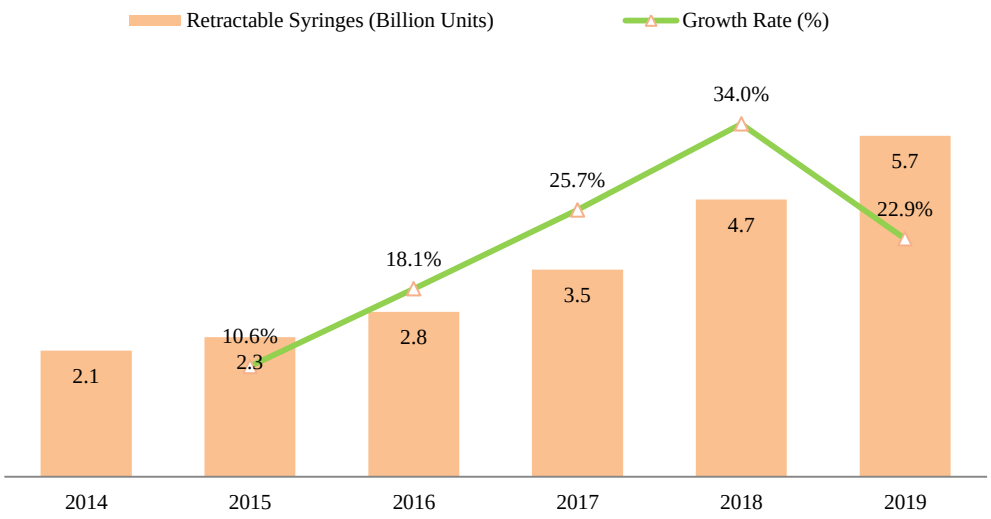
From an estimated 2.1 billion syringes in 2014, we have forecasted the market to grow to 5.7 billion and 7.6 billion by 2019 and 2024 respectively (in our base scenario).

Figure 4.5 **Number of Retractable Safety Syringes, Short-Mid Term (2014 - 2019): Base Scenario (Billion Units)**



Source: Roots Analysis

The details of the conservative and the optimistic scenarios are presented in Appendices.

As the market for retractable syringes evolves, the percentage composition of each of the three classes, high price, mid price and low price will undergo some variation. For instance, we have estimated the percentage composition for high-price retractable syringes to increase from 12% to 30% in the period 2014-2024.

Detailed market forecast (both in terms of value and volume) for various types of syringes available in Section 8 of the full report

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