



DISPOSABLE SYRINGE MARKETS

(SAMPLE COPY, NOT FOR RESALE)

Trends, Industry Participants, Product Overviews and Market Drivers

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1. Introduction

1.1 Statement of Report

The report examines the disposable syringe market. It provides detailed forecasts for the traditional and safety-engineered sharps markets. It describes the major drivers and restraints, technology trends, and industry challenges for the disposable syringe market. It examines the markets for blood collection sets, hypodermic access syringes and needles, sharps-based insulin delivery devices, and other specialty syringes and needles. Additionally, the study considers the disposable syringe supplies utilized in clinics and by patients in their homes to diagnose and monitor diseases, as well as to administer medications. This analysis is intended to provide basic market data pertaining to the U.S. and worldwide market segments. Each market segment is analyzed to determine size, growth rates, sales projections and factors influencing growth in the U.S. and internationally. Unit and dollar volumes have been used to indicate market sizes.

1.2 About this Report

The study specifically focuses on market dynamics, current market drivers and emerging trends within the disposable syringe markets. Additionally, this review examines industry challenges and potential threats to syringe and needle supply manufacturers. The emphasis is on those companies actively developing and marketing products to hospitals, physicians and the public for medically-related uses. The reader should consult other TriMark Publications reports at <http://www.trimarkpublications.com> for a detailed discussion of the important individual market segments related to syringes, such as glucose testing, blood constituent analyses as used in hospital, point of care and doctor's office settings, and diabetic markets.

1.3 Scope of the Report

The market segments for disposable syringes are:

- Prefilled syringes.
- Safety syringes.
- Insulin injector pens.
- Needleless injectors.
- Vaccination injectors.
- Blood collection needles and syringes.
- Hypodermic needles and syringes.
- Insulin needles and syringes.
- Specialty needles and syringes.

This analysis provides an overview of individual disposable syringe market segments, some of which possess the elements that will lead to high and sustained growth rates for the near future. The report also presents a description of the ancillary supplies marketed by major companies in each market segment. The study presents qualitative and quantitative data, and information on key market measures and benchmarks such as:

- Market size by segment.
- Company market share.
- Product market share.
- Technology market share.
- Industry structure.
- Economic factors.
- Syringe design criteria.
- Product pricing.
- Emerging markets.
- Market projections.
- Strategic alliances.
- Proprietary technology.

- Technology factors.
- Market factors.
- Regulatory factors.

Technology areas include:

- *Auto-Disable/Single-use Syringes*: Syringes that deactivate after one use and are especially useful for vaccinations in developing countries.
- *Blood Collection Syringes and Needles*: Winged and standard phlebotomy access devices.
- *Retractable Syringes*: In retractable syringes, the needles retract into the syringe barrel after use, so the barrel acts as the sharps container.
- *Needleless Injectors*: Injection devices that deliver the pharmaceutical through the skin without the use of a needle.
- *Autoinjector Pens*: In autoinjector pens, syringe automatically triggers to insert the needle to deliver the pharmaceutical.

This report does not cover peripheral devices such as lancing devices for patients with diabetes. Moreover, it does not discuss non-syringe devices such as breast examination kits, temperature-measuring devices, fertility control devices, condoms, gels or creams. This review, furthermore, does not cover disposable plastic supplies for the healthcare market unless the products designed specifically for use and sale in one of the designated market segments covered in this report.

A number of companies that market syringe products are primarily distributors of these products, rather than the primary developer. These companies—necessary and important to the medical products industry—are covered here to a limited degree. Concentration is placed on the disposable medical supplies market segment in important worldwide markets such as the U.S., Japan and Europe. It focuses primarily on the hospital market segment, and, separately, on a description of the devices and supplies marketed by major companies in this segment for home use. Additionally, the report focuses on the vaccine segment of the disposable syringe market, and its growth in developing countries.

1.4 Objectives

The primary objectives of this study are to:

- Identify important market drivers through a comprehensive look at various sales segments for disposable syringes.
- Obtain a complete understanding of the structure of the disposable syringe business from its basic principles to its applications.
- Discover feasible market opportunities by identifying high-growth applications in different medical areas, with a focus on the biggest and expanding markets.
- Focus on global industry developments through an in-depth analysis of the major world markets for disposable syringe supplies, including forecasts for growth.
- Define the disposable syringe market including definitions, processes and trends.
- Assess the market drivers and bottlenecks, from the perspective of the medical and commercial communities.
- Discuss the potential benefits of disposable syringes for various sectors of the medical and commercial communities.
- Establish the current total market size and future growth of the disposable syringe market, and analyze the current size and growth of individual segments.
- Provide current and forecasted market shares by company.
- Discuss profit and business opportunities by individual market segment.
- Provide strategic recommendations for near-term business opportunities.
- Assess current commercial uses of disposable syringes.
- Assess the disposable syringe business model.

- Analyze and evaluate safety syringe products, and assess the market potential for existing and probable future products.
- Analyze product designs, technologies and marketing challenges of syringe manufacturers.
- Provide detailed descriptions of segments in safety syringe market, market demographics and business strategies.
- Chart product sales data, market share and forecasts.
- Profile safety syringe companies, noting their product development activities, business strategies, and corporate alliances and affiliations
- To assess the importance of pharma-device alliances and design partnerships on future safety syringe products.
- Evaluate the impact of economic, technological and regulatory factors on parenteral drug delivery markets.

This report answers the following questions:

- What are the near term business opportunities in disposable syringes?
- What are the current and forecasted sizes of the disposable syringe market?
- What are the business models currently used by companies in disposable syringe market?
- What are the technologies used in disposable syringe supplies?
- Who holds the proprietary rights to disposable syringe technology?
- What regulatory processes must disposable syringes undergo in the U.S., Japan and Europe?
- How will technology changes in disposable syringes affect treatment and payment paradigms?
- How will litigation concerns increase physician and hospital use of disposables?
- How will technology reduce adverse growth trends and decrease total patient care cost?
- What are the drivers and impediments to growth for each market segment covered?

1.5 Methodology

The author of this report has a Ph.D. with over 40 years of consulting experience. He has written over 1,000 articles, and has published four books. The editor holds a Ph.D. and is a retired college professor with vast experience in biochemistry, biotechnology, pharmacology and environmental biology. Company-specific information is obtained mainly from industry trade publications, academic journals, news and research articles, press releases and corporate websites, as well as annual reports for publicly-held firms. Additionally, sources of information include the non-governmental organizations (NGOs) such as the World Health Organization (WHO) and governmental entities like the U.S. Department of Health and Human Services (HHS) and U.S. federal agencies such as the National Institutes of Health (NIH), the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Where possible and practicable, the most recent data available have been used.

Some of the statistical information was taken from Biotechnology Associates' databases and from TriMark's private data stores. The information in this study was obtained from sources that we believe to be reliable, but we do not guarantee the accuracy, adequacy or completeness of any information or omission or for the results obtained by the use of such information. Key information from the business literature was used as a basis to conduct dialogue with and obtain expert opinion from market professionals regarding commercial potential and market sizes. Senior managers from major company players were interviewed for part of the information in this report.

Primary Sources

TriMark collects information from hundreds of Database Tables and many comprehensive multi-client research projects, as well as Sector Snapshots that we publish annually. We extract relevant data and analytics from TriMark's research as part of this data collection.

Secondary Sources

TriMark uses research publications, journals, magazines, newspapers, newsletters, industry reports, investment research reports, trade and industry association reports, government-affiliated trade releases and other published information as part of its secondary research materials. The information is then analyzed and translated by the

Industry Research Group into a TriMark study. The Editorial Group reviews the complete package with product and market forecasts, critical industry trends, threats and opportunities, competitive strategies and market share determinations.

TriMark Publications Report, Research and Data Acquisition Structure

The general sequence of research and analysis activity prior to the publication of every report in TriMark Publications includes the following items:

- Completing an extensive secondary research effort on an important market sector, including gathering all relevant information from corporate reporting, publicly-available data and proprietary databases.
- Formulating a study outline with the assigned writer, including important items, as follows:
 - Market and product segment grouping, and evaluating their relative significance.
 - Key competitors' evaluations, including their relative positions in the business and other relevant facts to prioritize diligence levels and assist in designing a primary research strategy.
 - End-user research to evaluate analytical significance in market estimation.
 - Supply chain research and analysis to identify any factors affecting the market.
 - New technology platforms and cutting-edge applications.
- Identifying the key technology and market trends that drive or affect these markets.
- Assessing the regional significance for each product and market segment for proper emphasis of further regional/national primary and secondary research.
- Completing a confirmatory primary research assessment of the report's findings with the assistance of expert panel partners from the industry being analyzed.

1.6 Executive Summary

The main product groups within the syringe and needle sector of this report include disposable and safety syringes, injection pens, needleless injectors and specialty needles. This market is driven substantially by a disparate collection of situations from disease management and prevention to the social condition of intravenous (IV) drug abuse. Each of this area and its potential to influence demand for injection equipment is discussed. Detailed examination of the injection pen and needleless injector market segments is presented here, as well as a comment on reusable syringes. While the market for injection devices is largely driven by safety concerns, as well as by trends in disease management, a number of key issues affecting the use of disposable syringes in the home healthcare market are discussed in this report. They include such topics as ease-of-use/patient compliance and sharps disposal.

User-friendly designs and the availability of an increasing number of drugs in prefilled disposable cartridges and syringes are propelling the growth of injector pens at the expense of other drug delivery methods such as traditional syringes. Advances in synthetic materials and concurrent development partnerships between pen designers and drug developers are important factors in the growth of this segment. Already a leading drug delivery method in Europe and the U.S.—more than half of all diabetics in Europe and the U.S. administer insulin via pen injectors—pen growth will expand as new therapies become available for pen devices. The widespread acceptance of pen devices among adults and children in the U.S., Europe and Japan demands for devices with very easy and error-free handling, and high accuracy in dose delivery. Insulin pens should be accurate and precise, especially for low-dose administration. While many, especially older patients, use prefilled pen devices, some insulin pen models have a refill system so that they can be used over a period of several months or even years, which requires a high quality product line in terms of stability and accuracy.

Administration of insulin through pen devices in the ambulatory care setting has been shown to improve insulin regimen adherence and patient satisfaction. Authors of a survey evaluating insulin pen use in patients who previously used vials and syringes found that more patients who used pens reported not missing any injections and

felt it was easier to comply with their insulin regimen than when they used conventional vials and syringes. Patients also reported a strong desire to continue using the pens and stated that they would recommend the method to other patients.

The traditional needle and syringe for the delivery of vaccinations and other liquid medications either IM or SubQ are on the verge of major transformation. Numerous studies by nearly all needle free device manufacturers conclude that patients prefer needle free injections to those made with the traditional needle and syringe. There are always two sides of the equation to consider—the healthcare practitioner and the patient. Advantages of needle free injection devices for the healthcare worker are the 100% reduction in needle stick injuries, easy disposal, as there is no chance of a biohazard incident, and ease of use. For the patient, needle free injections just feel less threatening, are not intrusive, and there is a 100% reduction in the risk of blood-borne disease transference.

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2. Disposable Syringe Markets

2.1 Overview

The main product groups within the syringe and needle sector of this report include:

- Disposable syringes.
- Disposable safety syringes.
- Injection pens.
- Needleless injectors.
- Specialty needles.

Syringe and needle device products are sold to and used by healthcare providers, including acute care hospitals, alternate care facilities, doctor's offices, clinics, emergency centers, surgical centers, convalescent hospitals, Veterans Affairs facilities, military organizations, public health facilities and prisons. Important syringe markets are:

- Critical care hospitals.
- Clinics and ambulatory facilities.
- Large managed care practices.
- Independent physician practices.
- Long-term care facilities.
- Medical research.
- Home healthcare.

The syringe and needle device market continues to be a market in transition. The nature of the products comprising the market is changing from customary devices to those developed with safety as a priority. The implementation of these safety-driven products is primarily in the U.S. disposable syringe market, with sales improving outside the U.S. The impetus for the change to safety devices is the risk that coexists with needlestick injury, which includes the transmission of over █ blood-borne pathogens, including human immunodeficiency virus (HIV, the virus that causes acquired immune deficiency syndrome [AIDS]), hepatitis B and hepatitis C. Because of the occupational and public health hazards posed by conventional disposable syringes, public health policy makers, domestic organizations and government agencies have been involved in the effort to get more effective safety needle products to healthcare workers. Federal legislation requiring that safety needle products be used for the vast majority of procedures (the Needlestick Safety and Prevention Act) was signed into law in November 2000, was implemented thereafter by the Occupational Safety & Health Administration (OSHA) and became effective for most states in April 2001.

According to Investrend Communications, Inc., the worldwide unit market for syringes and needles was █ units. With an annual growth rate of about █%, this market is estimated to reach █ units in █. According to Penrith Valley Economic Development Corporation (PVEDC), the U.S. market for disposable syringes in █ was \$ █ and with an annual growth rate of about █% the market is estimated to reach \$ █ in █. According to an estimate by the █, the global market for safety syringes was \$ █ and it is likely to reach \$ █ in █. According to █, the European Union (E.U.) market for prefilled Syringes was \$ █ in █ and is likely to reach \$ █ in █. According to █, in █ the global market for prefilled syringes is in the range of █ to █ units. The growth rate remains at a high level of more than █% annually due to a number of factors, such as greater medication safety and increased convenience from using a prefillable device. According to █, European Insulin Delivery Devices Market earned revenues of \$ █ in █ and this is estimated to reach \$ █ in █.

The disposable syringe market is driven substantially by a variety of arenas, including disease management and prevention, and IV drug abuse. Each of these areas has the potential to increase injection equipment sales. Disposable needles and syringes, including prefilled syringes, hold a dominant share, and despite significant advances in the use of needleless injectors, the disposables are expected to retain their position. While the U.S. is and will remain the region of highest share in the overall injection devices market, it is forecast that Europe will