NanoMarkets Report

Worldwide Medical Polymer Markets: 2013 – 2020

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Summary

NanoMarkets believes that medical polymers represents a major opportunity in the medical materials market over the next few years. Several factors are leading to growth in this market. Perhaps the most obvious is the aging of the population in developed nations is expanding the addressable market for polymer implants. Many polymer implants are specifically intended to assist elder patients.

Opportunity in this market has also expanded because the latest technical developments in medical polymers can fine tune implant capabilities, enable better fits for implants, and increased biocompatibility. Polymer structures can also now substitute for cartilage or enable doctors to grow a patient's tissue for transplants.

At the same time the new legal protections that followed the silicone breast implant debacle have considerably reduced the risk in the medical polymer space. And as a result of all of these factors, the medical polymer business has taken off, with the emergence of new start-ups and plenty of M&A activity.

With all that is happening in this space, NanoMarkets is publishing a report that identifies current and future opportunities in the medical space and provides guidance on the technical and regulatory framework in which these opportunities are arising. As with all NanoMarkets reports in the medical materials field, this report includes a granular eight-year forecast and also profiles key suppliers and analyzes the complete supply chain for medical polymers. For the firms covered we discuss their strategies and needs along with their strengths and weaknesses. Finally, the report provides an analysis of the market for medical polymers in various important country-specific markets.

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Worldwide Medical Ceramics Markets: 2013

Chapter One: Introduction

1.1 Background to this Report

This report summarizes the escalating opportunity for polymers in the healthcare sector. On account of their versatile properties, polymers have gained respectable popularity in this field, resulting in their wide-scale use. A direct impact has been the improvement in technologies for the production of high-quality polymer resins on a large scale.

In addition, major polymer producers are making investments in order to portray themselves as medical polymer manufacturers. This interest is driven by the market growth of this sector, which should continue to experience sustained profitability.

Applications: The use of medical polymers in general can be classified into three major domains:

- Implants and devices—systems that are used either inside the body or in conjunction with the body, such as cardiovascular prostheses, ocular lenses, orthopedic implants, etc.
- Diagnostic systems—materials in which the analysis and detection of the causative reasons for illness are carried out in a timely fashion, ensuring follow up treatment procedures.
- Hospital accessories—surgical, microbiological, pathological, and clinical labware commonly employed in day-to-day operations.

All of these applications are expected to grow in size and volume as people in both developing and developed nations vie for better medical treatments and procedures. Advances in polymer technology are overcoming certain performance barriers and enabling these materials to meet the stringent requirements of this sector, particularly for the implants and devices segment, where the polymers are intended for "inside the body" usage.

Segmentation: The medical polymer market is segmented based on the physical nature of the polymer materials into two categories: plastic resins and fibers and elastomers. They are also classified as biostable/non-biodegradable or biodegradable. Resins are liquid-soluble polymers, while fibers come in long elongated shapes.

Resins and fibers: Non-biodegradable medical resins and fibers are rigid plastics, including thermally remoldable and fixed thermoplastics and thermosets. Examples are polyethylene (PE), polypropylene (PP), polyvinyl chloride (PVC), polyethylene terephthalate (PET), polyamides (PA), polyfluoroterephthalate (PFTE), polyvinyl alcohols (PVA), polymethyl methacrylate (PMMA), polyhydroxy ethyl methacrylate (PHEMA), polycarbonate (PC), polystyrene (PS), polyesters, etc.

These resins are all polymerized from their respective monomers via different polymerization techniques in processes that have been optimized to provide high yields of high-quality product. Thermoplastics are predominately used in the healthcare sector because they meet the demanding property requirements of the medical industry.

The mechanical properties of plastics are further improved with the help of additives, such as coloring agents, stabilizers, rheology modifiers, etc. Extensive cross-linking results in a random three-dimensional network of interconnected chains. As one might expect, extensive cross-linking produces a substance that has more rigidity, hardness, and a higher melting point than the equivalent polymer without cross-linking.

While these polymers are easily processed, the threat of additive or unreacted monomer leaching during use is significant, particularly for in-vivo implantable devices, and must be addressed. Dow Chemical, for example, suffered a major setback due to the leaching of small molecules into the bloodstream of patients from implants manufactured with its polymeric material. Better processability is sought in order to reduce such side effects, while utmost care is also taken to characterize any biomaterial in order to prevent the ghastly scenario of tissue reaction.

Elastomers: Unlike plastics, elastomers are able to withstand large deformations and still regain their original dimensions once the stretching force is released, and thus have a rubber-like elasticity. Such materials have a combination of stiffness, stretchability, resilience, and toughness. Non-biodegradable elastomers include silicon (Si) rubber, polyurethanes (PU), natural rubber (NR), butyl rubber, and very recently, machined thermoplastic elastomers. Although all have extensive applications in the mechanical and electrical world, Si rubber, Pus, and TPEs also have many medical uses.

1.1.1 Boom in Thermoplastic Elastomers (TPES) and Engineered Plastics (Super Specialty Plastics)

In addition to the commodity polymers mentioned above, new-age elastomers are gaining importance in the medical market today. Commercial elastomers synthesized without physical or chemical crosslinks or vulcanization have more flexible molecular networks. They have both thermoplastic and elastomeric properties, providing a “soft touch”. In addition, because they are easily manufactured using a variety of techniques, they are being added to the portfolios of large polymer manufacturers.

The device industry is specifically using them to coat accessories, such as catheters, gloves, and syringes, in order to impart a soft touch feel. Their use is expected to grow in intravenous drug delivery systems, cardio systems, and blood collection devices because engineered TPEs have high barrier properties along with other benefits.

Copolymeric products, or engineered polymers, improve the working efficiency of some of the above-mentioned polymers by incorporating unique feature that can benefit the medical industry. With this approach, significant properties of individual polymer chains can be specifically introduced into the final product. A good example is the gas-permeable ocular lenses provided by major eye care companies such as Bausch and Lomb. The lens is an amalgamation of many polymeric components and also has minute pores that make it permeable to oxygen, providing better efficiency than previously available rigid lenses.

Selection of a polymer for a given application also depends on it sterilizability, because all instruments and devices must be sterilized before they are implanted. Elastomers, TPEs, and engineered thermoplastics can be sterilized by radiation or steam, and they are also autoclavable. The challenge is to render them stable where repeatable sterilization cycles are employed for different applications, such as for diagnostics and labware products.

1.1.2 Rise of Degradable Polymers

The last decade has seen the rise of biodegradable polymers in terms of both production and utilization in the medical sector. These materials are crucial to the paradigm shift from biostable polymers, particularly for the facilitation of drug delivery in a controlled manner while leaving little material inside the body. The current trend suggests that in the near future, entire prostheses will be developed from these materials.

While they will not be used to manufacture diagnostic products, biodegradable polymers will be incorporated into implants and some clinical labware to a large extent. In fact, drug eluting stents available on the market today already contain biodegradable polymer coatings.

The market for such innovative devices will undoubtedly grow due to the explosion of lifestyle diseases. The limiting factor for these polymers is, again, the leaching of small molecules from the materials. At present, natural polymers and degradable polymers approved by regulatory bodies such as the U.S. Food and Drug Administration (FDA) are predominant. There is some additional interest in discovering new biodegradable polymers for medical applications, but investment in this area is limited due to the need to complete extensive long-term studies in order to validate new materials.

1.1.3 Important Points for Manufacturers

- Companies venturing into medical polymer manufacturing must comply with strict production technology processes and procedures, taking care not only during the synthesis of these materials, but also ensuring storage of these products in a contamination-free environment.

- It is critical to control the quantity, quality, molecular characteristics, and leaching properties of all of the ingredients used to prepare the polymeric material, including not only the monomers, but any plasticizers, crosslinkers, coloring agents, stabilizers, fillers, reinforcements, impact modifiers, flame retardants, etc. Concerns about leaching of such molecules are pertinent for implants, but not so critical for diagnostic systems. It should be noted here that the additive processing industry will also be affected by the determination of acceptability of such biomaterials.

- Biocompatibility and compliance with region-specific regulations is imperative for the optimal use of any medical product. There is some flexibility in working with previously approved polymers. It is recommended that new manufacturers build their base with such polymers before investing in new polymer development efforts.

- The various medical applications require specific polymers engineered to give unique features. It is therefore recommended that players in this market deal with individual segments one at a time.

  For home-based healthcare appliances, such as glucometers, blood pressure monitors, and kidney dialysis, blood filtering, nebulizing, and breathing machines, color branding and aesthetics often drive consumer preferences. Diagnostics systems and hospital accessories require polymers with easy processability, flexibility, optical clarity, etc. Prostheses, grafts, and devices placed internally should be favorably designed to provide optimal implantation.

1.2 Scope and Objectives of this Report

This report is the first analysis from NanoMarkets on the market for polymers used in medical applications. It is a comprehensive study of current trends in the market, including industry drivers and limitations on the growth of polymers in the healthcare sector. The report provides an outline of the technological aspects of various polymers used for the production of implantable devices, surgical accessories and disposables, and diagnostic systems.

Specifically, the objective of this report is to analyze the polymers currently used in medical applications and evaluate their opportunities in this field. Market projections for the next eight years are provided along with a brief description of various essential medical products, their manufacturers, and the raw polymeric materials.

The forecasts are executed based on an inherent technical understanding of currently used polymers and their characteristics. We have also relied on various scientific papers from journals and literature from various companies (brochures, annual reports, and articles) in order to understand the requirements for polymers used in the medical industry.

In addition, we have also focused our attention on the regulatory mechanisms, policies, laws, and authorities in the U.S., Europe, and the Asia-Pacific regions in order to provide an idea of what it takes for a manufacturer producing polymers to generate medically-approved materials. The report also covers what is required for a medical device or system to be accepted clinically and the implications for long-term use of polymeric materials.

Readers of this report will gain the following:

- An analytical review of polymers used for medical applications, including developing implants, diagnostic systems, and hospital labware.
- Knowledge on current technical and market trends, including general market drivers for improvement in the healthcare sector, polymer production, and evaluation for clinical approval.
- An understanding of key medical products and their future implications.
- A pin-pointed analysis of the changing dynamics of polymer producers.
- Eight–year forecasts established based on expected market growth.
- A brief technological road map for understanding industry growth.
- Profiles of major companies operating as manufacturers of medical polymers.
- Insight into important geographical locations pertaining to polymer and healthcare sectors.
- Information on the size of the medical polymer market in developed nations and the fast-growing economies in Asia, such as China and India.
- Details of the regulatory requirements of these countries for producing high-quality, medically approved polymers and their use in various applications.

- Help in making business decisions for venturing into the medical polymer market.
- Descriptive and distinctive graphics, along with concise, tabular analyses of various domains.

1.3 Methodology and Information Sources

The forecasting approach in this report identifies and quantifies the underlying addressable markets, various polymer applications and penetrations in those markets, and the performance of the medical polymers industry in leading geographical regions. We also evaluate the stated plans of key firms in the market in our forecasting analysis. Forecasting is done for an eight-year period.

To determine where the opportunities lie, we have based this report on information from a variety of sources:

- Information is gathered largely from primary sources through NanoMarkets' analysis of relevant applications markets and market trends based on discussions with key players, including interviews with entrepreneurs, business owners, business development and marketing managers, and technologists involved with various aspects of the medical polymer markets.
- Secondary research for this report was also taken from information available on the World Wide Web, commercial and government databases, trade press articles, technical literature, information learned at technical conferences and trade shows, and SEC filings and other corporate literature.

This report is international in scope. The forecasts are worldwide forecasts and we have not been geographically selective in the firms that we have covered in this report or interviewed in order to collect information.

1.4 Plan of this Report

Chapter Two examines the various advantages, disadvantages, and applications of medical polymers. It also identifies some of the leading suppliers and their products on the market.

Chapter Three analyzes the current and future uses of medical polymers and provides detailed eight-year forecasts. The current and future uses of medical polymers are further divided into various applications, such as regenerative medicine and orthopedic implants, contact lenses, defibrillators, blood filters, etc. In addition, applications of polymers in diagnostic systems and laboratory and surgical accessories are also discussed. Forecasts are presented for each device type and application.

In Chapter Four, we focus on leading national markets (U.S., Europe, Japan, China, and India) and regulatory factors. National laws and regulations impacting the medical polymer markets are analyzed for each of the leading markets. The analysis examines both the positive and negative aspects of these regulatory factors. Eight-year forecasts are also presented for each of the leading national markets.