Biocompatible Materials

US Industry Study with Forecasts for 2018 & 2023

Study #3223 | December 2014 | $5200 | 333 pages
# Table of Contents

## EXECUTIVE SUMMARY

## MARKET ENVIRONMENT

- General ........................................ 4
- Macroeconomic Environment ............. 5
- Population Trends .......................... 7
- Healthcare Trends ............................ 9
- Health Insurance & Healthcare Reform .. 10
- Acute Conditions ............................ 13
- Chronic Conditions ......................... 14
- National Health Expenditures ............. 17
- Spending Categories ........................ 18
- Funding Sources ............................. 22
- Medical Providers ........................... 25
- Hospitals ..................................... 26
- Physicians ................................... 27
- Dentists ....................................... 28
- Outpatient Facilities ......................... 29
- Skilled Nursing Homes ...................... 32
- Other Medical Providers ................. 33
- Patient Activity .............................. 34
- Hospital Activity ............................ 35
- Surgical Procedures ......................... 36
- Outpatient Episodes ........................ 37
- Diagnostic Tests ............................. 38
- Medical Product Shipments .............. 40
- Pharmaceuticals ............................. 41
- Medical Supplies & Devices ............... 42
- Plastics Industry Overview ............... 45
- Biocompatible Materials Historical ... 49
- Demand Patterns ............................ 49
- US Trade ..................................... 51
- International Markets ..................... 53
- Regulatory Considerations ............... 54
- Medical Devices ............................. 55
- Drug Delivery Systems ..................... 56

## PRODUCTS

- General ......................................... 58
- Synthetic Polymers .......................... 60
- Synthetic Biocompatible ................... 60
  - Engineered Polymers ..................... 62
  - Silicones .................................. 64
  - Thermoplastic Elastomers ............... 73
  - Polycarbonate ............................. 81
  - Fluoropolymers ........................... 84
  - Acrylonitrile-Butadiene-Styrene ...... 90
  - Thermoplastic Polyesters ............... 93
  - Sulfone Resins ............................ 96
  - Nylon ...................................... 100
  - Other Biocompatible ......................
    - Engineered Polymers ................. 103

## APPLICATIONS

- General ....................................... 201
- Surgical & Medical Instruments ........ 205
- Surgical Appliances & Supplies ...... 207
- Dental Products & Materials ......... 215
- Drug Delivery Products ................. 218
- Electromedical Equipment .......... 221
- Diagnostic Products ................... 223
- Ophthalmic Goods ....................... 225

## INDUSTRY STRUCTURE

- General ....................................... 227
- Market Share ................................ 230
- Competitive Strategies ................. 238
- Mergers & Acquisitions ................. 239
- Cooperative Agreements ............... 240
- Research & Development ............... 244
- Marketing & Distribution ............. 245
- Manufacturing ............................. 247

## COMPANY PROFILES

- AdvanSource Biomaterials .............. 249
- Allegheny Technologies ................. 251
- Archer-Daniels-Midland Company ... 254
- Ashland Incorporated ..................... 255
- Axiall Corporation ......................... 257
- BASF SE ..................................... 259
- Baxter International ....................... 265
- Bayer AG ..................................... 268
- Cargill Incorporated ....................... 271
- Celanese Corporation ..................... 273
- Chevron Phillips Chemical ............. 276
- Codex International ....................... 277
- Dow Chemical ............................... 278
- Dow Corning ................................ 282
- DuPont (EI) de Nemours ................. 284
- Eastman Chemical ......................... 287
- Evonik Industries ......................... 289
- Exxon Mobil ................................ 293
- FMC Corporation ........................... 295
- Huber (JM) Corporation ................. 298
- Mexichem SAB ............................... 299
- Momentive Performance Materials .. 301
- Occidental Petroleum ..................... 303
- PolyOne Corporation ....................... 305
- Royal DSM .................................. 309
- Sanofi ....................................... 313
- Solvay SA .................................... 315
- Stryker Corporation ........................ 318
- Teknor Apex ................................ 323
- Teledyne Incorporated ................... 325
- Zeus Industrial Products ................ 327
- Other Companies in the Biocompatible Materials Industry ................. 329-333

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List of Tables

EXECUTIVE SUMMARY
1 Summary Table .............................................. 3

MARKET ENVIRONMENT
1 Macroeconomic Indicators .................................. 6
2 Resident Population by Age Group ....................... 9
3 Health Insurance Coverage of the US Population .... 12
4 Acute Conditions by Type ................................ 14
5 Chronic Conditions by Type ............................... 17
6 National Health Expenditures by Spending Categories .22
7 National Health Expenditures by Payment Source ....25
8 Hospitals ...................................................... 27
9 Physicians .................................................. 28
10 Dentists ..................................................... 29
11 Outpatient Facilities ...................................... 32
12 Skilled Nursing Homes ................................... 33
13 Other Medical Providers ................................. 34
14 Hospital Activity ........................................... 36
15 Surgical Procedures ....................................... 37
16 Outpatient Episodes ....................................... 38
17 Diagnostic Tests ........................................... 40
18 Medical Product Shipments by Type ................. 41
19 Plastic Resin Supply & Demand ......................... 49
20 Biocompatible Materials: Historical Demand Patterns, 2003-2013 ... 51
21 US Trade in Biocompatible Materials ................ 52
22 World Biocompatible Materials Demand by Region .. 54

PRODUCTS
1 Biocompatible Materials Demand by Product Group .......... 59
2 Synthetic Biocompatible Polymer Demand by Resin Group .... 62
3 Synthetic Biocompatible Engineered Polymers Demand by Resin Group ........ 63
4 Biocompatible Silicone Demand by Application ........... 66
5 Biocompatible Thermoplastic Elastomer (TPE) Demand by Application .... 75
6 Biocompatible Polycarbonate Demand by Application ........ 82
7 Biocompatible Fluoropolymers Demand by Application ... 86
8 Biocompatible Acrylonitrile-Butadiene-Styrene Demand by Application .... 91
9 Biocompatible Thermoplastic Polyesters Demand by Application .......... 94
10 Biocompatible Sulfone Resins Demand by Application ........... 97
11 Biocompatible Nylon Demand by Application ............... 101
12 Other Biocompatible Engineered Polymers Demand by Application .... 104
13 Synthetic Biocompatible Commodity Polymer Demand by Resin Group .... 114
14 Biocompatible Polyvinyl Chloride (PVC) Demand by Application .... 116
15 Biocompatible Polypropylene Demand by Application ........ 121
16 Biocompatible Acrylic Resins Demand by Application ....... 125
17 Biocompatible Thermoset Polyurethane (PUR) Demand by Application ...... 130
18 Biocompatible Low Density Polyethylenes (LDPEs) Demand by Application .... 132
19 Biocompatible High Density Polyethylene (HDPE) Demand by Application ........ 136
20 Biocompatible Polystyrene Demand by Application .......... 137
21 Natural Biocompatible Polymer Demand by Type ........... 139
22 Biocompatible Cellulose Polymer Demand by Type & Application ....... 141
23 Biocompatible Starch Compounds Demand by Application .......... 153
24 Biocompatible Collagen Demand by Application .......... 158
25 Other Natural Biocompatible Polymer Demand by Type & Application .... 162
26 Biocompatible Ceramics Demand by Type ................... 174
27 Biocompatible Alumina Demand by Application .......... 177
28 Biocompatible Porcelain Demand by Application .......... 178
29 Biocompatible Hydroxyapatite Demand by Application .......... 180
30 Biocompatible Zirconia Demand by Application .......... 182
31 Other Biocompatible Ceramics Demand by Application .......... 183
32 Biocompatible Metals Demand by Type ................. 187
33 Biocompatible Precious Metals Demand by Application .......... 189
34 Biocompatible Stainless Steel Demand by Application .......... 195
35 Biocompatible Titanium Demand by Application .......... 198
36 Other Biocompatible Metals Demand by Application .......... 200

APPLICATIONS
1 Biocompatible Materials Demand by Application .......... 204
2 Surgical & Medical Instruments: Biocompatible Materials Demand .......... 207
3 Surgical Appliances & Supplies: Biocompatible Materials Demand .......... 209
4 Dental Products & Materials: Biocompatible Materials Demand .......... 215
5 Drug Delivery Products: Biocompatible Materials Demand .......... 219
6 Electromedical Equipment: Biocompatible Materials Demand .......... 223
7 Diagnostic Products: Biocompatible Material Demand .......... 224
8 Ophthalmic Goods: Biocompatible Materials Demand .......... 226

INDUSTRY STRUCTURE
1 US Biocompatible Materials Sales by Company, 2013 ............... 228
2 Selected Acquisitions & Divestitures ......................... 240
3 Selected Cooperative Agreements ......................... 242

List of Charts

PRODUCTS
1 Biocompatible Materials Demand by Product Group, 2013 ............. 60
2 Synthetic Biocompatible Engineered Polymers Demand by Resin Group, 2013 .......... 64
3 Synthetic Biocompatible Commodity Polymer Demand by Resin Group, 2013 .......... 115
4 Natural Biocompatible Polymer Demand by Type, 2013 ................. 140
5 Biocompatible Ceramics Demand by Type, 2013 .................. 175
6 Biocompatible Metals Demand by Type, 2013 .................. 188

APPLICATIONS
1 Biocompatible Materials Demand by Application, 2013 ............ 205

INDUSTRY STRUCTURE
Reflecting quality, performance, and cost advantages, synthetic polymers will remain the dominant-selling product group, while ceramic materials will generate the fastest long-term growth.

US demand to rise 4.9% annually through 2018

US demand for biocompatible materials is forecast to increase 4.9 percent annually to $5.6 billion in 2018. Reflecting quality, performance, and cost advantages in a broad range of applications, synthetic polymers will remain the dominant-selling product group. Ceramic materials will generate the fastest long-term growth in demand among all biocompatible materials as advances in nanotechnology lead to the introduction of new and improved compounds for orthopedic implants, spinal fixation devices, and dental repair and restoration products. Spurred by increasing applications in cosmetic surgery, wound management, and arthritis therapy, hyaluronic acid will post the fastest revenue gains among natural biocompatible polymers. Titanium and titanium alloys will grow the fastest in demand among biocompatible metals as high strength, lightweight, and shape memory advantages promote their expanding use in cardiac, orthopedic, and dental implants. Competition from alternative polymer materials will limit revenues from other biocompatible metals, including precious metals and stainless steel.

Natural polymers to outpace synthetic types

Demand for synthetic biocompatible polymers will increase at an annual rate through 2018 that is slightly below the industry average. Engineered resins -- especially thermoplastic elastomer, silicone, sulfone, and polyketone materials -- will command the fastest revenue and volume growth based on quality and safety advantages in high value-added catheters and implants. By contrast, demand for polyvinyl chloride, the most widely used biocompatible resin, will drop slightly in volume terms due to recurring safety controversies and competition from improved polypropylene and thermoplastic polyesters. Widening use in drug delivery systems, cosmetic implants, tissue engineering products, wound management supplies, and orthopedic pain therapies will boost demand for natural biocompatible polymers at an above average annual rate of growth through 2018. Cellulose polymers and starch derivatives will remain the top-selling product groups based on well-established performance results in drug formulations and drug delivery systems. Hyaluronic acid will generate the fastest revenue gains spurred by expanding applications in injectable arthritis treatments. Lastly, collagen will continue to fare well in the marketplace following growth in the volume of cosmetic surgical procedures.

Advances in alumina-zirconia nanocomposites will broaden the use of biocompatible ceramics in dental and orthopedic implants. Due to their high density structure, these nanocomposites incorporate greater resistance to cracking than joint replacements composed of conventional ceramics.
Hydroxyapatite

Demand for hydroxyapatite in biocompatible applications will increase from $179 million in 2013 to $185 million in 2018, representing a compound annual growth rate (CAGR) of 12%. The expanding use of hydroxyapatite in orthopedic and dental implants is driving gains by expanding opportunities in orthopedic and dental implant applications. Ceramic materials based on hydroxyapatite have been shown to provide effective bone replacements and supplements.

Hydroxyapatite is a naturally occurring mineral form of calcium apatite. The substance occurs naturally in teeth and bones within the human body. Synthetic forms of hydroxyapatite produced by wet chemical deposition, biomimetic deposition, wet chemical precipitation, or electro-deposition methods are stable in body fluids, not vulnerable to decomposition, and exhibit bioresorbable characteristics. As a result, the ceramic material is adaptable to a wide range of medical and dental products.

Among medical uses, hydroxyapatite serves as a filler material that replaces amputated or damaged bones. It is also employed as a coating that stimulates the ingrowth bone into prosthetic implants. Additionally, hydroxyapatite coatings are often applied to bone, dental, and artificial joint implants to promote osseointegration. Other dental applications of the ceramic extend to the repair of tooth enamel lesions. Lastly, porous formulations of hydroxyapatite can be adapted to implants for the targeted delivery of therapies to bone structures.

Alfa Aesar (Johnson Matthey), Canton Chem, Continental Chemical, FLUIDINOVA, High Purity Inorganics, IGMA, Premier Biomaterials, and Waitaki Biosciences are among the suppliers of hydroxyapatite ceramic materials to US dental and medical markets. Recent advances in the material have brought the commercialization of a highly pure synthetic nanocrystalline hydroxyapatite by Fluidinova. Sold worldwide....

**TABLE III-5**

<table>
<thead>
<tr>
<th>Item</th>
<th>2003</th>
<th>2008</th>
<th>2013</th>
<th>2018</th>
<th>2023</th>
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<td>1050</td>
<td>1400</td>
<td>1820</td>
<td>2300</td>
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<tr>
<td>% TPEs</td>
<td>12.1</td>
<td>11.8</td>
<td>12.5</td>
<td>12.9</td>
<td>13.3</td>
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<td>Biocompatible TPE Demand</td>
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<tr>
<td>Surgical &amp; Medical Instruments</td>
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<td>111.0</td>
<td>146.0</td>
<td>183.0</td>
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<td>Surgical Appliances &amp; Supplies</td>
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<td>30.8</td>
<td>43.3</td>
<td>59.5</td>
<td>80.0</td>
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<td>Electromedical Equipment</td>
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<td>8.8</td>
<td>12.2</td>
<td>16.7</td>
<td>23.0</td>
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<td>Drug Delivery</td>
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<td>1.6</td>
<td>3.9</td>
<td>6.7</td>
<td>11.0</td>
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<td>1.6</td>
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<td>Ophthalmic Goods</td>
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<td>2.2</td>
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<tr>
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<td>1.0</td>
<td>1.4</td>
<td>1.9</td>
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<td>$/lb</td>
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<td>2.58</td>
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<td>Biocompatible TPE Demand (mil lbs)</td>
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<td>54.9</td>
<td>67.8</td>
<td>85.9</td>
<td>109.0</td>
</tr>
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</table>

**CHART V-1**

US BIOCOMPATIBLE MATERIALS INDUSTRY MARKET SHARE

($4.4 billion, 2013)

Copyright 2014 The Freedonia Group, Inc.
AdvanSource Biomaterials Corporation
E229 Andover Street
Wilmington, MA 01887
978-657-0075
http://www.advbiomaterials.com

Revenues: $3 million (FY 2014)
Employment: 12 (FY 2014)

Key Products: polycarbonate-based urethanes, polyether-based materials, hydrophilic materials, and elastomeric materials

AdvanSource Biomaterials (ASB) develops advanced polymer materials used in the production of medical devices designed to treat a wide range of anatomical sites and disease states. The Company conducts polymer development and manufacturing operations at a 26,000 square foot facility in Wilmington, Massachusetts.

ASB participates in the US biocompatible materials industry via the production of polycarbonate-based urethanes, polyether-based materials, hydrophilic materials, and elastomeric materials. These advanced polymers are used in the fabrication of medical devices for cardiovascular, gastroenterology, endoscopy, laparoscopy, neurology, oncology, urology, ear/nose/throat, orthopedic, interventional radiology, and diabetes management applications.

Polycarbonate-Based Urethanes -- ASB’s polycarbonate-based urethanes include CHRONOFLEX C biodurable aromatic thermoplastic urethanes, CHRONOFLEX AL aliphatic thermoplastic urethanes, and CHRONOSIL silicone elastomers. These medical-grade polymers feature enhanced tensile and mechanical strength, a low modulus of elasticity, and resistance to chemicals and solvents. In

TABLE IV-4

<table>
<thead>
<tr>
<th>Item</th>
<th>2003</th>
<th>2008</th>
<th>2013</th>
<th>2018</th>
<th>2023</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental Equipment/Supplies Shpts (bil $)</td>
<td>3.4</td>
<td>4.8</td>
<td>6.2</td>
<td>7.9</td>
<td>10.0</td>
</tr>
<tr>
<td>Dental Products &amp; Materials Demand</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>Synthetic Polymers:</td>
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<td></td>
</tr>
<tr>
<td>Engineered Resins</td>
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<tr>
<td>Commodity Resins</td>
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<tr>
<td>Natural Polymers</td>
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<td>Ceramics</td>
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<tr>
<td>Metals</td>
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<td>286.0</td>
<td>280.0</td>
<td>278.0</td>
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<tr>
<td>% dental products &amp; materials</td>
<td>22.4</td>
<td>19.4</td>
<td>18.1</td>
<td>17.4</td>
<td>16.9</td>
</tr>
<tr>
<td>Biocompatible Materials Demand</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

"Biocompatible Materials" is a Freedonia study that presents historical demand data (2003, 2008, 2013) plus forecasts (2018, 2023) by product and application. In addition, the study considers key market environment factors, examines the industry structure, evaluates company market share and profiles 31 competitors in the US industry.
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Other Studies

Engineering Plastics
Demand for engineering plastics in the US is expected to rise 2.6 percent per year to 5.1 billion pounds in 2019. Nylon, ABS, and polycarbonate will remain the three largest engineering plastics by volume, with nylon the fastest growing of the three. Smaller-volume engineering plastics such as polyphenylene sulfide, sulfone polymers, and fluoropolymers will grow the fastest. This study analyzes the 4.5 billion pound US engineering plastic industry, with forecasts for 2019 and 2024 by resin and market. The study also evaluates company market share and profiles industry players.

#3242 ............... April 2015 .................. $5300

World Medical Disposables
Global demand for medical disposables is forecast to rise 6.6 percent annually to $245 billion in 2018. The Asia/Pacific region will remain the largest and fastest growing market. Products used to treat widely prevalent chronic conditions such as kidney failure, urinary incontinence and arthritis-related pain will grow the fastest. This study analyzes the $178 billion world disposable medical supply industry, with forecasts for 2018 and 2023 by product, world region, and for 16 countries. The study also evaluates company market share and profiles industry competitors.

#3146 ............... March 2014 .................. $6400

Silicones
US demand for silicones is forecast to climb 4.7 percent annually to $4.3 billion in 2018, with volume rising 3.2 percent per year to 900 million pounds. Silicone elastomers will grow the fastest, overtaking fluids as the leading product type. The construction and medical markets will be the fastest growing segments, while the industrial market will remain dominant. This study analyzes the $3.4 billion US silicones industry, with forecasts for 2018 and 2023 by product, market and application. It also evaluates company market share and profiles industry players.

#3138 ............... March 2014 .................. $5100

Disposable Medical Supplies
US demand for disposable medical supplies is forecast to expand 4.1 percent annually to $49.3 billion in 2018. Drug delivery and related products will remain the fastest growing and largest single category. Among other supplies, safety enhanced devices and infection resistant nonwovens will see the most rapid growth. This study analyzes the $40.3 billion US disposable medical supplies industry, with forecasts for 2018 and 2023 by raw material, product and market. The study also evaluates company market share and profiles industry players.

#3111 ............... February 2014 .................. $5300

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