

# **Single-use Assemblies Market - Global Industry Size, Share, Trends, Opportunity, and Forecast, Segmented By Product (Bag Assemblies (2D bag assemblies, 3D bag assemblies), Filtration Assemblies, Bottle Assemblies, Tubing Assemblies, Others), By Application (Filtration, Storage, Cell Culture & Mixing, Sampling, Fill-finish Applications, Others), By End user (Biopharmaceutical & Pharmaceutical Companies, CROs & CMOs, Academic & Research Institutes), By Region and Competition 2019-2029F**

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## **Abstracts**

Global Single-use Assemblies Market was valued at USD 2.52 Billion in 2023 and is anticipated to project steady growth in the forecast period with a CAGR of 5.25% through 2029. The single-use assemblies market is experiencing remarkable growth and transformation, driven by the increasing adoption of single-use technologies in biopharmaceutical manufacturing. As the biopharmaceutical industry continues to expand and evolve, the demand for flexible and cost-effective solutions has propelled the global single-use assemblies market to new heights. Single-use assemblies are an integral part of the biopharmaceutical manufacturing process, as they enable the efficient, sterile, and disposable handling of critical fluids and processes. These assemblies encompass a wide range of components, such as bags, tubing, connectors, filters, and sensors, which are designed for single-use applications. Single-use systems reduce the risk of cross-contamination, simplify cleaning and validation processes, and offer significant cost savings.

The global single-use assemblies market has witnessed rapid growth in recent years. This growth is mainly driven by the expansion of the biopharmaceutical industry, which has been fueled by advancements in biotechnology and increasing demand for biologics. Single-use assemblies have gained popularity due to their cost-effectiveness. Traditional stainless steel systems require significant investment in cleaning, maintenance, and validation, whereas single-use systems offer a lower total cost of ownership. Regulatory bodies, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), have provided guidelines and support for the use of single-use technologies in biopharmaceutical manufacturing, further promoting their adoption. Single-use assemblies allow manufacturers to quickly adapt to changing production needs and easily scale up or down as required. This flexibility is crucial in the fast-paced world of biopharmaceuticals.

## Key Market Drivers

### Increasing Research and Development is Driving the Global Single-use Assemblies Market

In today's fast-paced world of biotechnology and pharmaceuticals, innovation is the key to staying competitive. The Global Single-use Assemblies Market is no exception to this rule. With increasing research and development (RD) activities, this market is experiencing remarkable growth. Single-use assemblies, also known as disposable systems, are a crucial component in the biopharmaceutical manufacturing process, enabling cost-effective and flexible solutions while maintaining high-quality standards. Single-use assemblies eliminate the need for extensive cleaning and validation processes, significantly reducing operational costs. With the increasing demand for cost-efficient production methods, biopharmaceutical companies are turning to single-use solutions to achieve substantial savings. The flexibility of single-use assemblies allows manufacturers to quickly adapt to changing production needs, making them ideal for small-batch and personalized medicine production. As RD leads to the development of more adaptable single-use systems, the market's potential for innovation continues to grow. The elimination of cross-contamination risks associated with traditional stainless steel systems has a direct impact on product quality. Single-use assemblies ensure product integrity and reduce the risk of batch failures. Ongoing RD efforts are focused on improving the reliability and performance of these assemblies, further boosting their adoption. The environmental impact of single-use assemblies is also a growing concern. RD in this field aims to address sustainability concerns by developing biodegradable and eco-friendly materials, which align with the industry's increasing focus on green manufacturing practices.

As biopharmaceutical companies allocate more resources to RD, innovations in single-use assembly technologies are accelerating. These investments lead to the development of advanced, efficient, and customizable solutions. The biopharmaceutical sector is continually expanding, driven by a growing global population, increased healthcare spending, and the development of novel therapies. This expansion necessitates the use of more sophisticated manufacturing technologies, further boosting the demand for single-use assemblies. Regulatory bodies, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), have supported the adoption of single-use technologies due to their positive impact on product safety and quality. This support enhances the market's growth potential. The COVID-19 pandemic highlighted the importance of flexible and rapid manufacturing processes. Single-use assemblies played a vital role in expediting vaccine development and production. This experience has underscored the benefits of single-use technologies and is likely to drive their increased adoption in the future.

### Increasing Environmental Concerns is Driving the Global Single-use Assemblies Market

The global single-use assemblies market has been experiencing significant growth in recent years, with an increasing emphasis on environmental concerns playing a pivotal role in driving this expansion. Single-use assemblies have gained immense popularity in the biopharmaceutical and biotechnology industries, offering a more sustainable and efficient alternative to traditional stainless steel systems. As the world grapples with escalating environmental issues, the single-use assemblies market is poised to flourish due to its ability to reduce waste, conserve resources, and enhance operational efficiency.

One of the primary benefits of single-use assemblies is their ability to minimize waste production. Traditional stainless steel systems involve extensive cleaning and sterilization processes, leading to significant water and energy consumption. In contrast, single-use assemblies are designed for one-time use, eliminating the need for cleaning and reducing the environmental impact. The production of stainless steel systems requires substantial raw materials, including steel, which has a significant carbon footprint. Single-use assemblies are made from plastics and other materials that are often more environmentally friendly. Additionally, their lightweight nature reduces transportation-related emissions, contributing to a lower overall environmental impact. Single-use assemblies are known for their flexibility and adaptability. They can be easily scaled up or down, allowing manufacturers to meet changing demand more efficiently. This adaptability reduces overproduction and waste, aligning with the

principles of sustainable production.

The growing awareness and concern for environmental sustainability have prompted industries to rethink their manufacturing processes and embrace greener alternatives. The single-use assemblies market has been quick to respond to these concerns and is experiencing remarkable growth as a result. Regulatory bodies around the world have been increasingly supportive of environmentally friendly initiatives. They have recognized the potential of single-use assemblies to reduce environmental impact and have introduced guidelines that promote their use. This regulatory backing has accelerated the adoption of single-use assemblies in various sectors. Many companies are embracing sustainability as a core value and are actively seeking ways to reduce their ecological footprint. Single-use assemblies align with these goals, making them a preferred choice for organizations committed to environmental responsibility. Beyond their sustainability benefits, single-use assemblies can lead to cost savings by eliminating the need for extensive cleaning, sterilization, and maintenance of traditional systems. This cost-efficiency has been a key driver in the market's growth, as it appeals to both environmental and economic sensibilities. Ongoing research and development efforts are continuously enhancing the performance, quality, and safety of single-use assemblies. These advancements are making these systems increasingly attractive to industries looking to adopt environmentally friendly practices without compromising operational excellence.

## Key Market Challenges

### Standardization and Compatibility

One of the major challenges in the single-use assemblies market is the lack of standardization and compatibility among products from different manufacturers. As various industry players produce components with different specifications, connectors, and materials, end-users often face difficulties in mixing and matching components. Standardization efforts are underway, but achieving consensus across the industry remains a formidable task.

### Material Selection and Quality

The choice of materials used in single-use assemblies is critical to ensure biocompatibility and product safety. The challenge lies in selecting materials that can withstand the harsh conditions of bioprocessing, including extreme pH levels, temperature fluctuations, and exposure to various chemicals. Manufacturers need to

continuously improve the quality and integrity of materials to maintain the highest standards and comply with stringent regulatory requirements.

### Regulatory Compliance

The biopharmaceutical industry is highly regulated, and any change in manufacturing processes or materials must adhere to strict guidelines imposed by health authorities like the FDA and EMA. Companies in the single-use assemblies market need to stay updated on the ever-evolving regulatory landscape, invest in testing and validation, and ensure that their products meet the required standards.

### Sterilization and Quality Control

Maintaining the sterility of single-use assemblies is paramount to prevent contamination during bioprocessing. The challenge is ensuring that every component remains sterile from the point of manufacture to the point of use. Quality control and sterilization processes are labor-intensive and require meticulous attention to detail. Any lapse in these procedures could compromise product safety.

### Cost Considerations

While single-use assemblies offer cost advantages in terms of capital expenditure and reduced cleaning and validation, the initial investment in single-use systems can be higher than traditional stainless-steel equipment. Companies must carefully assess the long-term cost benefits, considering factors like disposal costs and the overall lifecycle of single-use systems.

### Key Market Trends

### Technological Advancements

In recent years, the global single-use assemblies market has witnessed remarkable growth, and this surge can largely be attributed to the rapid pace of technological advancements. The use of single-use assemblies in bioprocessing has revolutionized the way biopharmaceuticals are produced and has garnered significant attention in the pharmaceutical, biotechnology, and healthcare industries. The development of advanced materials with superior properties is one of the primary drivers behind the growth of single-use assemblies. The introduction of materials like thermoplastic elastomers (TPE) and fluoropolymers has improved the durability, flexibility, and chemical

resistance of single-use components. These materials allow for the safe handling of a wide range of biopharmaceutical substances.

Integrating smart sensors and monitoring systems into single-use assemblies has brought a new level of control and automation to bioprocessing. These sensors can track parameters such as temperature, pressure, and fluid flow in real-time, allowing for precise process control and immediate responses to deviations, ultimately improving product quality and reducing the risk of contamination. Sterility is of paramount importance in biopharmaceutical manufacturing. Technological advancements in sterilization methods, such as gamma irradiation and electron beam irradiation, have made single-use assemblies safer and more reliable. These methods ensure the elimination of microorganisms while maintaining the integrity of the disposable components.

Additive manufacturing techniques like 3D printing have enabled the creation of highly customized single-use assemblies tailored to specific applications. This level of customization offers greater flexibility and efficiency in bioprocessing, as components can be designed to fit the exact needs of a particular process. The integration of data management and connectivity solutions has revolutionized the single-use assemblies' market. These technologies enable the seamless collection, analysis, and sharing of data, leading to improved process optimization and decision-making.

The impact of technological advancements on the single-use assemblies' market is evident in the numbers. The market is experiencing substantial growth, and this trend is expected to continue in the coming years. Factors such as cost-effectiveness, reduced environmental impact, and the ability to meet the demands of small-batch production contribute to the market's expansion. Moreover, the growing interest in personalized medicine and the rise of complex biopharmaceuticals will further drive the demand for advanced single-use solutions. The shift towards decentralized and agile manufacturing facilities has also placed single-use assemblies in the spotlight, as they provide the flexibility needed to adapt to changing market demands rapidly.

## Segmental Insights

## Product Insights

Based on the category of product, filtration assemblies emerged as the dominant player in the global market for Single-use Assemblies in 2023. Filtration assemblies play a crucial role in the biopharmaceutical and biotechnology industries, where the purity and



sterility of products are of utmost importance. These assemblies consist of various components, such as filter cartridges, housings, connectors, and tubing, which are designed for the efficient removal of particles, microorganisms, and other impurities from process fluids.

The biopharmaceutical industry is heavily regulated, with strict requirements for product purity and safety. Filtration assemblies help companies meet these stringent regulations by ensuring that process fluids are free from contaminants. The use of single-use filtration assemblies simplifies validation processes, making it easier for companies to comply with regulatory standards. Filtration assemblies are versatile and can be customized to meet the specific needs of different bioprocessing applications. Whether it's microfiltration, ultrafiltration, depth filtration, or sterile filtration, these assemblies can be tailored to provide the desired level of filtration and purity. Single-use filtration assemblies can be quickly implemented in bioprocessing operations, reducing downtime and speeding up production processes. Traditional stainless steel systems often require significant time and resources for setup, cleaning, and validation, which single-use systems eliminate. Single-use assemblies, including filtration assemblies, can significantly reduce capital expenses associated with cleaning and maintaining traditional stainless steel systems. Additionally, these systems lower operating costs by minimizing the need for cleaning, steam sterilization, and the use of harsh chemicals. Filtration assemblies contribute to the reduction of cross-contamination risks in bioprocessing, as they are designed for single use and disposal after a single operation. This minimizes the potential for product carryover and ensures product integrity.

## End user Insights

The Biopharmaceutical Pharmaceutical Companies segment is projected to experience rapid growth during the forecast period. Biopharmaceutical and pharmaceutical companies often require flexibility and scalability in their manufacturing processes. Single-use assemblies provide them with the ability to easily scale up or down production, change processes, and adapt to varying market demands. This flexibility is essential for responding to the ever-changing healthcare landscape. Traditional stainless steel equipment and systems can be expensive to install and maintain. Single-use assemblies offer a cost-effective alternative, as they eliminate the need for complex cleaning and validation processes, as well as reduce the risk of cross-contamination. This cost-efficiency aligns well with the economic pressures faced by the healthcare industry.

## Regional Insights

North America emerged as the dominant region in the global Single-use Assemblies market in 2023, holding the largest market share in terms of value. North America has been at the forefront of technological advancements in the field of biopharmaceutical manufacturing. The region is home to many renowned biotechnology and pharmaceutical companies, as well as leading research institutions. This has fostered a culture of innovation, leading to the development of cutting-edge single-use assembly technologies that are more efficient, cost-effective, and flexible. These technological advancements have given North American companies a competitive edge in the global market. North America boasts one of the largest and most developed biopharmaceutical industries in the world. The region is a hub for research, development, and production of biologics, vaccines, and other advanced therapeutics. As the demand for biopharmaceuticals continues to rise globally, North American companies have turned to single-use assemblies to meet these growing needs efficiently and sustainably. This strong biopharmaceutical sector has been a driving force behind the dominance of North America in the single-use assemblies market.

#### Key Market Players

Thermo Fisher Scientific inc.

Sartorius AG

Danaher Corporation

Merck KGaA

Avantor, Inc.

Parker Hannifin Corp.

Repligen Corporation

Corning Incorporated

Meissner Filtration Products, Inc.

Dover Corporation



TSE Industries, Inc.

Fujimori Kogyo Co., Ltd.

Report Scope:

In this report, the Global Single-use Assemblies Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Single-use Assemblies Market,By Product:

- oBag Assemblies

- oFiltration Assemblies

- oBottle Assemblies

- oTubing Assemblies

- oOthers

Single-use Assemblies Market,By Application:

- oFiltration

- oStorage

- oCell Culture Mixing

- oSampling

- oFill-finish Applications

- oOthers

Single-use Assemblies Market,By End user:

- oBiopharmaceutical Pharmaceutical Companies

oCROs CMOs

oAcademic Research Institutes

Single-use Assemblies Market, By Region:

oNorth America

United States

Canada

Mexico

oEurope

France

United Kingdom

Italy

Germany

Spain

oAsia-Pacific

China

India

Japan

Australia

South Korea

oSouth America

Brazil

Argentina

Colombia

oMiddle East Africa

South Africa

Saudi Arabia

UAE

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Single-use Assemblies Market.

Available Customizations:

Global Single-use Assemblies market report with the given market data, Tech Sci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

Company Information

Detailed analysis and profiling of additional market players (up to five).

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