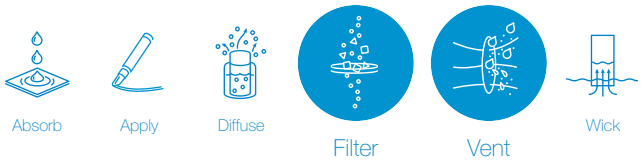
technical brief



Certified Pure Materials: Expedite FDA Approvals for Medical Devices

Challenge

The Food & Drug Administration (FDA) has recently established a stringent approval process which includes classification and testing for all medical devices manufactured in the United States.

At Stake

FDA approvals occur during the final stages of bringing a device to market, which can jeopardize project timelines and risk potential delays in product launch.

Solution

Work with a vendor who has the material expertise and testing capabilities so that device manufacturers can choose the right materials for their products and expedite the FDA approval process.

Ensure industry-wide criteria is met

For medical device manufacturers looking to go to market, product safety and efficacy are critical for launch. To ensure industry-wide criteria is met, the Food & Drug Administration (FDA) has established classification as part of its risk assessment process for medical devices manufactured in the United States. This includes a premarket review of materials that are intended for use in the device. To promote a seamless process for manufacturers, the FDA has published guidance which provides recommendations for the types of biocompatibility information typically needed to support device material safety.

To assess the biocompatibility of a material used in their device, manufacturers need to determine how the human body may interact and respond to the material being used. This risk-based approach typically includes an assessment of the specific properties of the material components, the clinical use of the device including the intended anatomical location, and the functional characteristics of the device.

To understand the FDA device classes, manufacturers need to assess the level of harm and risk a device can post to an end-user. While the degree of risk to a patient's health is the major determinant that differentiates Class I, II and III devices, the intended use of the device and indications for use are also important factors.

Key Facts about FDA Classification

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- The FDA has published guidance which provides recommendations for the types of biocompatibility information typically needed to support device material safety
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Contact us for more information

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FDA Device Classifications & Regulatory Controls

Class I devices account for 47% of all medical devices and are considered low-risk since they do not come in contact with internal organs, the central nervous system or cardiovascular system. For example, an electric toothbrush touches the teeth and the inside of the mouth but does not interact with the internal body, which rules out any risk. Additional examples of Class I devices include bandages, tongue depressors and oxygen masks.

By contrast, **Class II devices** make up 43% of medical devices and are considered intermediate-risk, which suggests contact or impact on the body indirectly or directly. For instance, catheters, which transport necessary fluids in and out of the body, can have an indirect impact on the patient's health if contaminated and pose a slightly elevated risk of harm to the end user. Other Class II devices include syringes, infusion pumps for intravenous medications, and contact lenses.

Class III devices fall under the remaining 10% of all medical devices and are defined as high-risk since they are usually critical to a patient's health. This is the highest risk category and usually sustains or supports life, are implanted or present a potential unreasonable risk of injury or illness to the end-user. Examples typically include implantables such as pacemakers, prosthetics, and deep-brain neurostimulators.

Depending on the device class, the device undergoes a regulatory review process by the FDA or is deemed exempt from review. For Class I and II devices, projects will likely undergo general controls that provide guidelines around material purity, quality, safety and effectiveness of the device. Special controls are an additional category primarily intended for Class II devices where general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of the device. Premarket approval is required for Class III devices, which mandates scientific and regulatory review of the product. Understanding the class to which a device is assigned is critical and will ultimately determine the type of submission required, timeline and cost for FDA clearance to market.

What This Means for the Industry

A medical device starts with an idea and grows into countless hours of research, project timelines, funding strategies and later, prototype development. On average, it takes approximately 3 to 7 years to bring a medical device to market with FDA approvals being one of the final stages of the process. Class I devices usually take between 18 to 24 months to launch, Class II devices within three to six years and Class III devices up to nine years before they're market ready.

> Taking the right measures during the early stages of development can alleviate concerns, accelerate FDA approvals, help mitigate risk and avoid product recalls.

With the time and effort it takes to bring an idea for a device to reality, manufacturers want to avoid any potential roadblocks or setbacks. By neglecting to proactively identify pre-market requirements in initial planning, manufacturers are at risk of facing last minute obstacles with the FDA and prolonging launch to market. Taking the right measures during the early stages of development can alleviate concerns, accelerate FDA approvals, help mitigate risk and avoid product recalls.

Eliminating Roadblocks at the Source

The first step to reducing risk of delays in FDA approvals is by taking a proactive approach for submitting your device for review. Gathering validation testing ahead of FDA submission is a guaranteed way to eliminate roadblocks and expedite the approval process. Coordinating with a lab to conduct testing and validation in advance can provide manufacturers with reassurance that their device meets regulatory requirements.

Choosing a collaborative partner is a critical component in making sure your device is prepared for FDA submission. Partnering with a supplier that will innovate with you through the full product lifecycle, from testing to development, can bring insight and expertise to your team to guarantee a successful submission. Working with a company that has the resources, expertise and solutions, as well as a small hands-on personalized approach to product development can give you the upper hand on your journey to market.

Additionally, determining the right material for an end device early on in the process is another important measure manufacturers can take to avoid delays in approval. Leaning on a team of experts and engineers who can provide guidance on which material best matches application needs based on the FDA testing tier can remove the regulatory stress that comes with bringing a device to market.

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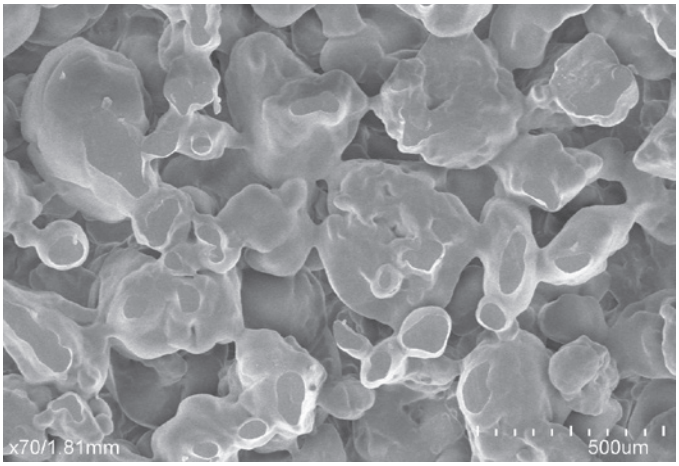
High-purity Materials for Quality Assurance

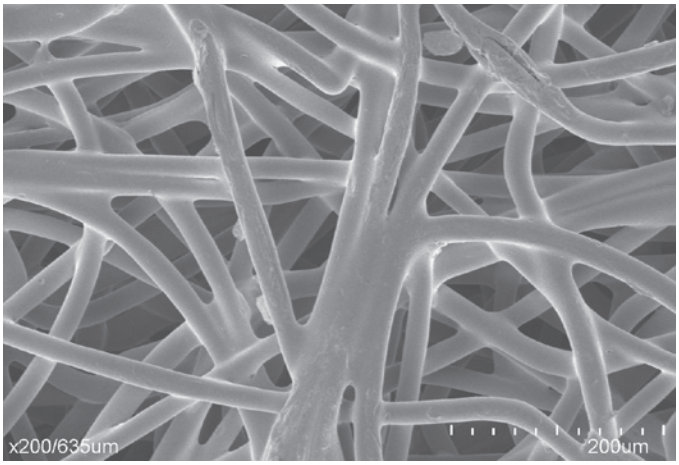
At Porex, we can provide manufacturers with custom-engineered porous polymer materials that can take a product's performance to the next level by providing versatility for next-generation products. Over the last 60 years, we have applied our extensive porous polymer material science, product design, and custom plastic manufacturing expertise to developing porous solutions that overcome complex product development challenges and accelerate product launches.

Sintered porous plastics are engineered from various polymers with controlled pore sizes to provide strength, durability, chemical resistance, resiliency, and design flexibility across multiple applications. Porex manufactures sintered porous plastics from various thermoplastic materials exhibiting a broad range of properties.



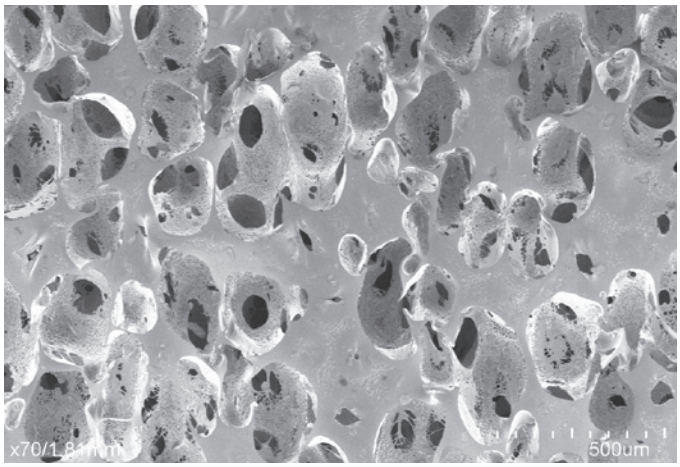
Sintered porous plastics

In addition to sintered porous plastic, Porex offers material expertise in **porous bonded fiber** media. Our production methods utilize synthetic fiber binding processes to produce parts cost-effectively and with a wide assortment of extruded profile geometries. A blend of polymeric fibers are bonded together for ideal fluid handling capillary structures.



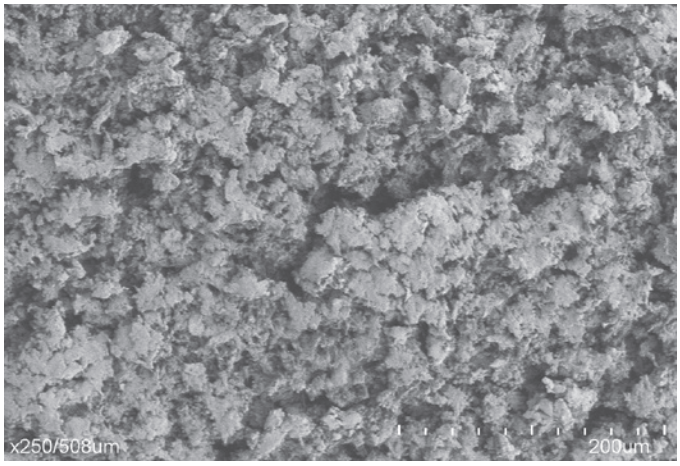
Porous bonded fiber

Porous foam is created via a two-step prepolymer process that creates open-cell polyurethane foam. Our open-cell foam technology platform is developed using proprietary or customized blends of raw materials created through a clean polyurethane process without the use of catalysts. Different formulations offer wide-ranging densities, porosities, and levels of softness to meet customers' requirements.



Porous open-cell foam

Sintered PTFE membrane (Polytetrafluoroethylene) technology uses patented and proprietary processes to sinter then skive PTFE into rolled membrane materials that can then be converted into numerous other forms. Our processing methods ensure a consistent and repeatable pore structure that provides strength, durability, chemical and thermal resistance, and design flexibility across multiple applications.

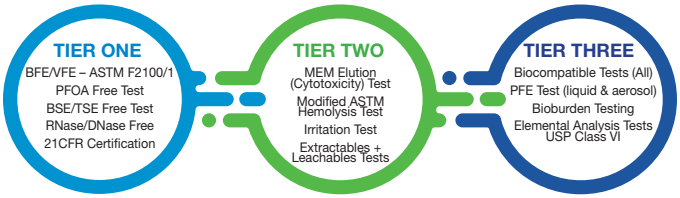


Sintered PTFE membrane

POREX Filtration Group®

Certified Pure Porex® for Purity Assurance

Porex offers a tiered, comprehensive technical performance and certification program that provides purity assurance of select Porex® porous media through certified third-party testing. The Certified Pure Porex® program provides manufacturers with the required testing needed to speed up approval processes with confidence and ease. Porex has created three tiers that categorically align with each of the FDA classifications for medical devices to increase the chance of success. These include tests falling into the categories of filtration performance, safety, sterility assurance, biocompatibility, extractables and leachables, and elemental analysis.



Filtration performance testing includes bacterial filtration efficiency, viral filtration efficiency and particle filtration efficiency testing. The performance is based on the dimensional qualities of the material components themselves. These tests provide a standard of reference for the comparison of filtration used within the drug, liquid, or gas of choice within the medical device.

Safety testing and certification provides confidence that the component material does not contain molecules that can put a patient at risk. This can include but is not limited to: TSE and BSE certification for bovine bacteria and contamination, PFOA-free certification, Rnase/Dnase testing, and 21 CFR 177.1520 food safety certification.

Biocompatibility testing assesses the compatibility of medical devices with a biological system by studying their interaction with living tissues and cells exposed to the device when used by patients. Tier Two includes individual biocompatibility tests based on application, whereas Tier Three includes all biocompatibility tests.

Extractables and leachables testing is a new requirement that is dominating the medical device market and one that Porex is committed to. The test identifies potential chemicals derived from the interaction of the constituent parts and determines the impact to human health and/or drug efficacy that those chemicals pose. This ensures protection from material contamination for the highest purity within your device.

Sterility assurance or bioburden testing is used for premarket submissions to determine if the sterility information is in accordance with internationally agreed upon voluntary consensus standards that the FDA recognizes. It tests the microbiological quality and cleanliness of the test unit for any early warning signs for possible production and raw material problems that could lead to potential material contamination and/or sterility concerns within the device.

Elemental analysis testing includes three tiers of analysis that each provide various levels of analysis related to assessing the presence of heavy metals within the material. Highly sensitive instrumentation is used to measure elements that can impact the quality and safety of the material used.

Material Characteristics	What It Means	Associated Testing
Antimicrobial	Protected against bacteria, mold, mildew, and otherhazardous microbes	VFE / BFE; BSE/TSE
Biocompatible	Certifies that the device/ materials is not harmful to living tissue	Cytotoxicity; Hemolysis; Irritation; USP Class VI
Filter Media Purity	Certifies that the filter media is free from potentially harmful and performance inhibiting contaminants or pollutants	VFE; BFE; PFE
Food Safe	Certifies that food-grade materials are suitable for their intended use and will not create food safety hazard	21 CFR
Inorganic Element Non-Interference	Certifies that inorganic material components do not interfere with device safety or performance capability	Extractables & Leachables; ICP-MS; PYMS; PIXE
PCR Inhibitor Free	Certifies that the device/ material do not contain inhibitors which decrease PCR efficiency	RNase/DNase; PFOA
Surfactant Free	Certifies that the device/ material does not contain surface active agents that could pose harm to the end-user	PFOA

The process of bringing a medical device to market can be multifaceted and complex but partnering with a collaborative supplier can eliminate stress and uncertainty, while improving the likelihood of clearance to market. Having initiated material purity testing over a decade ago, Porex has the custom-design engineered solutions and material science expertise to expedite processes, cut down project timelines and give manufacturers peace of mind from concept to FDA approval.

To connect with an expert and learn more about which Certified Pure Porex tier makes sense for you, please visit: https://www.porex.com/about-porex/contact-us/ask-an-engineer/

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