



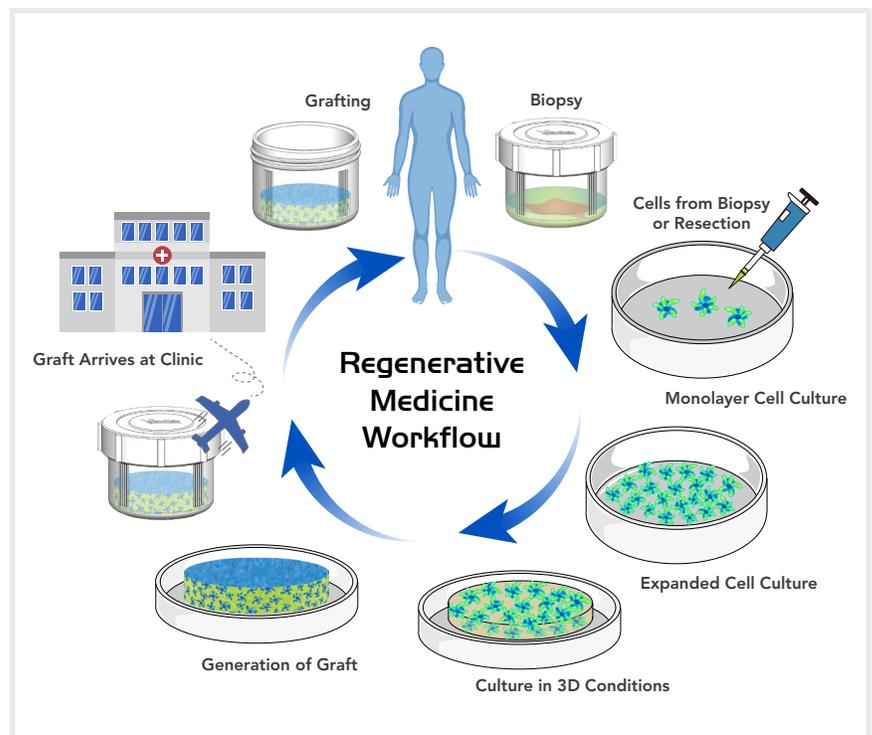
Purillex® Fluoropolymer Containers for Tissue Handling and Transport

In tissue processing and transplantation, tissue engineering, and regenerative medicine, there's a growing demand for appropriate-quality containers that can be used from R&D through to product commercialization. Often, containers used during the R&D phase are commonly available lab vials and jars made from polycarbonate, polystyrene, or polypropylene. These containers have variable extractables and leachables profiles, limited seal integrity, and frequently lack a complete package of USP (United States Pharmacopeia) and extractables testing. And when pre-sterilized, they sometimes don't have the appropriate sterility validation for commercial use.

A much safer choice for tissue handling and transport is the Purillex® range of containers from Savillex. Purillex containers are specifically designed for tissue transport and manufactured from high purity inert PFA fluoropolymer, feature high seal integrity across a wide temperature range, and come with a complete validation package.

Extremely Low Extractables and Leachables Profile Improves Patient Outcomes and Surgeon Satisfaction

An increasing number of tissue engineering and regenerative medicine companies are finding that contaminants leached from the container impact the viability of live tissues and cell cultures. Biopsies taken from patients could be damaged beyond reasonable recovery when stored and transported from the clinic to the cell therapy facility. The more valuable finished transplant tissue can also be damaged by contaminants from the container during transport back to the patient.



Purillex® Fluoropolymer Containers for Tissue Handling and Transport

Savillex Data Sheet

Purillex containers are molded from high purity virgin PFA, which has the lowest extractables and leachables profile of any polymer and has been shown to dramatically improve tissue and cell health compared to commodity containers molded from other polymers. This means you can use the same container from research through commercial and increased speed to market for your therapeutic. Purillex containers have been identified as a critical component for an FDA-approved, commercial autologous tissue transplant, where they are making a positive difference in patient outcomes.

Leak-Free Performance

Another significant issue facing tissue engineering and regenerative medicine companies is the failure of the container seal during tissue transport. Commodity containers typically don't have closures designed to withstand the rigors of cold chain transport or have undergone shipping and container closure integrity testing (CCIT). Purillex containers, however, feature a unique ferrule-style closure system that maintains seal integrity under the most challenging conditions – even down to liquid nitrogen temperatures. In addition, our containers have been validated with process-specific closure torque specifications, ensuring reliable, leak-free performance.

Purillex® PFA Jars, Bottles and Vials: the Ultraclean, Reliable Solution

The Purillex range of products for tissue storage and transport includes jars, bottles, and vials. Bottles feature either a 33 mm or a GL45 (45 mm) closure. Jars are an ideal container for tissue handling and storage because their wide-mouth openings allow for the easy transfer and removal of contents, including large or irregular-shaped tissues. A range of vials is also available for smaller samples. All containers include a screw threaded closure. Due to the closure design, no closure insert or gasket is required to obtain a high integrity seal. All containers and closures are made from the same grade of high purity virgin PFA resin, simplifying testing and validation of your procedure. No release agent or other material is used. Purillex containers are also available pre-sterilized and ready-to-use for greater convenience and time savings. A range of options, such as drains, porting, and support inserts, are available, along with different-sized containers for specific applications – please contact Savillex.

Testing

Savillex has performed comprehensive internal testing on all Purillex products, including pressure decay, ASTM leakproof and shipping tests, vacuum resistance, and pressure burst tests. Test data is available upon request.

In addition, the Purillex products are Class VI, have undergone complete USP testing, and come with manufacturing lot certification and full support for bioprocess and cell therapy applications. Please contact us for pricing and to request the validation binder, which is available under NDA.

Key Benefits of Purillex® Containers for Tissue Handling and Transport

- Extremely low extractables and leachables levels
- Non-stick and non-reactive surface - gentle to live tissues and cells
- High integrity seal across a wide temperature range, with supporting CCIT data
- Inert to virtually every solvent and chemical
- Available clean packaged, autoclaved to a SAL of 10⁻⁶ and ready-to-use
- Long shelf life
- Validation package and full manufacturing lot traceability
- Passed ASTM D4991-07(2015) standard test method for leakage testing of empty rigid containers by vacuum method

Purillex® Product Range for Tissue Storage and Transport

Part Number	Product Description
Jars	
171-01-0060-01	60 mL Purillex PFA Jar
171-01-0060-01-A	60 mL Purillex PFA Jar, Pre-Sterilized
171-01-0120-01	120 mL Purillex PFA Jar
171-01-0120-01-A	120 mL Purillex PFA Jar, Pre-Sterilized
171-01-0240-01	240 mL Purillex PFA Jar
171-01-0240-01-A	240 mL Purillex PFA Jar, Pre-Sterilized
Bottles	
170-01-0050	50 mL Purillex PFA Bottle
170-01-0050-A	50 mL Purillex PFA Bottle, Pre-Sterilized
170-01-0100	100 mL Purillex PFA Bottle
170-01-0100-A	100 mL Purillex PFA Bottle, Pre-Sterilized
170-01-0250	250 mL Purillex PFA Bottle
170-01-0250-A	250 mL Purillex PFA Bottle, Pre-Sterilized
Vials	
271-01-003-20	3 mL Purillex PFA Vial
271-01-003-20-A	3 mL Purillex PFA Vial, Pre-Sterilized
271-01-007-20	7 mL Purillex PFA Vial
271-01-007-20-A	7 mL Purillex PFA Vial, Pre-Sterilized
271-01-015-20	15 mL Purillex PFA Vial
271-01-015-20-A	15 mL Purillex PFA Vial, Pre-Sterilized

Purillex is registered trademark of Savillex, LLC.



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