

Fluoropolymer Packaging for Cell Therapy Product

SUCCESS STORY



Photo provided by Vericel Corporation

ABOUT SAVILLEX

Savillex specializes in providing high-quality containers and containment designed for critical applications across a broad spectrum of pharmaceutical and biopharmaceutical processes. Our range of products ensures reliability and performance in the most demanding life science environments. Every product we sell is designed to help the scientific community to preserve sample integrity, ensure regulatory compliance, facilitate reliable data, and safeguard your assets.



CHALLENGE

Evolving standards for packaging advanced, autologous cell-based therapies.



SOLUTION

Purillex® 100 mL PFA bottle.



RESULT

Improved ease of use by surgeons and critical quality attributes met.



Vericel Corporation, based in Cambridge, Massachusetts, develops and manufactures advanced, autologous cell-based therapies that use a patient's own healthy cells to treat serious diseases and conditions.

One such cell therapy product marketed by Vericel is MACI® (autologous cultured chondrocytes on porcine collagen membrane).

Due to evolving standards in container closure integrity testing, Vericel felt it necessary to revisit and potentially improve the way in which they package and ship their MACI implant. This is what led them to partner with Savillex.

Chief among Vericel's reasons for wanting to choose a fluoropolymer product was the material's lack of reactivity and sturdiness. Fluoropolymer products from Savillex also come with a comprehensive validation binder documenting acceptable extractable levels and container closure integrity.

Vericel ultimately selected Savillex's 100 mL Purillex PFA bottle as the primary packaging used to store and transport MACI, which the FDA regulates under an approved biologics license.

When asked about working with Savillex, John Duguid, Executive Director, Research & Development at Vericel Corporation stated, "Savillex proved highly responsive to Vericel's requests and provided all the rigorous documentation needed for submission in this heavily regulated industry."

The updated MACI packaging proved easier for surgeons to use and allows the product to retain all its critical quality attributes. As an added benefit, the Purillex PFA bottles were made available pre-sterilized and ready-to-use.



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- *John Duguid, Executive Director, Research & Development*

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