EASTMAN

Closing the contamination gaps in medical packaging

How MEDPETG 6763 helps Medipack AG become an integrated system supplier

The medical industry continues to demand higher standards of quality and regulatory compliance for medical device packaging. Any break from processing resin to the final sealed package creates an opportunity for contamination.

Swiss-based Medipack AG has applied decades of clean room thermoforming experience to raise the bar for rigid medical packaging by using Eastar[™] 6763 copolyester in its patented sealed skin blister (SSB) packaging process.

The innovative technology of SSB and Eastar 6763—enabled by Medipack's class 7 and 8 ISO 14644-1 clean room thermoforming environments—lets Medipack offer a process-oriented quality assurance system that complies with ISO 9001: 2008 and ISO 13485: 2003 standards.

MEDPETG 6763 is the lifeblood of the system.

"Medipack AG began producing its own thermoformable films from Eastar 6763 in 2013," according to Georg Oesterreicher, Head of Development & Design at Medipack AG. "This control and system integration lets us stay ahead of evermore rigorous requirements for purity, production conditions, and traceability of raw materials." The premium line of MEDPETG 6763 is made from 100% virgin material, with no reuse of edge trim or process-recovered scrap. Eastar 6763 is especially well-suited to high quality blister applications because of its unique combination of properties:

- Excellent clarity
- Excellent toughness
- Color and functional stability after gamma, e-beam, and EtO sterilization
- No dusting
- No stress whitening
- Good heat sealability

How Eastar 6763 fits within the MEDIPACK SSB process

To further improve quality and security, Medipack AG developed a unique kind of sealed skin blister packaging called MEDIPACK SSB. The patented process combines the best of conventional blister packaging and bag packaging. Advantages of the system include savings in package and tool design, and the product being held securely and aesthetically within the SSB packaging.



Medipack AG uses proprietary MEDPETG 6763 and its patented MEDIPACK SSB process to achieve reliable packaging and elegant device presentation. The MEDIPACK SSB process creates a sealed skin blister in 2 steps:

Skinning—the product is inserted in the mold insert, and the prefabricated inlay is placed on the mold insert.

Sealing—with the product safely enclosed as a finished molded inlay, it is sealed.

By consciously specializing in Eastar PETG, removing outside sources, and automating key elements of the extrusion process, Medipack AG has been able to improve product quality and ensure no foreign particles are introduced into the system. The resulting advances in quality assurance and traceability helped Medipack AG win a prestigious innovation award in 2014.

Providing the benefits of a system supplier

By starting its own validated thermoform production of MEDPETG 6763 and patented SSB technology, Medipack AG is now a true system supplier for medical packaging—with its own development department, mold construction, and advanced clean room production and sealing technology. This lets customers get everything from one source.

"Advantages of this full-system approach go well beyond one-stop convenience," says Oesterreicher. "In today's highly regulated environment, this single-source approach eliminates potential sources for contamination. Production is traceable and complies with prescribed standards."

Eastman contact:

Jeanine de Bos Phone: +31 (0) 10 2402 880 jdebos@eastman.com

About Eastman Chemical Company

Eastman is a global advanced materials and specialty additives company that produces a broad range of products found in items people use every day. With a portfolio of specialty businesses, Eastman works with customers to deliver innovative products and solutions while maintaining a commitment to safety and sustainability. Its market-driven approaches take advantage of world-class technology platforms and leading positions in attractive end-markets such as transportation, building and construction, and consumables. Eastman focuses on creating consistent, superior value for all stakeholders. As a globally diverse company, Eastman serves customers in more than 100 countries and had 2017 revenues of approximately \$9.5 billion. The company is headquartered in Kingsport, Tennessee, USA, and employs approximately 14,500 people around the world.

For more information, visit www.eastman.com.

About Medipack AG

2017 celebrates 40 years of successful innovation for this family-owned company. Since 1977, Medipack AG has grown from a small production facility to a system supplier for medical packaging. It built its first class 100,000 certified clean room in 1993 and now provides materials, technology and support for blister packaging, sealing lids, MRP systems and bag packaging as well as packing tests and validation. Since introducing MEDPETG 6763 and the patented MEDIPACK SSB method, Medipack AG has grown PETG granule usage by more than 300% and has helped customers ensure beautiful, reliable packaging and regulatory compliance. Today, Medipack AG employs approximately 180 technical, development and support professionals and delivers high quality products around the world.

For more information, visit http://www.medipack.ch/page/medipack_ag.



Eastman Corporate Headquarters P.O. Box 431 Kingsport, TN 37662-5280 U.S.A.

U.S.A. and Canada, 800-EASTMAN (800-327-8626) Other Locations, +(1) 423-229-2000

www.eastman.com/locations

Safety Data Sheets providing safety precautions that should be observed when handling and storing Eastman Chemical Company ("Eastman") products are available online or by request. You should obtain and review the available material safety information before handling any of these products. If any materials mentioned are not Eastman products, appropriate industrial hygiene and other safety precautions recommended by their manufacturers should be observed.

It is the responsibility of the medical device manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including any Eastman product, used in its final product to ensure safety and compliance with requirements of the United States Food and Drug Administration (FDA) or other international regulatory agencies.

Eastman products have not been designed for nor are they promoted for end uses that would be categorized either by the United States FDA or by the International Standards Organization (ISO) as implant devices. Eastman products are not intended for use in the following applications: (1) in any bodily implant applications for greater than 30 days, based on FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" tests (including any cosmetic, reconstructive, or reproductive implant applications); (2) in any cardiac prosthetic device application, regardless of the length of time involved, including, without limitation, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass assisted devices; or (3) as any critical component in any medical device that supports or sustains human life.

For manufacturers of medical devices, biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The ranges of tests under FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (subacute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available on request. The Manufacturer of the medical device is responsible for the biological evaluation of the finished medical device.

The suitability of an Eastman product in a given end-use environment is dependent on various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof.

© 2018 Eastman. Eastman brands referenced herein are trademarks of Eastman or one of its subsidiaries or are being used under license. The © symbol denotes registered trademark status in the U.S.; marks may also be registered internationally. Non-Eastman brands referenced herein are trademarks of their respective owners.