

Proper sterilization of packaging with Eastar™ copolyester 6763

Medical devices and their packaging must be free from bacteria to ensure patient safety and health. Sterilization, a rigorous process of eliminating these microorganisms, can subject the device-package combination to extreme temperatures, gases, radiation, and other elements that may alter the performance of certain materials. Prior to designing a medical-device package, packaging engineers should first consider the method by which the packaged product will be sterilized. Engineers, therefore, need to fully understand the effects of the chosen sterilization method on packaging materials. This technical tip contains guidelines for the proper method of ethylene oxide, gamma irradiation, and electron beam sterilization of copolyesters. These guidelines should be followed to optimize the performance of packaging made with Eastar™ copolyester 6763.

Sterilization methods

Ethylene oxide (EtO) method

- Bacteria are eliminated by penetration of EtO gas mixture into the sealed package.
- Efficiency is boosted by the use of moderately high temperature and humidity.
- Chamber gas can either be 100% EtO or 88% EtO/12% Freon (Dupont).
- Typical cycle includes 18–24 hours preconditioning (110°F [43°C], 60% relative humidity), 8 hours total cycle (with the average gas dwell of 3–4 hours) all at 125°F (52°C), and a 24-hour aeration at 115°–120°F (46°– 49°C).
- Recommended conditions for copolyesters: minimize cycle time; maximum chamber temperature of 130°F (54°C); maximum relative humidity of 50%.

Gamma radiation method

- Bacteria are eliminated by penetration of gamma radiation from a cobalt-60 source.
- Gamma radiation provides a high level of penetration at a low dosage rate without the generation of heat. Eastar™ copolyesters are highly resistant to gamma radiation.
- Typical dose is 25 to 50 kGy (2.5 to 5 M Rads). Eastar™ copolyester 6763 has been sterilized up to 95 kGy without any significant physical property loss.

Electron beam (E-beam) radiation method

- An electron beam is focused on the product. The beam scans over the product to ensure uniform treatment.
- Bacteria are eliminated by penetration of high-energy electrons without heat.
- Low penetration and high dose rate.
- Typical dose is 25 to 50 kGy (2.5 to 5 M Rads). Eastar™ copolyester 6763 has been sterilized up to 75 kGy without any significant physical property loss.

Table 1
Radiation device specifications

Property	Gamma radiation	E-beam
Energy spectrum	1.17 and 1.33 MeV	3–10 MeV
Useful power range	15 to 100 kW	10 to 200 kW
Typical dose rate	25-50 kGy	25–50 kGy

Conclusion

Gamma and E-beam are the gentlest methods for sterilizing copolyesters. However, Eastar™ copolyester is successfully sterilized by EtO, vapor hydrogen peroxide, and plasma without any significant changes in physical properties as long as proper processing conditions are used. If high humidity, high temperature, and/or long dwell times are used, increased physical aging will occur. This will cause brittleness in the package material and could lead to package integrity failure.



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**Eastman Chemical Company
Corporate Headquarters**

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

Telephone:
U.S.A. and Canada, 800-EASTMAN (800-327-8626)
(800-327-8626)
Other Locations, (1) 423-229-2000
Fax: (1) 423-229-1193

Eastman Chemical Latin America

9155 South Dadeland Blvd.
Suite 1116
Miami, FL 33156 U.S.A.

Telephone: (1) 305-671-2800
Fax: (1) 305-671-2805

Eastman Chemical B.V.

Fascinatio Boulevard 602-614
2909 VA Capelle aan den IJssel
The Netherlands

Telephone: (31) 10 2402 111
Fax: (31) 10 2402 100

**Eastman (Shanghai) Chemical
Commercial Company, Ltd. Jingan Branch**

1206, CITIC Square
No. 1168 Nanjing Road (W)
Shanghai 200041, P.R. China

Telephone: (86) 21 6120-8700
Fax: (86) 21 5213-5255

Eastman Chemical Japan, Ltd.

ALG Aoyama Building 5F
2-11-16 Minami Aoyama
Minato-ku, Tokyo 107-0062 Japan

Telephone: (81) 3-3475-9510
Fax: (81) 3-3475-9515

Eastman Chemical Asia Pacific Pte. Ltd.

#05-04 Winsland House
3 Killiney Road
Singapore 239519

Telephone: (65) 6831-3100
Fax: (65) 6732-4930

www.eastman.com

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