EASTMAN

Sterilization of medical devices & packaging

The effect on polymer properties & color

Eastman™ specialty plastics
Committed, knowledgeable, and enabling

Sterilization of medical devices & packaging

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A wide variety of sterilization methods are used in the medical industry, including electron beam (e-beam) irradiation, gamma irradiation, ethylene oxide (EtO), autoclave, and low-temperature hydrogen peroxide gas plasma. Selecting the best sterilization for a medical device depends on many factors. As a result, it is extremely important that manufacturers and processors be acutely aware of the effect of various sterilization methods on the physical and optical properties of different types of polymers.

The objective of sterilization is to reduce the bioburden to a safe level, while minimizing any changes to the physical and optical properties of the final part. The most common effect on polymers exposed to radiation is a shift in color to yellow. In the medical device market, a significant color shift to yellow is undesirable as it may be interpreted as a contaminated device. A color shift in the packaging may be interpreted as a breach in sterility due to degradation of the polymer. Therefore, minimal shift in the polymer color after sterilization can be an important factor when specifying a polymer for a medical device or rigid thermoformed package.

The following discussion will examine the effect of four sterilization methods on the optical properties of Eastman™ specialty plastics and various other competitive transparent polymers. The sterilization methods evaluated in this study were EtO, gas plasma, gamma irradiation, and e-beam irradiation. The color in all testing was measured with a HunterLab UltraScan Sphere 8000 and reported using the CIE b* color scale. In order to establish comparable results, tests were performed on injection molded plaques, and these results are indicative for medical devices and for clear, rigid thermoformed packaging. It should be noted that none of the sterilization methods caused a significant negative effect on the physical properties of the materials tested.

Materials assessed under conditions include Eastman Tritan™ copolyester MX711 and MX731, Eastar™ MN006 and MN211 and DuraStar™ MN611. Eastar™ copolyester 6763 was assessed with gas plasma sterilization. Finally, materials assessed using radiation-based sterilization methods are listed in Table 1.

Table 1

Formula and resin type gamma and E-beam radiation testing

Formula	Resin type
Eastman Tritan™ MX711 & MX731	Copolyester
Eastar™ MN052, Natural	Polyester
Eastar™ MN211, Natural	Copolyester
Eastar™ DN004, MN006	Copolyester
DuraStar™ MN611, Natural	Copolyester
Makrolon Rx 1805[a]	Polycarbonate (PC)
Terlux 2802[b]	Transparent ABS (TABS)
Cyrolite G20[c]	Acrylic (PMMA)

[a]Bayer Material Science, [b]BASF Group, [c]Cyro Industries

Ethylene oxide (EtO) sterilization

Among the sterilization technologies currently available to the medical device industry, EtO gas sterilization is one of the most established, proven, and widely accepted methods in the medical industry. Even with the recent technological advances of other types of sterilization, EtO is expected to continue to be widely used because of the high capital costs associated with the other technologies. Disadvantages of this method include a complex, four-phase process with each phase requiring careful planning to ensure safety and efficacy. This multi-phase, time-consuming process can take up to 14 days. It also exposes the device and packaging materials to elevated temperatures that can have a negative effect on their physical properties.

EtO does have an advantage over e-beam and gamma irradiation in that it minimally affects the color of polymeric materials. In applications where drugs are involved, EtO has a minimal effect on typical drug efficacy and will be the preferred sterilization method. EtO is also a good choice for plastics that may undergo physical property degradation when irradiated.

Gas plasma sterilization

Gas plasma sterilization utilizes low-temperature hydrogen peroxide gas plasma technology in the sterilization process. The advantages of gas plasma sterilization include its ability to provide safe, nontoxic, dry, low-temperature sterilization in about one hour. Water and oxygen, the primary by-products of plasma sterilization, are harmless, so there is no need for aeration as is needed with EtO sterilization.

One of the disadvantages of gas plasma sterilization is that it may not penetrate narrow, long channels in devices. In addition, gas plasma sterilization may corrode some materials and cannot be used on paper, cellulose or linen. Though not used on medical devices as often as other types of sterilization methods, it does find use in hospitals and doctors' offices for sterilizing surgical equipment.

In one study, film made from Eastar™ copolyester 6763 was sterilized by low-temperature hydrogen peroxide gas plasma sterilization. The results showed no change in the physical properties of the copolyester film when compared to those of the unexposed control film. It was also found that the sterilization caused no change in the film color.

Radiation sterilization

Gamma irradiation

Gamma irradiation of single-use, disposable medical devices is an increasingly popular choice in the medical device industry. Ionizing energy, in the form of gamma rays, penetrates deeply, giving it an advantage over the lower penetration depths of e-beam radiation. This makes gamma irradiation a good fit for products with various densities and packaging types. The gamma process is easy to use and has a proven track record. The major disadvantage of gamma irradiation is that it uses Cobalt 60, a radioactive element that requires special handling and disposal, causing some to prefer e-beam when irradiation is required.

Injection-molded plaques were sent to Ion Beam Applications in Charlotte, North Carolina, where they were exposed to 50 kGy of gamma radiation to simulate the typical medical device validation test. The exposed plaques were returned to Eastman for color measurements and photography. Color measurements were made 1, 7, 14 and 42 days after gamma irradiation. Samples remained in dark enclosures until color and physical property testing occurred. As discussed earlier, shifts in color to the yellow (higher b* value) are the most prevalent change after exposure to gamma radiation.

Figure 1 illustrates the typical color changes before and after gamma irradiation at 50 kGy. A 50 kGy dose was used for validation even though the typical dosage is 25 kGy, which would result in lower color shift. Figure 2 provides the data supporting the visual findings in Figure 1.

The Eastman™ resins tested and Makrolon Rx 1805 polycarbonate have the lowest b* values after sterilization. Although Makrolon Rx 1805 has a low b* after sterilization, the shift in b* from the control to the sterilized sample is significant. Forty-two days after sterilization, there is some recovery relative to the control sample, but the resins depicting the best color stability continue to be the Eastman™ specialty plastics.

Eastman™ specialty plastics provide the best overall performance in maintaining color integrity post gamma sterilization when compared to competitive plastics, as demonstrated by the luer on the right.

Figure 1

Photographs of molded resins before and after exposure to 50 kGy of gamma radiation

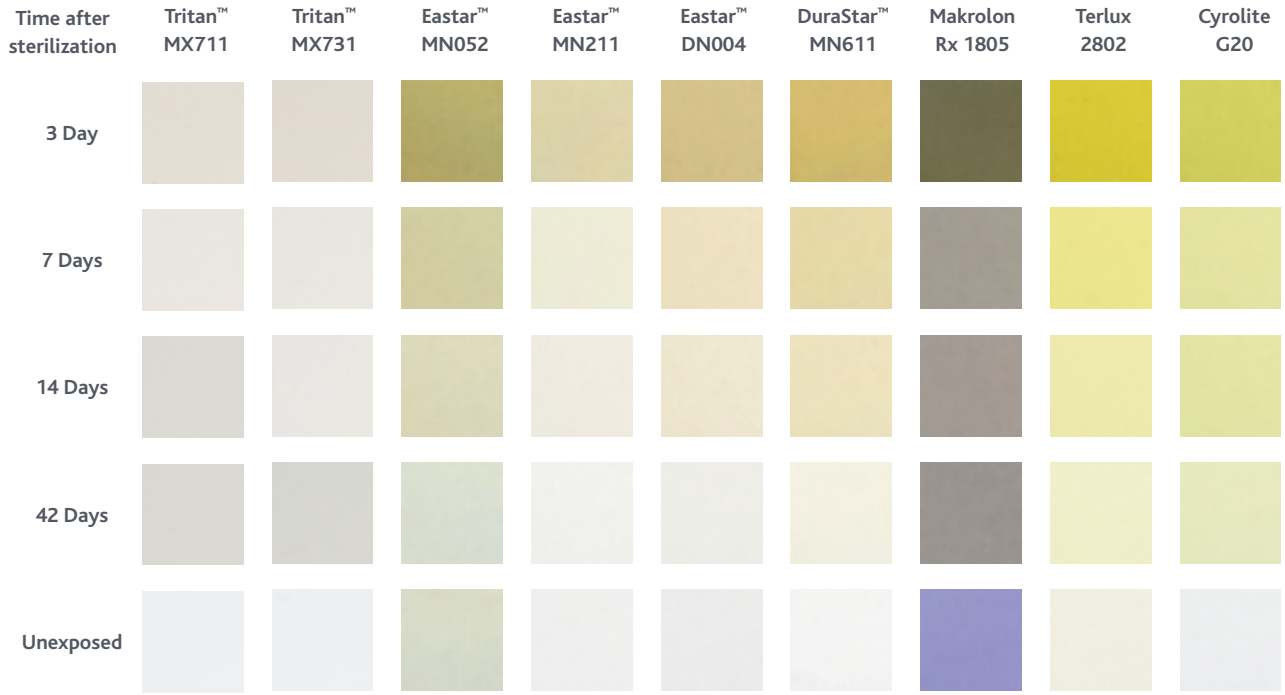
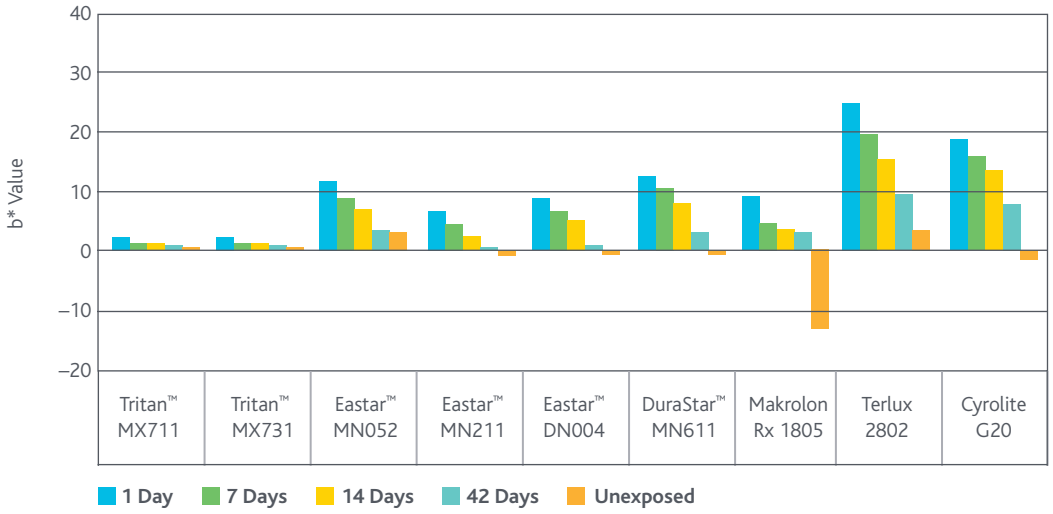


Figure 2

b* Color measurements of Eastman™ specialty plastics and competitive resins after exposure to 50 kGy of gamma radiation



E-beam irradiation

E-beam irradiation is rapidly gaining popularity due to the development of smaller-scale equipment. Recent technological advances have also improved e-beam operating efficiency making it a safe, efficient, reliable source of energy.

The same products tested with gamma irradiation, as listed in Table 1, were also evaluated after e-beam irradiation. After exposure, samples were stored in the dark until testing at 3, 7, 14 and 42 days.

Figure 3 illustrates the typical color changes observed before and after e-beam irradiation at a dosage of 50 kGy. In practice, the typical dosage is 25 kGy, which would further reduce the color shift.

Visual inspection of the plaques indicates that Eastman Tritan™ copolyester MX711, Eastar™ MN211, and Eastar™ MN006 showed the smallest color shift after exposure when compared to the other resins tested. In addition, their color shifted to near their initial color after forty-two days. Measurements of b*, confirming the visual results, are shown in Figure 4.

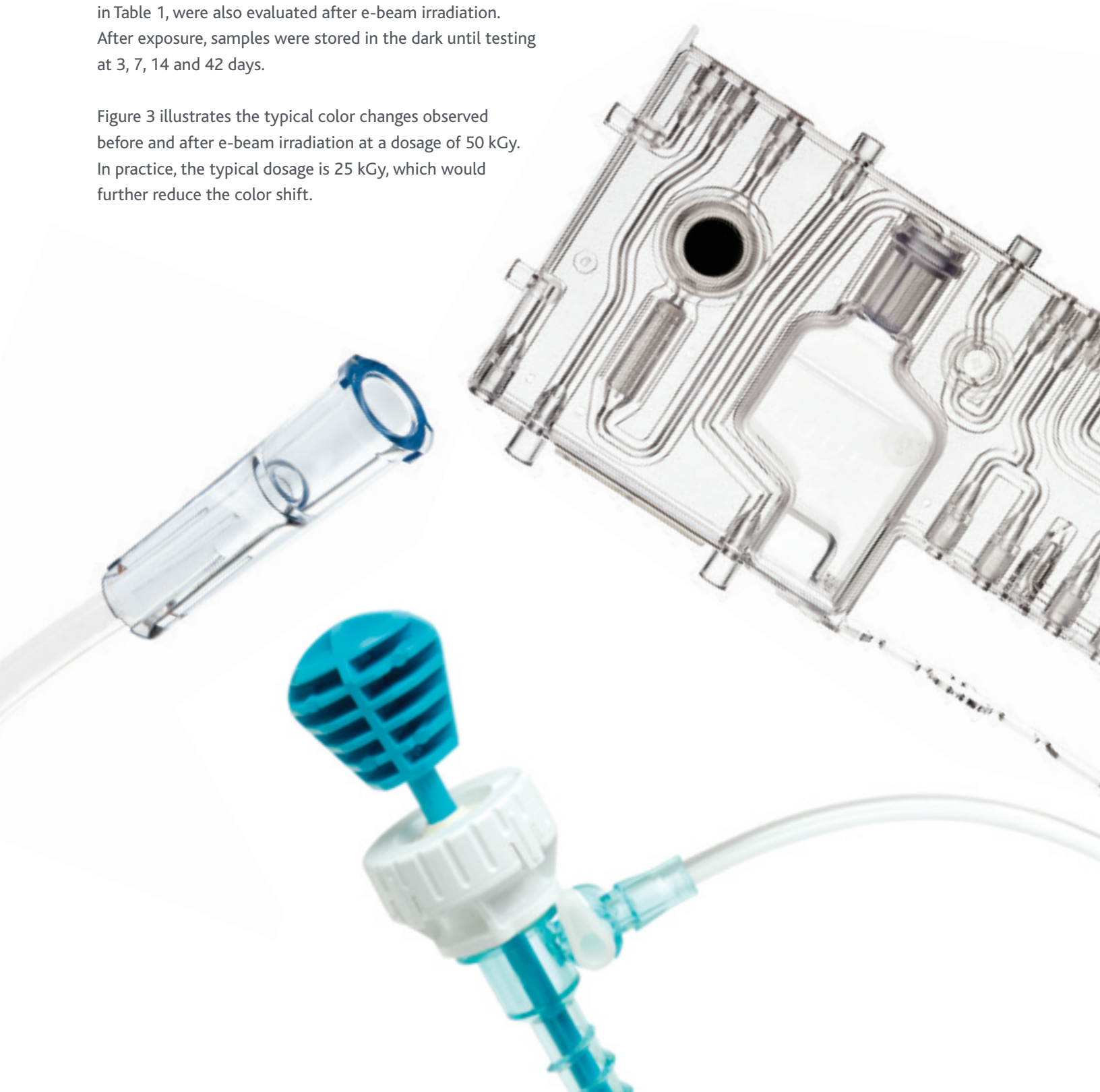
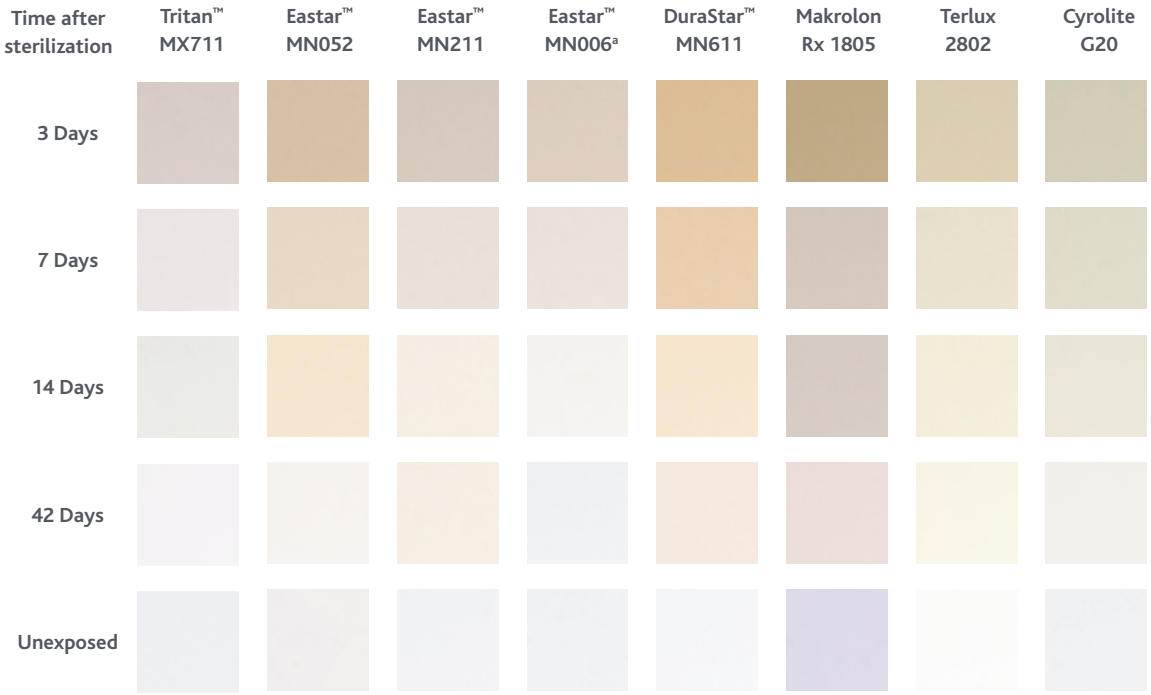


Figure 3

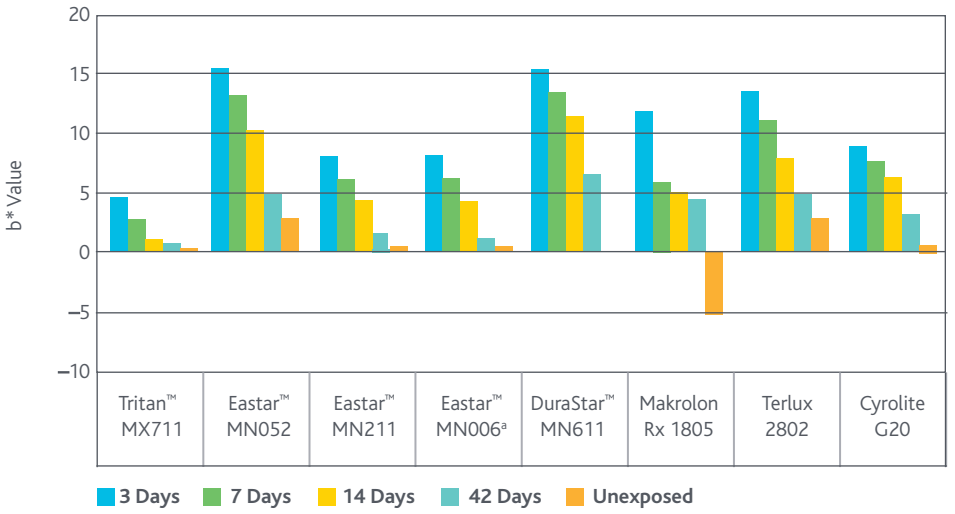
Photographs of molded resins before and after exposure to 50 kGy of e-beam radiation



[a]*Next-generation Eastar™ DN004*

Figure 4

b* color measurements of Eastman™ specialty plastics and competitive resins after exposure to 50 kGy of e-beam radiation



[a]*Next-generation Eastar™ DN004*

A cannula system case study

Eastar™ copolyester lets surgeons see what they're doing

Smith & Nephew Endoscopy, the recognized leader in arthroscopic or minimally invasive joint surgery has selected Eastman's Eastar™ copolyester for the manufacture of the company's new Clear-Trac Complete cannula system for use in arthroscopic surgery.

The Clear-Trac system includes cannulae in nine sizes, enabling surgeons to find the best fit, depending on the size of the patient, the size of the joint being treated, and the thickness of the muscle around it. Each cannula is tinted so surgeons can distinguish between different cannulae during surgery. The clarity of Eastar™ copolyester provides the surgeon with an unobstructed view of the instruments and the suture inside them, as well as the bone and soft tissue that surround the surgery site.

"We chose Eastar™ copolyester over other materials like polycarbonate for its improved color stability and clarity after undergoing gamma sterilization," said John Lipchitz, R&D project engineer at Smith & Nephew. "Additionally, Eastar™ copolyester is easy to work with, even in difficult molds."

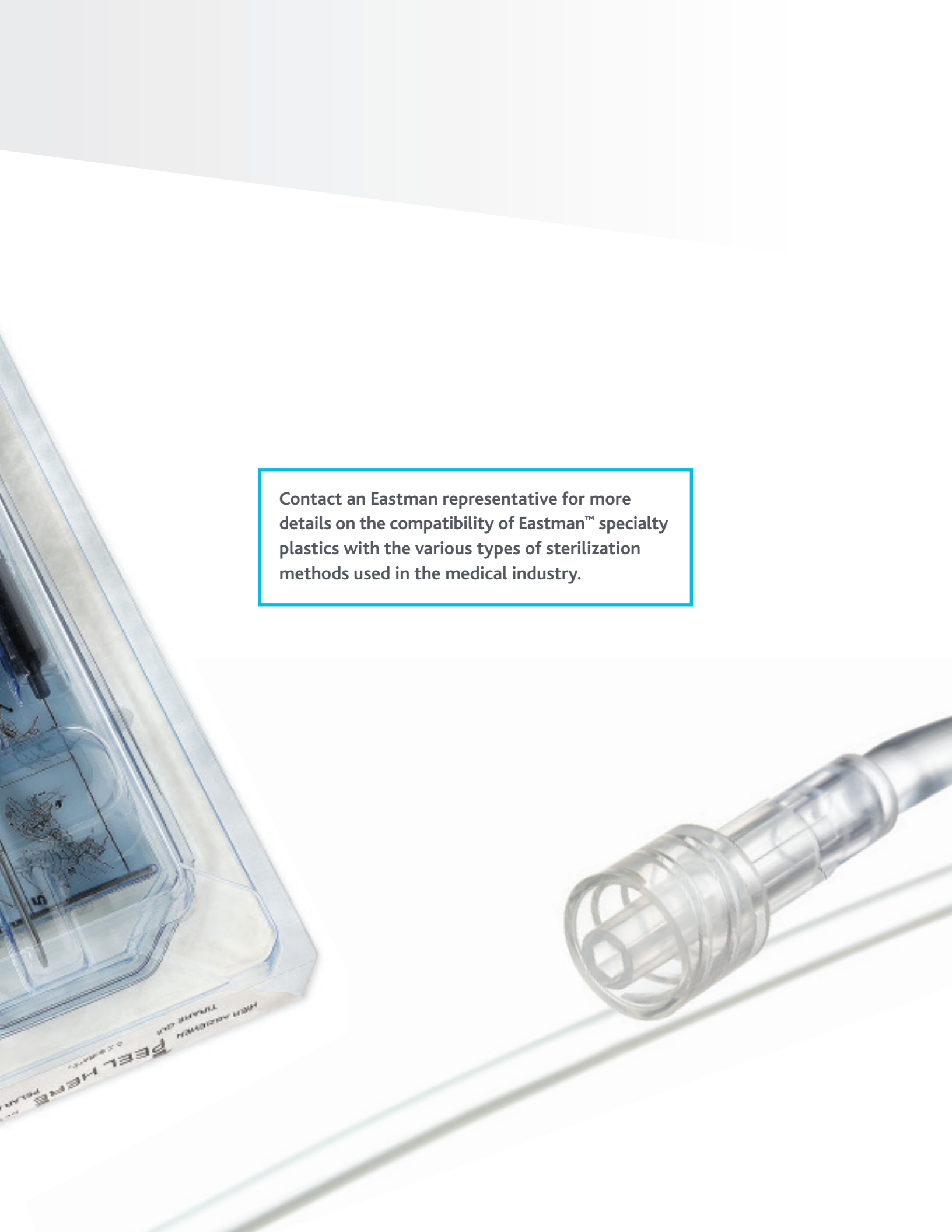
During arthroscopic procedures, cannulae provide sterile pathways to the joint that surgeons will treat. Each cannula in the Clear-Trac system features a unique cap, or dam, that prevents fluid from escaping during the procedure. In addition, the cap can be removed, enabling surgeons to clear small pieces of bone or soft tissue from the treatment area without having to remove the cannula from the incision.

GW Plastics, the device's molder, is producing the new cannula body line in complex hot-runner, multi-cavity tooling for Smith & Nephew. "Eastman was instrumental in helping us select the correct material for this application and was an integral member of our extended development team," said Tim Reis, vice president of healthcare marketing at GW Plastics. "Their awareness of the medical industry's material requirements is well in hand. The list of Eastar™ copolyester properties is a perfect match for the requirements of this application, bringing a major program to a successful conclusion."

Conclusion

Color-stable, transparent medical devices and packages are of the utmost importance in the healthcare field as they embody the idea of safety, quality, and peace of mind for both the patient and healthcare professional. Though many factors must be taken into consideration when deciding which polymer to choose in the development of a new medical device or rigid thermoformed package, understanding the effect of sterilization is critical. This study has shown that Eastman™ specialty plastics provide the best overall performance in maintaining color integrity when compared to competitive plastics.

Committed, knowledgeable, enabling—
That's the Eastman Material Difference.™



Contact an Eastman representative for more details on the compatibility of Eastman™ specialty plastics with the various types of sterilization methods used in the medical industry.

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Material Safety Data Sheets providing safety precautions, that should be observed when handling and storing 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 in order 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 (sub-acute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available upon 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 upon 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.

PPM-222B 05/10
Printed in U.S.A.