TERILIZATION

Tough on germs, tough on plastics, too

LaVerne Leonard

Selecting the most appropriate plastic material for a medical device is no easy task. Designers must balance cost-containment pressures that favor using the least-expensive material and processing techniques against the need to ensure the patients' safety and well-being at any cost. Product liability also is a concern. So for any given application, the designer ends up specifying the most affordable material that delivers the desired function, yet provides maximum assurance against failure during use.

Before arriving at that point, the designer must analyze many types of materials data and evaluate them in light of current safety, environmental, and regulatory issues. That process can be very time-consuming because of the many plastic materials used in the medical device industry.

"The problem increases each year as the variety of new or modified materials being introduced to the medical device industry increases," says Charles E. Lundy of Miles, Polymers Division (Pittsburgh, Pennsylvania). But the materials maze is manageable, he says, if the engineer follows established guidelines. Those are provided in "Criteria for Selecting Polymeric Materials in Medical Device Applications," a paper Lundy presented in February at the Medical Design & Manufacturing West conference in Anaheim, California.

The first step Lundy cites is to determine the performance requirements for a specific device, based on four attributes: mechanical properties, environmental issues, regulatory issues, and sterilizability. By defining the significance of each attribute, Lundy says, the designer can determine the overall material performance requirements for a particular medical device application.

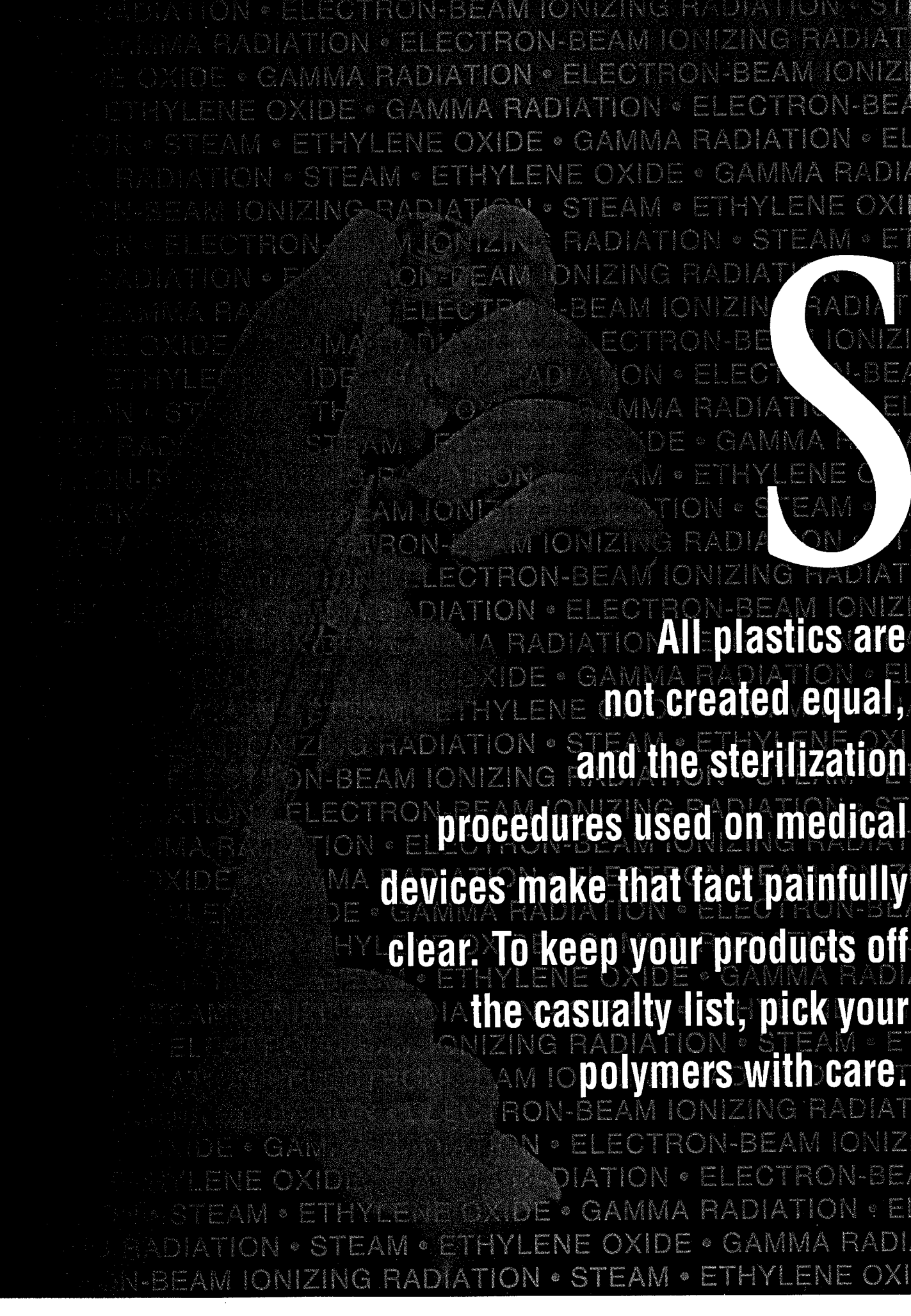
Sterilizability is a particularly important performance attribute, because every reusable medical device destined to contact the body or bodily fluids must be sterilized. But sterilization processes also alter the materials of construction — their mechanical properties, clarity, color, bondability, and shelf life.

This article examines the various sterilization methods, their effects on commonly used thermoplastics, and new resin formulations that offer more resistance to sterilization processes. It also provides examples of design approaches that can reduce sterilization's negative impact.

Strive for simple, modular designs

A device's design plays an important role in determining which method and amount of processing time will be needed to achieve sterilization. Simple is best. Areas most difficult to sterilize include lumens, hinges, stopcocks, mated surface sites, strain-relief devices, ratchets, and other areas where sterilant penetration may be difficult.

If difficult-to-reach parts can't be eliminated, try a modular approach. That did the trick for Birtcher Medical Systems (Irvine, California) when it developed an alternative to both the disposable and reusable laparo-


All plastics are
not created equal,
and the sterilization
procedures used on medical
devices make that fact painfully
clear. To keep your products off
the casualty list, pick your
polymers with care.

scopic probes on the market. The reusable probes had an intricate valve mechanism for controlling irrigation and aspiration that made them hard to sterilize.

The company developed the modular SwivelGrip laparoscopic probe, shown in Figure 1. Three of the probe's four modules are designed to be reused at least 20 times, but the fourth module, which contains the valves, is disposable. The new product is said to be *reposable,* which stands for reusable disposable. The device costs only one-tenth as much per operation as a traditional, disposable laparoscope.

Stainless steel, epoxy, and a high-heat polycarbonate (Apec, Miles, Polymers Division) are used for the three reusable modules. "We've autoclaved the laparoscope more than 40 times without a single problem," says Roger Etherington, a consulting engineer at Birtcher Medical who designed the device. "The resin gave us the heat-deflection temperature and physical properties we needed, at a reasonable cost."

Kill the spores, spare the plastic

Different plastics react differently to the sterilization methods most commonly used for medical devices: ethylene oxide (ETO), gamma and electron-beam ionizing radiation, and steam sterilization, as shown in Table 1. Sometimes the sterilization method is predetermined by the nature of the product; in other instances it's the designer's call.

As a rule of thumb, you first figure out the function and what you can afford, then you figure out the sterilization modes. Those choices are largely influenced by the particular market and the cost factors that drive it. A product that is used for a long time, or reused, can stand higher materials costs and a little more sterilization cost.

Designers need to anticipate that their customers might use any or all of the common sterilization methods unless expressly directed not to. "Unreasonably limiting the users' choices can be a significant detriment to marketing the product," says James Whitbourne, president, Sterilization Technical Services (Rush, New York).

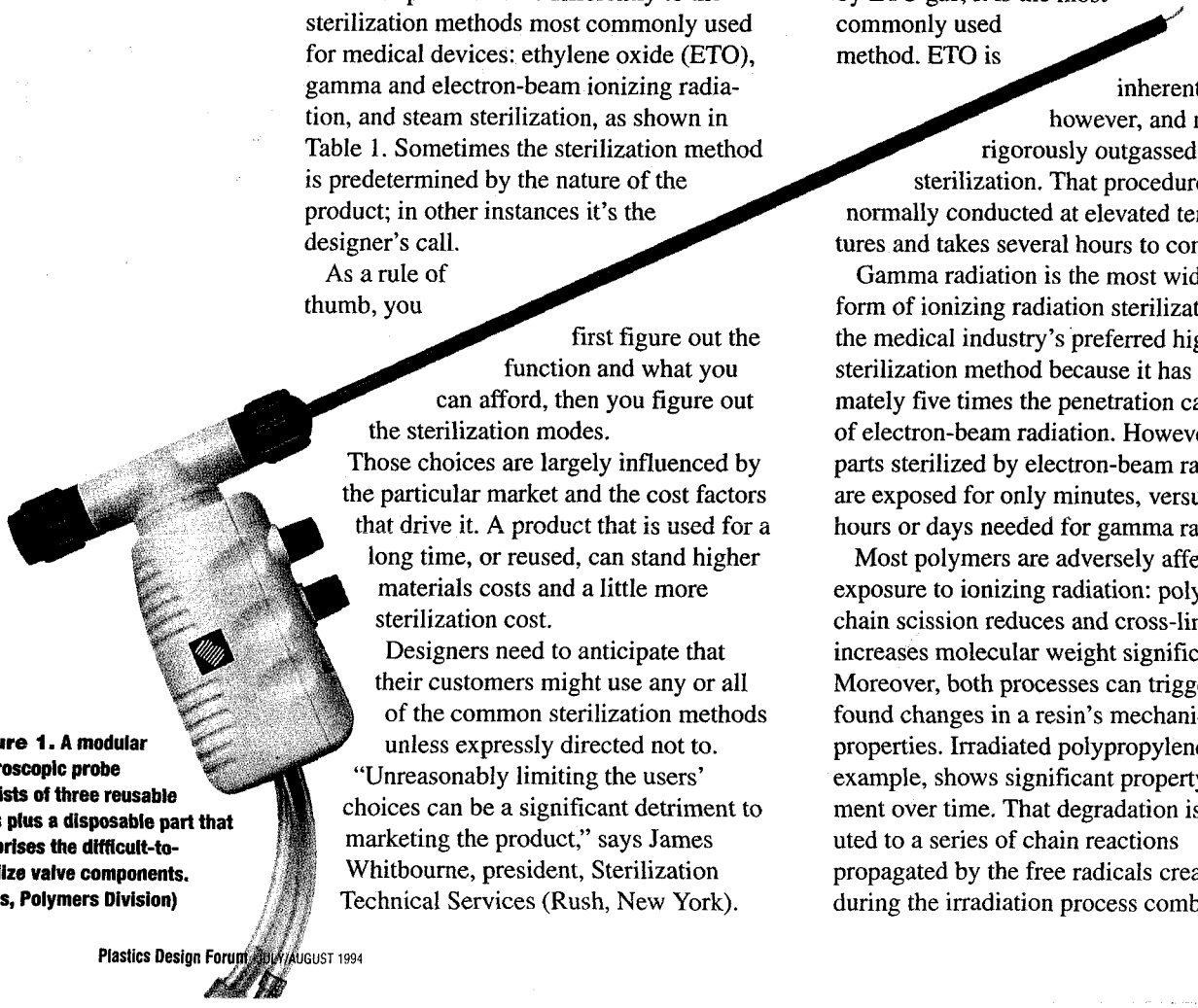


Figure 1. A modular laparoscopic probe consists of three reusable parts plus a disposable part that comprises the difficult-to-sterilize valve components. (Miles, Polymers Division)

Table 1. Sterilization behavior of polymers commonly used in medical devices

Polymer	Autoclaving	Radiation	Ethylene oxide
ABS	Poor	Good	Varies
Acrylic	Poor	Varies	Good
Polyamide	Poor	Good	Good
Polycarbonate	Varies	Good	Good
Polyester	Poor	Good	Good
Polyethylene	Poor	Poor	Good
Polypropylene	Good	Varies	Good
Polystyrene	Poor	Good	Good
Polysulfone	Good	Good	Good
Polyurethane	Poor	Good	Good
PVC, flexible	Varies	Good	Good
Silicone	Good	Good	Good

Source: Lundy, Charles E. 1994. "Criteria for Selecting Polymeric Materials in Medical Device Applications." Unpublished paper.

Disposable medical devices typically are sterilized using ETO gas or gamma or electron-beam ionizing radiation. Because most polymeric materials can be sterilized by ETO gas, it is the most commonly used method. ETO is inherently toxic, however, and must be rigorously outgassed after sterilization. That procedure is normally conducted at elevated temperatures and takes several hours to complete.

Gamma radiation is the most widely used form of ionizing radiation sterilization. It is the medical industry's preferred high-energy sterilization method because it has approximately five times the penetration capability of electron-beam radiation. However, plastic parts sterilized by electron-beam radiation are exposed for only minutes, versus the hours or days needed for gamma radiation.

Most polymers are adversely affected by exposure to ionizing radiation: polymer chain scission reduces and cross-linking increases molecular weight significantly. Moreover, both processes can trigger profound changes in a resin's mechanical properties. Irradiated polypropylene, for example, shows significant property impairment over time. That degradation is attributed to a series of chain reactions propagated by the free radicals created during the irradiation process combining

with oxygen abundantly available in the polypropylene matrix. So polypropylene must be stabilized to be useful as a medical plastic.

Other materials, such as polycarbonate, undergo significant yellowing after exposure to radiation, but their mechanical properties are not impaired. At the other end of the spectrum are materials such as general-purpose polystyrene (GPPS) and styrene acrylonitrile (SAN), unmodified styrenics that essentially are unaffected by radiation processes. Polystyrene is particularly compatible with gamma sterilization; it maintains almost all of its crystal clarity on exposure.

The effects of gamma radiation and ETO sterilization on ultrasonic weld strength are worth noting. A study by Dow Chemical (Torrance, California) of a variety of thermoplastic resins concluded that those effects were minimal in most cases, but ETO did affect the weld strength of some polymers such as SAN and high-impact polystyrene (HIPS), as shown in Table 2.

Table 2. Ultrasonic weld strength of medical plastics

The three letters in each box represent, in order, bonds subjected to: (No sterilization/ETO/Gamma radiation)

	Potential (MPa)*	Resin	15	14	13	12	11	10	9	8	7	6	5	4	3	2	1
1	5.030	High-gloss, high-impact ABS	EEE	SSS	GGE	GFG	FFF	XXX	EEG	EEG	FGF	EEE	FGG	SSS	EEE	EEE	SSS
2	4.650	Low-gloss, medium-impact ABS	EEE	SSS	GEG	GGE	GGG	XXX	GEE	GGG	FGF	EEE	GFG	GGG	EGG	EEE	
3	6.205	Impact-modified RTPU	GGG	GFF	NW	NW	NW	NW	NW	NW	NW	GEG	FXX	GGG	GEG		
4	8.960	Clear, low-impact RTPU	GGG	FFF	GGG	NW	NW	NW	XXX	FXX	FFF	GEE	FXX	GGG			
5	10.275	High-heat RTPU	WFF	FFF	FFG	FFF	FFF	XXX	FFF	FFF	WXX	GGF	FFF				
6	4.620	Medical-grade, 75 Shore D TPU	FFF	FFF	NW	NW	NW	NW	XXX	FXX	FXX	EEE					
7	3.450	Medical-grade, 55 Shore D TPU	FFF	FXX	NW	NW	NW	NW	NW	NW	XXX						
8	8.135	Medical-grade, 15 MFR PC	FGF	GFG	GGF	FFF	FFF	FFF	SEE	SSS							
9	8.410	Gamma-stable, 15 MFR PC	GGG	GGG	GFF	FFF	WFF	FFF	EEE								
10	5.410	Medium molecular weight GPPS	FFF	GFG	WWF	EEE	GGG	GGG									
11	6.790	High molecular weight GPPS	FFF	GFG	FFW	EEE	GGG										
12	3.965	High-impact polystyrene (HIPS)	FFF	EGE	FFF	EEE											
13	6.825	Polycarbonate/ABS blend	GGG	GGG	GGG												
14	7.860	Low acrylonitrile SAN	EFG	EGE													
15	9.030	High acrylonitrile SAN	GGG														

NW: No bonding occurred in the weld area.
W: Weak bond (<5% of potential)
F: Fair bond (6–15% of potential)
G: Good bond (16–30% of potential)
E: Excellent (31–50% of potential)
S: Superior (>50% of potential)
X: No data

*Potential: the force necessary to break a homogeneous piece, having no weld, of the same structure. If different resins are welded together, it refers to the potential of the weaker resin.

Source: Kingsbury, R. 1991. "Ultrasonic Weldability of a Broad Range of Medical Plastics." ANTEC Conference Proceedings, *Vol. 1. Brookfield, Connecticut: Society of Plastics Engineers, pp. 1844–1847.*

Formulations to the rescue

A wide range of thermoplastic resins are commonly used in the health care industry. They include various grades of acrylonitrile butadiene styrene (ABS), polycarbonate (PC), PC/ABS blends, SAN, polyamide, polyethylene, polypropylene, polyvinyl chloride, polysulfone, thermoplastic polyurethane, rigid TPU, HIPS, GPPS, silicone, liquid-crystal polymer (LCP), acrylic, and polyester. New medical grades of those resins are being introduced regularly, many specifically formulated to withstand sterilization processes. Material suppliers are making a major effort to help device designers accommodate gamma radiation's increasing use as an alternative to ETO gas sterilization. (For more about that trend, see "Medical products — costs on the critical list," *PDF,* November/December 1993, pp. 29–32.)

Radiation sterilization's effect on a plastic material's optical characteristics is a design concern. The standard gamma radiation dosage — 2.5 to 3.5 Mrad — causes devices made of a standard grade of PC to turn yellow-green. The color shift is caused by the production of free radicals along the polycarbonate chain during radiation exposure that form chromophores. That problem has been addressed by three new grades of Makrolon polycarbonate resin (Miles, Polymers Division). A radiation stabilizer helps reduce the number of free radicals and thus reduces color change. Makrolon Rx 2530, the first of the gamma radiation–stabilized resins to be marketed, is used to make a single-patient, autologous transfu-

When reading the results reported on Table 2, begin by matching a particular box with the two resins that make up the sample. The *numbers listed on the top of the* table correspond to the numbers of the resins on the left side of the table. The three letters in each box represent, first the nonsterilized test results, second the ethylene oxide (ETO) sterilized test results, and third the gamma radiation–sterilized results. Refer to the key under the grid for definitions of the letters.

MILES, POLYMERS DIVISION

Figure 2. A single-patient, autologous transfusion system for blood salvage (inset) incorporates a radiation-stabilized polycarbonate that resists discoloration.

Figure 3. The polycarbonate used for the barrel of a high-pressure syringe (back-ground) remains durable and clear even after exposure to gamma radiation sterilization.

GE PLASTICS

sion system for blood salvage (Gish Biomedical, Santa Ana, California), shown in Figure 2.

Gamma radiation's effect on clarity was a concern for designers developing the new 1-mL Luer-Lok high-pressure syringe (Becton-Dickinson, Franklin Lakes, New Jersey), shown in Figure 3. Lexan GR polycarbonate (GE Plastics, Pittsfield, Massachusetts) was ultimately selected for the syringe's rigid barrel, which is little more than 3 inches long. That resin also provides the strength the barrel needs to withstand the high pressure generated during rapid infusions of viscous fluids. Brad Noe, product manager at Becton-Dickinson, says the new syringes come through gamma sterilization "looking like glass and having the durability of polycarbonate."

Electron-beam sterilization is no problem for the plastic hub component of the Protector Syringe Safety Cap System (InjectiMed, Ventura, California). The part is made of Calibre MegaRad 2081 polycarbonate resin (Dow Plastics, Midland, Michigan). The material's exceptional clarity allows UV light penetration through the hub, which is necessary to properly cure the UV adhesive bond between it and the stainless steel cannula, or needle. The selection of materials and processing methods was strongly influenced by the company's concern for the environment. "We use E-beam sterilization because it does not require the radioactive sources necessary for gamma radiation or produce the toxic gases associated with ETO sterilization," says Thomas Kuracina, InjectiMed president.

The perils of frequent sterilization

Selecting materials for products that will undergo many cycles of steam sterilization is an even tougher challenge. Only a few plastic materials — polysulfones, polyetherimides (PEIs), polyetherketones, and temperature-resistant polyesters and polycarbonates — can be used in such applications. So manufacturers of equipment destined for such hostile environments are paying more attention to high-performance engineering resins. That approach worked

well for Ohmeda (Madison, Wisconsin) when it chose a polyphenylsulfone resin for an assembly capable of steam autoclave sterilization, thereby gaining entry into the European market. The company's approach is described in the sidebar "Rites of passage, from ETO to steam."

Another autoclavable resin, Vectra LCP (Hoechst Celanese, Chatham, New Jersey), offers designers a way to extend the life of reusable surgical instruments because it retains high mechanical properties after numerous heat sterilizations. In-house comparison tests showed the Vectra A130 exhibited as much as five times the flexural modulus or stiffness of polyarylsulfone (PAS), PEI, and PC after 1,500, 30-min cycles of steam sterilization, each held at 270 °F for 10 min. Throughout the testing, the LCP had a flexural modulus of 1.9–2.0 $\times$ 10^6 psi, and the other resins ranged from 0.35–0.5 $\times$ 10^6 psi.

Because of its better flow and cycle time, Vectra LCP also reportedly does a better job of improving productivity than PAS and other high-performance resins. "The resin flows at much lower pressures than the other USP Class VI resins, so parts have less molded-in stress that can cause warpage and crazing during autoclaving," says Steve Hanley, applications engineer, Hoechst Celanese. United States Pharmacopeia (USP) Class VI certification confirms that leachates from the resin cause no biological reactions under test conditions.

Dental equipment is another genre of products that must be designed to take a lot of abuse. "Dental sterilization is much more demanding than medical because of the much higher frequency of instrument use

Rites of passage, from ETO to steam

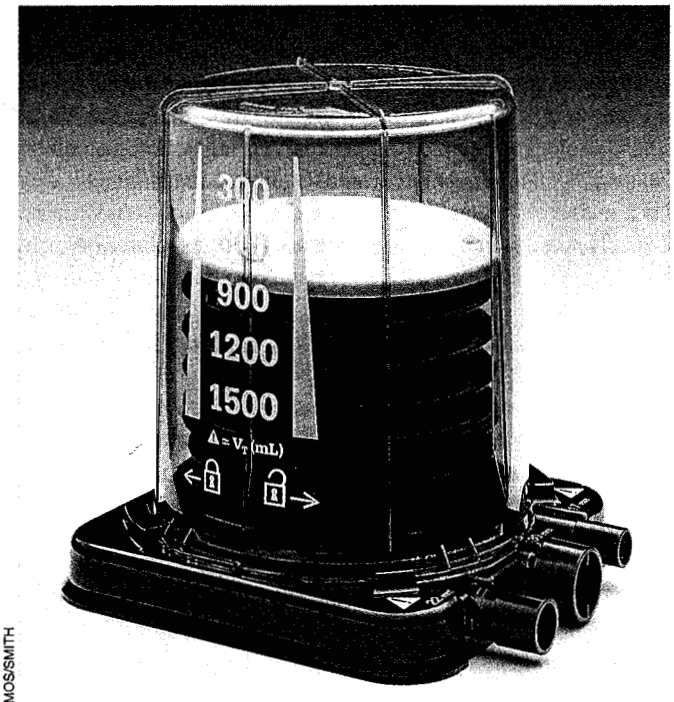
Redesigning an existing product to withstand a more rigorous sterilization procedure can be quite an undertaking. That was the experience of Ohmeda (Madison, Wisconsin), when it had to make over its ETO-sterilizable ventilator bellows assembly to accommodate steam autoclave sterilization, to enter the German market.

The autoclave environment, awash with chemicals that are added to inhibit pipe corrosion and producing temperatures as high as 134 °C, was far too hostile for the resins used in the existing bellows assembly. The redesigned equipment required a resin having better chemical resistance and a higher heat-deflection temperature. The year-long materials evaluation process resulted in selection of Radel R polyphenylsulfone, an engineering resin (Amoco Performance Products, Alpharetta, Georgia).

Early in the program, the OEM teamed with Phillips Plastics (New Richmond, Wisconsin), an experienced custom injection molder. "We went to them with our design, explained which autoclaving parameters needed to be met, and what material we had in mind," says Ohmeda's senior product manager.

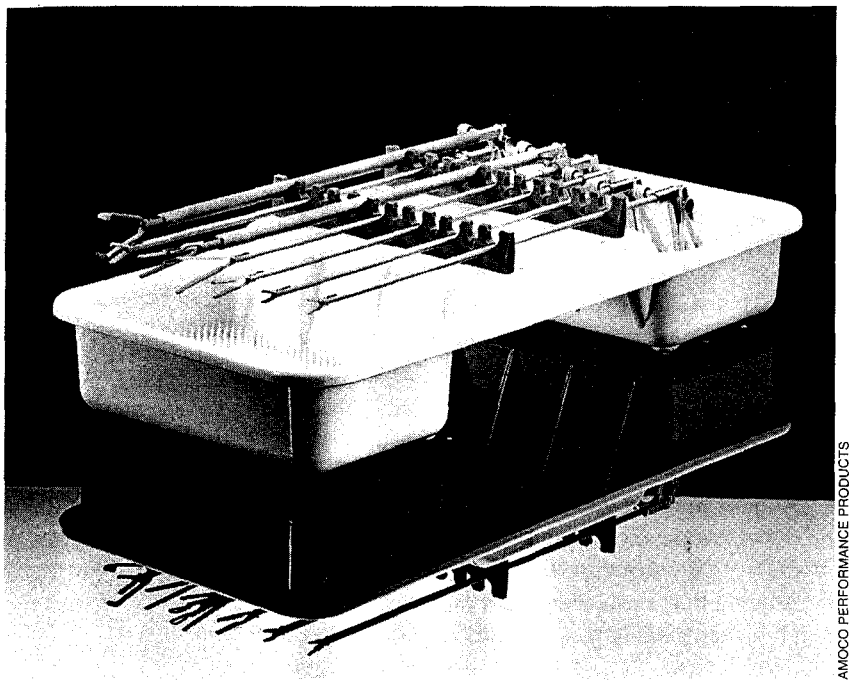
The molder made recommendations to enhance overall moldability, and the OEM incorporated those ideas into an updated concept. The result is a ventilator bellows assembly that can be disassembled easily and has less than half the part count of the old design. "By reducing part count and making the unit disassemble and reassemble without the need for screws or fasteners, a smooth transition to the cleaning process was ensured," says Phillips' project engineer Bob Smith. The parts molded at Phillips' Short Run Facility — a mounting plate and lever, base, latch, rim, housing, seat, and the bellows disk and ring — can be assembled and ready for operation in less than a minute.

The redesigned assembly is a winner. It offers the customer a unit that not only withstands steam autoclave sterilization, but also is easily disassembled. As a result, the OEM is supplying the redesigned units to both European and U.S. markets.



AMOS/SMITH

A ventilator bellows assembly was redesigned using polyphenylsulfone to better withstand steam autoclave sterilization.



AMOCO PERFORMANCE PRODUCTS

Figure 4. A sterilization tray made of polyphenylsulfone has high impact strength, good chemical resistance, and is autoclavable by all commercial means.

and between-patient sterilization requirements," says Ralph Lavi, medical market manager, Amoco Performance Products (Alpharetta, Georgia).

To help designers meet such challenges, the company developed Radel R polyphenylsulfone. The material is well suited for applications that must exhibit superior long-term performance in critical requirement areas. It reportedly provides superior impact strength, is autoclavable by all commercial means, and offers a high degree of chemical resistance to all kinds of boiler-treating chemicals encountered in hospital steam supplies. Consequently, the material is now a popular choice for a variety of sterilization tray systems, including the one shown in Figure 4 (Poly-Vac, Manchester, New Hampshire).

Summing up

Conventional wisdom says that determining the mechanical property requirements for a medical device is the most technically challenging aspect of the material-selection process. But it's also essential for part designers to understand the effects of sterilization techniques on commonly used medical plastics before specifying a material. If you neglect to consider the long-term effects of sterilization on polymers, a seemingly well-designed medical device could be a time bomb in disguise.

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