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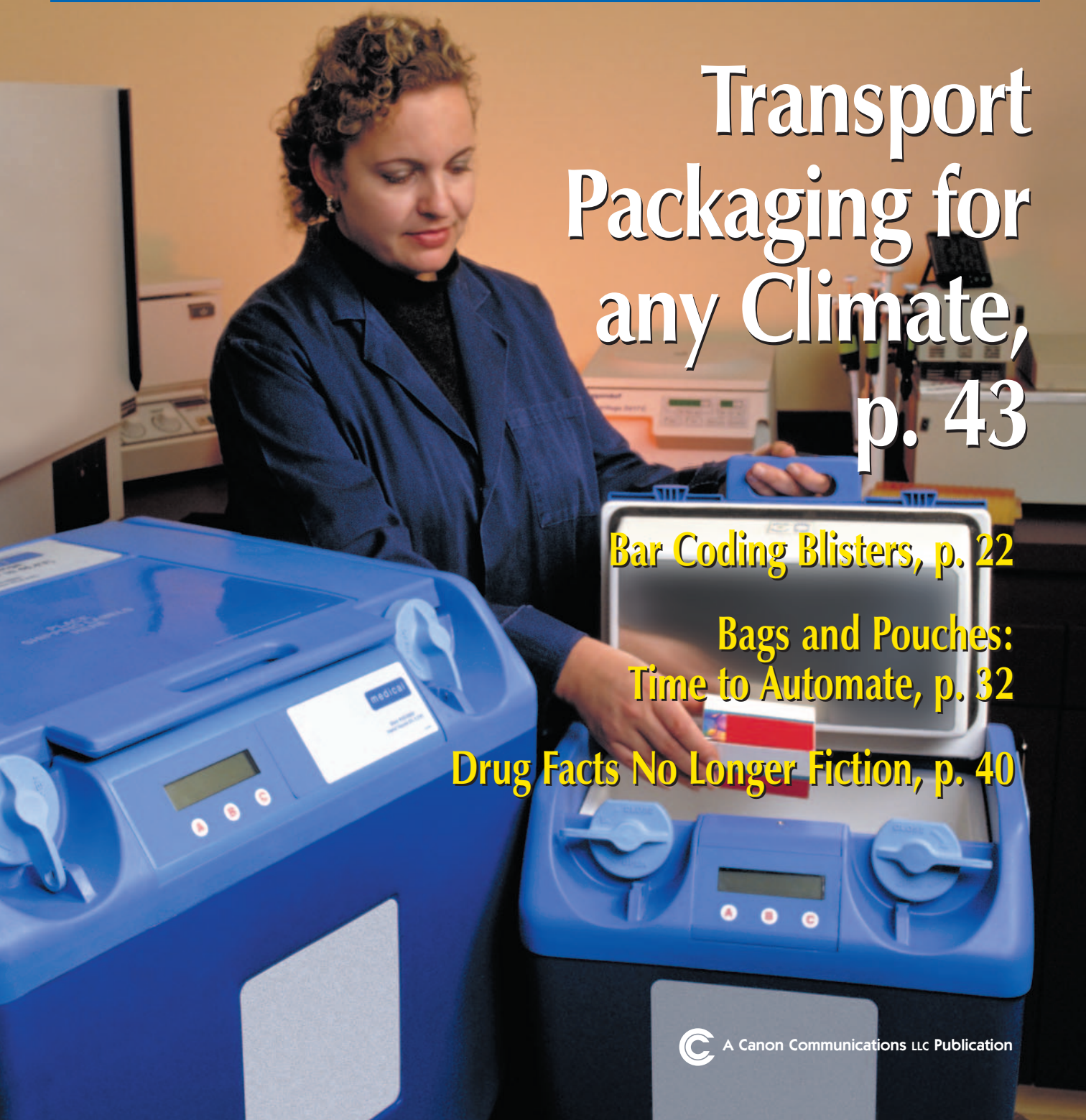

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Sterilizing Acrylic with Low-Temperature Hydrogen Peroxide Gas Plasma

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Popular acrylic polymers used for medical device trays and components are evaluated for compatibility with an emerging sterilization method.

Joint evaluation by Cyro Industries and Advanced Sterilization Products (ASP), a Johnson & Johnson company, was done to determine the suitability of Cyro's acrylic polymers, used for packaging and devices, with low-temperature hydrogen peroxide gas plasma (LTHPGP) sterilization.

LTHPGP sterilization is a relatively new technology, marketed under the trade name Sterrad by ASP. Sterrad offers a number of advantages, compared with established technologies. Advantages include a short sterilization cycle (1–4 hours), low temperature and humidity, no aeration requirement, no toxic chemical residues, negligible environmental impact, broad compatibility with materials, and in-house control of sterilization. Disadvantages include an inability to process liquids, powders, or strong hydrogen peroxide absorbers, like cellulosics.

The five phases or stages of the LTHPGP sterilization process consist of vacuum, H_2O_2 injection, diffusion, plasma, and vent. These phases are programmable through software to modify the duration and repetition of the cycle stages to allow for specific medical device loads and configurations. The sterilization system monitors all critical parameters, including real-time hydrogen peroxide concentration.

It is essential that a material's compatibility with the technology be established prior to or during sterilization validation. A vast array of polymeric materials, metals, and ceramics commonly used for medical devices have been evaluated for compatibility with LTHPGP sterilization. Testing of such compatibility has been performed at more than 50 industrial manufacturers of medical devices. Information gained from this testing can be used to provide guidelines of material or device compatibility to industrial manufacturers interested in LTHPGP. This information can be used as a guideline when assessing compatibility, but should not take the place of specific testing.

Packaging compatibility with LTHPGP sterilization is also critical. The technology depends heavily on sterilant diffusion through the load and into packaging. Packaging must be designed using LTHPGP-compatible materials, feature sufficient vapor permeability, and provide a bacterial barrier to maintain postprocessing sterility. This vapor-permeable element can be designed in the package in the form of a nonwoven spunbonded fibrous outlay, such as Tyvek from DuPont. Cellulose-based packaging and wraps, such as paper, are not recommended.

Cyro's acrylics are used for medical trays, like this one from Cordis. Photo courtesy Cyro Industries.

The objective of this study is to determine the suitability of LTHPGP sterilization with acrylic polymers made by Cyro for use as packaging materials and as medical device components. These materials are: Acrylite acrylic molding grades, varying in molecular weight; Acrylite Plus grades, which incorporate acrylic core-shell-type impact modifiers in an acrylic base; and XT/Cyrolite acrylic multipolymers, which incorporate a grafted-olefinic-rubber impact modifier in an acrylic multipolymer base. These are processed using injection molding, extrusion, and thermoforming.

Property	Acrylite	Acrylite Plus	XT/Cyrolite
Tensile Properties	Slight reduction in elongation	Slight reduction in elongation	No change
Notched Izod Impact	Slight reduction	Very slight reduction	No change
DTL/Vicat	No change	No change	No change
Hardness	No change	No change	No change
Chemical resistance to lipids	Slight reduction in elongation of higher-molecular-weight grades; greater reduction in elongation and tensile strength of lower-molecular-weight grades	No change	No change
Transmittance	No change	No change	No change
Yellowness Index	Very slight reduction	Slight reduction	Slight reduction
Haze	No change	Increase	Increase
Gloss	No change	Decrease	Decrease
Refractive Index	No change	No change	No change

Table I: Comparison of effects of Sterrad processing on key physical properties of acrylic-based materials.

EXPERIMENTAL METHODS

Acrylite H15, H12, M30, and L40 are grades of decreasing molecular weight; Acrylite Plus ZK-6, ZK-D, ZK-P, and ZK-F are grades of varying molecular weight with different levels of impact modifier. XT/Cyrolite XT-250, XT-375, G20 HiFlo, GS-90, and CG-97 are grades of different molecular weight and differing levels of impact modifier. GS-90 and CG-97 also contain a stabilizer package used in minimizing color formation in gamma sterilization. Various specimens (tensile bars, ⅛-in. plaques, Izod bars) were supplied by Cyro. Controls (unexposed to sterilization) were retained by Cyro.

Exposure of Acrylite, Acrylite Plus, and XT/Cyrolite to LTHPGP sterilization was conducted in the Sterrad 100 SI GMP sterilization system. The polymer samples were exposed to LTHPGP under the following conditions: Samples were exposed to moderate industrial full-cycle parameters consisting of a four-dose exposure at maximum volume (1800 µl) to hydrogen peroxide [(6-min injection, 5-min diffusion, and 2-min plasma) × 4].

Exposed samples were returned to Cyro for functionality evaluation, including the following evaluations of both control (unexposed) and sterilization-exposed samples:

- Optics (haze, gloss, transmittance, refractive index, and yellowness index).
- Tensile (mechanical properties: tensile strength and elongation at break).
- DTL/Vicat.
- Notched Izod impact.
- Hardness.
- Chemical resistance to lipids was determined by subjecting tensile bars to 1.2% strain for 24 hours and 30°C while exposed to lipid solution.

RESULTS

The functionality assessment of the Acrylite, Acrylite Plus, and XT/Cyrolite polymer samples was done by Cyro after exposure to the Sterrad sterilization system. The general trends in the results of the functionality testing are summarized in Table I. As an example, specific numerical data for Acrylite H15-003 polymeric material are indicated in Table II.

The results indicate that, in general, the Acrylite grades show no significant effects on optical properties contrary to the effect of gamma sterilization on the polymer, after which a significant yellowing is observed. The mechanical and thermal properties also show no significant property deterioration, except for a reduction in elongation at break in some of the Acrylite grades tested. Chemical resistance to lipids was slightly reduced in the higher-molecular-weight grades after sterilization exposure and was significantly reduced in the lower-molecular-weight grades. An increase in haze and a decrease in gloss were noted and may be due to the process's effect on the impact modifier. Mechanical, thermal, and chemical-resistance properties were unchanged.

Property		Test Method	Acrylite H15-003	
			Control	Sterrad Processed
Tensile strength, psi		ASTM D-638	11640	11400
Elongation @ yield, %		ASTM D-638	5.7	5.5
Elongation @ break, %		ASTM D-638	10.3	5.5
Tensile modulus, psi		ASTM D-638	470,000	473,000
Notched Izod Impact, fppi (⅛ inch)		ASTM D-256	0.36	0.31
Hardness, M		ASTM D-785	94	94
Chemical resistance to lipids (1.2% strain for 24 hours @ 30°C) [In-house test]	Tensile strength, psi	ASTM D-638	11,290	10,390
	Elongation @ break, %	ASTM D-638	11.8	5.9
Retention after lipid exposure, %	Tensile strength	ASTM D-638	97	91
	Elongation @ break	ASTM D-638	115	107
Transmittance, %		ASTM D-1003	93	93
Yellowness Index		ASTM D-1003	0.4	0.3
Haze, %		ASTM D-1003	0.7	0.9
Gloss @ 60°C		ASTM D-523	137	138
Visual		—	No effect	No effect
Refractive Index		ASTM D-542	1.49	1.49

Table II: Results for Acrylite H15-003 polymer (unprocessed control versus sterilization processed).

The XT/Cyrolite grades also exhibit no change in transmittance or color formation, but, similarly to Acrylite Plus, show increased haze and reduced gloss, again potentially due to the effect of the sterilization process on the impact modifier. From a practical standpoint, the haze observed—though increased—is not high enough to be objectionable, because medical device packaging trays and components are typically thinner than the specimens evaluated in this study.

Thus, these materials can be recommended for use with LTHPGP, with consideration to peroxide absorption evaluation. PMP News

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