Stretching flexo technology for medical packaging

Allegiance Healthcare harnessed the expertise of three key vendors to identify a more cost-effective lidding material printed on-line and sealed to thermoformed trays holding medical instruments.

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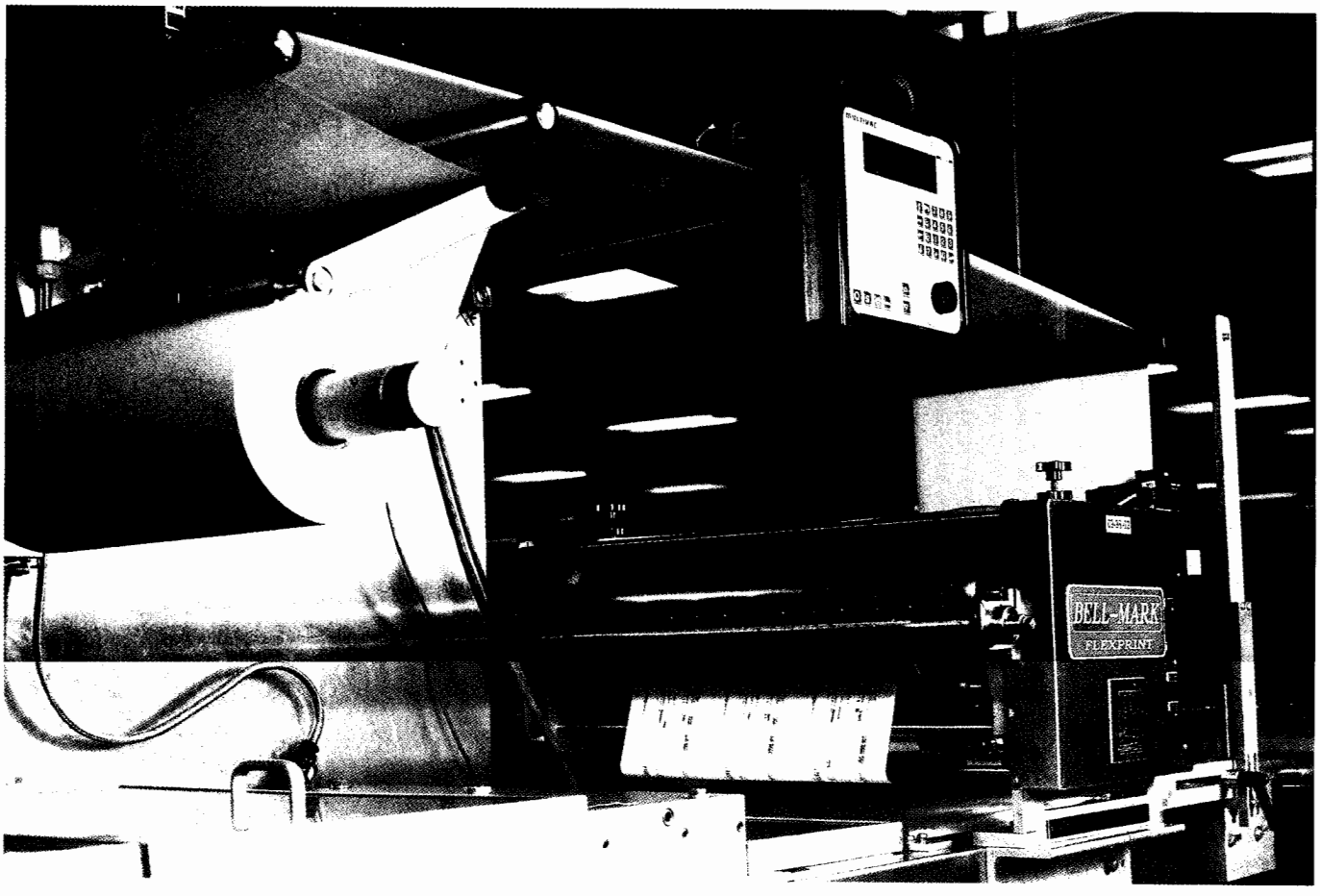
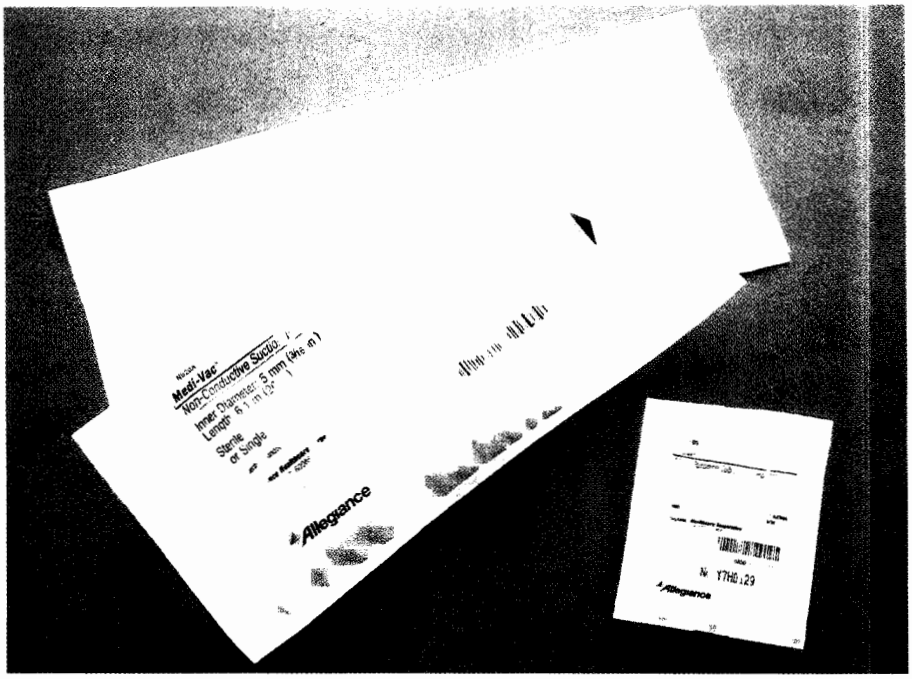
Allegiance Healthcare Corp. has achieved a significant breakthrough in the packaging of medical instruments that are gamma-sterilized in their packages. The McGaw Park, IL-based firm is believed to be the first to use a polyethylene film printed entirely on-line rather than a medical-grade paper or spun-bonded polyolefin for lidstock.

"Lidding costs have been cut by forty-five percent on two lines where twenty different products are packaged," says Arturo Ochoja, senior project manager at the Mexicali, Mexico, plant where the new film has been in use since



On-line printing of PE lidding material has allowed Allegiance to replace preprinted medical-grade paper and spun-bonded polyolefin, thus cutting costs by 45%.



Allegiance relied on a team effort by a printer manufacturer, an ink supplier and a film vendor to succeed in its quest to print PE lidstock on-line.

June. He also adds that the new material wasn't adopted without thorough prequalification and validation.

"It included accelerated aging, distribution tests, final inspection, bubble test, seal strength, peel test, and burst test," says Ochoja.

Allegiance packages products like suction tubes and connecting hoses used in surgery. At the Mexicali plant, 20 different products are packaged on either an R7000 or R530 horizontal form/fill/seal machine from Multivac (Kansas City, KS). The R530, running two shifts daily, handles 11 different products always in a two-up format. The R7000 packs nine products, but tooling permits it to run in a three-, five- or seven-up configuration. It runs around the clock five days a week.

Until last July, the R7000 used lidding material made of either medical-grade paper or spun-bonded polyolefin. Static information like product identification, company name and catalog number was always preprinted by the converter supplying the material. Variable information like date and lot number was printed on-line by ink-jet equipment from Markem (Keene, NH).

The R530, on the other hand, applied only unprinted medical-grade paper as lidding. Unlike the R7000, it was equipped with a flexographic printer that imprinted the static information on-line. Variable information was added on-line by another Markem ink-jet unit.

These methods and materials were inherited by the facility when, in 1994, production and packaging of this product line was moved to Mexicali from a plant in Puerto Rico. In 1996, Ochoja took on the challenge of making the Mexicali packaging operation more cost effective.

Substituting inexpensive film for the more costly medical-grade paper and spun-bonded polyolefin was the objective from the start. Printing the film lidding on-line for all 20 products was also a key target. But the water-based inks used in medical packaging typically don't dry fast enough on plastic film.

Vendors team up

What Allegiance sought, then, was a material substitution that could only be made through new technology. To develop it, Ochoja harnessed the talents of three key vendors. Bell-Mark (Pine Brook, NJ) supplied two of its Flex-Print™ in-line printers to Allegiance, one for each Multivac. Colorcon (West Point, PA) developed the necessary water-based ink. And Rexam Medical Packaging (Mundelein, IL) supplied the lidding material. Retained were the Multivac thermoforming/lidding machines and

the Markem ink-jet coders.

The 4-mil lidstock is Rexam's Integra® Peel product. From the outside in, this three-layer blown film coextrusion consists of high-density polyethylene/HDPE/blended low-density polyethylene. The two outer layers of HDPE differ slightly from each other. The outermost one includes ingredients that enhance the ultimate printability of the finished structure.

Colorcon's Jerry Napiecek says his firm demonstrated several years ago that a water-based ink can be applied to such a film and dried on-line successfully *if* additional drying capacity is added to the flexographic printers. But full commercialization of such inks had to wait until manufacturers of flexographic printers were willing to incorporate the necessary drying units on the machines they build.

So far the only printer maker to show such a willingness is Bell-Mark, says Napiecek. On the printers it installed at Allegiance, the first thing the freshly printed lidding encounters as it exits the print station is an air plenum that stretches across the full width of the film. It blows air at temperatures from ambient to 180°F to help dry the ink. The plenum is aimed so that none of the air is directed back onto the printing plate or anilox roll, which could cause the ink to dry before it's delivered to the lidstock.

As critical as this air plenum is, the Bell-Mark system has two other features that contribute significantly. One is the enclosed doctor blade, which keeps air from reaching the ink and drying it prematurely.

The other key feature is timing. The Flex-Print differs from other on-line printing and coding systems, where the print drum receives ink immediately after the previous imprint. That method can allow too much time for drying before the ink is delivered to the substrate. It isn't a problem on spun-bonded polyolefin or medical-grade paper because the ink used on such substrates doesn't evaporate so quickly. It doesn't have to dry quickly because these substrates absorb it readily.

With the fast-drying Colorcon inks that Allegiance uses, the lag between application of the ink on the drum and imprint on the substrate is kept to an absolute minimum. With the aid of a PLC, the print drum doesn't rotate past the anilox roll for fresh ink until the instant before the next print cycle.

Could faster-drying solvent-based inks have been substituted for the water-based variety? Probably not for medical packaging. Solvent emissions just aren't acceptable in a clean-room environment, and venting them outside presents problems with clean-air regulations and/or incineration equipment.

Film is a challenging substrate

Rexam's Dan Penny appreciates the effort that went into the Bell-Mark system and its effectiveness in printing on a film substrate. "Paper and spun-bonded polyolefin are so much easier because they absorb some portion of the ink," he says. "But when you print on film, all the ink is sitting directly on the surface. If you don't get the right surface tension in the ink, you wind up smearing everything.

"It took considerable work on Bell-Mark's part to refine the process and take it to a user-friendly stage. It's one thing to do it in the lab. It's another thing doing it around the clock at a medical device manufacturer's plant."

Colorcon's contribution to the Allegiance project was no small feat either. It formulated an ink that would stay "open," as Napiecek puts it, on the DuPont (Wilmington, DE) Cyrel® photopolymer plate, yet dry fast enough after application to avoid being smeared or picked off the substrate. "It was certainly not a standard formulation," says Napiecek. He also credits Bell-Mark's people. "Without a buy-in from the engineers at Bell-Mark, it would have been impossible to pull this off."

Rexam also supplies the monolayer forming web, a 10-mil Integra® Form Peelform® Plus, which is blown from a LDPE blend. Maximum depth of draw on the Allegiance packs is 1¾", and machine speeds on the two lines are similar, with cycle times in the 13 to 15/min range.

Allegiance is so pleased by the material cost savings gained by the switch in lidding materials that it now plans a similar transition at a plant in Malaysia.

"Cost savings drives it all," says Ochoja. "The medical device business is very competitive, so you have to do what you can to reduce cost while maintaining quality."

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