

# Healthcare Packaging

TM

PACKAGE TESTING

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## New pouch DESIGNS PUT TO THE TEST

*Dental and medical pouch  
maker relies on third-party  
testing for 510(k) process*

Headquartered in Montreal, Quebec, Canada, **Medicom** ([www.medicom.com](http://www.medicom.com)) manufactures self-sealing sterilization and heat-sealing pouches for dental and medical applications as well as dental instruments and medical products, such as surgical gowns and masks.

According to Jason Ludvig, Medicom's product development manager, the majority of the company's pouches are sold to the dental industry. "The main



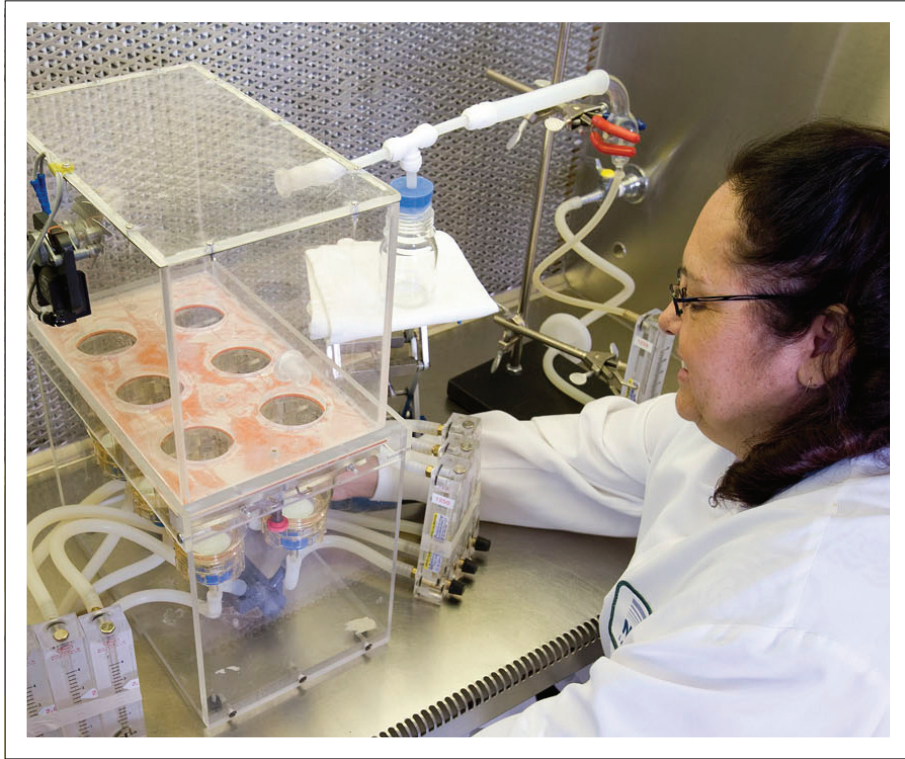
**BURST TEST.** A Nelson Labs study director performs a burst test.

product we sell is a Kraft paper sealed to polyester-polypropylene film," he says. "A self-sealing adhesive strip goes across the top, which is peeled off and sealed

over by the end user after they load their instrument into the product."

Finished pouches are produced via a laminating process and range in size from approximately 2.25 x 4 in. to 18 x 22 in., with the smallest pouches being used for dental instruments, such as burs or drill bits. Four-color printing takes place offline, and process indicators for ethylene oxide (EO) and steam sterilization are applied to the material prior to the pouches' formation.





**MICROBIAL RANKING.** A Nelson Labs study director conducts a microbial ranking, ASTM F1608 test to evaluate porous packaging materials.

Although much of Medicom's pouch testing is done in house, the manufacturer also relies on the lab facilities at **Nelson Laboratories ([www.nelsonlabs.com](http://www.nelsonlabs.com))** in Salt Lake City for testing surgical masks and gowns. "When we want to submit to regulatory agencies, we need to have good laboratory practices in place," explains Ludvig. "We don't have that facility set up, so we do testing at Nelson Labs to supplement the testing we do."

Medicom also turned to Nelson Labs when the company started manufacturing its pouches in house rather than relying on a third-party supplier. "I approached Nelson Labs with the pouch program when we wanted to submit our own 510(k)," says Ludvig. Medicom's products are classified as Class I and Class II medical devices, he explains, most of which require 510(k) submissions.

The company looks to Nelson Labs for guidance when dealing with varying

standards and regulatory agencies. "For me, our use of Nelson Labs isn't necessarily for routine testing," says Ludvig. "I use it when I am designing new products. If there are changes to any materials, pouch configurations, or anything of that nature, that's when I would go to Nelson Labs."

Key tests performed at Nelson Labs for Medicom's pouch program include package integrity testing, such as a bubble emission testing and seal strength testing; microbiological tests for gamma radiation; and indicator testing. "We have indicators on our inks that need to conform to specific standards," explains Ludvig. "A little dot turns a different color after it has been processed with steam or EO sterilization. These indicators tell the end user that the product has been processed."

Medicom sends Nelson Labs between 13 and 20 samples per test. The company then uses data from the design verification test conducted by Nelson Labs to file the 510(k). During the design validation stage, Medicom tests its products in the field to ensure that they meet end-user expectations.

"I do engage [end users] with regard to polling and doing any design changes," says Ludvig, "and they do mention that they like certain products that we tested through Nelson Labs over others. Nelson Labs is very well-versed in the regulatory requirements, so I lean on them a lot for their expertise." [HCP]