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**Ethicon pursues lead role in radical surgery research**

BY JAMES RITCHIE
jritchie@bizjournals.com

Ethicon Endo-Surgery Inc. has built much of its business on minimally invasive surgery. Using its instruments, surgeons do procedures through cuts sealable with only a couple of stitches, sparing patients the pain, scarring and long recovery times that can follow traditional operations.

But the $3 billion Blue Ash company sees potential for even less invasive methods. It's pushing research into surgery done with no skin incisions at all, through openings the body already has.

"We expect to be the leader," said Kevin Lobo, who took over as president at the Johnson & Johnson subsidiary in July. "The mix of surgery types will change. We'll let the patient outcomes determine that."

In natural-orifice surgery, the gall bladder could be removed, for instance, through the mouth. The doctor would snake a tube down the esophagus, puncture the digestive tract to gain access to the abdominal cavity and take the organ out by the same route. The approach is called natural-orifice translumenal endoscopic surgery, or NOTES.

A range of procedures could be performed this way, such as gastric bypass, fallopian tubal ligation, removal of the ovaries and diagnostic work. Some operations could be done via the rectum or vagina, as well.

Possible advantages include an even quicker recovery and lower need for anesthesia and pain medication than with laparoscopic procedures, in which surgery is performed using long, thin instruments guided through the body with tiny cameras.

Because NOTES is so new, research generally has been confined to animals, mainly pigs. But there are reports, not yet published in a peer-reviewed academic journal, of its use in humans.

In October, Ethicon Endo-Surgery gave the concept its largest financial boost, pledging $1 million to fund investigation into it. The National Orifice Surgery Consortium for Assessment and Research issued a request for proposals based on the money.

Lobo said his company would continue supporting NOTES by funding independent research, developing products and making small equity investments in startups. He believes it will be five years or more before the approach is widely available to patients.

The Canadian-born executive, who had been president of Johnson & Johnson Medical Products in Toronto, wouldn't say how big he thinks NOTES could be for Ethicon Endo-Surgery, which employs 1,800 people here.
For now he's got plenty to focus on with the company's business lines in minimally invasive and open surgery. The firm launched seven products and grew 9 percent in 2006; it expects similar numbers this year.

"Our people have really good ideas," Lobo said. "The challenge is how to prioritize and fund all of our opportunities. This is a problem most companies only dream about having."

Lobo replaced Bob Salerno, who left Ethicon to work at Johnson & Johnson's headquarters in New Brunswick, N.J. Much opportunity could await companies developing equipment to grow natural-orifice surgery, said Dr. Anthony Kalloo, director of gastroenterology and hepatology at Johns Hopkins University in Maryland. He believes the approach, which he pioneered, could become widespread in two to five years and someday account for the majority of genitourinary, gastroenterological and gynecological surgeries.

"In my humble, biased opinion, I see it becoming a mainstay of how we practice abdominal surgery," he said, adding that both gastroenterologists and surgeons are likely to use NOTES.

The area could take a place alongside current techniques, said Dr. Michael Nussbaum, interim chairman of surgery at the University of Cincinnati.

"A lot of leaders in American surgery are very excited about the potential and want to be part of it," he said. "But the technology just hasn't been developed."

And the process always will have limits.

"If you're taking out somebody's liver," Nussbaum said, "you can't bring it through the stomach and out the mouth."

The group to which Ethicon Endo-Surgery is providing money - the National Orifice Surgery Consortium for Assessment and Research - formed in 2006 to track and help organize research efforts. It's made up of leaders from two gastro-related physician societies. The group's idea was to press for a measured path to human trials of NOTES. Questions remain about how best to penetrate and close the gastric wall, maintain spatial orientation with the camera, prevent infection and manage complications.

But two doctors in India, N. Reddy and V.G. Rao, already have done appendix removals with the technique. Kalloo also has heard of NOTES cases being performed on humans in the United States and believes reports will be published soon.

The real question might not be whether NOTES can be done but whether it's worth doing. Current laparoscopic techniques, developed in the 1980s and '90s, already have a track record of safety and effectiveness. They're used for a range of surgeries, including those of the heart, spine, joints and prostate as well as the gastrointestinal tract.
After a laparoscopic procedure in the abdomen, a patient is typically home within a day and back to work within 10, with negligible scars. Kalloo said NOTES might work well for obese patients, because the doctor won't have to pass instruments through layers of fat. And it could be a good choice for those who are "cosmetically conscious" or have problems with anesthesia.

One operation in India involved a patient with severe burn injuries, according to Surgery News, a publication of the American College of Surgeons.

"How will we know if we don't do it?" Kalloo said. "We have to get to the point where we have expertise in this and can do randomized, controlled trials, and then we'll have the answer. We feel that intuitively, based on trends in surgery, this could be logical."

The president
Kevin Lobo, president, Ethicon Endo-Surgery
Last job: President, Johnson & Johnson Medical Products, Canada
Previous companies: Rhone-Poulenc, Kraft Foods, Unilever
Age: 41
Wife: Shazie
Children: Sara, 12, and Seth, 9
Building a home in Indian Hill