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The trocar is a razor-sharp instrument used in millions of laparoscopic surgeries each year, including hysterectomies and gall bladder operations. But some in the medical community are alarmed at the numbers of serious injuries and deaths they say are linked to this device.

Just how safe is it on surgery's cutting edge?

## THE TROUBLE WITH TROCARS

By Linda Carroll and Alfred Lubrano  
Photographs by Robert Lewis

*Reprinted from the November 2001 issue of SmartMoney. Taut, Inc. had no influence on the editorial content of this article. SmartMoney does not endorse any product or service of Taut, Inc.*

# BARELY CONSCIOUS,

the young woman could hear the rushed panic of nurses scrambling around her. Someone in the hospital recovery room yelled "Stat!" just like they do on TV.

A friend, on hand to lend emotional support, started screaming, "Oh my God!"

Jamie Maglio Zinkus had just collapsed in the bathroom, felled by dizzying nausea as her anesthesia wore off. Her eyes rolled into the back of her head and she could feel herself fading . . . just fading away . . . as though she would lose consciousness and never wake up. "I felt like that was it for me," she remembers.

It was supposed to be a simple procedure. Maglio Zinkus, a 24-year-old mother of two, had decided to get her tubes tied. So in February of this year, the athletic, blond South Philadelphia woman went to a doctor who said he could perform the surgery laparoscopically. This less invasive technique, the doctor explained, would mean a quick, painless operation, tiny scars and a short recovery time.

But the operation went horribly wrong. When the doctor made his initial incision, using a razor-sharp instrument called a trocar, he accidentally severed an artery, Maglio Zinkus says. She collapsed because she was bleeding to death internally. The doctors rushed Maglio Zinkus back to the OR and performed a second surgery, cutting her abdomen open from hip to hip. The artery damage was repaired, but her suffering only intensified.

After the second procedure, Maglio Zinkus says, she was gripped by abdominal pain like she'd never known—worse than labor. "It was like getting beaten over and over with baseball bats," she remembers. Lying in agony in her hospital room, she moaned loudly. A priest walking by heard her and came in to ask if she wanted a prayer. Suddenly, Maglio Zinkus was

seized with guilt over her choice to have the surgery. "Father," she said, panting and aching, "please tell me God is not punishing me for deciding not to have more children. If I'm going to feel pain like this, God can just take me now."

Maglio Zinkus survived, and today she's back at work, helping run her family's food business. But she still lives with incapacitating headaches, horrible cramps, stomach pains and limited mobility, she says. Maglio Zinkus is suing the doctor for malpractice. (Attorneys for her doctor failed to return phone calls seeking comment.) "She went in for a routine procedure," says her attorney, Derek Layser. "They told her she'd be home that day. And she's still suffering."

The sad truth is that Maglio Zinkus's surgery *was* a simple one, extremely common, and the technique the doctor used is widely considered to be state of the art. If you or someone in your family is considering a tubal ligation, hysterectomy, surgery for endometriosis or other common gynecological problems, or gall bladder surgery, the odds are good that the operation will be done laparoscopically. In this method, doctors guide tiny cameras and long, thin instruments through small incisions in the body. Some hernia and heart operations are performed this way as well—all told, as many as 4 million laparoscopic surgeries are performed in the U.S. annually, estimates Mike Kavic, a board member of the Society of Laparoendoscopic Surgeons. (By comparison, 830,000 people had laser eye surgery last year.)

But as this technique's popularity con-

tinues to grow, some highly respected physicians are becoming alarmed at the number and severity of injuries they say are associated with the trocar. The trocar is essentially a metal spike the doctor forces into the abdomen at the beginning of a laparoscopic surgery. Once a hole is made, the doctor withdraws the spike and inserts the instruments. The problem is, during that first piercing cut—before any cameras have been inserted—the doctor is flying blind. "Really, it's like taking a spear and sticking it in someone, not knowing if you'll hit the liver, an artery or anything else below the skin," says Suzanne Parisian, formerly a chief medical officer at the Food and Drug Administration's Office of Device Evaluation.

Accurate numbers of trocar-related injuries are extremely difficult to pin down. The FDA, which regulates medical devices, can't provide numbers of injury reports relating specifically to trocars. Based on her own analysis of FDA data, Parisian estimates there have been more than 40,000 trocar-related injuries over the past 10 years. Clinical studies show injury rates in line with Parisian's numbers and suggest that those injuries may include 50 to 240 deaths a year.

The instrument companies that make trocars say these injuries are extremely rare and that trocars are safe if used properly. "Based on clinical success of laparoscopic surgery for years, trocars are safe and effective," U.S. Surgical, one of the biggest manufacturers, said in a faxed statement. "Also, without laparoscopic surgery, patients would be required to undergo open surgery, with [all] the attendant risks."

But even some doctors who routinely use trocars say there's some inherent danger. "It's true, we are initially stabbing patients blindly at the beginning of every surgery," says Tom Margolis, former chief of gynecology at Stanford University Medical Center, who's now in private practice. "I don't feel safe doing it. Anytime I use a trocar, I always say a prayer, cross my fingers, then do it. I understand it to be a risk of surgery."

But doctors can do a lot more than cross their fingers—there is a better way to do these operations. Cutting down to the abdominal cavity with traditional surgical instruments, then inserting a rounded, blunt kind of trocar has been shown to substantially reduce the risk. But even though this method—known as the "Hasson technique," after the man who invented it—has won the endorsement of some highly respected clinicians, 87 percent of doctors continue to use the sharp trocar today, according to ECRI, a nonprofit company that evaluates medical devices.

When contacted by SmartMoney, FDA spokeswoman Sharon Snider said the agency is "looking into the entire issue of trocar safety." But there is no organized opposition or vocal advocacy group trying to effect change. Doctors' concerns have mostly stayed within the medical community. The instrument companies, which take in hundreds of millions every year from trocar sales, have a powerful incentive to maintain the status quo.

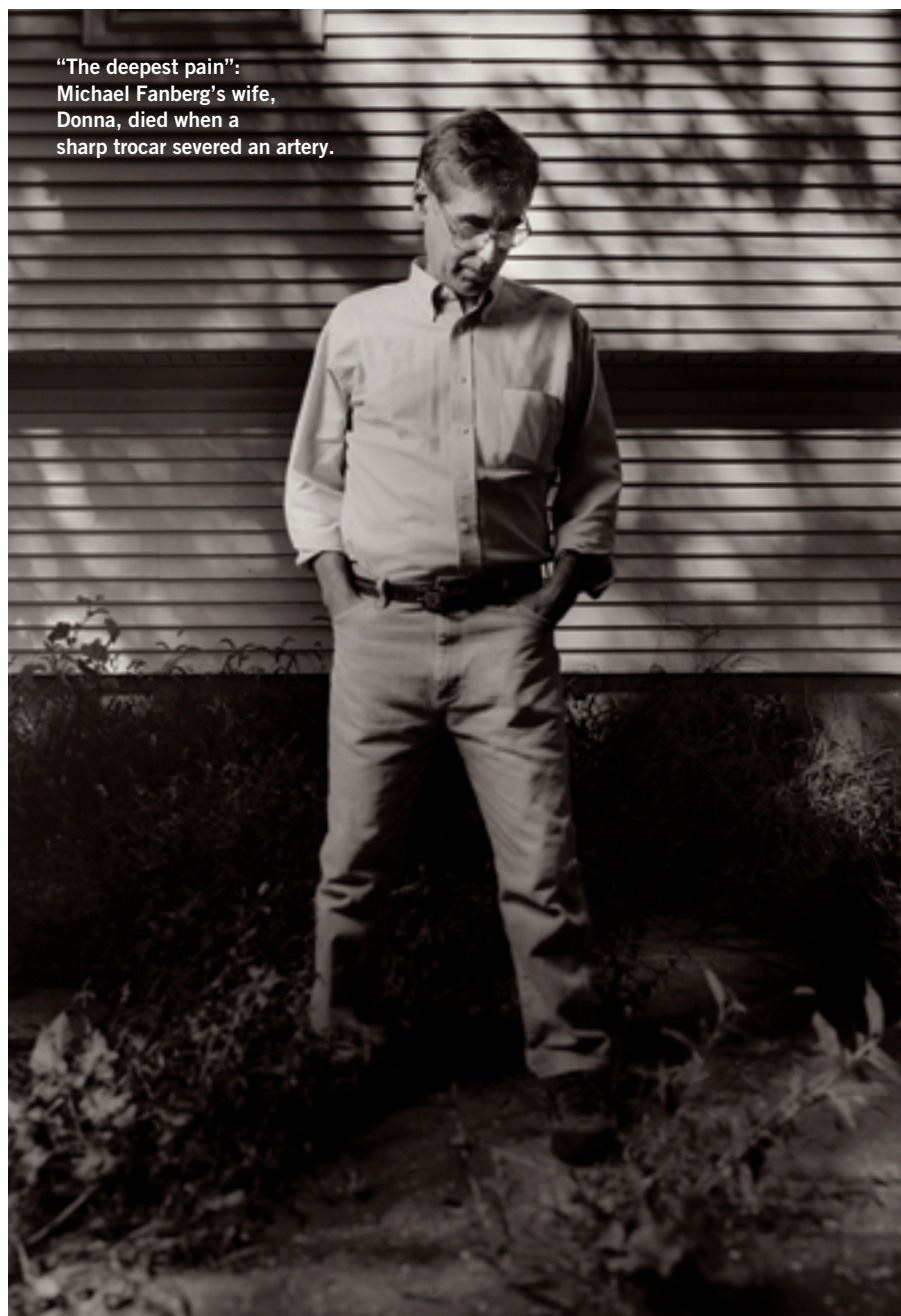
One force for change may be doctors' malpractice insurers. Tired of paying out claims, they have recently begun to study trocar injuries and educate their clients about the risks and alternatives. As in almost every other aspect of health care these days, however, patients are ultimately going to have to look out for themselves. If people facing laparoscopic surgery begin to ask more questions and demand better safeguards, doctors and hospitals might have to reevaluate their methods. At the very least, patients can protect themselves. So if you're disturbed by the image Margolis invokes—a surgeon saying a prayer, then blindly plunging a wickedly sharp instrument

into your body—you need to know more about the trouble with trocars.

**In a way**, you can blame it on the gall bladder. Up until the late 1980s, laparoscopy was practiced only by gynecologists, who mostly used it to take a closer look at women's reproductive organs. But then a Tennessee surgeon, Douglas Olsen, developed a technique for removing diseased gall bladders laparoscopically. Once general surgeons learned

that, they figured you could do almost any operation with it.

The tiny cameras acted as the surgeon's eyes beneath the skin, projecting real-time images on a video screen mounted above the patient. As he watched the screen, the doctor would cut, suture and fire lasers. Because the initial incisions were so small—they could be patched over by a Band-Aid—patients had less pain and scarring, and recovery times were often significantly shorter than in



**"The deepest pain":**  
Michael Fanberg's wife,  
Donna, died when a  
sharp trocar severed an artery.

conventional, more invasive surgery.

Laparoscopic cholecystectomies—“lap cholys” to the cognoscenti—suddenly became the rage. And doctors all over the country concocted new operations with dizzying speed. With patients clamoring for the new “Band-Aid” or “drive-by” surgeries, hospitals saw a way to blacken their bottom lines. And U.S. Surgical Corp. saw a big opportunity: Surgeons wanted a way to quickly punch holes in abdomens. So the Connecticut company adapted an older technology and created a slick new device—the disposable trocar—to do the job.

Typically, trocars are made of metal (some have plastic components) and vary in length from 6 to 8 inches and from one-quarter inch to a half inch in diameter. The trocar has essentially two parts, which look and act like “a nail inside a soda straw,” says Robert Schaefer, CEO of Apple Medical, a small trocar manufacturer in Marlboro, Mass. When a doc-

tor starts a laparoscopic operation, he typically injects carbon dioxide gas into the patient’s abdomen through a thin needle to create more space between the abdominal wall and the organs. Then he grabs and lifts the skin just below the navel with one hand and the trocar with the other. (Some doctors will make a very shallow incision using a scalpel first, a sort of “starter hole.”) Holding it in his clenched fist, he then pushes the device through the skin, fat and connective tissue, into the abdominal cavity. Once the trocar’s “nail” has been driven, the doctor withdraws it from the “straw” and inserts his instruments and camera through the now-hollow tube. The result, when no blood vessels or organs are cut, is quick, easy access to the abdomen.

U.S. Surgical’s device was a hit. “It blew up big,” recalls Tony Pergola, who sold the company’s first disposable model. “Demand was higher than production, which is a beautiful thing in medical sales.

People thought they were safe; everybody loved them.” Soon enough, Ethicon Endo-Surgery of Ohio, a Johnson & Johnson subsidiary, joined the fray, pumping out its own line of disposables. (Ethicon and U.S. Surgical still dominate the trocar market.)

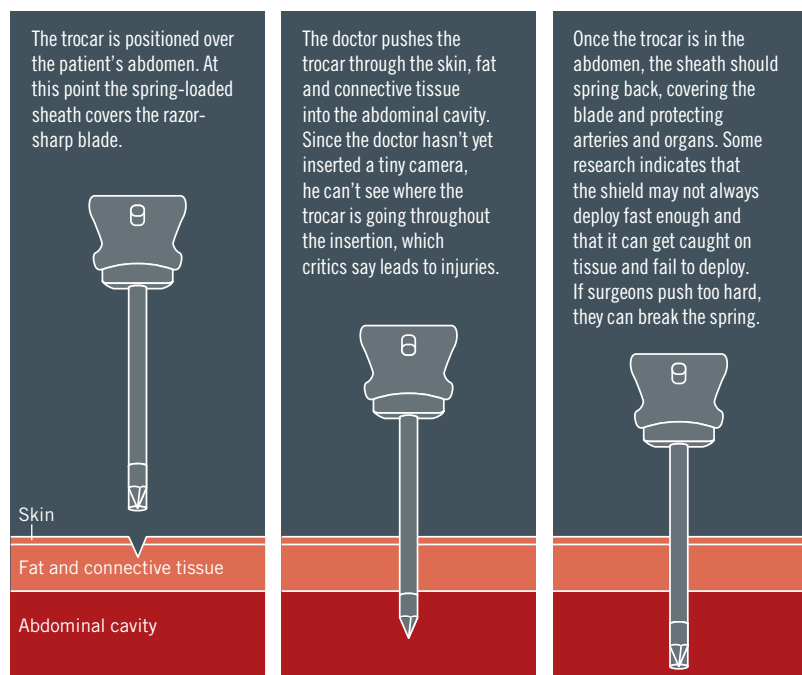
The manufacturers vied furiously for leading doctors to endorse their wares at laparoscopy seminars throughout the country. “You wanted a big doctor to endorse your trocar,” Pergola says. “It was like getting Michael Jordan to say your basketball shoes were better.” The trocar makers spared no expense trying to win doctors’ hearts and minds. “The companies would entice you by buying your dinner, paying for your next trip to a meeting in Paris,” says Isolde Semm, an OB/GYN who lives in Arizona. “And people liked it.”

Since laparoscopy was not then widely taught in medical schools, doctors learned how to use the new equipment at workshops, often sponsored by the in-

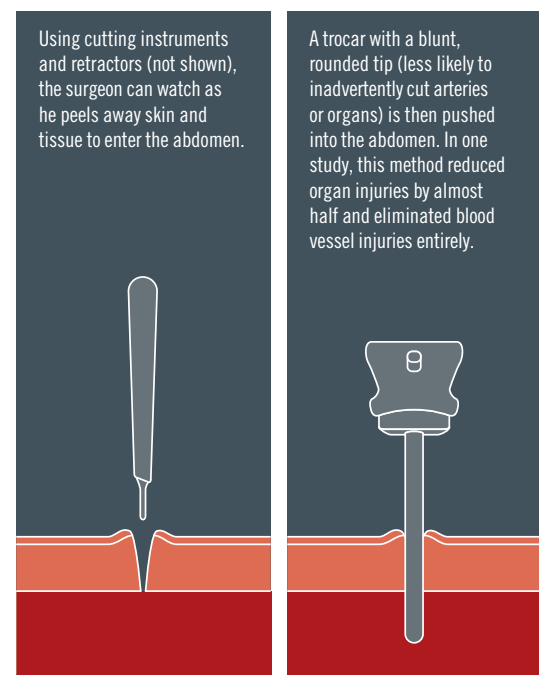
## Point of Contention: Two Trocar Techniques

**THOUGH SOME PHYSICIANS** and clinical studies have raised serious questions about the safety of sharp trocars, 87 percent of surgeons still use them when performing laparoscopic surgeries (below, left). In the alternative laparoscopy method, which some in the medical community believe is safer (below, right), a blunt trocar is used to enter the belly. In both methods, carbon dioxide gas (not shown) is injected to inflate the abdomen.

### BLIND OR CLOSED TECHNIQUE [using sharp trocar]



### HASSON OR OPEN TECHNIQUE [using blunt trocar]



strument companies. In this feverish period, doctors would show up at a laparoscopy workshop with their \$3,000 fees in hand on a Friday, operate on pigs over the weekend, then cut into patients the following Monday.

Tennessee gynecologic surgeon James Daniell remembers running into a surgeon at one such weekend seminar who was carrying a handful of glossy brochures. The brochures advertised the surgeon's prowess in laparoscopic gall bladder removal. "I thought he was one of the teachers," says Daniell, who for a time was a paid consultant to trocar companies. "But

tients—and their bottom lines. "Trocar injuries are the kinds of cases many doctors tend to settle," says Tom Nolan, an OB/GYN at Charity Hospital in New Orleans. Why is that? "You don't ever want a jury to see that damn nail," Nolan explains. If they do see the scary-looking trocar, he believes, it can mean bad news for the insurance company.

Lori Bartholomew is the principal researcher for Physician Insurers Association of America, a group whose companies insure 60 percent of U.S. physicians. Last year she headed a study of claims arising from injuries related to laparo-

casional fatal and entirely avoidable."

In its statement, U.S. Surgical cited the Champault study and two others, saying they showed injury rates of 0.5 to three injuries per thousand, to support the company's contention that trocar injury rates are "reassuringly low." Ethicon did not respond to specific queries regarding numbers of injuries, but spokesman Marc Monseau said, "Trocars have been used safely and effectively in millions of procedures worldwide... We believe that all of our surgical devices are inherently safe when used properly."

Ironically, some critics of the sharp

## A New York health department study said that the blind entry of the trocar into the abdomen could mean 'a **MUCH HIGHER RISK** of severe, life-threatening injury.'

he was actually there to learn and had patients lined up for surgery as soon as he got back home. People don't know how little training these doctors had."

In 1993 Donna Fanberg checked into a small northern New Jersey hospital for a hysterectomy. But at the beginning of the laparoscopic operation, Donna's doctor accidentally sliced open a major artery in the lower abdomen with a trocar, according to her husband, Michael. As she lay in the recovery room, Donna's pulse dropped to near zero, and doctors raced to stop the internal hemorrhage. But they were too late, and Donna died three days before her 41st birthday.

"Donna's mother wanted to hire a hit man and have the doctor killed," says Michael, a truck driver for the U.S. Postal Service who eventually settled a lawsuit with the doctor. "I was like a walking zombie. It was the deepest emotional pain I ever felt. You don't realize how much you love somebody until they're gone."

As lawsuits like Fanberg's accumulate and doctors make cash settlements, physician malpractice insurers are becoming uncomfortably aware of the risk to pa-

scopic surgery. Her findings: "Trocars cause more injury than any other device in [laparoscopic] malpractice claims," Bartholomew says. More than 31 percent of all the claims studied cited trocar insertion as the prime cause of injury. That's 10 times the number of injuries caused by scissors or scalpels.

These insurance company findings are the most recent evidence against sharp trocars. But previous research had already set off danger signals. In New York state, for example, 158 laparoscopic "incidents" were reported to the state's department of health from 1990 to 1992, which led to a study of trocars. The health department didn't like what it saw. "Based upon our review," its 1992 report said, "the blind entry of the trocar... may subject the patient to a much higher risk of severe, life-threatening injury, without recognizable compensating benefits."

A major 1996 European study found that injuries to organs or blood vessels occurred at a rate of roughly one in 1,000 surgeries and that seven deaths occurred per 100,000 procedures. The French researchers, led by Dr. G. Champault, concluded that trocar injuries are "rare, oc-

trocar contend that calamities occur in part because Ethicon and U.S. Surgical tried to make their devices safer. In the late 1980s both companies added a "safety shield" to their devices. Once the trocar enters the abdominal cavity, this built-in spring-loaded sheath is supposed to lower, covering the blade before it hits anything it shouldn't. The safety trocar is now the most prevalent kind in use.

However, the 1996 French study, which looked at more than 100,000 laparoscopic surgeries, concluded that safety shields did not prevent serious accidents. Also in 1996, the FDA sent a letter directing device companies to stop advertising these trocars as "safe." Some companies took the word "safety" off their labels. But according to Tennessee surgeon Daniell and others, instrument salesmen still promote trocars as having a safety shield that will protect patients.

How can a safety trocar be unsafe? Igor Paul, an adjunct professor of mechanical engineering at MIT, is a consultant in malpractice and product liability cases. In experiments using flank steak and thick foam pads, Paul says, the shield can get caught on tissue, allowing the tip

to move forward unprotected. Paul also maintains that when surgeons push hard on the trocar to pierce tough tissue, they can break the spring that pops the shield into place. “The manufacturers say [on their labels], don’t push too hard,” Paul says. “But there’s no way of gauging how hard is too hard.” Compounding these problems, critics say, is the fact that safety-shielded trocars might actually lead to more accidents because they give doctors a false sense of security, encouraging them to use more force.

Franklin Chow, a Vail, Colo., OB/GYN, says a safety shield failed to deploy in a 1995 surgery, causing him to cut a major vein and artery in patient JoAnn Utzig. She died, and her family sued Chow. A jury found he was not negligent, but, Chow’s attorney Eric Pearson says, Chow’s name was sullied and his career ruined. He is suing U.S. Surgical for allegedly destroying his medical practice. “The shield makes a trocar more dangerous than it is without one,” Pearson says. (U.S. Surgical declined to comment on pending litigation. The company did say that “trocar malfunction is rarely involved in laparoscopic access-related injuries,” which, in its view, “primarily involve differences in patient anatomy” and surgeons’ training and expertise.)

**It was way** back in 1971 that Dr. Harrith Hasson of Chicago developed his method of entering the abdomen. Then he spent 10 years trying to convince doctors that the Hasson or “open” technique was safer. “I went all over the world doing workshops and speaking about it,” says Hasson, now chairman of the department of OB/GYN at Weiss Memorial Hospital. “I fought the whole hierarchy in gynecologic laparoscopy.”

Hasson uses a scalpel, scissors and retractors to carefully dissect each layer of tissue and enter the abdominal cavity. He then inserts a blunt-headed trocar. As gas is being pumped through the tube, the trocar’s head is withdrawn; the instruments can then be inserted. This method allows the doctor to follow more of what he’s doing visually—it’s less blind. It also requires less force, and the dull trocar tip is unlike-



**Open-minded:** Harrith Hasson’s “open” method and blunt trocar may be gaining momentum.

ly to cause collateral damage on entry.

But Hasson won few converts in his 10-year battle. The instrument companies who sold sharp trocars were more vocal and persuasive. Doctors who had learned laparoscopy with the sharp devices were reluctant to change. “I gave up on it,” Hasson says.

In 1997, years after Hasson had ended his crusade, a study comparing some 489,000 closed laparoscopies and 12,400 open procedures was conducted in the Netherlands. The Hasson method was shown to cut organ injuries almost in half, and no patient suffered a single blood vessel injury. The study concluded that the open method “is advocated in laparoscopic surgery because it is safer than

the closed method.” Surgeon and University of Mississippi clinical professor Randy Voyles also believes in the Hasson technique. His message to colleagues is straightforward: “I tell doctors, ‘Your mama told you not to put sharp things in your ear. Why put sharp things in a patient’s belly, when you can’t even see where they’re going?’”

If there’s even a chance that the sharp trocar is unsafe, why is it still the instrument of choice? And why doesn’t someone do something about it?

You might think that someone should be the FDA, which was given the authority by Congress in 1976 to scrutinize new medical devices. But the trocar didn’t have to be tested to win approval; early nondis-

posable models that were already on the market were grandfathered in. Later versions, including the safety-shielded trocar, were essentially rubber-stamped. In 1990, Congress directed the FDA to reevaluate already approved devices and to collect reports of injuries from instrument makers.

But that supervision is compromised, at best. As a chief medical officer in the FDA's Office of Device Evaluation from 1993 to 1996, Suzanne Parisian wasn't specifically involved in trocar issues. But she did have an insider's view of how instrument problems can fly under the FDA's radar. "It's mandatory for manufacturers to report to the FDA when... their product may have contributed to a patient's injury," Parisian explains. The companies get their reports from doctors and hospitals using their devices—who don't always call attention to their own mishaps. Then, Parisian says, it's up to the manufacturers to decide whether a particular injury is worth reporting. The

would be reluctant to rock the boat: Their little devices are big business. Neither U.S. Surgical nor Ethicon would provide sales figures, but according to medical market research firm IMS Health, 3,267,000 trocars were sold in the U.S. last year. IMS estimates total sales for sharp and blunt trocars (at \$50 to \$60 a pop) at around \$180 million a year. Bill Mavity, former CEO of InnerDyne, an instrument company bought by U.S. Surgical parent Tyco earlier this year, says trocars are a \$300 million to \$350 million industry. Others say that's still low.

As for doctors, many simply don't know that an alternative to blind entry exists. Money may also figure into their decisions to use the quick-slicing devices. Some doctors who don't use the Hasson method say the careful cutting takes them an additional five to 10 minutes per surgery. "Time in the operating room is money—money for the hospital," says D. Alan Johns, director of the gynecologic la-

occurring, and then how they might be able to minimize the risk." Then Olsen invokes the fear factor: "Next we talk about malpractice cases."

What can patients do to minimize their risk? Certainly, no one is suggesting that you avoid laparoscopy altogether. If you or a loved one is considering one of these procedures and you have concerns about trocars and the blind technique, Olsen recommends that you ask your doctors how they begin their surgeries. However, Olsen says he wouldn't ask a surgeon used to sharp trocars to change to the open method, because it takes practice to master. "Go around and talk to several surgeons, then choose one who routinely uses the open method," Olsen says. "Probably the same caution that prompted him to use that technique will guide him through the surgery."

Of course, many doctors still honestly believe in the sharp trocar's safety. And they can truthfully tell you that they've

Trocar injuries are **PROBABLY UNDERREPORTED**, admits the FDA. One reason: It's basically up to the instrument companies to decide what's worth reporting.

result, Parisian says, is that "probably about 3 to 8 percent of the injuries are reported." FDA spokeswoman Sharon Snider admits, "We know there is probably a lot of underreporting."

In Parisian's view, the agency needs to do more risk/benefit analysis of devices, including the trocar. "You have to figure out when you've got enough deaths to outweigh the benefits," she says. "Have we established that there's a benefit to using the sharp trocar? Indeed, there are safer ways to gain access [to the abdomen]. If there is no clear benefit, one death is too much."

Since sharp trocar manufacturers maintain their instruments are basically safe, there's no reason for them to make changes in their products. Critics point to another reason why these companies

paroscopy center at Harris Methodist Hospital in Fort Worth. "And we're partners with the hospital."

**Randy Voyles**, the Mississippi surgeon, says he's seeing a gradual increase in the use of the Hasson method. "The consensus is becoming that the open technique is better." If the medical community does move away from the blind method, it may be the insurance companies that do the pushing. State Volunteer Mutual Insurance, the major malpractice insurer in Tennessee, now offers a risk-reduction seminar to its doctors. Among other things, surgeons are taught about the open technique. "It's hard to teach an old dog new tricks," says Dr. Douglas Olsen, who helps lead these seminars. "We try to present the facts about injuries

used the blind technique for years without a problem. "To me, it would be a real shame if sharp trocars went away," says pioneering laparoscopist Harry Reich, who practices in Pennsylvania. "It would really hurt the operation. It would be much more time-consuming, and you'd have more scarring, making succeeding surgeries more difficult."

To Reich and doctors who share his views, Voyles has this answer: "For those who did 3,000 blind techniques and say it's better, I know that on number 3,001, you can get in trouble." **SM**

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LINDA CARROLL IS THE WOMEN'S HEALTH COLUMNIST FOR MSNBC.COM. ALFRED LUBRANO IS A REPORTER FOR THE PHILADELPHIA INQUIRER.

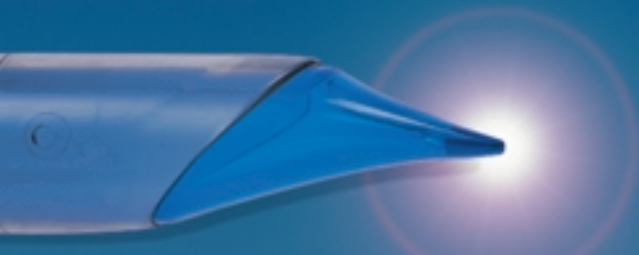
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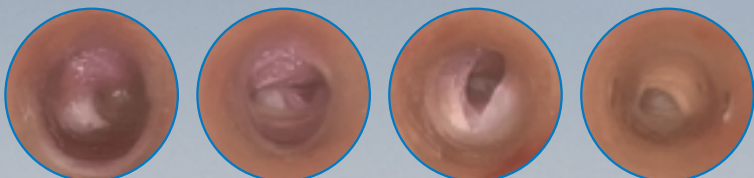
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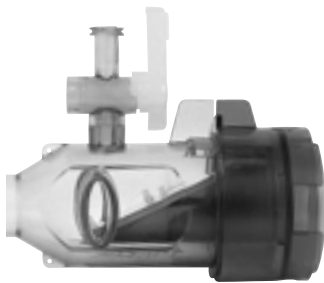
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