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The Bulletin

Forward thinking

Local physician's medical device may help recovery after surgery

By Markian Hawryluk / *The Bulletin*

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Trained as a heart surgeon, Dr. Edward Boyle of Inovia Vein Specialty Center in Bend knows the risk of fluid buildup around the heart and lungs. Such fluid can interfere with breathing or lead to serious complications, including a collapsed lung. It's why doctors insert chest tubes after heart surgery to let fluids drain out and to monitor for continued bleeding.

“They have a reputation for being very painful, and what I learned over the years is they don't work that great,” Boyle said. “They tend to get a goo clogged in them that causes them not to function.”

And when they do get clogged, the fluid doesn't drain properly and patients go home with a high risk of complications. According to a recent study, about 60 percent of patients are discharged after heart surgery with fluid around their hearts and lungs.

Because of the risk of clogging, doctors tend to use larger diameter chest tubes, and patients wake up after surgery with garden hose-size tubes sticking out of the sides of their chests. Meanwhile, nurses are charged with keeping the tubes flowing. They tug on them, tap them, bend and squeeze them to break up the clogs, none of which is comfortable for the patient.

“I started thinking of ways we could develop a tube that would perform that function better,” Boyle said. In 2003, he came up with a simple solution to the problem: a chest tube with a wire loop inside that can be used to dislodge clogs as they form. With a lower risk of clogging, the tube could be much smaller — the width of a drinking straw — and more comfortable for the patient.

Six years later, Boyle's idea for a better medical mousetrap is about to become a reality. The device will be tested during actual surgeries for the first time early next year.

It's a classic example of how innovation in medicine occurs. Unlike with pharmaceutical drugs, which are typically developed by large companies with billion-dollar research and development budgets, a large percentage of medical devices are invented by practicing doctors like Boyle, who see a need and figure out a way to meet it.

Increasingly, medical devices are coming to market only after

Andy Tullis / The Bulletin

Dr. Edward Boyle, a physician at Inovia Vein Specialty Center in Bend, invented a device that helps clear chest tubes after heart surgery. “I started thinking of ways we could develop a tube that would perform that function better,” Boyle said.

physician entrepreneurs form small startup companies to bring a device from idea through development, testing and regulatory approval. And if they succeed, they'll likely end up selling the rights to the product to a large device company that will manufacturer and market it to hospitals and physicians.

The device has the potential to drastically improve medical care for patients, and Boyle said a number of surgeons who have learned about the system are already asking when they can get it.

In October, Boyle learned the device had won the prestigious Techno-College Innovation Award from the European Association of Cardio-Thoracic Surgery.

Using a small startup company for device development, as Boyle has done, in many ways shields doctor-inventors from the potential conflicts that can come along with funding from large device manufacturers (see “The ethics question: Do corporate ties raise conflict of interest issues?”).

But that shifts the financial burden onto the physicians, their partners and investors. And few devices make it into hospitals and offices without the sales and marketing staff of these large companies.

“We all have to recognize that new innovations, in medical devices especially, have always come through at some point clinical doctors and interaction with industry,” Boyle said. “That's something we all benefit from — society, patients, everyone.”

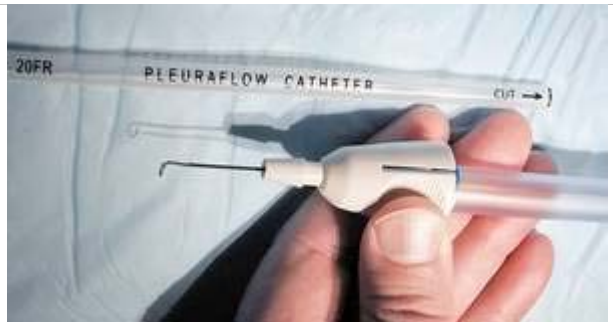
A recent analysis by researchers at the Fuqua School of Business at Duke University showed just how important physicians are to the innovation process. They found that one in five medical device patents are held by physicians and that devices invented by physicians were more likely to represent significant advances and to be much more profitable than those invented by non-physicians.

“The physician is often the only one who knows what might be needed,” said Matt Hoskins, a medical device engineer in Bend. “It's just hard for an engineer, a businessman, a marketing person, to get that kind of insight into the needs out there.”

Even when medical devices are invented by non-clinicians, it often takes a physician to understand whether the product will work in a medical setting and to evaluate its effectiveness.

“Our country would not like the products that would come out if you had engineers in a vacuum designing medical products,” said Dr. Knute Buehler, an orthopedic surgeon with The Center: Orthopedic & Neurosurgical Care & Research in Bend.

“It's something I've seen over and over again. I've been involved in redesigning products that have not had enough physician surgeon



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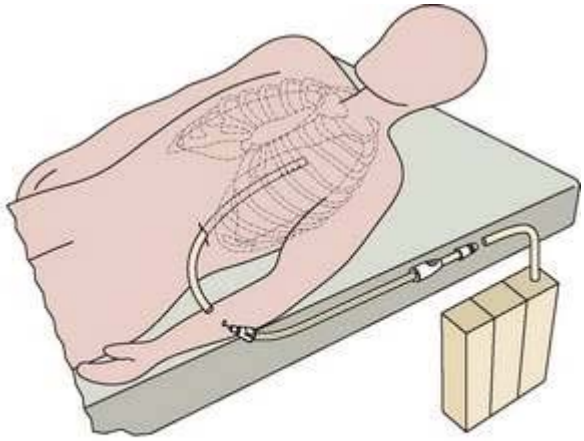
The PleuraFlow Active Tube Clearance System, invented by Bend surgeon Dr. Edward Boyle, uses a wire ring to clear clots in chest tubes after surgery. That allows doctors to use smaller diameter chest tubes which are more comfortable for patients.



Pleuraflow

When the chest tube is inserted, the Pleuraflow catheter tube is attached between the chest tube and the collection device.

input from the beginning. It's just too hard as a non-physician to really know the issues, and to try out the products and work out the bugs."

When doctors work on developing cutting-edge tools and techniques, patients also benefit. Such doctors must be much more in tune with the state of medicine in other places and develop relationships with other doctors involved in innovation. And patients often get access to devices sooner than they otherwise would, as doctors validate and test new technology.

"The type of stuff that Dr. Boyle does, it really enhances the reputation of the medical community," Buehler said. "If you're going to be a world-class medical institution, you can't just use scientific data, you have to generate new data, and that's really distinguishing a world-class place from just another medical community, Hopefully this will build and become a bigger and bigger emphasis here."

Device development experts say it takes hundreds of thousands of dollars to bring a promising device through the so-called "valley of death" between discovery and commercialization. Boyle and Dr. Marc Gillinov, a cardiac surgeon with the Cleveland Clinic, co-founded Clear Catheter Systems to develop and test the chest tube clearing device.

"What worries me is sometimes the overall economic environment can make that difficult," Boyle said. "There's a lot of uncertainty about the future, but we know that the country is going to need innovation and this is how it's going to get done."

The company received an early investment of $150,000 from the Bend Venture Conference in 2006 that helped fund the early steps of bringing the device to market. Boyle and Gillinov expect approval to market the device from Canadian regulators by the end of the year and have made arrangements to begin testing the device in surgeries at the Montreal Heart Institute early in 2010. They have also submitted their regulatory application to the FDA for clearance, a process that usually takes 90 to 180 days.

Such success is only adding fuel to Boyle's creative fire. He and his partner at Inovia, Dr. Andrew Jones, are working on a new device to treat spider veins, and they are serving as scientific advisers on some other new devices.

"I think it shows a commitment to the patients and the disease processes we treat," Boyle said. "You're constantly having to justify your ideas to other people, to companies that come and want to market it. You've got to be on top of your game to do it. You can check; I don't have a good golf game."

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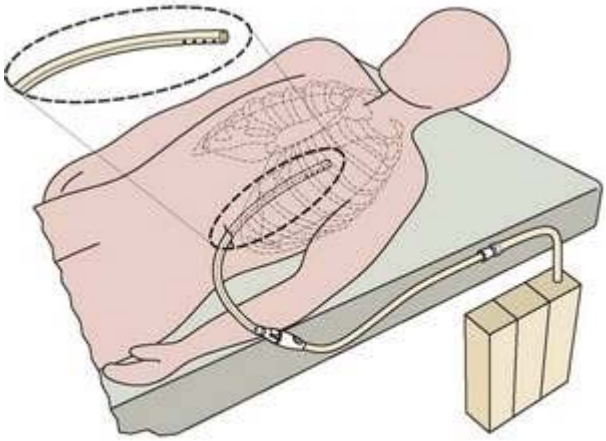
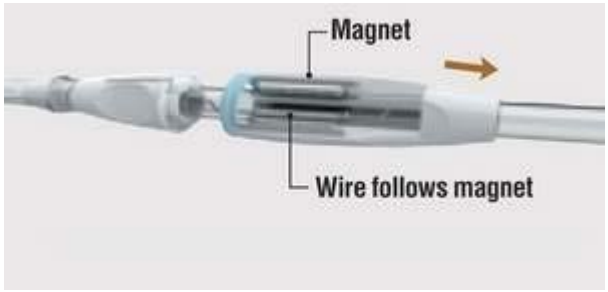


Pleuraflow

The Pleuraflow features a metal ring attached to a long wire that is pushed into the chest tube almost to the end. In order to keep the system closed to reduce the risk of infection, the wire is pushed and pulled through the chest tube using a magnet on the outside handle.



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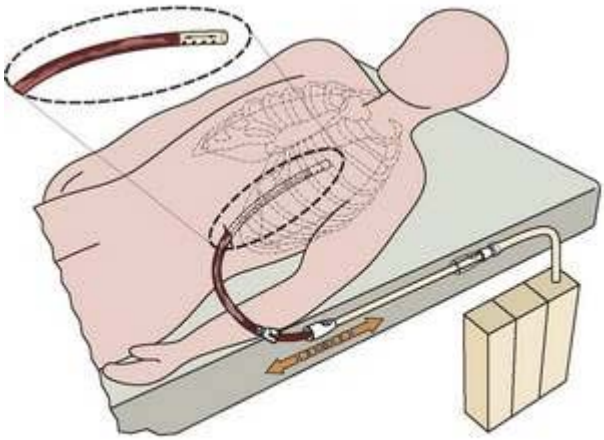
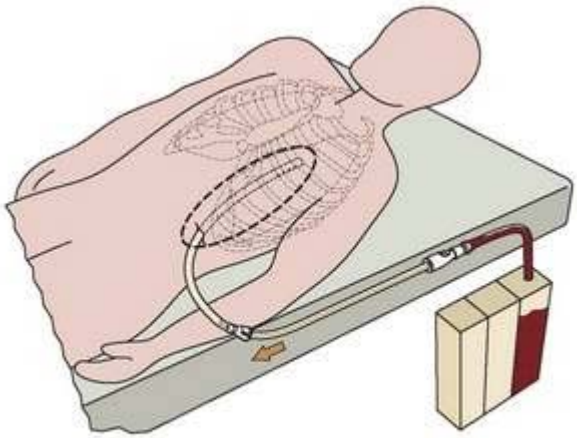


Pleuraflow

Once a clot begins to form, a nurse only needs to use the magnetic handle to pull the wire and metal ring, which pushes the clot material down toward the collection device.



Once the clot material is pushed into the collection device, the metal ring and wire can be pushed back into the chest tube, ready to remove future clots.

The problem

After open-heart and other invasive surgeries, temporary tubes inserted into the chest are used to drain excess fluid or air, which can lead to complications or even death if not properly drained.

Chest tubes are long, clear tubes that are connected to a closed drainage system that uses suction to remove

excess fluid and air.

Chest tubes often clog as the blood draining through them clots. These clots can interrupt drainage and cause complications. Traditionally, the only way to remove clots from chest tubes is to use methods that can be uncomfortable for patients. In addition, a clot in the internal section of the chest tube might go unnoticed.

The solution

The catheter system Dr. Edward Boyle developed aims to make removing clots from chest tubes easy and safe for patients. Here's how it works:

•**1:** When the chest tube is inserted, the Pleuraflow catheter tube is attached between the chest tube and the collection device.

•**2:** The Pleuraflow features a metal ring attached to a long wire that is pushed into the chest tube almost to the end. In order to keep the system closed to reduce the risk of infection, the wire is pushed and pulled through the chest tube using a magnet on the outside handle.

•**3:** Once a clot begins to form, a nurse only needs to use the magnetic handle to pull the wire and metal ring, which pushes the clot material down toward the collection device.

•**4:** Once the clot material is pushed into the collection device, the metal ring and wire can be pushed back into the chest tube, ready to remove future clots.

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