

# Innovation Through Collaboration:

## The Story Behind the Launch of the EchoTip ProCore®



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Before Cook Medical introduced the EchoTip ProCore® High Definition Ultrasound Biopsy Needle in 2011, histological samples in the GI tract were commonly acquired by other more invasive modalities. What the ProCore has given clinicians is the ability to retrieve high-value tissue samples from hard-to-reach regions within or adjacent to the GI tract, using the less-invasive EUS procedure.

“One of our main goals with the EchoTip ProCore was to increase tissue yield while decreasing the number of needle passes needed to reach a diagnosis,” says Kevin Chmura, Senior Product Manager for Cook’s EUS product line. “The idea was that increased yields could lead to shortened procedure times, which would be a benefit from both a clinical and economic viewpoint.”

When the needle was released, Dr. Sri Komanduri, Director of Interventional Endoscopy, Feinberg School of Medicine, Northwestern University, observed: “The design of the new EchoTip ProCore needle assists the physician in consistently obtaining histological samples through endoscopic ultrasound. In our early experience, the ProCore needle has improved our diagnostic yield over standard fine needle aspiration and has already impacted patient outcomes.”

“At the time of the ProCore’s launch at DDW 2011,” says Chmura, “we already had several abstracts that reflected the efficacy of this new EUS needle. Each year at DDW, the number of abstracts grows, including DDW 2014, where we had seven new ProCore-related abstracts presented. These studies are confirming positive procedural outcomes, including the

**“This was fun, helping a medical device transition from the early concept to the initial lab experiments to limited European trials to a worldwide launch.”**

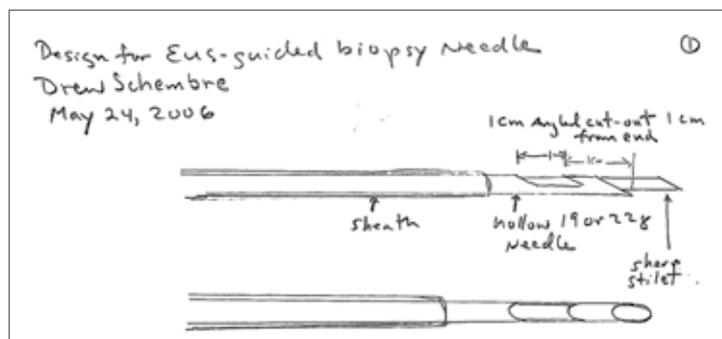
– Dr. Drew Schembre

potential for fewer needle passes for diagnosis and tissue acquisition, as well as the overall economic value that the ProCore can bring to clinicians and their healthcare facilities.”

### Creating Simple Solutions to Complex Problems

So, how does novel technology like the EchoTip ProCore come about? In a word: collaboration.

“Our company has always collaborated with clinicians to create simple solutions to complex problems,” says Barry Slowey, Global Business Unit Leader for Cook Medical’s Endoscopy division. “So when Dr. Drew Schembre approached us with a simple but inspired concept, we listened.



“His idea was to create a hollowed-out reverse bevel or notch in our existing EchoTip Ultra needle and use that device to obtain histology. We all saw this type of needle configuration had the potential to acquire larger amounts of tissue with preserved architecture.

“Our research and development engineers, clinical specialists, product managers, marketing teams and others worked together with Dr. Schembre for many hours, weeks and years, really, in meetings and bench top experimentation, redesigns, multiple prototypes and clinical trials. Together we solved one of EUS clinicians’ most pressing problems—obtaining adequate histology. That solution—the EchoTip ProCore—has become a true procedural game changer that benefits thousands of patients around the world.”

### Opening New Procedural Avenues

Dr. Schembre, Chief of Gastroenterology at Seattle’s Swedish Medical Center, felt comfortable from the beginning, bringing his idea to Cook. “Cook has always been a big supporter and innovator in the EUS space from the time that I did advanced training in EUS in the late 1990s,” says Schembre. “Even then, the people at Cook realized early on that EUS was important and could open up all sorts of procedural avenues.

“In the early years of EUS,” continues Schembre, “my colleagues and I gravitated toward the Cook needles because they worked well, were dependable and highly visible. But, at the same time, a lot of



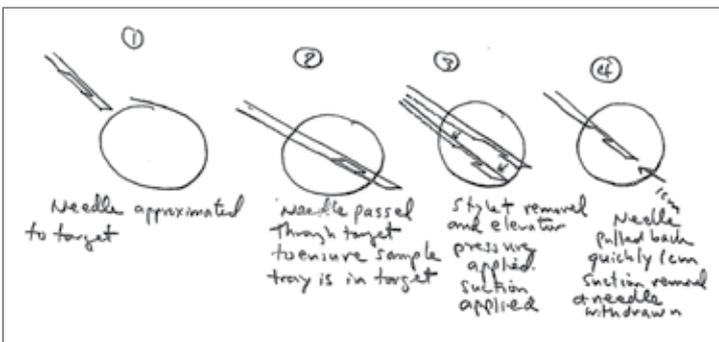
Dr. Schembre made his prototype from 2-inch PVC.

us around the country realized that it was sometimes hard to get an adequate sample, especially when working with a non-cytology pathologist. We were frequently doing many passes—four, five, sometimes six. This was getting very frustrating for us and for the pathologists who had to look at all those slides with scant specimens. So, we were always looking for better ways of collecting more tissue to get a more consistent, reliable diagnosis. Many people focused on the technique of FNA rather than the inherent limitations of the technology.”

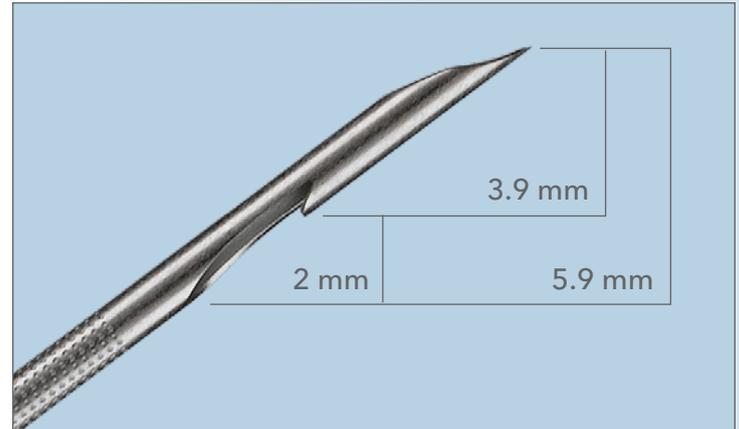
### An Assist from Regional Sales

“Then, at Digestive Disease Week 2007,” says Schembre, “I was speaking with my local Cook sales rep, Leslie Vitelli, about an idea. She said, ‘why don’t you talk to our guys here at Cook’s Endoscopy division booth and see if they can mock up something for you.’ I had heard from some of my mentors about how Cook was always very good at working with clinicians in a hands-on way: mocking up prototypes and allowing the clinician to work and experiment with them for a while.

“Leslie introduced me to Greg Skerven (Vice President, Physician and Institutional Relations) and Kevin Chmura there at the booth. I had a couple of fairly crude drawings depicting the reverse-bevel concept. This was loosely based on some vague recollections from residency of a pleural biopsy needle designed to collect shreds of pleura on the way out rather than on the way in.



“It seemed to make sense to apply modifications to an EUS needle that fundamentally would not change the procedure from what we were currently doing. I wondered if we removed part of the needle wall and added a cutting edge angled backward, that maybe we could collect more tissue with each pass. This would hopefully result in better cytological yield, faster procedures and ultimately faster and more consistent diagnoses.”



Final EchoTip ProCore design (22 gauge).

While it is a bit unusual for a sales representative to be involved with a physician developing a new product, Vitelli, then District Sales Manager for Cook Medical’s Endoscopy division, took full advantage of the opportunity. “It’s very cool being even a small part of that process with Dr. Schembre. I loved it. And I am so proud of how responsive the Cook team has been, working with Dr. Schembre and making the changes and adjustments necessary to create the best product possible.”

### Building the Prototypes

The EchoTip ProCore team’s next task was to produce device prototypes for an experimental animal lab. That’s when Cook Research and Development Technician Marcie Yount and her team began producing prototypes. Yount, who began her career at Cook in the production area, has been working with the Research and Development group since 2005.

“One big plus, for me, about working in R&D, is that I get to work hands-on with so many of our products. For the ProCore project, Kevin Chmura and [Engineering Team Leader] David Hardin brought me some rough sketches. We tried various notch sizes and configurations, various needle sizes. We eventually settled on the beveled notch concept. What was unique and interesting about this is, in endoscopic sampling, it’s predominately about pushing actions. With the ProCore, it was about getting tissue as the needle was retracted, not advanced.”

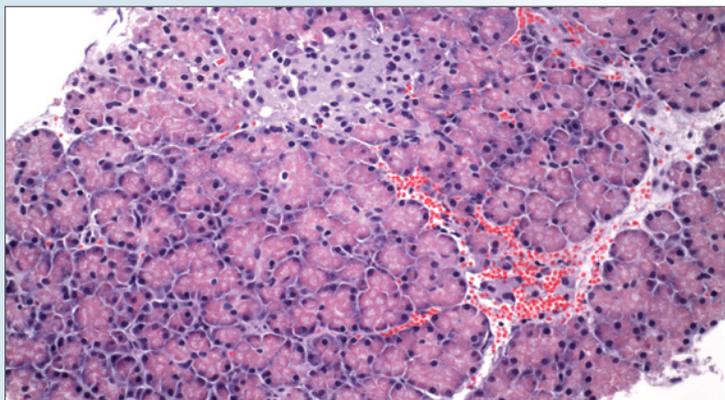
### The “Aha” Moment

With the prototypes in hand, Dr. Schembre put together a rudimentary home-improvement-and-grocery-store anatomy model for some basic testing. “I worked in my off hours with some PVC pipe from Home Depot and a bucket of water and some pieces of chicken and an old EUS scope. The idea was to see if the needle would extend properly and if, indeed, it was capable of taking bigger samples. Working first with sausage as a target, then uncooked chicken, it began to appear as though we were getting chunks of tissue rather than just smears, which was certainly encouraging.”

Then Schembre and Chmura organized an animal lab at the Dotter Institute in Portland, Oregon. “There, we tried various techniques and needle sizes in the pig pancreas and liver,” Schembre says. “We could see little pieces swirling around in the formalin but we didn’t have any idea how good the samples were till we got the slides to a pathologist at home. He was kind enough to fix them and make some slides ‘off the record.’ He made some slices and sent me some

*Continued on page 6*

photomicrographs. I still have a picture on my laptop: a beautiful chunk of normal pig pancreas with all the glandular architecture intact. My pathologist said, 'Here's a beautifully preserved islet of Langerhans!' It was almost perfectly preserved like a core biopsy. This was sort of the 'aha' moment, the proof of concept in this very limited pig model. It confirmed that this device concept did indeed work."



### Changing the EUS Conversation

"Once we realized it was a viable project," says Chmura, "we made several, refined prototypes that we transferred to the engineering team at Cook Ireland, who performed an engineering analysis of the needle for functionality and reproducibility. In the meantime, Simon Brouwers began communicating with key opinion leaders in Europe about the potential of this new design."

"When we got the project here," says Cook Ireland Senior Product Development Engineer Michael Clancy, "I collaborated closely with our team and with Senior Product Managers Simon Brouwers and Kevin Chmura. As with most new, novel devices, there were quite a few engineering obstacles that had to be overcome, which required a lot of intense analysis and testing. It was tough going for a while, but everyone involved had a lot of belief in ProCore and we overcame those obstacles and proceeded with a limited launch and the rest is history: a novel device that has totally changed the EUS conversation."

### Better Than the Existing Standard

"The next step was human trials in Europe," says Brouwers. "We obtained a CE mark and I created the so-called CORE group—five European hospitals where the first cases would be performed." The hospitals were in Rome, Milan, Rotterdam, Santiago de Compostella and Marseille and included some of Europe's most prominent physicians.

"During the European trials, Kevin Chmura and I were in constant contact on all aspects of the study," Brouwers says. "including making sure we were on the same page as regards Dr. Schembre's original ideas. For my European CORE group, however, we intentionally did not involve Dr. Schembre during that phase to avoid inventor bias of any kind. After experimenting with various techniques, an overall accuracy for diagnosis of malignancy (92.9%) was shown in results from a multicenter, pooled, cohort study.\* So, when it came to the US launch, ProCore shook up the world of EUS FNA and FNB, no doubt."

"When the new needle launched," says Schembre, "there was excitement because this was an area of EUS that really had not changed in 15 years. Everyone knew there was a need for something better but nobody was quite sure what that something new was going to be. So when ProCore came onto the scene, clinicians were hungry to try something new. There were a lot of trials and abstracts rolling out in the first couple of years. When the results were viewed side by side you got a good sense of the differences pretty quickly and that ProCore was almost always shown to be better than the existing standard."

### The Ultimate Goal of Innovation

The collaboration to develop the EchoTip ProCore is nothing new for Cook Medical and neither is the reason for collaborating in the first place: Creating better ways for clinicians to deliver the best possible care to their patients. Says Schembre, "I think it is now clear that the ProCore enhances the procedure. Certainly the hope is that if a patient is undergoing an EUS with tissue acquisition, when they're done, they will have a diagnosis. No one wants to have to repeat a procedure or worse, perform a percutaneous or open biopsy due to inadequate or non-confirmatory tissue. The additional benefit of ProCore is an overall shorter procedure time. That's good for the patient who doesn't want to be under sedation any longer than necessary."

The EchoTip ProCore benefits clinicians and pathologists, as well. "For the physician," continues Schembre, "it can mean that a procedure you've booked out at an hour or hour and a half can be completed in 30 or 45 minutes, which means more efficient scheduling, ultimately better revenue and less physician fatigue."

"Pathologists benefit as well," Schembre says. "What I'm seeing now in my practice is that I give them a couple of passes and their comment is often: 'Wow, that's a great sample. I see what I need to see. We have a diagnosis. You don't have to do any more passes.' They're much more certain of their diagnosis and there's less of that anxiety and stress that they may be making a mistake."

### Always Open to New Ideas

"The fun thing about working with Cook," says Schembre, "is their openness to these new ideas. They don't have the attitude that only their engineers can have all of the solutions. They welcome input from the clinician community who are using devices on a daily basis. They have always believed that the end users can have good insights into how to build a better mousetrap, or in this case, tissue-trap." ■

\*"Feasibility and yield of a new EUS histology needle: results from a multicenter, pooled, cohort study," Julio Iglesias-Garcia, MD, et. al., *Gastrointestinal Endoscopy*, Vol. 73, No. 6 : 2011, pgs. 1189-1196.