Designing the

Expect™ Slimline (SL) Handle

A novel approach to physician engagement yields new options for meeting their needs

In its very first year on the market, the Expect[™] Endoscopic Ultrasound Aspiration Needle commanded an impressive market share, and was widely praised for its superior needle penetration and ability to retain its sharpness and form through multiple passes.



But word came back from the marketing and field sales groups that not all customers had the same ergonomic and actuation preferences — and some were looking for a different shape or tactile feel to accommodate their individual techniques. That set Boston Scientific off on a unique journey to uncover and meet their customers' needs.

The company had a novel idea: Instead of only engaging the company's satisfied customers, what if they also reached out to physicians who preferred the competition? And what if they gave them a chance not only to suggest iterative changes, but to actually "blue sky" their idea of the perfect EUS Needle? "By engaging physicians who liked the original Expect needle, physicians who didn't, physicians who regularly use our devices and physicians who didn't, we hoped to get a variety of opinions and allow them to define their ideal EUS device," explained Kurt Geitz, vice president of research and development at Boston Scientific.

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— **Brandon Alexopolous** R&D Technical Team Lead

A FRESH APPROACH TO PHYSICIAN ENGAGEMENT

Boston Scientific reached out to a wide range of thought-leading physicians, from the needle's biggest fans to its toughest critics. "Working with marketing and sales, we engaged more than 50 physicians from the U.S., Europe, Japan and Latin America to better understand what they liked and didn't like about the current handle," explains Brandon Alexopolous, R&D technical team lead on the Expect Slimline Handle design project.

The team promised to meet with these physicians consistently over a short period of time. "We held regular interviews and developed multiple rounds of prototypes based on their feedback, which they then used in animal labs to simulate real life experience," Alexopolous says. "We worked with physicians in our R&D facility, in their hospitals, at conferences such as DDW and UEG, and at live courses held around the world."

Dr. David Robbins, associate chief of endoscopy, Lenox Hill Hospital, recalls being particularly impressed with the integrity of the process. "In the lab, we spent a lot of time trying to quantify things like resistance, tissue compliance and ergonomics," he says. "It was a really well-designed analysis, not a one-size-fits-all proposition."

What doctors are saying about the Expect™ Slimline Needle

Early Clinical Outcomes

With this new needle, because it's so sharp, you immediately go exactly where you want to go. And in small lesions, we found in the early experience, cases where I was pretty sure it was going to be very difficult to get a diagnosis, we actually got a diagnosis. ? ?

— Anand Sahai, M.D.

Ergonomic Comfort

66 Ergonomics have been sort of a lost art in endoscopy and this needle is a step forward. The Slimline has several positions that I can assume during the course of a fine needle aspiration that will reduce fatigue and probably yield better samples. This is probably the most comfortable needle I've used. **9**

— David Robbins, M.D.

Enhanced Tissue Feedback and Tactile Feel

66 There's an intimate connection between what you feel in the handle and what's happening at the tip. It translates into really amazing precision.

— Anand Sahai, M.D.

66 Tactile feel allows you to feel the hardness of or softness of a lesion, and gives you a clue as to what that lesion could possibly be. The ability of the Slimline Needle to give us that nice one-to-one motion and to allow that feel in the handle was a great improvement in the product.

— Adam Goodman, M.D.

Dr. Ann Chen, director of endoscopic ultrasound at Stanford University School of Medicine, was similarly impressed. "My experience working with Boston Scientific was unexpected in many ways," she says. "They brought all of my thoughts back to the drawing board and were very innovative with the design, every step of the way."

"The team from Boston Scientific really took the time to listen. You can feel they have a passion for what they're doing and, in the end, it produced amazing results," said Dr. Anand V. Sahai, professor of medicine and chief, Gl Division, Centre Hospitalier de l'Université de Montréal (CHUM).

PHYSICIAN INPUT YIELDS MEANINGFUL RESULTS

Feedback was consistent from region to region: Physicians wanted a handle that was easy to grip, with minimal resistance during FNA. Thanks to the accelerated customer engagement and development process, a final design incorporating these features was available to them in less than a year.

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— Dr. Ann Chen

Director of Endoscopic Ultrasound Stanford University School of Medicine

"Physician preference matters," said Bryan Bannon, senior product manager, Boston Scientific. "So much of GI endoscopy is about how a device feels in the physician's hands. We wanted the Slimline Handle to accommodate these ergonomic and tactile feel preferences so the Expect Needle could be an option for them when performing EUS FNA

The new Slimline Handle features a smaller handle profile and a low-friction gliding mechanism for a smoother actuation motion. The Control ZONE™ gives physicians two ergonomically defined areas



Dr. Ann Chen, director of endoscopic ultrasound at Stanford University School of Medicine

where their fingers can rest, to increase comfort and control as well as to accommodate different hand sizes and techniques. The new design also features lower profile locking knobs.

Physicians reported that the new handle design exceeded their expectations. "The improvement in the landing zone is significant," said Dr. Chen. "You can place your thumb either on the top or the bottom depending on your preference. The groove in the middle can also serve as a resistance point, which allows you to easily move the needle to and fro within the tissue with simple up-and-down motion of the thumb. Lastly, the gliding mechanism has been improved significantly to allow a smoother movement of the needle during biopsy."

Physicians also praised the Slimline Needle for enhancing tissue feedback. "I can get a sense of whether a lesion is solid or semi-soft or even cystic as I'm sampling," said Dr. Robbins. "That's an element that is unique to this needle."

Physicians predict great success for the Slimline Needle. "You put the device in your hand and it just feels like quality, from beginning to end," said Dr. Sahai. "I'm not an expert in marketing but I think that given the quality of the device, if you can just get it into physicians' hands, it will speak for itself."



Smooth Gliding Mechanism

Upring EUS FNA, it's very important to be able to move the needle to and fro very quickly within the target lesion to increase the areas being sampled so the gliding mechanism has to be almost frictionless. I can move the needle device back and forth very quickly with just my thumb and my index finger, without a lot of resistance. This will aid in FNA tremendously. ?

— Ann Chen, M.D.

66 I was really struck by how easy the to-and-fro motion of the needle was in a variety of positions, short or long, and across all different needle gauge sizes, between 19, 22 and 25. That's a real step forward.

— Raman Muthusamy, M.D.

Maintaining Shape and Sharpness

There's very little bend in the needle, even after multiple passes. Its ability to get into difficult-to-access parts of the pancreas where there's a lot of torque on the scope and stay true to its initial form will ultimately benefit our patients.

— David Robbins, M.D.

66 Because the needle is so sharp, you immediately go exactly where you want to go, and it maintains that sharpness. It works just as well the first time as the last time.

— Anand Sahai, M.D.

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Indications, Contraindications, Warnings and Instructions for Use can be found in the product labeling supplied with each device.

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