

Expect™ Slimline (SL)

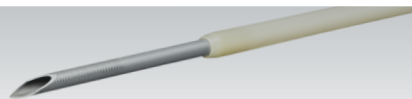
Endoscopic Ultrasound
Aspiration Needle

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Expect™ Slimline (SL)

Endoscopic Ultrasound (EUS) Aspiration Needle



The Expect Slimline (SL) Needle is an EUS-FNA needle that is indicated for four diagnostic and therapeutic indications, providing physicians with clinical options to manage their patients.

The Expect Slimline (SL) Needle is designed to sample targeted submucosal and extramural gastrointestinal lesions through the accessory channel of a curvilinear echoendoscope. It can also be used for the delivery of injectable materials (fluids) or fiducials into tissue or for passage of accessory devices.*

Device Selection	19 Ga Flexible	19 Ga Standard	22 Ga	25 Ga
Sampling of submucosal and extramural gastrointestinal lesions (fine needle aspiration)	x	x	x	x
Delivery of injectable materials (fluids)	x	x	x	
Delivery of fiducials (luer loading)**	x	x	x	
Delivery of fiducials (loading via needle tip)**	x	x	x	
Passage of accessory devices*	x			

Needle Size	Maximum Fiducial Outer Diameter (mm)	Maximum Fiducial Length (mm)
19 Ga Flexible and 19 Ga**	0.80	10
22 Ga**	0.46	10

19 Ga Flexible has demonstrated to be compatible for the delivery of the Mauna Kea Cellvizio AQ-Flex™ 19 Confocal Miniprobes™ accessory device.

**LumiCoil™ Platinum Fiducial Markers are only compatible with the Expect Slimline (SL) 22ga EUS Needle.

+ Device Indications for Use

Design Feature

Intended Benefit

- **Sharp needle grind**

For precise targeting and sampling²

- **Cobalt-Chromium construction***

Cobalt Chromium as compared to Stainless Steel provides distinct benefits in shape set, column strength, and tensile strength. These properties may provide certain advantages, particularly when sampling difficult target sites:³

- 1) Higher resistance to deformation which may aid physician control
- 2) Higher column strength for navigation to sample site
- 3) A harder material to retain sharpness for performance over multiple passes

- **Echogenic pattern extends onto needle tip^{4,5}**



- Provides precise guidance within the target site
- Helps maintain tip visibility

- **Stylet cap with integrated clip**

• Keeps stylet safely contained⁶



- **Custom sheath sizes**

• Designed to improve passability⁷



* Cobalt-Chromium is used for all Expect Slimline Needles except for the 19ga Flexible Needle which is made of Nitinol.

1 Catheter and Specialty Needle Alloys, an abstract from Materials & Processes for Medical Devices Conference & Exposition, Minneapolis, MN, August 10-12, 2009. *

** This study compared a cobalt-chromium alloy with nanoflex and 304 stainless steels.

2 Data on File: Document # 909795363 Needle and Stylet Sub-assembly

3 Footnote reference: Keehan E., Gergely L. 2009 Materials & Processes for Medical Devices Conference & Exposition, Minneapolis, August 10-12, 2009

4 Data on File: Document # 90334981 Design Requirements

5 Data on File: Document # 90449830 Echo Visibility Specification

6 Data on File: Expect Slimline IFU

7 Data on File: Document # 91795363 Needle and Stylet Sub-Assembly

Expect™ Slimline (SL) 19ga Flexible Needle

Understanding your need to obtain core material for advanced testing, we developed a 19ga needle made of Nitinol, the Expect Slimline 19ga Flexible Needle. Compared with the current Expect Slimline 19ga Cobalt-Chromium Needle, the Expect Slimline 19ga Flexible Nitinol Needle can offer flexibility and durability for increased utility in more tortuous applications and anatomies.²

The Nitinol Difference

- Nitinol is more resistant to needle deformation through tortuous anatomy compared to stainless steel^{1*}

Highly Functional Stylet Facilitates Easy Removal and Reinsertion^{3,4}

Same Highly Visible Echogenic Pattern^{5,6}

¹ Data on file

* Comparable size

² Data on File: Document # 97118043

³ Data on File: Document # 90438523, TM EUS FNA Simulated Use, BSC, AL3

⁴ Data on File: Document # 90334981 EUS-FNA and EUS-FNB Design Inputs: Design Requirements

⁵ Data on File: Document # 90438523 EUS Simulated Use

⁶ Data on File: Document # 90334981 EUS Design Inputs



Liver Biopsy Study

3. *Endoscopic Ultrasound-Guided Liver Biopsy (EUS-LB) with Expect 19ga and Expect 19ga Flex: A Multicenter Experience*; *Gastrointestinal Endoscopy*, Vol. 77, Issue 5, Supplement, Page AB375 (updated data from DDW 2013 abstract #Su1583). D. L. Diehl et al. Affiliations: Geisinger Medical Center, Winthrop Hospital, University of Alabama, Dartmouth-Hitchcock, Southern Illinois Medical Center, Yale University. **Results/Conclusion:**
- EUS-LB was successful in achieving a pathological diagnosis in 109 of 110 cases (99%).

Does Technique Matter?

4. *Randomized trial comparing fanning with standard technique for endoscopic ultrasound-guided fine needle aspiration of solid pancreatic mass lesions*. J. Y. Bang, S. H. Magee, J. Ramesh, J. Trevino, S. Varadarajulu. Affiliations: University of Alabama at Birmingham, Birmingham, Alabama (USA); Florida Hospital, Orlando, Florida, USA. *Endoscopy*, Vol. 45, June 2013.

Results/Conclusion:

54 Patients: Cytopathology was blinded to method used.

In this study, the fanning technique was superior to the standard technique with fewer passes required to establish a diagnosis.

Standard Technique = 26 Patients

Fanning Technique = 28 Patients

Diagnostic Accuracy = 76.9%

Diagnostic Accuracy = 96.4%

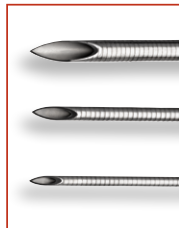
Note: Although both cohorts required a median of 1 pass to reach a diagnosis, there was a significant difference in the total number of passes required to establish the diagnosis between the standard and fanning cohorts (median 1 [IQR 1–3] vs. 1 [IQR 1–1]; $P=0.02$).

Expect™ Slimline (SL) Endoscopic Ultrasound Aspiration Needle

Ordering Information

Order Number	Needle Size	Minimum Working Channel	Sheath Diameter	Packaging (color coded)
M00555500	19ga (1.10mm)	2.8mm	1.83mm	Each
M00555510	22ga (0.72mm)	2.4mm	1.65mm	Each
M00555520	25ga (0.52mm)	2.4mm	1.52mm	Each
M00555530	19ga Flexible (1.14mm)	2.8mm	1.73mm	Each
M00555501	19ga (1.10mm)	2.8mm	1.83mm	Box 5
M00555511	22ga (0.72mm)	2.4mm	1.65mm	Box 5
M00555521	25ga (0.52mm)	2.4mm	1.52mm	Box 5
M00555531	19ga Flexible (1.14mm)	2.8mm	1.73mm	Box 5

- Packaging includes a 20cc syringe and one-way stopcock*
- Working length: 137.5cm to 141.5cm, adjustable*
- Needle length: 0cm to 8cm, adjustable*



* Data on File. Document # 90334981 EUS-FNA and EUS-FNB Design Inputs: Design Requirements



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Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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