

Supporting Clinical References

Histology / Using Larger Gauge Needles

1. *Multi-Center Randomized Trial Comparing the 19ga and 25ga Needles for EUS-Guided FNA of Solid Pancreatic Mass Lesions.* Affiliations: J. Y. Bang, S. H. Magee, J. Ramesh, J. M. Trevino, S. Varadarajulu; University of Alabama at Birmingham, Birmingham, Alabama, (USA); Florida Hospital, Orlando, Florida, (USA). DDW 2013 abstract #1022.

Results/Conclusion:

72 randomized patients:	36 patients (19G)	36 (25G)
On-site diagnostic sufficiency:	94.4 %	88.9%
Median FNA passes:	1	1
Histological core:	86%	33%
Technical failures:	0	2.8
Complications (%)	2.8	0

In this study, the 19G needle performed significantly better than the 25G needle for procuring core tissue in solid pancreatic mass lesions.

2. *EUS-Guided Core Biopsy with a Novel 19-Gauge Flexible Fine Needle Biopsy (FNB) Device: Multi-Center Experience.* M. Al-Haddad et al. Affiliation: Indiana University Medical Center, Indianapolis, Indiana (USA); Southern Illinois University School of Medicine, Springfield, Illinois (USA). DDW 2013 abstract #M01496.

Results/Conclusion:

The diagnostic yield of core biopsies using this 19ga EUS-FNB device was 90.9%, consistent with our earlier clinical experience.

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%).
- EUS guided liver biopsy is a newer approach for performing liver biopsy. It is efficient and provides diagnostic tissue adequate for histological evaluation.

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).

FNA vs FNB Study

5. *Randomized trial comparing the 22-gauge aspiration and 22-gauge biopsy needles for EUS-guided sampling of solid pancreatic mass lesions.* S. Varadarajulu, J.Y. Bang, J. Ramesh, J. Trevino, S.H. Magree. Affiliations: University of Alabama at Birmingham, Birmingham, Alabama (USA). GIE, Vol. 76, No. 2: 2012.

Results/Conclusion:

FNA and FNB needles are comparable in terms of diagnostic sufficiency, technical performance and safety profiles with no significant difference in yield or quality of the histologic core.

Expect™

Endoscopic Ultrasound Aspiration Needles

Ordering Information

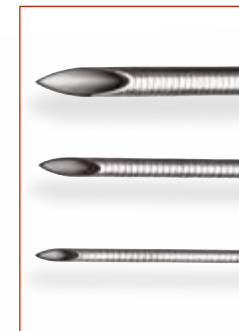
Slimline (SL) Handle Needles:

Order Number	Needle Size	Minimum Working Channel	Sheath Diameter	Packaging (color coded)
M00555500	19ga (1.10mm)	2.8mm	1.83mm	Box 1
M00555501	19ga (1.10mm)	2.8mm	1.83mm	Box 5
M00555530	19ga Flex (1.14mm)	2.8mm	1.73mm	Box 1
M00555531	19ga Flex (1.14mm)	2.8mm	1.73mm	Box 5
M00555510	22ga (0.72mm)	2.4mm	1.65mm	Box 1
M00555511	22ga (0.72mm)	2.4mm	1.65mm	Box 5
M00555520	25ga (0.52mm)	2.4mm	1.52mm	Box 1
M00555521	25ga (0.52mm)	2.4mm	1.52mm	Box 5

Standard Handle Needles:

Order Number	Needle Size	Minimum Working Channel	Sheath Diameter	Packaging (color coded)
M00550000	19ga (1.10mm)	2.8mm	1.83mm	Box 1
M00550001	19ga (1.10mm)	2.8mm	1.83mm	Box 5
M00550040	19ga Flex (1.14mm)	2.8mm	1.73mm	Box 1
M00550041	19ga Flex (1.14mm)	2.8mm	1.73mm	Box 5
M00550010	22ga (0.72mm)	2.4mm	1.65mm	Box 1
M00550011	22ga (0.72mm)	2.4mm	1.65mm	Box 5
M00550020	25ga (0.52mm)	2.4mm	1.52mm	Box 1
M00550021	25ga (0.52mm)	2.4mm	1.52mm	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



Boston Scientific
Advancing science for life™



Find more information on Boston Scientific products by using your smartphone to scan this code or visit the Boston Scientific website
www.bostonscientific.com/global-endoscopy

Boston Scientific International SA
Parc Val Saint Quentin - Bâtiment H
78960 Voisins-le-Bretonneux - France
+33 1 39 30 97 00

All cited trademarks are the property of their respective owners.
CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for the use only in countries with applicable health authority product registrations.
ENDO-203004 - AA Dec 2013. Printed in The Netherlands by DeBudeluse/Gosling.

© 2013 by Boston Scientific Corporation or its affiliates. All rights reserved.
DINEND2293EB

Expect™

Endoscopic Ultrasound Aspiration Needles

Boston Scientific



Your Patient. Your Needle. Your Preference.

Endoscopic Ultrasound Aspiration Needles

With applications for endoscopic ultrasound and fine needle aspiration continuing to expand, ergonomics and tactile feel have become as important as device performance. Because it's not just about the device – it's about how the device feels in your hands.

New Ergonomic Handle and Actuation Preference

Slimline (SL) Handle

- Control ZONE™
 - Two ergonomically defined areas designed to optimize control during actuation
 - Accommodates different hand sizes and techniques
- Smaller diameter handle
- Preference around tactile feel may help:
 - facilitate control when targeting lesions
 - reduce tension and friction during actuation
- Low-profile locking knobs

Control ZONE

Low-profile knobs

Design Feature

Intended Benefit

- **Sharp needle grind** For precise targeting and sampling
- **Cobalt-Chromium construction*** Provides benefits over some stainless steel alloys including greater needle hardness and excellent tensile properties to deliver:1**
 - Superior needle penetration¹
 - Improved pushability and kink resistance¹
 - Increased resistance to needle damage or deformation after multiple passes¹

Echogenic pattern extends onto needle tip



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

Stylet cap with integrated clip

- Keeps stylet safely contained



Custom sheath sizes

- Designed to improve passability



Two handle designs

- Accommodates user ergonomic and actuation preferences



Expect™ 19ga Flex Needle

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

The Nitinol Difference

- Nitinol construction provides flexibility, passability and actuation comparable to the 22ga Expect Needle¹
- Nitinol is more resistant to needle deformation through tortuous anatomy compared to stainless steel^{1*}

Custom Needle Grind for Improved Sampling

- Sharp grind and deep needle bevel help provide precise penetration into the target area and the potential for improved tissue sampling

Highly Functional Stylet Facilitates Easy Removal and Reinsertion

Same Highly Visible Echogenic Pattern

Available in Two Handle Designs

* Cobalt-Chromium is used for all Expect Needles except for the 19ga Flex 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.

¹ Data on file
 * Comparable size