

Supporting Clinical References

Histology/Using Larger Gauge Needles

1. 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 #MO1496.

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

2. Endoscopic Ultrasound-Guided Liver Biopsy (EUS-LB) with Expect 19ga and Expect 19ga Flex: A Multicenter Experience; Endoscopy International Open. 2015;3(3):E210-E21.

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 108 of 110 cases (98%).
- 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?

3. 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).

Ordering Information

Acquire™

Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device

Order Number	Description	Needle Size	Minimum Working Channel	Sheath Diameter	Packaging (color coded)
M00555540	22Ga Acquire FNB Needle	22Ga (0.72mm)	2.4mm	1.65mm	Box 1
M00555541	22Ga Acquire FNB Needle	22Ga (0.72mm)	2.4mm	1.65mm	Box 5
M00555560	25Ga Acquire FNB Needle	25Ga (0.52mm)	2.4mm	1.52mm	Box 1
M00555561	25Ga Acquire FNB Needle	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

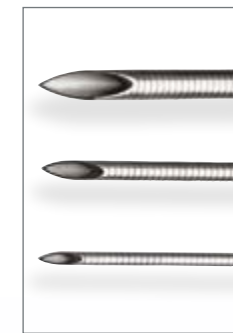


Expect™

Endoscopic Ultrasound Aspiration Needles

Order Number	Description	Needle Size	Minimum Working Channel	Sheath Diameter	Packaging (color coded)
M00555500	Slimline (SL) Handle FNA Needle	19ga (1.10mm)	2.8mm	1.83mm	Box 1
M00555501	Slimline (SL) Handle FNA Needle	19ga (1.10mm)	2.8mm	1.83mm	Box 5
M00555530	Slimline (SL) Handle FNA Needle	19ga Flex (1.14mm)	2.8mm	1.73mm	Box 1
M00555531	Slimline (SL) Handle FNA Needle	19ga Flex (1.14mm)	2.8mm	1.73mm	Box 5
M00555510	Slimline (SL) Handle FNA Needle	22ga (0.72mm)	2.4mm	1.65mm	Box 1
M00555511	Slimline (SL) Handle FNA Needle	22ga (0.72mm)	2.4mm	1.65mm	Box 5
M00555520	Slimline (SL) Handle FNA Needle	25ga (0.52mm)	2.4mm	1.52mm	Box 1
M00555521	Slimline (SL) Handle FNA Needle	25ga (0.52mm)	2.4mm	1.52mm	Box 5
M00550000	Standard Handle FNA Needle	19ga (1.10mm)	2.8mm	1.83mm	Box 1
M00550001	Standard Handle FNA Needle	19ga (1.10mm)	2.8mm	1.83mm	Box 5
M00550040	Standard Handle FNA Needle	19ga Flex (1.14mm)	2.8mm	1.73mm	Box 1
M00550041	Standard Handle FNA Needle	19ga Flex (1.14mm)	2.8mm	1.73mm	Box 5
M00550010	Standard Handle FNA Needle	22ga (0.72mm)	2.4mm	1.65mm	Box 1
M00550011	Standard Handle FNA Needle	22ga (0.72mm)	2.4mm	1.65mm	Box 5
M00550020	Standard Handle FNA Needle	25ga (0.52mm)	2.4mm	1.52mm	Box 1
M00550021	Standard Handle FNA Needle	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

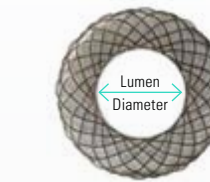


Hot AXIOS™

Stent and Electrocautery Enhanced Delivery System

Order Number	Lumen Diameter (mm)	Saddle Length (mm)	Flange Diameter (mm)	Catheter Outer Diameter (Fr)	Catheter Working Length (cm)	Catheter Total Length (cm)
M00553520	6	8	14	9	138	146
M00553530	8	8	17	9	138	146
M00553540	10	10	21	10.8	138	146
M00553550	15	10	24	10.8	138	146

• Compatible with Therapeutic EUS scopes with working channel 3.7mm or more



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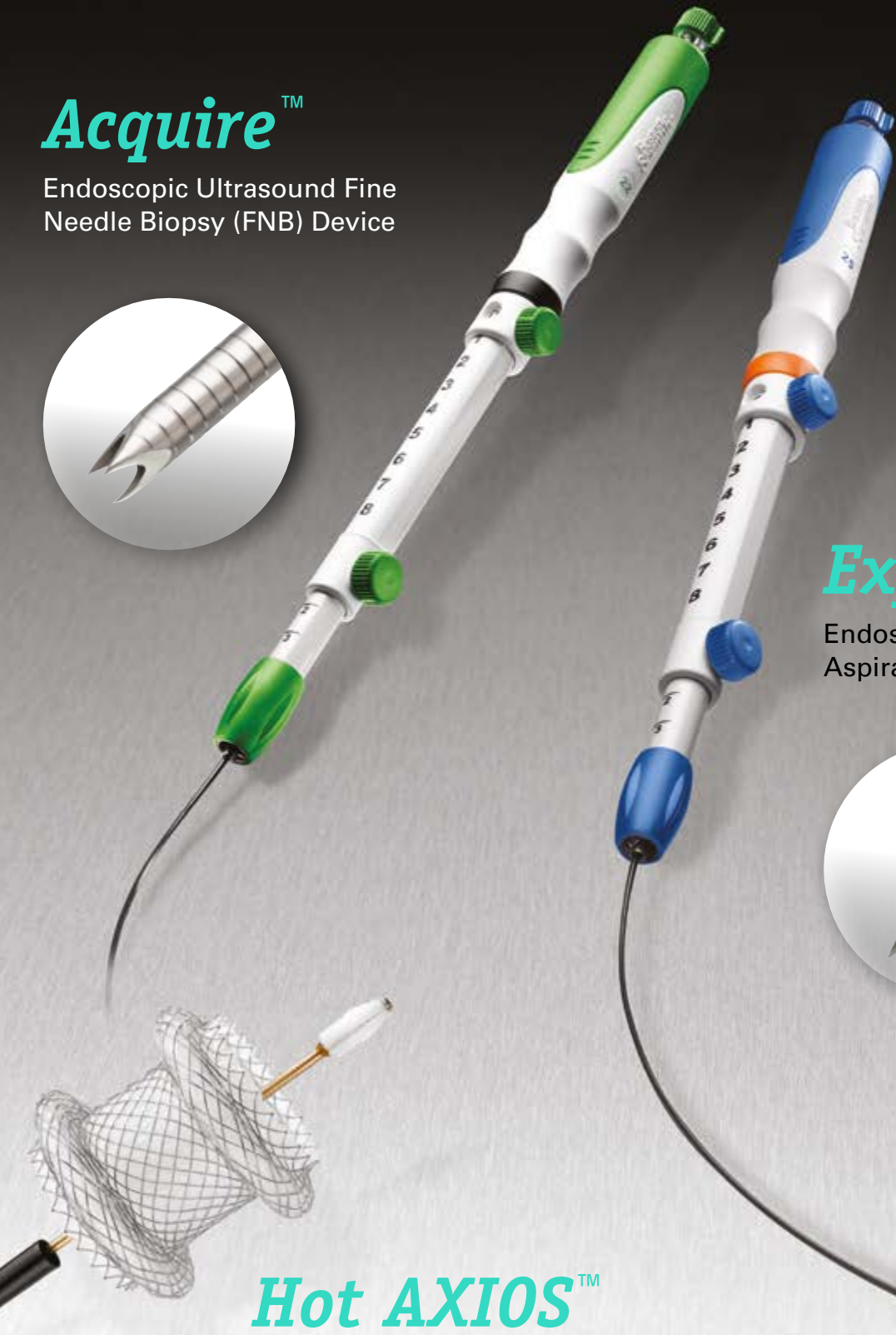
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Diagnostic and Therapeutic EUS Solutions

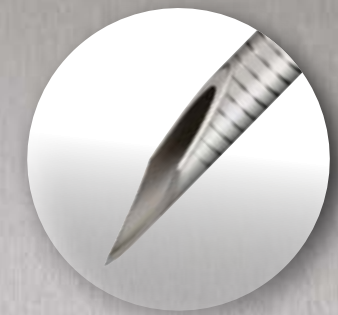
Acquire™

Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device



Expect™

Endoscopic Ultrasound Aspiration Needles



Hot AXIOS™

Stent and Electrocautery Enhanced Delivery System

Acquire™

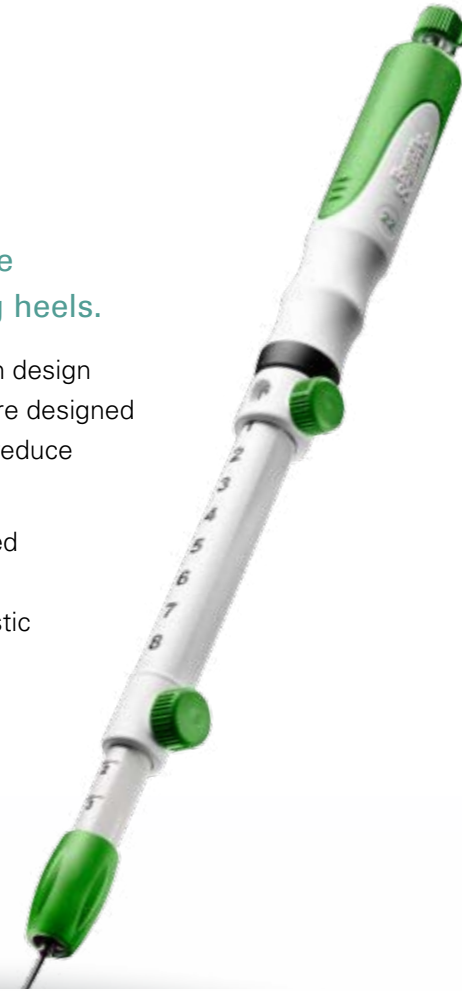
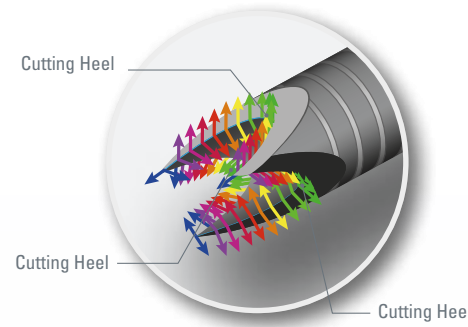
Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device



The Acquire FNB Needle has three symmetrical, fully formed, cutting heels.

Based on the Franseen needle tip, a proven design for tissue biopsy, the three angled points are designed to help promote stability in the tissue and reduce the likelihood of passability issues.

High quality, fully formed heels are designed to maximize tissue capture and minimize fragmentation, which may improve diagnostic yield and specimen adequacy to support oncology research.



Expect™

Endoscopic Ultrasound Aspiration Needles



Expect™ and Expect Slimline (SL) EUS-FNA Needles provide choices designed to accommodate your preferences for:

- Handle size and shape
- Actuation/tactile feel
- Flexibility** and durability*** of the needle* 1, 2

19ga Flex Needle for flexibility

The Nitinol Difference

- Provides flexibility, passability and actuation comparable to the 22ga Expect Needle²



Your patient. Your needle. Your preference.

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

Slimline Handle

- Smaller diameter handle
- Preference around tactile feel may help to:
 - facilitate control when targeting lesions
 - reduce tension and friction during actuation
- Low-profile locking knobs

Control ZONE™

- Two ergonomically defined areas designed to optimize control during actuation
- Accommodates different hand sizes and techniques

Echogenic pattern extends onto needle tip

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



Hot AXIOS™

Stent and Electrocautery Enhanced Delivery System

The first stent CE Marked for endoscopy ultrasound guided transluminal therapy

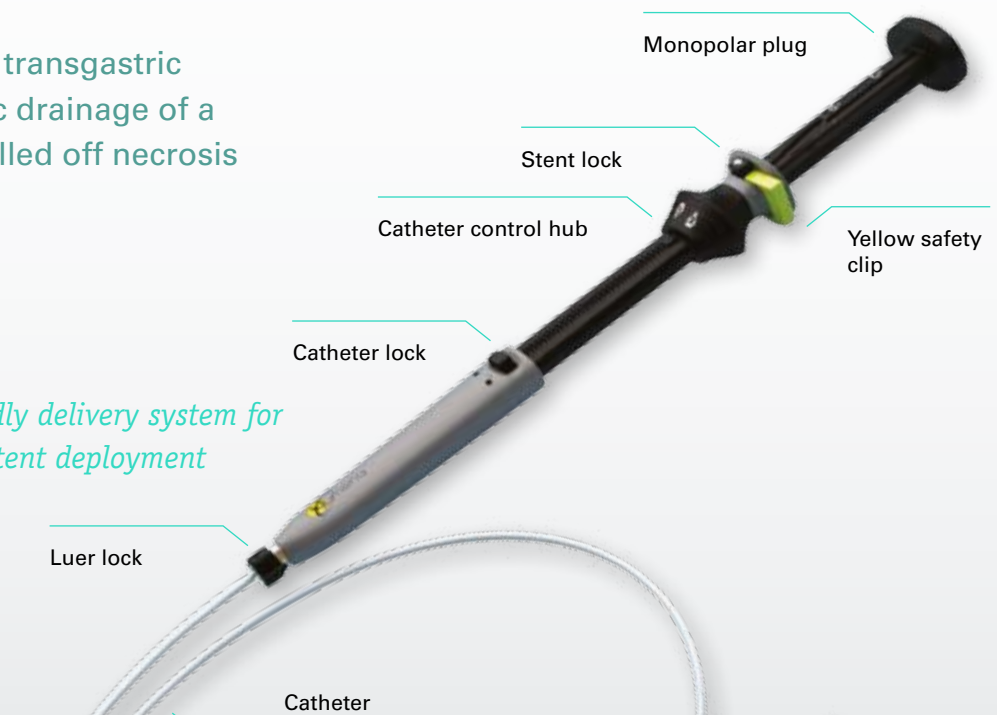


Cautery-enabled access and delivery catheter with the preloaded therapeutic AXIOS Stent for an exchange-free procedure

- Proprietary one-step combined diathermic ring and cut-wire provides easy access into target tissue
- Perpendicular flanges secure tissue layers and help to prevent migration
- Stent creates anastomotic conduit between two lumens
- Large diameter fully covered lumen apposition stent enables rapid, effective drainage and passage of the endoscope for additional therapeutic procedures

Indicated for use to facilitate transgastric or transduodenal endoscopic drainage of a pancreatic pseudocyst or walled off necrosis (>= 70% fluid content)

Intuitive user-friendly delivery system for easy and efficient stent deployment



* Cobalt-Chromium is used for all Expect Needles except for the 19ga Flex Needle which is made of Nitinol.
 ** When comparing between Nitinol and stainless steel it is supported by citation #1 and 2
 *** When comparing between Cobalt - Chromium and stainless steel it is supported by citation #1.
 1. Catheter and Specialty Needle Alloys, an abstract from Materials & Processes for Medical Devices Conference & Exposition, Minneapolis, MN, August 10-12, 2009.
 2. Data on file: EUS FNA 19 Flex Needle Material Source Document, Gaudet, C., No. Document 90525207, EUS FNA 19 Flex E0403