

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 #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

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.

Pancreatic Fluid Collections Drainage

6. **EUS-guided drainage of pancreatic fluid collections using a novel lumen-apposing metal stent on an electrocautery-enhanced delivery system: a large retrospective study, GIE 2015; 1-8.**
13 centres (Emanuele Rinninella, Rastislav Kunda, Markus Dollhopf, Andres Sanchez-Yague, Uwe Will, Ilaria Tarantino, Joan Gornals Soler, Sebastian Ullrich, Alexander Meining, Josè Miguel Esteban, Thomas Enz, Geoffroy Vanbiervliet, Frank Vleggaar, Fabia Attili, Alberto Larghi)
Results/Conclusion:
Ninety-three patients with PFCs (80% with complex collections) underwent drainage using the study device. Penetration of the PFC was accomplished directly with the study device in 74.2% of patients, and successful stent placement was accomplished in all but 1 patient, mostly without fluoroscopic assistance. Direct endoscopic necrosectomy (DEN) was carried out in 31 of 52 cases (59.6%) of walled-off necrosis and in 2 of 4 cases (50%) of acute peripancreatic fluid collection. Complete resolution of the PFC was obtained in 86 cases (92.5%), with no recurrence during follow-up. EUS-guided drainage with the electrocautery-enhanced delivery system is a safe, easy to perform, and a highly effective minimally invasive treatment modality for PFCs.

Reduction in Procedure Time

7. **Use of a single-step lumen-apposing covered metal stent delivery system can decrease the cost of pancreatic cyst drainage.**
Andres Sanchez-Yague, Angel Gonzalez Canoniga, Cristina Lopez Muñoz, Andres Sanchez Cantos, Roy M. Soetikno. DDW 2015 Abstract #2163949.
Results/Conclusion:
A single-step LA-CMS (lumen-apposing covered metal stent) placement procedure significantly decreases initial procedure time and facilitates necrosectomy sessions. The cost of LA-CMS is offset by the cost of additional accessories used for necrosectomy sessions in the classic strategy. Placement of a LA-CMS using a single-step procedure should be considered if necrosectomy is anticipated.

Ordering Information

Expect™

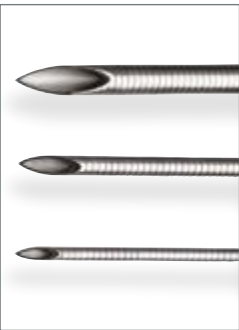
Endoscopic Ultrasound Aspiration Needles

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

Hot AXIOS™ and AXIOS™ Stents and Delivery Systems

Hot AXIOS™

Stent and Electrocautery Enhanced Delivery System

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

AXIOS™

Stent and Delivery System

Order Number	Flange Diameter (mm)	Lumen Diameter (mm)	Saddle Length (mm)	Catheter Outer Diameter (Fr)	Catheter Working Length (cm)	Catheter Total Length (cm)
M00553440	21	10	10	10.8	138	146
M00553450	24	15	10	10.8	138	146

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



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Advancing science for life™

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CAUTION: 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.
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DINEND2350EA

Diagnostic and Therapeutic EUS Solutions

Expect™

Endoscopic Ultrasound Aspiration Needles



Hot AXIOS™

Stent and Electrocautery Enhanced Delivery System

Diagnostic Solutions

Expect™

Endoscopic Ultrasound Aspiration Needles

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

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

Your patient. Your needle. Your preference.

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

Control ZONE

19ga Flex Needle for flexibility and durability

The Nitinol Difference

- Provides flexibility, passability and actuation comparable to the 22ga Expect Needle²
- More resistant to needle deformation through tortuous anatomy compared to stainless steel^{1*}

Therapeutic Solutions

Hot AXIOS™

Stent and Electrocautery Enhanced Delivery System

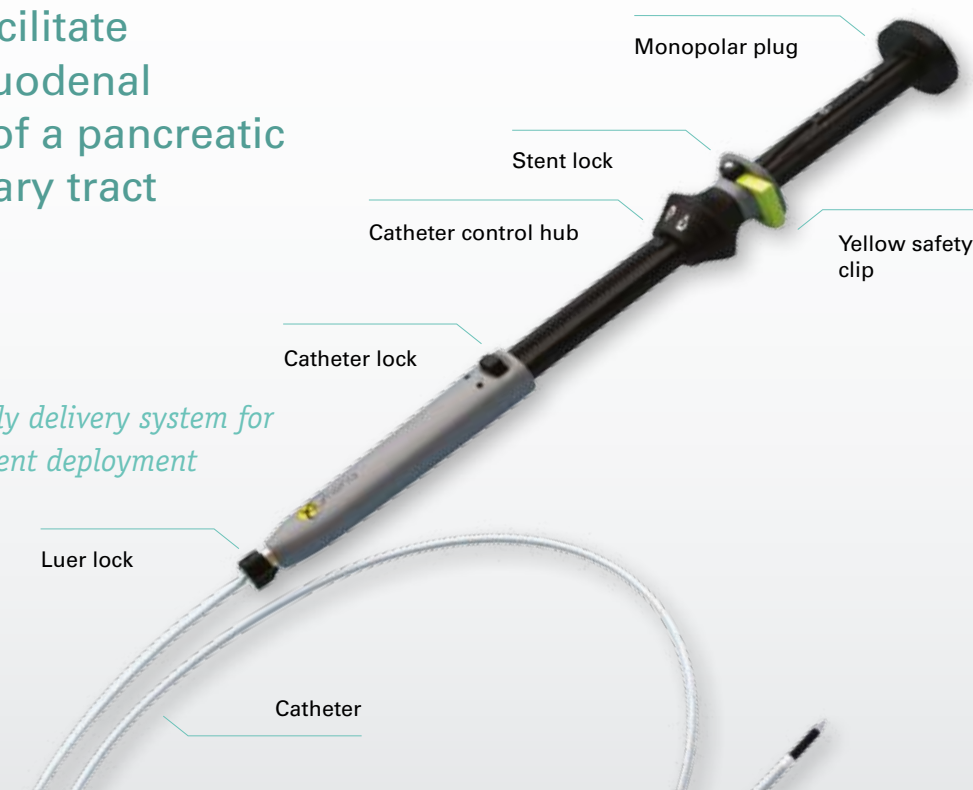
The world's first stent designed for endoscopic ultrasound guided transluminal therapy

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 the biliary tract

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.

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

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