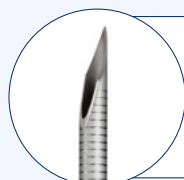




Endoscopic Ultrasound (EUS) Fine Needle Aspiration (FNA) and Fine Needle Biopsy (FNB) Devices

Boston Scientific's portfolio of EUS FNA and FNB devices continue to expand its diagnostic capabilities to meet evolving EUS technologies and a range of clinical needs.

The Portfolio

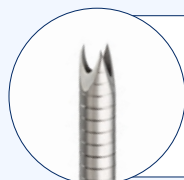


Expect™ Slimline EUS Needle

An EUS-FNA needle indicated for four diagnostic and therapeutic indications, providing physicians with clinical options.

Needle Sizes

19ga, 19ga Flex, 22ga, 25ga

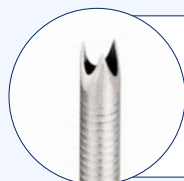


Acquire™ EUS FNB Device

End-cutting Franseen style needle tip.

Needle Sizes

22ga, 25ga

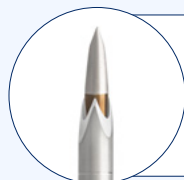


Acquire™ 19ga Flexible

An option for EUS-guided liver biopsy and the largest needle size in the Acquire needle family.

Needle Sizes

19ga



Acquire™ S EUS FNB Device

Designed for ease-of-puncture¹ and to maximize diagnostic yield without compromising the quality of core tissue samples to obtain an accurate diagnosis.²

Needle Sizes

22ga, 25ga

Clinical Significance

Expect™ Slimline EUS Needle

Can be used for the delivery of injectable materials (fluids) or fiducials into tissue for passage of accessory devices.

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

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



Acquire™ EUS FNB and Acquire 19 ga Flexible FNB Devices

The Acquire and Acquire 19ga Flexible Needle are designed with a Franseen needle tip—a three-point cutting design proven for sample acquisition.^{2,3}

The Acquire 19 ga Flex is an option for EUS-Guided Liver Biopsy

Well-suited for liver biopsy that requires needle flexibility for navigation and acquisition in challenging lobe anatomy.

As the biggest needle size in Acquire Needle family, the Acquire 19ga Flexible Needle may help meet the American Association for the Study of Liver Disease (AASLD) guidelines for liver biopsy.

Acquire™ S EUS FNB Device

The Taper Point Stylet is designed for ease of puncture when performing EUS FNB.³ Bench top testing has demonstrated utilization of the Acquire S Taper Point Stylet offers a 36.6% reduction in puncture force as compared to leading with the Franseen 22ga needle (stylet retracted).¹

Materials and Needle Design

Cobalt Chromium:

As compared to stainless steel provides distinct benefits over in shape set, column strength, and tensile strength.⁴ These properties may provide certain advantages, particularly when sampling difficult target sites:

- Higher resistance to deformation which may aid physician control⁴
- Higher column strength for navigation to sample site⁴
- A harder material to retain sharpness for performance over multiple passes⁴

Nitinol:

Nitinol needle construction provides flexibility, passability, and resistance to permanent deformation.^{5,6,7}

Only Nitinol is used in our 19ga Flexible Needles.

Franseen Needle

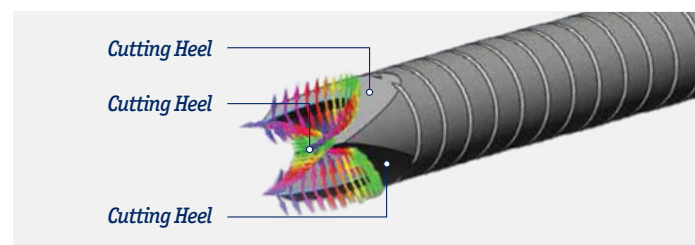
Based on more than 50 years of clinical use in interventional radiology¹ and use in diagnostic EUS since 2016, the Franseen Needle design has a proven track record for diagnostic yield and accuracy.²

End-cutting Needle Design:

- Franseen style needle tip
- 3 symmetrical needle points with fully formed cutting heels
- Electropolished for cutting heel sharpness

End-cutting EUS needles may be preferred when larger histological specimens and preserved tissue architecture are required which may aid in histologic processing.

Adequate diagnostic yield is critical to getting a diagnosis and is playing an increasingly important role in oncology research and genomic sequencing to aid targeted cancer therapies.⁸



	Expect Slimline	Acquire	Acquire 19ga Flex	Acquire S
Needle Design	Lancet	Franseen	Franseen	Franseen
Nitinol	19ga Flex	NA	19ga Flex	NA
Cobalt Chromium	19ga (non flex), 22ga, 25ga	22ga, 25ga	NA	22ga, 25ga



Expect™ Slimline (SL) Endoscopic Ultrasound Aspiration Needle*

Order Number	GTIN	Description	Minimum Working Channel (mm)	Sheath Diameter (mm)	Packaging
M00555500	08714729848141	19 gauge (1.10mm)	2.8	1.83	Each
M00555510	08714729848158	22 gauge (0.72mm)	2.4	1.65	Each
M00555520	08714729848165	25 gauge (0.52mm)	2.4	1.52	Each
M00555530	08714729848172	19 gauge Flex (1.14mm)	2.8	1.73	Each
M00555501	08714729848714	19 gauge (1.10mm)	2.8	1.83	Box 5
M00555511	08714729848121	22 gauge (0.72mm)	2.4	1.65	Box 5
M00555521	08714729848138	25 gauge (0.75mm)	2.4	1.52	Box 5
M00555531	08714729848806	19 gauge Flex (1.14mm)	2.8	1.73	Box 5

*Packaging also includes: 20cc syringe and one-way stopcock

*Needle length: 0cm to 8cm, adjustable

*Working length: 137.5cm to 141.5cm, adjustable

Acquire™ Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device*

Order Number	GTIN	Description	Minimum Working Channel (mm)	Sheath Diameter (mm)	Packaging
M00555540	08714729931782	22 gauge (0.72mm)	2.4	1.65	Each
M00555560	08714729931805	25 gauge (0.52mm)	2.4	1.52	Each
M00555580	08714729931829	19 gauge Flex (1.14mm)	2.8	1.73	Each
M00555541	08714729931843	22 gauge (0.72mm)	2.4	1.65	Box 5
M00555561	08714729931867	25 gauge (0.52mm)	2.4	1.52	Box 5

*Packaging also includes: 20cc syringe and one-way stopcock

*Needle length: 0cm to 8cm, adjustable

*Working length: 137.5cm to 141.5cm, adjustable

Acquire™ S Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device

Order Number	GTIN	Description	Minimum Working Channel (mm)	Sheath Diameter (mm)	Packaging
M00555640	00191506030742	Acquire S 22ga (0.72mm)	2.4	1.65	Each
M00555660	00191506030759	Acquire S 25ga (0.52mm)	2.4	1.52	Each
M00555641	00191506030766	Acquire S 22ga (0.72mm)	2.4	1.65	Box 5
M00555661	00191506030773	Acquire S 25ga (0.52mm)	2.4	1.52	Box 5

1. Data on File. Windchill document #92959483 Bench Test Data. Acquire S Puncture Force Claims Technical Report A. The testing was performed by BSC. Data on file. Test Method Summary: P<.001, 15 unit sample size for each needle type and performed three consecutive punctures with each needle in a synthetic gel block material to assess puncture force required after three punctures. The Acquire 22ga EUS FNB Needle was tested with the stylet retracted for puncture with the needle tip. The Acquire S 22ga EUS FNB Needle was tested using the stylet in the forward position for puncture with the stylet. Needles tested are the Acquire 22ga EUS FNB Needle (Boston Scientific Corporation, Marlborough, MA) and Acquire S 22ga EUS FNB Needle (Boston Scientific Corporation, Marlborough, MA). Bench testing results may not necessarily be indicative of clinical performance.
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4. Keehan E, Gerlely V. Catheter and Specialty Needle Alloys. 2009 Aug.
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