

Medtronic

Value analysis brief

Beacon™ EUS Delivery System



Achieve more with EUS

We're committed to partnerships with pathologists, oncologists, and the GI community in pursuing early detection and treatment of GI diseases and cancers.

The Beacon™ EUS delivery system offers enhanced innovation, choice, and flexibility to help with diagnosis and treatment of GI diseases. Interchangeable needles are designed for improved tissue acquisition and greater procedural flexibility. Physician workflow is optimized with an exchange of needles through a single delivery system. And healthcare staff safety is increased with built-in safety features designed to reduce needlestick injury.

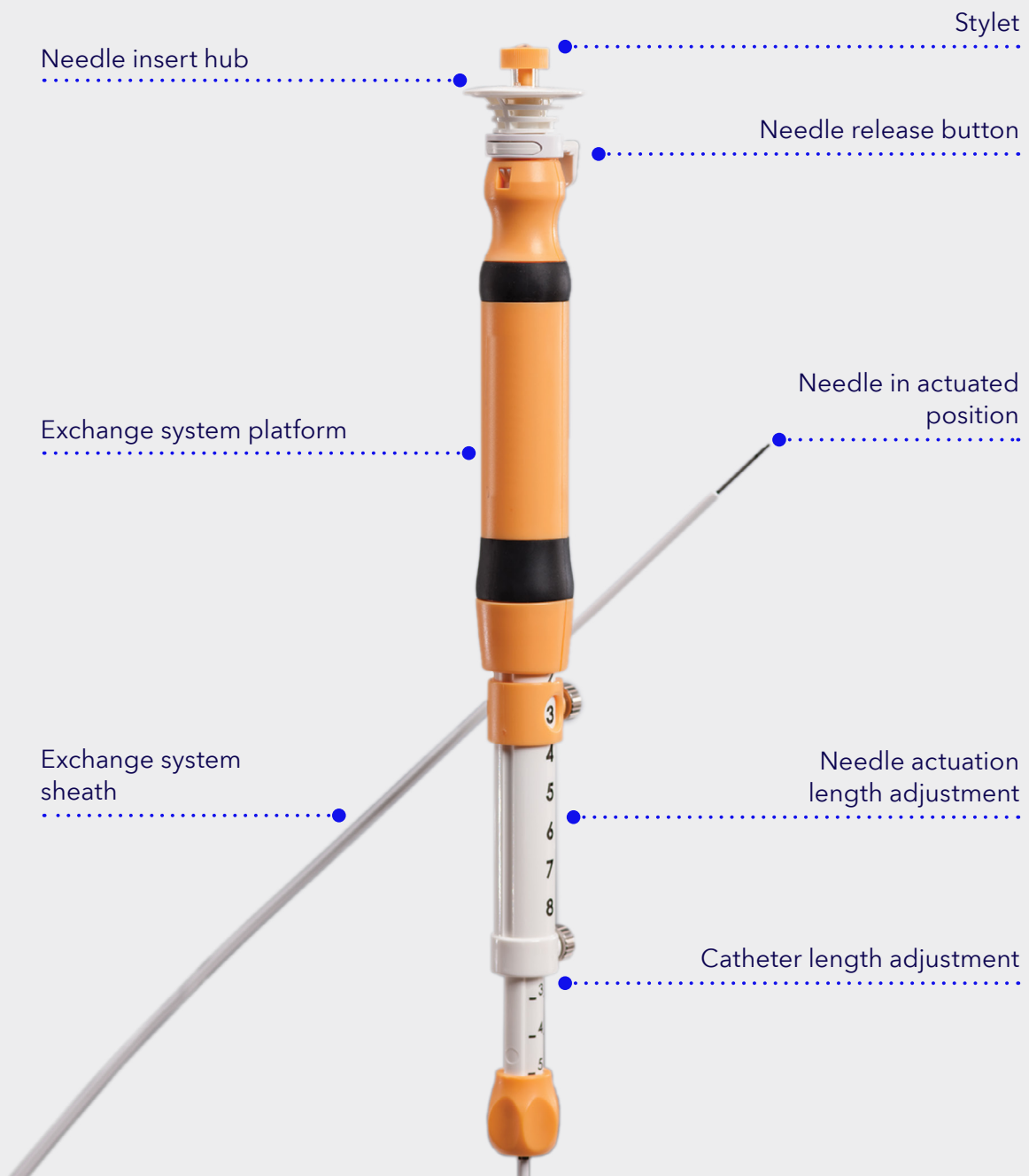
We offer staff training and education for the use of the Beacon™ EUS delivery system. We also partner with healthcare professionals around the world to increase GI disease awareness.



The Power of One

Engineered to improve procedure workflow, the Beacon™ EUS delivery system facilitates exchange of multiple needles through a single delivery system. Exchanges are achieved without removing the delivery system from the scope.¹

- The Beacon™ EUS delivery system offers universal compatibility with all Beacon™ EUS devices, including 25, 22, and 19-gauge needles.¹
- The Beacon™ EUS delivery system enables faster needle exchange without changing scope position, may result in reduced procedural time when multiple devices are used.²



More choices, better flexibility

SharkCore™ FNB needle

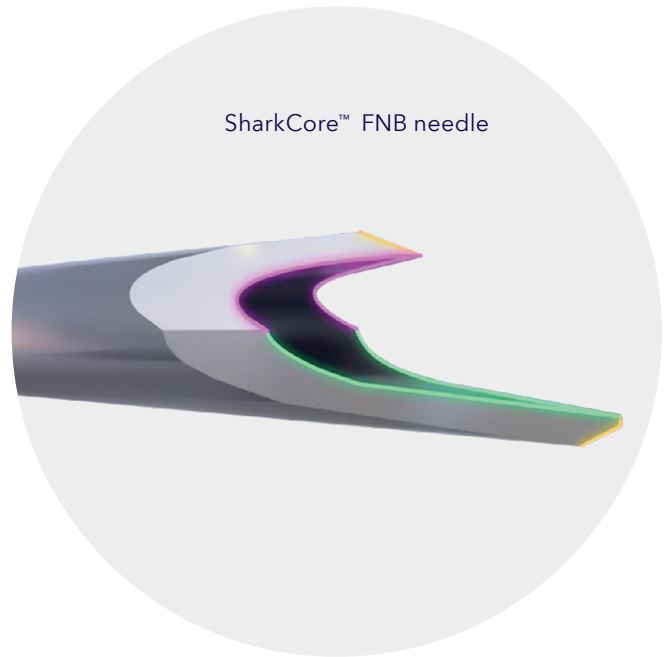
Features six distal cutting-edge surfaces for collecting cohesive units of tissue with intact cell architecture. This provides improved diagnostic yield by collecting significantly more histologic specimen compared to FNA (p value < 0.001).³⁻⁵

Beacon™ FNA needle

Features four cutting edges designed to improve tissue yield^{2,6}

Interchangeability, efficiency, and procedural safety

- Streamlined procedure enables **greater flexibility in the face of unpredictable hurdles** while performing FNA or FNB placement
- **Reduced procedural time** when multiple needles are used²
- Passively activated **safety sheath** minimizes risk of needlestick injury



What your colleagues think*

SharkCore™ FNB needle

“The SharkCore™ FNB needle enhances my diagnostic capabilities because it provides more tissue, so the pathologist can actually see the cells and the preserved tissue architecture. This also reduces the probability that the patient has to come back for a repeat procedure.”

Dr. Ryou - Gastroenterologist, Brigham and Women's Hospital, Boston



“When the pathologist looks at these tissue samples, they're able to see tissue architecture, they're able to do better stains, they're able to make a better diagnosis.”

Dr. Murad - Gastroenterologist, NorthShore University Health System, Chicago

Beacon™ FNA needle

“EUS with FNA is one of the higher risk procedures for staff because there can be an exposed needle during the case. The Beacon™ FNA needle is designed with an automatic safety shield over the needle that prevents needlesticks for my staff.”

Tyler Berzin, M.D. - Assistant Professor of Medicine at Harvard Medical Center, Center for Advanced Endoscopy, Beth Israel Deaconess Medical Center

*This content is based on individual opinion and experience from clinical practice. The conclusions are those of the individual, unless otherwise cited. The speakers didn't receive funding from Medtronic.



Unique design, improved outcomes

Use the SharkCore™ FNB needle
for better tissue collection^{4,5}

Not all needle designs are created equal.
The currently available EUS-FNB needles
have markedly different designs.



SharkCore™
FNB needle



Franseen
needle
design



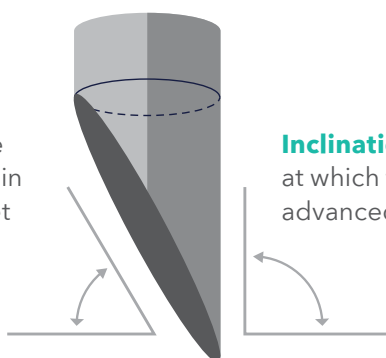
Reverse
bevel
needle
design



Preclinical testing has shown
that cutting-edge geometry is
important for tissue cutting.⁶

Needles of higher inclination
angle produce lower insertion
forces and longer biopsy
sample lengths.⁷

Rake angle = angle
of the cutting edge in
relation to the target



Inclination angle = angle
at which the tool is being
advanced toward the target

Rake angle + inclination angle = effective needle angle

In a study of EUS-guided liver biopsy using the SharkCore™
FNB needle, mean total specimen length was 6.6 cm.
This result was significantly greater than the AASLD
recommendations of 3.0 cm.⁸

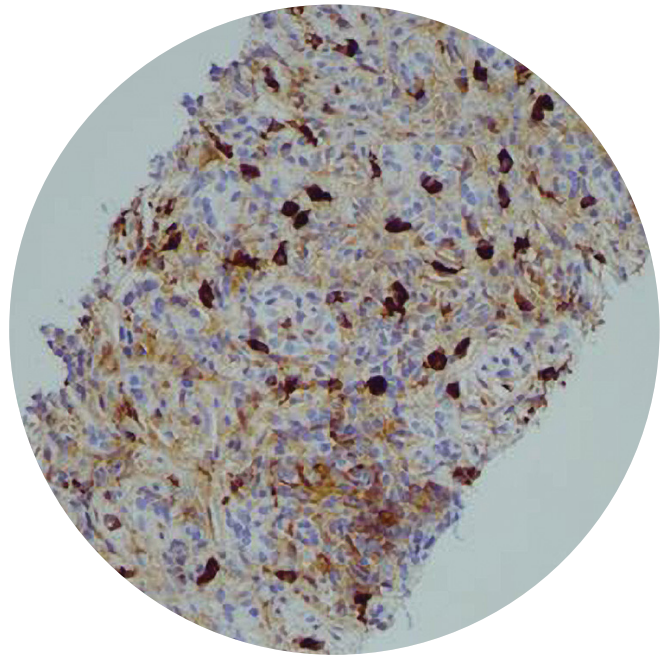
Staff safety is our concern

The Beacon™ EUS delivery system with interchangeable needles (FNA and FNB) is designed to reduce the risk of needle sticks to staff with a passive safety shielding feature.⁹

The Beacon™ EUS delivery system includes a **passively activated safety sheath** that shields the needle tip and reduces opportunities for staff injury.

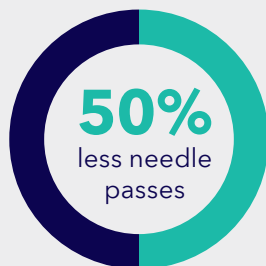


The evolution of care



Procedural impact of the SharkCore™ FNB needle

Reduces the number of needle passes required to obtain a tissue diagnosis by half as compared to a standard FNA needle.²



Produces diagnostic results without use of rapid on-site evaluation comparable to the use of standard FNA with rapid on-site evaluation.¹⁰

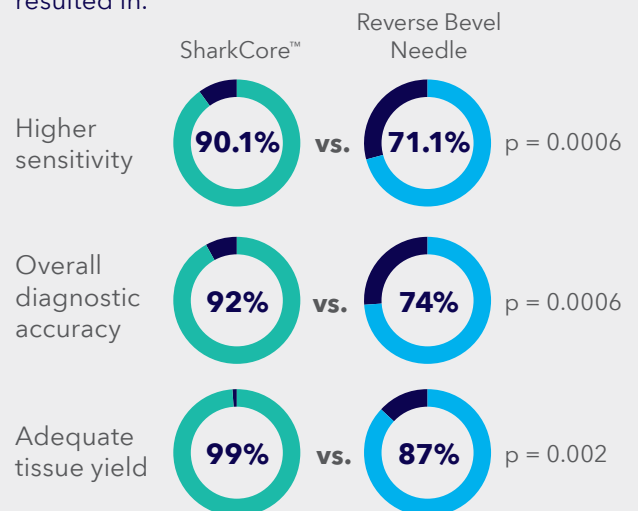


Collects significantly more histological tissue than standard FNA needles during EUS guided biopsy.⁵

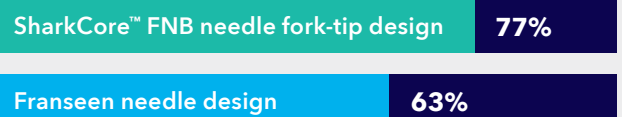


The difference of enhanced cutting edge design

Compared to a reverse bevel needle design,¹¹ tissue collected using SharkCore™ FNB needle resulted in:



In a retrospective, single-center cohort study, the SharkCore™ FNB needle fork-tip design resulted in a **higher diagnostic yield compared to the Franseen needle design (77% vs. 63%, p = 0.027).**¹²



More options for success

Endoscopic ultrasound (EUS) guided liver biopsies produce results that are noninferior to those obtained by percutaneous and transjugular routes.¹³

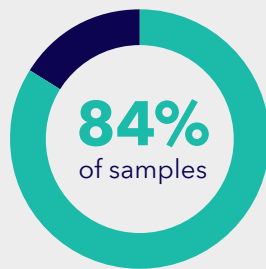
Two clinical studies demonstrate that EUS guided liver biopsies using the SharkCore™ FNB needle produce adequate biopsy specimens as defined by several liver societal organizations.^{8,14}



Total specimen length was **greater than 3 cm** in **100% of samples (165/165)**



and **greater than 10 complete portal tracts (CPT)** in **84% of samples (139/165)**.¹⁴



Specimen adequacy for complete portal tracts (CPT) and total specimen length (TSL) using SharkCore™ FNB needle during liver biopsy was

95.8% and 87.5% respectively

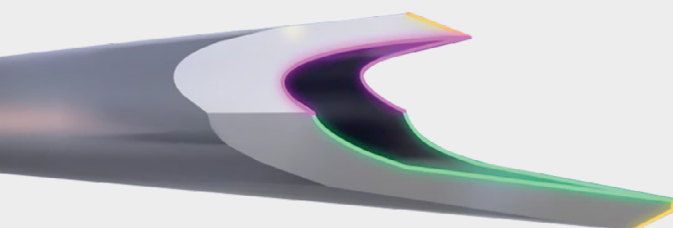


Adequacy of samples was defined based on American Association for the Study of Liver Diseases (AASLD) guidelines.^{8,16}

AASLD Guidelines for adequate liver biopsy specimen are¹⁴:

Length **2 cm**

Complete portal tracts **≥ 11**



Indications for use

Beacon™ FNA exchange system¹

The device is used to sample targeted sub-mucosal and extramural gastrointestinal lesions through the accessory channel of an ultrasound endoscope.

The needle is designed with a passive (i.e., automatic) safety shielding feature to aid in the prevention of needlestick injury.



SharkCore™ FNB exchange system²¹

The device is used with an ultrasound endoscope for fine needle biopsy (FNB) of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the gastrointestinal tract.

The needle is designed with a passive (i.e., automatic) safety shielding feature to aid in the prevention of needlestick injury.



Medtronic is committed to partnership in the GI community and supporting healthcare professionals as they work towards early detection of GI diseases.

Beacon™ product list		
Code	Description	Unit of measure
DSN-19-01	Beacon™ EUS Delivery System with FNA Pre-loaded Needle 19 Gauge Nitinol	Each
DSN-22-01	Beacon™ EUS Delivery System with FNA Pre-loaded Needle 22 Gauge Stainless Steel	Each
DSN-25-01	Beacon™ EUS Delivery System with FNA Pre-loaded Needle 25 Gauge Stainless Steel	Each
Individual Beacon™ Fine Needle Aspiration (FNA) Needle		
N-19-05	Beacon™ FNA Pre-loaded Needle 19 Gauge Nitinol	Box of 5
N-22-05	Beacon™ FNA Pre-loaded Needle 22 Gauge Stainless Steel	Box of 5
N-25-05	Beacon™ FNA Pre-loaded Needle 25 Gauge Stainless Steel	Box of 5
SharkCore™ product list		
DSL-19-01	Beacon™ EUS Delivery System with SharkCore™ LG FNB Pre-loaded Needle 19 Gauge Nitinol	Each
DSC-22-01	Beacon EUS Delivery System with SharkCore™ FNB Pre-loaded Needle 22 Gauge Stainless Steel	Each
DSC-25-01	Beacon EUS Delivery System with SharkCore™ FNB Pre-loaded Needle 25 Gauge Stainless Steel	Each
Individual SharkCore™ Fine Needle Biopsy (FNB) Needle		
C-22-05	SharkCore™ FNB Individually Packed Needles 22 Gauge Nitinol	Box of 5
L-19-05	SharkCore™ LG FNB Individually Packed Needles 19 Gauge Stainless Steel	Box of 5
C-25-05	SharkCore™ FNB Individually Packed Needles 25 Gauge Stainless Steel	Box of 5



References

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3. Internal test report #1085, July 2014 and Internal test report #1090, Sept 2014.
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13. Pineda JJ, Diehl DL, Miao C, et al. EUS-guided liver biopsy provides diagnostic samples comparable with those via the percutaneous or transjugular routes. *Gastrointest Endosc.* 2016;83(2):360-365.
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15. Rockey DC, Caldwell SH, Goodman ZD, et al. American Association for the Study of Liver Diseases: liver biopsy. *Hepatology* 2009;49(3):1017-1044.
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Beacon™ Fine Needle

Contraindications

Those specific to primary endoscopic procedure to be performed in gaining access to desired site. Coagulopathy.

Risk information: Procedural risks associated with gastrointestinal endoscopy include, but are not limited to: perforation, hemorrhage, aspiration, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest, infection/fever, damage to blood vessels, nerve damage, tumor seeding of the needle tract and acute pancreatitis.

Procedural risks associated with EUS needle biopsy include but are not limited to: bleeding, pain, death, peritonitis, infection/bacteremia, tumor seeding of the needle tract, and needle fracture requiring intervention for removal.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

Contact customer service or your sales representative for the most up-to-date revision of the package insert.

This material is only intended for distribution in Europe. Indications, claims, and intended use may be different in other regions.

Important: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

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