VALUE ANALYSIS BRIEF

Beacon™ EUS Delivery System

Medtronic
Further, Together

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.

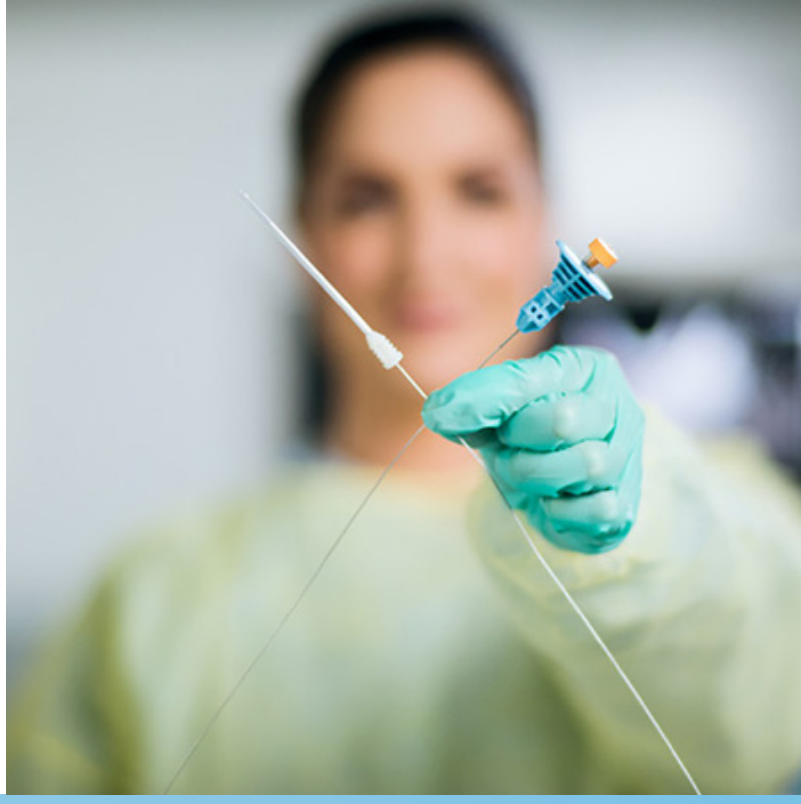
The Beacon™ EUS delivery system offers enhanced innovation, choice, and flexibility for diagnosis and treatment of GI diseases. Three interchangeable needles — the FNA, FNB, and FNF — assure improved tissue acquisition, accurate fiducial placement, and greater procedural flexibility. Physician workflow is optimized with a seamless exchange of needles through a single delivery system. And healthcare staff safety is increased with built-in safety features designed to reduce needlestick injury.

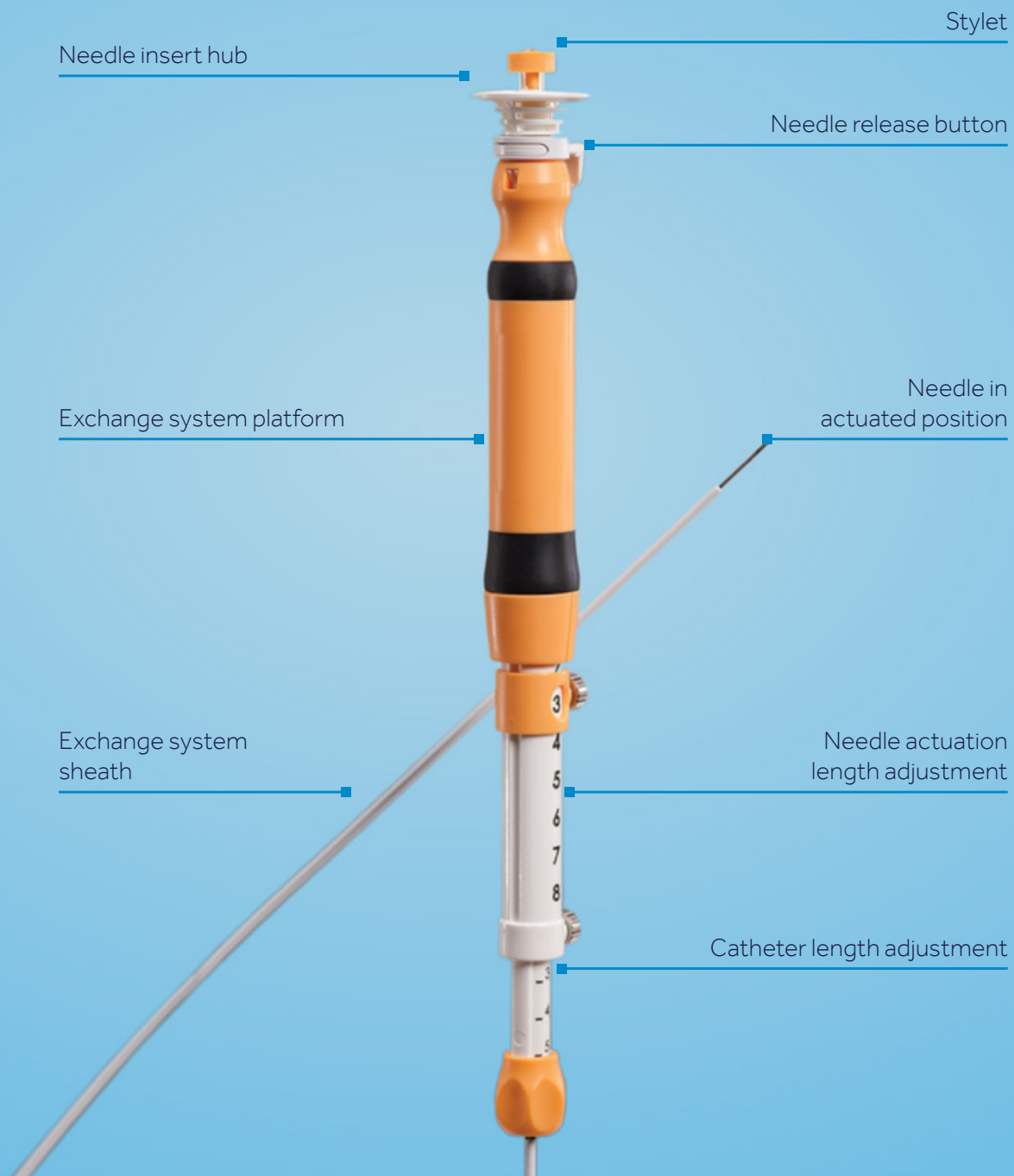
We offer staff training and education for the use of the Beacon™ EUS delivery system. We also partner with healthcare professionals around the world to increase GI disease awareness.

THE POWER OF ONE

Engineered to improve procedure workflow, the Beacon™ EUS delivery system facilitates seamless 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 fast needle exchange without changing scope position, resulting in reduced procedural time when multiple devices are used.[2]





MORE CHOICES BETTER FLEXIBILITY

SharkCore™ FNB needle

- Unique needle tip geometry features six distal cutting edges **engineered to collect cohesive units of tissue** with the SharkCore™ FNB needle[3–5]
- Minimizes tissue stacking and fracturing, leading to better core samples[3–5]

Beacon™ FNF needle

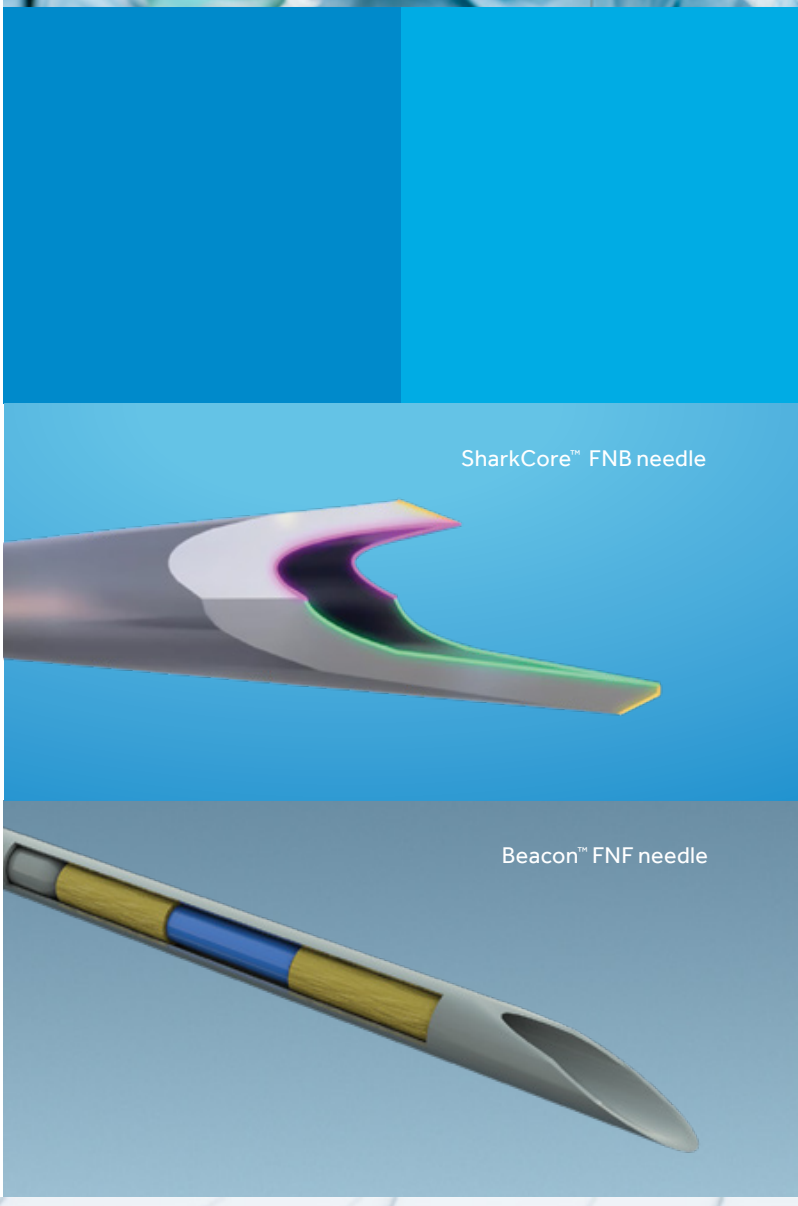
- Unique fiducial needle **pre-loaded with two solid-gold markers for easy, efficient placement**[6,7]
- Markers generate a clear echogenic response[8]
- Fiducial markers feature a **knurled design intended to reduce migration**[9–12]
- Physician deployment indicator provides **visual and tactile feedback** for the confident deployment of each fiducial marker

Beacon™ FNA needle

- Four cutting edges **improve tissue yield for cytology** with the Beacon™ FNA needle[3]

Interchangeability, efficiency, and procedural safety

- Streamlined procedure enables **greater flexibility in the face of unpredictable hurdles** while performing FNA, FNB, or FNF placement
- **Reduced procedural time** when multiple needles are used[2]
- 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

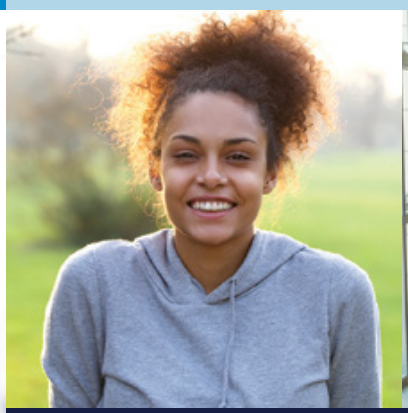
"When the pathologist looks at these tissue samples, they're able to see tissue architecture, they're able to do better stains, they're able to make a better diagnosis."

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



UNIQUE DESIGN IMPROVED OUTCOMES

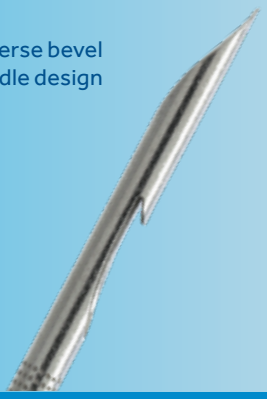
Use the SharkCore™ FNB needle for better tissue collection[4,5]

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

SharkCore™ FNB needle

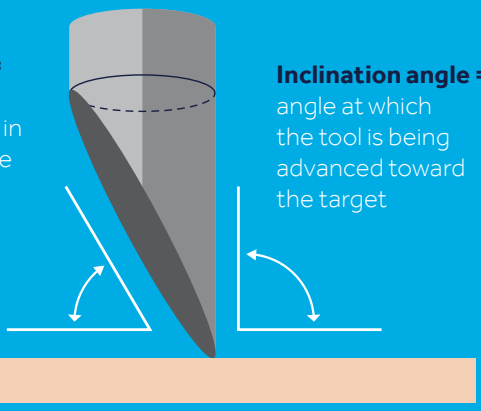
Franseen needle design

Reverse bevel needle design



Preclinical testing has shown that cutting-edge geometry is important for tissue cutting.[13] Needles of higher inclination angle produce lower insertion forces and longer biopsy sample lengths.[14]

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 6.5 cm. This result was significantly greater than the AASLD recommendations of 2.0 cm.[15]

STAFF SAFETY IS OUR CONCERN

Needlestick injuries can be reduced, if needles with passive safety features are utilized.[16]

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

It is the only endoscopic ultrasound needles system with an **FDA-cleared safety indication.†**

†As of June 2018.

PRODUCT CROSS REFERENCES

Beacon™ FNF needle			
Manufacture code	**Description**	**Unit**	**Each qty.**
DSF-19-01	Beacon™ EUS delivery system with FNF pre-loaded needle 19 gauge	EA	1
F-19-05	Beacon™ EUS delivery system with FNF pre-loaded needle 19 gauge	BX	5
DSF-22-01	Beacon™ EUS delivery system with FNF pre-loaded needle 22 gauge	EA	1
F-22-05	Beacon™ EUS delivery system with FNF pre-loaded needle 22 gauge	BX	5

Boston Scientific Expect™ EUS FNA				Beacon™ FNA needle			
Manufacture code	**Description**	**Unit**	**Each qty.**	**Manufacture code**	**Description**	**Unit**	**Each qty.**
M00555500	19 Ga. EUS aspiration needle - slimline	EA	1	DSN-19-01	Beacon™ EUS delivery system with FNA pre-loaded needle 19 gauge	EA	1
M00555530	19 Ga. EUS aspiration needle - slimline flex	EA	1				
M00550000	19 Ga. EUS aspiration needle - standard	EA	1				
M00550040	19 Ga. EUS aspiration needle - standard flex	EA	1				
M00555501	19 Ga. EUS aspiration needle - slimline	BX	5				
M00555531	19 Ga. EUS aspiration needle - slimline flex	BX	5				
M00550001	19 Ga. EUS aspiration needle - standard	BX	5				
M00550041	19 Ga. EUS aspiration needle - standard flex	BX	5				
				N-19-05	Beacon™ FNA individually packed needles 19 gauge	BX	5
M00555510	22 Ga. EUS aspiration needle - slimline	EA	1	DSN-22-01	Beacon™ EUS delivery system with FNA pre-loaded needle 22 gauge stainless steel	EA	1
M00550010	22 Ga. EUS aspiration needle - standard	EA	1				
				N-22-05	Beacon™ FNA individually packed needles 22 gauge stainless steel	BX	5
M00555520	25 Ga. EUS aspiration needle - slimline		1	DSN-25-01	Beacon™ EUS delivery system with FNA pre-loaded needle 25 gauge stainless steel	EA	1
M00550020	25 Ga. EUS aspiration needle - standard		1				
				N-25-05	Beacon™ FNA individually packed needles 25 gauge stainless steel	BX	5

PRODUCT CROSS REFERENCES

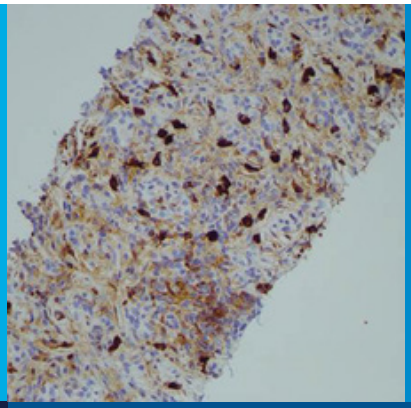
Cook EchoTip™* EUS FNA needle				Beacon™ FNA needle			
Manufacture code	**Description**	**Unit**	**Each qty.**	**Manufacture code**	**Description**	**Unit**	**Each qty.**
G31520	19 Ga. ECHO- 19 EUS needle	EA	1	DSN-19-01	Beacon™ EUS delivery system with FNA pre-loaded needle 19 gauge	EA	1
				N-19-05	Beacon™ FNA individually packed needles 19 gauge	BX	5
G31518	22 Ga. ECHO- 1-22 EUS needle	EA	1	DSN-22-01	Beacon™ EUS delivery system with FNA pre-loaded needle 22 gauge stainless steel	EA	1
G31521	22 Ga. ECHO- 3-22 EUS needle	EA	1				
				N-22-05	Beacon™ FNA individually packed needles 22 gauge stainless steel	BX	5
G31519	25 Ga. ECHO- 25 EUS needle	EA	1	DSN-25-01	Beacon™ EUS delivery system with FNA pre-loaded needle 25 gauge stainless steel	EA	1
				N-25-05	Beacon™ FNA individually packed needles 25 gauge stainless steel	BX	5

Cook EchoTip ProCore™* HD ultrasound FNB needle				SharkCore™ FNB needle			
Manufacture code	**Description**	**Unit**	**Each qty.**	**Manufacture code**	**Description**	**Unit**	**Each qty.**
G53585	19 Ga. Echotip ProCore™* EUS needle	EA	1	DSL-19-01	Beacon™ EUS delivery system with SharkCore™ FNB pre-loaded needle 19 gauge	EA	1
				L-19-05	Sharkcore™ FNB individually packed needles 19 gauge	BX	5
G34785	20 Ga. Echotip ProCore™* EUS needle	EA	1				
G55736	22 Ga. Echotip ProCore™* EUS needle	EA	1	DSC-22-01	SharkCore™ FNB exchange system with pre-loaded needle 22 gauge	EA	1
				C-22-05	SharkCore™ FNB individually packed needles 22 gauge	BX	5
G55738	25 Ga. Echotip ProCore™* EUS needle	EA	1	DSC-25-01	SharkCore™ FNB exchange system with pre-loaded needle 25 gauge	EA	1
				C-25-05	SharkCore™ FNB individually packed needles 25 gauge	BX	5

Acquire EUS FNB needle			SharkCore™ FNB needle			
Product code	**Description**	**qty.**	**Manufacture code**	**Description**	**Unit**	**Each qty.**
M00555540	22ga Acquire EUS FNB needle	Box 1	DSC-22-01	SharkCore™ FNB exchange system with pre-loaded needle 22 gauge	EA	1
			C-22-05	SharkCore™ FNB individually packed needles 22 gauge	BX	5
M00555560	25ga Acquire EUS FNB needle	Box 1	DSC-25-01	SharkCore™ FNB exchange system with pre-loaded needle 25 gauge	EA	1
			C-25-05	SharkCore™ FNB individually packed needles 25 gauge	BX	5

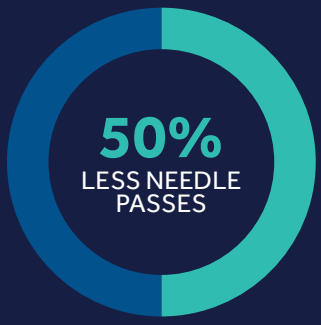
THE EVOLUTION OF CARE

More than 15 peer reviewed publications have provided clinical evidence demonstrating the advantages of SharkCore™ FNB needles.



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.[17–19]

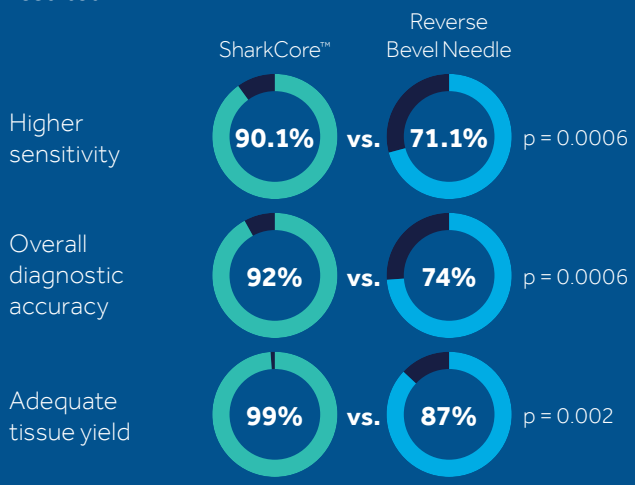


Produces diagnostic results without use of rapid on-site evaluation comparable to the use of standard FNA with rapid on-site evaluation.[20]

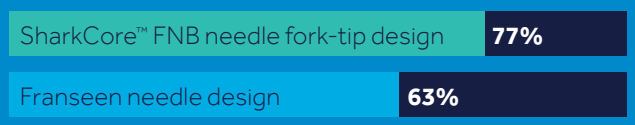
Collects significantly more histological tissue than standard FNA needles during EUS guided biopsy.[21]

The difference of enhanced cutting edge design

Compared to a reverse bevel needle design,[22] 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).**[23]



MORE OPTIONS FOR SUCCESS

Endoscopic ultrasound (EUS) guided liver biopsies produce results that are noninferior to those obtained by percutaneous and transjugular routes.[24]

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.[25,26]

Total specimen length was

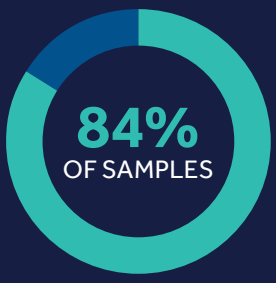
GREATER THAN 3 CM

in 100% of samples (165/165)

and

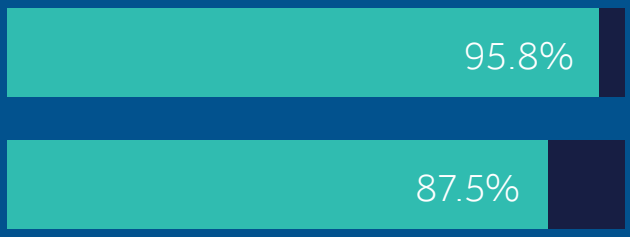
GREATER THAN 11 COMPLETE PORTAL TRACTS (CPT)

in 84% of samples (139/165).[26]

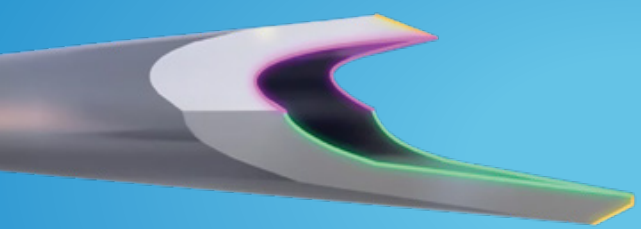


Specimen adequacy for complete portal tracts (CPT) and total specimen length (TSL) using SharkCore™ FNB needle during liver biopsy was

95.8% AND 87.5% RESPECTIVELY



Adequacy of samples was defined based on American Association for the Study of Liver Diseases (AASLD) guidelines.[25,27]



AASLD GUIDELINES FOR ADEQUATE LIVER BIOPSY SPECIMEN ARE[27]:

LENGTH

2–3 cm

COMPLETE PORTAL TRACTS

> 11

INDICATIONS FOR USE

Beacon™ FNA exchange system[1]

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.

The 19Ga and 22Ga Beacon™ FNA needles are also intended to implant fiducial markers under endoscopic ultrasound to radiographically mark soft tissue for future therapeutic procedures.

SharkCore™ FNB exchange system[28]

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.

Beacon™ FNF exchange system[6]

The device is intended to implant fiducial markers under endoscopic ultrasound to radiographically mark soft tissue for future therapeutic procedures. The needle is designed with a passive (i.e., automatic) safety shielding feature to aid in the prevention of needlestick injury.

ADVANCED PLATFORM

An innovative design that offers you unique benefits:

- High echogenic visibility, efficient device exchange and ease of use
- A braided wire design maintains an open lumen even in a tortuous position

Beacon™ Product List		
All Beacon™ EUS Delivery Systems comes with one vacuum syringe.		
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
DSN-22-05	Beacon™ EUS Delivery System with FNA Pre-loaded Needle 22 Gauge Stainless Steel	Box of 5
DSN-25-05	Beacon™ EUS Delivery System with FNA Pre-loaded Needle 25 Gauge Stainless Steel	Box of 5
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-25-05	Beacon EUS Delivery System with SharkCore™ FNB Pre-loaded Needle 25 Gauge Stainless Steel	Box of 5
DSC-25-01	Beacon EUS Delivery System with SharkCore™ FNB Pre-loaded Needle 25 Gauge Stainless Steel	Each
DSC-22-05	Beacon EUS Delivery System with SharkCore™ FNB Pre-loaded Needle 22 Gauge Stainless Steel	Box of 5
Individual SharkCore™ Fine Needle Biopsy (FNB) Needle		
L-19-05	SharkCore™ LG FNB Individually Packed Needles 19 Gauge Nitinol	Box of 5
C-22-05	SharkCore™ FNB Individually Packed Needles 22 Gauge Stainless Steel	Box of 5
C-25-05	SharkCore™ FNB Individually Packed Needles 25 Gauge Stainless Steel	Box of 5
Beacon™ FNF Needle Product List		
DSF-19 - 01	Beacon™ EUS Delivery System with FNF Pre-loaded 19 Gauge	Each
DSF-22- 01	Beacon™ EUS Delivery System with FNF Pre-loaded 22 Gauge	Each
Individual Pre-loaded Beacon™ Fine Needle Fiducial (FNF) Needle		
F-19 - 05	Beacon™ EUS FNF Pre-loaded 19 Gauge Needle	Box of 5
F-22- 05	Beacon™ EUS FNF Pre-loaded 22 Gauge Needle	Box of 5

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

Risk Information: Beacon™ fine needle pre-loaded fiducial system: 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, bacteremia, allergic reaction to medication, damage to blood vessels, nerve damage, tumor seeding of the needle tract, and acute pancreatitis. Those associated with EUS fiducial placement include, but are not limited to: improper fiducial placement, fiducial migration, infection/fever, allergic reaction, local inflammatory foreign body response, minor bleeds, pain, pancreatitis, and needle fracture requiring intervention for removal. Please refer to the product user manual for detailed information.

Contact your Medtronic representative for more information

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22
GA

Caution: Federal law restricts this device sale by or on the order of a licensed healthcare practitioner. Rx only.

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, bacteremia, allergic reaction to medication, 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.

Procedural risks associated with EUS fiducial placement include, but are not limited to: improper fiducial placement, fiducial migration, infection/fever, allergic reaction, local inflammatory foreign body response, minor bleeds, pain, pancreatitis, 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.

Medtronic

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

18-weu-beacon-eus-value-analysis-brief-2585032

medtronic.com/covidien/en-gb/index.html