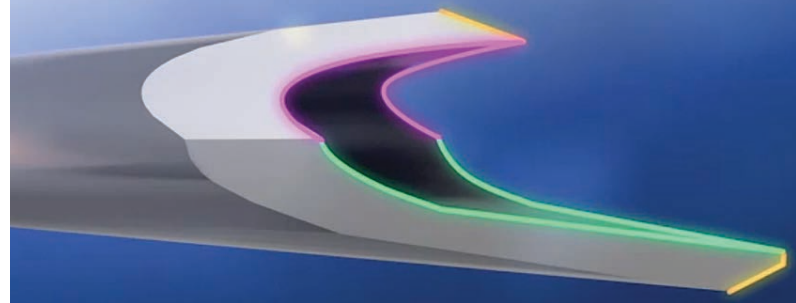


# ACHIEVE CONFIDENCE IN YOUR SAMPLE

With the SharkCore™ FNB needle,  
part of the Beacon™ EUS delivery system

We understand the importance of adequate tissue samples in the early detection and diagnosis of GI diseases.

That's why we've developed an innovative FNB needle that works with the Beacon™ EUS delivery system. The SharkCore™ FNB needle collects cohesive units of tissue with intact cell architecture, improving the diagnostic yield.<sup>1-8</sup>



The SharkCore™ FNB needle helps to improve diagnostic yield by optimising the consistency, volume\*, and quality of tissue collected.<sup>1-4,7,8,18</sup>



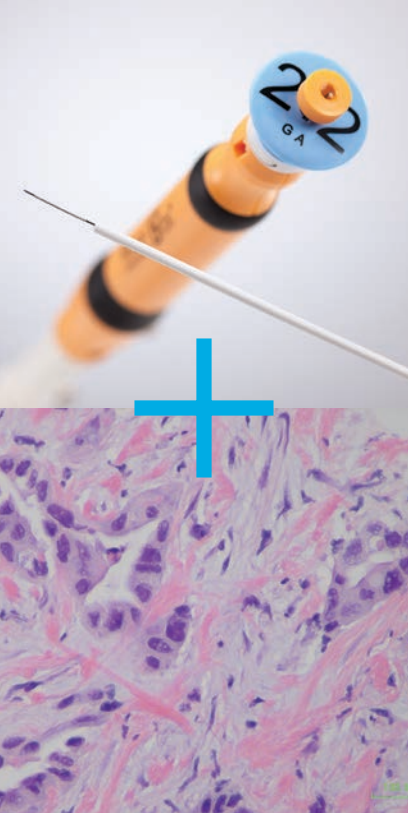
## Designed with unique needle tip geometry

- Collect cohesive units of tissue with intact cellular architecture<sup>1,3,5-8</sup>
- Maximize sample acquisition with six cutting edge surfaces<sup>1,3,5-8</sup>
- Minimizes damage to the tissue as it is collected enhancing tissue acquisition and diagnostic yield.<sup>3,8,18</sup>
- Support flexibility with 19, 22, and 25 gauge needles

## Save time and ensure procedural safety

- Part of the interchangeable Beacon™ EUS delivery system<sup>9-12</sup>
- Efficient exchange between FNA, FNB, and FNF needles without losing scope position<sup>9-12</sup>
- Automatic safety shield protects the staff from needle stick injury during needle exchange<sup>12-17</sup>
- Option for both histologic and cytologic sample preparation<sup>7</sup>

# ACHIEVE MORE WITH EUS



## SharkCore™ FNB needle product list

Code	Description	Unit of Measure
DSL-19-01	Beacon™ EUS delivery system with Sharkcore™ FNB pre-loaded needle – 19 gauge	Each
L-19-05	Sharkcore™ FNB individually packed needles – 19 gauge	Box of 5
DSC-22-01	Sharkcore™ fine needle biopsy system with pre-loaded needle – 22 gauge	Each
DSC-25-01	Sharkcore™ fine needle biopsy system with pre-loaded needle – 25 gauge	Each
C-22-05	Sharkcore™ FNB individually packed needles – 22 gauge	Box of 5
C-25-05	Sharkcore™ FNB individually packed needles – 25 gauge	Box of 5

We are committed to partnership in the GI community and supporting healthcare professionals as you work towards early detection of GI diseases.

Contact your Medtronic representative for more information, or visit [medtronic.com/gi](http://medtronic.com/gi)

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

**Risk Information:** SharkCore™ FNB Needle: Procedural risks associated with gastrointestinal endoscopy include, but are not limited to: perforation, hemorrhage, aspiration, fever, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest, infection, allergic reaction to medication, damage to blood vessels, nerve damage, 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 refer to the product user manual or [medtronic.com/gi](http://medtronic.com/gi) for detailed information.

### References:

1. Based on internal testing data, Report #1085 dated July 8, 2014; and Report #1090, dated September 25, 2014 (Data on file). 2. Adler AG, Witt B, Chadwick B, Well J, Taylor LJ, et al. Pathologic evaluation of a new endoscopic ultrasound needle designed to obtain core tissue samples: A pilot study. *Endosc Ultrasound*. May-June, 2016; 5(3): 178-183. 3. DiMaio C.J., et al. Initial Experience with a novel EUS-guided core biopsy needle (SharkCore): results of a large North American multicenter study. *Endosc Int Open* September, 2016;4(9): E974-E979. 4. Bang JY, Hebert-Magee S, Navaneethan U, Hasan MK, Hawes R, Varadarajulu S. Randomized trial comparing the Franseen and Fork-tip needles for EUS-guided fine-needle biopsy sampling of solid pancreatic mass lesions. *Gastrointest Endosc* June, 2018;87(6):1432-1438. 5. Kandel P., Tranesh G., Nassar A., Bingham R., Raimondo M., Woodward T.A., Gomez V., Wallace M.B. EUS-guided fine needle biopsy sampling using a novel fork-tip needle: a case-control study. *Gastrointest Endosc* December, 2016; 84(6):1034-1039. 6. Abdelfatah M.M., Grimm I.S., Gangarosa L.M. Baron T.H. Cohort study comparing the diagnostic yields of 2 different EUS fine-needle biopsy needles. *Gastrointest Endosc* February, 2018;87(2):495-500. 7. Rodrigues-Pinto E., Jalaj S., Grimm I.S., Baron, T.H. Impact of EUS-guided fine-needle biopsy sampling with a new core needle on the need for onsite cytopathologic assessment: a preliminary study. *Gastrointest Endosc* December, 2016; 84(6). 8. Jovani M., Abidi W.M., Lee L.S. Novel fork-tip needles versus standard needles for EUS-guided tissue acquisition from solid masses of the upper GI tract: a matched cohort study. *Scand J Gastroenterol* June-July, 2017;52(6-7):784-787. 9. James TW, Baron TH. A comprehensive review of endoscopic ultrasound core biopsy needles. *Expert Review of Medical Devices* 2018. 10. TR110601 Rev 01 DV Report dated November 11, 2011 (Data on file). 11. PPQ Report: TR-20009 Rev 01 dated March 9, 2015 (Data on file). 12. AA study report: TR-20003 Rev 01 dated March 18, 2014 (Data on file). 13. FDA-K 133008 Report REP 1049 dated March 6, 2013 (Data on file). 14. FDA 510(K) K133008\_BNX FNA System Safety Feature, dated November 20, 2019. 15. FDA 510(K) K141894\_SharkCore FNB System, dated October 6, 2014. 16. FDA 510(K) K152586\_Beacon Fine Needle Fiducial System, dated December 30, 2015. 17. FDA 510(k) K142198\_BNX FNA System Fiducial Marker indication, dated October 8, 2014. 18. When compared to the BNX™ FNA needles based on test results. Data on file. (Based on internal testing data, Report #1085 dated July 8, 2014).

\* When compared to FNA needles for histological analysis (59% versus 4%; p<0.001)