



Pancreaticobiliary endoscopy, reimagined.

Dragonfly™* pancreaticobiliary endoscope





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Product overview

Rotational control



Tip deflection knob

Rotational handle

20 cm
advancement rail

- **42%** increase in working channel diameter vs. current standard¹
- No increase in scope outer diameter



- 90-degree tip deflection
- Fully rotatable
- 10.5 Fr highly flexible shaft

The result

- Larger biopsy forceps
- Larger electrohydraulic lithotripsy (EHL) probes
- Rotational control can help overcome the therapeutic limitations of the current standard



10.5 Fr

1.7 mm

Product overview

Diagnostic accuracy

Accuracy of
other GI biopsy
procedures
exceeds 90%²

Cholangioscopy
biopsy sensitivity
can be
as low as 64%³

**Unsuccessful
ERCPs can lead to**
increased hospital
stay and overall
cost to treat⁴

**The Dragonfly™ pancreaticobiliary scope
makes larger direct visualization
biopsies possible**

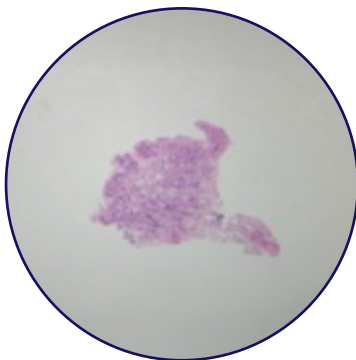
A larger working channel is necessary
to accommodate an increased Bx
forceps cup size⁵

Custom Luke™ biopsy forceps

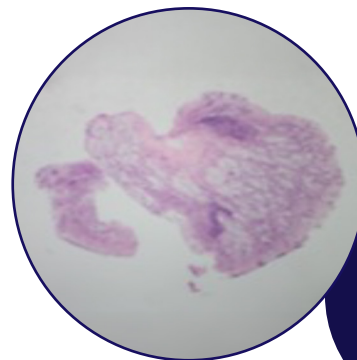
6 mm
jaw height



Current standard of care[†]
1.0 mm biopsy forceps sample



The Dragonfly™ endoscope
1.5 mm biopsy forceps sample



**40% larger
tissue samples
than the current
standard^{‡,6}**

[†] SpyBite™ Max

[‡] Findings based off an ex vivo study.

Product overview

Enhanced stone therapy

Higher power settings and increased number of shots may reduce probe life⁶

Existing EHL solutions have a **76.5% median stone clearance success**⁷

Incomplete stone clearance rates can be as **high as 15% in single session**⁸

Larger EHL probes are now available

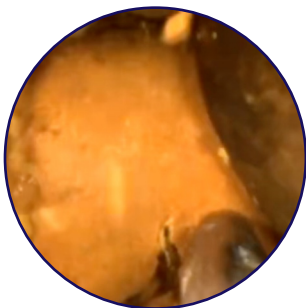
Standard EHL solutions often require multiple probes and long procedure times to achieve ductal clearance⁸

New 3.0 and 4.5 Fr EHL solution

2.4X larger probe size compared to the current standard



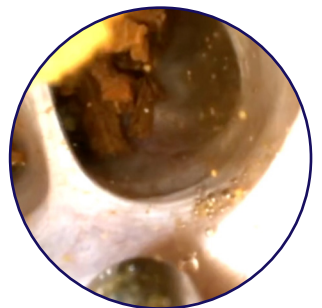
Before



Intra-procedural



After



Adjusted **power and durability** may improve stone clearance in a single-setting

Product overview

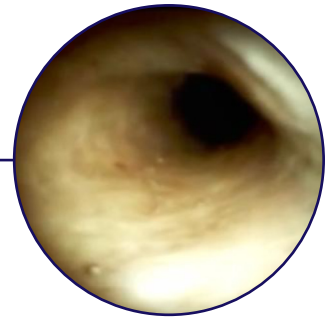
User advantages

High-resolution visualization for improved ductal inspection

The Dragonfly™ pancreaticobiliary system offers greater resolution than the current standard.



Dragonfly™ system
visualization



Standard
visualization

Next-generation engineering for enhanced 1:1 rotational control and precision⁹

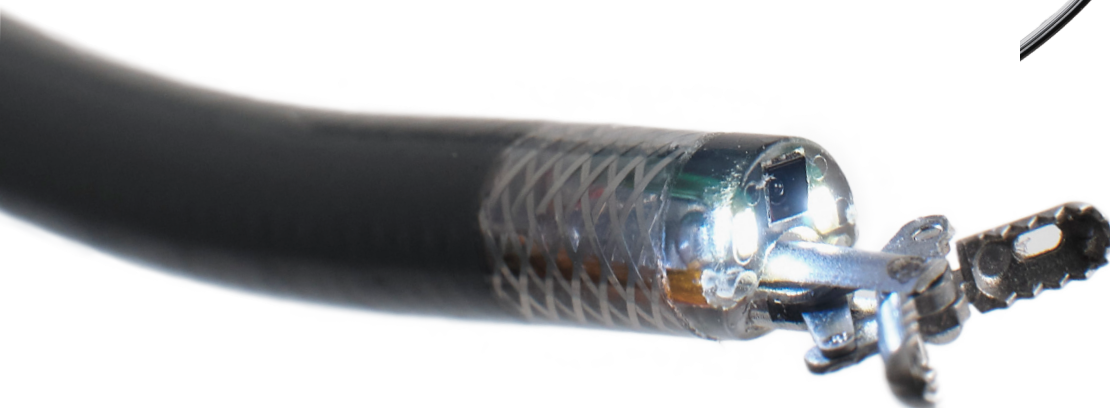
1 Geared handle mechanism

- Equipped with auto-locking feature
- Easy torque transmission with natural movements⁹

2 Advanced catheter design

- Reinforced catheter for durability and performance⁹
- Maintains cylindrical shape for easy device passability⁹

Flexible catheter designed to maintain shape integrity for efficient device passability⁹



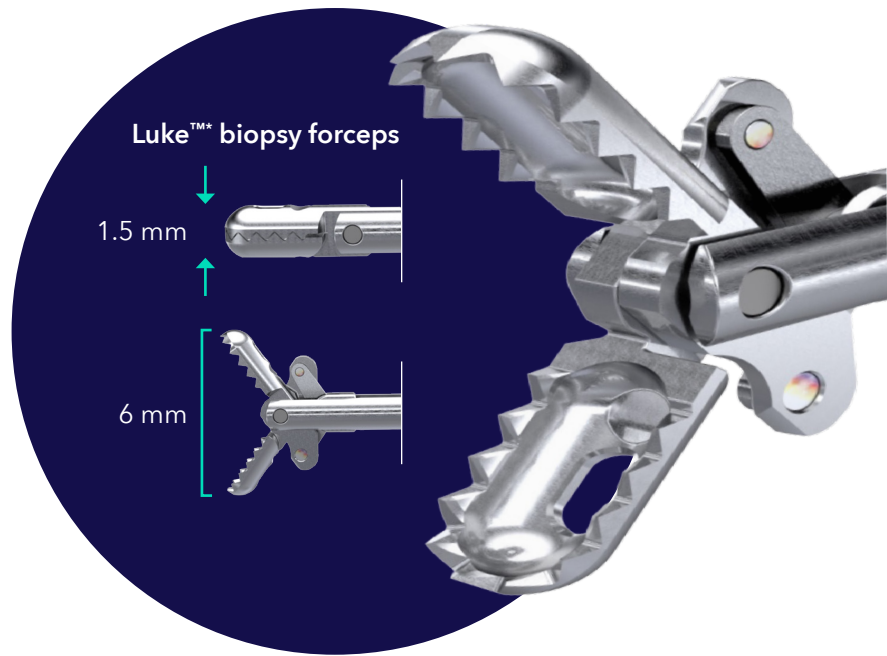
Product overview

Accessories

Diagnostics

Next-generation biopsy forceps

- Jaw rotation for enhanced control and positioning.
- Up to a 40% increase in tissue sample size^{†,12}



Therapeutics

Electrohydraulic lithotripsy system

- Three intensity options allow users to adjust energy levels based on stone densities
- Reduced tensile phases of concentrated energy enable accurate stone fragmentation while minimizing harm to soft tissue
- Centered micro-shockwaves facilitate targeting with fast pulses and sharply rising amplitudes

Accessories purpose-built to help improve clinical outcomes

3.0 and 4.5 Fr EHL probe



Before

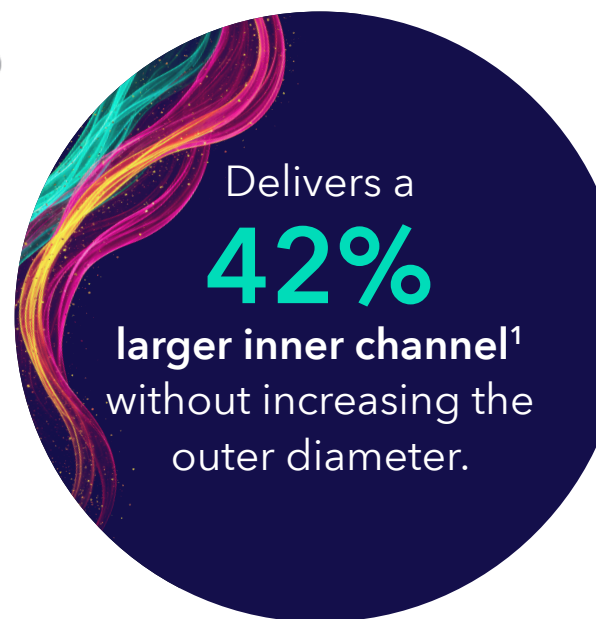


After







[†] Findings based off an ex vivo study.

Competitive comparisons

Cholangioscope catheter				
	Dragonfly™ endoscope	SpyGlass™ DS II	eyeMax™	eyeMax™
Outer diameter	10.5 Fr	10.5 Fr	11.7 Fr	9.6 Fr
Working length	176 cm	214 cm	220 cm	220 cm
Working channel	1.7 mm	1.2 mm	2.0 mm	1.2 mm
Biopsy forceps				
	Luke™ forceps	SpyBite™ Max Forceps	eyeMax™ Cam Alligator	eyeMax™ Twin Wire Alligator
Cup size	1.5 mm	1.0 mm	1.6 mm	1.0 mm
Working length	230 cm	286 cm	290 cm	290 cm
Working channel	1.7 mm	1.2 mm	2.0 mm	1.2 mm
EHL				
	Walz™	Autolith™ Touch System	Walz™ Lithotron EL27	Walz™ Lithotron EL27
Probe outer diameter	3.0 and 4.5 Fr	1.9 Fr	3.0 Fr	2.4 Fr
Probe working length	300 cm	375 cm	300 cm	300 cm
Working channel	1.7 mm	1.2 mm	2.0 mm	1.2 mm



Ordering information

Dragonfly™ pancreaticobiliary system				
	Product code	Description	Unit of sale	Items per unit of sale
	DFE-MD-000652	Dragonfly™ pancreaticobiliary scope	EA	1
	DFE-MD-000658	Dragonfly™ digital controller (DDC)	EA	1
	BFC-MD-000650	Luke™ biopsy forceps - 1.5mm	EA	1
	EL27C115VEHL	Walz™ electrohydraulic lithotripsy (EHL) generator	EA	1
	P303000FST	Walz™ electrohydraulic lithotripsy (EHL) probe - 3.0Fr	EA	1
	P453000FST	Walz™ electrohydraulic lithotripsy (EHL) probe - 4.5Fr	EA	1

Regulatory clearance



May 2, 2024

CenterPoint Systems LLC
Conner Johnson
Regulatory/Quality Associate
3338 Parkway Blvd
West Valley City, Utah 84119

Re: K233752

Trade/Device Name: Dragonfly™ Pancreaticobiliary Scope; Dragonfly™ Digital Controller;
Dragonfly™ Instrument Channel Caps
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FBN, NTN, FET, ODC
Dated: April 2, 2024
Received: April 2, 2024

Dear Conner Johnson:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov



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representative for more
information or visit
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