Medtronic

Quick setup guide



For use with the Dragonfly^{™*} digital controller and Dragonfly^{™*} pancreaticobiliary scope

Inspection and preparation

- 1. Inspect the packaging for damage; do not use if compromised.
- 2. Ensure the device is sterile and not past the expiration date.
- 3. Check all components for damage before use.

System setup

Connect to the controller:

- Insert the power supply and video cable into the corresponding receptacles on the back of the Dragonfly™* Digital Controller (DDC).
- Insert the Dragonfly[™] Pancreaticobiliary Scope (DPS) cable connector into the DDC until it is fully seated (arrows will be facing up). Push the power button to turn on/off (the power button will illuminate blue when DDC is on).
- 3. Verify a clear video image on the screen. When a DPS is not plugged in, you will see color bars on the screen.
- 4. Adjust brightness using the brightness control knob.

Articulation controls

1. The flexible shaft of the DPS can be torqued 220 degrees from neutral in either direction by rotating the torque control knob on the catheter controller.

2. The deflection section of the DPS can be deflected upward (from 6 o'clock to 12 o'clock) by rotating the deflection control knob clockwise (away from the user).

Attach to duodenoscope

- 1. Select the appropriate instrument channel cap and attach it to the duodenoscope.
- 2. Connect irrigation pump and flush the working channel of the DPS with saline to minimize air bubbles when later irrigating the target duct.
 - If desired, connect a contrast or aspiration source to the working channel port of the DPS via tubing or syringe.
 - The luer type cap supplied on the working channel port can be removed.
 - To use the working channel port, close the Tuohy Borst valve to prevent the influx of air or egress of fluid from the working channel.
- 3. Insert the tip of the DPS through the instrument channel cap with or without a guidewire in place.
- 4. Secure the attachment strap to the plastic tab after wrapping it around the duodenoscope and onto the clip. Actuate the clip to tighten the attachment strap around the body of the duodenoscope.

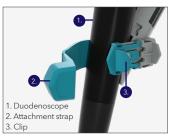


Figure 1a. Securing the Dragonfly Pancreaticobiliary Scope to the duodenoscope. Wrap attachment strap around body of duodenoscope and seat onto clip. Actuate the clip to tighten.

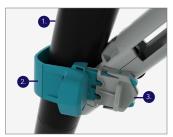


Figure 1b. Strap shown seated onto clip in tightened position. Depress arms of clip to release tension.

5. Detach the yellow loading lock from the DPS (set aside the loading lock during the entirety of the procedure as it is important to have this attached to the DPS anytime you're introducing it down the duodenoscope channel).

Position and advance the DPS

- 1. Advance the flexible shaft using short, controlled movements of the catheter controller.
- 2. Adjust rotation using articulation control knob and adjust tip deflection using the deflection control knob.
- 3. Apply irrigation and suction as needed for visualization and continue to advance the shaft into the pancreaticobiliary system.



Electrohydraulic lithotripsy

- When utilizing Walz^{™*} EHL, plug in the power cord, probe connector cable, foot pedal, and potential equalization cable. Turn on the generator.
- 2. Attach the desired probe (3.0 or 4.5Fr) to the connector on the generator face (only after verifying that the physician will in fact be utilizing the probe).

- 3. The generator will auto-recognize which probe you are using, and the corresponding probe indicator light will start to blink. Insert the probe down the DPS working channel first, then push the button to confirm probe size (once you push the probe button, disconnecting will deactivate probe use as probes are programmed for one use).
- 4. NOTE there is no "standby" feature on the generator, therefore DO NOT turn on the generator until confirming with the physician that the EHL probe is advanced and visualized in the duct on the endo screen. EHL is then initiated through powering on the generator. Following completion of each EHL treatment, unplug the foot pedal as a best practice to avoid inadvertent activation (while keeping the generator on).

Removal and disposal

- 1. Retract the flexible shaft and remove the accessory.
- 2. Detach DPS from the duodenoscope by releasing the attachment strap.
- 3. Disconnect any other tubing, unplug the cable connector from the DDC, and remove DPS from the duodenoscope.
- 4. Dispose of the device following biohazard protocols.

Troubleshooting

- Loss of Image: Check all connections, clean cable contacts, restart the controller.
- **Deflection Control Failure:** Use a guidewire to help straighten the scope before removal.

Indications for use

The Dragonfly[™] pancreaticobiliary scope is intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.

The Dragonfly™ digital controller is intended to provide illumination power and receive, process and output images from the Dragonfly pancreaticobiliary Scope for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.

For detailed safety, warnings, and instructions, refer to the Instructions for Use (IFU).

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