



EXALT™ Model D
Single-Use Duodenoscope
The World's First Single-Use Duodenoscope



EXALT™ Model D Single-Use Duodenoscope is designed to support your mission to deliver the highest quality patient care.

Start every ERCP with a **brand new, sterile duodenoscope** for each patient. The single-use platform delivers consistent, predictable performance. EXALT Model D Duodenoscope builds on our legacy of delivering **innovative, single-use devices** designed to enhance patient safety and streamline procedures.

Out of the box, consistent performance.

**One patient.
One duodenoscope.
One dramatic advancement
in single-use technology.**

Familiar Design

The EXALT™ Model D Single-Use Duodenoscope provides clinicians a familiar design in a single-use platform.



Lightweight, familiar design in a single-use platform



4-way bending capability at the distal tip with a range of motion comparable to reusable duodenoscopes that will not degrade over time



The elevator is designed to deliver consistent performance and facilitate guidewire locking at the distal tip of the duodenoscope



Designed to facilitate image capture and integrate with your endoscopic report writer

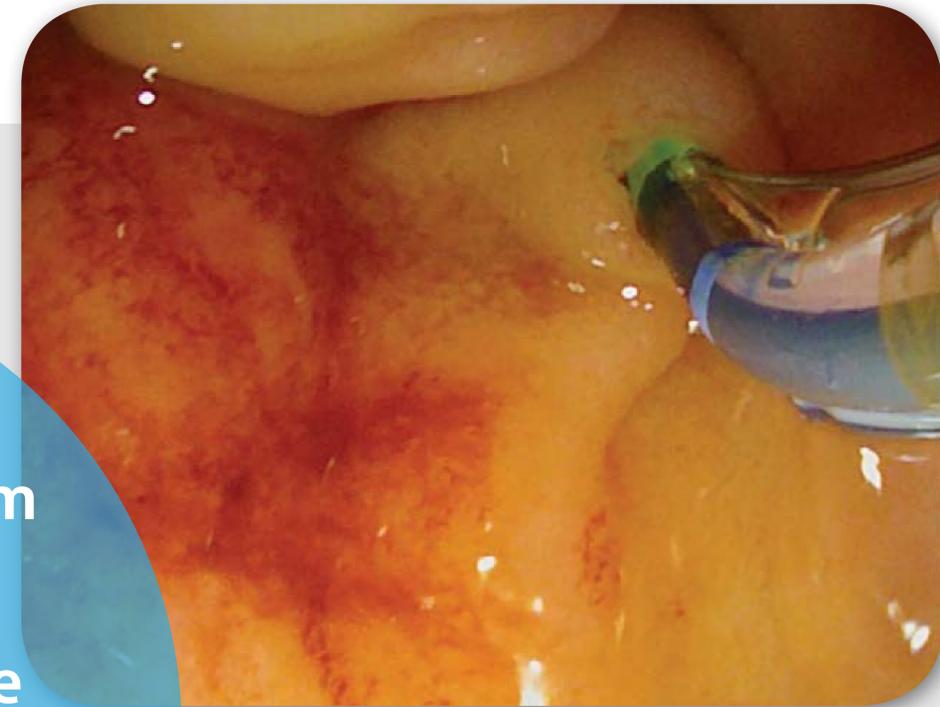
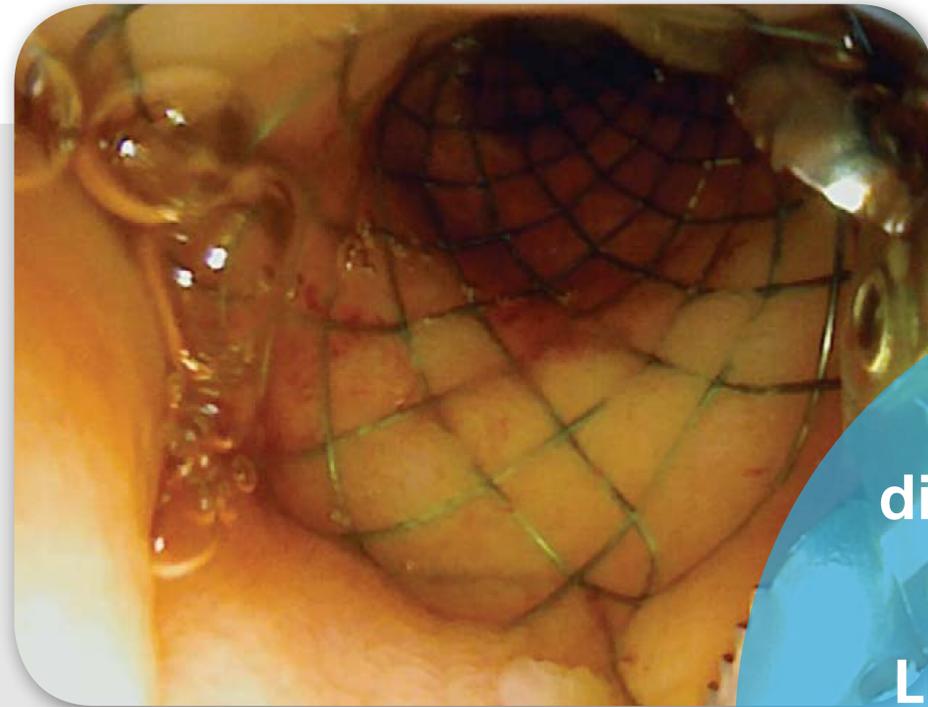


Use with the EXALT Controller, designed to provide a reduced capital footprint during ERCP



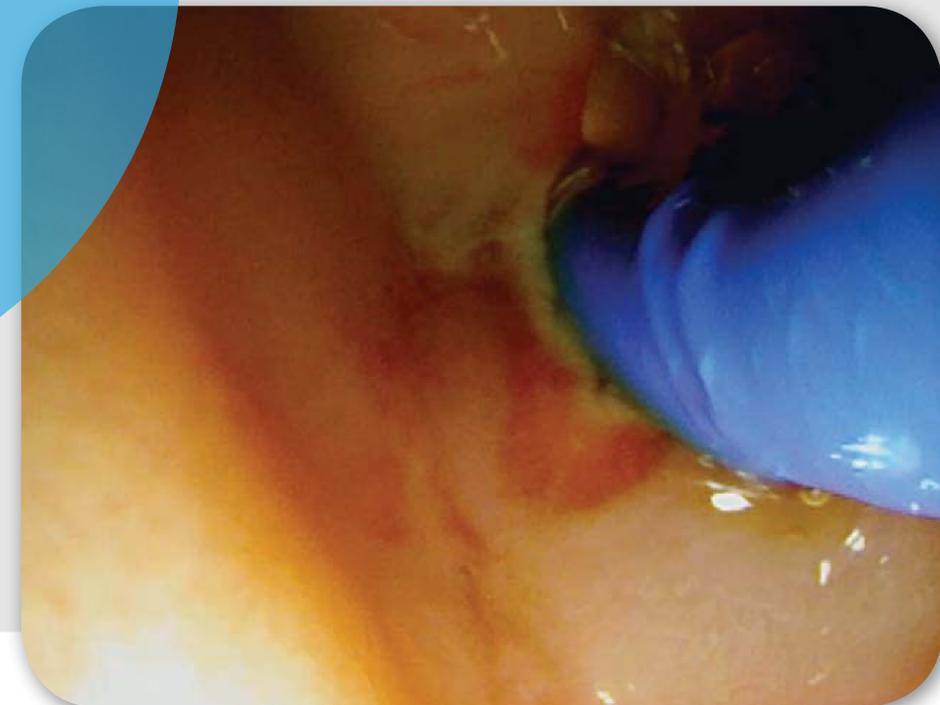
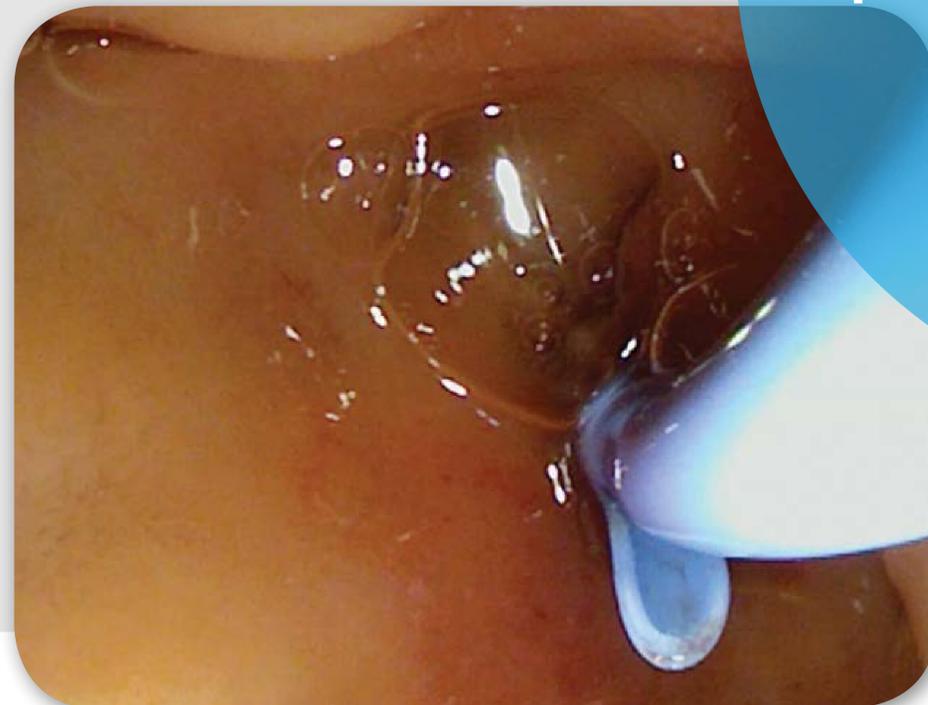
Compatible with Boston Scientific single-use endoscope accessories

EXALT™ Model D Single-Use Duodenoscope



High resolution,
digital camera system
for clear imaging.

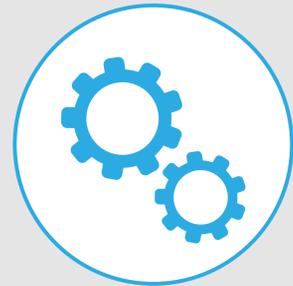
LED lighting in scope
tip designed for optimized
illumination.



Reprocessing

Duodenoscope Reprocessing is in a State of Transition

The environment, equipment, and guidelines that inform cleaning procedures are frequently changing.



Increased endoscope complexity

Reprocessing manuals are complex and outbreaks have occurred despite adherence to manufacturer's instructions.¹



Emergence of multi-drug resistant organisms (MDRO)

MDROs provided an indicator to recognize duodenoscope transmitted infections.



Changes in reprocessing guidance

In addition to meticulous adherence to manufacturers' instructions, the FDA recommends health care facilities performing ERCP implement supplemental reprocessing measures to further reduce risk of infection.²



Regular personnel turnover

Staff turnover makes it challenging to maintain compliance to evolving guidelines.



Focus on auditing standards

In 2017, 72% of Joint Commission surveyed hospitals were found to be non-compliant with the IP Standard IC.02.02.01.³

1. Ofstead et al. Endoscope Reprocessing Methods A Prospective Study on the Impact of Human Factors and Automation. Gastroenterology Nursing. 2010. 33(4): 304-311.

2. U.S. Food and Drug Administration. Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication. August 2015. <https://www.fdanews.com/ext/resources/files/08-15/081015-duodenoscopes-fda.pdf?1520541508>

3. The Joint Commission. Joint Commission 4-1-1 on Survey Enhancements: New scoring revisions for IC.02.02.01 now in effect. https://www.jointcommission.org/assets/1/23/JC_Online_Sept_5.pdf

Single-Use Efficiency

EXALT™ Model D Duodenoscope is a sterile single-use device, providing an option that foregoes reprocessing.

EXALT Model D Duodenoscope **eliminates the burden of reprocessing** reusable duodenoscopes including staff time and material costs to manage involved reprocessing recommendations. By eliminating the work load burden required to reprocess and service reusable duodenoscopes, the EXALT Model D Duodenoscope may alleviate certain burdens placed upon hospital staff.



Scope of the Problem

Duodenoscope reprocessing manuals are complex and can average*:

100+ PAGES & **150+** STEPS

Duodenoscopes are more intricate in design than other endoscopes, including a movable “elevator” mechanism at the tip which may be extremely difficult to access and clean effectively.



STORAGE



DRYING



HIGH LEVEL DISINFECTION



VISUAL INSPECTION



MANUAL CLEAN



LEAK TEST



PRE-CLEAN

*Olympus Reprocessing Manuals

Comprehensive Integration Services

**Boston
Scientific**
Advancing science for life™

EXALT Model D
Duodenoscope



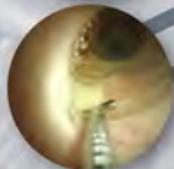
Endoscopic
Ultrasound



Colonoscopy
& EGD



Cholangioscopy



"White glove" integration services provided by our team of specialized Customer Integration Coordinators

Seamless integration with existing technology, including SpyGlass™ DS II System, Endoscopic Ultrasound, and many medical writing software

System integration helps ensure compatibility with major endoscope manufacturers allowing for full or partial adoption of EXALT Model D Duodenoscope based on your needs

Ordering Information

UPN	Item	Description	Packaging
M00542420	EXALT™ Model D Single-use Duodenoscope	Sterile Single-use Duodenoscope for use with EXALT Controller	Box 1
M00542421	EXALT Model D Single-use Duodenoscope	Sterile Single-use Duodenoscope for use with EXALT Controller	Box 2
M00542423	EXALT Model D Single-use Duodenoscope	Sterile Single-use Duodenoscope for use with EXALT Controller	Box 4
M00542424	EXALT Model D Single-use Duodenoscope	Sterile Single-use Duodenoscope for use with EXALT Controller	Box 8
M00542430	EXALT™ Controller	100-240 VAC Controller for use with single-use duodenoscope (including detachable US power cable, DVI and HDMI cables)	Box 1



Familiar Design Specifications

Specification	Value
Retro viewing angle (°)	5
Field of view (°)	108
Depth of field (mm)	5-60
Distal end outer diameter (mm)	15.1
Insertion tube outer diameter (mm)	11.3
Working length (mm)	1240
Working channel inner diameter (mm)	4.2
Angulation range Up (°)	120
Angulation range Down (°)	90
Angulation range Right (°)	110
Angulation range Left (°)	90



Boston Scientific is dedicated to environmental sustainability



95%

Solid Waste
Landfill
Avoidance

47%

Reduction
76,000 Tons
in greenhouse gas
emissions since 2009,
exceeding our goal of 35%
reduction by 2019

30%

Reduction
in Water Use
since 2009

EXALT™ Model Single-Use Duodenoscope



Decreases
waste from
disinfecting
consumables



May contribute
to reduction of
water and
energy costs



Can minimize staff
exposure to
potentially harmful
toxic chemicals

EXALT™ Model D Recycling Program

Boston Scientific has partnered with an industry leader in medical recycling to offer the EXALT Model D Recycling Program

How It Works:



Place used EXALT Model D Single-use Duodenoscope in the designated collection container.



Place closed collection container in small, 4-mil, leak-proof, biohazard labeled plastic bag and securely seal using included tie wraps. Place bag in shipping box.



Close flaps on the shipping box and tape the box closed with the included packing tape. *Make sure the UPS prepaid return shipping label is visible.



Transport sealed shipping box to designated receiving area for hand-off to UPS. A UPS pickup can be scheduled at 800-772-5657. *Return freight is prepaid. No additional charges apply.



Fill out included list of Contents Form noting the device and quantities. Place form on top of pre-bagged containers but within shipping box liner.



Boston Scientific will provide an annual sustainability report outlining the environmental benefits specific to your program.



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Indications, Contraindications, Warnings and Instructions for Use can be found in the product labeling supplied with each device.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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