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

EXALT" Model D

Boston Scientific Advancing science for life[™]

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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 to enhance patient safety and streamline procedures.

Out of the box, consistent performance.

One patient.

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

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



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



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



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



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



Compatible with Boston Scientific single-use endoscope accessories

Performance

EXALT[™] Model D Single-Use Duodenoscope





High resolution, digital camera system for clear imaging.

LED lighting in scope tip designed for optimized illumination.







Clinical Trial EXALT^m Model D Single-Use Duodenoscope



In a consecutive case series of the EXALT Model D Duodenoscope, 60 ERCPs, of all 4 ASGE complexity levels, were completed across six sites in the United States for indications including pancreaticobiliary stone clearance, stent placement, exchange and/or removal and balloon dilation.

Data on file.



96.7%

All ERCP procedures were successfully performed, of which 96.7% were completed with the single-use duodenoscope alone and 3.3% with crossover to a reusable duodenoscope.

Muthusamy VR1, Bruno MJ, Kozarek RA3, Petersen BT4, Pleskow DK5, Sejpal DV6, Slivka A7, Peetermans JA8, Rousseau MJ8, Tirrell GP8, Ross AS3. Clinical evaluation of a single-use duodenoscope for endoscopic retrograde cholangiopancreatography. Clin Gastroenterol Hepatol. 2019 Nov 6. pii: S1542-3565(19)31261-3. doi: 10.1016/j.cgh.2019.10.052. [Epub ahead of print]



OF10

The median overall satisfaction with the single-use duodenoscope by physicians was rated as 9 out of 10.

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.



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.



Regular personnel turnover

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

Increasing focus of auditing bodies

Auditing bodies increasingly focus on Endoscopy and especially on reprocessing of Duodenoscopes.



Single-Use for Efficiency **EXALT[™] Model D Duodenoscope is a sterile single-use device,** providing you an option that foregoes reprocessing.

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



Scope of the Problem* **Duodenoscope reprocessing manuals are complex and can average:**

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.

PAGES





PRE-CLEAN



LEAK TEST

Ordering Information

UPN	ltem	Description	Languages	Packaging
M0054242CE0	EXALT [™] Model D Single-use Duodenoscope	Sterile Single-use Duodenoscope for use with EXALT Controller	NA	Box 1
N0054242CE1	EXALT Model D Single-use Duodenoscope	Sterile Single-use Duodenoscope for use with EXALT Controller	NA	Box 2
00542430	EXALT [™] Controller	100-240 VAC Controller for use with single-use duodenoscope (including detachable power cable, DVI and HDMI cables)	English, Spanish, French, German, Italian, Dutch and Portuguese	Box 1
	EXALT Controller	100-240 VAC Controller for use with single-use duodenoscope (including detachable power cable, DVI and HDMI cables	English, Danish, Greek, Portuguese-Brazil, Swedish, Hungarian, Czech, Polish, Norwegian, Korean, Turkish, Finnish, Romanian and Slovak	Box 1
	Example vitalities system Besterning			
	A LE MARIO			

Familiar Design Specifications

Specifications Value

Retro viewing angle (°)

Field of view (°)

Depth of field (mm)

Distal end outer diameter (mm)

Insertion tube outer diameter (mm)

Working length (mm)

Working channel inner diameter (mm)

Angulation range Up (°)

Angulation range Down (°)

Angulation range Right (°)

Angulation range Left (°)

EXALT™ Model D Duodenoscope	
5	
108	
5-60	
15.1	
11.3	
1240	
4.2	
120	
90	
110	
90	
1	



Innovative products and a commitment to the way we conduct business GOOD FOR YOU, GOOD FOR YOUR PATIENTS, **GOOD FOR THE ENVIRONMENT.**

EXALT[™] Model D Single-use Duodenoscope



Decreases waste from disinfecting consumables



Helps reduce your water and energy costs



Eliminates staff exposure to potentially harmful toxic chemicals

The Boston Scientific environmental, health and safety programs show positive results around the globe

95% LANDFILL **AVOIDANCE** for our solid waste

41% REDUCTION (66,000 Tons) in greenhouse gas emissions since 2009, exceeding our goal of 35% reduction by 2019

NEWSWEEK GREEN RANKING:

https://www.newsweek.com/full-list-US-companies-green-rankings-2017-18

30% REDUCTION

> in water use since 2009

Ranked 16th greenest US company in 2017 - 2018



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