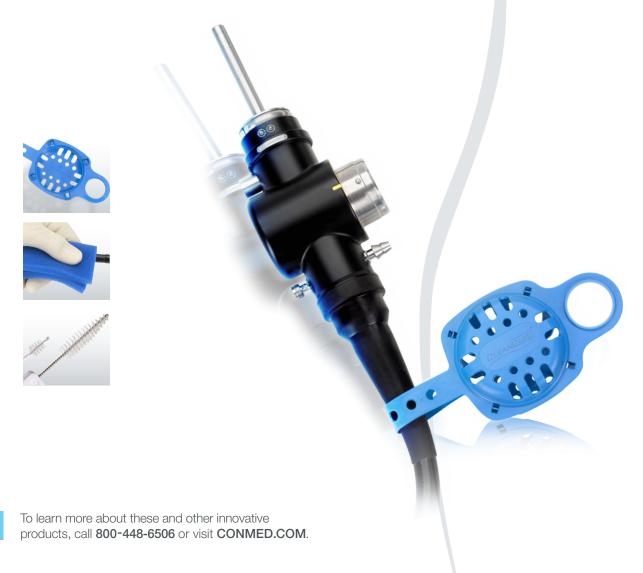




# Improper Scope Reprocessing is Dangerous and has caused Patient Infections.<sup>1-6</sup>

Meeting the standards of ASGE, SGNA and AAMI, CONMED has a portfolio of products designed to help ensure your patients' safety and reduce the risk of endoscopy-related infections.



# Problem:



The improper cleaning of scopes used in ERCP procedures can expose patients to carbapenem resistant enterobacteriaceae (CRE) infections. Resistant to most available antibiotics, the CDC states that these infections are very difficult to treat, and can be deadly — with one report citing they can contribute to death in up to 50% of patients who become infected.<sup>1</sup>

A widespread problem, the FDA found that as many as 350 patients at 41 medical facilities in the U.S. and worldwide were infected or exposed to tainted gastrointestinal scopes while a separate Senate Investigation found 250 scope-related infections at 25 hospitals and clinics in the U.S. and Europe.<sup>6</sup>

Recently, there have been a string of high-profile cases that have resulted in patient deaths, infections, product recalls and nationwide negative press, investigations, lawsuits and scrutiny of the offending facilities.<sup>1-6</sup>

2012	38 patients at a hospital contracted the deadly superbug CRE after
2013	being treated with duodenoscopes. <sup>3,4</sup>

2014 39 patients at a hospital were infected with antibiotic-resistant infections after undergoing ERCP. At least 18 of those patients later died.<sup>2,3</sup>

2015 In another outbreak at a hospital, 5 patients were sickened, and 3 died.<sup>6</sup>

2016 2 patients died and 6 more were sickened in a new outbreak suspected of being caused by contaminated medical scopes.<sup>5</sup>



# FDA & Professional Societies Respond with New Standards.

Following these outbreaks, many of the world's leading authorities for healthcare professionals issued new standards and best practices for safer, more effective reprocessing.

- In 2015, The FDA issued a Safety Communication recommending strict adherence to general endoscope reprocessing guidelines and practices established by the infection control community and endoscopy professionals.<sup>12</sup>
- The Society of Gastroenterology Nurses and Associates (SGNA) released a revised version of their Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes that included new endoscope reprocessing protocols for the cleaning and high-level disinfection of endoscopes, from pre-cleaning through storage.<sup>8</sup>
- The American Society for Gastrointestinal Endoscopy (ASGE) released new guidelines
  recommending endoscope pre-cleaning should be performed at the point of use, before bioburden
  has an opportunity to dry and before complete decontamination by removing visible debris with
  appropriate detergent solution and aspiration of a large volume of detergent through the air/water
  and biopsy channels.<sup>13</sup>
- In 2015, The Association for the Advancement of Medical Instrumentation (AAMI) and American National Standards Institute (ANSI) released ANSI/AAMI Standard ST91:2015 with new guidelines for pre-cleaning, leak-testing, cleaning, storage, high-level disinfecting and sterilizing of flexible Gl endoscopes.<sup>7</sup>
- In 2015, The ECRI Institute issued a High Priority Hazard Report with recommendations to help reduce the risk of ERCP endoscope-related patient infections. They recommended scope culturing<sup>9</sup> as well as called for increased identification and tracking of endoscopes during cleaning and patient use.<sup>10-11</sup>

### **How Can Your Facility Comply?**

Considering the potential for patient death, infection, lawsuits, reputation damage and/or worse, facilities can't afford to risk not following these new infection control standards. **CONMED** has a portfolio of products designed to help ensure your patients' safety and reduce HAIs.

## **CONMED Solution:**

INFECTION PREVENTION SOLUTIONS

# **CleanCage**™ Endoscope Valve-Tracking System

CleanCage<sup>™</sup> helps ensure safe handling and tracking of endoscope valves during cleaning, disinfection & storage.

#### **Traceability**

New reprocessing standards require you to track which scope is used with which patient. CleanCage $^{\sim}$  keeps your valves and other detachable parts together with the parent endoscope during reprocessing so you can track where they were used.

#### Meets the Standards of AAMI, ANSI & SGNA

CleanCage™ meets standards of AAMI, American National Standard ST91; 2015 & SGNA Standards of Infection Prevention in Reprocessing of Flexible Gastrointestinal Endoscopes.

#### Single-Use for Safety

Unlike mesh bags that get reused, remain wet after reprocessing and have the potential for contamination, CleanCage™ is a disposable, single-use product to help ensure your patients' safety and your peace of mind.







Simply add water to this all-in-one tray, channel cleanser and scope sponge to simplify and standardize your immediate post-procedure bedside endoscope pre-cleaning.

#### **Meets Industry Guidelines**

CleanTray™ meets the pre-cleaning guidelines as defined in ASGE's Multisociety Guideline on Reprocessing Flexible GI Endoscopes as well as the SGNA Practice Committee Standards of Infection Control.

#### **Reduced Costs**

Using the CleanTray™ System is as simple as adding water. This reduces the shipping costs of pre-mixed products as well as reduces the storage space needed in your facility.

#### **Sturdy Construction**

The solid tray construction helps make it easier to maneuver the scope compared to competitive products that use a pouch.





Meeting the standards and pre-cleaning guidelines of industry organizations.







# **CONMED Solution:**



# ClearGuard™ Single-Use Biopsy Valves

Sterile, single-use clear biopsy valves are the only means of eliminating all risk of transferring infection by way of accessories from one patient to another.<sup>14</sup> Their disposability also eliminates the need for tracking and registration, enabling the use of simpler processes that require less training.

# Channel Master™/ Blue Bullet® Disposable Cleaning Brushes

CONMED offers a full range of cleaning brushes to clean a variety of scope channels prior to sterilization. We provide the Channel Master™ and the Blue Bullet® series of endoscopic cleaning brushes.

Both product lines offer single, double and a variety of combo and dual-ended brushes. The Blue Bullet® provides a stiffer bristle and a longer working shaft option.



# Take the next step toward ensuring your facilities safety.

Call 800.448.6506 to locate your local CONMED Sales Representative or visit CONMED.com for more information.

¹ Centers for Disease Control & Prevention. http://www.cdc.gov/HAI/organisms/cre/

<sup>&</sup>lt;sup>2</sup> "Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients' *United States Senate Health, Education, Labor & Pensions Committee.* Minority Staff Report. 1/13/2016.

<sup>3</sup> McCaughey, Betsy, "The Feds Dawdle While Patients Die Needlessly," The New York Post, 4/6/2016.

McCoppin, Robert and Cynthia Dizikes, "Superbug found at suburban hospital," The Chicago Tribune, 1/10/2014

<sup>&</sup>lt;sup>5</sup> Peterson, Melody. "Two more deaths may be linked to contaminated medical scopes." *The Los Angeles Times.* 4/25/2016.

<sup>&</sup>lt;sup>6</sup> Terhune, Chad. "Tainted Scope Infections Far Exceed Earlier Estimates." Kaiser Health News. 4/15/2016

<sup>&</sup>lt;sup>7</sup> "Flexible and semi-rigid endoscope processing in health care facilities." ANSI/AAMI ST91:2015 Association for the Advancement of Medical Instrumentation (AAMI), 4/8/15.

SGNA Releases Revised Standards of Infection Control in Reprocessing of Flexible GI Endoscopes." Infection Control Today. Press Release. 9/10/2012.

<sup>&</sup>lt;sup>9</sup> "High Priority Hazard Report: ECRI Institute Recommends Culturing Duodenoscopes as a Key Step to Reducing CRF Infections." *FCRI Institute*, 5/13/2015.

<sup>&</sup>lt;sup>10</sup> "Superbug Outbreak Triggers Need for Better Tracking of Scopes." *ECRI Institute*. Press Release. 9/9/2015

<sup>&</sup>quot;Tracking Scopes: Best Practices for Identifying Endoscopes During Cleaning and Patient Use." ECRI Institute. Press Release. 9/30/2015.

<sup>&</sup>quot;Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning." FDA Safety Communication. 2/23/2015.

<sup>&</sup>lt;sup>13</sup> Multi-society guideline on reprocessing flexible GI endoscopes: 2011 1078 *GASTROINTESTINAL ENDOSCOPY* Volume 73, No. 6 : 2011

<sup>&</sup>lt;sup>14</sup> BSG Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy. The Report of a Working Party of the British Society of Gastroenterology Endoscopy Committee. February 2008.





## Ordering Information

Description			Qty.	Catalog No.	
CleanCage <sup>™</sup> Endoscope Valve-Tracking System					
Endoscope Valve Cage			100/box	CC8475	
CleanTray™ Endoscope Pre-Cleaner					
Bedside Pre-Cleaning Endoscope Kit	100/box	CT7357			
ClearGuard™ Single-Use Biopsy Valves					
Biopsy Valve for Olympus and Fujinon	100/case	000522			
Biopsy Valve for Pentax	100/case	000523			
	Pruch (Dio v "I")	Choft ("I")			
Channel Master™ Endoscope Cleaning Brushes Brush (Dia x "L") Shaft ("L")  (Biopsy channel range 2.0-4.2mm, Shaft 0.D. 1.8mm)					
Pediatric Brush	6.4mm x 7.4mm	160cm	50/box	000610	
Dual-Ended Brush	6.4mm x 7.4mm	230cm	50/box	000615	
Single-Ended Brush	6.4mm x 7.4mm	230cm	50/box	000639	
Combination Valve Cleaning Brush	7.9mm x 29.2mm	230cm	50/box	000617	
for Gastroscope/Colonoscope	6.4mm x 7.4mm				
Large Combination Valve Cleaning Brush for Gastroscope/Colonoscope	9.7mm x 45.2mm 6.4mm x 7.4mm	230cm	50/box	000619*	
Blue Bullet® Disposable Cleaning Brushes** Brush (Dia x "L")		Shaft ("L")			
Bronchoscope	3mm x 13mm	250cm	50/box	480	
Gastro/Duodeno/Colonoscope	3mm x 13mm	250cm	50/box	473	
Gastro/Duodeno/Colonoscope	4mm x 13mm	250cm	50/box	474	
Gastro/Duodeno/Colonoscope	5mm x 13mm	250cm	50/box	478	
Gastro/Duodeno/Colonoscope	6mm x 13mm	250cm	50/box	476	
Combination Valve/Channel Cleaning Brush for Gastroscope/Colonoscope	10mm x 38mm 5mm x 13mm	250cm	50/box	478C	
Double-End Cleaning Brush for Gastroscope/Colonoscope	5mm x 13mm	250cm	50/box	478D	
Whistle® Endoscope Cleaning Brushes*** Brush (Dia x		Shaft ("L")			
( Biopsy channel minimum 2.8mm, Shaft O.D. 1.8mm)					
Whistle® Cleaning Brush	6.4mm x 13.1mm	230cm	50/box	000101	

Customer Service: 1-800-448-6506 CONMED.com International Sales: 1-315-797-8375 info@mail.conmed.com Fax: 1-800-438-3051

©2016 CONMED Corporation, MCM2016120 5/16

<sup>\*</sup> Large combination brush includes longer and larger diameter bristles on valve brush.

\*\* The 400 series Blue Bullet<sup>®</sup> feature a blue opaque tubing.

\*\*\* Contains female luer adapter, hollow shaft, and port hole for fluid injection to soften channel obstructions.