

Comparative Cleaning Brush Test Report

DuoSwift® combination squeegee brush

US Endoscopy is an industry leader in infection prevention within the Gastroenterology suite, and offers a complete line of single-use cleaning brushes to fit Customers' cleaning needs. US Endoscopy's cleaning brushes include features such as textured, non-slip catheters, specially designed nylon bristles, and gently rounded brush tips – ideal elements when caring for delicate endoscopes.

Cleaning brushes are intended to be used during manual cleaning in the reprocessing and care of equipment, instruments, and endoscopes after a procedure. They aid in the removal of biomaterial present in endoscope channels, instrument lumens, and on accessories prior to high level disinfection or sterilization. Manual cleaning is a critical reprocessing step, removing more than 99 percent of the bioburden from the endoscope prior to autoreprocessing.¹ SGNA Standards state that manual cleaning "is the most important step in removing the microbial burden from an endoscope."² For proper manual cleaning the standards require brushing all accessible endoscope channels, as well as the body, insertion tube, and the umbilicus of the endoscope, using a brush size compatible with each channel.³

US Endoscopy is committed to offering innovative solutions that help enhance the manual cleaning process. The DuoSwift® combination squeegee brush has been tested and proven to effectively clean endoscope channels per industry standards and endoscope manufacturer instructions. The DuoSwift® combination squeegee brush has also proven to enhance manual cleaning efficiency when compared to the leading endoscope manufacturer's channel cleaning brush.

FEATURES

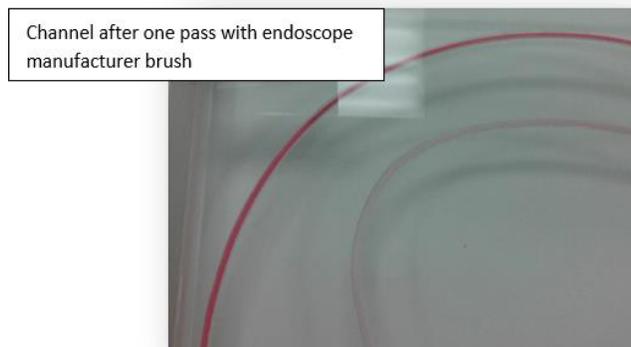
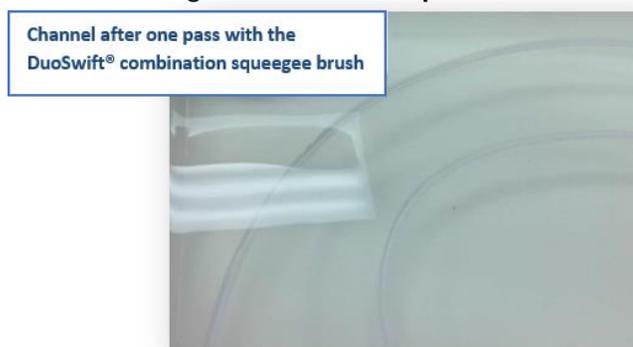
- Patent-pending **brush & squeegee combination** offers a unique design that reduces the number of passes required to effectively clean endoscope channels.
- Brush head on the leading end is **2 times longer than a standard brush** with a **denser bristle pattern** to help maximize cleaning touches and loosen and remove bioburden with friction.
- **Multiple squeegee discs** on the trailing end are flexible enough to conform to a wide range of channel diameters and effectively remove remaining liquid and debris after brushing.

SUMMARY OF TESTING

Third-party laboratory testing was conducted to compare the cleaning efficacy between the US Endoscopy DuoSwift® combination squeegee brush with the leading endoscope manufacturer channel cleaning brush, and found the DuoSwift® combination squeegee brush to outperform the manufacturer's channel cleaning brush when tested under equivalent conditions. This testing included manual cleaning of an endoscope following the endoscope manufacturer's instructions and an analysis of the bioburden present post-cleaning to measure manual cleaning effectiveness.⁴

Test results revealed that the DuoSwift® combination squeegee brush:

- Achieved the **industry benchmark of <6.4 µg/cm²** for effective cleaning **after a single pass** in extreme manual cleaning conditions.
- Removed more bioburden **in a single brush pass** than the leading endoscope manufacturer's standard channel cleaning brush in **10 brush passes**.



¹ Eddie Garces. "Consequences of improper scope cleaning". Infection Control Today. March 1, 2008

² SGNA Practice Committee. "Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes." Society of Gastroenterology Nurses and Associates (SGNA), 2016

³ SGNA Practice Committee. "Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes." Society of Gastroenterology Nurses and Associates (SGNA), 2016

⁴ Biotest Laboratories. "Efficacy Testing of Cleaning Brushes for US Endoscopy." 2016. Test Report on file with US Endoscopy.

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Specification Comparison	DuoSwift® combination squeegee brush	Endoscope Manufacturer channel cleaning brush
		
Brush bristle diameter	5-7mm tapered	6mm
Squeegee diameter	2.5-5.2mm	n/a
Brush head length	2.25cm	0.80cm
Working catheter length	230cm	220cm

Test Method

- Testing was conducted using two simulated endoscope channels. Each test channel was inoculated with a predefined amount of Browne disinfectant testing soil.
 - Channel 1 measured 2.8mm in diameter and was inoculated with 7mL of testing soil.
 - Channel 2 measured 3.7mm in diameter and was inoculated with 10mL of testing soil.
- The test channels were cleaned following the steps written in the endoscope manufacturer's instructions using each channel cleaning brush evaluated.
 - To simulate an **extreme manual cleaning scenario**, testing eliminated the bedside pre-cleaning step in endoscope reprocessing and the test soil was allowed to sit for two hours prior to brushing.
- The number of passes required to clean each channel was recorded and a residual protein analysis was conducted after manual cleaning was deemed completed.
 - Per SGNA Standards, manual cleaning is deemed completed when there is no longer debris visible on the brush.⁵
- This test was repeated using a new inoculated channel for each new cleaning brush evaluated.
- Residual protein was compared to a published industry benchmark used to determine cleaning efficacy.
 - ANSI/AAMI identifies a realistic benchmark of **<6.4 µg/cm² of protein** achieved by routine manual cleaning of flexible endoscopes.⁶

Test Results⁷

Simulated Device Cleaned	Channel Cleaning Brush	Residual Protein (µg/mL)	Residual Protein (µg/cm ²)*	# Brush Passes	% Reduction**
Channel 1 (2.8mm)	DuoSwift® combination squeegee brush	50.9	5.99	1	99.9%
	Endoscope Manufacturer channel cleaning brush	1626.1	191.24	10	97.7%
Channel 2 (3.7mm)	DuoSwift® combination squeegee brush	33.3	2.85	1	99.9%
	Endoscope Manufacturer channel cleaning brush	133.6	11.45	10	99.8%

*Industry benchmark for residual protein is <6.4 µg/cm².

** Positive control of 69,220 µg/mL was used to determine percent reduction.

Based on this testing, US Endoscopy can conclude that the DuoSwift® combination squeegee brush:

- Effectively cleans endoscope channels following industry standards and endoscope manufacturer instructions.
- Outperforms the leading endoscope manufacturer's channel cleaning brush under equivalent conditions.
- Enhances manual cleaning efficiency when compared to the leading endoscope manufacturer's channel cleaning brush.

⁵ SGNA Practice Committee. "Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes." Society of Gastroenterology Nurses and Associates (SGNA), 2016

⁶ Association for the Advancement of Medical Instrumentation (AAMI). "ANSI/AAMI ST91:2015 Flexible and Semi-Rigid Endoscope Processing in Health Care Facilities". 2015

⁷ Biotest Laboratories. "Efficacy Testing of Cleaning Brushes for US Endoscopy." 2016. Test report on file with US Endoscopy.