

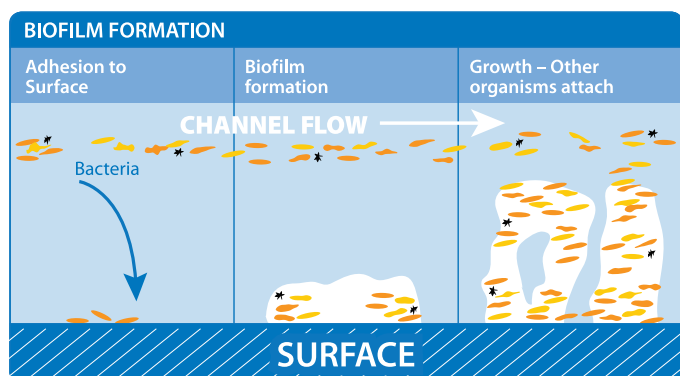
Matrix®

BIOFILM REMOVER



Matrix® is a breakthrough, revolutionary step forward in validated cleaning protocols

WHAT IS A BIOFILM?



A biofilm is a thin layer of micro-organisms adhering to a surface. These adherent cells produce a matrix of Extracellular Polymeric Substance (EPS), a sticky type of glue like material. The cells then become embedded within the EPS which protects viable bacteria and viruses.

Biofilms can be found everywhere in the environment. Biofilms are present on teeth as dental plaque. They are found in water supplies, air conditioning, ship hulls, paper manufacturing, oil recovery, food processing and many other applications including healthcare.

BIOFILMS IN HEALTHCARE

Medical devices are prone to biofilm growth and are responsible for a wide range of health related infections.

Biofilm growth has been reported on:

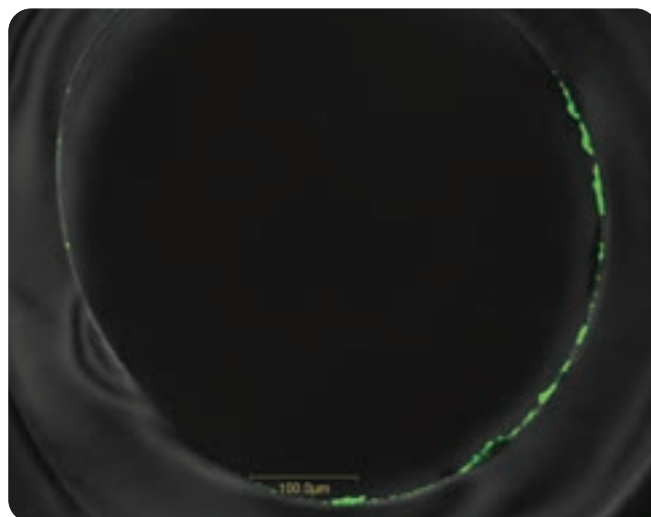
- Environmental healthcare surfaces
- Catheters
- Endoscopes
- Medical Devices (Breast, Orthopaedic, Cardiac and other implants)

Biofilms protect potentially colonising bacteria and viruses. Micro-organisms embedded in a biofilm can be up to 1,000 times more resistant to antibiotics and it is estimated by the US FDA that up to two thirds of all healthcare infections are related to a biofilm.

Scientific studies on reusable flexible endoscopes showed that 100% of patient ready endoscopes had biofilm present in their air/water channels. Biofilm has also been detected on working channels and other endoscopic surfaces.

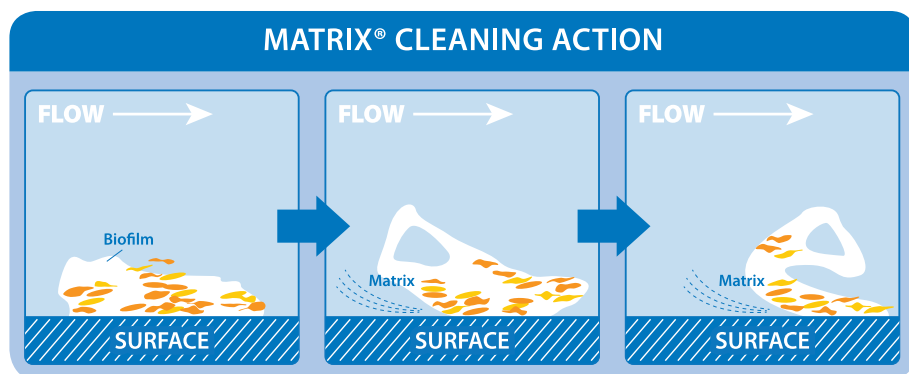
Biofilms differ from conventional biological soils as they adhere to a surface and “protect” themselves from both thermal and chemical attack.

Scientific studies on reusable flexible endoscopes showed that 100% of patient ready endoscopes had biofilm present in their air/water channels.



Lumen of patient ready endoscope in healthcare facility with green stain showing viable bacteria.

WHAT IS A BIOFILM?



MATRIX®

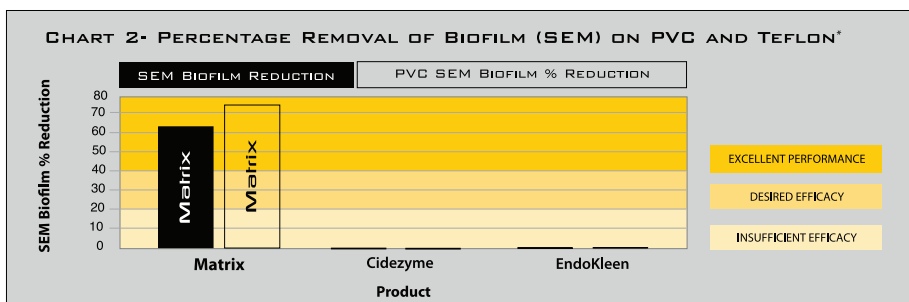
- MATRIX® breaks the surface adhesion causing the biofilm to 'peel-back' and collapse on itself
- MATRIX® dissolves the complex carbohydrates - EPS [Exo Poly Substance]
- MATRIX® impacts viable bacteria within the biofilm

MATRIX® is a formulation of surfactants specifically designed for removing conventional biological soils, bacterial biofilms and other microorganisms on medical devices.

MATRIX® is a breakthrough in validated cleaning protocols. MATRIX® has been scientifically proven to remove conventional biological soils and bacterial biofilms. Bacterial biofilms in which both bacteria and other micro-organisms may be embedded are more difficult to remove than conventional biological soils alone. Disease causing organisms have been proven to be transferred when protected within biofilms on improperly cleaned Medical Devices. Traditional cleaning solutions, most notably enzymatic detergent cleaners, have been demonstrated to be ineffective against bacterial biofilm soiling.

SCIENTIFIC DATA

RESULTS OF UNIVERSITY TESTING

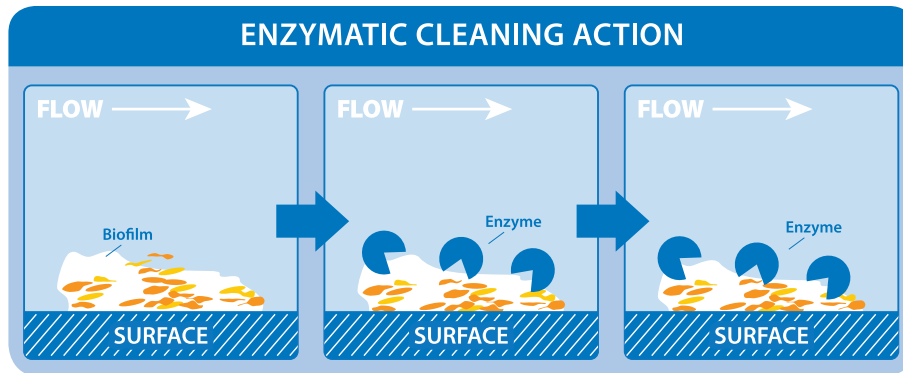


MATRIX® outperformed enzymatic detergents in every measure, in every test. Cleaning of Medical Devices has been identified as the critical first step in any effective instrument reprocessing system.

It is not always possible to see the accumulation of soils and bacterial biofilms in narrow lumens and on complex medical instruments due to their design. Bacterial colonies require microscopic examination by Scanning Electron Micrographs [SEM's] as they are not visible to the naked eye. Thus, even when internal and inaccessible surfaces can be visually inspected, contamination with biofilms may not be readily visible.

Biofilms are tenacious and subject to regrowth if they are not removed. Scientific testing on multiple processing cycles has shown MATRIX® should be used continuously at normal dilutions to ensure both biofilm removal and to stop regrowth.

HOW ENZYMATICS WORK



It is an important scientific finding that enzyme cleaners as a class of product, regardless of brand tested, failed in these worst case simulated models to remove biofilm.

ENZYMATIC CLEANERS

- Enzyme cleaners attempt to digest biological contaminants.
- Enzymatic detergents fail to sufficiently remove biofilms and associated viable bacteria found on medical devices.
- Enzymatic detergents have demonstrated to be ineffective against bacterial biofilms in simulated soil tests and institute research.
- Enzymatic detergents that use highly active enzymes are classified as chemical sensitisers and are a hazard to human health.
- MATRIX® does not contain enzymes.

PROVEN STUDIES

MATRIX® is the first documented and proven solution to the complex problem of validated cleaning of modern medical devices.

MATRIX® is formulated to effectively clean medical devices in both normal and worst case applications. MATRIX® will rapidly solubilise blood, proteins, body tissue, carbohydrates, lipids and mucopolysaccharides. The formulation of MATRIX® is specifically intended for use on endoscopes (rigid and flexible), ultrasound probes, complex medical devices and all other medical instruments. As biofilm research in healthcare is a new scientific frontier in many countries, regulators have not yet set appropriate standards for testing. As such some companies claim biofilm removal with dubious data and no supporting scientific publications. Whiteley Medical strongly recommend all customers request to see international, peer reviewed scientific publications from respected journals when evaluating products.

Outlined below is a list of scientific publications on MATRIX® and Biofilms:

- **'Biofilms and their importance in infection control.'** Whiteley RK, Pajkos A and Vickery K. *J Gast Enterological Nurses College Aust* 2001;11(3):18-22.
- **'Biofilms that impact on human health.'** Whiteley RK, Pajkos A and Vickery K. *Pharm Practice Res* 2002;32(2):153-158.
- **'Removal of biofilm from endoscopes: Evaluation of detergent efficiency.'** Vickery K, Pajkos A and Cossart Y. *Am J Infect Control* 2004;32(3): 170-176.
- **'Is biofilm accumulation on endoscope tubing a contributor to the failure of cleaning and decontamination?'** Pajkos A, Vickery K, Cossart Y. *J Hosp Infect.* 2004 Nov;58(3):224-9. PubMed PMID: 15501338.
- **'The effect of multiple cycles of contamination, detergent washing, and disinfection on the development of biofilm in endoscope tubing.'** Vickery K, Ngo QD, Zou J, Cossart YE. *AJIC.* 2009 Aug;37(6):470-5. doi: 10.1016/j.ajic.2008.09.016. Epub 2009 Jan 19. PubMed PMID: 19155094.
- **'Biofilm in Duodenoscope: hospital infection by pan-resistant aeruginosa pseudomonas related to Endoscopic Retrograde Cholangiopancreatography [ERCP].'** S.Muller, I. Maguilnik, L. Konkewicz, A. Barth, R. Kuchenbecker. *J GENCA*, 01 January 2010, vol./is. 20/1[13-14], 1444027X.
- **'A study of the efficacy of bacterial biofilm cleanout for gastrointestinal endoscopes.'** Ying Fang, Zhe Shen, Lan Li, Yong Cao, Li-Ying Gu, Qing Gu, Xiao-Qi Zhong, Chao-Hui Yu, You-Ming Li *World J Gastroenterol.* 2010 February 28; 16(8): 1019-1024.
- **'Evaluation of detergents and contact time on biofilm removal from flexible endoscopes.'** Wei Ren MD, Xiaoyan Sheng, Xi Huang, Fachao Zhi, Wenzhi Cai. *AJIC: American Journal of Infection Control* Volume 41, Issue 9 , Pages e89-e92, September 2013.

Matrix®

BIOFILM REMOVER

ABOUT MATRIX®

ARTG: 125529.

DIRECTIONS FOR USE

MATRIX® can be used safely in ultrasonic cleaning devices in place of existing enzymatic cleaning products.

Manual Cleaning:

For normal instrument cleaning with regular usage dilute MATRIX® 1:100 in potable water (10mL/Litre). Worst case cleaning for heavily soiled instruments with dried surgical soils, use MATRIX® diluted 1:20 (50mL/Litre). Use at room temperature (20 °C - 25 °C) is recommended.

Use below 35 °C. Immerse device for a minimum of 2 minutes while cleaning the medical device. Longer soaking/cleaning will depend on level of soiling or complexity of device.

Automated Endoscopic Reprocessors:

For normal use dilute MATRIX® at rate of 1:200 (5mL/L).

Ultrasonic Use:

MATRIX® is the only cleaning solution shown to repeatedly and reliably remove conventional biological soils and bacterial biofilms. Dilute MATRIX® 1:100 in potable water (10mL/Litre).

PRECAUTIONS FOR USE:

Refer to the Safety Data Sheet (SDS) for Personal Protective Equipment (PPE) recommendations. Please read the SDS prior to first use. Non hazardous and free rinsing when used as directed. Store below 30 °C, out of direct sunlight. Do not mix with detergents or other chemicals.

SAFETY

It is imperative that those using MATRIX® should read the Safety Data Sheet prior to first use.

MATRIX® should ONLY be used in a well ventilated area.

MATRIX® should only be used in warm water (less than 35 °C).

HEALTH STATEMENT

Whiteley Medical makes every effort to ensure that its products are always safe to use, however products can affect individuals differently and the company cannot predict individual responses. Therefore careful reading of the MATRIX® SDS is essential prior to first use.

ENVIRONMENTAL STATEMENT

Whiteley Medical manufactures products that comply with Australian and International environmental policy. Whiteley Medical aims to ensure that every product is 100% biodegradable, whilst achieving optimal performance and benefit to customers.

All Whiteley Medical products are supplied in 100% recyclable containers.

Packsizes available:

- ✓ 1L Matrix®
- ✓ 5L Matrix®
- ✓ 5L Matrix® Mint*
- ✓ 15L Matrix®*

*Available in NZ only.

Chemical Composition and Properties

Surfactant system	Blended
Colour	Matrix® - Aqua blue Matrix® Mint - Green
Odour	Matrix® - Lemon perfumed Matrix® Mint - Mint perfumed
pH concentrate	5 - 7
Solubility	100% in water
Rinsibility	Excellent, free rinsing, no residue
Foam Properties	Low foam / no foam
Abrasives	Nil
Dangerous Goods Rating	None applicable
Hazardous (Worksafe Criteria)	Non Hazardous
Safety Equipment	Use of gloves and eye protection is recommended

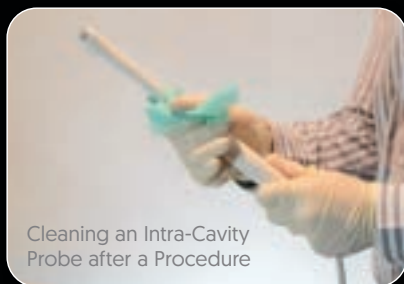


Matrix[®] wipes

MATRIX[®] WIPES:

Unique biofilm removing detergent wipes for pre-cleaning endoscopes, TOE probes, Ultrasound probes and other medical devices.

- Apertured wipe to ensure sufficient density for removing gross organic soiling.
- MATRIX[®] Wipes contain MATRIX[®] biofilm removing solution - a patented formulation of surfactants specifically designed for removing biological soils and biofilms.



Cleaning an Intra-Cavity Probe after a Procedure

Packsize:
✓ Flatpack (80 Wipes)
– 190x200mm



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EDUCATIONAL VIDEOS

The Gastroenterological Nurses College of Australia [GENCA] offer an educational video on 'Manual Cleaning Process for Flexible Endoscopes'. This is a useful training tool for Endoscopy Staff as it demonstrates correct applications and procedures for cleaning endoscopes using MATRIX[®]. For more information or to request a copy visit www.genca.org



Whiteley Medical offer a training video on 'How to clean an Ultrasound Probe using Matrix Wipes'. To view the video online visit http://www.whiteley.com.au/Education/Educational_Videos



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