(PATENTS PENDING)

Matrix™

Biofilm Remover

SUMMARY

MATRIX™ is a breakthrough in validated cleaning protocols. MATRIX™ has been demonstrated to remove conventional biological soils and bacterial biofilms. Cleaning of Medical Devices has been identified as the critical first step in any effective instrument reprocessing system. Bacterial biofilms in which both bacteria and other micro-organisms may be imbedded are more difficult to remove than conventional biological soils alone. Traditional cleaning solutions, most notably enzymatic detergent cleaners, have been demonstrated to be ineffective against bacterial biofilm soiling. Disease causing organisms have been proven to be transferred when protected within biofilms on improperly cleaned Medical Devices.

MATRIX™ IS THE FIRST PROVEN ANSWER TO THIS COMPLEX CLEANING PROBLEM

INTRODUCTION

Cleaning is the key to effective instrument reprocessing and reuse. All of the key publications in the field of endoscopy and other medical device reprocessing make the same comment. Cleaning is the key factor determining success or failure in achieving an instrument that is fit and safe for reuse on, in or with patients.

But how do you measure the performance of your cleaning products? Research in this key area has shown that the presence of biological soils on a reusable medical device is often accompanied by the presence of a bacterial biofilm matrix. Not only has the cleaning product failed to remove the soil, but bacteria that are naturally present on the instrument have constructed a protective coating called a biofilm.

Following more than five years of world class research in this area, Whiteley Industries have found a breakthrough product that is the best cleaning solution available in Australia and the United States of America. This product, under the new brand name MATRIX™ is now available for cleaning applications in the Australian Healthcare Market.

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MATRIX™ has been subjected to a wide array of testing both in Australia and in North America. This testing is currently in the process of peer review publication, thesis documentation and review, and is subject to continuing research through a Post Doctoral Research Program.

Work thus far has shown that MATRIX™ is superior to all other cleaning solutions tested. Equally important has been the finding that current medical enzyme cleaning products are largely ineffective and sub standard in performance as simple cleaning solutions.

BACKGROUND

Medical Devices and Instruments are becoming increasingly complex, and are often very expensive. These devices are intended to be reused and subjected to reprocessing including thorough cleaning, followed by either Sterilisation or High Level Disinfection (HLD). Reprocessing is often difficult and whilst instrument or device design can improve clinical performance, the same design can lead to difficulties in cleaning.

The cleanability of new approved devices has not been considered as part of the process of device approval except by a vague reference to documented substantiation for claims made (including device reusability)[i]. This has led to approval of devices that for practical reasons are not thoroughly cleaned prior to HLD or sterilisation. Work in Australia has shown that where cleaning is insufficient disease-causing organisms can be shielded and survive HLD[ii] or Sterilisation[iii]. Biofilms have been demonstrated in this work as the significant protective soil in which disease causing micro-organisms can survive.

Many medical devices have hidden recesses and non-visible internal channels that simply cannot be inspected for cleanliness. It is in these areas that cleaning performance is most critical. Cleaning product performance must show both penetration of soils and biofilms as well as solubilisation of the biofilms. Where penetration cannot be achieved such as with enzyme cleaners, then cleaning performance cannot be demonstrated and the cleaning system cannot be verified.

Practical, well functioning cleaning protocols/systems can overcome poor instrument design, and some endoscopy clinics have systems in place that regularly monitor internal channel cleaning as a normal part of maintenance and upkeep. However, things can go wrong. Given that enzyme cleaners cannot meet the new standards of measurement, even with regular monitoring, gaps will be present that give an undesirable risk profile to cleaning system/product performance.

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THE HISTORY OF MATRIX™

Whiteley Industries have been working to develop better, world leading cleaning and sterilising systems for two decades. Our patents have been globally accepted and still represent the Worlds Best Practice performance. From our ongoing funding of third party, independent, university based research into Infection Control, we have again demonstrated best practice performance.

However, we observed that many improvements are still possible. The work with biofilms using Hepatitis B Group Virus models has been innovative in its own right. This has allowed us to re-examine cleaning product performance in practical systems, using worst case scenario planning. Only extended time, elevated pressure steam sterilisation systems have been shown to be able to withstand cleaning system complete failure.

Elevated pressure steam sterilisation has been shown to lead to premature end-life for instruments and devices. There are also many instruments that cannot be subjected to this treatment regime. Our focus shifted to pre-cleaning as an essential prerequisite to minimising failure risk in sterilisation processing.

So we started to re-examine the cleaning solutions in systems where steam sterilisation was not possible as a post cleaning sterilisation process. Our first focus was enzyme cleaners. Whiteley Industries were the first Australian firm to introduce enzyme cleaners (Medizyme™) to the endoscopy market back in 1986. Medizyme has been subjected to periodic adjustment as better enzyme systems have become available and was a natural starting point for our work.

We quickly discovered that the research had its challenges. The University researchers first had to develop new methods for assessing cleaning of biofilms. The starting point for this work was to develop practical methods of growing biofilms, in relevant models, that were reproducible and controlled unwanted variables. This alone took a considerable amount of time.

Once the methods for biofilm production were dependable, work examining cleaning product performance began. It was apparent from the very first experiment, that although the enzyme cleaners performed a useful general cleaning function, the enzyme cleaners could not penetrate the residual bacterial biofilms and remove viable bacteria. The work looked at the major enzyme cleaning solutions available, including those from Whiteley.

However, none of the enzyme cleaners worked much differently. All were poor cleaners and all failed to penetrate the biofilm or remove viable bacteria[iv]. 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. Some detergent solutions were better in performance than the enzyme cleaners, but no standard solution would achieve the desired performance criteria. The findings of this work showed that bacterial biofilms behaved more like a natural polymer than a loose accumulation of mixed soil deposits[v].

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The implications were twofold:

i. the current confidence in enzyme cleaning products is severely misplaced; and,
ii. a new style of cleaning product would have to be developed.

"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."

A PRODUCT NAMED MATRIX™

Through this research, new technology has been developed to grow and test bacterial biofilms for research purposes. New cleaning product technology has also been developed to remove these films from Medical Devices. As with any new technology, further work was required to prove the systems and ready the product for market.

The biofilm growing systems are being written into a thesis and numerous papers for publication. Further studies are continuing to look more deeply and extensively into the role of biofilm contamination in practical infection control. There are broad concerns over the role played by bacterial biofilms in a range of disease outcomes, and the work will investigate ways of preventing disease transfer or breaking the cycle of infection.

MATRIX™ as a product has been subjected to repeated testing under a variety of conditions. Work commenced focused not just on the capacity of the product to penetrate the deepest biofilm matrix, but also to quantify the removal of the biofilm. This work is continuing and each month brings new findings in this exciting area of new scientific study. Two separate patent applications have now been lodged following successful research in the development of MATRIX™.

Importantly, confirmatory work at a North American university has been able to independently repeat the results found in the Australian based research. What has been equally important is the confirmatory finding by the North American research institution that enzymatic cleaning products neither penetrate the biofilm nor remove the bulk of the fixed biofilm matrix.

There is a growing awareness in Infection Control over the role of biofilms in post-procedural and nosocomial infections. The application of MATRIX™ to solving these problems is an integral part of the work being done. MATRIX is suitable for both manual use and use in and with Automatic Endoscopic Reprocessing (AER) machines including Medivators AER's.

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WHY CHOOSE MATRIX™ FOR REGULAR CLEANING APPLICATIONS?

The movement towards quality assurance systems in healthcare settings has been a welcome development. Various guidelines are available providing advice on practical infection control as it relates to device reprocessing and their associated environments including AS 4187[vi], AS 4815[vii], and HB 228[viii] in addition to guidelines from other professional groups[ix].

In these guidelines, the universal focus is on effective cleaning and using the best solution available for the task. We absolutely agree with this view.

However, their advice on appropriate cleaning solutions is now specifically dated by our research findings. Essentially the principles outlined in these documents rely on the best evidence at the time of printing. In as much as these esteemed documents suggest soaking in enzymatic detergents for standard cleaning, those statements are now a less than best recommendation.

MATRIX™ OUTPERFORMED ENZYMATIC DETERGENTS ON EVERY MEASURE, IN EVERY TEST.

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 patented formulation of MATRIX™ is specifically intended for use on endoscopes (rigid and flexible), orthopedic instruments, complex medical devices and all other medical instruments.

MATRIX™ can be used safely in Ultrasonic Cleaning devices in place of existing enzymatic cleaning products. MATRIX™ is the only cleaning solution shown to repeatedly and reliably remove conventional biological soils and bacterial biofilms.

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 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.

MATRIX™ is guaranteed to keep working even when you cannot see the biofilm. It becomes readily apparent why Whiteley Industries is so excited about the performance of this revolutionary and breakthrough product that we have called MATRIX™.

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FREQUENTLY ASKED QUESTIONS [FAQ]

1. Does MATRIX™ have a smell?
   A: MATRIX™ HAS A MILD LEMON PERFUME.

2. Does MATRIX™ have a lot of Foam?
   A: TRIALS HAVE SHOWN MATRIX™ IS LOW FOAMING AND NO FOAM RESIDUE REMAINS ON DEVICES FOLLOWING NORMAL RINSING IN BOTH MANUAL SYSTEMS AND IN AN AER [MEDIVATOR 201].

3. Why should I use MATRIX™ rather than my usual enzymatic detergent?
   A: THE ADVANTAGES OF MATRIX™ ARE MOST VISIBLE UNDER SCANNING ELECTRON MICROSCOPY WHEN CHANNELS ARE CUT OPEN (BACTERIAL COLONIES ARE NORMALLY MICROSCOPIC). MATRIX IS INDEPENDENTLY VERIFIED TO WORK WHEN YOU CANNOT VISUALLY INSPECT THE ENDOSCOPE CHANNELS.

4. Do enzyme cleaners cause sensitisation?
   A: THE FIRST AUSTRALIAN PRIORITY EXISTING CHEMICAL REVIEW [1993], WAS ACTUALLY CONDUCTED ON ENZYME DETERGENT MOLECULES.
   ENZYME CLEANING SOLUTIONS CONTAIN ENZYME MOLECULES. THESE MOLECULES ARE KNOWN TO CAUSE SENSITISATION AND ALLERGIC RESPONSES IN SOME INDIVIDUALS WHERE OVER EXPOSURE IS A RISK. CARE SHOULD BE TAKEN WITH ENZYME CLEANING SOLUTIONS TO ENSURE THAT OVER EXPOSURE IS UNABLE TO OCCUR.
   MATRIX™ DOES NOT CONTAIN ANY ENZYMATIC MATERIALS.

5. Will there be a noticeable soil residue that comes from the channels in the scopes following cleaning with MATRIX™?
   A: MOST LIKELY NO, BUT IF THE PREVIOUS CLEANING MATERIAL HAS BEEN INEFFECTIVE AND SIGNIFICANT BIOFILM HAS DEVELOPED INSIDE YOUR ENDOSCOPE THEN ON THE FIRST USE OF MATRIX™ A SOIL RESIDUE MAY BE VISIBLY REMOVED.

6. My Endoscopes do not have brushable air/water channels. Will MATRIX™ assist in normal solution cleaning of non-brushable channels?
   A: APPROXIMATELY 90+% OF ENDOSCOPES DO NOT HAVE BRUSHABLE CHANNELS, THEREFORE 90+% OF SCOPES CANNOT BE EFFECTIVELY CLEANED WITH EXISTING CLEANING PRODUCTS. MATRIX™ IS THE ONLY VERIFIED ANSWER TO THIS COMPLEX CLEANING PROBLEM.

7. What is the published data supporting the evidence for using MATRIX™?
   A: SEVERAL REFERENCES ARE CURRENTLY UNDERGOING PEER REVIEW. ONE IS ALREADY PUBLISHED. ANOTHER ARTICLE HAS ALREADY BEEN ACCEPTED FOR PUBLICATION AND IS AWAITING PUBLICATION. A DOCTORATE THESIS IS CURRENTLY BEING FINALISED AND A POST DOCTORAL SUPPORTING FELLOW IS IN PLACE FOR OUR CONTINUING MULTI-CENTRE GLOBAL RESEARCH PROGRAM.

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8. How can I know that biofilm is present within my endoscope? We have not had any pathology results indicating contamination. We currently sample our endoscopes every 3-6 months with a turbulent water sample.
   A: SAMPLING IS A PROBLEM. POTENTIAL BIOFILMS MAY BE INACCESSIBLE AND TRANSMISSION MAY BE RANDOM. SO RANDOM PATHOLOGY SAMPLING HAS INCONCLUSIVE PROBABILITY OF DETECTING THE BIOFILM PRESENCE OR ABSENCE. EFFECTIVE CLEANING USING MATRIX™ WILL REDUCE THE RISK OF BIOFILM CONTAMINATION ACCUMULATING WITHIN THE MEDICAL DEVICE.

9. Why is the MATRIX™ dilution different for Automated systems verses Manual?
   A: A GREATER VOLUME OF PRODUCT IS USED IN AER's. THIS VOLUME PROVIDES GREATER SURFACE CONTACT AND ENHANCED CLEANING RESULTS.

10. What AER Cleaning program would we recommend if MATRIX™ were to be used in a Medivator AER to remove biofilms: would you recommend use of MATRIX™ once a day or once a week or every cycle?
    A: MATRIX™ SHOULD BE USED EACH CYCLE AT 1:100. OLDER MACHINES DILUTE AT A HIGHER RATE (1:400+) WHICH MAY ALSO BE ACCEPTABLE WHERE THE CLEANING PROTOCOL IS VALIDATED BY THE USER.

11. What is the MATRIX™ contact time; this should be clearly defined on the label. The time taken for cleaning as MATRIX™ works should be stated.
    A: RESEARCH WORK HAS BEEN CONDUCTED AT 2 MINUTES, FIVE MINUTES AND TEN MINUTES. MATRIX™ WORKS AS INTENDED IN JUST TWO MINUTES, BUT FOR WORST CASE CLEANING A LONGER SOAKING TIME IS RECOMMENDED. THE SHORTER THE CONTACT TIME, THEN THE GREATER THE CONCENTRATION OF MATRIX™ THAT SHOULD BE USED.

12. Is regular use (say every cycle) of MATRIX™ in a Medivator machine warranted or should I only use MATRIX™ once a week?
    A: WE RECOMMEND MATRIX BE USED IN EACH AND EVERY MEDIVATOR CYCLE. REGULAR USE WILL PROVIDE CLEANING PERFORMANCE SUPERIOR TO ANY ENZYMATIC OR NEUTRAL DETERGENT SOLUTION.
    THE MATRIX™ LABEL COVERS WORST CASE TESTING AND NORMAL USE. WHEN MATRIX™ IS USED AT HIGHER DILUTIONS [SAY 5 - 10 MLS PER LITRE OF WATER] CLEANING PERFORMANCE WILL REMAIN SUPERIOR TO EXISTING ENZYMATIC AND DETERGENT CLEANING SOLUTIONS.

13. Is MATRIX™ compatible with all Sterilisation systems and High Level Disinfectants?
    A: MATRIX™ IS COMPATIBLE WITH ALL STERILISATION AND HIGH LEVEL DISINFECTING PRODUCTS. HOWEVER, THOROUGH RINSING PRIOR TO STERILISATION OR HIGH LEVEL DISINFECTION WILL ENSURE THAT NO RESIDUE IS CARRIED OVER ON THE MEDICAL DEVICE.

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INDIVIDUAL HEALTH CARE FACILITIES SHOULD USE THEIR DISCRETION WHEN CONSIDERING SPILL OVER OF CLEANING MATERIALS AS PART OF RE-PROCESSING SYSTEM VALIDATION. NO DETERGENT OR CLEANING SOLUTION SHOULD BE MIXED WITH ANY HIGH LEVEL DISINFECTANT OR STERILANT. THOROUGH RINSING SHOULD SEPARATE THESE PRODUCTS AT ALL TIMES AND IN ALL PROCEDURES.

14. Is there more scientific data supporting the principles for use of MATRIX™ as a biofilm remover or is it all a circumstantial problem?
A: THE USA FDA, APIC, AUSTRALIAN STANDARDS, SCIENTIFIC AMERICAN JOURNAL AND MANY OTHERS HAVE ACKNOWLEDGED THE PROBLEM OF BIOFILMS FOR SEVERAL YEARS. THERE IS ABUNDANT INDEPENDANT SCIENTIFIC LITERATURE THAT SUPPORTS GENUINE CONCERNS OVER BIOFILMS AND THEIR ROLE IN DISEASE TRANSMISSION VIA MEDICAL DEVICES. THESE PROBLEMS ARISE RANDOMLY AND RISK IS HEIGHTENED IF BIOFILM CLEANING IS NOT ACHIEVED.

MATRIX™ IS THE FIRST DOCUMENTED AND PROVEN SOLUTION TO THE COMPLEX PROBLEM OF VALIDATED CLEANING OF MODERN MEDICAL DEVICES.

DIRECTIONS FOR USE

Manual Cleaning

For normal instrument cleaning with regular usage dilute Matrix 1:100 in potable water. Use in warm water is recommended.
Worst case cleaning for heavily soiled instruments with dried surgical soils, use Matrix diluted 1:15. Use in warm water is recommended.

Automated Endoscopic Reprocessors

For normal use dilute Matrix at rate of 1:100.

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HUMAN HEALTH, SAFETY AND ENVIRONMENTAL INFORMATION

Health Hazardous Statement

MATRIX™ is **Not Hazardous** when assessed using the National Worksafe Australia criteria.

ENVIRONMENTAL STATEMENT

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

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

Whiteley Industries and its staff are fully committed to ensuring that our Australian environment and those international environs in which our products are used, are enhanced by the use of our technology, and that these environments are preserved for the enjoyment of future generations.

CHEMICAL COMPOSITION AND PROPERTIES

Surfactant system:	Blended
Colour :	Yellow colour, clear at normal dilution
Odour :	Lemon perfumed
pH concentrate:	7.5 – 8.5
pH (2% solution):	7.0 – 8.0
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 is recommended
Shelf life:	One (1) year from date of manufacture

SAFETY

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

Use of Gloves is strongly recommended whenever cleaning medical devices. Care should be taken that vapours or aerosols containing potentially infectious microorganisms are not generated during cleaning when using MATRIX™. Where vapours or aerosols are generated then wearing of a lightweight mask may be advisable. MATRIX should be used in a well ventilated area.

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There is no way of predicting an individual's response to cleaning products. All cleaning products have a potential to cause skin and other irritation in susceptible individuals. Direct physical contact with the skin should be avoided. If irritation does occur when using this product or any other cleaning solution then the individual should be removed from direct contact with the solution until a satisfactory safe working environment for that individual is determined.

PACK SIZE: 2 x 5 Litre

REFERENCES:

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[ii] Vickery K, Pajkos A, Cossart YE, Evaluation of the effectiveness of decontamination of Dental Syringes, British Dental J., 189, 2000.
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[iv] Whiteley RK, Pajkos A and Vickery K, Biofilms and their Importance in Infection Control, J GENCA,v11, (3) 2001
[v] Ceri H, S S Block Edit., Disinfection, Sterilisation and Preservation. 5th Edition, 2001
[vi] AS/NZS 4187, "Cleaning, Disinfecting and Sterilising Reusable Medical and Surgical Instruments and Equipment, and Maintenance of Associated Environments in Health Care Facilities", 1998.
[vii] AS/NZS 4815, "Office-Based Health Care Facilities Not Involved in Complex Patient Procedures and Processes – Cleaning, Disinfecting and Sterilising Reusable Medical and Surgical Instruments and Equipment, and Maintenance of the Associated Environment" 2001.
[viii] HB 228 Guidelines for Managing Risk in The Healthcare Sector", 2001.
[ix] Various: RACGP, RACP, GENCA, NHMRC, AICA and others

Acknowledgements

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