Ygiene 206 Sterilant May be Effective At Removing Some Health Threatening Microorganisms In the Presence of Blood From Certain Contaminated Surgical Instruments

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BioNeutral Group Inc. (OTC Bulletin Board: BONU- News), a specialty life science technology-based company, and Barnabas Health of West Orange, New Jersey, are pleased to release the results of an initial collaborative research program. In this study of about fifty (50) surgical instruments conducted at Saint Barnabas Medical Center, a Barnabas Health facility, Ygiene 206 Sterilant was shown to effectively remove microorganisms in the presence of blood from contaminated surgical instruments in 90 seconds to two minutes. This use of Ygiene would represent an important preventive step in the reduction of serious occupational exposure to healthcare workers of blood or bodily fluids from surgical instruments. The results of the study follow: The Use of Ygiene 206 as a Possible Bloodborne Pathogen Exposure Strategy for Healthcare Workers Nancy Chobin, RN, AAS, ACSP, CSPDM ABSTRACT: Exposures to blood and/or body fluids from used surgical instruments continues to occur on a daily basis. Other than engineering and work practice controls, there is little else available to protect healthcare workers responsible for cleaning used instruments. This study was performed to determine the feasibility of using a disinfectant/sterilant chemical as a pre-treatment for used surgical instruments to protect healthcare workers from exposure to blood and/or body fluids when processing contaminated surgical instruments. The study included using the chemical in a variety of settings including exposure to human blood that had dried for twelve (12) hours. The results of the study confirm that the Ygiene 206 chemical may be used to disinfect surgical instruments as a precursor to cleaning and prior to terminal sterilization.

BACKGROUND Since the early 1980's, blood and other potentially infectious materials have been acknowledged as a potential risk to the health of employees who get an exposure from a contaminated needle or other sharps usually through the percutaneous route (penetration of the skin). The Centers for Disease Control states that "injuries from contaminated needles and other sharps have been associated with an increased risk of disease from more than 20 infectious agents." Currently, the major diseases of concern in the healthcare setting are the human immunodeficiency virus (HIV), hepatitis B (HBV) and hepatitis C virus (HCV). (1, 2) The CDC estimates that each year 385,000 needle sticks and other sharps-related injuries are sustained by hospital-based healthcare personnel; an average of 1,000 sharps injuries per day (3, 4). The transmission rates from exposure to sharps from an infected patient are very low and continue to drop. (5) The most common sharps injuries in instrument handling are caused by: -- Reusable and disposable scalpels 4% each -- Other sharp item (e.g. instrument) 22% -- Suture needle 24% (6) To reduce the potential for an employee exposure, OSHA states "reusable sharps that

are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed." (7). The Association of Peri-Operative Registered Nurses states, "sharp instruments should be segregated from other instruments. Segregation of sharp instruments minimizes the risk of injury to personnel handling the instruments during decontamination." (8). The Occupational Safety and Health Administration (OSHA) prohibits processes that require employees to place their hands into basins of sharp instruments submerged in water because of the risk of a percutaneous exposure to blood borne pathogens. (9).

According to the Association for the Advancement of Medical Instrumentation, "When handling contaminated items, personnel should wear appropriate personal protective equipment (PPE) and use work-practice controls and engineering controls, as appropriate, to minimize the risk of injury.(10) Because surgical instruments are used throughout a facility and segregation of sharps from non-sharps at the point of use may not always occur, sterile processing personnel need to take extreme care when handling used surgical instruments.

In early 2012, Barnabas Health (West Orange, New Jersey), became aware of a new chemical that asserts it has a disinfectant as well as a sterilant benefit. According to the information provided by the manufacturer, the chemical is fast acting. The manufacturer's data revealed that Ygiene 206 eliminated Staphlococcus aureus, Salmonella cholerasius, and Methicillin Resistant Staph Aureus (MRSA) in 90 seconds and Pseudomonas aeruginosa, and Aspergillus niger spores in two minutes.

In February 2012, a meeting was held with representatives from the BioNeutral Group, Inc. (manufacturer of Ygiene 206 ("Product")) and Barnabas Health representatives. U.S. Department of Environmental Protection (EPA) and the U.S. Food and Drug Administration ("FDA") testing as well as technical data for the product were also reviewed.

The Product is a combination of peracetic acid and hydrogen peroxide with a pH of 4.5-5.0. There was concern about the effects of the product on surgical instruments. The EPA and FDA has approved the use of the Product for disinfection, killing fungi and as a sporicide (sterilant) but these uses are not approved on any surface or instrument that is introduced on the human body.

Despite the concern, Barnabas Health and BioNeutral believed that it would be prudent to perform a research project to determine the feasibility of using the Product on surgical instruments prior to sterilizing the instruments. The thought was that if the Product does work in the presence of gross soil-even with instruments in the closed position-it would be a benefit to healthcare workers handling soiled surgical instruments to reduce or eliminate exposures to blood or bodily fluids from these surgical instruments. The parties realized that while tests would be performed in a closed environment without actual patient contact, a true test of the Product and its capabilities would be required in an actual healthcare setting.

METHODS Saint Barnabas Medical Center, one of the Barnabas Health facilities, was selected as the facility to test the effectiveness of the Product as a disinfectant on surgical instruments. All testing was performed by Barnabas Health staff members with technical support provided by BioNeutral. Only surgical instruments no longer used in patients and/or patient care were utilized for the testing. Therefore, none of the instruments used during any of the testing described below were intended for use in patient care.

We initially tested whether Ygiene was able to remove dried blood off certain surgical instruments (See Test #1 below). Once this was confirmed, we performed testing of various surgical instruments in the open and closed position using human blood that was contaminated either with MRSA or C.difficile toxin. (See Test #2 below) Test # 1- Heavy soils and Lumened devices Objective: To determine whether Ygiene 206 can remove heavy soils on stainless steel surgical instruments whether or not the instruments were contaminated. Lumened devices were used as these devices present unique challenges to cleaning.

Materials: Poole Suctions, Yankauer suctions and Frazier Suctions.

All samples were labeled to differentiate them in the testing: A-1 - Yankauer suction - regular curve B-1 - Yankauer Suction (big curve) A-2 - Poole Abdominal Suction B-2 - Frazier Suction # 1 french A-3 - Frazier suction - 9 Fr B-3 - Yankauer Suction (control) Protocols/Methods Used: The materials mentioned above were cleaned using an enzymatic detergent mixed according to manufacturer's instructions placed in an ultrasonic cleaner for a 5-minute cycle then processed in a washer-decontaminator for a complete instrument cycle.

Blood vials were obtained from the Saint Barnabas Medical Center Lab.

The vials contained blood from various patients and had unknown contaminates.

In the decontamination area of the Sterile Processing Department (SPD), wearing full personal protective equipment (PPE), the surgical instruments were exposed to the blood from the blood vials obtained.

The researcher made sure the blood made contact with all surfaces. A disposable syringe was used to bring the blood into all of the lumens. The instruments remained in the blood for 15 minutes. At the end of the 15 minute period, the instruments were removed from the blood and placed in a wire basket. The instruments were not treated or cleaned in any exposure way were quarantined on a cart and allowed to dry overnight (approximately 12 hours).

Result from Test #1: When the soiled instruments were soaked in Ygiene 206 for 90 seconds or two (2) minutes, the dried soils were removed.

Test #2: Test Product in actual human blood with MRSA and C.

difficile toxin on Lumened and Hinged surgical instruments Objective: To test the Ygiene 206 Product on suctions, scissors and hemostats in the open and closed

positions containing actual human blood and MRSA or C. difficile toxin and determine whether the Ygiene 206 removed the blood and these organisms from the instruments tested.

Protocols/ Method Used: Blood vials were obtained from the Saint Barnabas Medical Center laboratory. The blood was placed in sterile basins and contaminated. One basin's blood was contaminated with MRSA and the other with C. difficile toxin. Suctions were used to simulate a worst case scenario. Two instruments were used as controls. They were exposed to the blood for approximately 5 minutes; the blood was suctioned inside the lumens using a sterile syringe to ensure the lumen was contaminated. Then the instruments were processed according to the usual Sterile Processing Department (SPD) cleaning procedures previously described.

To confirm the presence of the microorganisms, the contaminated instruments were cultured for MRSA and C. difficile toxin respectively before immersion in the Ygiene 206. The instruments were placed in Ygiene 206 in the closed position for ninety (90) seconds.

The test specimens confirmed the presence of the microorganisms prior to immersion in the Ygiene 206. They also confirmed that the microorganisms were removed after immersion at 90 seconds.

The scissors were cultured before and after immersion in the Ygiene 206. The microorganisms were detected prior to immersion and were not identified after immersion in the Ygiene 206. The culture swabs were rubbed over the entire instrument and inside the box lock (joint).

Test Results from Test #2 Sample Number Sample Description Microbial Test Results A-1 #1 Frazier suction with MRSA Blood Inside; Before Ygiene Soak, Test for MRSA Moderate growth of MRSA A-2 #1 Frazier suction with MRSA Blood Inside; 90 Second Ygiene Soak, Test for MRSA No MRSA isolated B-1 #3 Frazier suction with C. diff toxin Blood Inside; Before Ygiene Soak, test for C. diff toxin Positive for C.diff toxin B-2 #3 Frazier suction with C. diff toxin Blood Inside; 90 Second Ygiene Soak, test for C. diff Negative for C.diff toxin D-1 Suture Scissors with MRSA Blood; Before Ygiene Soak, Test for MRSA Moderate growth of MRSA D-3 Suture Scissors with MRSA Blood Closed; 90 Second Ygiene Soak, Test for MRSA No MRSA isolated D-2 Hemostat with MRSA Blood; Before Ygiene Soak, Test for MRSA Moderate growth of MRSA D-4 Hemostat with MRSA Blood Closed; 90 Second Ygiene Soak, Test for MRSA No MRSA isolated Conclusions: In this controlled and limited study, Ygiene 206 was effective as a disinfectant in the presence of blood on surgical instruments even when the surgical instruments were grossly soiled and remained in the closed position.

Ygiene 206 is an enhancement to the process and a potential preventative step for healthcare workers in prevention of exposure to blood or bodily fluids from sharps injury when processing surgical instruments. The Ygiene 206 could possibly also replace the use of enzymatic detergents for pre-soaking as evidenced by the removal of the soils. This author does not see Ygiene 206 replacing regular washing (manual, sonic or mechanical). Again, further study is needed.

Healthcare personnel must comply with manufacturer's instructions for use of instruments which include cleaning chemicals and protocols recommended for optimum cleaning results. Surgical instrument manufacturers in the United States recommend neutral pH detergents to clean their instruments. Some orthopedic instrument manufacturers specify their instruments should not be exposed to alkaline detergents. It is recommended that the manufacturer of Ygiene 206 collaborate with several surgical and orthopedic instrument manufacturers to perform testing of this Product to determine if this Product can be used for surgical instrument disinfection.

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ABOUT THE AUTHOR: Nancy Chobin, RN, AAS, ACSP, CSPDM, is the Assistant Vice President for Sterile Processing Services for Barnabas Health. She has over 32 years' experience in Sterile Processing; has lectured extensively in the United States and internationally and been published numerous times. Nancy has authored three books on Sterile Processing and serves on numerous committees of the Association for the Advancement of Medical Instrumentation (AAMI) in Arlington, Virginia. Nancy is also the volunteer Executive Director of the Certification Board for Sterile Processing and Distribution, Inc.

ABOUT BARNABAS HEALTH: Barnabas Health is New Jersey's largest integrated health care delivery system with six acute care hospitals and a network of ambulatory care, behavioral health, home care and hospice programs. Barnabas Health provides treatment and services for more than two million patient visits each year. The system has 18,200 employees, 4,600 physicians and 445 residents and interns.

About BioNeutral Group, Inc. Headquartered in Morristown, New Jersey with lab facilities at the New Jersey Institute of Technology in Newark, Inc., Bioneutral Group, Inc. is a specialty technology-based life-science company which has developed a technology platform that neutralizes harmful environmental contaminants, toxins and dangerous micro-organisms including bacteria, viruses, mold, fungi and spores.

BioNeutral's products, Ygiene@ and Ogiene@, kill germs and clean surfaces with a dramatic increase in speed and power over their rivals in the marketplace. BioNeutral's proprietary platform technology has been proven effective in surface, water and airborne applications. Its antimicrobial line of products under the Ygiene@ brand have been approved by the EPA for sale in the United States and has previously been approved for sale in Germany and it is also permitted to be sold in the UK, France and Sweden. Auto Neutral is a registered trademark of BioNeutral Group, Inc. For more information on BioNeutral, including a listing of company products, leadership and background please visit www.bioneutral.com.

Find us on Facebook: http://www.facebook.com/pages/BioNeutral-Group/149109938452393 Follow us on Twitter: http://twitter.com/bioneutralgroup DISCLOSURE: BioNeutral Group, Inc. and Barnabas Health are parties to a collaborative agreement pertaining to the use or sale of the Ygiene 206 product.

Forward-Looking Statements: This release contains certain "forward-looking statements" relating to the business of the Company and its subsidiary companies. These forward-looking statements are often identified by the use of forward-looking terminology such as "believes," "expects" or similar expressions. Such forward-looking statements involve known and unknown risks and uncertainties that may cause actual results to be materially different from those described herein as anticipated, believed, estimated or expected. Investors should not place undue reliance on these forward-looking statements, which speak only as of the date of this press release. The Company's actual results could differ materially from those anticipated in these forward-looking statements as a result of a variety of factors,

including those described in the Company's filings with the Securities and Exchange Commission. BioNeutral routinely tests its formulations against those of its competitors. The results are published to let shareholders know how the Company's technology compares with known formulations in the market place. Any product claim for antimicrobial activity requires approval from the EPA or FDA, depending upon where and how the formulations are used. The EPA has approved and registered the Company's data and findings specific to Ygiene-206. BioNeutral's antimicrobial formulations will be marketed under the brand name Ygiene@ and are available for sale in the United States.

SOURCE BioNeutral Group, Inc.

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