

New Technology



Minimally invasive knee surgery in live webcasts

A patient whose knee has been seriously damaged by osteoarthritis underwent a newly developed procedure designed to restore maximum range of motion with minimal discomfort and recovery time. The minimally invasive surgical procedure was shown to the public and physicians on the Internet via a webcast. Gary G. Poehling, M.D., chair of orthopaedic surgery at Wake Forest University Baptist Medical Center, performed the procedure, which he has helped to develop over the past five years in conjunction with an international panel of surgeons. Known generically as "unicompartmental knee replacement," the procedure required an incision of only about three inches, compared with six to eight inches for total knee replacement. Precise measurements were taken that minimize bone loss in fitting both the femoral and tibial surfaces with synthetic replacements that are anatomically designed to create a natural movement.

Zimmer Inc., Warsaw, IN, also conducted a live April webcast of a minimally invasive knee replacement surgery with interactive commentary from faculty surgeons. That event featured Zimmer's MIS Mini-Incision Total Knee Arthroplasty procedure.

Hope for heart failure patients

The total artificial heart could benefit several thousand people a year in the U.S. if it is eventually proven to be safe and effective, according to a new ECRI evidence report. Each year, between 5,000 and 10,000 Americans experience advanced left and right ventricular heart failure and, if medical management fails, those people have few options. Heart transplantation is the most effective treatment for advanced heart failure, but far fewer donor hearts are available than there are patients who need them.

Thermal Angel saved lives on battlefield

American military forces in Iraq had an angel on their side in the form of a device called the Thermal Angel, which was used extensively by the Marines to treat casualties in their portable operating rooms, the Forward Resuscitative Surgical System (FRSS). Developed by Dallas-based Estill Medical Technologies Inc., the high-tech tool is the world's only blood and IV fluid infusion warmer that runs on batteries. It played a critical role in saving lives by quickly helping to prevent a trauma victim's core body temperature from dropping to a hypothermic level.

PRODUCTS & Services

Hospitals using all varieties of sterilants and disinfectants

by Curt Werner

Sometimes, a simple definition can make a major difference in a product, a technique, and in an outcome. That's true for the definitions of sterilants and disinfectants, and it's also true of the result of the use of these liquids.

"The two are not one and the same," says Diana Chamberlain, R.N., C.N.O.R., director of clinical services for Pilling Surgical in Fort Lauderdale, FL. She cites references that say disinfectants refer to products that reduce the level of disease-causing microorganisms. Not all microorganisms are killed when an instrument or other device is disinfected, however. Sterilants, meanwhile, are simply products that kill all microorganisms and spores.

That settled, hospitals use a variety of both to do the job of cleaning instruments (see accompanying chart of approved products). "Hospitals have to maintain a high level of sterilization not just because of their mission of providing quality care, but because if they don't Joint Commission can shut them down," she says. "So hospitals use every method out there."

Those methods include glutaraldehyde, ethylene oxide, steam, and hydrogen peroxide plasma. In fact, in the coming months a new entrant into that lineup could appear. That is ozone, a product already in use in Europe. Sources say that in the next six months, suppliers should be receiving FDA marketing clearances to sell ozone sterilization technologies in the U.S. Those products are said to be more cost-effective than current methods such as EtO, and act faster to boot.

Some hospitals have eliminated the use of ethylene oxide, while keeping other products on hand. But others in the sterile processing profession, like Bryant Broder, manager of surgery processing at Saint Mary's Mercy Medical Center, a 300-bed facility in Grand Rapids, MI, is not among them. "I want one of every method in our hospital," he says. "The CS department should make the decision on what is best, least expensive and what will provide the optimal results. Some hospitals get rid of EtO and it ends up costing them money because they are forced to contact with outside vendors."

"Sterilization can be a nightmare," Richard Schule, surgical processing manager for The Cleveland Clinic, says flatly. He says, for ex-

ample, that high-alkaline versus neutral base products need extra cycles at high Ph levels. But beyond that, Schule offers a simple reason why some good sterilization cycles and products go bad and money and time are wasted. "Hospitals spend a lot of money on equipment designed to decontaminate instrumentation, yet people still spend a lot of money on presoaking when all you have to do is use a wet towel," he says.

According to Schule, soaking instruments at the point of use makes a major difference in results, alluding to a logistical issue that his hospital, which performs a staggering 35,000 surgical procedures each year, appears to have solved. Cleveland Clinic has three locations for its sterile processing department. One can be found in the basement (the operating room is on the second floor). Another is alongside the second floor O.R., while the third sterile processing unit is actually within the O.R. itself.

Schule says that the SPD inside the O.R. is the optimum configuration. "It builds teamwork and camaraderie between SPD staff and clinicians, and as a result we have outstanding relations between our staff and the O.R.," he says. "In the basement, you are out of sight, out of mind."

Cleveland Clinic is a participating member of the GPO Premier Inc., and the hospital utilizes those group contracts for sterilants and disinfectants. Schule is a supporter of the products and equipment from STERIS Corp., Mentor, OH. Products from Calgon-Vestal, which is now owned by STERIS, have been used at the institution for at least five years. More recently, Huntington-brand products from Ecolab, St. Paul, MN, have made an entry, in particular a "consolidated brick" form of disinfectant that Schule says is simple to use and reduces spillage.

The sterilant and disinfectant market is one that is by and large led by three suppliers, STERIS, Ruhof Corp., Mineola, NY, which manufactures a line of enzymatic cleaners designed to eliminate bioburden, and Metrex, Orange, CA. According to Schule, pricing is "simply a matter of who wants the business." Naturally, an enormous facility that performs 35,000 surgeries a year will get its choice, but competition in this market is still strong and many hospitals, once settled on a particular brand, are usually reluctant to switch. **HPN**

FDA-cleared sterilants and high level disinfectants with general claims for processing reusable medical and dental devices

MANUFACTURER	ACTIVE INGREDIENT(S)	STERILANT CONTACT CONDITIONS	HIGH LEVEL DISINFECTANT CONTACT CONDITIONS
Cidex OPA Solution			
Advanced Sterilization Products	0.55% ortho-phthaldehyde	No indication for device sterilization. Passes the AOAC Sporidical Activity Test in 32 hrs. at 20°C and 25°C.	Manual Processing: 12 min at 20°C. 14 days Maximum Reuse. Automated Endoscope Reprocessor (AER): 5 min at 25°C 14 days Maximum Reuse (For processing in an AER only with FDA-cleared capability to maintain solution temperature at 25°C.) Contact conditions established by simulated use testing with endoscopes.
Sterilox Liquid High Level Disinfectant System			
Sterilox Technologies Inc.	Hypochlorite 650-675 ppm Active free chlorine	No indication for device sterilization. Passes the Modified AOAC Sporidical Activity Test in 24 hrs at 25°C	10 min at 25°C. Single use - generated on site. Contact conditions established by simulated use testing with endoscopes.
Sporidicin Sterilizing and Disinfecting Solution			
Sporidicin International	1.12% glutaraldehyde 1.93% phenol/phenate	Indication for device sterilization. 12 hrs at 25°C. 14 days Maximum Reuse. Contact conditions based on AOAC Sporidical Activity Test only.	20 min at 25°C. 14 days Maximum Reuse. Contact conditions established by simulated use testing with endoscopes.
Rapicide High Level Disinfectant and Sterilant			
MediVators Inc.	2.5% glutaraldehyde	Indication for device sterilization. 7 hrs 40 min at 35°C. 28 days Maximum Reuse. Contact conditions established by simulated use testing with endoscopes and additional supporting information.	Automated Endoscope Reprocessor 5.0 min at 35°C 28 days Maximum Reuse. (For processing in an AER only with FDA-cleared capability to maintain the solution temperature at 35°C.) Contact conditions established by simulated use testing with endoscopes.
Cidex OPA Solution High Level Disinfectant			
Advanced Sterilization Products	0.55% ortho-phthaldehyde	No indication for device sterilization. Passes the AOAC AOAC Sporidical Activity Test in 32 hrs at 20°C.	12 min at 20°C. 14 days Maximum Reuse. Contact conditions established by simulated use testing with endoscopes.
Cetylcide-G Concentrate and Diluent Concentrate			
Cetylite Industries Inc.	3.2% glutaraldehyde	Indication for device sterilization. 10 hrs at 20°C. 28 days Maximum Reuse. Contact conditions based on AOAC Sporidical Activity Test only.	40 min at 20°C. 28 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
MedSci 3% Glutaraldehyde			
MedSci Inc.	3% glutaraldehyde	Indication for device sterilization. 10 hrs at 25°C. 28 days Maximum Reuse. Contact conditions based on AOAC Sporidical Activity Test only.	25 min at 25°C. 28 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
EndoSpore Plus Sterilizing and Disinfecting Solution			
Cottrell Limited	7.35% hydrogen peroxide 0.23% peracetic acid	<i>Note: Due to the lack of test strips for monitoring the concentrations of the active ingredients, the reuse period is limited to 14 days.</i> Indication for device sterilization. 180 min at 20°C. 14 days Maximum Reuse. Contact conditions established by simulated use testing with endoscopes.	15 min at 20°C. 14 days Maximum Reuse. Contact conditions established by simulated use testing with endoscopes.
Sporox Sterilizing & Disinfection Solution			
Reckitt & Colman Inc.	7.5% hydrogen peroxide	Indication for device sterilization. 6 hrs at 20°C. 21 days Maximum Reuse. Contact conditions based on AOAC Sporidical Activity Test only.	30 min at 20°C. 21 days Maximum Reuse. Contact conditions established by simulated use testing with endoscopes.
Peract 20 Liquid Sterilant/Disinfectant			
Minntech Corp.	1.0% hydrogen peroxide 0.08% peracetic acid	Indication for device sterilization. 8 hrs at 20°C. 14 days Maximum Reuse. Contact conditions established by simulated use testing with endoscopes.	25 min at 20°C. 14 days Maximum Reuse. Contact conditions established by simulated use testing with endoscopes.
Procidex 14 N.S.			
Cottrell Limited	2.4% glutaraldehyde	Indication for device sterilization. 10 hrs at 20°C. 14 days Maximum Reuse Contact conditions based on AOAC Sporidical Activity Test only.	45 min at 20°C. 14 days Maximum Reuse. Contact conditions established by simulated use testing with endoscopes.
Omnicide Long Life Activated Dialdehyde Solution			
Cottrell Limited	2.4% glutaraldehyde	Indication for device sterilization. 10 hrs at 20°C. 28 days Maximum Reuse. Contact conditions based on AOAC Sporidical Activity Test only.	45 min at 20°C. 28 days Maximum Reuse. Contact conditions established by simulated use testing with endoscopes.
Omnicide Plus			
Cottrell Limited	3.4% glutaraldehyde	Indication for device sterilization. 10 hrs at 20°C. 28 days Maximum Reuse. Contact conditions based on AOAC Sporidical Activity Test only.	45 min at 20°C. 28 days Maximum Reuse. Contact conditions established by simulated use testing with endoscopes.

See STERILANTS on page 48

MANUFACTURER	ACTIVE INGREDIENT(S)	STERILANT CONTACT CONDITIONS	HIGH LEVEL DISINFECTANT CONTACT CONDITIONS
Metricide Plus 30 Long-Life Activated Dialdehyde Solution			
Metrex Research Inc.	3.4% glutaraldehyde	Indication for device sterilization. 10 hrs at 25°C. 28 days Maximum Reuse. Contact conditions based on AOAC Sporidical Activity Test only.	FDA accepted Metricide Plus as identical to Cidex Plus. 90 min at 25°C 28 days. Maximum Reuse. FDA accepted Metricide Plus as identical to Cidex Plus.
Metricide 28 Long-Life Activated Dialdehyde Solution			
Metrex Research Inc.	2.5% glutaraldehyde	Indication for device sterilization. 10 hrs at 25°C. 28 days Maximum Reuse. Contact conditions based on AOAC Sporidical Activity Test only.	FDA accepted Metricide 28 as identical to Cidex Formula 7. 90 min at 25°C. 28 days Maximum Reuse. FDA accepted Metricide 28 as identical to Cidex Formula 7.
Metricide Activated Dialdehyde Solution			
Metrex Research Inc.	2.6% glutaraldehyde	Indication for device sterilization. 10 hrs at 25°C. 14 days Maximum Reuse. Contact conditions based on AOAC Sporidical Activity Test only. FDA accepted Metricide as identical to Cidex.	45 min at 25°C. 14 days Maximum Reuse. FDA accepted Metricide as identical to Cidex.
Cidex Activated Dialdehyde Solution			
Johnson & Johnson	2.4% glutaraldehyde	Indication for device sterilization. 10 hrs at 25°C. 14 days Maximum Reuse. Contact conditions based on AOAC Sporidical Activity Test only.	45 min at 25°C. 14 days Maximum Reuse. Contact conditions based on literature references.
Cidex Formula 7 Long-Life Activated Dialdehyde Solution			
Johnson & Johnson	2.5% glutaraldehyde	Indication for device sterilization. 10 hrs at 20-25°C. 28 days Maximum Reuse. Contact conditions based on AOAC Sporidical Activity Test only.	90 min at 25°C. 28 days Maximum Reuse. Contact conditions based on literature references.
Cidex Plus 28-Day Solution			
Johnson & Johnson	3.4% glutaraldehyde	Indication for device sterilization. 10 hrs at 20-25°C. 28 days Maximum Reuse. Contact conditions based on AOAC Sporidical Activity Test only.	20 min at 25°C. 28 days Maximum Reuse. Contact conditions based on literature references.
Wavicide - 01			
Wave Energy Systems	2.5% glutaraldehyde	Indication for device sterilization. 10 hrs at 22°C. 30 days Maximum Reuse. Contact conditions based on AOAC Sporidical Activity Test only.	45 min at 22°C. 30 days Maximum Reuse. Contact conditions established by simulated use testing with endoscopes.
STERIS 20 Sterilant			
STERIS Corporation	0.2% peracetic acid	<i>Note: Only cleared for use with the STERIS System 1 Processor.</i> Indication for device sterilization. 12 min at 50-56°C. Single use only. Contact conditions established by simulated use testing with endoscopes and passing a modified AOAC Sporidical Activity Test.	No indication for high level disinfection.

Courtesy: Center for Devices and Radiological Health (March 2003)

Prion deactivation technologies a gold mine for suppliers

The critical need to control the transmission of deadly, infectious human prion diseases is stirring enormous demand for technologically advanced sterilizers/sterilants that can render prion pathogens inactive, according to recent analysis from San Jose, CA-based market researchers Frost & Sullivan. Their research shows that this market generated \$647 million in 2001 and is estimated to reach \$929 million by 2008.

Current sterilization techniques are ineffective in deactivating prions, the causative pathogens of four communicable and fatal human prion diseases. Consequently, there exists significant opportunity for manufacturers to devise an effective sterilization technology that can inactivate prions and prevent contagion.

"The effective solution is expected to be a combination of new methods in existing product line with some additional technology," says Frost & Sullivan industry analyst Dhiraj Ajmani. "The industry is expected to develop something that customers already have or something they can modify, thus facilitating uptake and driving growth."

The development of a prion indicator designed to reveal if prions are present and/or if they have been deactivated after sterilization, he says, presents an allied growth opportunity for suppliers.

Meanwhile, Ajmani says that sterilization supplies should continue accounting for the largest revenue share in the total disinfection and sterilization market, while biological indicators are poised to evolve into the highest growth area in sterilization supplies. In particular, rapid readout biological indicators are being hyped as the market of the future. Other areas within the sterilization supplies market poised to register strong growth are sterilization containers and metal trays.

Sterilization wraps are expected to grow at a slower rate than sterilization containers as hospitals and surgical centers slowly shift to sterilization containers, as metal trays are expected to gain in popularity over plastic trays. Demand for disinfection and sterilization technologies is likely to receive impetus from the expanding usage of endoscopes.