

## April ISR Disposables - Painting A Greener Picture

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There is a broad range of disposable medical products and devices in the health care industry.

With "disposable" as part of the description, it might not seem that these medical devices and a friendly "greener" environment could go hand-in-hand, but the industry segment is moving in a greener direction and trying to help reduce the millions of tons of medical waste generated each year - a portion of which is considered biohazardous.



A report by the Hospitals for a Healthy Environment (H2E) states that hospitals in the U.S. produce approximately 6,600 tons of waste per day. As much as 80% to 85% of this waste is non-hazardous solid waste like paper, cardboard, food, metal, glass and plastics. H2E believes that recycling would substantially reduce waste volume.

### **"Green disposables" begin with the design**

Chris Kadamus, Principal Design Engineer at Cambridge Consultants Inc, believes that with the introduction of new regulations, rules and purchaser preferences, many of the waste disposal methods of hospitals and ultimately the design decisions of medical device manufacturers will soon be changing. "True sustainable design considers the social and financial effect on a product as well as its effect on the environment," says Kadamus.

From a designer or engineer's perspective, sustainable design takes the entire product life cycle into account, from creation to disposal, during the initial design of the product. Regulations for waste reduction and minimization or elimination of hazardous substances have already been in place for the European Union (EU) for several years for everything but medical devices, and it is believed that medical devices will be included sometime between 2010-2012 in the EU. These regulations include: the Waste Electrical and Electronic Equipment (WEEE); Restriction on Hazardous Substances (RoHS); Registration, Evaluation and Authorization of Chemicals (REACH); and the Energy Using Products (EuP) regulations. The WEEE Directive is environmental legislation that hopes to reduce the amount of waste dumped into landfills. It encourages recycling and reusing electrical and electronic equipment. The RoHS applies to end-user electrical and electronic equipment (EEEE) and has in place maximum acceptable levels of six substances within the composition of the product including lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyl

(PBB) and polybrominated diphenyl ether (PBDE) flame retardants. Kadamus says that although similar legislation does not yet exist in the U.S., there is pressure from a non-domestic customer base that has already forced many American companies to comply with WEEE and RoHS.

"Many health care facilities are embracing sustainable practices as a smarter way to do business," according to Kadamus. To save on spending, they are purchasing and using eco-friendly products that are PVC-free, mercury free and lead-free. This, in turn, will allow the medical device industry to cut back on packing materials, design products for disassembly and recyclability and support end-of-life product reclamation programs. Kadamus says, "many of the key tenants of sustainable product concept of product life cycle design stem from understanding and developing a product life cycle, not just a product."

### **The product life cycle design concept**

The concept of product life cycle design considers all stages of product existence, including concept development, material selection, design and engineering, manufacturing, packaging, transportation, sales, use and end-of-life disposal during the initial product planning stages. Each stage is evaluated from the perspectives of energy efficiency, environmental impact, material usage, human effort and cost. "Performed correctly, product life cycle design can lead to significant improvements in manufacturing efficiency, and improve time to market, risk reduction efficient material and energy usage, safety and regulatory compliance, and packaging and transportation costs," says Kadamus. Designing products for easy disassembly, minimizing bulky or nonessential packaging, reducing part count, moderating the use of dissimilar injection-molded materials and eliminating toxic or hazardous materials (lead and PVC, for instance) help to meet the goals for sustainable design as well as those for efficient, low-cost design. "With respect to disposable medical products, choosing materials that limit environmental damage during disposal and incineration can reduce toxic air emissions and reduce waste processing costs," he says.

### **Reprocessing single-use-devices**

Single-use-devices (SUDs) reprocessing has been evaluated for safety and cleaning efficacy by various groups within the health care industry including The Association of Perioperative Registered Nurses, The American Hospital Association, The American Society for Gastrointestinal Endoscopy, and The American College of Cardiology. Among these groups, several have introduced Industry Statements that support the use of SUDs based on reports issued by the U.S. Government Accountability Office (GAO). The GAO concluded that FDA oversight has increased since 2000, and available information does not indicate that the use of SUDS presents an elevated health risk.



Brian Sullivan, President and CEO of SterilMed, Inc. says that using reprocessed devices has become a standard practice for most hospitals in the United States, as well as most of the leading teaching and research hospitals in the country. "Using at least some reprocessed devices is a standard practice in 70% of US hospitals," says Sullivan. "While over 3,000 hospitals currently have a reprocessing program, and over 93% of the US News' "Honor Roll" ,Hospitals use reprocessed devices, there are still some hospitals that have yet to fully integrate reprocessing as a standard practice at their facility."

Reprocessing medical devices positively impacts the environment by maximizing the use of existing devices, decreasing the volume of devices that are sent to landfills and reducing the production of methane gas required to make new products. The American Hospital Association and the U.S. Environmental Protection Agency have entered into a Memorandum of Agreement, which called for a number of action steps for hospitals to reduce medical waste. "Hospitals face the challenge of meeting the goal of a 50% reduction in medical waste volume by 2010. With US hospitals producing more than 6,000 tons of waste each day, this is a significant challenge. Recycling is one important step in reducing that impact on our environment," says Sullivan.

Association of Medical Device Reprocessors (AMDR) president Daniel Vukelich says, "As the U.S. Government Accountability Office indicates - medical device reprocessing is stringently regulated by FDA." With that assurance, it makes financial sense for hospitals. "Reprocessing saves hospitals millions of dollars," says Vukelich. He also pointed out that of all the disposable medical devices available - only 2% to 3% can be considered for reprocessing. That brings up the question, "What happens to the 97% to 98% of the disposables that can't be reprocessed - where do they go?"

### **Recycled disposables**

Vukelich explained that when the AMDR can no longer reprocess a medical device, it is usually stripped down and its components sold to third parties. For example, some plastics can be melted down and put into cinderblocks used for weatherproofing- the aftermarket for plastic is valuable. Other components, like titanium and carbon used by orthopedics for external fix bolts - can be sold, melted down and reused in certain consumer products. "This is a very exciting time for the reprocessing and recycling industry," says Vukelich. "The AMDA and other organizations and companies are working very hard to clean up and keep the environment clean." Sullivan of SterilMed explains that if a device cannot be

reprocessed, the company reclaims and recycles the metal and plastic. During 2008, more than 20,000 pounds of material was recycled at SterilMed. The reclaimed plastics and metals were refined and used to create other products.

### **Time limits on reprocessing**

Robert Copeland is a consultant in the North Carolina region with more than 25 years of experience in the industry. He says that disposables fall into several categories, and if they are candidates for reprocessing, they can usually only be reprocessed a certain amount of times - particularly those made of plastic. "The sterilizing process of plastics has to be carefully managed because if the temperature is too high, or an incorrect sterilizing method is used - chemical changes could cause damage to the composition of the plastic. "There is a time/temperature/method relationship that must be adhered to," says Copeland. He believes that hospitals must weigh the cost versus risk when it comes to deciding whether or not to go forward with reprocessing certain single use devices. "SterilMed limits the number of reprocessing cycles according to the specific construction and material composition characteristics of each device," says Sullivan. To assess this, the company performs an analysis that determines the structural integrity of a device, and then performs validation testing. Based on the results of the validation testing, Sullivan says, "We will determine the number of cycles a particular device can be reprocessed. The number of reprocessing cycles for devices ranges from one to five."

Landfills and incineration for medical disposables that cannot be reprocessed or recycled Hospitals and other health care facilities have been trying to deal with medical waste for years. Incineration is one strategy that many facilities have adopted because it reduces waste in landfills and saves health care facilities money. Still, incineration has its drawbacks.

Known emissions of organic pollutants and metals cause damage to the environment with mercury and dioxin being the main culprits. Dioxin is produced from materials like plastic that react at high temperatures with materials like PVC and chlorine. Accumulating dioxins released into the environment have been proven to have an effect on the endocrine systems of humans and animals. The EPA has regulations to control the emissions from medical waste incinerators and include stringent air emissions guidelines for states to use in developing plans to reduce air pollution from medical waste incinerators built on or before June 20, 1996; and final air emission standards for medical waste incinerators (MWIs) built after June 20, 1996.

The EPA's MWI standards and guidelines have caused many health care facilities to use alternative technologies for treating waste including microwave technologies, steam

sterilization like autoclaving, electropyrolysis and chemical mechanical systems. Many states have regulations requiring medical waste treatment technologies to be certified, licensed or regulated and individual states have their own requirements. Several Federal agencies also have regulations that cover the waste stream.

The Maine Hospital Association, which represents 29 community-governed Maine area hospitals generate about 190,000 pounds of waste per month. The Maine Medical Waste Facility utilizes 2H-1000 Hydroclase Vessels, which process 500 to 800 pounds of waste per day. The technology from Hydroclave Systems Corp (SC) of Canada has a patented treatment process that utilizes steam heat to sterilize waste and subsequently shred it making it acceptable material for landfill disposal. This is a positive move for the environment. Previously, medical waste was hauled to landfills in unmodified form.

Kate Flynn, FACHE, president of The Health Care Improvement Foundation (HCIF) - a Philadelphia-based nonprofit dedicated to building partnerships for better health care in Southeastern PA, says, "Hospitals' commitment to the 'green revolution' is a critical objective for the Delaware Valley." She says that the 20 hospitals in her region have been working together since mid-2007 to reduce the impact on the environment by reducing regulated medical and general waste, managing pharmaceutical and toxic waste and developing environmentally preferred purchasing. "A prominent achievement has been reducing the volume of infectious waste among the region's hospitals by more than 40% in the aggregate," says Flynn. "Best practices are being compiled and, along with case studies, will be posted on HCIF's web site as resource for other hospitals and health care providers."

### **Disposables in the home health care environment**

Disposable needles, syringes and lancets represent the lion's share of home health care SUDs. It is estimated that over three billion disposable needles and syringes and an additional 900 million lancets (collectively called "medical sharps") are used outside of health care facilities in the U.S., and two-thirds of these are used by those managing their own (or their pet's) health care at home. Self injectors are known to discard medical sharps in trash containers in homes and public places and in other public settings such as hotel rooms, airports and toilets. These disposal methods create potential dangers for the transmission of infectious diseases.

**Sierra E. Fletcher, Associate - Policy and Programs at the Product Stewardship Institute, Inc.** in Boston says that over the past year, PSI has facilitated meetings with pharmaceutical companies, device manufacturers, government officials, pharmacies, public health groups and other key stakeholders to recommend the development and implementation of a "model state program for Massachusetts" based on a modified producer responsibility system, the details of which remain to be negotiated. "The goal of the project is to maximize the safe collection and disposal of used medical sharp devices," says Fletcher. "The project is in-line with other PSI initiatives to directly involve the manufacturers of products that create challenging waste issues in creating solutions."

### **DOTmed users express their opinions**

Jennifer Westbrook, CEO of PrecisionSurgical Supply has firsthand knowledge as a former phlebotomist of many disposables on the market. She said that for her company, sales of disposable products have remained strong despite current economic conditions. As far as the environment goes, Westbrook says, "I find the biggest challenge is finding a balance between having an environmental conscience and awareness with providing supplies that will be of the most benefit to our clinics, hospitals and - ultimately the patients. Westbrook is confident that the SUD market will continue to grow. There continues to be a great need for these products," she says. As the world market grows, so will the need for reprocessing." Westbrook says that she can understand both sides of the reprocessing issue. When it comes to legislation in the works requiring patients to be informed about reprocessed single use- devices, she says, "In most cases, patients are more comfortable knowing that they are getting items that have never been used before - especially when considering an invasive procedure"

Scott Townsend, owner of Townsend Surgical relates that his disposable business has been average to slow and his biggest challenge has been finding precisely what customers want amongst the enormous variety of medical disposable devices available. He anticipates that business will continue as usual with "steady slow growth over the next six months, especially in markets outside of the U.S." Townsend sells and repairs equipment to hospitals, surgery centers, clinics and dealers, nationally and internationally. He said that he sometimes will sell disposables outright or on consignment from a medical facility, but he will not touch certain products that are injectable or contain liquids.

Another company, SONOTECH, has a product in unit dose packets that is designed to prevent cross contamination. Marian Larson, Marketing and Sales Manager at SONOTECH says, "57% less plastic waste is generated by the average hospital when it used Clear Image Singles rather than 250 ml bottles. It's not only cost effective for health care facilities - it's also kind to the environment because it reduces waste." When the 'average' hospital performs around 20,000 scans per year, that waste reduction is significant