

**I**N THESE JADED TIMES OF CORPORATE CORRUPTION AND greed, a story of hope and aspiration—like this one about product and packaging innovations from Edwards Lifesciences—can warm the heart.

Edwards is a global leader in products and technologies designed to treat cardiovascular disease. With approximately 5,000 employees globally, Edwards is the number one heart valve company in the world. While \$704 million in sales during 2002 was excellent, monetary gain is secondary to the impact the company's products have on customers—clinicians, physicians, hospitals and the patients who receive the company's heart valves that will, ultimately, prolong life.

## PRODUCT/PACKAGE SYNERGY

### DOESN'T MISS A BEAT AT EDWARDS LIFESCIENCES

Edwards focuses on four main cardiovascular disease states: heart valve disease, coronary artery disease, peripheral vascular disease and congestive heart failure. Subsequently, Edwards leverages its design, development and marketing expertise through its main product categories: cardiac surgery, critical care, vascular and perfusion. The company's brands are sold in 100 countries.

According to Randel Woodgrift, one of the company's corporate officers and the vice president of manufacturing and operations, the true core of Edwards' business is developing, manufacturing and commercializing devices to treat advanced cardiovascular disease. These devices include the Edwards MIRA Mechanical Valve, the Starr-Edwards Silastic Ball Valve, the Carpentier-Edwards Bioprosthesis (made from tissue valves harvested from pigs) and the Carpentier-Edwards PERIMOUNT Pericardial Prosthesis, (made from tissue derived from pericardium, the sac that surrounds a cow's heart).

Today, the Carpentier-Edwards line of heart valves are the most widely prescribed tissue valve in the world. Edwards is also one of the world's leading manufacturers of products for the surgical valve repair procedure—called annuloplasty—and its Carpentier-Edwards and Cosgrove-Edwards annuloplasty products are among the most sought after by surgeons.

#### **Synergy equals success**

The link between physicians with ideas and engineers at Edwards—a connection that took root with the initial Edwards-Starr collaboration—is what drives the company's success.

"What happens is, while doctors practice medicine, many times they're also figuring out better ways to fix problems," explains Barry Liden, director of global communications. "Many of them come to Edwards with their ideas, knowing that if the concept is workable, Edwards will do everything in its power to bring these new technologies to market for patients. Pulling

all of this off takes a lot of imagination if not a little bit of magic.”

Marketed products incorporate the physician’s name with the Edwards name, solidifying a strong partnership. This synergistic approach filters down to Edwards’ relationships among personnel, relationships with patients and, ultimately, the relationship between the product and its packaging. Liden concedes, however, that Edwards, like any medical device company, has its hands tied when it comes to packaging due to governmental regulations, both here in the U.S. and in other countries.

Sterility requirements for medical devices, for example, can place constraints on packaging creativity, says Liden. “A lot of the packaging design is based on utilitarian considerations and how the product/package can be efficiently used by professionals in a fast-paced medical environment. We design packages that are the right size—with the product name and correct patient indications clearly labeled—so that a nurse can quickly determine exactly what the product is and get it into the operating room.”

Pericardial Bioprosthesis Mitral Model 6900P, has a simple rotate-push-snap operation that speeds up the implantation process. A plastic sleeve around the valve is rotated clockwise until a holder reaches the unlock position. A handle is pushed into position until it indicates that it has been fully deployed through a distinctive click. The plastic sleeve and a clip are removed and the valve is rinsed and ready for implantation. Pericardial leaflets are pre-sewn, or sutured, onto the valve’s base ring.

According to David Hanson, Edwards’ manufacturing plant manager, packaging is often an integral part of the product solution.

“Edwards really worked to design a feature on the product/package that would allow the tips of the valve to be deflected inward during implantation,” explains Hanson. “So, as a center post comes through the valve, it actually extends and pushes against the product sutures, deflecting them from the surgeon’s sutures, so they won’t get hung up or stuck on the product. It’s really part of the packaging; it’s part of how the product works.”

**With packages and products operating as a team,  
the number one heart valve company in the world works hard to save lives.**

by Christopher Barry, Associate Editor

Prior to actual product usage, medical device packaging development at Edwards has to go through validation and, according to Karen Greene, Edwards’ senior manager, corporate package engineering, there’s also a strong focus on clinical trial packaging, too.

“Obviously speed and efficiency are keys to success,” says Greene, “but packages may change. If you bring a device to clinical, it may need to be modified or, if they drop a technology or therapy, we may need to go back and design the package again. So Edwards’ packaging group needs to come up with unique designs to get the product to a clinical site quickly while keeping flexibility in mind.”

### **Packaged for the surgeon**

It is packaging that works hand-in-hand with the product that led to the recent development of a system designed to make heart valve implantation easier for surgeons.

The Tricentrix Holder System, designed to deploy with the Carpentier-Edwards PERIMOUNT Plus

### **Temperature and shipping**

Prior to reaching a clinic or hospital, heart valves must remain sterile and protected from physical damage or severe fluctuations in temperature. If they freeze or are exposed to high heat, they could be rendered useless. Once again, packaging technology led to innovation.

According to Greene, one of the most important packaging developments for heart valves was including a temperature indicator, inside a product’s shipping container, that could be validated by the Food and Drug Administration (FDA).

“We incorporated an electronic temperature indicator with the packaging,” says Greene. “It’s used during the shipping and transport of all of Edwards’ tissue heart valves. We’re using a Sensitech unit that can show customers whether the product was exposed to either extreme cold or heat. It has an easy-to-read LCD component so customers know the heart valves are safe and that they were shipped between required temperature ranges. Plus, it meets FDA validation requirements.”

According to Robert Mcilmurray, Edwards' senior manager, global package engineering, the Sensitech indicator is 99.5% accurate when determining required temperature ranges.

"We tested over 1,200 units," says Mcilmurray. "The success rate was phenomenal."

#### Labels and more

Another area where Edwards is moving forward is in product labeling, particularly in the area of global labeling. Walter Wiegand, Edwards' director of Critical Care and Vascular (CCV) quality, says that including local language requirements and presenting necessary product information on the label can be a challenge.

"On the global level, the number of required local languages on a label has jumped in Europe from 15 to about 20," says Wiegand. "We're working out ways to include all of the language necessary—whether it's using booklet labels or smaller font sizes. It's an area that a lot of the industry is going to find challenging."

Another trend Edwards is addressing is the inclusion of product information and instructions within the packaging. Currently, a small booklet of instructions is included in the company's product packaging but there could be other, more efficient ways of presenting product information.

"I think, hopefully, that the instructions for usage will start to become Internet based, as opposed to being included in the packaging," says Mcilmurray.

The idea is to include a web site address on the package's label that end users can access to retrieve

product information.

"The ability to provide this information electronically, gives us a huge advantage in material handling and quality assurance," explains Wiegand.

#### Aiming for the future

Labeling initiatives, product protection, quality assurance, sterility and product implementation all lead to effective product/packaging synergy, something at the heart of the company's mission.

According to Woodgrift, the value of packaging as part of the whole process can't be understated. Clearly sterile barrier, product containment and damage control are at the core of any effective package and these elements are always going to be there.

But the goal at Edwards is to constantly raise the bar in efficiency.

"I see corporate functions such as research and development, engineering and packaging working even more closely," says Woodgrift. "It's all about co-development, co-engineering and even co-location of engineers so that marketing and physicians can come together to meet a common goal."

This goal sharing is vital to a product's success and its ability to reach the market quickly.

"All of these aspects give you a better chance of getting things right the first time out," says Woodgrift.

"We're shooting for a mistake-free environment and I think all the people involved—from our customers to their patients—are more satisfied. We're solving not just our portion of the problem—we're developing something to save somebody's life." **F&DP**

# PACKAGING HEART VALVES

## REQUIRES A HUMAN TOUCH

**O**ne striking element about the packaging operation for Edwards' Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis heart valve is its deceptively simple nature. After all, there's barely any automation throughout the product's packaging process and there's really not even a formal packaging line. But the reasoning for adopting a predomi-

**With very little automation, Edwards Lifesciences' packaging operation retains a human element.**

nantly manual operation is more philosophical than it is a matter of trying to keep costs down.

"Because this product will ultimately end up inside a human being," explains Barry Liden, Edwards' director of global communications, "it's important for us to maintain the product's humanity as whole, including the human touch in packaging."

The process begins when about 2,000 pig valves and

several sheets of bovine pericardial tissue arrive at the company's plant in Irvine, Calif. The tissue is packed on ice and arrives sealed and cleaned.

Tissue is passed through a chamber area and on to assembly in a cleanroom. The workers are as skilled as surgeons and must go through a minimum of six months certification/training prior to working in the assembly area.

Once valves are assembled, they move into the packaging area where six to 10 workers handle the product's packaging requirements. Assembled valves are put into sterilization tanks, built into the room's walls. Cylinders holding valves drop down into the tanks, each holding as many as 250 valves.

The tanks automatically empty and fill depending on the type of solution needed. Valves come out of the tanks and are packed into glutaraldehyde filled polypropylene (PP) jars, supplied by Parkway Plastics. The jars are topped off with a PP closure/lid—supplied by Saint-Gobain—with teflon seals. Jars with valves then go into ovens for a second level of sterilization. The heat, which isn't high enough to damage the valves, continues to destroy any microbes that may be on the tissues.

Jars are removed from the ovens to undergo leak testing using a Uson Sprint-LC Multi Air Tester.

Labels, supplied by Premier Resource, are printed at the time of product manufacture with variable information, including serial number, lot number and use-before-date using computer software with

Zebra brand thermal transfer printers. Final package labels are placed onto jars by hand.

Jars are placed in shrink seal material and put onto a conveyor that runs through a shrink tunnel that is supplied by Belco Packaging Systems. The shrink seal provides tamper evidence and provides coverage from the top of the lid down to the base of the jar. Jars are placed in paperboard cartons, which are then placed in square, clear plastic cartons for added protection. Paperboard cartons include the product name, variable information and Edwards Lifesciences branding. Instruction booklets are folded and placed into the plastic cartons. Shelf life for the heart valves is four years.

Sensitech temperature indicators are placed into shipping containers before placing heart valve packages into the shippers for transport.

"We're really a low volume manufacturer," says David Hanson, Edwards' plant manager of manufacturing. "We output about 300 to 400 jars per day so automating the system just wouldn't be cost effective." **F&DP**

**Belco Packaging Systems**  
800-833-1833;  
[www.belcopackaging.com](http://www.belcopackaging.com)

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### ***For more information***

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