

NIXON PEABODY LLP



**MEDICAL DEVICE
INNOVATION
AWARD**

*celebrating innovative products that improve the
quality and cost-effectiveness of healthcare*

As home to one of the world's most significant medical device clusters, Massachusetts' companies are designing and producing some of the most advanced medical technology products available. The Massachusetts Medical Device Industry Council (MassMEDIC) seeks to recognize innovative medical products, developed and manufactured by member companies that improve the quality and cost-effectiveness of healthcare delivery.

The Nixon Peabody / Smith & Nephew Medical Device Innovation Award will honor novel medical technologies that have demonstrated a positive outcome in the healthcare setting. Awards will be given in each of three main categories:

- Early-Stage companies with \$0-\$4.9 million in annual revenue.
- Emerging companies with \$5 - \$49 million in annual revenue.
- Established medical technology companies with \$50 million or more in annual revenue.

2006 MEDICAL DEVICE INNOVATION AWARDS

ESTABLISHED COMPANY CATEGORY

WINNER: HAEMONETICS CORPORATION **HAEMONETICS®**

cardioPAT™ Cardiovascular Perioperative Autotransfusion System



The Haemonetics® cardioPAT™ Cardiovascular Perioperative Autotransfusion System is indicated for use to salvage red blood cells from blood lost intraoperatively and postoperatively during cardiovascular surgical procedures. The cardioPAT device is the first and only system to offer uninterrupted washed blood salvage in both the operating room and post-operative ICU. It provides high quality, concentrated and washed red blood cells (RBCs) for transfusion back to the patient. Transfusing these RBCs may help the patient avoid a transfusion of allogeneic blood from the blood bank with all of the associated risks.

The cardioPAT system consists of an electromechanical device and a sterile single-use disposable set. It is a small portable system which mounts on an IV pole, and has a half hour battery back-up to allow moving the patient.

HONORABLE MENTION: ZOLL MEDICAL CORPORATION



ZOLL® AED Plus™ AHA Guidelines-compliant version



The ZOLL AED Plus can help treat nearly every victim of sudden cardiac arrest (SCA). The AED Plus helps guide infrequent rescuers with a unique graphical interface - pictures combined with text displays and voice prompts. This approach can help rescuers at every step during a rescue.

The AED Plus now follows the new AHA-recommended compression-to-ventilation ratio of 30 compressions to two breaths. It also allows one defibrillating shock, if needed, followed by a two-minute CPR interval. These enhancements are meant to help rescuers deliver high-quality, effective CPR by delivering more chest compressions while limiting interruptions.

According to the 2005 AHA Guidelines, evidence from two clinical studies show that chest compression rates during unprompted CPR is frequently inadequate in out-of-hospital and in-hospital settings, and note data that show the critical role of early, high-quality CPR in increasing cardiac arrest survival rates. Such findings reinforce ZOLL's efforts to incorporate instantaneous CPR feedback in its products, such as the AED Plus.

2006 MEDICAL DEVICE INNOVATION AWARDS

EMERGING COMPANY CATEGORY

WINNER: NMT MEDICAL, INC. **NMT Medical, Inc.**

STARFlex® Septal Repair Implant



The STARFlex® is a cardiovascular implant for minimally invasive repair of structural heart defects associated with brain attacks such as migraine headaches, stroke, and transient ischemic attack (TIA). The cardiac defect, known as a Patent Foramen Ovale (PFO), occurs in approximately 25% of the population although it is typically benign. In certain patient subsets, however, closure of the defect has demonstrated relief from a variety of ailments, as listed above.

NMT Medical's STARFlex® technology provides a minimally invasive alternative to surgical closure of PFO. Closure is conducted by an interventional cardiologist via a catheter-based procedure, similar to implantation of a coronary stent. Unlike open heart surgery, the STARFlex® implantation procedure does not require the use of general anesthesia and is often done in an outpatient setting in less than 20 minutes.

EARLY-STAGE COMPANY CATEGORY

CO-WINNER: INSULET CORPORATION

OmniPod® Insulin Management System



Cleared by the FDA in 2005, the OmniPod Insulin Management System combines the proven health benefits of continuous subcutaneous insulin delivery with blood glucose monitoring technology in an easy to use, two part system with no tubing, automated cannula insertion and a fully-integrated blood glucose meter. This innovative system eliminates the need for daily insulin injections, replaces conventional insulin pumps and makes intensive insulin therapy easier than ever for people living with diabetes.

The OmniPod System is the first and only continuous insulin delivery system of its kind. Unlike conventional insulin pumps, which require people with diabetes to learn, manage, and carry a number of cumbersome components (insulin reservoirs, infusion sets, insertion devices, and blood glucose meters) and deal with up to 42 inches of tubing, the OmniPod System has just two fully integrated wireless components.

2006 MEDICAL DEVICE INNOVATION AWARDS

EARLY-STAGE COMPANY CATEGORY

CO-WINNER: SUTURTEK, INC.



360° Fascia Closure Device



The SuturTek 360° Fascia Closure Device is an Engineered Sharps Injury Prevention (ESIP) device that enables hospitals to comply with OSHA regulations and Federal and State needle stick prevention and safety laws, reducing cost, risk, and liability exposure.

- Designed to meet the most demanding requirements of surgeons and nurses, the SuturTek 360° Fascia Closure Device is a robust, hospital sterilizable, ergonomic, reusable device.
- Sterile, pre-packaged, single-use disposable, needle-protected suture cartridges are attached to the device. Each cartridge contains a standard needle and suture.
- The SuturTek 360° Fascia Closure Device "Sutures Like a Surgeon™" allowing the surgeon to retain complete control of the placement, depth, and spacing of each stitch. The needle always follows the arc of its own curve, minimizing trauma to the tissue. The result is a series of consistent, high quality stitches.
- The SuturTek 360° Fascia Closure Device uses all standard types and sizes of sutures and a standard curved fascia closure needle, enabling placement of all types of continuous or interrupted stitches.

HONORABLE MENTION: BREAKAWAY IMAGING, LLC



O-Arm™



The O-arm is a multi-modality mobile surgical imaging system. It generates both fluoroscopy (2-D) and 3-D ('CT') images. This platform technology is initially targeted at orthopedic and spine procedures.

Current surgical imaging technologies used for these applications are c-arm fluoroscopes (single view 2-D x-rays), which have been in use for 40 years. By incorporating digital flat panel detector technology and high-precision robotics, the contribution to the surgeon and patient are fewer doses and less surgical time. By adding fast 3-D ('CT'), the surgeon can now complete a 'post-op CT' before closing the patient, enabling verification of instrumentation placement or anatomical alteration. This is added visualization and verification is especially valuable in minimally invasive surgical procedures. Should any adjustments be required, it can be done during the same surgery, potentially avoiding revision surgery. Other advantages include sterility, and patient and staff safety.