

## Global Medical Device Manufacturer Utilizes Tamper Evident Labels to Improve Security and Ease of Use in the OR

**THE SITUATION:** A global medical device manufacturer of pacemakers and leads determined that they needed to have a tamper evident feature on their product packaging (that assures operating room personnel the products have not been tampered with). Operating room personnel wanted visual assurance of package integrity before placing the product inside their patient. The first tamper evident label design made the packages difficult to open by the OR prep nurses in a gloved environment, so they decided to contact AWT.

**THE SOLUTION:** AWT worked with the medical device package engineering department to develop a seal that would meet all of their requirements.

- The packages need to be opened easily by a gloved individual.
- Visual evidence of any tampering.
- Consistent reliability in the OR prep environment.

After several rounds of prototyping and testing to develop the most effective and reliable tamper indicating label, a design was qualified and validated.

**THE RESULT:** The tamper evident label that was developed was eventually phased in across the medical device manufacturers' product line. Feedback from end users in the operating room environment was very positive and the design has become a staple in terminally sterilized device packages. Since the initial tamper evident solution, these seals have been designed to function on a number of substrates from SBS to polypropylene, to use clear materials for more product reveal, and in a number of sizes and shapes to conform to package size and shape.

### **THE BOTTOM LINE:**

- An easy visual test to indicate package tampering was created.
- End user complaints about package function were eliminated.
- Both hospital and device manufacturer had a subjective test for package integrity.
- Possible device tampering was made much more difficult.
- A human life is priceless and knowing that a medical device has not been tampered with can help bring reassurance to the OR personnel.