

Fortune 500 Medical Device Manufacturer Taps into AWT's Knowledge & Expertise

THE SITUATION: A new heart valve package was being designed by a Fortune 500 medical device manufacturer that would need to withstand the autoclave sterilization process. In addition to surviving the high temperature and humidity of steam sterilization, the labeling and sterile barrier system needed to address the issues of traceability, demand printing, marketing and package appeal, tamper evident features, and FDA regulatory requirements.

THE SOLUTION: Using AWT's knowledge of adhesive and face stock characteristics, we were able to work closely with the customers' package and manufacturing engineering departments to design a package that was both functional and aesthetically pleasing. A heat sealable Tyvek® material was identified that would survive the autoclave sterilization process. In addition, a polyester label set was designed that had all of the tracking and identification information for the shelf carton and sterile package in one label. Destructible paper seals for the inner package, hard vinyl for the outer seal, and clear polypropylene for the package ID and logo were also utilized.

THE RESULT: A terminally sterilized package that was functional, attractive, had tamper indicating features and was compliant with FDA requirements was released to the heart valve replacement market.

THE BOTTOM LINE:

- Traceability and manufacturing data were captured in one label set with 100% accuracy in identifying all components.
- The manufacturing process was streamlined and made more flexible.
- Sterilization costs were lowered using the autoclave, with in-house sterilization resources utilized rather than sending the packages to an outside vendor.
- The manufacturers total applied cost was reduced by more than 15%.