

**2009 North American Interventional Cardiology Product Innovation of the Year Award****CeloNova BioSciences**

The 2009 Frost & Sullivan North American Product Innovation of the Year Award in the field of Interventional Cardiology is conferred upon CeloNova BioSciences, in recognition of its development of the CATANIA™ coronary stent. The stent has been developed using Polyzene®-F, a pure inorganic polymer that bestows exceptional anti-thrombogenicity, biocompatibility, lubricity, and vastly improves the performance of the device. The unique characteristics of this stent make it particularly attractive for use in patients who may be especially prone to bleeding and who cannot, will not, or are unable to, go through dual anti-platelet therapy.

**Company Background**

Established in 2001, CeloNova BioSciences is a medical device company based in Newnan, Georgia. CeloNova's primary focus has been to develop advanced medical devices for key applications using its proprietary Polyzene®-F material. Under the direction of President and CEO Tom Gordy, CeloNova BioSciences is progressing toward its stated mission of providing unique, new healing options for patients and physicians while improving patient outcomes and reducing their pain and suffering.

**Technology Features**

The management and revascularization of chronic total occlusion of coronary arteries has remained a challenge for interventional cardiologists for years. Percutaneous coronary intervention with stenting has become the preferred treatment option. Bare metal stents appeared first; but, allowed the occluded artery to restenose about 30% of the time. Drug-eluting stents emerged to prevent the cellular growth associated with restenosis and have been successful. However, delayed and poor post-stent vessel healing, late stent thrombosis, and the unfavorable effects associated with long-term, and dual anti-platelet therapy are concerns for both physicians and patients. To help overcome such issues, CeloNova BioSciences has developed a novel biocompatible stent known as the CATANIA™ Coronary Stent System with NanoThin Polyzene®-F.

CATANIA™ stents have been shown to facilitate early and robust healing in blood vessels, provide protection against thrombosis, and even help patients' live without anti-platelet medications and ultimately help improve patient outcomes. CATANIA™ stents are coated with a 35-40 nanometer thin layer of an inorganic polymer called Polyzene®-F, which is what forms the foundation of the stent's functionality.

The Polyzene®-F material can be used in a wide array of bioscience and industrial applications, where it can be applied onto or mixed with other substances. Medical devices developed with the Polyzene®-F coating do not trigger a negative reaction when implanted in the body, eliciting a normal and positive body response. It is anti-inflammatory and anti-thrombogenic in nature; it also promotes endothelial cell growth without triggering platelet activity. The other salient features of Polyzene®-F: (a) it is lubricious, (b) acts like a camouflage, (c) excellent biocompatibility, and (d) highly resistant to bacterial activity.

The CATANIA™ stent features a highly deliverable, cobalt chromium, modified open cell design that utilizes a rapid exchange delivery system and is available in 60 sizes and two versions; a smaller and larger stent that differs in thickness, length and diameter. Finally, CATANIA™ stents are formulated without the use of additives and off-loaded agents of biological substitutes.

In October 2008 the company presented results from its one-year first-in-man at the Transcatheter Cardiovascular Therapeutics Conference in Washington DC. The results from these clinical trials demonstrated remarkable advantages and reaffirmed the safety of the CATANIA™ stent. Specifically, the results point to zero incidence of ARC stent thrombosis, death, myocardial infarction, stroke, or need for coronary artery bypass grafts. Clinical results at eighteen month results, presented at the International Symposium on Endovascular Therapy in January 2009, were the same.

### Best Practices

CeloNova BioSciences has a tight knit and innovation-oriented culture of growth. The company employs two practices, Castellan and Flight Plan, to ensure its development work adheres to certain standards. Members of the company's cross-functional core management team, the Castellan team, are keepers of the corporate culture. They accelerate speed to market through close collaboration with product and business developers and ensure product development is consistent with the company's philosophy and quality standards. The metaphorical Flight Plan approach is CeloNova's framework in which certain experts are designated to lead development in product areas that are high priority. But what really distinguishes the company's approach is its focus on tangible medical innovation, which is the nurturing of ideas that could yield vastly new and significant benefits, as opposed to narrow, incremental development that often characterizes innovation today.

CeloNova BioSciences has developed a deep and extensive intellectual property portfolio consisting of 143 issued patents, and has approximately 100 more in prosecution. CeloNova BioSciences has also been successful in obtaining CE-Mark approval, which will allow CATANIA™ stents to be marketed throughout Europe, as well as in certain Middle Eastern countries.

## Conclusion

The 2009 Frost & Sullivan Award for Product Innovation of the Year recognizes Celonova BioSciences' development of a unique coronary stent that provides excellent anti-thrombotic, anti-inflammatory, bacterial-resistant functionality along with exceptional biocompatibility.

## Award Description

The Frost & Sullivan Award for Product Innovation is presented each year to the company that has demonstrated excellence in new products and technologies within its industry. The recipient company has shown innovation by launching a broad line of emerging products and technologies.

## Research Methodology

To choose a recipient of this Award, the analyst team tracks all new product launches, research and development (R&D) spending, products in development, and new product features and modifications. This is accomplished through interviews with the market participants and extensive secondary and technology research. All new product launches and new products in development in each company are compared and evaluated based on degree of innovation and customer satisfaction. Companies are then ranked by number of new product launches and new products in development.

## Measurement Criteria

In addition to the methodology described above, there are specific criteria used to determine final competitor rankings in this industry. The recipient of this Award has excelled based on one or more of the following criteria:

- Significance of new product(s) in its industry
- Competitive advantage of new product(s) in its industry
- Product innovation in terms of unique or revolutionary technology
- Product acceptance in the marketplace
- New product value-added services provided to customers
- Number of competitors with similar product(s).

**About Best Practices**

Frost & Sullivan Best Practices Awards recognize companies in a variety of regional and global markets for demonstrating outstanding achievement and superior performance in areas such as leadership, technological innovation, customer service, and strategic product development. Industry analysts compare market participants and measure performance through in-depth interviews, analysis, and extensive secondary research in order to identify best practices in the industry.

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