



News Release

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**Arterial Remodeling Technologies (“ART”),
whose bioresorbable stent platform
restores remodeling capacity of arterial walls,
receives ISO 13485 certification**

**Certification comes on the heels of data published in
EuroIntervention Journal special supplement**

PARIS, Feb. 1, 2010—[Arterial Remodeling Technologies](#) (“ART”) announced today that it has earned ISO 13485 certification.

ISO 13485 is an internationally recognized medical device Quality Management System (QMS) standard developed by the International Organization for Standardization (ISO). To be certified to the standard, companies must implement a medical device QMS ensuring that steps have been taken to identify, manage and minimize the risks involved with the manufacturing and use of its medical devices. Certification to ISO 13485 reinforces through an independent third-party that ART operates its medical device QMS in accordance with the recognized standard.

"ART must be committed to the highest quality in manufacturing its bioresorbable stents," said **Machiel van der Leest**, CEO. "Certainly, achievement of ISO 13485 certification bears strong witness to our promise," added van der Leest, who has during his career developed and successfully introduced **15 Class III medical devices** that required premarket approval and a scientific review to ensure safety and effectiveness.

Last month, impressive *in vivo* and *in vitro* data related to ART’s bioresorbable stent platform—data that validates the Company’s approach to simultaneously balance **biocompatibility, biomechanics** and **bioresorption** in a bioresorbable PLA (polylactic acid) stent without altering healing by drug elution from the stent platform—were published a special supplement of *EuroIntervention*, a peer-reviewed journal. The paper was authored by **Antoine Lafont, M.D., Ph.D., Head, Interventional Cardiology Department, Georges Pompidou Hospital (Paris); Past Chairman, Interventional Cardiology Group, European Society of Cardiology (ESC).**

(more)

“There is no doubt: our novel approach to bioresorbable stenting has indeed been validated,” added van der Leest. “The data published by EuroIntervention show that ART’s bioresorbable stent provides the requisite *initial* mechanical scaffolding to resist recoil. Then, as it dismantles *over time* in a *controlled* fashion because of its polylactic acid makeup, *remodeling* returns to the artery. Also critical is that our bioresorbable stent causes little, if any, inflammation in the artery, which further suggests that we may have the option of using, or not using, antiproliferative drugs with our stent. Plus, the endothelialization we’ve seen at one month post-implant is outstanding,” concluded van der Leest.

ART’s novel biopolymers have been developed in conjunction with one of the world’s leading authorities in polymer chemistry, **Professor Michel Vert**, who is Former Director of the Research Center for Artificial Biopolymers at France’s National Center for Scientific Research (Centre National de Recherche Scientifique/CNRS).

[About Arterial Remodeling Technologies \(“ART”\)](#) Arterial Remodeling Technologies (“ART”) is developing bioresorbable coronary polymer stents that promote the natural remodeling of an injured artery after angioplasty. The Company’s technology is based on intellectual property originating from three esteemed institutions: the **Cleveland Clinic**; the French national research institute, **CNRS** (Centre National de Recherche Scientifique), Montpellier, France; and, **Descartes University**, Paris.

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