A Novel Bioabsorbable Omega-3 Fatty Acid Based Biomaterial

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A wide variety of biomaterials exist for use in implantable medical devices. These materials can be permanent or degradable, and when used as a coating can impart properties such as biocompatibility, lubricity, or antimicrobial action to the substrate device. Coatings may be used to help improve tissue adhesion or to make the surface of the device non-adhesive to tissue. Coatings for medical devices are also often used to carry and release therapeutic agents from the device.

Often, polymeric coatings are necessary to achieve desired traits on implanted devices. These traditional polymeric coatings may require the use of solvents during the coating process or necessitate the use of chemical cross-linking agents, and many of these traditional polymeric coatings, whether permanent or biodegradable, have been observed to elicit an inflammatory response *in vivo*. What is desired is a biomaterial that provides the necessary benefits without necessitating the removal of residual solvents or chemical cross-linking agents, and does not elicit an inflammatory response with the host tissue.

An alternative biomaterial has been developed to provide many of the same benefits of traditional polymer device coatings without the use of solvents or chemical cross-linking agents, and without eliciting an inflammatory response from the host tissue. The novel bioabsorbable coating platform consists of a non-polymeric omega-3 fatty acid (O3FA) based chemistry that can be formulated with a range of physical properties, such as liquid or gel. The coating is absorbed *in vivo* by hydrolysis, converting it into naturally occurring fatty acids, glycerides, and fatty alcohols. These smaller components are readily absorbed by local tissue and consumed through the normal lipid metabolism.

The versatile O3FA coating technology has been used to coat devices to minimize foreign body response and deliver therapeutic compounds; to minimize tissue attachment to the underlying device; and as a drug delivery system for restenosis, anti-adhesion, and anti-infection applications. The O3FA material can also be used as a stand-alone film for the prevention of adhesions in general surgery applications.

Several pre-clinical studies have been conducted with the O3FA material coated on coronary stents, and polypropylene hernia mesh. Pre-clinical coated mesh studies consistently show that the O3FA coating minimizes visceral adhesion formation and the inflammatory response.

In addition, clinical data have been collected from coated mesh (Atrium C-Qur™ Coated Mesh) explanted for reasons unrelated to the mesh implant. These explants consistently show good abdominal wall incorporation, minimal visceral tissue attachment and inflammation confirming the preclinical evaluation results.

The O3FA coating has also been used as a drug delivery vehicle on coronary stents. A variety of therapeutic compounds have been evaluated in both rabbit and porcine preclinical models to support a First In Man human clinical study with a calcineurin inhibitor as the API. Data will be presented on the preclinical program results and clinical plan.