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Microporous Coating Provides Superior Stent

CardioTech International and Implant Sciences recently concluded a successful *in vivo* animal study using a coronary artery stent covered in a microporous polycarbonate-based polyurethane membrane. The encapsulated device, the I-Plant Drug Eluting Stent, offers considerable advantage over currently available stents including improved tissue in-growth and higher drug-delivery capacity.

The stent coating is fabricated from ChronoFlex, a hemocompatible polyurethane polymer manufactured by CardioTech, which serves as a carrier for anti-restenosis drugs. Restenosis, the re-narrowing of a blood vessel due to growth of tissue at the site of stent implementation, can lead to a return of arterial disease symptoms. Stents are used in about 80% of all percutaneous coronary interventions, and restenosis occurs in 15% to 30% of patients. The polymer membrane must deliver the drug at a sustained, controlled and predictable rate, must be totally biocompatible with delicate coronary artery tissue and be capable of expanding simultaneously with the stent during deployment without flaking or delaminating.

Few polymer systems meet such exacting requirements. Most biodegradable polymers, such as polyglycolic-polylactic acid, polyethyleneoxidepolybutylene terephthalate, and polyortho-ester exhibit marked inflammatory reaction. CardioTech's bio-compatible matrix promotes thorough re-endotheliazation, resulting in a more effective long-term healing process. Microporous encapsulation is achieved with a proprietary electrostatic technique and the polymer sheath is then impregnated with one or more drugs, such as Rapamycin or Heparin.

In the recent animal trials, 11 Yorkshire pigs were implanted for 30 days with the microporous stent. At the conclusion of the experiment, implant sites were evaluated for neointimal area, medial area and percent stenosis at the proximal, middle and distal edge locations. The device showed no signs of causing inflammation or intimal hyperplasia in the arterial walls.

The coated stent will soon enter preclinical studies. Similar stents now in clinical trials elute drugs only from a polymer coating on the device's struts.

The technology is not limited to drug-eluting covered stents for cardiovascular applications, but also might be used in drug-eluting stent grafts for the treatment of abdominal aortic aneurysms. CardioTech estimates the potential market for drug eluting stents to be worth about $3 billion annually.

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MATERIALS

Fluoropolymer Resists Wide Range of Chemicals

Solvay Advanced Polymers, L.L.C. has added HALAR ECTFE to its portfolio of polymers for the membrane industry. Introduced at the American Water Works Association conference in June, the new high-purity fluoro-polymer features exceptional heat and chemical resistance, stability at high pH levels and good processing characteristics.

Membranes made with HALAR, a copolymer of ethylene and chlorotrifluoroethylene, can last longer and require fewer replacements because of the polymer's resistance to a wide range of chemicals. The membranes are not affected by direct exposure to strong bases such as sodium and potassium hydroxides, strong mineral and oxidizing acids such as sulfuric and hydrofluoric acids, or chlorinated compounds such as methylene chloride and sodium hypochlorite. HALAR ECTFE is also resistant to strong polar solvents, such as dimethylformamide, dimethylacetamide, and N-methyl pyrrolidone, typically used to fabricate polymeric membranes.

HALAR has advantages over many other materials used for polymeric membranes, and offers significant performance benefits for membranes used in both potable and wastewater treatment systems. The polymer has excellent resistance to aggressive cleaning agents used in