



Press Release

GISH Biomedical, Inc., a member of the MEDOS group, receives FDA clearance for GBS® – Heparin Free products

February 12, 2009

Today GISH announces that it has received FDA clearance for its perfusion products with GBS (GISH Biocompatible Surface) - Heparin Free Coating for the cardiopulmonary surgery market. This includes oxygenators, venous reservoirs, arterial filters, heat exchangers, and tubing used in perfusion circuits. The addition of the GBS-Heparin Free offering expands the GISH portfolio to address heparin sensitive patients such as those with heparin induced thrombocytopenia (HIT). This offering adds to the established line of GBS – Heparin products proven to be effective in preserving platelets and inhibiting the factors that cause Systemic Inflammatory Response.

GBS Coatings are covalently bonded, non-leaching coatings developed exclusively by GISH. Both GBS-Heparin and GBS-Heparin Free are biocompatible and composed of hyaluronic acid (hyaluronan) – an inert hydrophilic biopolymer that occurs naturally in the skin, vitreous humor, synovial fluids, and in the body's extracellular spaces. It coats and lubricates the body's cells and is instrumental in the healing process. Hyaluronan lacks immunogenicity and is completely blood compatible, making it an ideal coating for blood-contacting applications. GBS Coatings are the only hyaluronan based cardiovascular device coatings on the market.

A recent clinical evaluation concluded that GBS-Heparin Free Coating provided a better perioperative outcome versus uncoated controls. According to Serdar Gunaydin, MD, of University of Kirikkale, Kirikkale-Turkey, "In our clinical evaluations, the GBS-Heparin Free coated products performed better than competitive polymer (heparin-free) coated products. Intraoperatively, the circuit handles air better. Patients treated with GBS-HF coated products had better perioperative clinical outcomes including lower instances of systemic inflammatory response and arrhythmia, reduced bleeding and need for blood products, and fewer instances of respiratory support needed."

GISH Biomedical, Inc., designs, manufactures, and markets disposable medical devices for various surgical specialties including cardiovascular surgery, orthopedics, and oncology.

For more information, please visit the GISH website or contact:
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