

Stanmore receives European approval for silver modular implant technology

Use of silver in implants shown to materially reduce infection rates

05 January 2012 - Stanmore Implants (“Stanmore”), specialists in the design and manufacture of implants for complex orthopaedic reconstructions, announces it has received a European CE mark for its ionic silver treated massive endoprosthesis tumour system (“METS”) modular implant system. Silver-treated implants have been shown to materially reduce infection rates in patients undergoing surgery.

The METS modular implant system is a ready to use modular kit, with interlocking junctions, which is quick and easy to assemble during surgery. Stanmore manufactures METS systems for a number of orthopaedic skeletal locations including the femur, tibia, knee, pelvis and humerus. It is estimated that, globally, c. 15,000 patients receive modular implants every year and this market is valued at £120-150 million and growing at an annual rate of approximately 10%.

Silver is a well known anti-microbial agent and Stanmore has incorporated it in around 400 of its custom-made implants (where the implants are tailor made for each individual patient) over the last five years. In Stanmore’s procedures using silver, the infection rates have been significantly reduced comparative to non-silver treated custom limb sparing implants that historically have an infection rate of around 11%. Infection is currently the most common serious complication of endoprostheses and may result in the amputation of patients’ limbs. In addition, the cost of treating an infected prosthesis is considerable and infections often recur.

Stanmore has the exclusive, long term licence to Accentus Medical’s Agluna® silver surface modification technology for use in custom made limb sparing implants and patient specific joint replacements. The technology uses a patented anodising process, where the surface is modified through the stitching of ‘silver’ into the upper layer of the titanium alloys. This surface modification eliminates the delaminating effect found in silver coatings whilst significantly reducing the amount of silver required.

Brian Steer, Executive Chairman of Stanmore, said:

“With infection being a major burden on the healthcare system and often leading to avoidable amputations, we are delighted to secure approval for our silver treated METS system.

“There is increasing evidence to support silver’s anti-microbial properties and incorporating it into our METS system puts Stanmore in a very strong competitive position. We expect to see demand rapidly increase and we look forward to working with doctors around the world to help improve the lives of patients.”

Stanmore currently sells its METS devices in more than 16 countries worldwide.

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Notes to Editors

Agluna® is Accentus Medical’s novel surface modification technology applied during the manufacture of medical devices to effectively prevent deep-seated infection. During the Agluna® process, silver is ‘stitched’

into the titanium surface in the form of positively charged ions and is therefore considered to be a surface modification and not a coating. Silver is well known for its bactericidal properties and the use of silver on medical devices has previously been approved by worldwide regulatory bodies on a large number of products. Silver ions at low doses will eliminate bacterial cells with no toxicological effect on the human patient. The Agluna® treatment enables the steady release of silver ions from the implant's surface over several months by dissolution into body fluids, eventually leaving a silver-free implant that has long-term durability and biocompatibility. As patients are at highest risk of infection during the initial healing process following surgery the delayed release of silver ions is sufficient to provide a high level of protection.

In vitro testing has shown the Agluna® surface to have a bactericidal effect against bacteria known to cause post-operative infection, including drug resistant strains. Medical device materials have been shown to be susceptible to rapid colonisation by bacteria, which then produce a plaque or biofilm as protection against the body's defences. Implants treated with Agluna® technology have been shown to remain clear of biofilm formation and clinical data from the field of tumour implants has shown a demonstrable reduction in infection rates in patients treated with Agluna®-treated implants.

Stanmore Implants Worldwide

Stanmore Implants Worldwide is an innovative orthopaedic business focused on the design and manufacture of both bespoke and modular implants for limb sparing and complex primary and revision joint replacement.

Stanmore designs, manufactures and markets a custom implant service alongside a portfolio of orthopaedic implants for limb salvage and complex joint replacement, and is known for creating some of the world's most successful implants.

Stanmore acquired its robotic bone preparation technology through the acquisition of Acrobot, a medical devices company specialising in computer assisted orthopaedic surgery in August 2010.

For further information please visit www.stanmoreimplants.com