SMART-HIP, a research project led by Cambridge coating specialist Tecvac Ltd and leading UK hip prosthesis manufacturer, Corin Ltd, has demonstrated the potential of new enhanced wear resistant coatings to increase implant longevity in Metal-on-Metal (MoM) hip prostheses and future potential applications to trunnions and tapers to prevent fretting and corrosion. A new PVD silver bearing coating was developed which may protect against post-operative infection, and also minimise metal ion release. These inherent wear resistance and anti-microbial benefits have the potential to substantially reduce the lifetime cost of hip replacement implants to the NHS and health organisations worldwide, while providing a much improved patient experience.

Overall the SMART-HIP project demonstrated the potential of the new family of coatings to reduce initial post-operative implant wear by a factor of 4 and eventually to double implant service life. The new Chromium Nitride (CrN) coatings reduce induced wear to negligible levels. The incorporation of silver in the outer layer of the coatings provided the planned and self-sustaining release of beneficial silver anti-microbial particles. This gives both self-lubrication of the bearing surfaces and short and long term protection against post-operative infections.

Funded by the Technology Strategy Board (TSB), the Engineering and Physical Sciences Research Council (EPSRC), the Biotechnology and Biological Sciences Research Council (BBSRC) and the industrial partners, the SMART- HIP project included teams from the Research Centre in Surface Engineering at the University of Sheffield, Queen Mary College, University of London (QMUL), Imperial College London and Charing Cross Hospital. The coatings and other elements of the research are protected by international patents and relevant patent applications.

SMART-HIP is the first major research project to approach biomedical coating design and development in a multi-disciplinary, integrated way, and recognised that a successful outcome of the project would depend on an effective cross-disciplinary approach to the technical challenges. Indeed a substantial part of the successful innovation was the direct result of the interdisciplinary nature of the group. An important feature of the project was parallel evaluation of the toxicology and immunology as the coating formulation and orthopaedic work progressed. In Draft Media release 5354v3 Tecvac Ltd April 2012

particular, many of the immunological tests in this project had never previously been applied to the coating processes before. The work is particularly timely with the current concerns reported about Metal-on-Metal (MoM) total hip prosthesis implant designs and the potential impact of trunnion wear rates on large diameter bearings.

During the three year project, Tecvac and the University of Sheffield developed a variety of new coating strategies and formulations, which were then applied by Tecvac to MoM implants designed and produced by Corin. Coated implants were then assessed by QMUL using a full-scale hip simulator which included 8 simulation stations using bovine serum. Tests were also carried out on multiple samples to determine implant resistance to extreme and accidental loads. As the wear test progressed, endotoxin assays, ion release analysis, bio-compatibility, immunological and microbial evaluations were carried out by Imperial College, Charing Cross Hospital and QMUL.

The most successful coatings were based on a CrN PVD coating, including silver in the outermost layers and precision substrate pre-treatment to enhance wear properties and shock load performance. The bioactive coating provides controlled release of silver particles. These particles are generated in the normal wear process and have been shown to have effective anti-microbial properties. This controlled and engineered aspect of the wear process creates a benign environment around the implant reducing the post-operative chance of infection.

"This was of course a very complex multi-disciplinary project," commented Dr Jonathan Housden, "involving investigation of engineering, metallurgical, biological and chemical processes... sometimes at a very fundamental level. We were all very pleased the SMART-HIP was not only completed on time, but also on budget and with a very positive biomedical research outcome, including the development of methods to successfully monitor the evolution of ion release. Papers have been published in nine scientific publications covering the project. In addition, not only has the SMART-HIP project resulted in a proven new family of coatings, but they also include features that reduce structural metal ion release to almost negligible Draft Media release 5354v3 Tecvac Ltd April 2012

Draft Media release 5354v3 Tecvac Ltd April 2012

levels, while using the very same inevitable and unavoidable wear processes to impart new self-lubrication and beneficial anti-microbial properties to the implant surface."

More media information from Ewart Woolley, CMPR, Tel: 01594 516079 Mob: 07790865162 Newsweb: <u>www.cmprnews.co.uk</u> email: <u>mailto:ewart@cmpr.co.uk</u>

CMPR/5354/21.02.2012

INFORMATION NOTES

THE TECHNOLOGY STRATEGY BOARD is a business-led government body which works to create economic growth by ensuring that the UK is a global leader in innovation. Sponsored by the Department for Business, Innovation and Skills (BIS), the Technology Strategy Board brings together business, research and the public sector, supporting and accelerating the development of innovative products and services to meet market needs, tackle major societal challenges and help build the future economy. For more information please visit: www.innovateuk.org.

THE ENGINEERING AND PHYSICAL SCIENCES RESEARCH COUNCIL (EPSRC) is the main UK government agency for funding research and training in engineering and the physical sciences, investing more than £850 million a year in a broad range of subjects – from mathematics to materials science, and from information technology to structural engineering. More information at http://www.epsrc.ac.uk

CORIN PLC

As a leader in orthopaedic innovation, Corin has pioneered a number of landmark developments since its foundation and is associated with some of the most important advances in orthopaedic implant technology over the last 20 years. From its headquarters in the UK, Corin has direct operations in five more of the world's major orthopaedic markets and distribution arrangements in over 30 other countries. Its teams share a common commitment to Responsible Innovation, helping to improve the quality of life of thousands of patients around the world through the development and delivery of these groundbreaking products. Corin's research and development activities involve collaborative projects with companies, universities and research institutes worldwide. Dr Leona Morton, Research Manager at Corin, the BERTI Project Leader, is responsible for all research activities within Corin. Dr. Morton has considerable experience with the project management of collaborative,

industrial and academic programmes. More at http://www.coringroup.com/

TECVAC LTD is a leader in the Advanced Surface Engineering (ASE) Industry, supplying ultra-hard, wear resistant coatings and other ASE treatments, and exports equipment and services to over 20 countries worldwide. Part of the Wallwork Heat Treatment Group, Tecvac designs and builds coating equipment and provides advanced hard coating services including novel nano-composite coatings combining exceptional wear and corrosion resistance and inherent antimicrobial properties. Dr Jonathan Housden, Head of R&D at Tecvac Ltd, has many years experience of successfully managing and leading UK and EC funded collaborative projects including Brite Euram, CRAFT, Innovation, Info2000, LINK, RAIS award, EUREKA and GROWTH. The EUREKA "DUBIOP" project conceived by Dr Housden was selected as a "Best Practice Project" by the EC "USEandDIFFUSE" review. More at http://www.biomedicalsurfaces.com/ and http://www.tecvac.com

IMPERIAL COLLEGE LONDON & CHARING CROSS HOSPITAL, LONDON. The team has extensive surgical experience in hip and knee replacement surgery, including hip revision surgery, musculo-skeletal inflammation research and related research topics, and includes Alister Hart, senior lecturer and NHS consultant orthopaedic surgeon, Dr Ewa Paleolog, reader in cytokine biology, and Dr Hugo Donaldson, microbiologist, as an adviser to the project.

More at

http://www1.imperial.ac.uk/surgeryandcancer/divisionofsurgery/clinical_themes/musculo/retrie_val/

QUEEN MARY, UNIVERSITY OF LONDON Professor Julia Shelton, PhD, School of Engineering and Materials Science and her team, developed novel approach for accelerated wear processes, focusing on metal-on-metal bearing surfaces, supporting areas of research focusing on the development and evaluation of surface coatings, controlling and characterising ion release from the bearing surfaces, understanding the role of proteins on the joint and particle surfaces as well as evaluating the influence of the geometrical parameters of the bearing designs.

More at http://www.sems.qmul.ac.uk/staff/staff.php?j.shelton

THE UNIVERSITY OF SHEFFIELD (USFD) has strengths in Materials Engineering and Coatings Tribology and Professor Allan Matthews and Dr Adrian Leyland supported the scientific PVD coating development objectives of the project. Professor Matthews, Head of Department, Professor of Surface Engineering and Director of the Research Centre in Surface Engineering, in the Department of Materials Science & Engineering (MSE) at USFD, who pioneered work on the development of reactive ion plating and other enhanced-plasma PVD processes, worked with Dr Leyland, Senior Lecturer in Surface Technology in the Department of MSE at USFD, who has developed new approaches to PVD-based duplex and hybrid surface modification techniques.

More at http://www.sheffield.ac.uk/materials/staff/amatthews.html

More media information from Ewart Woolley, CMPR, Tel: 01594 516079 Mob: 07790865162

Newsweb: www.cmprnews.co.uk email: mailto:ewart@cmpr.co.uk

Draft Media release 5354v3 Tecvac Ltd April 2012

Draft Media release 5354v3 Tecvac Ltd April 2012