

Acusure® Technology

Accentus Medical is the UK's largest independent supplier of a range of inert/reducing gas plasma spray coatings, Acusure®, to global orthopaedic device manufacturers.

Accentus Medical has developed and commercialised the Acusure® range, a series of advanced coatings that are applied using proprietary inert/reducing gas thermal plasma spraying techniques to orthopaedic and certain other implants manufactured by medical device companies worldwide. The Acusure® range is designed to improve both the biocompatibility and durability of implantable medical devices and includes medically pure titanium, titanium alloy, cobalt chrome alloy and hydroxyapatite.

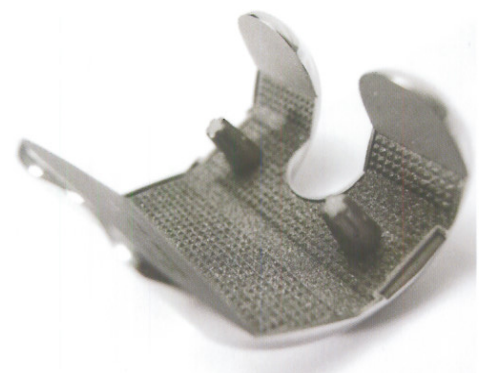
How Acusure® works

The Acusure® coatings are applied to implant surfaces with the purpose of improving the implant fixation by encouraging the growth of new host bone adjacent to the implant which results in increased long term stability of the device and a better outcome for the patient.



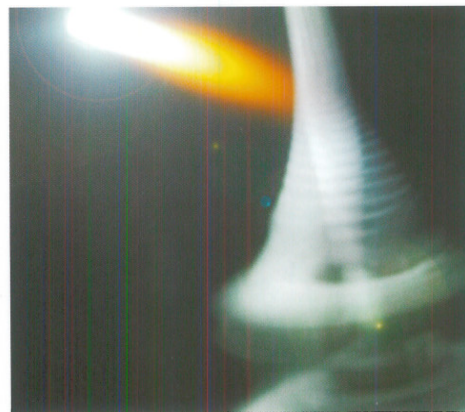
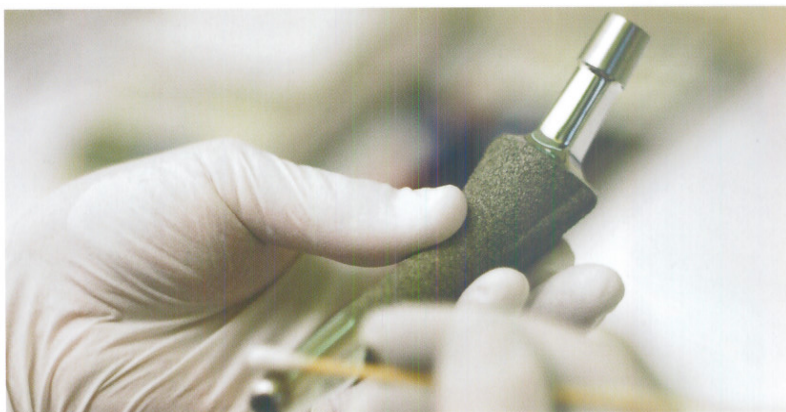
Acusure® quick facts

- Designed to improve the biocompatibility and/or durability of orthopaedic and certain other implantable medical devices
- Coatings produced using proprietary inert/reducing gas thermal plasma spraying techniques
- Coatings include medically pure titanium, titanium alloy, cobalt chrome alloy and hydroxyapatite
- Utilised on orthopaedic and certain other implants manufactured by medical device companies around the world
- In clinical usage for over 12 years



Acusure® process

Accentus Medical has over 30 years of experience in the development, refinement and application of inert/reducing gas plasma spray coatings onto metallic surfaces as this technique was invented by the company's historical parent, the UK Atomic Energy Authority. A key driver in the development of Acusure® was to find a replacement for the traditional expensive and time-consuming vacuum plasma spraying techniques, while producing coatings with the level of purity, strength and adhesion required by international medical device regulations.



Clinical status – benefiting patients globally

Clinical studies undertaken by both Accentus Medical and its customers have proved the safety and efficacy of Acusure® coatings and several of the coatings in this range have been in continuous clinical usage for more than 12 years.^{1,2,3} Devices incorporating Acusure® have been used in all regions of the world including Europe, the USA and Japan, and an estimated one hundred thousand patients are benefiting from Acusure® coated implants.

Manufacturing and regulatory

Acusure® coatings are applied using one of two purpose-built inert/reducing gas plasma spray machines. Both machines have been subjected to full process validation studies as required by regulatory authorities in Europe and North America.^{4,5}

Acusure® coatings comply with all applicable ASTM, ISO and BS standards as well as with the US Food and Drug Administration (FDA) guidelines on metal/hydroxyapatite coatings.

Accentus Medical has been awarded ISO-13485 accreditation by its notified body, Lloyds Quality Register (LRQA). The company has also been fully audited by the US FDA and has been awarded an FDA licence no 3005913272 as a manufacturer of medical devices. The company has also taken the initiative to lodge a masterfile related to Acusure® coatings with the FDA. This file MAF-1961 can be utilised and referred to by any customer submitting relevant devices for marketing approval in the USA.

Accentus Medical plc

Accentus Medical is a leading developer of advanced surface technologies, coatings and treatments that provide unique and innovative solutions to the medical device industry. The company collaborates closely with industry partners to develop novel surface technologies that address the challenges of implantable medical device design and performance. Accentus Medical is also a recognized provider of medical device regulatory testing services to the orthopaedic manufacturing sector.

Bibliography

1. Acc-O7 coating Validation reports prepared by Accentus Medical *
2. "Assessment of early osteo-integration as a function of coating material in rabbit femoral implants" :Report BR/JF/06 prepared by AEA Technology August 2002*
3. "Cornet Hip Resurfacing Multi-centre study", Spencer et al; Proceedings of British Hip Society – Leeds March 2007
4. "Guidance for Industry on the testing of metallic plasma sprayed coatings on Orthopaedic implants to support reconsideration of post-market surveillance Requirements" US Food and Drug Administration – February 2002
5. "510 K information needed for hydroxyapatite coatings" US Food and Drug Administration – March 1995.

Contact

Accentus Medical plc
528.10 Unit 2, Rutherford Avenue
Harwell Science and Innovation Campus
Didcot, Oxfordshire OX11 0DF
United Kingdom

T: +44 (0)1235 434320 F: +44 (0)1235 434329
Email: enquiries@accentus-medical.com

To find out more visit:

www.accentus-medical.com

