FDA Clears Sculptor Robotic Guidance Arm For Unicompartmental Knee Replacement Surgery

Stanmore Implants ('Stanmore'), specialists in the design and manufacture of patient specific and modular orthopaedic implants, announced today that it has received 510(k) clearance from the US Food and Drug Administration (FDA) to market its Sculptor Robotic Guidance Arm(TM) ("Sculptor RGA(TM)") for precision implant placement in unicompartmental knee surgery, also known as partial knee resurfacing.

Partial knee resurfacing only replaces the parts of the knee that are worn out and painful rather than cutting away the entire joint. This preservation technique retains the natural ligaments around the knee, reduces surgical damage to tissue and is less invasive compared to total knee replacement. Sculptor RGA(TM) utilises a robotic guidance arm to assist the surgeon's operation of a cutting tool, limiting the removal of bone to a pre-defined safe area using Stanmore's patent protected 'Active Constraint(TM)' technology.

Stanmore's unique personalised procedural approach to surgery seamlessly integrates advanced technologies. From proprietary planning software, personalised implants are designed in-house, then manufactured and placed precisely. During surgery, bone is removed corresponding to the implant shape whilst a tracking arm determines and monitors the location of the patient ensuring that the surgeon accurately prepares the bone surface to match the implant precisely.

This new and unique approach to the treatment of osteoarthritis of the knee has been used at a number of leading centres in the UK since the first patient specific personalised knee was implanted in July 2011 and builds upon the earlier clinical work undertaken using the Active Constraint(TM) technology featured in the Sculptor RGA(TM) device. Active Constraint(TM) technology has been shown to provide better functional outcome at 7 year follow up for partial knee surgery compared to the saws and jigs currently used in most knee surgery procedures, which are prone to a much higher degree of placement error.

The Sculptor RGA(TM) will be introduced in the United States for unicompartmental knee surgery in a limited release to a select group of surgeons from mid-2013, as Stanmore continues its evidence based approach to new product introduction. The Company is also developing additional applications for Sculptor RGA(TM) with the goal of broader commercialisation next year.

Brian Steer, Executive Chairman of Stanmore, said:

"Following this FDA clearance for Sculptor RGA(TM) we are excited by the opportunity to bring our personalised approach to knee surgery to patients in the United States. Robotic technology represents a major advance in orthopaedics,

providing accurate placement that is critical to implant longevity and reproducibility along with tangible cost benefits, making access to robotic surgery more widely available to patients. Stanmore is now looking forward to working further with surgeons to continue to develop innovative solutions for the global orthopaedic market."

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