



PRESS RELEASE

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'Groundbreaking Surgery on Woman's Spine Ends Years of Pain'.

For the first time in five years, Kathleen Mo woke up without a splitting headache and was up and walking around her room at New Milford Hospital, just hours after she became the first person in the United States of America to have spinal reconstruction surgery using a plastic implant developed in England', reported the Republican-American Newspaper on 22 December 2004.

The plastic implants are marketed under the STALIF™ product name by Surgicraft Limited based in Redditch, Worcestershire, a major business servicing the global healthcare market, who designed & developed them with their Cambridge based manufacturing partner Precise Component Manufacture Limited.

'As manufacturers of the STALIF™ medical implants, used in the above surgery, all of us at PCML are very proud and happy to be associated with such a wonderful outcome' says Gavin Goates, Commercial Director, Precise Component Manufacturer Limited (PCML)

Doctors have successfully used the STALIF™ medical implants in Europe for several years and it was that success that won them approval from the U.S. Food and Drug Administration in September 2004.



The STALIF™ implant, otherwise known as a stand-alone anterior lumbar fusion cage, is the latest product development from Surgicraft and is the natural evolution of the Hartshill Horseshoe, which has over 10 years clinical success as a stand alone implant.

The new STALIF™ medical implant is manufactured from a biocompatible material called PEEK-OPTIMA®, first introduced to the market in 1999. PEEK-OPTIMA® offers the Surgeon and patient many benefits including reduced operating times, better bone fusion, less shrinkage & loss of height and much improved spinal alignment.

PEEK-OPTIMA® is a material that mimics the characteristics of bone. The implants can be inserted between vertebrae where they can serve as a substitute for degenerative spinal discs.

In first time spinal operations, they can simply be inserted into place, with a grip-like tread on their surface and screws holding them in place. However with patients like Kathleen Mo, who have also lost bone mass, four screws hold the implant in place.

Unlike metal, the material is much more elastic, so it can absorb energy and handle the normal weight of the body. The implants are made very similar to the elasticity of skeleton and the body accepts the presence of the implants.

An additional benefit offered by PEEK-OPTIMA® is its Radiolucency (opaqueness to x-rays) for easier and improved view of the fusion mass that is taking place. However in order to be able to offer X-ray imaging for optimal positioning interoperatively and post-operative assessments through, CT or MRI scans, titanium trace wires are push fitted into each of the STALIF™ implants.

The reason why recovery for the patient is so much faster is because the implant is inserted through the patient's stomach where reconstructing the spine is much less invasive than through the back.

Although some patients need to have the operation from the back, some only need a small incision from the front or side in which case recovery



can be quite rapid requiring only a four or five day hospital stay followed by a period of rest and recuperation to allow the fusion to knit.

As well as being involved in the initial design & development of the STALIF™ PCML manufacture the individual implants from raw plastic biocompatible material billets using several machining operations. Implants are manufactured on HAAS Automation UK Super Mini Mill high speed CNC machining centers.

The Super Mini Mill takes up only 6.5' x 6.5' of shop floor space yet provides a generous work envelope of 16" x 12" x 10". It comes standard with a 10,000-rpm spindle, 1200-ipm rapids, 1 MB of program memory, rigid tapping and a high-speed tool changer. It is the ideal machine for the type of drilling and milling required by the medical devices industry, or for high-speed contouring of small components.

The Super Mini Mill runs on three-phase power, and features a 15-hp vector drive spindle that accepts standard 40-taper tooling. With cutting feedrates up to 833 ipm, 1200-ipm rapids and 2.5-second tool changes, cycle times on the Super Mini Mill are kept to a minimum. The 36" x 12" table (28.75" working surface) provides plenty of room for fixturing, and like all Haas machines, the Super Mini Mill comes equipped with the powerful Haas control.

The complex design of the STALIF™ required PCML to apply their innovative work holding design, development and manufacturing capabilities to the full, requiring jigs & fixtures capable of handling small batch production runs using 4th axis machining capability.

'The HAAS Mini Mills with their modular 4th axis capabilities, are ideally suited for the Surgicraft applications', says Kevin Miller, Technical Director, PCML, 'Furthermore with their excellent accuracy, repeatability and reliability we are able to guarantee consistent product quality so essential for the medical device industry'

Following an assessment recently by an independent body, BSI, PCML has been awarded BS EN ISO 9001: 2000 Certification as applicable to the Manufacture of Precision Engineering Components to Customer



Specifications including Light Assembly Work. This prestigious award for quality is supported by the UK Government and is recognised worldwide.

The award recognises PCML's commitment to an exceptional quality of service. With only a small percentage of UK businesses holding this certificate, PCML are now officially recognised to be at the forefront of quality service and customer care.

'Having ISO 9001: 2000 certification provides our customers with further confirmation that the products and assemblies they are buying from us are manufactured and delivered to a high standard giving us a further competitive advantage', says Gavin Goates, Commercial Director

Editors Note

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