

Episurf's knee implant eyes European launch

08 July 2013 | Regulatory | By BioSpectrum Bureau



Singapore: Episurf Medical received CE certification for its personalized implant, the Episealer Femoral Condyle, which treats cartilage damage in the knee, restoring movement and reducing pain. CE certification is a prerequisite for the sale of medical devices in the European market.

CE certification was obtained after the Episealer Femoral Condyle and its technical documentation underwent review by regulatory authorities and successfully demonstrated that it met EU standards for medical equipment. CE certification means that Episurf Medical has the formal approval required to market and sell the product in the EU.

"The approval is an important milestone for the company, allowing us to launch products in Europe and bringing Episurf Medical into the first phase of commercialization. This new approval, in combination with a recent 70 million SEK rights issue and signed distribution contracts in Switzerland and Poland, puts us in a strong position for our product launch this fall," said Ms Nina Bake, CEO of Episurf Medical.

As a first step, Episealer Femoral Condyle will be launched in the European market. To ensure high quality and to provide maximum safety for patients and surgeons, the launch will be rolled out in stages under controlled conditions to a limited number of qualified orthopedic clinics in strategically selected European countries. While this first phase is underway, Episurf will continue working to establish distribution contracts in other selected markets.

Episealer Femoral Condyle is the company's first commercial product based on Episurf's unique patented technology, in which small personalized implants grow in the bone, fixing cartilage damage at an early stage, restoring movement and reducing pain. Several patients have already successfully received treatment with Episurf's implants in an ongoing clinical trial.