



QualiMed Innovative Medizinprodukte GmbH, based in Winsen Germany receives CE Mark Approval for its Drug Eluting Balloon (DEB) for the treatment of coronary arteries and especially restenosis. It is especially indicated to dilate the restenotic or de novo diseased segment(s) including small vessels and bifurcation lesions located in a coronary artery or a coronary bypass, to improve myocardial perfusion. The CE Mark approval for our latest DEB is an important milestone and it will enable us to provide this innovative device to a wide range of patients throughout the world.

About the QualiMed Drug Eluting Balloon (DEB)

The DEB is a new technology developed to treat coronary arteries and restenosis. The latest in drug-eluting technology, resulting in a DEB, may be an effective alternative to stenting, in particular to overcome the problems of coronary in-stent restenosis (ISR). Such a device would potentially overcome the drawbacks of stenting, polymer-related delayed endothelialization, and stent delivery, while at the same time providing homogenous drug delivery to the vessel wall, allowing earlier endothelialization and flexibility of use in complex lesions. However, its limitations include the failure to provide a mechanical scaffold for the prevention of acute recoil and the problem of not being able to treat dissection flaps. Drug eluting balloons achieve local drug delivery by means of an angioplasty balloon coated with Paclitaxel, which are well established in DES technology.

The treatment of paclitaxel-coated balloon catheters significantly reduced the incidence of restenosis. This suggests that the inhibition of restenosis by local drug delivery may not require stent implantation and sustained drug release at the site of injury. We use automated machines and specifically designed equipment to perform automated micro deposition technology with a micropipette. A homogenous distribution is performed and a very low standard deviation process is obtained. Therefore, BTHC allows homogenous Paclitaxel distribution on the balloon surface and enhances the drug penetration through the vessel wall. It is very well tolerated and allows a controlled drug loss between hip and heart.

Paclitaxel is a mitotic inhibitor and is used as an antiproliferative agent for the prevention of restenosis (recurrent narrowing) of coronary stents; locally delivered to the wall of the coronary artery, a paclitaxel coating limits the growth of scar tissue. Paclitaxel's mechanism of action involves its stabilization of cellular microtubules; as a result, it interferes with the normal breakdown of microtubules during cell division.

About QualiMed Innovative Medizinprodukte GmbH

QualiMed, based in Winsen, Germany, is pioneering the development of innovative medical device technology to a large variety of interventional and surgical specialties doctors and the patients they treat globally. QualiMed is continually focused on enhancing its team of medical device professionals who are interested in working in the fast paced ever changing environment of medical device development. The company is currently evaluating investment opportunities in various products, facilities, and strategic relationships that will enhance its long term strategic plans for growth in the mechanical, catheter, drug-device combination, and bioabsorbable technology areas. Privately held, the company is backed by Q3 Medical Devices Limited. For more information please visit www.q3medical.com

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