

Concept Medical gets CE certification for their MagicTouch products

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Concept Medical is Granted CE Certification for Their Sirolimus coated MagicTouch Group of Products



Concept Medical B.V. has announced that, they have received the CE certification for their MagicTouch group of products.

The CE certified products/brands are as listed below:

1. **MagicTouch – PTA** (Sirolimus Coated PTA Balloon Catheter) for peripheral arterial disease
2. **MagicTouch – ED** (Sirolimus Coated Balloon Catheter) for Erectile Dysfunction
3. **MagicTouch – AVF** (Sirolimus Coated PTA Balloon Catheter) for Arterio-Venous Fistula and Graft

MagicTouch – PTA is the only commercially available and CE certified Sirolimus coated balloon catheter for peripheral arterial diseases. Percutaneous transluminal angioplasty (PTA) is a procedure that can open a blocked blood vessel using a small catheter, with a "balloon" at one end. Currently accepted procedure is, to use drug delivery devices to deliver drugs that inhibit the inflammatory and proliferative pathways that lead to restenosis. Sirolimus is widely accepted as a drug of choice for such purpose.

Several studies have demonstrated that Erectile Dysfunction (ED) is increasingly prevalent with age. Approximately 40% of men are affected by the age of 40 years and nearly 70% of men are affected by the age of 70 years. MagicTouch ED is the only CE certified commercially available Sirolimus coated balloon catheter in the world for the therapeutic management of Erectile Dysfunction.

An arteriovenous fistula (AVF) is a connection created surgically (also called as a native fistula) between an artery and a vein so as to expand the bore of the vein. An AV fistula causes extra pressure and extra blood to flow into the vein, making it grow large and strong (maturing of the AVF). The larger vein provides easy, reliable access to blood vessels. Without this kind of access, regular hemodialysis sessions would not be possible. Untreated veins cannot withstand repeated needle insertions, because they would collapse the way a straw collapses under strong suction.

Arteriovenous graft (AVG), is another method for connecting an artery and a vein and is made by surgically suturing an external tube, made of a biomaterial, between the two vessels.

Common complications of AVF and AVG are an infection, stenosis of the fistula, thrombosis, aneurysm, and limb ischemia. PTA tackles the complications of AVF and AVG.

Concept Medical will now intensify its efforts to market and promote their products in all of Europe and other relevant markets that accept the CE certification for marketing authorization.