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Covidien's new device receives CE Mark

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Covidien has announced that it has received CE Mark approval for its Stellarex drug-coated angioplasty balloon (DCB). The Stellarex DCB is used to restore and maintain blood flow to the arteries of the leg in patients with peripheral arterial disease (PAD).

The Stellarex DCB's proprietary EnduraCoat technology provides a durable, uniform coating which reduces drug loss during transit and facilitates efficient drug delivery to the treatment site.

The 24 month results of the ILLUMENATE First-in-Human (FIH) study demonstrated a primary patency rate (ability to keep the artery open to restore blood flow) of 80.3 percent. Additionally, the study showed 87.9 percent freedom from target lesion revascularization at 12 months and 85.8 percent at 24 months.

"PAD is a progressive disease that affects millions of people around the world. DCBs are emerging as an alternative to traditional treatment options, such as angioplasty or stenting, because of their ability to restore blood flow, prevent the reoccurrence of new blockages and preserve future treatment options. In clinical trials, the Stellarex DCB has demonstrated promising results with strong patency rates and low reoccurrence of target lesions at 24 months," said Dr Henrik SchrÃ¶eder, radiologist, Vascular Center-Jewish Hospital, Berlin, and principal investigator, ILLUMENATE FIH Study.