Press release

Gothenburg, Sweden on March 24, 2023

Getinge receives FDA premarket approval for the iCast™ covered stent system in the US

Getinge's iCast™ covered stent system has received premarket approval from the U.S. Food and Drug Administration (FDA) for the treatment of patients with iliac arterial occlusive disease.

Iliac arterial occlusive disease is a type of peripheral arterial disease (PAD), a serious condition that only in the US affects 8 million persons,[i] in which atherosclerosis narrows and blocks peripheral arteries. As the world population ages and rates of diabetes and obesity rise, it is estimated that more people will be affected with iliac artery disease.

"We are pleased that the iCast™ stent system is approved in the United States for use in iliac arteries to benefit an even greater number of patients", says Elin Frostehav, President Acute Care Therapies at Getinge. "The global market for covered stents is growing at an annual rate of 5%. Getinge will continue to ramp up capacity throughout the year in order to meet the demand."

The iCast covered stent system, which is sold outside the US under the brand name Advanta V12 covered stent, has been used by clinicians for 20 years and is the most clinically evaluated balloon expandable polytetrafluoroethylene (ePTFE)-covered stent in the world, with clinical data published in more than 550 articles.

Media contact:

Anna Appelqvist, Corporate Communications
Phone: +46 (0)10 335 5906
E-mail: anna.appelqvist@getinge.com

About Getinge

Getinge is a global provider of innovative solutions for operating rooms, intensive-care units, sterilization departments and for life science companies and institutions. Based on our first-hand experience and close partnerships with clinical experts, healthcare professionals and medtech specialists, we are improving the everyday life for people, today and tomorrow.

[i] Norgren L, Hiatt WR, Dormandy JA, et al. Inter-society consensus for the management of peripheral arterial disease (TASC II). *J Vasc Surg*. 2007;45(Suppl S):S5–S67

Getinge AB
Box 8861
402 72 Gothenburg
Sweden

Telephone: +46 (0)10 335 00 00
Email: media@getinge.com

www.getinge.com