Press Release
November 17, 2025

Magle Group Completes European Medical Device Filing for the Use of EmboCept® S in Genicular Artery Embolisation

Magle Group today announces that it has successfully completed its European medical device filing to extend the clinical use of EmboCept® S, the company's proprietary degradable starch microsphere (DSM) technology, for Genicular Artery Embolisation (GAE).

GAE is a minimally invasive interventional radiology procedure used to treat symptomatic knee osteoarthritis by selectively reducing abnormal blood flow in the genicular arteries. The procedure provides a non-surgical treatment option for patients who have not responded to conservative management and offers meaningful improvements in pain and mobility.

EmboCept® S, already CE-marked for certain HCC embolisation procedures, it is designed to provide controlled, predictable, and fully degradable vessel occlusion. Extending its use to GAE further strengthens its position as a safe and versatile embolic across multiple therapeutic areas.

The filing submitted today begins the formal assessment under the European Medical Device Regulation (MDR 2017/745). The process involves a review of updated technical documentation and clinical evidence by Magle's Notified Body to confirm that the expanded intended use is adequately supported. Once approved, GAE will be added as an authorised indication for EmboCept® S across Europe.

"Today's submission marks a significant step in expanding the impact of EmboCept® S. Genicular Artery Embolisation represents an important therapeutic option for patients with knee osteoarthritis, and our degradable DSM technology is well suited to support physicians performing this procedure. This filing reflects the strength of our evidence generation and our commitment to advancing innovative care for patients," said Helena Ossmer Thedius, Chief Innovation & Marketing Officer at Magle Group.

Contacts

Justin Pierce, CEO, phone +46 (0)70 593 58 21, justin.pierce@maglechemoswed.com

About Us

The Magle Group aims to establish itself as a leader in high-quality life-changing healthcare innovations to meet medical needs through scientific excellence. The Magle Group is founded on strategic acquisitions aimed at driving growth and diversifying risk. Today, the Group includes three operational areas. Magle Chemoswed – a contract development and manufacturing organization (CDMO) with a strong reputation for its high-quality development and manufacturing expertise and Magle PharmaCept – an established sales and marketing company for development and direct sales of the Groups medical technology products. Magle Biopolymers A/S- a specialized manufacturing organization of Dextran technology. Learn more on **www.maglechemoswed.com** and **www.maglegroup.com** and **www.maglepharmacept.com** and **www.maglebiopolymers.com**

Vator Securities is the Company's certified adviser on Nasdaq First North Growth Market and can be reached at ca@vatorsec.se or +46 (0)8-580 065 99.

Attachments

Magle Group Completes European Medical Device Filing for the Use of EmboCept® S in Genicular Artery Embolisation