

## Positive results from post-market clinical follow-up of Magle Group's innovative medical device SmartPAN® presented at scientific congress

**Magle Group (Nasdaq Stockholm First North Growth Market: MAGLE) today announces the presentation of data from the company's first post-market clinical follow-up study of SmartPAN® – an innovative first-in-class medical device developed to improve the outcome of pancreatic surgery. The results were presented at the 140th German Surgery Congress, April 26-28th in Munich.**

Postoperative pancreatic fistula (POPF) is a common and potentially life-threatening complication that can emerge due to leaking pancreatic fluid after pancreatic surgery. SmartPAN® acts as an intraoperative indicator of leakage by providing an immediate and accurate color indication when in contact with the pancreatic fluid, guiding the surgeon to perform additional targeted closure. The product offers a completely new, simple approach to preventing pancreatic leaks to benefit patient outcomes.

The post-market clinical follow-up study was conducted at the University Hospital of Heidelberg and led by Prof. Hackert and Dr. Med. Pausch, with the aim to verify the feasibility and safety of intraoperative visualization of pancreatic leakage by indicator application<sup>1</sup>. If left undetected pancreatic fluid leakage can lead to significant postoperative complications, such as POPF. The study enrolled 30 patients.

The study results confirm the usability and safety of SmartPAN® when used as an indicator of pancreatic leakage in clinical setting of pancreatic surgery. Clinical usability evaluations showed high satisfaction with the device and that most surgeons would like to use the product again outside the study. No complications connected to SmartPAN applications were found. No traces of the indicator dye were detected in central venous fluid and initial minor concentrations in the abdominal fluid were eliminated within two days after surgery.

"The translational development of this novel surgical pancreatic leakage indicator will enable prediction and targeted reduction of postoperative pancreatic fistula to improve the success of pancreatic surgery in the future," says the study's lead investigator, Dr. med Pausch, Heidelberg University Hospital, Heidelberg.

Pancreatic operations are an important and growing field of surgery worldwide and are used to treat both benign and malignant conditions of the pancreas<sup>2</sup>. A leading cause of pancreatic surgeries is pancreatic cancer which more than doubled between 1990 to 2017<sup>3</sup> and continues to accelerate as the population ages and the prevalence of obesity and diabetes, increases.

"The positive data from the clinical follow-up study will serve as an important base for our stepwise efforts to establish SmartPAN in the market. The results show the immense potential of this first-in-class product and our technology and will support reimbursement applications in Europe and could also facilitate marketing approvals in other parts of the world," says Justin Pierce, CEO of Magle Group.

**About SmartPAN**

SmartPAN® is a patented first-in-class medical device developed jointly with the University of Heidelberg and Magle Group. SmartPAN® is based on Magle Group's patented bio-compatible and bio-degradable microsphere technology (DSM). The product is approved for medical use in Europe since 2021. A PMCF study is aimed at keeping up to date on the safety and efficacy of a medical device approved in the EU.

**References**

1. Thomas Pausch *et al.* SmartPAN® indicator proofs usability and safety of pancreatic leakage visualization after partial pancreatectomy in an IDEAL Stage I clinical trial. Abstract ID 773, 140th German Surgery Congress, 26-28th April in Munich.
2. AminiN *et al.* Trends in Hospital Volume and Failure to Rescue for Pancreatic Surgery. *Journal of gastrointestinal surgery: official journal of the Society for Surgery of the Alimentary Tract.* 2015;19(9): 1581-92.
3. GBD 2017 Pancreatic Cancer Collaborators. The global, regional, and national burden of pancreatic cancer and its attributable risk factors in 195 countries and territories, 1990-2017: a systematic analysis for the Global Burden of Disease Study 2017. *Lancet Gastroenterol Hepatol.* 2019 Dec;4(12):934-947.

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**About Us**

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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 two 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. Learn more on [www.maglechemoswed.com](http://www.maglechemoswed.com) and <https://maglegroup.com/> and [www.maglepharmaceut.com](http://www.maglepharmaceut.com)

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**Attachments**

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