

PolarCool chooses new opportunity for stronger approval in the US

PolarCool AB (publ), after consultation with the US Food and Drug Administration (FDA), has today decided to submit a De Novo application for the product PolarCap® System. The reason is the recently published strong clinical data for PolarCap® and the decision on a CPT® 3 code from the American Medical Association.

The fact that PolarCool now chooses to focus on a De Novo approval is because the recently published 5-year clinical study enables an approval of the PolarCap® System for treatment against a purely medical indication, "concussion". The fact that the American Medical Association (AMA) issued a first CPT® code for the treatment of concussion in July, a clear indication of the support for establishing non-invasive hypothermia as a treatment method for concussion, also makes the decision logical. In addition to being a significant milestone for hypothermia as concussion treatment, a CPT® code is an important step towards the possibility of reimbursement for this type of treatment.

The approval of a De Novo application, an approach where there is no established alternative product on the market, means that the PolarCap® System is seen as a so-called first-mover and also means better product protection. The choice to move to a De Novo procedure is taken in close consultation with the FDA where the technical file for the PolarCap® System is already extensively reviewed during a 510k process.

PolarCool's CEO Erik Andersson comments:

-We have, of course, closely followed up the AMA's decision to introduce a first CPT® code for concussion treatments, which could mean great benefits for concussion patients across the United States. The strong clinical data for the PolarCap® System recently published in the Journal of Neurotrauma creates an opportunity to obtain a unique approval by the FDA which will also benefit the process of establishing insurance reimbursement for treatment with the PolarCap® System.

This information is information that PolarCool (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out herein, on October 21th, 2022.

For more information

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About PolarCool AB (publ)

PolarCool AB (publ) is a medical device company that develops, markets, and sells products for sports medicine. The company focuses on treatment of concussive and sub-concussive brain injury with the portable cooling device PolarCap® System. PolarCool AB (publ) is based in Lund, Sweden, and its shares are listed on Spotlight Stock Market.