

Information om pressmeddelande distribuerat i USA angående att PolarCool AB (publ) lämnar in 510(k) ansökan för bolagets produkt PolarCap® System

Nedan bifogas ett pressmeddelande (utan MAR-etikett) som distribuerades idag i USA kl. 09.00 EST, för att ge information om PolarCap® System och den kliniska studien med produkten som publicerade i ”[Concussion](#)” ([Publication with PolarCap® System in a scientific journal \("Concussion"\)](#)) vilken är en viktig komponent i bolagets FDA ansökan.

Informationen är en del av en nyhets- och mediakampanj för att öka medvetenheten kring problemet med hjärnskakning samt möjligheterna att behandla denna allvarliga åkomma med kylning och produkten PolarCap® System i avvaktan på ett marknadsgodkännande för produkten i USA.

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Scientific Study Shows Significant Benefit of PolarCap® System in Player Recovery from Sports-Related Concussions

Results Published in the Journal Concussion Indicate that Use of Cooling Technology Hastened Safe Return to Play for Players of Top Swedish Hockey League Teams

Research paves the way for U.S. market clearance with submission of 510(k) pre-market notification to the U.S. Food and Drug Administration (FDA) for the PolarCap® System

LUND, Sweden—May 11, 2021—PolarCool AB (publ), a Swedish medical device company focusing on treatment of sports-related traumatic brain injury (TBI) and whiplash, today announced that it has submitted a 510(k) pre-market notification to the U.S. Food and Drug Administration (FDA) for the PolarCap® System.

This submission follows publication of statistically significant [clinical results](#) in the scientific journal **Concussion**, showing clear benefit for use of the PolarCap® System in the treatment of concussions among players of 15 elite Swedish Ice-Hockey teams in the Swedish Hockey Leagues (SHL).

The incidence of sports-related concussions is a significant national health concern in Sweden, as it is here in the U.S., and there is growing evidence that repetitive traumatic brain injury can cause long-term changes in brain structure and function. This is of particular concern in the field of contact sports, such as ice hockey, where available treatment options are limited.

“With this important FDA submission, we are paving the way for the first-ever sports-related TBI treatment model,” said Martin Waleij, PolarCool Chairman of the Board. “Supported by robust clinical evidence enabling players to safely return to play much earlier, our 510(k) submission is the first step in the FDA review process. We look forward to this review and are confident that speedy clearance for the PolarCap® System is on the horizon.”

The study, led by investigators from Lund University at Skåne University Hospital in Lund, Sweden, Luleå University of Technology in Luleå, and BrainCool AB, represents the largest study population focused on sports-related concussion treatment in Sweden or the U.S., and shows statistical benefits of therapeutic cooling using the PolarCap® System head and neck cooling technology.

*“Publication of these study results in the journal **Concussion** marks a significant milestone for sports medicine around the globe,” said Erik Andersson, Chief Executive Officer of PolarCool, maker of the PolarCap® System that was used in the Lund study. “We are eager to proceed with larger studies and to partner with academic medical centers and professional sports organizations to further validate the benefits of this medical cooling technology—with the ultimate goal of improving both short- and long-term safety for players of all contact sports.”*

The Swedish Hockey League, the players organization [SICO](#) and PolarCool are actively collaborating to improve player safety. Two PolarCap® Systems are available at all games and the league is working to establish a standardized acute treatment method concussion injuries.

“It is very positive that we can constitute that the introduction of the Polar Cap has meant fewer long time absences among players that were treated by cooling directly after a concussion, with this treatment we have another tool to use (against head injuries),” said SHL Sports Director & Vice CEO Johan Hemlin in a [recent SHL press release](#).

Fifteen teams from elite ice-hockey leagues for males in Sweden were given the option to participate in the intervention group (receiving selective head–neck cooling after a sports-related concussion) or the control group (standard sports-related concussion management). Selective head–neck cooling was initiated at a mean of 12.3 ± 9.2 min after the concussion in 29 players, and 52 SRC controls received standard management. Results showed significant benefits of cooling in treating concussions with a median time to return to play for the players who underwent cooling of 7 days, versus 12 days for those who did not. The study also shows promising reduction in the proportion of long-term absence, which can be as long as three weeks or more, among treated players.

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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.