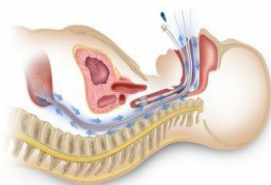


Advanced Cooling Therapy Receives FDA Clearance for Esophageal Cooling Device



Emerging medical device firm Advanced Cooling Therapy has received a *de novo* clearance from the US Food and Drug Administration (FDA) to market its first product, the Esophageal Cooling Device (ECD), in the United States. The ECD is the only temperature modulation device available today that uses the esophageal space to cool or warm patients. It received its CE Mark in Europe in 2014, is licensed for sale in Canada and Australia, and will be available to medical professionals in the US within 30 to 45 days.

The ECD is designed to modulate and control patient temperature when clinically indicated through a single use, fully-enclosed triple lumen system that is inserted into the esophagus. Two lumens attach to existing temperature modulation equipment while a third lumen simultaneously allows gastric decompression and drainage. The ECD can be rapidly inserted by most trained health care professionals, in similar fashion to a standard gastric tube, and can be used to control patient temperature in the operating room, recovery room, emergency room, or ICU. No other product on the market is approved to use the esophageal environment for whole-body temperature modulation.

De Novo clearance by the US FDA is granted for novel, breakthrough and low to moderate risk Class I or II medical devices for which there are no similar products in the marketplace. FDA clearance is required for the commercial sale and distribution of Class II medical devices in the US, like the ECD.

"ACT pioneered the field of core temperature management through the esophagus. With this regulatory milestone, we are looking forward to bringing the ECD to the US, offering advanced patient temperature management in an efficient, easy to use device that can be quickly placed by a range of healthcare providers in the ER, OR and ICU," commented ACT's President and Co-Founder, Erik Kulstad, MD, MS. "Our feedback from clinicians in Canada, Europe, and Australia using the ECD to both cool and warm patients has been impressive, and we anticipate strong adoption in the US."

Advanced Cooling Therapy's technology platform provides a novel method to control patient temperature where clinically indicated using the esophageal environment.

Source and image credit: ACT

Additional Resources

During ISICEM 2015 in Brussels ICU Management held a I-I-I Interview (I Minute, I Question, I Answer) with Erik Kulstad, CEO, Advanced Cooling Therapy, USA.

I Question: What is the Esophageal Cooling Device?

<https://healthmanagement.org/video/view/129025643>

Published on : Fri, 26 Jun 2015