ICU
MANAGEMENT & PRACTICE

Esophageal Cooling Device Receives Expanded CE Mark Approval for Use to 120 Hours

Advanced Cooling Therapy (ACT) has received CE Mark approval for an expanded indication for use of its Esophageal Cooling Device (ECD). The ECD, the only temperature management device to modulate patient temperature using the esophageal space, now has CE Mark approval for use up to 120 hours in patients who need either warming or cooling.

The ECD was originally cleared for 36 hours of use, but as appreciation for the importance of temperature management to cool or warm patients grows across a wide range of specialties (neurology, critical care, surgery, trauma, burns, and anesthesia), the need for longer treatment durations has grown.

"We are encountering more and more clinicians who want to use our ECD for longer durations of treatment, for cooling, warming, or maintaining patients at ideal body temperature when clinically necessary," Maria Gray, ACT's Director for Clinical Services commented. "Being able to use the ECD for up to 120 hours will allow clinicians to better manage patient temperature in a variety of circumstances and enhance patient care."

Dr. Ahmed Hegazy, an Anesthesiologist and Critical Care Physician with London Health Sciences Centre and an early adopter of the ECD, notes "We are using the ECD for an increasing number of patient conditions that require longer treatment, and look forward to being able to optimize patient care with this expanded indication."

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 products on the market are approved to use the esophageal environment for whole-body temperature modulation.

The ECD01 received FDA de novo clearance in June of 2015 for use with the Medi-Therm III by Stryker®. The ECD02 received FDA 510(k) clearance in January 2016 for use with the Blanketrol® II and III Hyper-Hypothermia systems made by Cincinnati Sub-Zero. It received its CE Mark in Europe in 2014, and is licensed for sale in Canada and Australia.

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

Source & Image Credit : Advanced Cooling Therapy

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