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ASIA EDITION

Rapid Medical announces FDA approval for Comaneci device

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Comaneci is the only non-vessel-occluding temporary intracranial coiling embolization assist device



Rapid Medical, an Israeli company focused on the development of next generation neurovascular devices announced that its Comaneci device received FDA clearance as a Temporary Coil Embolization Assist Device. The Comaneci is the first and only device in a new category of temporary coil embolization assist devices.

Peter Kim Nelson, MD, Professor in the Departments of Radiology and Neurosurgery in the New York University School of Medicine and Chief of the Bernard and Irene Schwartz Interventional Neuroradiology Section within the NYU Langone Health system said, "I am excited about having the Comaneci in the US. It should be a valuable alternative for ruptured and unruptured wide neck aneurysms, typically requiring balloon assistance for coil embolization, since it provides temporary protection of the parent artery during aneurysm coiling without arresting flow."

Dr. Orit Yaniv, VP of Regulatory Affairs at Rapid Medical said, "We are extremely pleased by FDA's clearance of the Comaneci device, which will be our first device available in the US. We want to thank the FDA team for their efforts during the review process to bring it to a successful completion."

The Comaneci is adjustable, fully-visible aneurysm remodeling device. It acts as a temporary bridge used to aid in the coiling processes while minimizing the risk of coil protrusion or prolapse. Once the coiling procedure is completed the device is removed from the parent artery. It is the only temporary coiling assist device that does not require parent vessel occlusion during coiling procedure or the need for long-term antiplatelet medication in case of permanent stenting. Until now the Comaneci have been successfully used in about 3,000 procedures outside the US.