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Innovative Mechanical Thrombectomy Approach: *In Vivo* Comparison of the Vicora Vibrato Device and Standard of Care in a Porcine Model

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Purpose: To assess the safety and performance of the Vicora Vibrato 16Fr thrombectomy device in a porcine model, compared to the current standard of care.

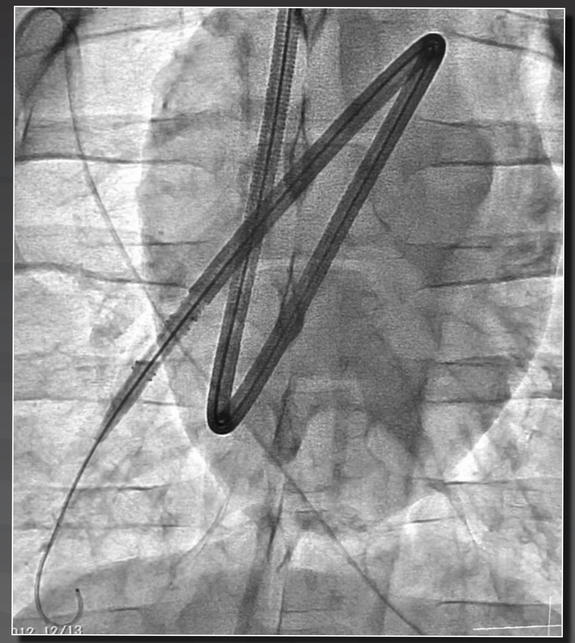
Background: Vicora aims to obtain FDA 510(k) clearance for the Vibrato's use in peripheral venous vasculature followed by an indication for pulmonary embolism (PE). In 5–10% of PE thrombectomy procedures the clot may become "corked" during aspiration, creating a significant clinical challenge. The Vibrato features improved navigation, and a novel vibrating distal tip designed to enhance thrombus removal during aspiration, while minimizing vascular injury. This vibrating mechanism may reduce procedure times, improve clot removal efficiency, and decrease the need for adjunctive interventions.

Methods: To further assess the Vibrato, it was navigated to the inferior vena cava (IVC) and both pulmonary arteries (PAs). In the IVC, vibration was activated 5 times in the distal region and 10 times in the proximal region, each for 10s. In the right and left PAs, vibration was activated 5 and 10 times, respectively, each for 10s. Only the first activation in each PA was paired with a 60cc aspiration.

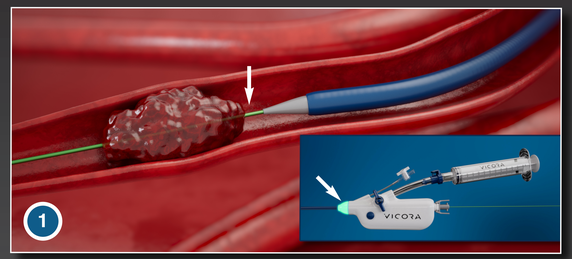
Results: The Vibrato successfully navigated to all target sites. Physician feedback, based on clinical experience with the standard of care and previous Vibrato studies, indicated that the Vibrato exhibited superior navigability, particularly in tortuous anatomy, highlighting the device's enhanced ability to navigate in the peripheral and pulmonary vasculature.

The Vibrato showed no adverse impact on hemodynamics or cardiac rhythm. Histological analysis revealed comparable levels of vascular injury between the Vibrato and the standard of care, with no clinically noteworthy differences observed.

Conclusion: The Vibrato demonstrated promising navigational performance and safety profile compared to the current standard of care PE thrombectomy device.



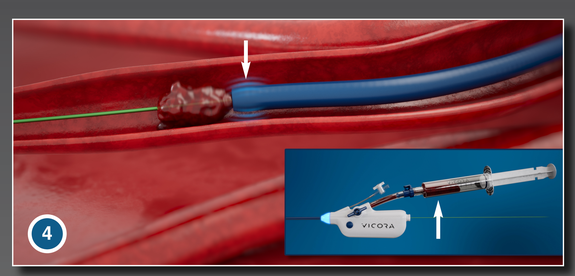
In the porcine model, the device navigated the tortuous anatomy from the right jugular access site and successfully reached the Right Pulmonary Artery without kinking or deformation.



With the device powered on and the dilator in place, navigate the catheter proximal to the clot. The light indicator on the handle will illuminate green to depict 'ready mode'.

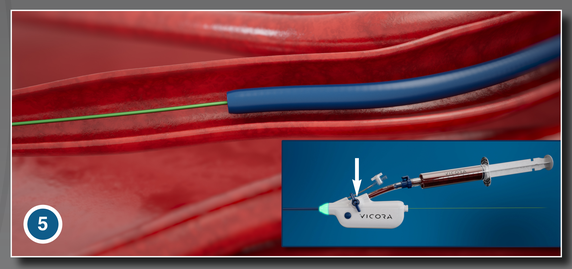
With the dilator removed and the syringe attached, retract the syringe and lock in place.

Open the stopcock on the handle to allow for clot ingestion and press the button on the handle to activate vibration. The light indicator on the handle will blink blue to depict 'active mode'.

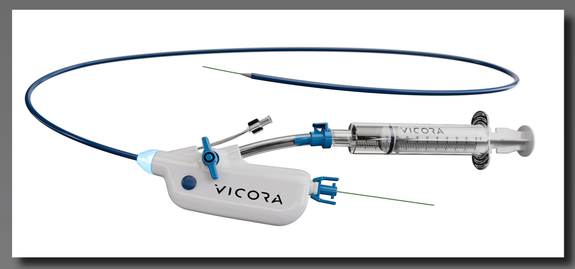


The syringe begins aspirating blood and thrombus until it is completely filled. Vibration remains active for up to 10 seconds, after which it automatically stops. If the syringe is not yet fully filled, the vibration can be reactivated.

Vicora Team (left to right): Matt Colpoys, CFO; Dr. Chris Manion, Clinical Advisor; Shawn Patterson, CEO; Jim Kinney, Operations Director; Erin Garcia, Director of Engineering



Once the syringe is filled, close the stopcock and detach the syringe. Vibration can be stopped manually by pressing the button or will automatically stop after 10 seconds, returning to 'ready mode'. These steps can be repeated as needed.



Vibrato is the first catheter with controllable distal tip vibration for thromboembolism treatment. The tip's targeted vibration is designed to gently agitate thrombus, enhancing removal efficiency. Its compact, single-catheter design uses syringe aspiration and features a reduced French size, enhanced trackability, and kink resistance for improved thrombus removal.

For more information on the Vicora Vibrato device, contact Erin Garcia, Director of Engineering, at (716) 863-2552 (egarcia@egrethealthcareventures.com).

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