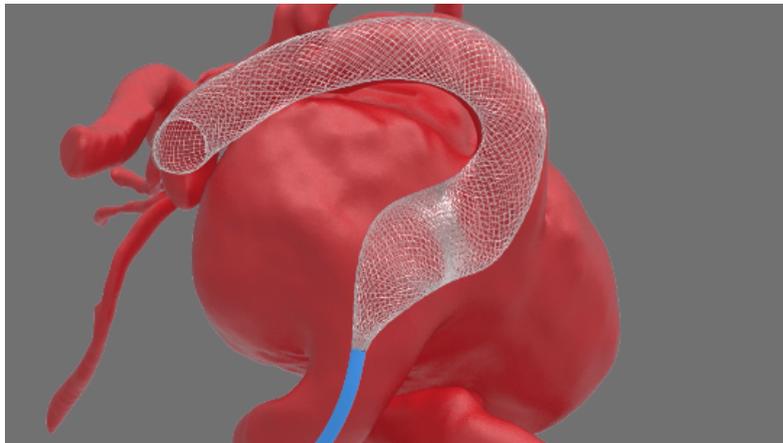


Endovantage gains US FDA 510(k) clearance for Surgicalpreview

14th November 2017



Surgicalpreview

Endovantage has announced receiving 510(k) clearance from the US FDA for Surgicalpreview, its preoperative planning system for the endovascular treatment of cerebral aneurysms.

Precise sizing and placement of endovascular devices can be challenging and Surgicalpreview enables the clinician to **plan** the procedure before surgery and visualise how the device fits.

Using any computer with internet access clinicians can access Surgicalpreview and upload a patient's CT imaging data. The system then converts that two-dimensional data to functional three-dimensional model, enabling the clinician to manipulate the model as well as take anatomical measurements.

The clinician may also request computational models of multiple treatment scenarios for a patient, each representing a different treatment device and/or deployment strategy.

Surgicalpreview includes a library of 3D models of neurological treatment devices approved by the FDA from which the clinician can select. The clinician can then view side-by-side static models and video models of the catheter delivery, landing and deployment. It also enables the clinician to evaluate multiple devices, sizes, placements, and deployment strategies.

"Endovantage has put forth groundbreaking technology that will allow physicians to model and test a multitude of endovascular devices in patient specific scenarios without any risk to the patients themselves," stated Felipe C Albuquerque, editor-in-chief of the *Journal of NeuroInterventional Surgery* and director of Endovascular Neurosurgery at Barrow Neurological Institute. "This revolutionary technology will facilitate the performance of complex, life-saving treatments. This is truly a new era in endovascular neurosurgery," he said.

Practical tool

"Endovantage provides surgeons and interventionalists with a practical tool to "do the operation before the operation," according to Bernard Bendok, chair, Department of Neurologic Surgery, Mayo Clinic Arizona. "This breakthrough technology promises to revolutionise precision surgery by better matching devices to patient specific anatomy.

This important advance promises to substantially improve clinical outcomes and reduce risk of procedures. We are approaching a time when preoperative procedural modelling will be considered the standard of care. The tools which have been pioneered by Endovantage will accelerate the advent of this next new exciting and higher standard in healthcare," stated Bendok.

In addition to preoperative planning, Endovantage has been advancing the product development efforts of leading medical device companies using its simulation technology, revolutionising the way devices are designed and developed. Its computational models provide far more detail than traditional physical

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testing and dramatically shorten development time. The company also tests devices in hundreds of patient anatomies without the patients, creating a "virtual clinical trial." This dramatically reduces the time and cost to regulatory approval and market.

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