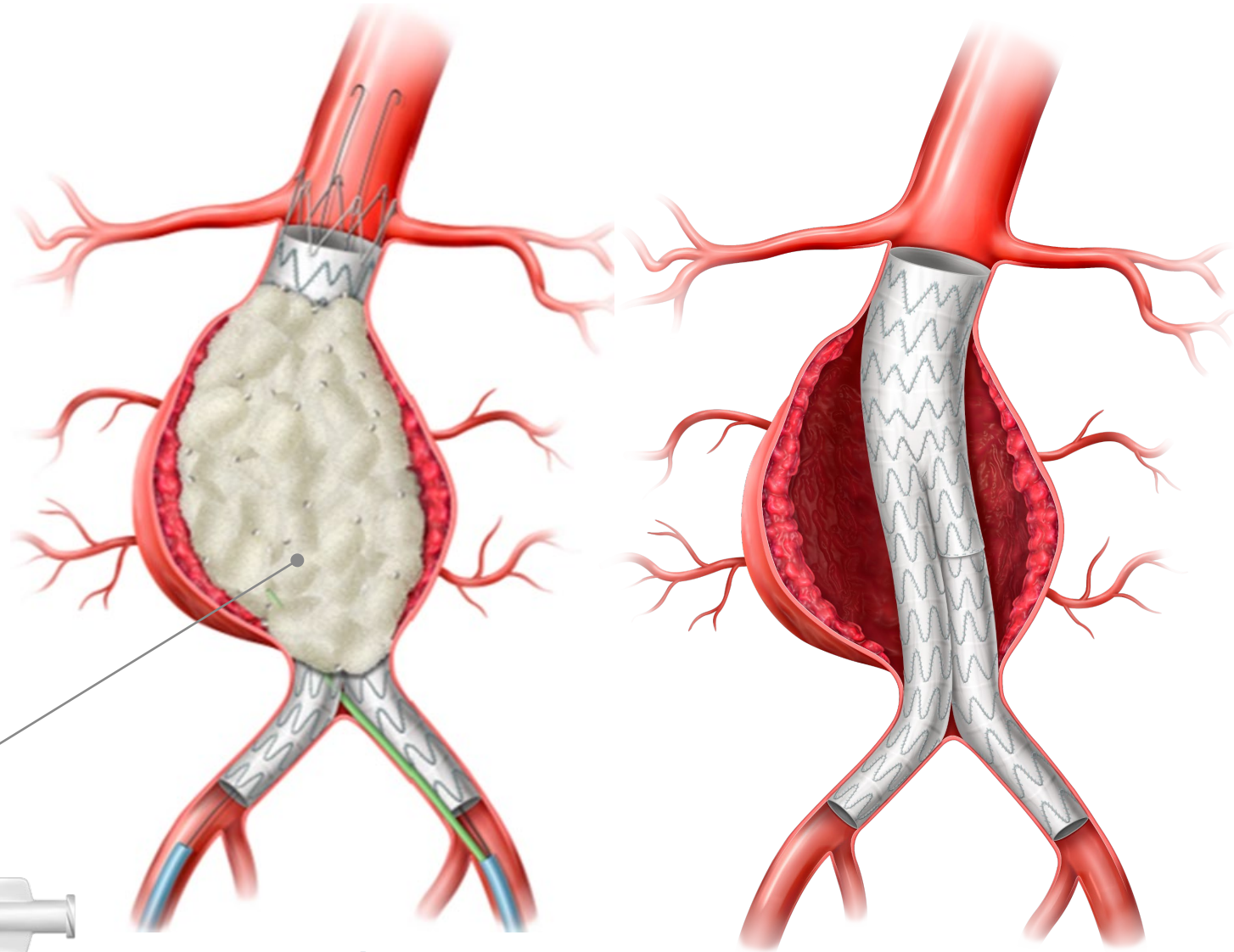


# AAA↑SHAPE

Abdominal Aortic Aneurysm Sac Healing and Prevention of Expansion

**Study Purpose:** To determine the safety and effectiveness of IMPEDE-FX RapidFill to improve AAA sac behavior when used with EVAR stent graft treatment.

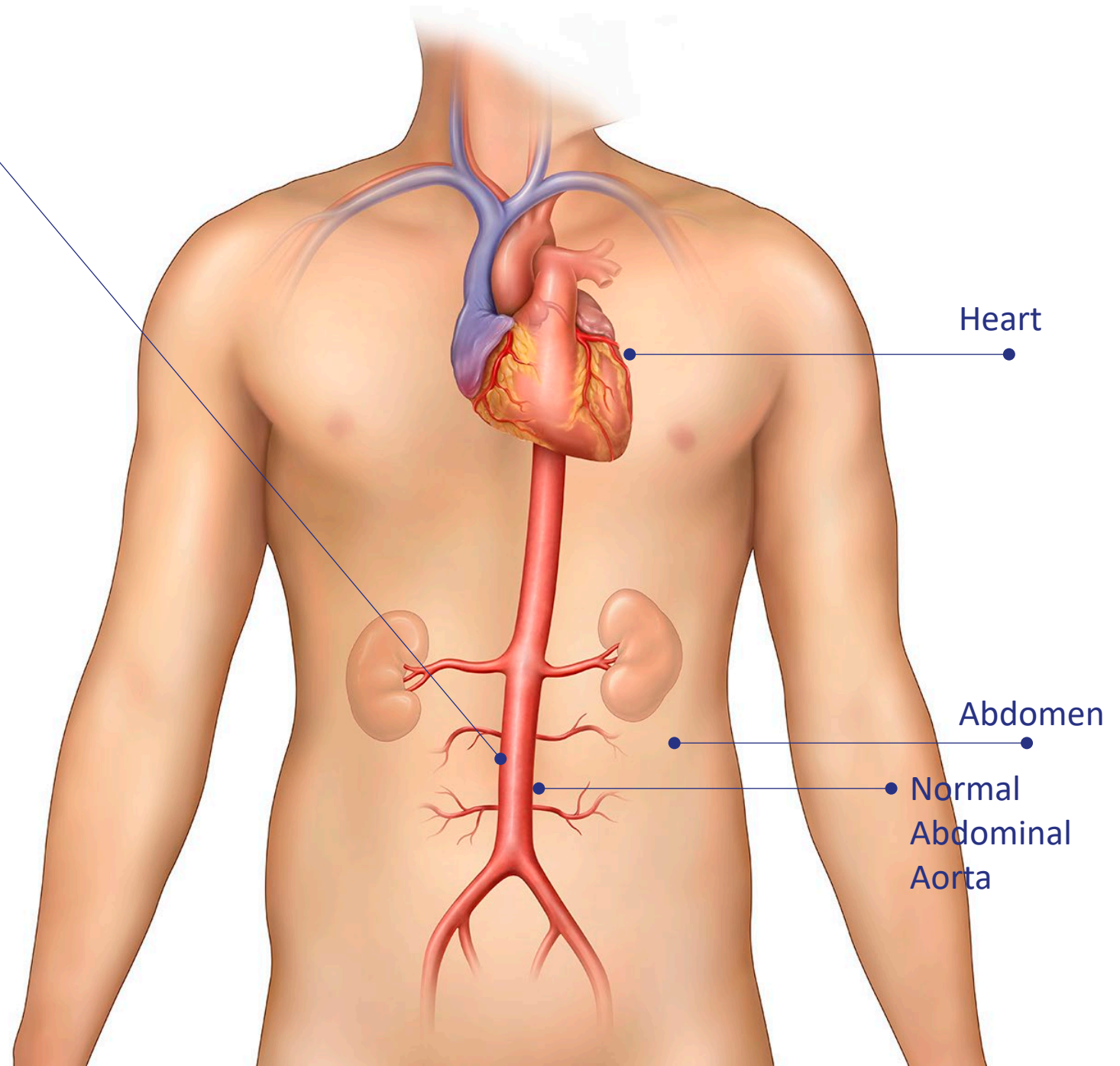
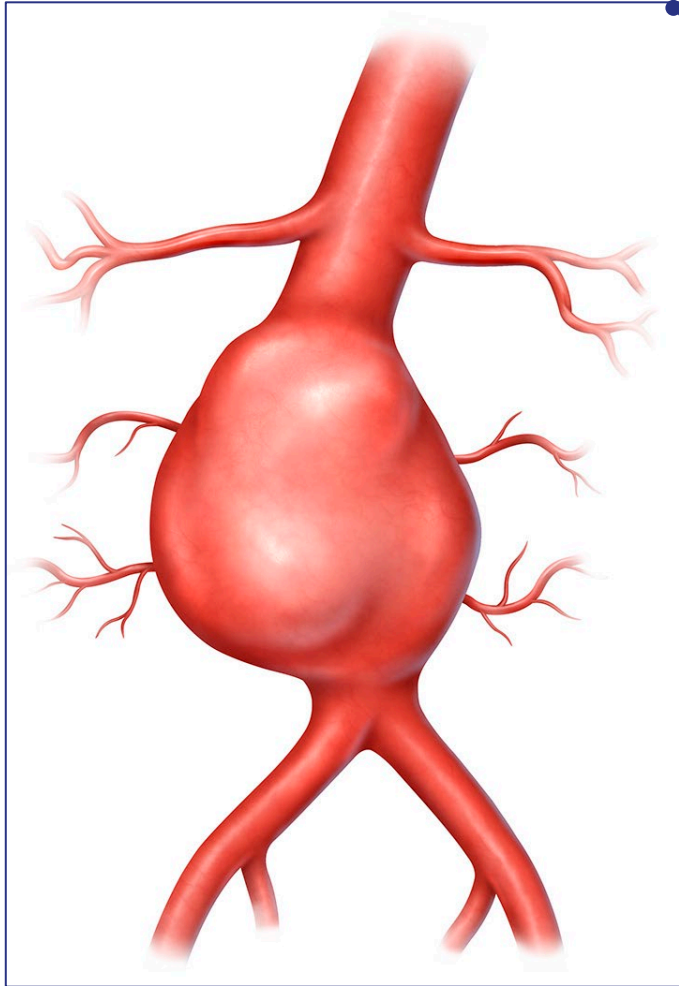


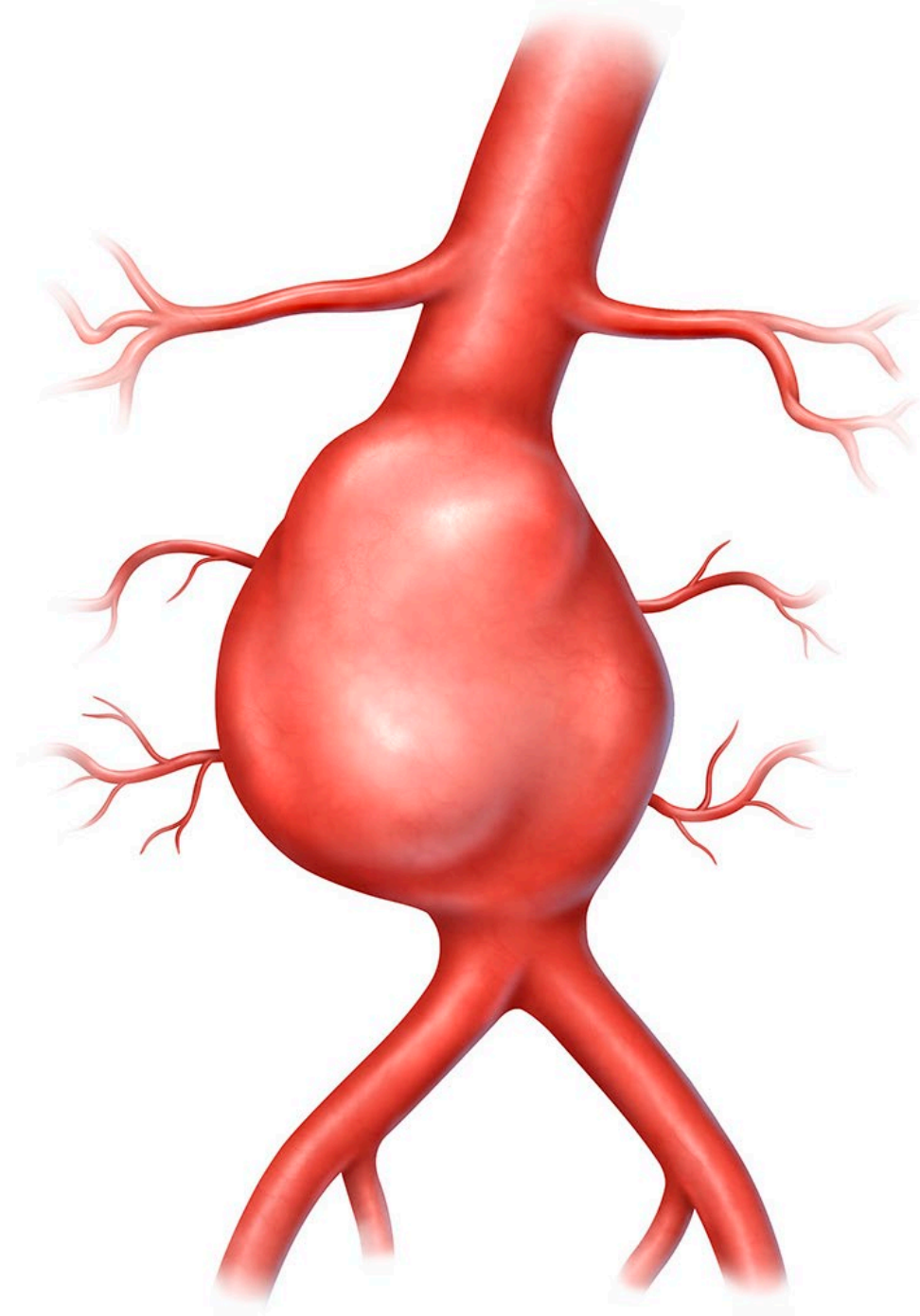
**EVAR plus  
IMPEDE-FX RapidFill**

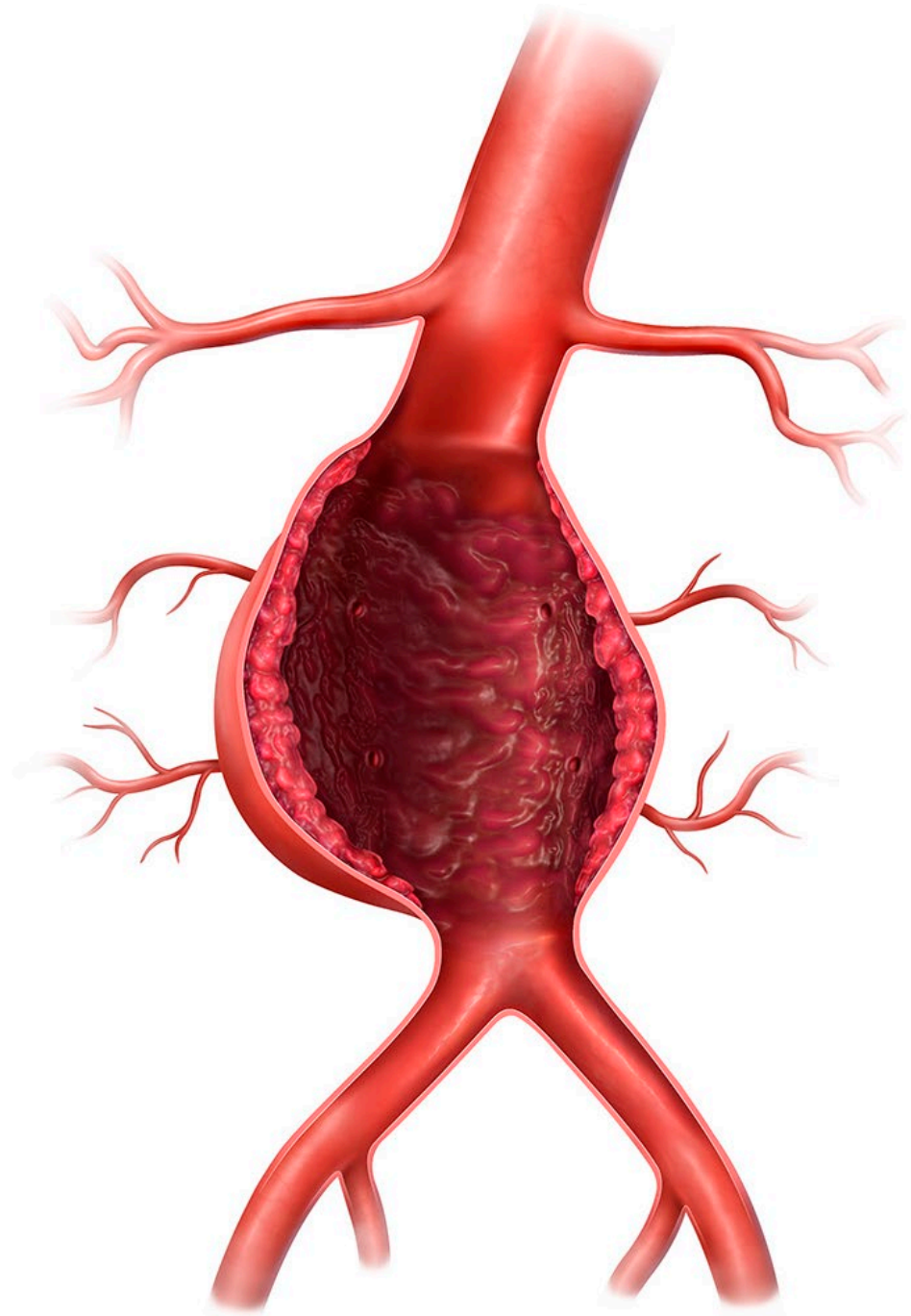
**versus**

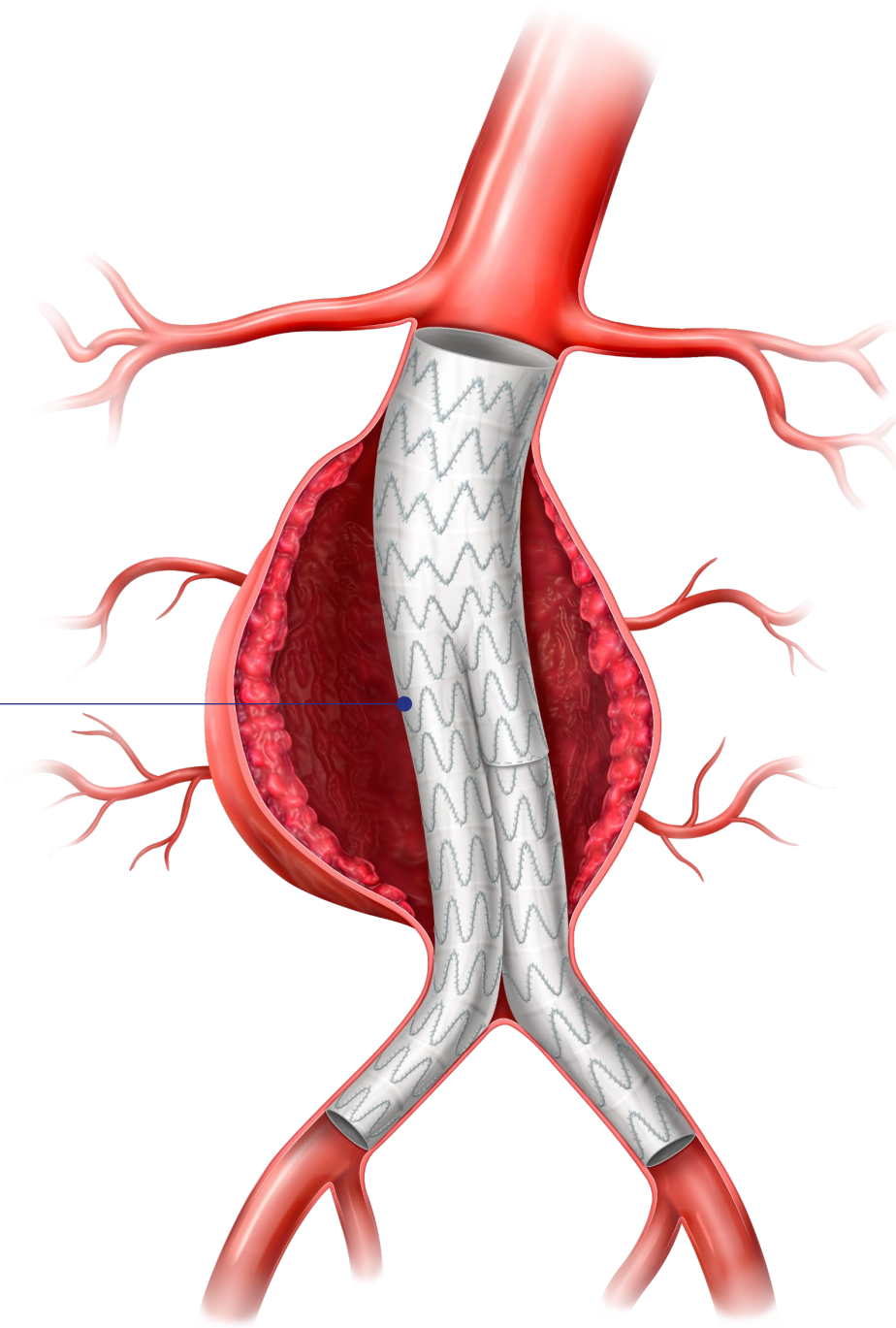
**EVAR**

## Abdominal Aorta with an Aneurysm

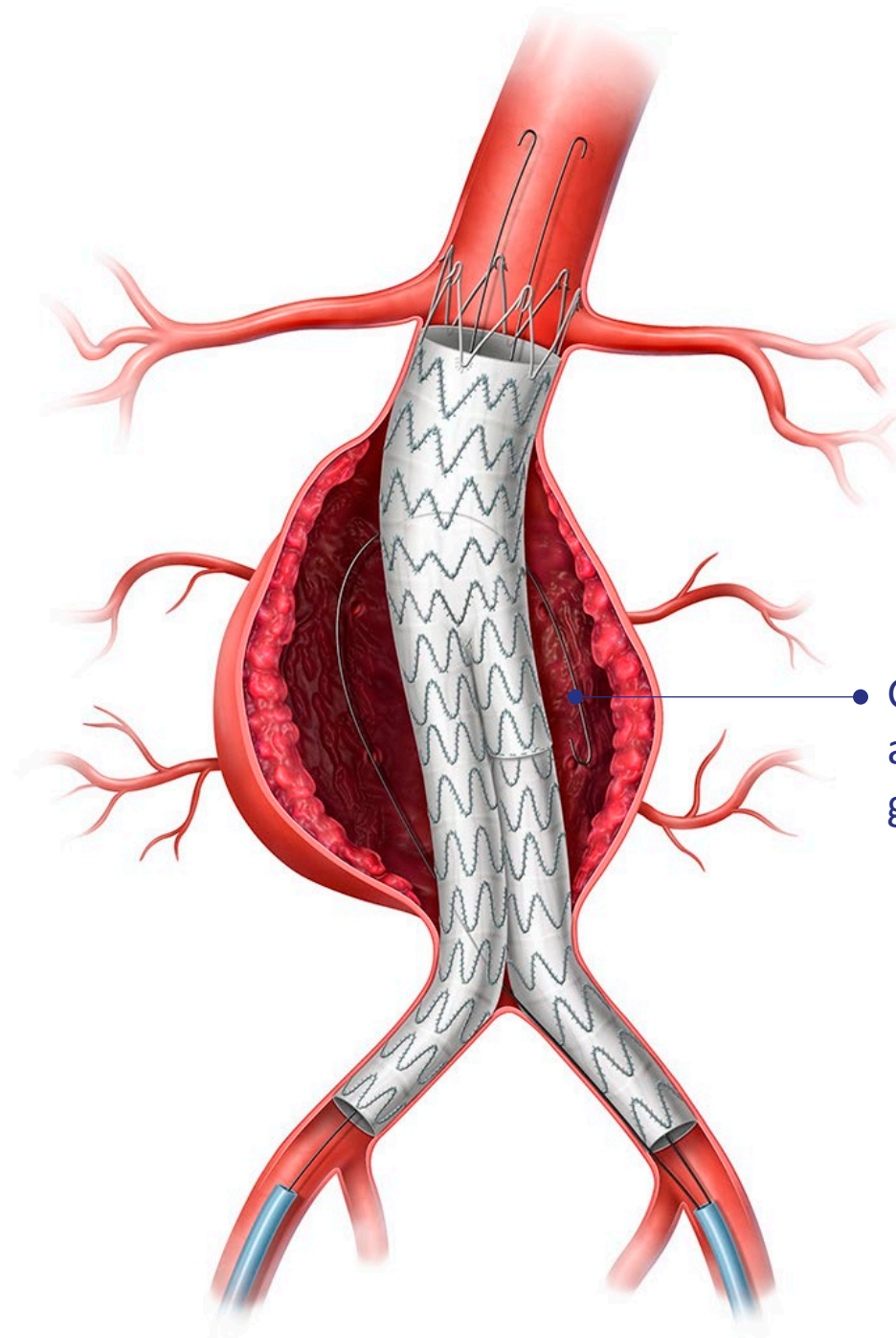




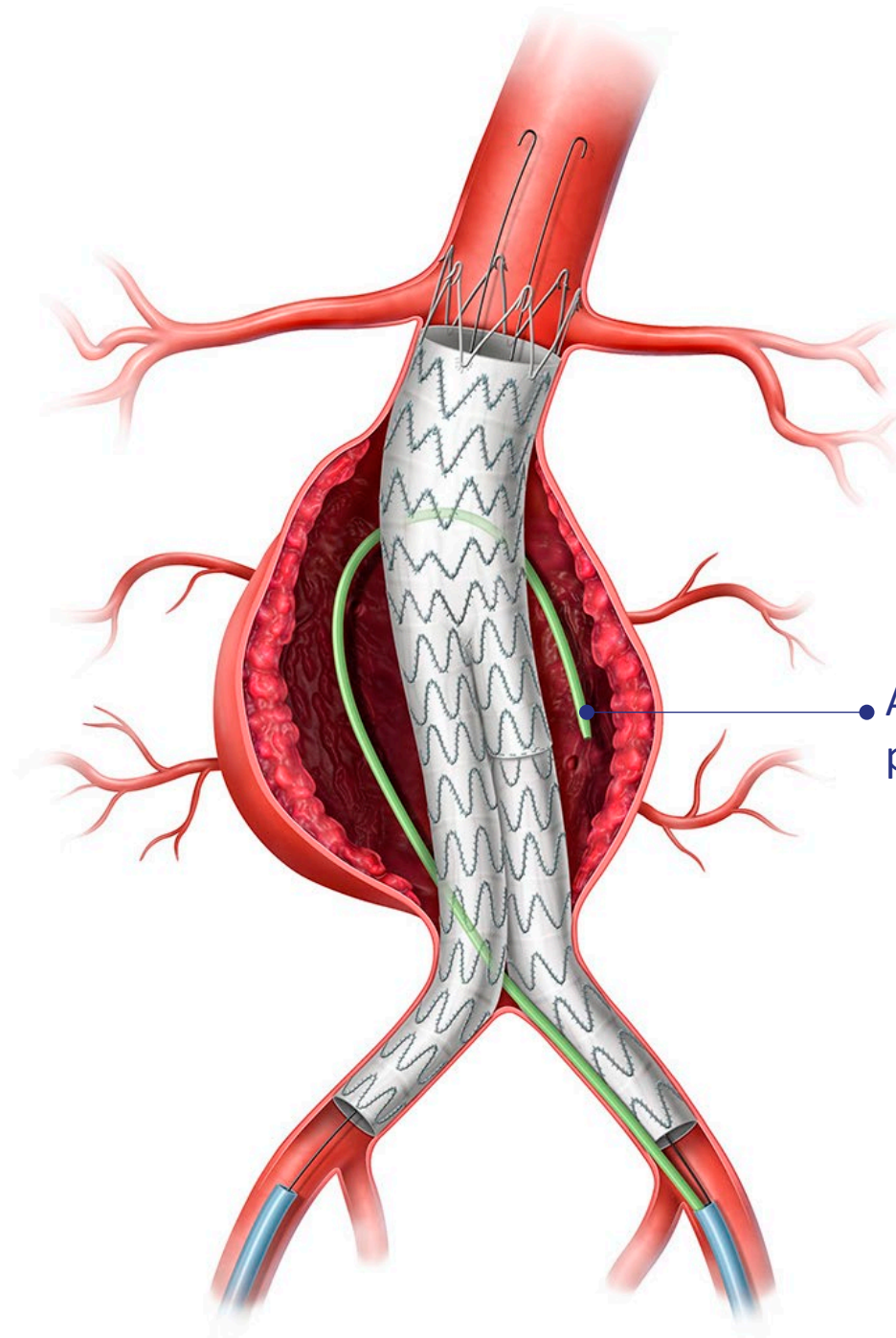




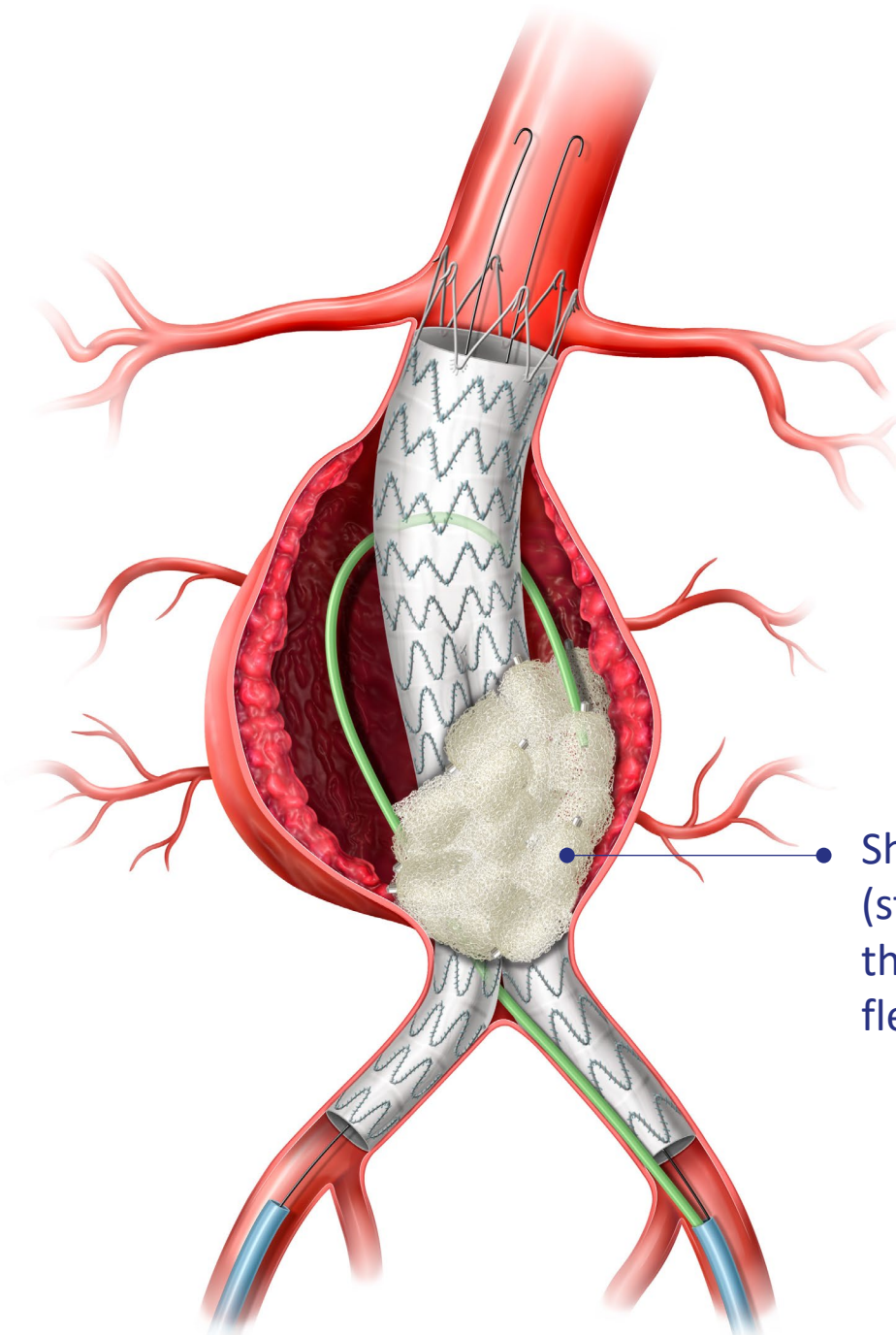
EVAR stent graft is placed



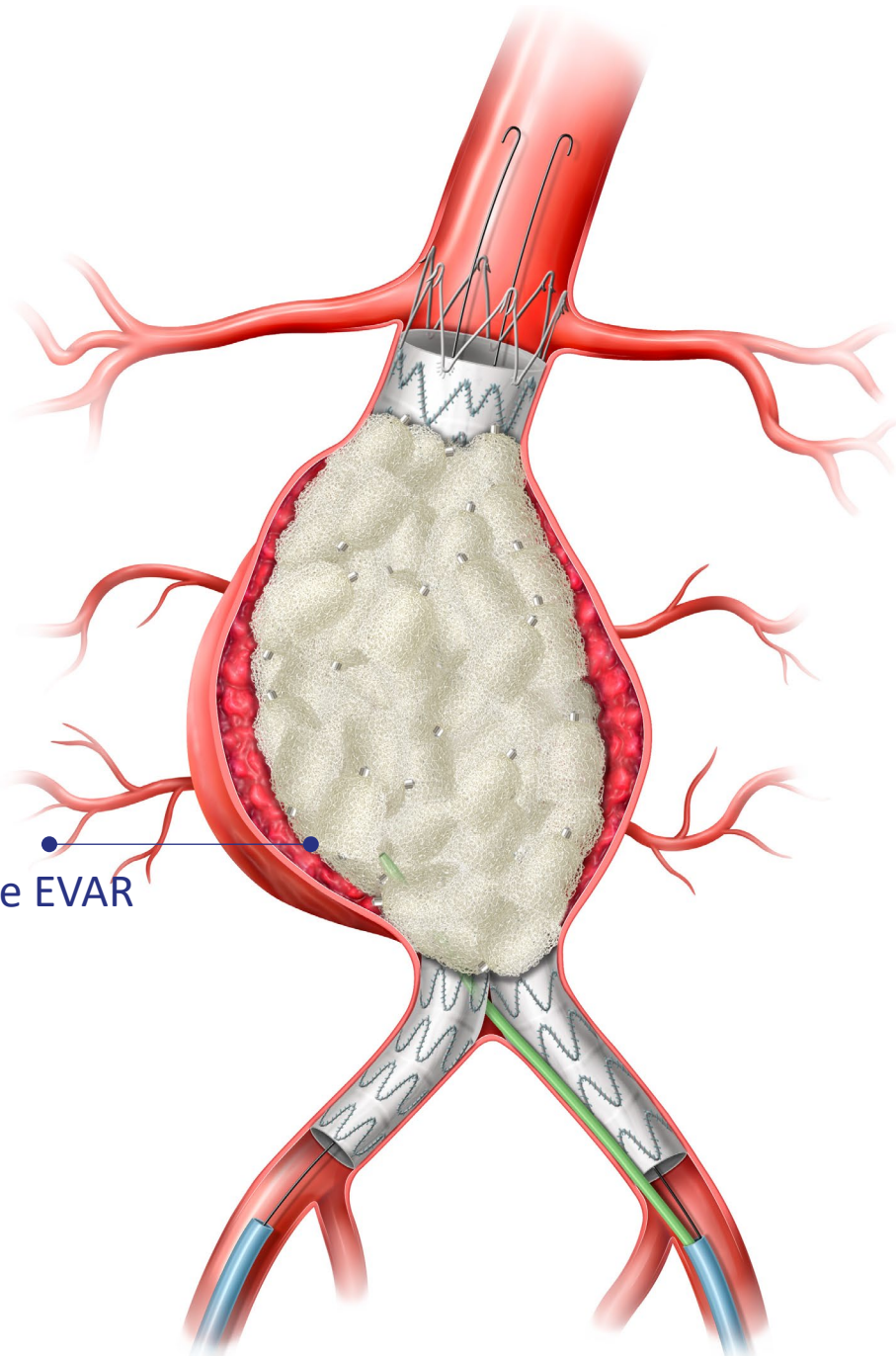
- Guidewire placed inside the aneurysm sac, around the stent graft



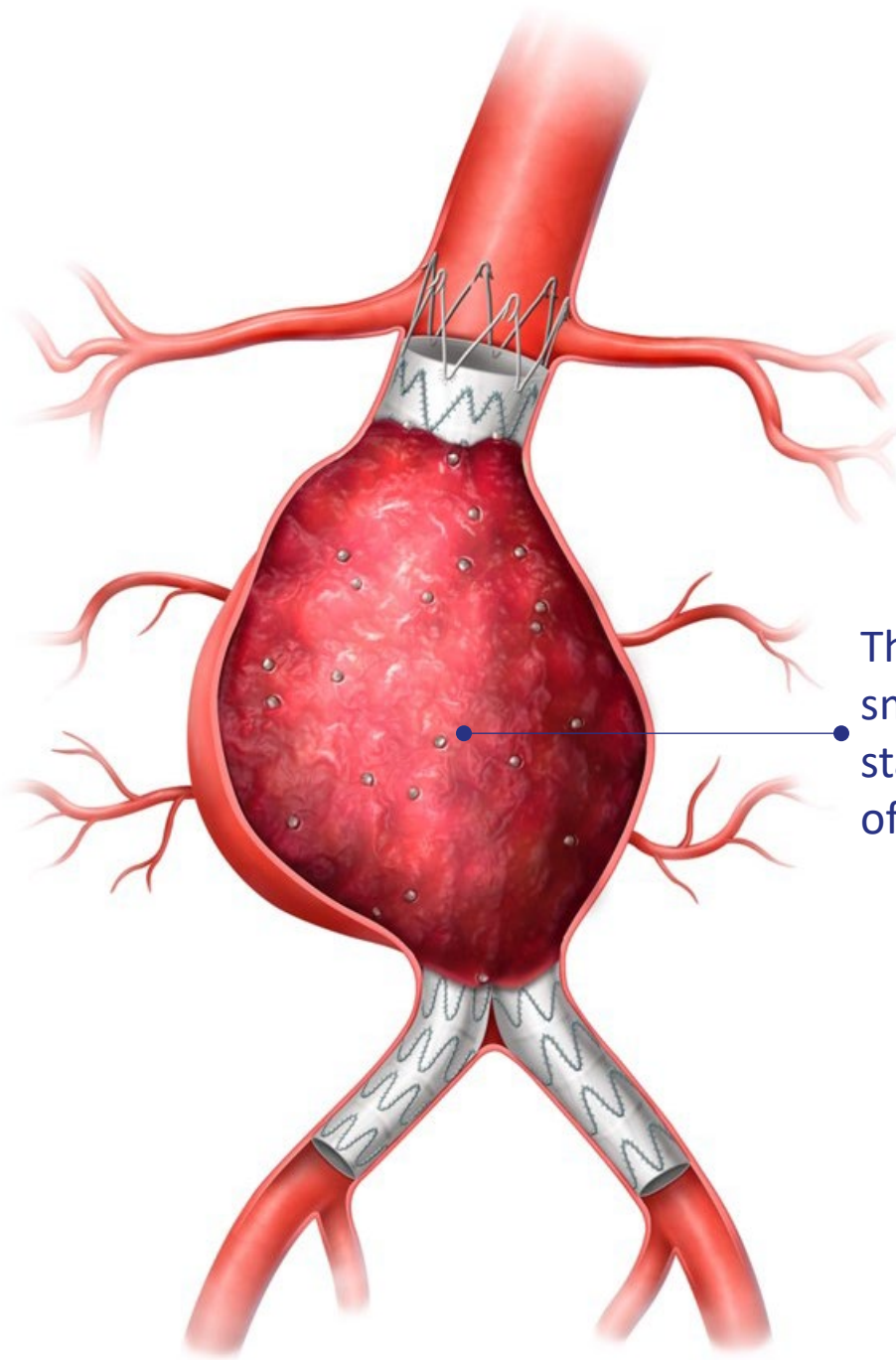
• A flexible sheath (tube) is placed over the guidewire



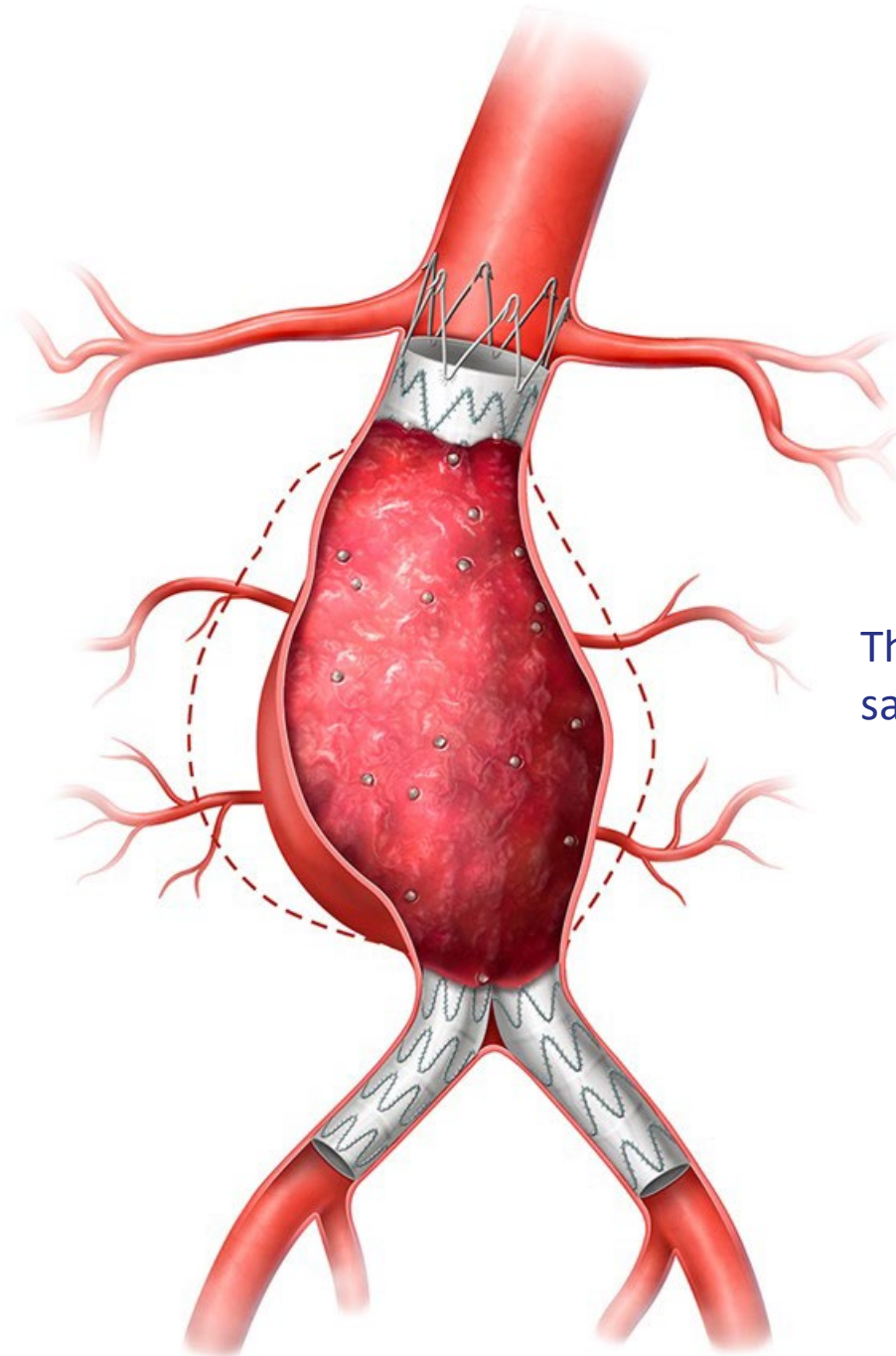
• Shape Memory polymer plugs (study device) are delivered into the aneurysm sac through the flexible sheath.



Complete filling of the aneurysm sac around the EVAR stent graft.



The embolization plugs are soft, like small sponges. Blood will form a stable clot as it flows into the holes of the plugs.



The intention is for the aneurysm sac to become smaller over time.

## Disclaimers

- **Caution – INVESTIGATIONAL DEVICE, LIMITED BY FEDERAL (OR UNITED STATES) LAW TO INVESTIGATIONAL USE.**
- *The following content contains information about AAA-SHAPE, a prospective, multicenter, randomized, open-label study of the IMPEDE-FX RapidFill device when used for prophylactic abdominal aortic aneurysm (AAA) sac filling during elective endovascular aneurysm repair (EVAR). For more information regarding the AAA-SHAPE Pivotal Trial, please visit <https://clinicaltrials.gov/study/NCT06029660>*
- **Refer to the IFU – supplied with each device – for a complete statement of the indications, contraindications, warnings, and instructions for use.**