


Peripheral Embolization With TEVAR And EVAR Procedures: How Widespread And Important Is It And An Update On Devices To Prevent It

Embolic and Micro-Embolic Kidney Injury

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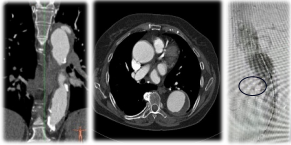
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Conflict of Interest

No Conflict of interest in conjunction to this presentation .

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61-year-old patient with acute kidney injury following TEVAR (Thoracic Endovascular Aneurysm Repair) / EVAR (Endovascular Aneurysm Repair).



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Postoperative AKI – current situation

Postoperative acute kidney injury (AKI) may complicate both open and endovascular aortic aneurysm repair (EVAR) and is associated with substantial morbidity, mortality, and health care expense.



Evidence and predictors of early and delayed renal function decline after aortic aneurysm repair in the Vascular Quality Initiative database Zdenek Hoxak, MD et al. Nov. 2021





Renal function impairment is a frequent complication of endovascular aneurysm repair (EVAR), occurring in as many as 30% of patients


Gustavo S. Oderich, MD EndoVascular Today Nov. 2019

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Peripheral Embolisation Devices for TAVI only

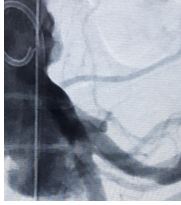
CURRENT APPROVED PROTECTION DEVICES

Device	Company	Design	Access	Delivery System	Comment
	Boston Scientific, MA, USA	Filter	Radial	4FR	Partial Protection
	Keystone Heart IL, USA	Deflector	Femoral	8-9FR	
	Edwards LiveScience CA, USA	Deflector	Radial	4FR	Partial Protection
	Edwards LiveScience CA, USA	Filter	Direct Aortic	14FR	



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Multifactorial Postoperative AKI – main known reasons




- ▶ CIN – Contrast induced Nephropathy
- ▶ Kidney ischemia > Low blood pressure
- ▶ Atherosclerotic & blood clots dislodged particles
- ▶ Micro Embolic particles shower .

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Postoperative Kidney injury – Contrast INDUCED NEPHROPATHY

Currently minimized by:

- (a) Using **low osmolality** contrast media
- (b) Reducing the quantity of Contrast media used per procedure
- (c) Aggressive hydration before and during the procedure
- (d) Administration of N-acetylcysteine NAC ??



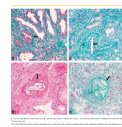
NOTE : CIN - contrast induced nephropathy is considered preventable, as shown in a number of studies.

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Postoperative Kidney injury -

Hypotension
(Low Blood Pressure): Persistent low blood pressure reduces perfusion to the kidneys.

Vascular obstruction
Blockage of the renal arteries or veins can lead to ischemia.



European Heart Journal, Volume 39, Issue suppl_1, August 2018, ehy364-235, <https://doi.org/10.1093/eurheartj/ehy264-235>

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Postoperative Atheroembolic particles

- (a) Dislodged atherosclerotic CALCIFICATION particles, crystals \ cholesterol particles
- (b) Aortic wall \ Endothelial tissue particles
- (c) Dislodged acute thrombus particles
- (d) Organizing thrombus particles
- (e) Microembolic calcification , thrombus particles - of $30\mu > 50\mu$ (demonstrated by DW MRI during Cardio Vascular procedures)
- (f) Foreign materials - polymer particles .

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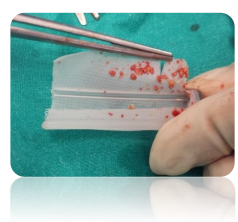
Currently available embolic protection devices

NO CURRENTLY available dedicated aortic device for temporary Embolic & Micro Embolic protection to the RENAL arteries , and the CELIAC TRUNK , SMA .

 Accuset Abbott Vascular Filter size: up to 150 μ m Basket length: 11 mm	 Angioguard Cookte Filter size: 160 μ m Basket length: 5.5 mm	 FilterWire Boston Scientific Filter size: 150 μ m Basket length: 10 mm
 Cave Embolic Filter W.L. Gore & Associates Filter size: 160 μ m Basket length: 11 mm	 NAVE Abbott Vascular Filter size: 120 μ m Basket length: 5.5 mm	 SpiderFX formerly ev3 / Covidien Filter size: 70-250 μ m Basket length: 75 mm

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Lessons from the Carotid Circulation

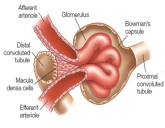


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Postoperative Kidney injury Micro-Embolic shower

Micro embolic injury results in tubular epithelial cell necrosis.


- **Endothelial Injury:** Hypoxia causes endothelial dysfunction, which impairs vasodilation and increases vasoconstriction.
- **Tubular Cell Damage:** The proximal tubules are highly susceptible to ischemic damage. Lack of oxygen depletes ATP, leading to cellular injury, loss of polarity, and cell death.
- **Inflammation and Oxidative Stress:** Ischemia triggers an inflammatory response and reactive oxygen species (ROS) production, which further injure kidney cells.
- **Microvascular Dysfunction:** Hypoxia-induced injury to small vessels can exacerbate ischemia and lead to more damage.



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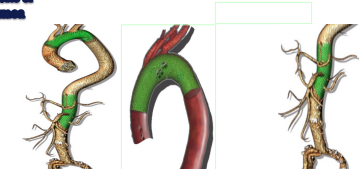

Temporary Renal Embolic protection The clinical WISH LIST

1. **Protects Renal arteries, CEJAC trunk and the SMA** from Embolic and Micro-Embolic particles *throughout the duration of the procedure*
2. **Protects Distal abdomen & pelvic organs** - upon activation of the CAPTURE
3. **Debris is evacuated** from the body after the conclusion of the procedure
4. **minimizing impact on Aortic walls and possible dislodgement** of atherosclerotic particles



THE STENT-FILTER AREA OF PLACEMENT

Main gate way for Stroke & Ischemia

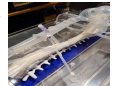





Minimizing Kidney embolic & Micro Embolic injury The FUTURE

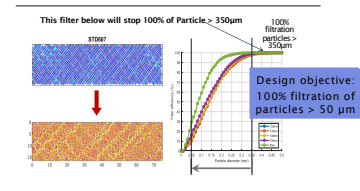
WE are actively involved in a current Scientific Study geared towards finding a solution for Embolic & Micro embolic Kidney protection during EndoVascular procedures. This study holds a promise to significantly reduce this complication.

Study design endpoints will address

- (a) minimizing kidney embolic injury
- (b) minimizing Micro-embolic kidney injury
- (c) No interference with EVAR\TEVAR WORK-FLOW
- (d) minimal impact to aortic walls.

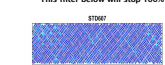
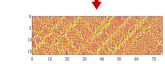





The technology allows a filtration capacity from 50µm window sizes w/o altering blood components



This filter below will stop 100% of Particle > 350µm

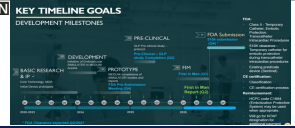

100% filtration particles > 250µm

Future Steps

Key Differentiation Points	Capricorn	EnCompass	TriGuard	ProTEmbo	CAPTIS	FLOWER	Embolizer
360 Embolic Protection	V	V	X	X	X	V	V
Variable Dynamic permeability	V	X	X	X	X	X	X
Capturing	V	X	X	X	V	V	V
Small Bore Femoral Access	V	X	X	V	X	X	X
Flexible working channel	V	Semi	Semi	X	Semi	Semi	Semi

KEY TIMELINE GOALS

Conclusion

EVAR \ TEVAR are mainstay treatments, with over 300,000 procedures performed worldwide annually.

Advanced EVAR\TEVAR devices lead to a growing success rate, lower mortality and complications.

KIDNEY injury is a devastating complication that calls for a definitive solution on the way to make EVAR\TEVAR a safer, successful procedure.




Thank You !

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Procedures: How Widespread And Important
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