Hydrogel

In multiple randomized controlled trials (RCTs) hydrogel coils repeatedly demonstrated equivalent safety, greater effectiveness, and higher efficiency when compared to bare platinum coils.[1-3]

The only neurovascular coil repeatedly proven for better clinical results[1-3]

EQUIVALENT SAFETY

- As safe as bare platinum coils in:
  - Intraprocedural complications
  - Long-term clinical outcomes

GREATER EFFECTIVENESS

- More effective than bare platinum coils:
  - Less recurrence
  - More progressive occlusion

HIGHER EFFICIENCY

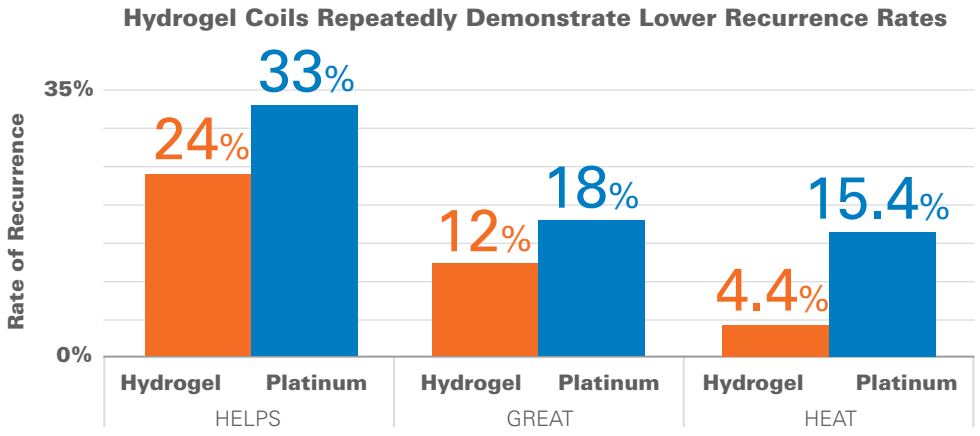
- Higher packing density
- Fewer coils used
- Less coil length

All 3 RCTs adjudicated by blinded third party core labs.[1-3]

RCT Name	Hydrogel Coils Used	Year Published	# of Patients	Aneurysm Size	Follow-up Time
HELPS	**1st Generation** HydroCoil	2011	499	2 - 15mm	18 mo.
GREAT	**2nd Generation** HydroFrame, HydroSoft	2018	484	4 - 12mm	18 mo.
HEAT	**2nd Generation** HydroFrame, HydroSoft, HydroFill	2018*	600	3 - 14mm	24 mo.

*Results presented at SNIS July 2018; publication pending

All 3 RCTs demonstrated **lower recurrence** rates in the hydrogel arm compared to bare platinum.[1-3]



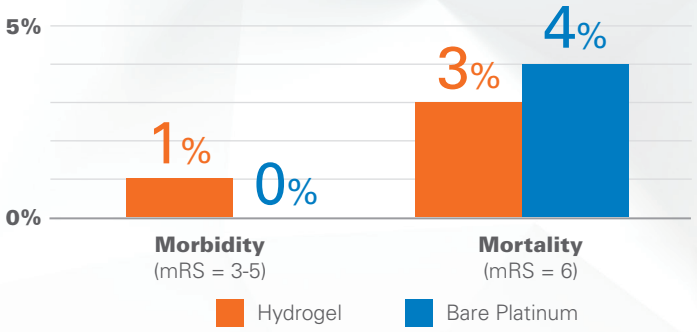
Hydrogel coils are equally safe and outperform bare platinum coils[1-3]:

Equivalent safety

All 3 RCTs concluded that hydrogel coils are as **safe as platinum coils**:

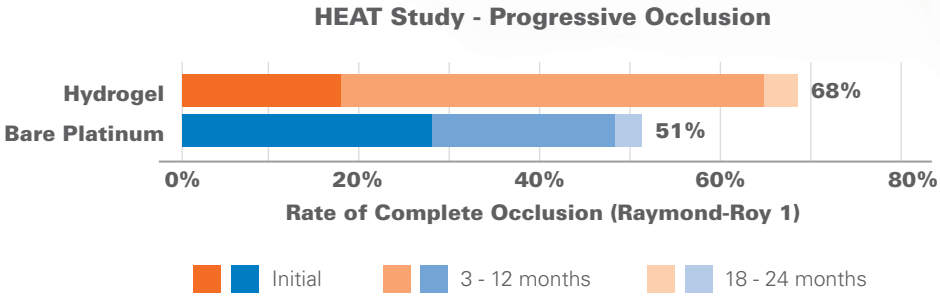
- Comparable complications and procedural safety[1-3]
- Equivalent morbidity and mortality rates

GREAT: No statistical difference in morbidity and mortality.[2]



Greater effectiveness

All 3 RCTs concluded greater efficacy through **superior progressive occlusion** and long term occlusion rates.[1-4]



Higher efficiency

All 3 RCTs concluded hydrogel coils provided **higher packing density** with **fewer coils used** and less overall coil length compared to bare platinum.[1-3]

GREAT and HEAT: Greater aneurysm packing density and reduction in coil length/aneurysm was achieved with hydrogel coils vs bare platinum (p = .001).[1,2]

	GREAT		HEAT	
	Hydrogel	Bare platinum	Hydrogel	Bare platinum
Average packing density	39.0%	31.0%	33.0%	24.8%
Coil length used	51.2 cm	61.6 cm	51.1 cm	56.2 cm
Average number of coils used	6.5	7.0	5.3	6.0

[a]Based on medium-sized aneurysm subanalysis.
[b]Statistically significant.

References:

1. Bendok BR. New Generation Hydrogel Endovascular Aneurysm Treatment Trial. The HEAT study. Presented at: 15th Annual Society of NeuroInterventional Surgery Meeting; July 23–26, 2018; San Francisco, CA.
2. Taschner C, Chapot R, Costalat V, et al. GREAT-a randomized aneurysm trial. Design of a randomized controlled multicenter study comparing HydroSoft/HydroFrame and bare platinum coils for endovascular aneurysm treatment. *Neuroradiology.* 2015;57(6):599-604.
3. White PM, Lewis SC, Nahser H, Sellar RJ, Goddard T, Gholkar A; HELPS Trial Collaboration. HydroCoil® Endovascular Aneurysm Occlusion and Packing Study (HELPS trial): procedural safety and operator-assessed efficacy results. *AJNR Am J Neuroradiol.* 2008;29(2):217-223.
4. Dabus G. New Generation Hydrogel Endovascular Aneurysm Treatment Trial. The HEAT Study. Presented at: 10th Congress of the European Society of Minimally Invasive Neurological Therapy; September 6-8, 2018; Nice, France.

RX Only: Federal (USA) law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE: The HydroCoil® Embolic System (HES) is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature. The device should only be used by physicians who have undergone pre-clinical training in all aspects of HES procedures as prescribed by MicroVention. For complete indications, contraindications, potential complications, warnings, precautions, and instructions, see instructions for use (IFU provided with the device).

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