

GEL-THE-NEC REGISTRY¹

Article Summary

HydroSoft[®]
Helical Coils
 HydroCoil[®] Embolic System

KEY TAKEAWAYS:

- ◆ *Treatment of the aneurysm neck with HydroSoft[®] Helical coils is safe and effective, with high rates of aneurysm occlusion and low rates of treatment-associated complications¹*
- ◆ *GEL-THE-NEC validates the clinical benefits of HydroSoft[®] Helical coils when positioned at the aneurysm neck*

Hydrogel Provides Clinical Benefits:

- ◆ *Deployment success rate: **96.4%***
- ◆ *Low recanalization rates: **10.8%***
- ◆ *Low retreatment rates: **3.4%***
- ◆ *Procedure-related major morbidity and mortality were **1.3%** and **0.5%** respectively*



Image of neointima growth leading to complete occlusion of the aneurysm sac

REGISTRY BACKGROUND

Purpose: To assess the safety and efficacy of HydroSoft[®] Helical coils in treating intracranial aneurysms when deployed at the aneurysm neck as a finishing coil (≤ 3 mm)

- Prospective multicenter registry in 27 centers across 5 countries
- Enrollment: 599 aneurysms in 599 patients
- Principal Investigator: David F. Kallmes, MD
- 35.7% ruptured vs. 64.3% unruptured aneurysms
- Mean aneurysm maximum diameter: 7.3 mm; mean aneurysm neck size: 3.4 mm

SUMMARY OF RESULTS

- HydroSoft[®] Helical coils were successfully deployed in **96.4%** of patients
- Nearly **90%** of patients exhibited complete or near complete occlusion at long-term follow-up as determined by an independent core laboratory
- Progressive occlusion was observed in **13.4%** of cases

Physician Feedback:

"The study shows us that hydrogel plays a role in aneurysmal healing by achieving high rates of aneurysm occlusion."

David Kallmes, MD. Principal Investigator

SNIS 13th Annual Meeting-Boston, MA- MV Symposium- Overview of the Results of the GEL-THE-NEC Study-Presented by Harry J. Cloft, MD, PhD, Professor of Radiology, Mayo Clinic, Rochester, MN (USA).

STUDY LIMITATIONS

- Long-term angiographic outcomes were assessed in 73.7% of patients by an independent core laboratory. Immediate angiographic outcomes were not analyzed by an independent core laboratory
- Adverse events were not graded using a scale such as the modified Rankin score

FREQUENTLY ASKED QUESTIONS

Q: What does GEL-THE-NEC mean?

A: Gaining Efficacy Long Term: HydroSoft®, an Emerging, New, Embolic Coil

Q: Who was the sponsor of the GEL-THE-NEC registry?

A: The registry was sponsored by the Mayo Clinic in Rochester MN, and was funded by MicroVention, Inc.

Q: Of the total amount of coils used in the registry, what percentage were HydroSoft® Helical coils?

A: The mean percent length of HydroSoft® Helical coils in treated aneurysms was 42.8% ± 25.1%.

Q: What was the mean follow-up duration during the registry?

A: The mean follow-up duration was 9.0 ± 6.3 months.

Q: Where were the locations of the aneurysms in the registry?

A: Of the aneurysms treated: 48.7% were ICA, 26.9% were ACA, 9.5% were MCA, and 14.9% were vertebrobasilar aneurysms.

Q: Was the use of adjunct devices allowed?

A: Yes. Adjunctive devices were used in 56% of patients. Stent assisted coiling was performed in 14.8%, balloon assisted coiling was performed in 38.3%, and both stents and balloons were used in 2.8% of patients.



Hydrogel Expanded

Reference

1. GEL THE NEC: a prospective registry evaluating the safety, ease of use, and efficacy of the HydroSoft coil as a finishing device. Brinjikji W, Amar AP, Delgado Almandoz JE, et al. J NeuroIntervent Surg 2018;10:83–8

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.

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