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

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### 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

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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\textsuperscript{1-3}:

**Equivalent safety**

\textbf{All 3 RCTs} concluded that hydrogel coils are as \textit{safe as platinum coils}:

- Comparable complications and procedural safety\textsuperscript{1,3}
- Equivalent morbidity and mortality rates

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{mortality.png}
\caption{Mortality (mRS = 6) comparison between Hydrogel and Bare Platinum in GREAT and HEAT trials.}
\end{figure}

\textbf{GREAT} and \textbf{HEAT}: No statistical difference in morbidity and mortality.\textsuperscript{2}

\textbf{References}:

\textbf{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.

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