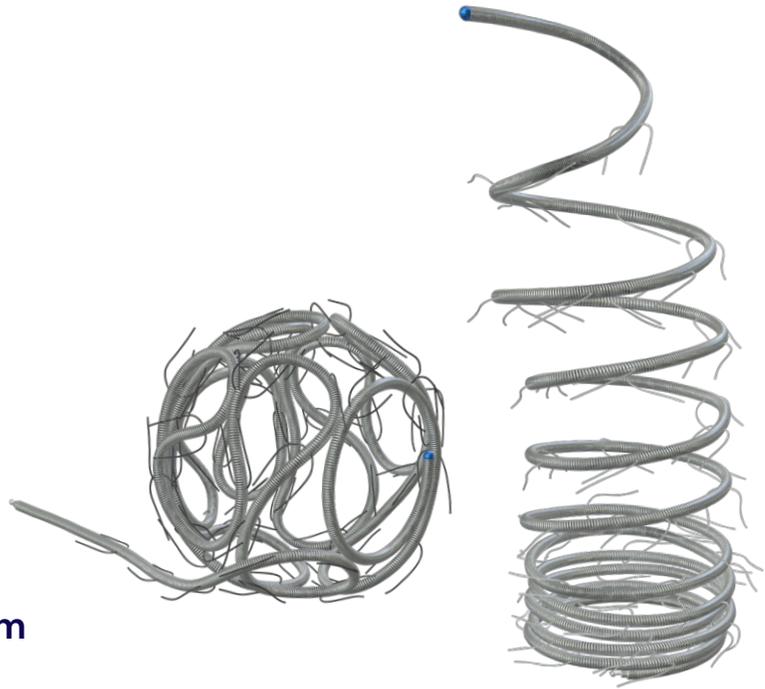


# Medtronic

## Product surveillance registry

Concerto™ detachable coil system



Embolization with the Concerto Helix and/or 3D detachable coil systems were performed for a wide variety of indications including hemorrhage, peripheral aneurysms, and pelvic venous disorders.

**130** patients were evaluated from participating sites within the U.S. and Europe

**44.6%** of patients were female

**48.1%** of procedures were classified as emergent

Overall, safety of the Concerto coil system was confirmed with zero non-target tissue ischemia and zero non-target embolization reported. Effectiveness post-embolization procedure was also confirmed.

Risks include thromboembolic episodes, vessel perforation, hemorrhage, ischemia, neurological deficits.



technical success defined as successful delivery of the device to the target lesion



secondary embolization



clinical success defined as successful embolization of the target lesion (absence of bleeding)



occlusion at 12 months†

† Data from indications with 12 month follow-up; not available from all enrolled patients.

Source: Primary Results from a Real-World Registry of the Concerto™ Detachable Coil System for the Treatment of Hemorrhage, Peripheral Aneurysms, and Pelvic Venous Disorders

**Important Information:** Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

**Indications for Use:** The Concerto™ detachable coil system is indicated for arterial and venous embolizations in the peripheral vasculature.

**Potential Adverse Effects of the Device on Health:** The potential complications include, but are not limited to, the following: puncture site hematoma, thromboembolic episodes, vessel perforation, neurological deficits including stroke and death, vasospasms, vascular thrombosis, hemorrhage and ischemia.

**CAUTION:** Federal (USA) law restricts these devices to sale, distribution and use by or on the order of a physician

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[Medtronic.com/concerto](https://www.Medtronic.com/concerto)

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