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# OBSIDIO™ Conformable Embolic | OCCLUDE Registry

**OCCLUDE:** A PrOspeCtive, Post-Approval, Open-Label, Multi-Center United States (US) Registry to EvaLUate the Effectiveness and Safety of ObsiDio in Clinical PracticE

## STUDY SYNOPSIS

| Study Design |
|---|
| Prospective, post-approval, open-label, single arm, multicenter |
| **Number of Sites** |
| 19 US sites |
| **Number of Patients** |
| 125 patients |

## OCCLUDE OVERVIEW

### STUDY OBJECTIVE

This registry assessed effectiveness and safety outcomes of patients who underwent embolization with Obsidio Embolic in a real-world setting.

### PRIMARY EFFECTIVENESS ENDPOINT

Technical success, defined as occlusion of the target vessel(s) after embolization with Obsidio Embolic.

### PRIMARY SAFETY ENDPOINT

Freedom from major adverse events (MAEs), defined as non-target embolization events that meet serious adverse event (AE) criteria, unintended target organ or soft tissue infarction, vessel perforation/injury, and catheter entrapment through 30 days of the index procedure.

### SECONDARY ENDPOINTS

- Clinical success for bleeding/hemorrhaging and bleeding hypervascular tumors (HVTs), defined as the absence of bleeding from the target vessel(s) without further intervention within 30 days of the index procedure.
- Incidence of device/procedure related AEs
- All device and procedure related serious adverse events
- All unanticipated adverse device effects
- All-cause mortality

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## KEY INCLUSION CRITERIA

- Patients ≥ 18 years
- Patient provides consent
- Patient has planned or is undergoing embolization treatment with Obsidio Embolic

## KEY EXCLUSION CRITERIA

- Patient life expectancy < 30 days
- Contraindication to receiving Obsidio Embolic
- More than two discrete lesions, defined as a treatment area that may be fed by one or more vessels
- Embolization of uterine fibroids, prostate, bronchial or genicular artery, ovarian or spermatic vein, pulmonary arteriovenous malformations or asymptomatic benign tumors, portal vein, varices, lymphatic/thoracic duct, nonvascular channel (e.g. ureter, intestinal fistula).

## CONCLUSION

The real-world multicenter OCCLUDE study met its objectives in a range of treatment scenarios with multiple users.

**100%** technical success

**100%** clinical success

**97.4%** freedom from MAEs

This study is sponsored by Boston Scientific. The full dataset is scheduled to be published in 2026, pending journal review, and will include details on effectiveness, safety, patient poulation, target vasculature and more.

**Obsidio™ Conformable Embolic Indications, Safety, and Warnings**

https://www.bostonscientific.com/obsidio-indications



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