



OBSIDIO™ Conformable Embolic

Limited Market Evaluation (LME) Report

BACKGROUND

Obsidio Conformable Embolic is a pre-mixed solution that starts as an injectable soft solid, flows as a liquid when force is applied, and returns to a soft solid to occlude the vessel when force is removed. Obsidio received 510(k) clearance in July 2022 from the FDA for use of treating hypervascular tumors and bleeds in the peripheral vasculature. Boston Scientific acquired Obsidio (formerly GEM/Gel Embolic Material) from Obsidio, Inc. in August 2022. Boston Scientific chose to launch Obsidio Embolic in the US through a limited market evaluation (LME) to obtain early user experience prior to moving into a full commercial launch.

METHODS

27 sites in the US were chosen for the LME. Post completion of each case, the commercial representatives were tasked with completion of a case report survey. The survey requested responses to both specific and open-ended questions pertaining to the type of case, technical success of achieving embolization using Obsidio Embolic, and some additional information regarding the case.

TECHNICAL SUCCESS

Technical success for a Obsidio Embolic case was defined as successful embolization of the target vasculature.

In the LME, Obsidio Embolic was able to achieve embolization target in all cases and had a success rate of 100% (131/131 cases).

SUMMARY OF CASES

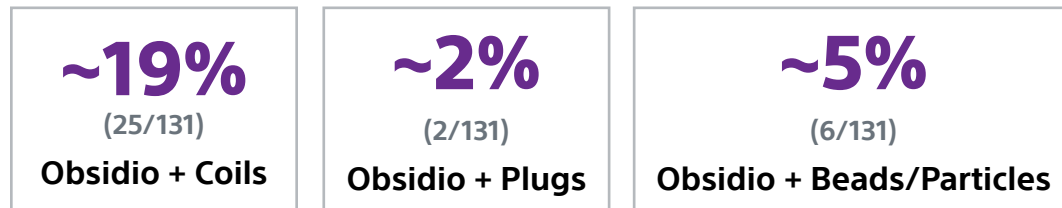
The 131 Obsidio Embolic clinical cases were categorized as 35 Gastrointestinal (GI) cases, 77 non-GI cases, 17 “other” arterial use cases, and 2 venous use cases.

Location of Embolization	Number (%), N=131
Bleed Embolization n=90 (69%)	
Gastrointestinal	34 (26%)
• Gastroduodenal artery	19 (15%)
• Other	15 (12%)
Renal artery	14 (11%)
Hepatic artery	10 (8%)
Splenic artery	10 (8%)
Varices	3 (2%)
Other Bleed Embolizations	19 (15%)
Tumor Embolization n=19 (15%)	
Renal angiomyolipomas	9 (7%)
Primary renal cell carcinomas (RCC)	2 (2%)
Metastatic RCC	2 (2%)
Other Tumor Embolization	6 (5%)
Other n=22 (17%)	

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EMBOLIC PAIRINGS USED

Physicians indicated they used Obsidio Embolic in combination with other embolics:



CONCLUSION

- 100% technical success was reported in all cases and across a broad range of applications
- Embolization using Obsidio Embolic with or without adjunctive mechanical devices was successful
- The upcoming OCCLUDE study will provide prospective data on technical/clinical success rates, safety, and other endpoints related to patient selection

LME Report #97151301

OBSIDIO™ CONFORMABLE EMBOLIC

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

INTENDED USE / INDICATIONS FOR USE: Obsidio Conformable Embolic is indicated for use in the embolization of: • Hypervascular tumors, • Blood vessels to occlude blood flow for controlling bleeding/hemorrhaging in the peripheral vasculature. **CONTRAINDICATIONS:** • Patients with a known hypersensitivity to porcine product • Patients intolerant to occlusion procedures • Vascular anatomy or blood flow that precludes catheter placement or embolic agent injection, such as: • Presence or likely onset of vasospasm • Presence of severe atheromatous disease • Presence of collateral vessel pathways potentially endangering non-target vascular territories during embolization • Presence of arteries supplying the lesion not large enough to accept the selected device • Vascular resistance peripheral to the feeding arteries precluding passage of the product • Arteriovenous shunts (i.e., where the blood does not pass through an arterial/capillary/venous transition but directly from an artery to a vein) • Presence of patent extra-to-intracranial anastomoses or shunts • Presence of end arteries leading directly to cranial nerves • Use in the pulmonary, coronary, and intracerebral vasculature • Use in any vasculature where the product could pass directly into the internal carotid artery, vertebral artery, intracranial vasculature **WARNINGS:** • Serious adverse events have been observed with use in the gastrointestinal tract. When Obsidio Embolic is aliquoted or pushed with saline, it may alter the performance of the device. This can lead to unintended ischemia or necrosis of tissue especially in anatomic structures with little vascular collateralization. • Serious adverse events have been observed with use in the gastrointestinal tract. Immediately post deployment of Obsidio Embolic, avoid forceful fluid injections in or near the Obsidio Embolic material which could alter Obsidio Embolic performance and may increase the risk of non-target embolization. • The physician should be sure to carefully select the amount of Obsidio Embolic used according to the size of the catheter appropriate for the target vessels at the desired level of occlusion in the vasculature. • Extreme caution should be used for any procedures involving the extracranial circulation encompassing the head and neck. The physician should carefully weigh the potential benefits of using embolization against the risks and potential complications of this procedure, which may include blindness, hearing loss, loss of smell, paralysis and death. • Presence of air bubbles or voids within the Obsidio Embolic material may indicate a damaged product. If present, do not use syringe as patient injury may result. Replace with new Obsidio Embolic syringe. • As Obsidio Embolic syringe is being prepared for a wet-to-wet connection, the cohesivity of the product should be observed. If water or a water/tantalum suspension elutes from the syringe tip, the product should not be used, as this may indicate a damaged product that could result in patient injury. Replace with new Obsidio Embolic syringe **PRECAUTIONS:** Refer to Instructions for Use for all applicable information on Precautions. **POTENTIAL COMPLICATIONS:** Vascular embolization is a high-risk procedure. Complications may occur at any time during or after the procedure, and may include, but are not limited to, the following: • Paralysis resulting from non-targeted embolization • Ischemic injury from adjacent tissue edema • Undesirable reflux or passage of Obsidio Embolic into non-target arteries adjacent to the targeted lesion or through the lesion into other arteries or arterial beds of systemic circulation or, pulmonary, or coronary circulations, resulting in non-target embolization • Pulmonary embolism and/or stroke due to arterial-venous shunting, for example from a patent foramen ovale • Ischemia at an undesirable location including ischemic stroke, ischemic infarction (including myocardial infarction), and tissue necrosis • Capillary bed occlusion and tissue damage, which may lead to abscess formation and sepsis • Vessel or lesion rupture and hemorrhage • Recanalization • Foreign body reactions necessitating medical intervention • Infection necessitating medical intervention • Complications related to catheterization (e.g., hematoma at the site of entry, clot formation at the tip of the catheter and subsequent dislodgment, and nerve and/or circulatory injuries, which may result in leg injury) • Allergic reaction to medications (e.g., analgesics), contrast media or embolic material • Pain and/or rash, possibly delayed from the time of embolization • Death • Neurological deficits, including cranial nerve palsies/injury (e.g., blindness, hearing loss, loss of smell and/or paralysis) • Additional information is found in the Warnings section **97222344 B**

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Boston Scientific
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Peripheral Interventions
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

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