



OBSIDIO™ Conformable Embolic

SIMPLY DIFFERENT



Rapid Hemostasis
Occludes in seconds



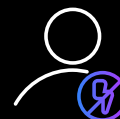
Easy Preparation
Pre-mixed 1 mL
syringes



Time Insensitive
Non-adhesive,
no entrapment risk



Controlled Delivery
Start-and-stop via
shear thinning



Patient Experience
No pain or odor



Enhanced Visualization
No CT artifacts

CASE STUDY: RIGHT INTERNAL ILIAC ARTERY EMBOLIZATION

Courtesy of Dr. Abhishek Kumar | Rutgers New Jersey Medical School



PATIENT PRESENTATION

60-year-old man presented to a trauma center s/p two story fall. CT abdomen and pelvis revealed a complex right pelvic fracture with extraperitoneal hemorrhage and active extravasation (circle). Patient was started on a massive transfusion protocol and transferred to Interventional Radiology.



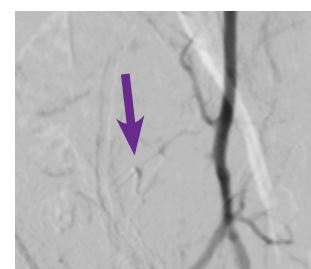
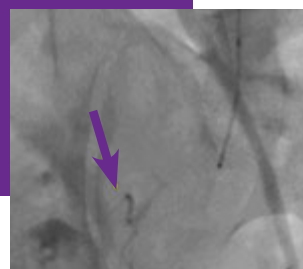
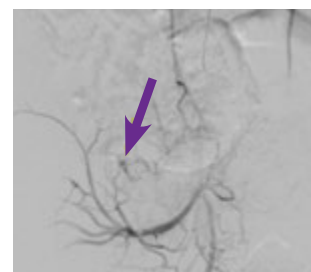
INTERVENTION USED

Left radial artery access was obtained and a 5 F sheath was placed. A 4 F angled catheter was used to select the right internal iliac artery. Angiography revealed active extravasation from a branch of the lateral sacral artery (red arrow). A 2.8 F microcatheter and 0.014" wire were used to catheterize the bleeding vessel. Embolization was performed with 0.2 cc of Obsidio Embolic using standard technique (purple arrow). Completion angiography from the internal iliac artery showed no further contrast extravasation.



OUTCOME

The patient was transferred to SICU in stable condition and discharged from the hospital 7 days post procedure.



Your new go to for emergent situations.

Obsidio Conformable Embolic is a 510(k) cleared device with shear-thinning technology, the first embolic of its kind to have a specific on -label indication for peripheral use in the US. Obsidio Embolic is indicated for the use in the embolization of hypervascular tumors and blood vessels to occlude blood flow for controlling bleeding/ hemorrhaging in the peripheral vasculature.

Obsidio Embolic 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. It’s quick to deploy, provides rapid occlusion, and ensures procedural confidence.

Product Number	GTIN	Material Description	Volume	Minimum Catheter Inner Diameter (ID)	Maximum Vessel Size
M0013972101010	00191506043124	Obsidio Syringe	1 mL (1 cc)	0.024" (0.62 mm)	3 mm
Obsidio Embolic must be stored in a refrigerator (2 °C – 8 °C) in a dry place in original device packaging One-Year Shelf Life					

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**

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary. All trademarks are the property of their respective owners.



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contact customer service at 1.888.272.1001.

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PI-1484304-AC