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OBSIDIO™ Conformable Embolic | OCCLUDE Registry

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
Up to 23 US sites
Number of Patients
Up to 125 patients enrolled
Anticipated Timeline
Study start: Q2 2024 **Study completion:** 16 months **Enrollment period:** 10-15 months

STUDY OBJECTIVES AND ENDPOINTS

STUDY OBJECTIVE

This registry will assess technical success rate and safety outcomes for patients receiving Obsidio Embolic for peripheral embolization of hemorrhages or Hyper Vascular Tumors (HVTs) in a real world setting.

PRIMARY EFFICACY ENDPOINT

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

PRIMARY SAFETY ENDPOINT

Assess the freedom from Major Adverse Events (MAEs) (non-target serious AEs, unintended target organ or soft tissue infarction, vessel perforation/injury, and catheter entrapment) up to 30 days post index procedure.

SECONDARY ENDPOINTS

- Rate of clinical success of embolizing peripheral bleeding/hemorrhage or HVTs, defined as absence of bleeding from the target vessel(s) without further intervention within 30 days.
- Incidence of device/procedure related AEs

OBSIDIO™ Conformable Embolic

INCLUSION/EXCLUSION CRITERIA

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

OBSIDIO™ CONFORMABLE EMBOLIC
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, 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 products • 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:** • When Obsidio Embolic is aliquoted in small amounts there can be a dilution of the material, which 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. • Immediately post deployment of Obsidio Embolic, avoid forceful fluid injections in or near the Obsidio Embolic material which could disrupt the Obsidio Embolic. • Performing therapeutic embolization to occlude blood vessels is a high-risk procedure. Perform the procedure only under the direction of personnel with vascular embolization experience and thorough knowledge of angiographic techniques. • Obsidio Embolic contains gelatin of porcine origin, and therefore, could cause an immune reaction in patients who are hypersensitive to collagen or gelatin. Careful consideration should be given prior to using this product in patients who are suspected to be allergic to injections containing gelatin. • The physician should be sure to carefully select the amount of the Obsidio Embolic used according to the size of the catheter appropriate for the target vessels at the desired level of occlusion in the vasculature. • As with any embolization device, non-target embolization such as due to arterial-venous shunting, or 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, pulmonary, or coronary circulations, may potentially lead to significant complications. • 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. • Avoid embolization near branch points as this may increase the risk of non-target embolization. • Serious radiation induced skin injury may occur to the patient due to long periods of fluoroscopic exposure, large patient diameter, angled x-ray projections, and multiple image recording runs or radiographs. Refer to your facility's clinical protocol to ensure the proper radiation dose is applied for each specific type of procedure performed. Physicians should monitor patients that may be at risk. • Onset of radiation-induced injury to the patient may be delayed. Patients should be counseled on potential radiation side effects and whom they should contact if they show symptoms. • Pay careful attention for signs of non-targeted embolization. During injection carefully monitor patient vital signs to include SpO2 (e.g., hypoxia, central nervous system changes). Consider terminating the procedure and investigating for possible shunting if non-target embolization is suspected or patient symptoms develop. • Consider increasing amount of Obsidio Embolic injected if angiographic evidence of embolization does not quickly appear evident during Obsidio Embolic injection. • Post embolization swelling may result in ischemia to tissue adjacent to target area. Care must be given to avoid ischemia intolerant, nontargeted tissue such as nervous tissue. • 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:** • Additional evaluations or precautions may be necessary in managing periprocedural care for patients with conditions such as, but not limited to bleeding diathesis or hypercoagulative state and immunocompromise. • Do not use the Obsidio Embolic if the syringe or packaging appear damaged. • Do not use devices after "Use By" date. • The syringe is intended for embolization use only. Do not use for any other application. For single patient use only – contents are supplied sterile – do not reuse, reprocess or resterilize the contents of a syringe or the syringe itself. Reusing, reprocessing or resterilizing may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reusing, reprocessing or resterilizing may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. All procedures must be performed according to accepted aseptic technique. • Embolization with Obsidio Embolic should only be performed by physicians experienced in vascular embolization and angiographic techniques. **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 A.1**

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