INVAMED

INSTRUCTION FOR USE

FILLER
EMBOLIZATION AGENT

ATTENTION

By law, this device may only be purchased by or on the order of a physician.
This device should only be used by physicians familiar with angiography and percutaneous interventional procedures.

WARNING

The content provided is STERILIZED by treating it with ethylene oxide (EO). Do not use if sterile barrier is damaged. If damaged, do not use. It is for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or result in device failure, which may subsequently result in patient injury, illness, or death. Reuse, reprocessing or resterilization may also pose a risk of contamination of the device and/or lead to infection and/or cross-infection in patients, including but not limited to transmission of infectious disease from one patient to another. Contamination of the device may result in patient injury, illness, or death. After use, dispose of the product and packaging in accordance with hospital, administrative, and/or local government policy. Do not use after the expiry date on the package.

1. PRODUCT NAME

Filler Non-Adhesive Embolization Agent (1cc)

2. DEVICE DESCRIPTION

It is a liquid embolic agent formed by Synthesis of Solvent Dimethyl Sulfur Oxide (DMSO) to N-butyl polymer. It is a ready-to-use, transparent liquid. It is used together with 1:2 Dextrose (5% and/or 10%) during use. Invamed Injector (DMSO Compatible) Invamed Embolization Catheters are used together. Different brands of Injectors and catheters may not be DMSO compatible. It is High Density. It is rendered radiopaque with Lipiodol.

3. PRINCIPLE

It is administered via a microcatheter into the AVM under fluoroscopic control. The DMSO solvent disperses into the blood and interstitial fluids, causing the N-Butyl Polymer to form a spongy, coherent embolus. As the polymeric embolus solidifies from the outside to the inside, it immediately forms a layer as it moves more distally in the vessel. Because it is non-adhesive, the microcatheter can be left in place while performing slow, controlled injections. Post-embolization angiography can be performed with the delivery microcatheter in place, so physicians can make additional injections via the same microcatheter as needed. 1:2 suspension with Lipiodol to render it radiopaque.
Additional DMSO or Dextrose (5% and/or 10%) may also be used to remove the air gap of the catheter.

4. PRESENTATION

Sterile: The Embolization Agent (1cc) product is sterile. Sterilized with dry air and ethylene oxide. It is not pyrogenic.

Storage: Store in a dry, dark, controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light.

5. INDICATIONS

Embolization of peripheral vascular and neurovascular lesions, including arteriovenous malformations and hypervascular tumors.

6. CONTRAINDICATIONS

- Patients with a critical allergy to contrast materials.
- Patients for whom antiplatelet or anticoagulation therapy is contraindicated.
- Pregnant women or women who may be pregnant.
- Patients for whom surgery is contraindicated due to their condition.

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7. POTENTIAL COMPLICATIONS

Possible complications include but are not limited to:
• Hematoma.
• Arterial thrombosis.
• Embolic migration,
• ischemic events due to vasospasm, thrombosis
• Catheter entrapment.
• Catheter rupture.
• Device migration and caste movement.
• Cases of haemorrhage: vascular rupture – perforation.
Hemodynamic changes caused by embolization may cause hemorrhagic complications.
• Hemorrhagic complications associated with attempts to move a stuck catheter.
• These ischemic or hemorrhagic complications,

8. PRECAUTIONS

Examine product packaging before use. Do not use if the sterile enclosure has been opened or damaged. Use before expiration date. Read the Instructions for Use of both the catheter and the interface adapter before use. Verify that catheters and accessories used in direct contact with the polymer are clean and compatible with the material and do not induce precipitation or degrade on contact. See the corresponding Warnings and Instructions for Use sections. If not waited a few seconds to remove the microcatheter after its injection, the Polymer may disintegrate and enter non-targeted vessels. Catheter removal may be difficult or the catheter may become stuck due to one or more of the following factors:

• Long catheterization time
• Angio structure: excess distal arteriovenous malformation fed by afferent, elongated, small or curved pedicles
• Vasospasm
• Reflux
• Injection time To reduce the risk of catheter entrapment, carefully select catheter placement and manage reflux to minimize the factors listed above.

9. WARNINGS

This device is supplied STERILE and is for single use only. Do not reprocess or sterilize. Reprocessing or sterilization may increase the risk of patient infection and impaired device performance.
• Use only Invamed DMSO compatible syringes to inject. Other syringes may not be compatible with DMSO.
• Use only Invamed DMSO compatible microcatheters. Other microcatheters may not be compatible with DMSO and their use may lead to thromboembolic events due to catheter wear.
• Always consider the possibility of this device interacting with other embolic agents such as cyanoacrylates, coated coils, particles, and/or embolic spheres.
• Embolization for occlusion of blood vessels is a high-risk procedure. The procedure should be performed by a specialist who is adequately trained in neuro- or peripheral intervention and has extensive knowledge of the pathology to be treated, angiographic techniques, and superselective embolization.
• The patient's angio anatomy should be conducive to insertion of a microcatheter tip in a distal position to arterial branches likely to supply a cranial nerve.
• Additional coil use should be considered if angiography shows that venous drainage of the AVM occurs almost simultaneously with arterial opacification.
• This device may solidify prematurely if the microcatheter luer comes into contact with any amount of saline, blood, or contrast.
• Failure to continuously stir this device for the required time may result in insufficient Lipiodol suspension, resulting in inadequate fluoroscopic imaging during administration. Inject immediately after mixing with Lipiodol. If the suspension is injected late, it may precipitate in the syringe, preventing adequate visualization of the polymer during injection.
• Use of this device's Syringe-Catheter Interface Adapter will reduce the labeled dead space of the microcatheter. Failure to leave appropriate spaces may result in undesired embolization.
• See the invamed SyringeCatheter Interface Adapter Instructions for Use for a list of compatible microcatheters and dead space information. As the polymer is injected, it should be seen to progress through the catheter lumen on fluoroscopic imaging. In order to visualize the embolic material before it exits the tip of the catheter, it is recommended that the fluoroscopic image be obtained before the minimum catheter + adapter dead space value is reached.
• Press only with your thumb to inject. Using the palm of the hand to depress the syringe plunger may result in catheter rupture due to excessive pressure in the event of catheter occlusion.
• Do not use after the “Expiration date” on the package.

10. APPLICATION

Prior to embolization agent application, all equipment to be used for the procedure should be carefully inspected for defects. Check the package to make sure it has not been damaged during shipping and make sure the sterile barrier is intact and the vial is undamaged. Check the fluidity and transparency of the embolizing agent in the vial.

Follow these steps to prepare the product for use:

1. Remove the Embolization Agent Delivery Kit from its sterile packaging.
2. Remove 1 cc of Embolization Agent from its packaging.
3. Draw the embolizing agent in the vial into the syringe.
4. 2 cc of 5% dextrose solution is drawn into another syringe.
5. Injectors to be used should not be washed with any liquid.
6. 2 injectors are connected to the 2 ends of the 2-way faucet.
7. The interconnection is adjusted so that the flow direction of the tap is in the direction of the injector. the third output is turned off.
8. By pressing the injectors sequentially, the 2 materials are fully mixed. The process is repeated 3 times.
9. As a result of the process, no phase difference should be observed in the mixture
10. If desired, depending on the superficiality or sensitivity of the application area, dextrose can be used to keep the application area softer after the procedure. It can be mixed in the injector and given to the treatment area by adding more dextrose at a ratio of 1:2 (Agent: Dextrose) or if desired.
11. For Radiopaque Appearance, Lipiodol should be added at a ratio of 1:2:3 and mixed.
12. Insert the Luer-Lock tip of the syringe into the luer-lock tip of the Embolization Agent Delivery Kit and screw it in.

11. SHELF LIFE

When preserved in the specified conditions, the product has a shelf life of 1 year from the date of manufacture. Do not use after expiration date.

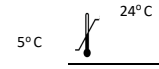
12. DISPOSION

Dispose of Embolization Agent products according to standard institutional procedures for medical waste, including disposable, blood contact devices.

13. WARRANTY DISCLAIMER AND SETTLEMENT LIMITATION

There are no warranties of any kind, express or implied, including, without limitation, the implied warranty of merchantability or fitness for a particular purpose for the INVAMED product(s) described in this publication. Under no circumstances will INVAMED be liable for any direct, incidental or consequential damages other than those expressly provided in the specific law. No one has the authority to bind INVAMED to any representations or warranties other than those specifically stated here. Descriptions or specifications in this publication and INVAMED printed material are for general identification of the product at the date of manufacture only and do not imply any express warranty.
INVAMED will not be liable for any direct, incidental or consequential damages resulting from the reuse of the product.

14. DESCRIPTION OF LABEL / MARKING

	It is sterilized with ethylexide.
	It is sterilized with dry air.
	Read the pre-use instructions
	Do not use damaged packaged products
	Frangible
	Not used a second time
	Attention, see instructions for use
	Production date
	Cannot be sterilised a second time
	Do not expose to sunlight.
	Keep at 5°C-24C° Temperature
	It could potentially bioact.
	Reference Number
	Expiration date
	Keep in dry place
	Batch/Lot Number
	Production Location

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