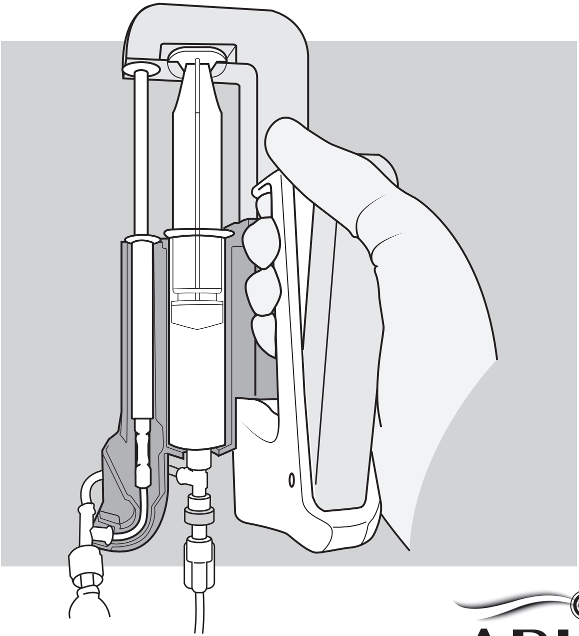
Easi-Vue™ System
embolic microspheres

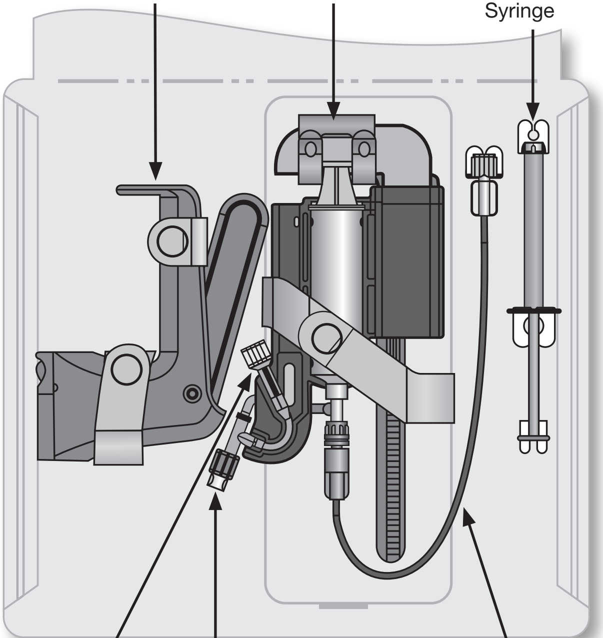
Instructions for Use

CAUTION: Federal (U.S.A.) law restricts this device to use by or on the order of a licensed physician.



ABK BIOMEDICAL™

Easi-Vue™ embolic microspheres Adminstration Kit (EVA) Contents



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Description

Easi-Vue™ embolic microspheres are biocompatible, radiopaque, non-compressible, non-resorbable glass microspheres. Radiopacity allows visualization with X-ray based imaging (ie: fluoroscopy, Computed Tomography (CT), etc.) without the added use of contrast. The Easi-Vue embolic microspheres are included with the Easi-Vue embolic microspheres System which is comprised of Easi-Vue embolic microspheres Administration Kit and the Easi-Vue embolic microspheres Refill Syringe.

Each device is described below:

1) **Easi-Vue embolic microspheres Administration Kit** includes:
- **Control Handle** consists of custom plastic components and springs.
- **Cartridge Assembly** which includes plastic components, PVC tubing, polycarbonate fluid connectors and a separate flush syringe
- **Microsphere Syringe** prefilled with 1.25g (approximately 0.7 ml) of Easi-Vue embolic microspheres mixed within <1 ml of 0.9% NaCl saline.

2) **Easi-Vue embolic microspheres Refill Syringe** includes:
- **Microsphere Syringe** prefilled with 1.25g (approximately 0.7 ml) of Easi-Vue embolic microspheres mixed within <1 ml of 0.9% NaCl saline.
- 1 female luer cap
- 1 male luer cap

How Supplied

1) **Easi-Vue™ embolic microspheres Administration Kit** are sterile, non-pyrogenic and individually packaged in a die card and Tyvek pouch. Each size is color coded according to their size.

Administration Kits:			
Ref Number	**Color Code**	**Size Range (µm)**	**Units**
EVA50	Orange	50 ± 20 µm	5 units per box
EVA100	Yellow	100 ± 35 µm	5 units per box
EVA150	Blue	150 ± 50 µm	5 units per box

2) **Easi-Vue embolic microspheres Refill Syringe** are sterile, non-pyrogenic and individually packaged in a die card and Tyvek pouch. Each size is color coded according to their size.

The Refill Syringes will be available to order for embolization procedures that require more than one Microsphere Syringe of Easi-Vue embolic microspheres to achieve the intended procedural endpoint.

Refill Syringes:			
Ref Number	**Color Code**	**Size Range (µm)**	**Units**
EVR50	Orange	50 ± 20 µm	5 units per box
EVR100	Yellow	100 ± 35 µm	5 units per box
EVR150	Blue	150 ± 50 µm	5 units per box

Indications For Use/Intended Use

The Easi-Vue™ embolic microspheres System is intended for embolization of arteriovenous malformation and hypervascular tumors.

Contraindications

- Patients intolerant to occlusion procedures.
- Vascular anatomy or blood flow that precludes catheter placement or embolic agent injection.
- Presence or likely onset of vasospasm.
- Presence or likely onset of hemorrhage.
- Presence of severe atheromatous disease.
- Presence of feeding arteries smaller than distal branches from which they emerge.
- Presence of collateral vessel pathways potentially endangering normal territories during embolization.
- Presence of arteries supplying the lesion not large enough to accept Easi-Vue embolic microspheres.
- Vascular resistance peripheral to the feeding arteries precluding passage of Easi-Vue embolic microspheres into the target artery.
- In the pulmonary vasculature.
- Presence of blood coagulation disorder that would prohibit arterial punctures.
- Presence of any vasculature where Easi-Vue embolic microspheres could pass directly into the central nervous system, central circulatory system or other non-target territories.
- Patient has high-flow arteriovenous shunt with diameter greater than the selected Easi-Vue embolic microspheres.
- Patient is pregnant.

Warnings

- The physician should be sure to carefully select the size of Easi-Vue™ embolic microspheres according to the size of the target vessels at the desired level of occlusion in the vasculature and after consideration of the arteriovenous angiographic appearance.
- Easi-Vue embolic microspheres size should be selected to prevent passage from artery to vein.
- Because of the significant complications of non-target embolization, extreme caution should be used for any procedures involving the extracranial circulation encompassing the head and neck, and the physician should carefully weigh the potential benefits of using embolization against the risks and potential complications of the procedure. These complications can include blindness, hearing loss, loss of smell, paralysis and death.
- 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 counselled on potential radiation side effects and whom they should contact if they show symptoms.
- Pay careful attention for signs of mistargeted embolization. During injection carefully monitor patient vital signs to include SAO2 (e.g. hypoxia, CNS changes). Consider terminating the procedure, investigating for possible shunting, or increasing microsphere size if any signs of mis-targeted embolization occur or patient symptoms develop.
- Consider upsizing the microspheres if evidence of embolization does not quickly appear evident during injection of the microspheres.
- Care must be taken to choose larger size Easi-Vue embolic microspheres when embolizing arteriovenous malformations

with large shunts to avoid passage of the spheres into the pulmonary or coronary circulation.
- Do not use Easi-Vue™ embolic microspheres in conjunction with embolization devices based on organic solvents such as ethyl alcohol or dimethyl sulfoxide (DMSO) at the same embolization site.
- Do not use ionic contrast agent with this product. Ionic contrast could alter the microsphere characteristics. Non-ionic contrast is compatible with Easi-Vue embolic microspheres.
- Should microcatheter occlusion occur, remove the catheter from the patient. Do not use forceful injection, guidewires, or other instruments to dislodge the blockage.
- Patients with prior biliary surgery, bile duct dilation or vessels close to bile ducts may be at increased risk from infection (e.g. biloma/ liver abscess)

Warnings about use of small microspheres

- Careful consideration should be given whenever use is contemplated of embolic agents that are smaller in diameter than the resolution capability of your imaging equipment. The presence of arteriovenous anastomoses, branch vessels leading away from the target area or emergent vessels not evident prior to embolization can lead to mistargeted embolization and severe complications.
- Microspheres smaller than 100 microns will generally migrate distal to anastomotic feeders and therefore are more likely to terminate circulation to distal tissue. Greater potential of ischemic injury results from use of smaller sized microspheres and consideration must be given to the consequence of this injury prior to embolization. The potential consequences include swelling, necrosis, paralysis, abscess and/or stronger post-embolization syndrome.
- Post embolization swelling may result in ischemia to tissue adjacent to target area. Care must be given to avoid ischemia intolerant, non-targeted tissue such as nervous tissue.

Precautions

- Patients with known allergy to contrast medium may require corticosteroids prior to embolization.
- Additional evaluations or precautions may be necessary in managing peri-procedural care for patients with the following conditions:
  - Bleeding diathesis or hypercoagulative state
  - Immunocompromise
- Do not use if the Refill Syringe, delivery components, or any package appears damaged.
- For single patient use only – Contents supplied sterile – Never reuse, reprocess, or re-sterilize the contents of a package once it has been opened. Reusing, reprocessing, or re-sterilizing may compromise the structural integrity of the system and or lead to delivery system failure, which in turn may result in patient injury, illness or death. Reusing, reprocessing, or re-sterilizing 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 techniques.
- Select the size and quantity of Easi-Vue™ embolic microspheres appropriate for the pathology to be treated.
- Embolization with Easi-Vue embolic microspheres should only be performed by physicians who have received appropriate interventional embolization training in the region to be treated.
- Do not connect the Refill Syringe with Easi-Vue embolic microspheres directly to a microcatheter for embolic delivery, as a catheter occlusion may result.

- Physicians must decide the most appropriate time to stop the infusion of Easi-Vue™ embolic microspheres. Typically, artery will accept fewer microspheres as the treatment progresses. Proximal slowing or termination of flow evaluated by intermittent injection of contrast through flush port may indicate that the vessel or the target area is occluded by the Easi-Vue embolic microspheres. Careful fluoroscopic monitoring is required.
- Microsphere embolization must be performed slowly. The injection speed manner must be controlled. Excessive injection rate may result in retrograde flow in the vessel leading to embolization of other non-target healthy tissue.
- **The Easi-Vue embolic microspheres Administration Kit and Refill Syringes are intended for embolic use only. Do not use for any other application.**

Clinical Studies

Easi-Vue embolic microspheres has yet to be studied in human trials.

MRI Safety

- Easi-Vue embolic microspheres are MR Safe.
- Easi-Vue embolic microspheres do not produce MRI image artifact.

Adverse Reactions

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 untargeted embolization or ischemic injury from adjacent tissue edema.
- Ischemic stroke or ischemic infarction.
- Neurological deficits including cranial nerve palsies.
- Undesirable reflux or passage of Easi-Vue™ embolic microspheres into normal arteries adjacent to the targeted lesion or through the lesion into other arteries or arterial beds, such as the internal carotid artery, pulmonary, or coronary circulations
- Pulmonary embolism due to arterial venous shunting.
- Ischemia at an undesirable location including ischemic stroke, ischemic infarction (including myocardial infarction), and tissue necrosis.
- Capillary bed occlusion and tissue damage.
- Vasospasm
- Recanalization
- Liver Abscess
- Foreign body reactions necessitating medical intervention.
- Infection necessitating medical intervention.
- Post-embolization syndrome
- Thrombosis
- Complications related to catheterization (e.g., hematoma at the site of entry, clot formation at the tip of the catheter and subsequent dislodgement, and nerve and/or circulatory injuries, which may result in leg injury).
- Allergic reaction to medications (e.g. analgesics).
- Allergic reaction to contrast media or embolic material.
- Death

- Blindness, hearing loss, loss of smell, and/or paralysis.
- Vessel or lesion rupture and hemorrhage.
- Radiation Injury related to excessive X-ray imaging including Fluoroscopy.

Storage And Sterility

Easi-Vue™ embolic microspheres Administration Kit and Refill Syringe must be stored in a cool, dry, and dark place in their original packaging at room temperature.

Do not use if package is opened or damaged.
Do not use if labeling is incomplete or illegible.
Do not freeze.
Do not re-sterilize.
Use by the date indicated on the outer box and pouch label.

Microcatheter Compatibility

Product Description	Minimum Catheter Inner Diameter
Easi-Vue (50 ± 20 μm)	0.021"
Easi-Vue (100 ± 35 μm)	0.021"
Easi-Vue (150 ± 50 μm)	0.021"

Instructions For Use

<u>Inspect packaging prior to use to ensure seal integrity for maintenance of sterility.</u>

- Carefully evaluate the vascular network associated with the lesion using high resolution imaging prior to beginning the embolization procedure.
- Both Easi-Vue™ embolic microspheres Administration Kits and Refill Syringes are available in 3 diameter size options. Because of the potential for non-target and the inherent variability in microsphere sizes, the physician should be sure to carefully select the size of Easi-Vue embolic microspheres according to the size of the target vessels at the desired level of occlusion in the vasculature.
- When embolizing arteriovenous malformations (AVM), choose an Easi-Vue embolic microsphere size that will occlude the nidus without passing through the AVM.
- Choose a delivery catheter based on the size of the target vessel and the microsphere size being used (refer to catheter I.D. compatibility chart).
- Introduce the delivery catheter into the target vessel according to standard techniques. Position the catheter tip as close as possible to the treatment site to avoid inadvertent occlusion of normal vessels.
- Easi-Vue embolic microspheres are radiopaque and can be monitored directly under x-ray fluoroscopy. It is recommended that the embolization be monitored using fluoroscopic visualization.

1.1 Components

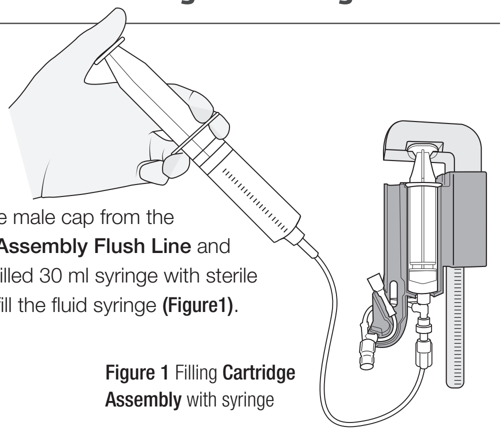
The arrangement of components required to use Easi-Vue™ embolic microspheres are outlined in in the following table:

Item No.	Description
1	Easi-Vue embolic microspheres Administration Kit contains: a) Control Handle b) Cartridge Assembly c) Microsphere Syringe
2	Easi-Vue embolic microspheres Refill Syringe contains: a) Microsphere Syringe b) Female Luer Cap c) Male Luer Cap

1.2 Components Assembly and Procedure Prep

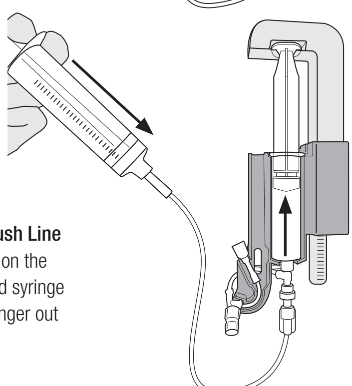
To assemble the Easi-Vue™ embolic microspheres components, and prepare for patient use, the steps below must be followed in order:

Preparation of Cartridge Assembly



1. Remove the male cap from the **Cartridge Assembly Flush Line** and connect a filled 30 ml syringe with sterile saline and fill the fluid syringe **(Figure1)**.

Figure 1 Filling **Cartridge Assembly** with syringe



Note: Alternatively submerge the **Flush Line** in a basin of sterile saline. Pull back on the syringe plunger support until the fluid syringe is filled. Take care not to pull the plunger out of the syringe barrel.

2. Remove the male cap from **Microsphere Syringe Connection Hub** and invert the filled **Cartridge Assembly** such that any air in the fluid syringe can exit the **Cartridge Assembly** via the open **Microsphere Syringe Connection Hub** when the fluid syringe plunger is pushed **(Figure 2)**.

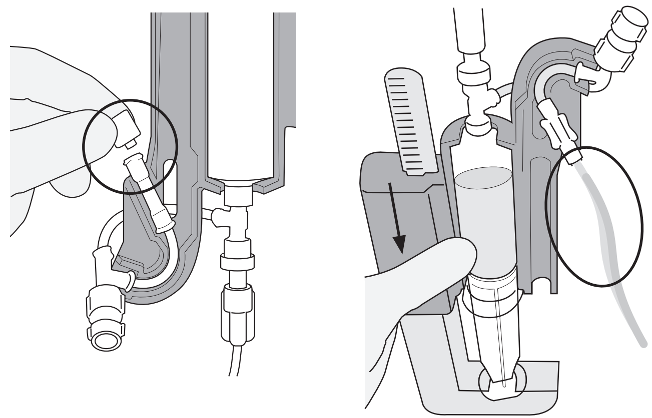
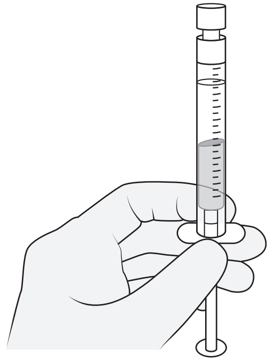


Figure 2 Priming Cartridge Assembly syringe

Attachment of Microsphere Syringe to Cartridge Assembly

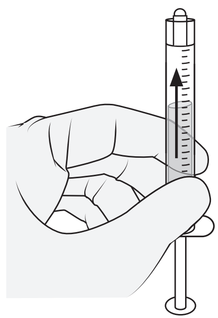
3. Holding the **Microsphere Syringe** vertically, inspect the level of saline within the syringe.
   To ensure all air is collected at the top of the syringe, slowly roll the capped **Microsphere Syringe** horizontally between your hands then quickly shake and/or tap the syringe barrel. Repeat these actions until all visible air within the syringe is collected at the top.



Microsphere Syringe after all air is collected at the top of the syringe

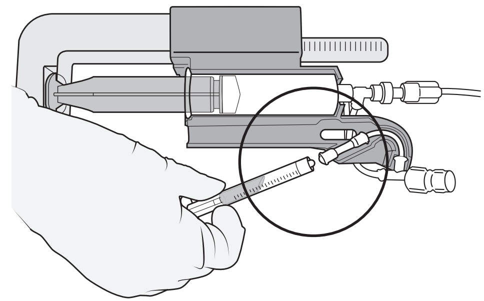
4. Remove the female cap from the **Microsphere Syringe** and purge the air by depressing the plunger.

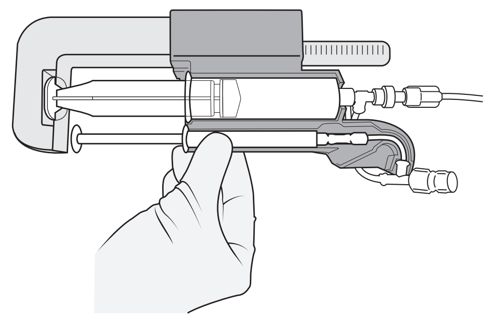
   a. **Note:** Do not remove excess saline from the Syringe. If the total amount of Saline and Microspheres is less than 0.8 ml as per the graduation marks on the syringe, refill the syringe with sterile saline from a basin to the 1 ml mark. This should be done quickly; microspheres can fall from the syringe into the basin if left inverted. Discard basin once this action is complete.



Microsphere Syringe is uncapped, and all air is removed by depressing the plunger

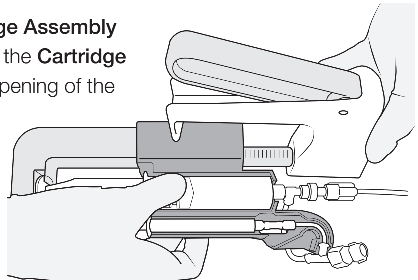
5. Make a wet-to-wet connection between the **Microsphere Syringe** and the filled **Cartridge Assembly**. Once the luer threads are engaged snap the **Microsphere Syringe** into the **Cartridge Assembly**.





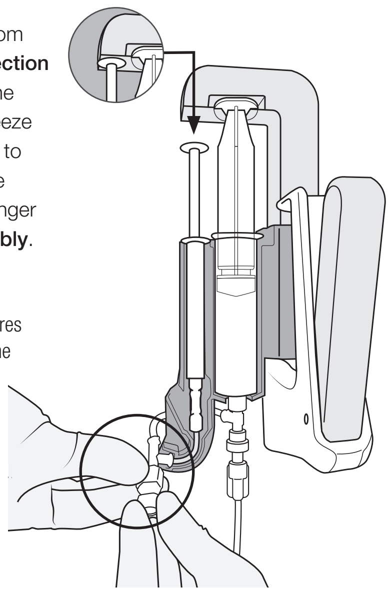
Assembly with Control Handle

6. Keeping the **Cartridge Assembly** flat (horizontal) insert the **Cartridge Assembly** into the opening of the **Control Handle**.

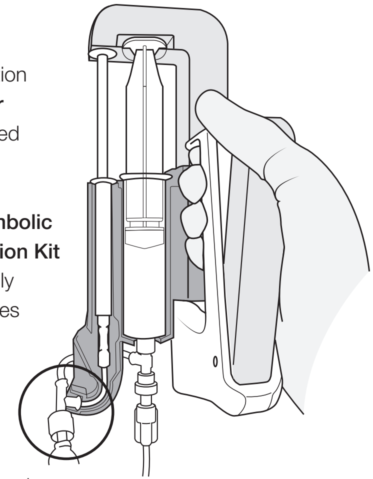


7. Remove the female cap from the **Microcatheter Connection Hub**. Before connecting the microcatheter, gently squeeze the **Control Handle** Lever to make contact between the **Microsphere Syringe** plunger and the **Cartridge Assembly**.

   Note: Before connecting the catheter, if excessive microspheres or air bubbles are apparent in the fluid lines of the device flush the system by connecting a filled syringe of sterile saline to the **Flush Line**.



Microsphere Delivery



8. Make a wet-to-wet connection between the **Microcatheter Connection Hub** and desired microcatheter.

9. Keeping the **Easi-Vue™ embolic microspheres Administration Kit** in an upright position, visually confirm that the microspheres are traveling down from the **Microsphere Syringe** into the attached tubing. Squeeze the lever of the **Control Handle** to deliver microspheres into the attached microcatheter. Under fluoroscopy observe tip of microcatheter and radiopaque microspheres as they deposit into the target area of vasculature. Continue until satisfied with visual aggregation of microspheres blocking the intended vessel. To administer any remaining microspheres in the microcatheter, flush a 20cc of saline by connecting a prefilled syringe to the **Flush Line**.

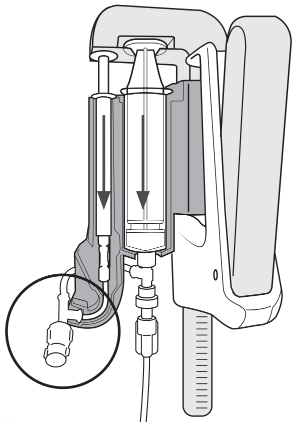
   a. **Note:** The **Control Handle** lever may be squeezed and released several times before all microspheres are delivered. Remaining microspheres can be visualized by viewing the **Microsphere Syringe** and attached tubing.

   b. **Note:** When the **Easi-Vue embolic microspheres Administration Kit** is not in use place on a flat surface.

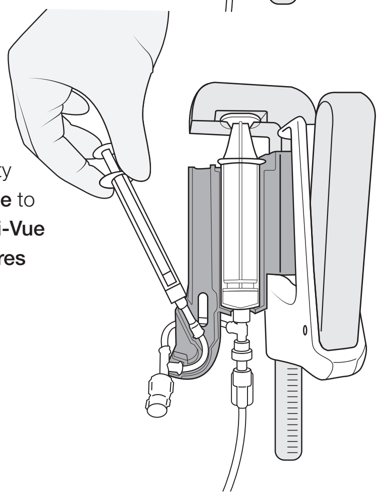
   c. **Note:** If desired to flush with contrast or saline, connect a prefilled syringe to the **Flush Line** of the **Cartridge Assembly** and depress prefilled syringe.

Use of Additional Easi-Vue™ Embolic Refill Syringe

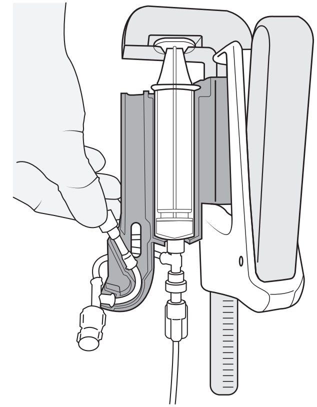
10. At the completion of delivery both syringe plungers will be completely depressed. If there is a clinical need to administer more microspheres remove the microcatheter and recap the **Microcatheter Connection Hub** with the female cap supplied in the **Easi-Vue embolic microspheres Refill Syringe** package.



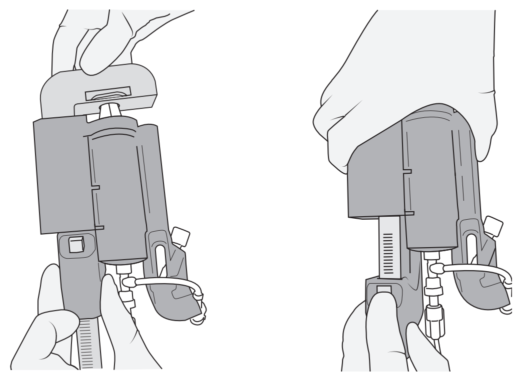
11. Re-position the empty **Microsphere Syringe** to detach from the **Easi-Vue embolic microspheres Administration Kit**.



12. Recap the **Microsphere Syringe Connection Hub** with the male cap supplied in the **Easi-Vue™ embolic microspheres Refill Syringe** package.



13. Remove the **Cartridge Assembly** from the **Control Handle** by pressing the release button located at the back of the **Control Handle**. While keeping the button pressed, pull the **Cartridge Assembly** out of the **Control Handle**. Repeat steps 1-7 above to complete the system set up.



Completion of Embolization

14. Upon completion of embolization at the target site, disconnect the delivery system from the catheter and dispose.

    - Arterial puncture can result in arterial spasm. This may predispose to arterial thrombosis (e.g. limb injury). Arterial patency should be re-assessed prior to final catheter removal.
    - Apply pressure to the puncture site until hemostasis is complete.
    - Discard any open, unused Easi-Vue™ embolic microspheres Refill Syringe.

Disposal

Used and partially used syringes, administration kits and microcatheters could be biohazardous and should be handled and disposed of in accordance with facility medical practices and local, state, or federal regulations.

Warranty

ABK Biomedical, Inc. warrants that reasonable care has been exercised in the design and manufacture of this product.

THIS WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES NOT EXPRESSLY SET FORTH HEREIN, WHETHER EXPRESSED OR IMPLIED BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ITS PARTICULAR PURPOSE.

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Information on Packaging

SYMBOL	DESIGNATION
	Legal Manufacturer
	Use by date: year-month-day
LOT	Batch Code
REF	Catalogue Number
	Do no resterilize
	Do not use if package is damaged
	Keep away from sunlight
	Keep dry
	Do not re-use
	Consult instruction for use
	Caution – Refer to Instructions for Use
	Non-Pyrogenic
Rx *ONLY*	Prescription Only
STERILE R	Sterilized using Gamma
MR	MR Safe

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ABK-REG-IFU-3 Rev 1

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