

INSTRUCTIONS FOR USE

DC Bead

Drug Delivery Embolisation System

STERILE • SINGLE USE ONLY • NON-PYROGENIC

DESCRIPTION:

DC Bead comprise a range of hydrogel microspheres that are biocompatible, hydrophilic, non resorbable, precisely calibrated and capable of loading doxorubicin. DC Bead is produced from polyvinyl alcohol and are available in the following size ranges:

Nominal Bead Size	Label Colour	<i>Upon loading with doxorubicin, DC Bead undergo a slight decrease in size, up to 20% when loading at 25mg/ml.</i>
100 – 300 µm	Yellow	
300 – 500 µm	Blue	
500 – 700 µm	Red	
700 – 900 µm	Green	

PRESENTATION:

- 10 ml glass vial.
- Each vial contains approximately 2 ml of DC Bead in non-pyrogenic, sterile, physiological buffered saline. Total volume of saline and DC Bead is approximately 8ml.
- The vial is stopper sealed by an aluminium cap equipped with a colour-coded lid.
- Each vial is intended for single patient use only. Do not resterilise. Discard any unused material.

INDICATIONS:

- DC Bead are intended to be loaded with doxorubicin for the purpose of:
- Embolisation of vessels supplying malignant hypervascularised tumour(s).
 - Delivery of a local, controlled, sustained dose of doxorubicin to the tumour(s).

CONTRAINDICATIONS – DC BEAD:

- Patients intolerant to vascular occlusion procedures.
- Vascular anatomy that precludes catheter placement or emboli injection.
- Presence or likely onset of vasospasm.
- Presence or likely onset of haemorrhage.
- Presence of severe atheromatous disease.
- Presence of feeding arteries smaller than distal branches from which they emerge.
- Presence of patent extra-to-intracranial anastomoses or shunts.
- Presence of collateral vessel pathways potentially endangering normal territories during embolisation.
- Presence of end arteries leading directly to cranial nerves.
- Presence of arteries supplying the lesion not large enough to accept DC Bead.
- Vascular resistance peripheral to the feeding arteries precluding passage of DC Bead into the lesion.
- Do not use DC Bead in the following applications:
 - i. Embolisation of non-malignant tumours.
 - ii. Embolisation of large diameter arteriovenous shunts (ie. where the blood does not pass through the arterial/capillary/venous transition but directly from artery to vein).

- iii. Any vasculature where DC Bead Embolic Agent could pass directly into the internal carotid artery or other non-target territories.

CONTRAINDICATIONS – DOXORUBICIN:

- See doxorubicin package insert for contraindications regarding use.

WARNING: Studies have shown that DC Bead do not form aggregates and, as a result, penetrate deeper into the vasculature as compared to similarly sized PVA particles.

CAUTIONS:

- Do not use if the vial or packaging appear damaged.
- Select the size and quantity of DC Bead appropriate for the pathology to be treated.
- Embolisation with DC Bead should only be performed by a physician with appropriate interventional occlusion training in the region intended to be embolised.
- **Exceeding a loading dose of 37.5mg doxorubicin per 1ml DC Bead may lead to some systemic distribution of doxorubicin and related side effects.**

POTENTIAL COMPLICATIONS:

- Undesirable reflux or passage of DC Bead into normal arteries adjacent to the targeted lesion or through the lesion into other arteries or arterial beds.
- Non-target embolisation.
- Pulmonary embolisation.
- Ischaemia at an undesirable location.
- Capillary bed saturation and tissue damage.
- Ischaemic stroke or ischaemic infarction.
- Vessel or lesion rupture and haemorrhage.
- Neurological deficits including cranial nerve palsies.
- Vasospasm.
- Death.
- Recanalisation.
- Foreign body reactions necessitating medical intervention.
- Infection necessitating medical intervention.
- Clot formation at the tip of the catheter and subsequent dislodgement.

DRUG LOADING INSTRUCTIONS:

DC Bead is suitable for loading doxorubicin-HCl ONLY. Liposomal formulations of doxorubicin are not suitable for loading into DC Bead.

To obtain a final loading of 50mg doxorubicin per 2ml vial of DC Bead:

- i. Reconstitute a vial containing 50mg of doxorubicin with 2ml of sterile water for injection. Mix well to obtain a clear red solution (25mg/ml).
- ii. Remove as much saline as possible from a vial of DC Bead using a syringe with a small gauge needle.
- iii. Using a syringe and needle add the 2ml of reconstituted doxorubicin solution directly to the vial of DC Bead.
- iv. Agitate the DC Bead/doxorubicin solution occasionally to encourage mixing until the DC Bead is red. Although the solution retains a red colour, the doxorubicin will be loaded.
- v. Loading will take a minimum of 20 minutes for the smallest size DC Bead and up to 120 minutes for the

largest size DC Bead.

- vi. Prior to use, transfer the DC Bead loaded with doxorubicin to a syringe and add an equal volume of non-ionic contrast media. Invert the syringe gently to obtain an even suspension of DC Bead.
- vii. A dose of up to 37.5mg doxorubicin per ml DC Bead can be loaded.
- viii. **The maximum recommended total dose of doxorubicin per procedure is 150mg.**

STORAGE OF DRUG LOADED DC BEAD:

- i. DC Bead loaded with doxorubicin may be stored for up to 24 hours in a fridge at 2-8°C in the presence or absence of non-ionic contrast media.








DELIVERY INSTRUCTIONS:

- Carefully evaluate the vascular network associated with the lesion using high resolution imaging prior to beginning the embolisation procedure.
- DC Bead are available in a range of sizes. Care should be taken to choose the appropriate size of DC Bead that best matches the pathology (ie. vascular target/vessel size) and provides the desired clinical outcome.
- Choose a delivery catheter based on the size of the target vessel. DC Bead can tolerate temporary compression of 20% to 30% in order to facilitate passage through the delivery catheter.
- 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.
- DC Bead are not radio-opaque. It is recommended to monitor the embolisation under fluoroscopic visualization by adding the desired amount of contrast medium to the suspension fluid.
 - i. Take care to ensure proper suspension of the DC Bead in the contrast medium to enhance distribution during injection.
 - ii. Draw the DC Bead into a syringe needle of a size greater than or equal to 19 gauge (1.07 mm).
 - iii. Slowly inject DC Bead into the delivery catheter under fluoroscopic visualization while observing the contrast flow rate. Exercise conservative judgment in determining the embolisation endpoint.
- Upon completion of the treatment, remove the catheter while maintaining gentle suction so as not to dislodge DC Bead still within the catheter lumen.
- Discard any unused DC Bead loaded with doxorubicin.

CONSERVATION AND STORAGE:

- Store unopened DC Bead in a cool, dry and dark place in its original packaging.
- Use by the date indicated on the vial label.
- Do not freeze.

PACKAGE LABEL:

REF	Catalogue number		Steam Sterilised		Protect from moisture
LOT	Batch number/Lot number		Use before/Expiry		Attention see instructions for use
	Do not reuse		Protect from light		Do not freeze