Loading of DC Bead™ *using* Doxorubicin SOLUTION *in syringe*

Loading and preparation of DC Bead™ must be carried out using strict aseptic technique under controlled conditions.

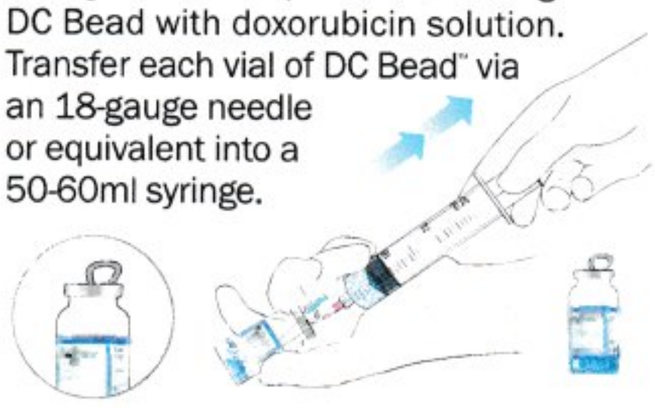
Loading times for up to 50mg or 75mg of doxorubicin per vial of DC Bead*

Doxorubicin Uptake	100-300µm up to 50mg per vial	100-300µm up to 75mg per vial	300-500µm up to 50mg per vial	300-500µm up to 75mg per vial	500-700µm up to 50mg per vial	500-700µm up to 75mg per vial
93%	3 hours	4 hours	7 hours	10 hours	8 hours	24 hours
98%	4 hours	5 hours	8 hours	14 hours	10 hours	30 hours
100%	5 hours	7 hours	9 hours	18 hours	11 hours	36 hours

* Tolerance of ±3%

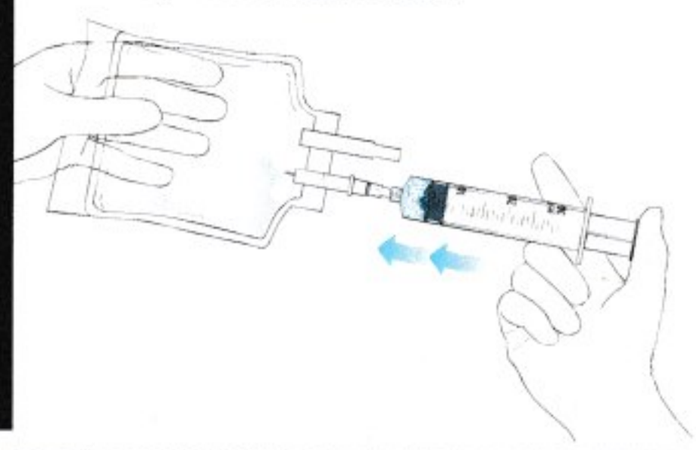
Step 1

Take flip cap off DC Bead™ vial(s) but do not remove metal around the bung. For doses >50mg, more than one syringe will be required for loading DC Bead with doxorubicin solution. Transfer each vial of DC Bead™ via an 18-gauge needle or equivalent into a 50-60ml syringe.



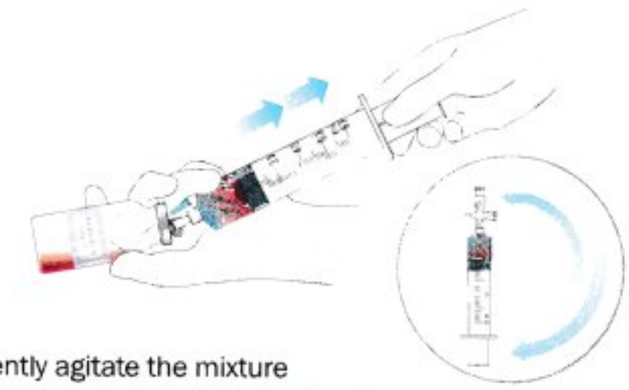
Step 2

Expel excess packing solution from the syringe. A 5-micron filter needle can help with this process.



Step 3

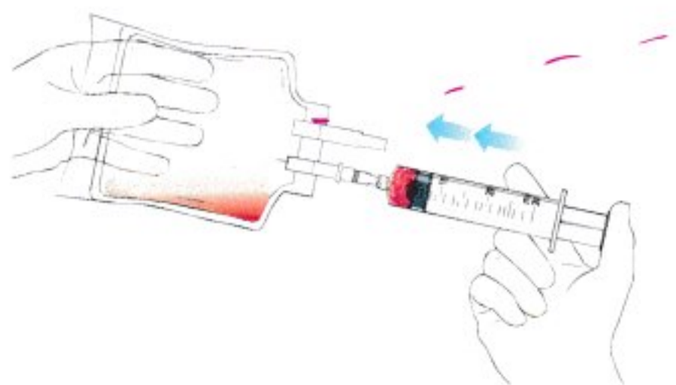
Draw up the required dose of doxorubicin into the syringe containing DC Bead™ before standing for required loading time.



Gently agitate the mixture occasionally during the loading time.

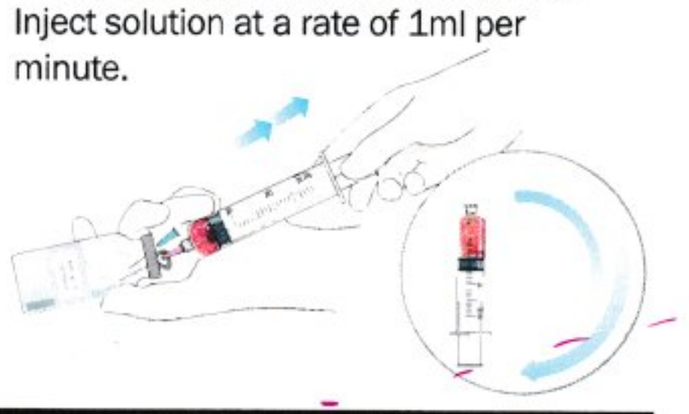
Step4

When loading time is complete, expel the excess liquid from the syringe. A 5-micron filter needle can help with this process.



Step 5

To prepare the loaded DC Bead™ for injection, add 5-10ml of non-ionic contrast medium per ml of DC Bead and mix gently to give a good suspension. Inject solution at a rate of 1ml per minute.



After loading, the solution in the syringe will retain some red colouration as shown. This is to be expected and is not an indication that the DC Bead™ has failed to load.

Biocompatibles
Excellence in Interventional Oncology

DC Bead™

To give required dose of doxorubicin	Number of doxorubicin 50mg solution vials (2mg per ml)	Number of vials of DC Bead
75mg	2	1
100mg	2	2
150mg	3	2

Physical and chemical stability
DC Bead 100-700µm

Doxorubicin-loaded DC Bead™ (75mg/2ml)	14 days (at 2-8°C)
Doxorubicin-loaded DC Bead™ with non-ionic contrast	7 days (at 2-8°C)

DC Bead™ Ordering Information

Nominal Bead Size	Volume of Beads	Product Code
100-300µm	2ml	DC2V103
300-500µm	2ml	DC2V305
500-700µm	2ml	DC2V507

DC Bead™: Important information
DC Bead™ Indications:

- DC Bead is CE marked and is indicated for the treatment of malignant hypervascular tumours and loading with doxorubicin drug
- DC Bead is also indicated for loading with irinotecan for the treatment of metastatic colorectal cancer (mCRC).

Both indications may not be available in your territory

DC Bead™ Cautions:

- 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
- Exceeding a loading dose of 50mg irinotecan per 1ml DC Bead may lead to some systemic distribution of irinotecan and related side effects
- On addition of contrast/water mixture to loaded beads some irinotecan will be eluted. On delivery a bolus of between 10-20mg irinotecan may be delivered
- Do not use irinotecan loaded beads with contrast agents containing salts (eg. Calcium chloride)

DC Bead™ Potential Complications:

1. 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
2. Non-target embolisation
3. Pulmonary embolisation
4. Ischemia at an undesirable location
5. Capillary bed saturation and tissue damage
6. Ischemic stroke or ischemic infarction
7. Vessel or lesion rupture and haemorrhage
8. Neurological deficits including cranial nerve palsies
9. Vasospasm
10. Death
11. Recanalisation
12. Foreign body reactions necessitating medical intervention
13. Infection necessitating medical intervention
14. Clot formation at the tip of the catheter and subsequent dislodgement causing arterial thromboembolic sequelae

For instructions for use, please refer to www.biocompatibles.com/dcbead-ifu

DC Bead™ is not currently cleared by the FDA for sale or distribution in the USA.

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