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Additional Information for Irinotecan Loading of DC Bead[®]

DESCRIPTION:

Upon loading with irinotecan, DC Bead undergo a slight decrease in size, up to 30% when loading at 50mg/ml.

INDICATIONS:

DC Bead are intended to be loaded with irinotecan for the purpose of:

- Embolisation of vessels supplying malignant colorectal cancer metastasised to the liver (mCRC)
- Delivery of a local, controlled, sustained dose of irinotecan to the mCRC.

CONTRAINDICATIONS – IRINOTECAN:

See irinotecan package insert for contraindications regarding use.

CAUTIONS:

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.

Exceeding a loading dose of 50mg irinotecan per 1ml DC Bead may lead to some systemic distribution of irinotecan and related side effects.

Do not use irinotecan loaded beads with contrast agents containing salts (eg. Calcium chloride)

DRUG LOADING INSTRUCTIONS:

DC Bead are suitable for loading irinotecan Solution (20mg/ml) ONLY.

To obtain a final loading of 100mg irinotecan per 2ml vial of DC Bead:

- Remove as much saline as possible from a vial of DC Bead using a syringe with a small gauge needle.
- Using a syringe and needle add the 5ml of irinotecan solution directly to the vial of DC Bead.
- Agitate the DC Bead / irinotecan solution gently to encourage mixing then allow to stand. The beads will turn a turquoise colour as the loading progresses.
- Loading will take a minimum of 2hrs for all sizes of DC Bead.
- Prior to use, transfer the DC Bead loaded with irinotecan 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.
- A dose of up to 50mg irinotecan per ml DC Bead can be loaded.
- The maximum recommended total dose of irinotecan per procedure is 200mg.

STORAGE OF DRUG LOADED DC BEAD:

DC Bead loaded with irinotecan may be stored for up to 24 hours in a fridge at 2-8°C or 4 hrs at room temperature in the presence or absence of non-ionic contrast media.

DELIVERY INSTRUCTIONS:

Discard any unused DC Bead loaded with irinotecan.