**DC Bead** Mode of Loading

Grafting point

Substituted polymer chain backbone

Hydration shell associated with PVA and ionic groups

Bulb (non-bead) water

Hydrated Beads

Loaded Beads

Doxorubicin interaction of doxorubicin with SO3 groups displaces water from the hydration shells

Loading DC Bead™ with doxorubicin:
Storage and stability update

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**Important Safety Information**

**All the indications:**

- DC Bead™ and DC Bead™ M1 are intended for the treatment of malignant hypervascular tumours.
- DC Bead™ and DC Bead™ M1 are also intended for the treatment of malignant hypervascular tumours after embolisation.
- DC Bead™ and DC Bead™ M1 are intended for use in transarterial chemoembolization.
- DC Bead™ and DC Bead™ M1 are intended for the treatment of malignant hypervascular tumours after embolisation.
- DC Bead™ and DC Bead™ M1 are also intended for the treatment of malignant hypervascular tumours after embolisation.
- DC Bead™ and DC Bead™ M1 are intended for use in transarterial chemoembolization.

**Reference:**


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**References:**

3. Biocompatibles UK Ltd data on file. SP2146
4. BTG International Ltd. BTG International group company. BTG and the BTG roundel logo are trademarks of BTG International Ltd and are registered trademarks in US, EU and certain other territories.

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**Bio compatibles UK**

**Excellence in Interventional Oncology**

**Bio compatibles UK Ltd is a BTG International group company**
The DC Bead™ instructions for use (IFU) have recently been updated to include a storage period of **14 days** for the doxorubicin-loaded product, as supported by internal and external studies. DC Bead™ loaded with doxorubicin may be stored for **up to 7 days** once mixed with non-ionic contrast medium.

<table>
<thead>
<tr>
<th>Physical and chemical stability of DC Bead and DC BeadM1</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Doxorubicin-loaded DC Bead and DC BeadM1 (75mg/2ml)</td>
<td><strong>14 days</strong> (at 2-8°C)</td>
</tr>
<tr>
<td>Doxorubicin-loaded DC Bead and DC BeadM1 with non-ionic contrast</td>
<td><strong>7 days</strong> (at 2-8°C)</td>
</tr>
</tbody>
</table>

**Loading and preparation of DC Bead and DC BeadM1 must be carried out using strict aseptic technique under controlled conditions.**

These storage times:

- Optimise efficiencies for the pharmacy when loading DC Bead™ with doxorubicin
- Minimise waste of unused syringes of loaded product – even after the addition of contrast
- Do not affect the drug release and delivery properties of the loaded DC Bead™
- Do not affect the chromatographic purity of the doxorubicin – no impact on drug properties

**Microbiological stability of DC Bead and DC BeadM1**

Rigorous microbiological studies demonstrate that DC Bead™ loaded with doxorubicin and stored for 14 days at 2-8°C does not sustain or promote growth of micro-organisms likely to be present in the hospital environment at time of loading.

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**Doxorubicin-loaded DC Bead™ are shown to have adequate physiochemical stability over a period of 14 days when stored in syringes or vials under refrigerated conditions for up to 14 days. The admixtures of doxorubicin loaded beads with contrast medium are stable for up to 7 days under refrigerated conditions.**


For electronic copies, please scan here or visit www.biocompatibles.com/ifustability

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**Statistically equivalent elution profile of DC Bead™ on day of loading with doxorubicin vs DC Bead™ loaded with doxorubicin and stored for 14 days at 2-8°C**

In-vitro Elution of Doxorubicin (nominal 75mg dose) from DC Bead™ (500-700µm)

Statistically equivalent elution profile of DC Bead™ on day of loading with doxorubicin vs DC Bead™ loaded with doxorubicin and stored for 14 days at 2-8°C

Doxorubicin-loaded DC Bead™ maintained their spherical shape throughout the release.

**DC Bead** Mode of Loading

**Label Colour and Size**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>DC Bead™</th>
<th>DC Bead</th>
<th>DC Bead M1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume of Beads</td>
<td>2ml</td>
<td>2ml</td>
<td>2ml</td>
</tr>
<tr>
<td>Product Code</td>
<td>DC2V001</td>
<td>DC2V003</td>
<td>DC2V005</td>
</tr>
</tbody>
</table>

**Important Safety Information**

- **DC Bead™ and DC Bead M1™** are not cleared by the FDA for sale or distribution in the USA. DC Bead and DC Bead M1™ are not cleared by the FDA for sale or distribution in the USA. DC Bead and DC Bead M1™ are manufactured by Biocompatibles UK Ltd.

**DC Bead and DC Bead M1™** are indicated for the treatment of malignant hypervascularised tumour(s) and colorectal cancer (mCRC) after embolisation.

**Loading DC Bead™ with doxorubicin:**

**Storage and stability update**

**DC Bead™ and DC Bead M1™** are indicated for the treatment of malignant hypervascularised tumour(s) and colorectal cancer (mCRC) after embolisation.

**References:**

4. BTG International group company

**Biocompatibles UK Ltd is a BTG International group company**