DESCRIPTION
DC Bead® and DC BeadM1™ comprise a range of hydrogel microspheres that are biocompatible, hydrophilic, non-resorbable, and precisely calibrated. They are CE Mark approved for loading with doxorubicin and irinotecan which is released in a controlled manner after embolisation. DC Bead® and DC BeadM1™ are produced from polyvinyl alcohol and are blue-tinted to aid with visualisation during preparation and loading.

INDICATIONS
DC Bead® is 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)

DC Bead® is also 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

DC BeadM1™ is primarily intended as an embolic agent to treat vessels supplying malignant colorectal cancer metastasised to the liver (mCRC) and malignant hypervascularised tumour(s).
• DC BeadM1™ is compatible with irinotecan, which can be loaded prior to embolisation and then, as a secondary action, elute a local, controlled and sustained dose to the mCRC after embolisation
• DC BeadM1™ is also compatible with doxorubicin, which can be loaded prior to embolisation and then, as a secondary action, elute a local, controlled and sustained dose to the tumour after embolisation

Notes: Both products and/or all indications may not be available in your territory. DC Bead® and DC BeadM1™ are not cleared by the FDA for sale or distribution in the USA. DC Bead® and DC BeadM1™ may be loaded with a drug product, to elute a local dose of drug to tumour sites after embolisation. It is the doctor’s responsibility to give due consideration to the details contained in the drug product marketing authorisation in deciding which drug to load DC Bead®/DC BeadM1™ with and whether loading with that drug is appropriate for the patient under his/her care. The relevant Summary of Product Characteristics (SmPC) must be consulted. The type and dose of drug should also be assessed according to the individual patient’s clinical circumstances.

DC Bead® and DC BeadM1™ are the only drug-eluting beads which have loading with doxorubicin and irinotecan within their CE-Marked indication statement.

PRESENTATION
• Single-unit pack
  - 10ml vial containing 2ml beads in physiological buffered saline solution (total volume approx 8ml)
  - Each vial stopper-sealed with an aluminium cap and colour-coded lid
• Four-year shelf-life from date of manufacture
• Steam sterilised

PRODUCT CODES

<table>
<thead>
<tr>
<th></th>
<th>DC BeadM1™</th>
<th>DC Bead®</th>
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</thead>
<tbody>
<tr>
<td>Size</td>
<td>70-150μm</td>
<td>100-300μm</td>
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<tr>
<td>Label Colour</td>
<td>Black and yellow</td>
<td>Yellow</td>
</tr>
<tr>
<td>Volume of Beads</td>
<td>2ml</td>
<td>2ml</td>
</tr>
<tr>
<td>BTG Product Code</td>
<td>DC2V001</td>
<td>DC2V103</td>
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</tbody>
</table>

Upon loading, DC Bead® and DC BeadM1™ undergo a decrease in size of 20-30% with a corresponding reduction in volume.
LOADING AND ELUTION OF DC BEAD® AND DC BEADM1™
Loading and elution are achieved through a reversible ionic exchange mechanism.

Upon loading, DC Bead® and DC BeadM1™ undergo a decrease in size of 20-30% with a corresponding reduction in volume.

STORAGE AND STABILITY OF LOADED DC BEAD® AND DC BEADM1™
- Once loaded with irinotecan or doxorubicin, DC Bead® and DC BeadM1™ may be stored for 14 days at 2-8°C
- Once loaded with doxorubicin and mixed with non-ionic contrast medium, DC Bead® and DC BeadM1™ may be stored for 7 days at 2-8°C
- Once loaded with irinotecan and mixed with non-ionic contrast medium, DC Bead® and DC BeadM1™ must be used immediately

BTG CUSTOMER SERVICES TEAM: customer.services@btgplc.com

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MANUFACTURE AND CERTIFICATION
DC Bead® and DC BeadM1™ is manufactured by Biocompatibles UK Ltd, a BTG International group company. CE Mark 0086, Steam sterilised, single-use, non-pyrogenic, latex-free.

DC BEAD® IS MANUFACTURED BY:
Biocompatibles UK Ltd,
a BTG International group company,
Chapman House, Farnham Business Park
Weydon Lane, Farnham
Surrey, GU9 8QL, UK

PATENTS
US 5,583,163
US 6,652,883
US 6,676,971
Other patents pending

EXPLANATION OF SYMBOLS ON DC BEAD® AND DC BEADM1™ PACKAGE LABELS

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

DC Bead and DC BeadM7 are trademarks of Biocompatibles UK Ltd.

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