LIFEPEARL® Microspheres

INSTRUCTIONS FOR DRUG LOADING

Epirubicin for Injection

In order to minimize the risk of microbial contamination, loading and preparation of LifePearl® Microspheres must be carried out using strict aseptic technique under controlled conditions.

Throughout the loading process, avoid introduction of air bubbles into the system and eliminate any that occur.

1 DRUG PREPARATION

Use a total of 50mg of Epirubicin for injection as received from the manufacturer. i.e. 25ml of 2mg/ml concentration.

2 SYRINGE PREPARATION

Transfer syringe contents to a 50-60ml syringe and stand the syringe vertically for approximately 10 minutes on the plunger to allow the microspheres to settle. Use a 5 micron filter needle to expel most of the packaging media (PBS), leaving 3ml total contents in the syringe.

NOTE: DO NOT compress the microspheres.

3 ASPIRATE DRUG INTO SYRINGE

Transfer 25ml (50mg) of Epirubicin for injection from the vial into the syringe using a transfer device or needle. Moderately agitate syringe until contents are homogeneous (approximately 1 minute).

4 LOAD DEVICE

Allow microspheres to load for the duration of the loading period. Refer to the table below for the required loading times. During the loading period, agitate the microspheres occasionally.

NOTE: When loaded with 25mg Epirubicin per ml of microspheres, LifePearl shrinks up to 20% of their original size.

### Physical & Chemical Stability of LIFEPEARL® Microspheres

<table>
<thead>
<tr>
<th>Epirubicin-loaded LIFEPEARL® Microspheres (50mg/2ml) in supernatant</th>
<th>Epirubicin-loaded LIFEPEARL® Microspheres mixed with non-ionic contrast and sterile water</th>
</tr>
</thead>
<tbody>
<tr>
<td>14 days (at 2-8°C)</td>
<td>7 days (at 2-8°C)</td>
</tr>
</tbody>
</table>

These loading times are achieved for LifePearl® Microspheres and Epirubicin when the syringe is gently agitated every 30 minutes until loading time is complete. The use of the LifePearl® device in combination with drugs is not cleared or approved in the U.S.A. by the Food and Drug Administration.
**ORDERING INFORMATION**

<table>
<thead>
<tr>
<th>LifePearl Microspheres Sizes (µm)</th>
<th>Volume of Microspheres (ml)</th>
<th>Volume of PBS (ml)</th>
<th>Product Codes</th>
<th>Colour</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 ± 25</td>
<td>2</td>
<td>4</td>
<td>BLP2S100</td>
<td>Black</td>
</tr>
<tr>
<td>200 ± 50</td>
<td>2</td>
<td>4</td>
<td>BLP2S200</td>
<td>Yellow</td>
</tr>
<tr>
<td>400 ± 50</td>
<td>2</td>
<td>4</td>
<td>BLP2S400</td>
<td>Blue</td>
</tr>
</tbody>
</table>

**INDICATIONS FOR USE:** LifePearl® Microspheres are indicated for embolization of blood vessels supplying primary-hypervascular tumors or metastases in the liver.

**NOTE:** LifePearl® Microspheres can be loaded with chemotherapeutic drugs. When used for drug loading, drug loading should be done under a physician’s direction, choice and responsibility, based on type and dose of drug most beneficial to the patient.

1. Please refer to IFU/loading instructions provided in LifePearl packaging when using the technical handout.