LIFEPEARL® Microspheres

INSTRUCTIONS FOR DRUG LOADING

Doxorubicin for Injection (Liquid)

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.

### Required Number of LIFEPEARL® Syringes

<table>
<thead>
<tr>
<th>Doxorubicin (mg)</th>
<th>No. of vials of Doxorubicin (200mg)</th>
<th>No. of LIFEPEARL® Syringes</th>
</tr>
</thead>
<tbody>
<tr>
<td>75mg</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>100mg</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>150mg</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

**DRUG PREPARATION**

Use a total of 75mg of Doxorubicin Liquid for Injection as received from the manufacturer. i.e. 37.5mL of 2mg/ml concentration.

**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.**

**ASPIRATE DRUG INTO SYRINGE**

Transfer 75mg of Doxorubicin Liquid for Injection from the vial into the syringe using a transfer device or needle. Moderately agitate syringe until contents are homogeneous (approximately 1 min.).

**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 37.5mg Doxorubicin per ml of microspheres, LifePearl shrinks up to 20% of their original size.**

### Loading Times Per Syringe of LIFEPEARL® Microspheres

<table>
<thead>
<tr>
<th>Doxorubicin Uptake (75mg/syringe)</th>
<th>100±25µm</th>
<th>200±50µm</th>
<th>400±50µm</th>
</tr>
</thead>
<tbody>
<tr>
<td>98%*</td>
<td>1hr</td>
<td>4hr</td>
<td>6hr</td>
</tr>
</tbody>
</table>

### Physical & Chemical Stability of LIFEPEARL® Microspheres

<table>
<thead>
<tr>
<th>Doxorubicin-loaded LIFEPEARL® Microspheres (75mg/2mL) in supernatant</th>
<th>14 days (at 2-8°C)</th>
<th>Doxorubicin-loaded LIFEPEARL® Microspheres mixed with non-ionic contrast and sterile water</th>
<th>7 days (at 2-8°C)</th>
</tr>
</thead>
</table>

These loading times are achieved for LifePearl® Microspheres and Doxorubicin 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.
**5 EXPEL SUPERNATANT**

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 the drug supernatant from the syringe.

*NĐ: DO NOT compress the microspheres. DO NOT store loaded microspheres dry- please use sterile water to store the microspheres, in an event, the supernatant is expelled.

*NĐ: After the required loading time, the solution in the syringe may retain some coloration. This is **NOT** an indication that the LifePearl® embolic has failed to load.

**6 ADD NON-IONIC CONTRAST & STERILE WATER SOLUTION**

To prepare the loaded syringe of embolic for injection, add a minimum of **20ml** of **50:50** non-ionic contrast and sterile water solution.

*NĐ: At this point, product may be stored under refrigerated conditions (2-8°C) for a maximum of 7 days prior to use.

**7 AGITATE AND SUSPEND PRIOR TO USE**

Use a **20ml** syringe and a **3-way stopcock** to expel all air and agitate contents between two syringes until homogeneous suspension is achieved (approximately **2-3 minutes**).

*NĐ: DO NOT introduce air into the system.

During the treatment procedure, the recommended solution delivery rate is **1ml** per minute.

**ORDERING INFORMATION**

<table>
<thead>
<tr>
<th>LifePearl Microspheres</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>Sizes (µm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<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>

*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.*

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

*NĐ: 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.