



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

| To give required dose of Doxorubicin | No. of vials of Doxorubicin (200mg) | No. of LIFEPEARL [®] Syringes |
|--------------------------------------|-------------------------------------|--|
| 75mg | 1 | 1 |
| 100mg | 1 | 2 |
| 150mg | 1 | 2 |

1 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



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 5micron 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 **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.**).



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



Loading Times Per Syringe of LIFEPEARL[®] Microspheres

Tolerance of $\pm 3\%^*$

| Doxorubicin Uptake (75mg/syringe) | 100 \pm 25 μ m | 200 \pm 50 μ m | 400 \pm 50 μ m |
|-----------------------------------|----------------------|----------------------|----------------------|
| 98%* | 1hr | 4hr | 6hr |

Physical & Chemical Stability of LIFEPEARL[®] Microspheres

| Doxorubicin-loaded LIFEPEARL [®] Microspheres (75mg/2ml) in supernatant | Doxorubicin-loaded LIFEPEARL [®] Microspheres mixed with non-ionic contrast and sterile water |
|--|--|
| 14 days (at 2-8^o C) | 7 days (at 2-8^o C) |

5 EXPEL SUPERNATANT

Stand the syringe vertically for approximately **10 minutes** on the plunger to allow the microspheres to settle.

Use a 5micron filter needle to expel the drug supernatant from the syringe.

NOTE: 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.

NOTE: 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.

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

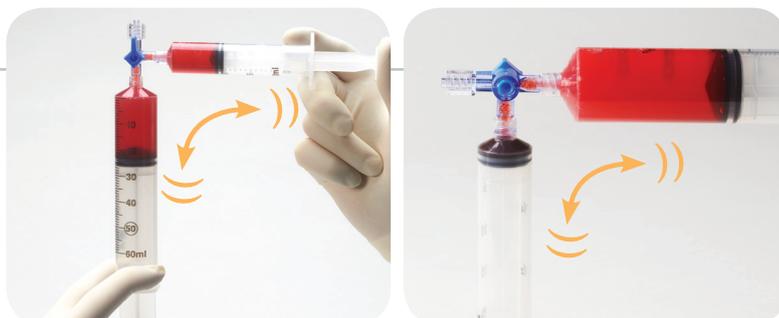


7 AGITATE AND SUSPEND PRIOR TO USE

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**).

NOTE: DO NOT introduce air into the system.

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



ORDERING INFORMATION

| LifePearl Microspheres Sizes (µm) | Volume of Microspheres (ml) | Volume of PBS (ml) | Product Codes | Colour |
|-----------------------------------|-----------------------------|--------------------|---------------|--|
| 100 ± 25 | 2 | 4 | 8LP2S100 | Black  |
| 200 ± 50 | 2 | 4 | 8LP2S200 | Yellow  |
| 400 ± 50 | 2 | 4 | 8LP2S400 | Blue  |

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. 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.

