



LIFEPEARL® Microspheres

INSTRUCTIONS FOR DRUG LOADING

Idarubicin 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 **10mg** of Idarubicin for Injection as received from the manufacturer.

i.e. 10ml of 1mg/ml concentration



2 SYRINGE PREPARATION

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 **10ml (10mg)** of Idarubicin for Injection from the vial into the syringe using a transfer device or needle.

Moderately agitate syringe until contents are homogeneous (approximately **1 minute**).



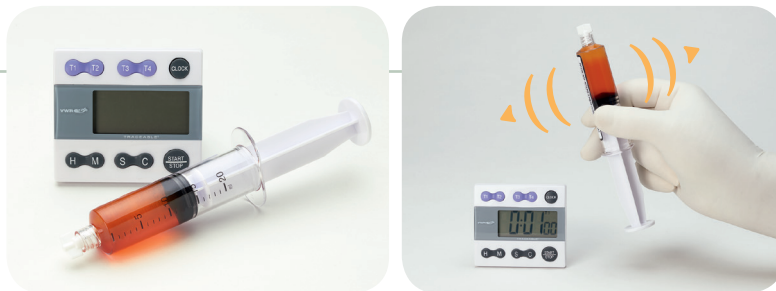
4 LOAD DEVICE

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 5mg Idarubicin per ml of microspheres, LifePearl shrinks up to 10% of their original size.



Loading Times Per Syringe of LIFEPEARL® Microspheres

Tolerance of $\pm 3\%^*$

10mg Idarubicin solution per 2ml of embolic	100 \pm 25 μ m	200 \pm 50 μ m	400 \pm 50 μ m
98%*	30 min	30 min	4hr

Physical & Chemical Stability of LIFEPEARL® Microspheres

Idarubicin-loaded LIFEPEARL® Microspheres (10mg/2ml) in supernatant

14 days (at 2-8° C)

Idarubicin-loaded LIFEPEARL® Microspheres mixed with non-ionic contrast and sterile water

7 days (at 2-8° C)

These loading times are achieved for LifePearl® Microspheres and Idarubicin 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.

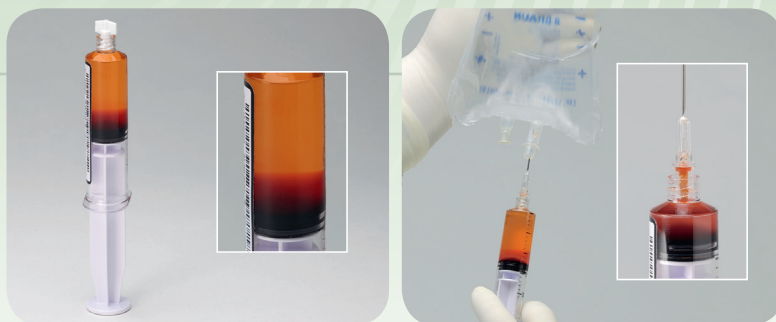
5 EXPEL SUPERNATANT

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

Use a 5micron filter needle to expel the drug supernatant leaving **3ml** total contents in 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, transfer all contents to a **50-60ml** syringe and 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.

