



# LIFEPEARL<sup>®</sup> Microspheres

## INSTRUCTIONS FOR DRUG LOADING

### Irinotecan for Injection

In order to minimize the risk of microbial contamination, loading and preparation of LifePearl<sup>®</sup> 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<sup>®</sup> Syringes

To give required dose of Irinotecan	No. of vials of Irinotecan Solution 100mg/5ml (20mg/ml)	No. of LIFEPEARL <sup>®</sup> Syringes
<b>100mg</b>	<b>1</b>	<b>1</b>
<b>200mg</b>	<b>2</b>	<b>2</b>

## 1 DRUG PREPARATION

Use a total of **100mg** of Irinotecan for Injection as received from the manufacturer.

i.e. 5ml of 20mg/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 **5ml** (100mg) of Irinotecan solution 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 50mg Irinotecan per ml of microspheres, LifePearl shrinks up to 15% of their original size.**

#### Loading Times Per Syringe of LIFEPEARL<sup>®</sup> Microspheres

Tolerance of  $\pm 3\%$ \*

Irinotecan Uptake (100mg/syringe)	100 $\pm$ 25 $\mu$ m	200 $\pm$ 50 $\mu$ m	400 $\pm$ 50 $\mu$ m
<b>98%*</b>	<b>30 min.</b>	<b>30 min.</b>	<b>30 min.</b>

#### Physical & Chemical Stability of LIFEPEARL<sup>®</sup> Microspheres

Irinotecan-loaded LIFEPEARL<sup>®</sup> Microspheres (100mg/2ml) in supernatant

**14 days (at 2-8° C)**

Irinotecan-loaded LIFEPEARL<sup>®</sup> Microspheres mixed with non-ionic contrast and sterile water

**USE IMMEDIATELY**

## 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, transfer all contents to a **50-60ml** syringe.

Add a minimum of **20ml** of **50:50** non-ionic contrast and sterile water solution.

**NOTE: At this point, product must be used immediately - DO NOT store for later 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.

