

Instructions for use

1

Prepare a vial of Nexsphere, two luer-lock syringes(20cc), an injection syringe(1cc or 3cc), a 3-way-stopcock, saline solution, contrast medium and a delivery catheter(microcatheter).

2

Take 10cc of saline solution using an empty 20cc of syringe(㉑), slowly inject the saline solution into a vial(㉒), and shake it to disperse and hydrate the Nexsphere in the vial(㉓).

※ Caution: To ensure proper hydration, add saline solution to the vial, shake it more than 1 minute, and wait few minute as the below table.

3

Transfer the hydrated Nexsphere to a 20cc syringe(㉔), and connect the syringe to a perpendicular valve of the 3-way-stopcock(㉕).

4

Take 10cc of contrast medium using an empty 20cc syringe, and purge all air from the syringe.

※ It is recommended to mix the product with a contrast medium for radiologic monitoring.

5

Connect the syringe containing the contrast to one port of the 3-way-stopcock where the syringe containing the Nexsphere mixture is connected.

6

Pump both of syringe's plunger back and forth slowly 3~4 times to dilute. Once the diluted mixture of Nexsphere is completely transferred into one of syringes, remove the other empty syringe.

7

Attach the injection syringe to the 3-way-stopcock and pump the plunger of the injection syringe back and forth several times to disperse the Nexsphere in solution.

8

Once suspension is confirmed, remove the injection syringe from 3-way-stopcock and connect the syringe to a delivery catheter. Inject the Nexsphere solution to the delivery catheter under fluoroscopic visualization using a slow pulsatile injection while observing the contrast flow rate.

Model	Hydration time
UIGB 100	30 sec.
UIGB 300	1 min.
UIGB 500	2 min.
UIGB 700	4 min.
Nexsphere-H	30 sec.

Product Specification

Ordering code	Size(μm)	Weight(mg)	Degradation Time	Applicable Catheter Size			
				Outside Diameter		Inside Diameter	
				Fr	mm	Inch	mm
UIGB 100	100-300	300	4 weeks	1.7	0.60	0.017	0.43
UIGB 300	300-500	300	4 weeks	1.7	0.60	0.017	0.43
UIGB 500	500-700	300	4 weeks	1.9	0.64	0.019	0.48
UIGB 700	700-900	300	4 weeks	2.8	0.93	0.027	0.70
Nexsphere-H	100-300	250	24 hours	1.7	0.60	0.017	0.43

This brochure was created to help medical professionals in countries other than Korea understand the product and cannot be used for advertising or sales promotion purposes in Korea.

6, Venture-ro 100beon-gil, Yeonsu-gu, Incheon, Republic of Korea, 22013
T. +82-32-454-4822, F. +82-32-454-4830,
E-mail. sales@nextbiomedical.co.kr



Global Company of Innovative Medical Devices for Clinical Unmet Needs
www.nextbiomedical.co.kr

Nexsphere™

Resorbable Embolic Microsphere



Resorbable Microspheres.
Tailored Embolization.

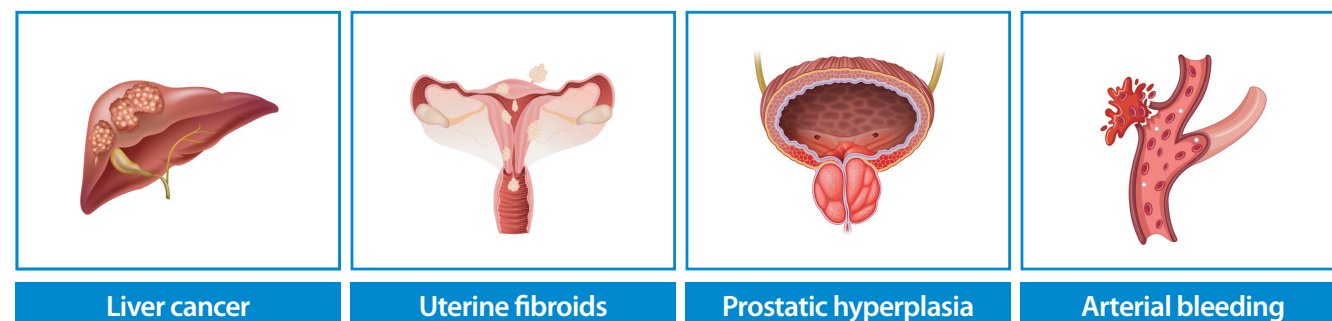
Nexsphere™

Resorbable Embolic Microsphere

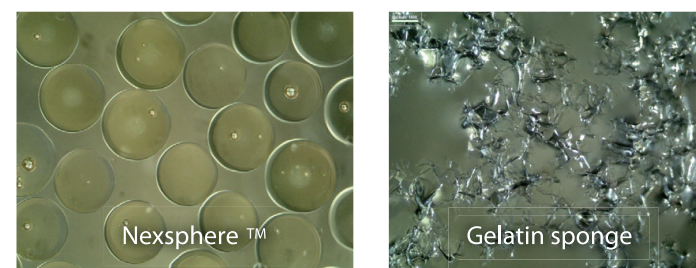
Nexsphere™ is a gelatin based hydrophilic material for endovascular embolization that is used together with a contrasting agent during vascular embolization for therapeutic and treatment purposes. It is injected into the blood vessel through a microcatheter in order to occlude the blood vessel. Nexsphere™ is a resorbable microsphere that exhibits embolic performance in a variety of indications with uniform spherical particles, high elasticity and strong cohesion.



Indication

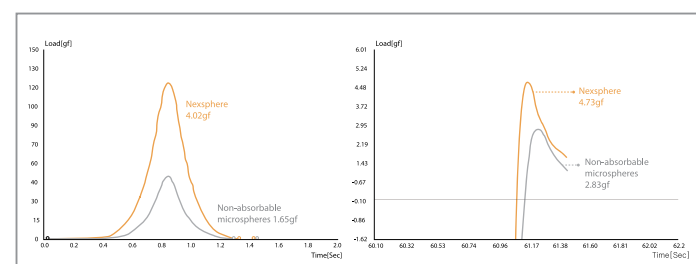


Features



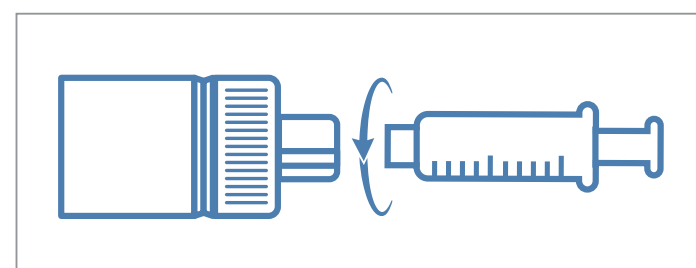
Resorbable microspheres

High performance gelatin microsphere for various embolization.



Optimal performance

High elasticity and strong cohesion¹⁾



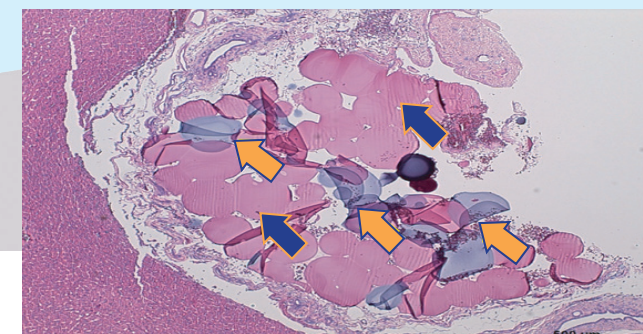
Patented vial design

Vial designed for contamination prevention (Korean design patent No : 3009879200000)

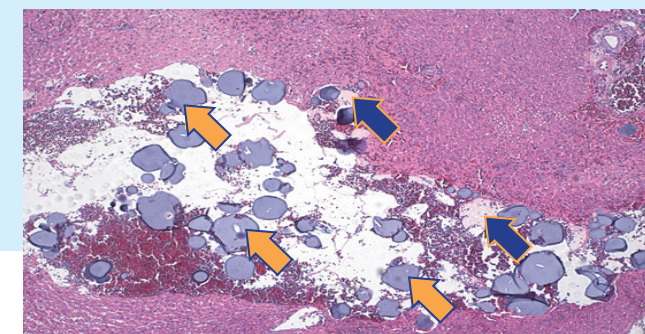
Tailored to various indications

Resorbable within 24 hours, applicable to various indications²⁾ (Nexsphere-H)

Histology of Rat Liver³⁾



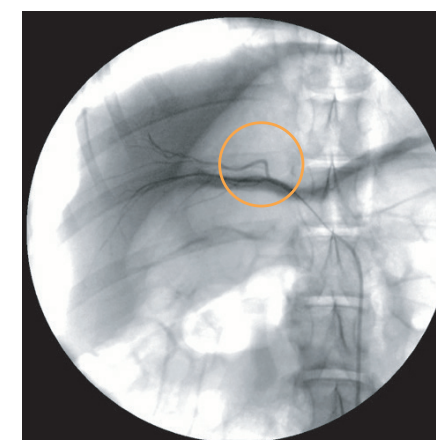
Embolization



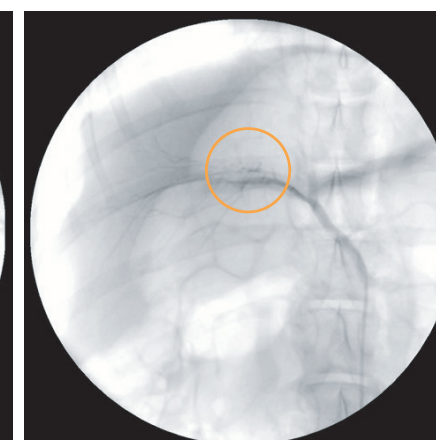
Few hours after embolization

← Non-Resorbable product ← Resorbable product

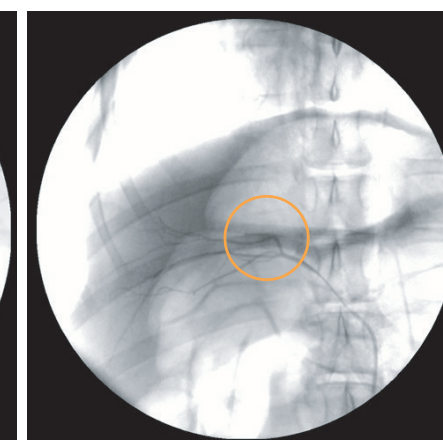
Angiography of Porcine Kidney³⁾



Pre-embolization



Embolization

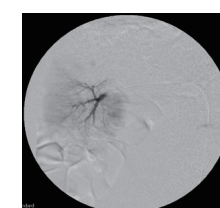


Recanalization few hours after embolization

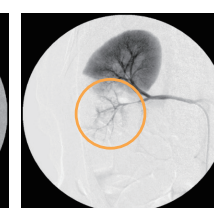
Preclinical study

Porcine Kidney Embolization³⁾

Angiography



Before embolization



1 week after embolization

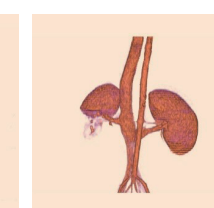


4 weeks after embolization

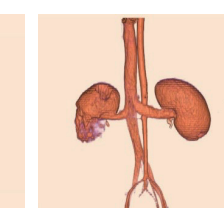
CT scan



Before embolization



1 week after embolization



4 weeks after embolization

- 1) In-house elasticity and cohesion tests were performed on monolayers of microspheres with a texture analyzer.
- 2) In-house in-vitro degradation test showed that Nexsphere-H was degraded in 37°C of warm saline within 24 hours.
- 3) Animal studies were conducted by external non-clinical CRO in Korea. Animal study results may or may not be indicative of clinical outcomes in humans.