



HydroPearl[®]

Compressible microspheres for embolization

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HydroPearl®

Compressible microspheres for embolization

A unique microsphere formulation exclusively developed to offer a controlled and targeted embolization.



HydroPearl® microspheres are intended to occlude blood vessels for therapeutic purposes in¹:

- Benign prostatic hyperplasia. (Prostatic Artery Embolization, PAE)
- Uterine fibroids (Uterine Fibroid Embolization, UFE)
- Bleeding and trauma and pre-operative reduction of bleeding
- Hepatocellular carcinoma
- Hypervascularised tumors
- Peripheral arteriovenous malformations
- Tumours of the neck, torso and skeletal system

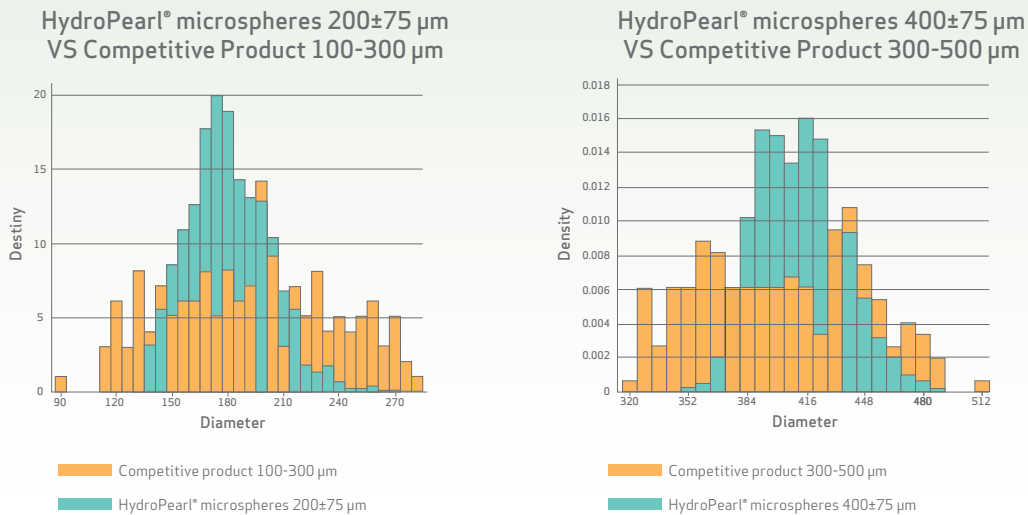
UNIQUE FORMULATION

HydroPearl microspheres based on polyethylene glycol (PEG) have **excellent suspension and compressibility features.**

1- Hydropearl IFU. Rev.A. Revised 2015-04

TIGHT CALIBRATION

HydroPearl® microspheres are available in a range of sizes from 75-1100 µm with a tighter size distribution* compared to other type of microspheres on the market. This precise calibration may allow: more **predictable and targeted embolization****^{2,3}.



* 90% or higher of HydroPearl® microspheres sizes are within specification as indicated on the labels.

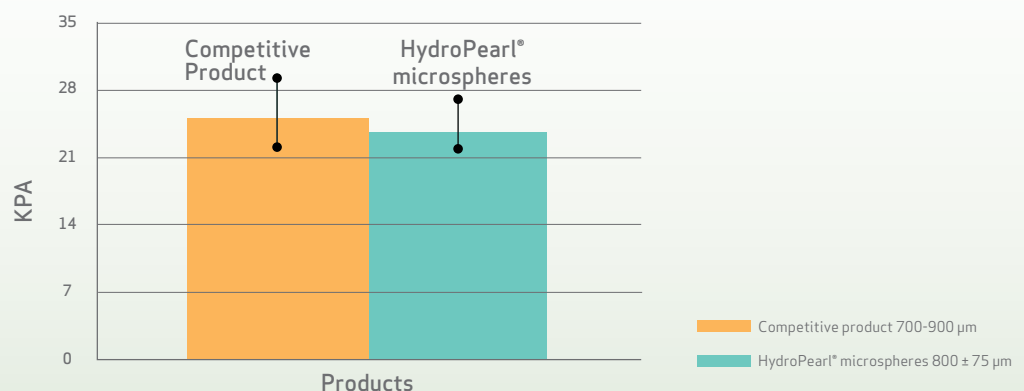
** Calibration data is 6 lots per each size of randomly selected HydroPearl® microspheres with 1 lot of competitive products. Sampling done at minimum 150 microspheres per syringe. Data on file: Comparison report TR14-296

COMPRESSIBILITY³

The HydroPearl® microspheres have shown to be **soft** while keeping its spherical shape and therefore allowing microspheres to be temporarily deformed to facilitate your procedure³:

Compressibility studies

Young's Moduls: 800±75 µm Size Range



Data on file: Comparison report TR14-296

2- Karolin J. Paprottka et. al In-vitro-study of physical properties of various embolization particles regarding morphology before, during and after catheter passage. Clinical Hemorheology and Microcirculation. 1386-0291/16

3- Data on file: Comparison report TR14-296

SUSPENSION FEATURES³

- The HydroPearl® microspheres have excellent **suspension features** when adding non-ionic contrast medium.
- The quantity of contrast medium needed depends on its concentration and also the size of HydroPearl® microspheres being used.

Size	Average Time to Suspension*	Average Time in Suspension*
75 ± 30 µm	0 - 1 minutes	>10 minutes
200 ± 75 µm	0 - 1 minutes	>10 minutes
400 ± 75 µm	3 - 4 minutes	2 - 4 minutes
600 ± 75 µm	3 - 4 minutes	2 - 4 minutes
800 ± 75 µm	4 - 5 minutes	1 - 2 minutes
1100 ± 75 µm	5 - 6 minutes	<1 min

* For all the sizes the testing was done using Omnipaque 300mg/ml
Data on file: Comparison report TR14-296

PRODUCT SPECIFICATIONS AND SIZES

- HydroPearl® microspheres are stored in a sterile 20cc pre-filled syringe
- Packaged in a pre-formed tray with Tyvek peel-away lid
- Each syringe contains approx. 2 ml of HydroPearl® microspheres in 4 ml of non-pyrogenic, sterile physiological buffered saline (PBS).
- HydroPearl® microspheres are available in 6 distinct sizes
- Microspheres are color-coded according to their sizes
- 3-years of shelf-life time starting from the manufacturing date

3- Data on file: Comparison report TR14-296

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ORDERING INFORMATION

HydroPearl® microspheres sizes (µm)	Volume of Microspheres (ml)	Volume of PBS (ml)	Product Codes	Colour
75 ± 30 µm	2	4	8HP2S75	Orange 
200 ± 75 µm	2	4	8HP2S200	Yellow 
400 ± 75 µm	2	4	8HP2S400	Blue 
600 ± 75 µm	2	4	8HP2S600	Red 
800 ± 75 µm	2	4	8HP2S800	Green 
1100 ± 75 µm	2	4	8HP2S1100	Purple 

Presentation: 2 ml in Syringe | Core Material: Poly-ethylene Glycol (PEG) | Storage Media: Phosphate Buffered Saline | Catheter Compatibility Large: Ø 0.035"

HydroPearl® microspheres are intended to occlude blood vessels for the Therapeutic and adjunctive Purposes. For complete list of indications, please refer to the instructions for use provided with the product.

HydroPearl® microspheres are not commercially available in all countries. Please contact your Terumo local sales representative for more information.

HydroPearl® microspheres is approved for U.S. sales.



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