



HydroPearl[®]

Compressible microspheres for embolization

BECAUSE
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Not all products are available for sale in all countries. This information is provided only in respect to markets where these products are approved or cleared. All products are not cleared or approved in the U.S.A. by the Food and Drug Administration. Please contact your Terumo local sales representative for more information.

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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

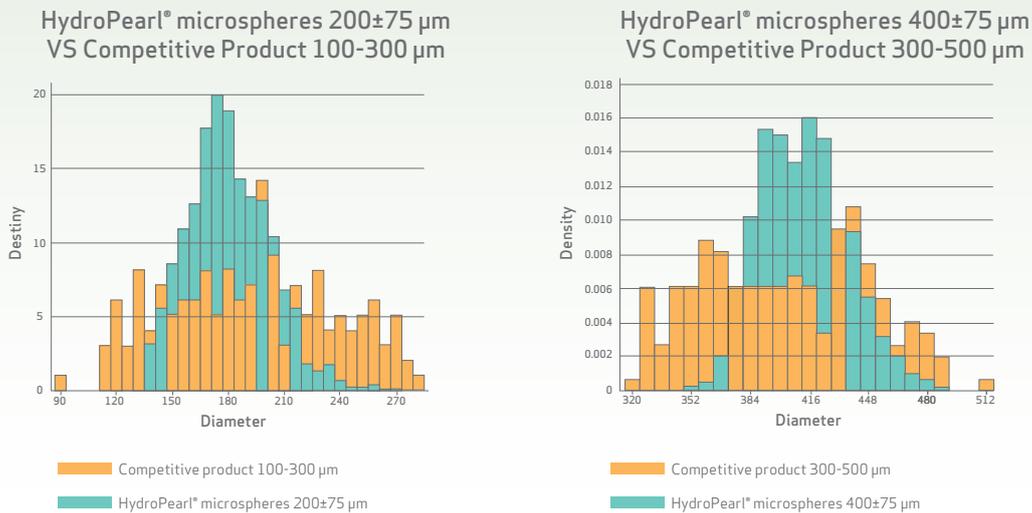
UNIQUE FORMULATION

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.



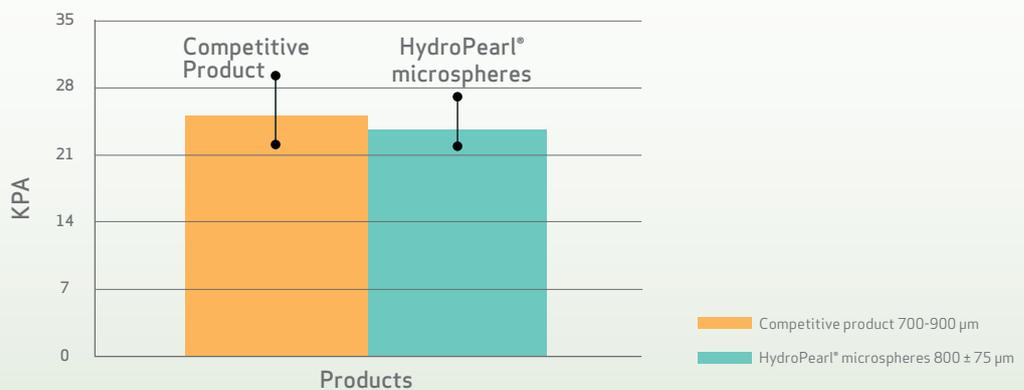
* 90% or higher of HydroPearl® microspheres sizes are within specification as indicated on the labels.
 ** Calibration data is 6 lots per each size of randomly selected HydroPearl® microspheres with 1 lot of competitive products. Sampling done at minimum 150 microspheres per syringe. Data on file: Comparison 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

HydroPearl®

Compressible microspheres for embolization

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.



Terumo Corporation
+81333748111

Terumo Europe NV
+3216381211

**Terumo
Interventional Systems EMEA**
+33147160930

EMEA Sales Offices

**Terumo Europe NV
Africa Business Division**
+3216381308

**Terumo Europe NV
BeNeLux Sales Division**
Belgium:
0800 14468
The Netherlands:
0800 0220396

**Terumo Europe NV
Emerging Market Division**
+3216381211

Terumo Deutschland GmbH
+49 6196 80 230

**Terumo Deutschland GmbH
Österreich**
+43 2236 378020

**Terumo Deutschland GmbH
Switzerland**
+41 56 419 10 10

Terumo Europe España SL
+34 902 10 12 98

Terumo France S.A.S.
+33 130 96 13 00

Terumo Italia S.r.l.
+39 06 94 80 28 00

Terumo Russia LLC
+7 495 988 4740

Terumo Sweden AB
+46 3174 85 880

Terumo Middle East FZE
+971 4 292 0200

Terumo UK Ltd
+44 1276 480 440

**Terumo BCT Tıbbi Cihazlar Dağıtım
ve Hizmetleri A.Ş.**
+90 216 645 92 00



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