



浩微生物
Hiwemed



FDA
K231554



Unipearls® Drug-Eluting
Microspheres



PRODUCT ADVANTAGES

UNIFORM PARTICLE SIZE

- ✓ Precise drug delivery and vascular embolization for different clinical scenarios, such as embolization of hypervascularized tumors including hepatoma, and peripheral arteriovenous malformations.
- ✓ Precise calibrated microspheres (CV controlled within 5%-10%) as small as 70 μ m show greater distal penetration and more effective embolization than larger microspheres without influencing patient safety [1,2].
- ✓ Study demonstrated that smaller size beads doxorubicin DEBs are superior to larger ones in terms of achieving a tumor response and have shown their therapeutic efficacy as a bridge to liver transplantation [3,4].
- ✓ The use of smaller bead sizes may result in improved tumor penetration resulting in more durable treatment response [5] have further shown the use of 40 μ m beads to be safe [6], even with concurrent systemic chemotherapy.

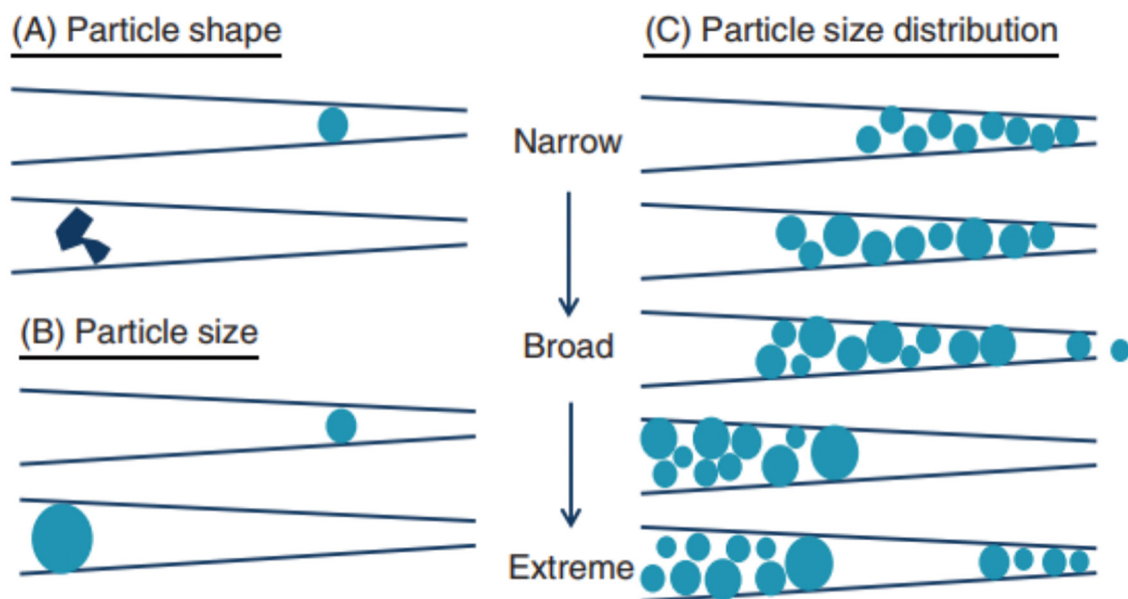
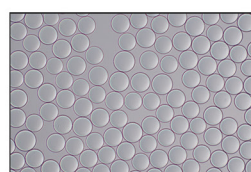


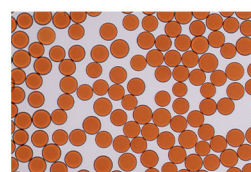
Fig 1 [1] more homogeneous distribution in the targeted tissue

FAST DRUG LOADING

- ✓ Load a series of drugs: doxorubicin, epirubicin, pirarubicin, Irinotecan, Bleomycin, FOLFOX, Triptorelin, etc;
- ✓ Efficient drug loading throughout the microsphere, load >95% Doxorubicin or Irinotecan <15 minutes.

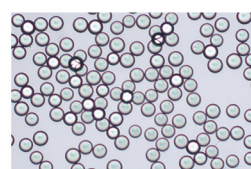
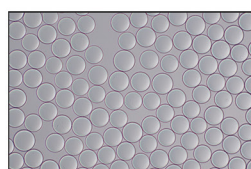


Before loading



After loading

Doxorubicin



Irinotecan

EFFICIENT & EFFICACY

- ✓ Ready-for-use, no need to reconstitution.
- ✓ Excellent effect of embolization.
- ✓ DEB-TACE is effective and safe for the treatment of HCC, and interventions with small-caliber DEBs (<100 µm) is recommended. TACE treatment with small-caliber DEBs (<100 µm) is indicated for super-selective embolization of feeding arteries in order to prevent major complications [7].
- ✓ DEB-TACE is associated with a better objective response, disease control, and lower all-cause mortality with severe complications compared to C-TACE treatment [8].
- ✓ Small particle DEBIRI using 40 and 75 µm drug-eluting beads is safe and provides survival benefits comparable to larger bead sizes [9].
- ✓ This recent meta-analysis shows that DEB-TACE provides significantly better tumor response compared with conventional TACE. One-year and 2-year survival are better with DEB-TACE. In addition, DEB-TACE is as safe as conventional TACE [10].
- ✓ The meta-analysis using a fixed-effects model showed significantly better objective tumor response rate for DEB-TACE compared with conventional TACE (OR = 1.92, 95% CI [1.34, 2.77]; P = 0.0004), with a relative risk difference of 0.15 [0.07, 0.24] (P = 0.0003) [10].

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COMPANY INTRODUCTION

Suzhou Haowei Medical Technology Co., Ltd specializes in the technological innovation of "Drug-Device Combined Product" technique, aiming to help TACE treatment fulfil clinical unmet needs through continuous research and development and innovation. A series of innovative products such as drug-eluting microspheres, resorbable microspheres, radioactive microspheres, balloon occluded microcatheters and steerable microcatheters developed by the company have gradually entered the stage of commercialization.

ORDERING INFORMATION

SN	Model	Sphere Size (μm)	Volume (ml)	Catheter I.D. (mm)	Spheres Color
	/Specification		(V _{spheres} : V _{0.9% physiological saline})		
1	B070V107	70	1:07	≥0.43	Blue
2	B070V206		2:06		
3	B100V107	100	1:07		
4	B100V206		2:06		
5	B250V107	250	1:07		
6	B250V206		2:06		
7	B400V107	400	1:07	≥0.65	
8	B400V206		2:06		
9	B500V107	500	1:07		
10	B500V206		2:06		
11	B700V107	700	1:07	≥1.05	
12	B700V206		2:06		
13	B1000V107	1000	1:07		
14	B1000V206		2:06		
15	C070V107	70	1:07	≥0.43	Colorless
16	C070V206		2:06		
17	C100V107	100	1:07		
18	C100V206		2:06		
19	C250V107	250	1:07		
20	C250V206		2:06		
21	C400V107	400	1:07	≥0.65	
22	C400V206		2:06		
23	C500V107	500	1:07		
24	C500V206		2:06		
25	C700V107	700	1:07	≥1.05	
26	C700V206		2:06		
27	C1000V107	1000	1:07		
28	C1000V206		2:06		

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