MicroVention®
TERUMO

January 18, 2019

URGENT: Field Safety Notice

HydroPearl® microspheres

Catalogue number: 8HP2S600
Lot number: 17030434

Hospital Name and Address
Attention to: name if available

Dear Device customer,

The purpose of this letter is to inform you that MicroVention Europe is voluntarily conducting a field action on one (1) lot of HydroPearl® microspheres because of conflicting information on the labeling.

The complaint device and the box's labelling indicated a 600 +/- 75 µm microsphere product. The complaint device peel pack's labelling indicated an 800 +/- 75 µm microsphere product.

The recall is limited to one (1) lot # 17030434 of HydroPearl® microspheres. No other MicroVention products are affected by this field action.

MicroVention is in the process of investigating the cause of this issue. As of now, we have received one (1) customer complaint associated with this issue. No patient injuries have been reported.

HydroPearl® microspheres are intended to occlude blood vessels for therapeutic or adjunctive purposes in hypervascularized tumors, hepatocellular carcinoma, uterine fibroids, benign prostatic hyperplasia, peripheral arteriovenous malformations, tumors of the neck, torso and skeletal system, bleeding and trauma and pre-operative reduction of bleeding.

Risk to Health

Product migration due to misinterpretation of product microsphere size prior to administration may result in an off-target embolization and tissue infarction that could result in potentially life-threatening patient injury.

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Actions to be taken by the Customer/User

- Immediately discontinue use of HydroPearl® microspheres from lot # 17030434
- Identify and quarantine all devices in your possession – immediately upon receiving this Urgent Field Safety Notice.
- Immediately return the completed "Customer Acknowledgment and Device Reconciliation" form attached to this Urgent Field Safety Notice via email. This information is essential to ensure effectiveness of the corrective action.
- Return all devices from this lot in your possession to Terumo Europe within 2 weeks of receipt of this Urgent Field Safety Notice and include a copy of the completed "Customer Acknowledgment and Device Reconciliation" form with the returned devices. This information is essential to ensure effectiveness of the corrective action.
- Notify customers of this field action to whom you may have further distributed or transferred this product. This field action should be conducted to the medical facility/user level.
- If a device from this lot was used and there was a suspected adverse event associated with the device, report the issue to the distributor using the form and the included contact information.
- Continue to report to the manufacturer any adverse events or quality problems in accordance with normal procedures.

Please send all "Customer Acknowledgment and Device Reconciliation" forms and direct questions to the contact detailed on this form

We appreciate your understanding as we act to ensure patient safety and customer satisfaction.

Sincerely,

I. Kulinets

Irina Kulinets, PhD, RAC
Sr Vice President of Regulatory Affairs, Clinical Research and Quality
MicroVention Inc.

Enclosed

- Customer Acknowledgment and Device Reconciliation form