

Voluntary Recall

Radifocus Introducer II™, Radifocus Introducer II Mcoat™ and Glidesheath Slender™

May, 2017

To: valued customer,

cc: Chairman Medical Board and relevant Head of Departments,

Terumo Corporation (headquartered in Japan) is conducting a global, voluntary recall of select lots of **Radifocus Introducer II™, Radifocus Introducer II M coat™ and Glidesheath Slender™**, which are used to support transradial intervention procedures.

The reason for the recall is a potential loss of package integrity that may compromise the sterility of the product. This issue was identified by Terumo during a routine inspection when an incomplete seal in the kit's peel pouch was observed.

There have been no customer complaints or reported patient injuries associated to this issue. The potential defect rate is estimated to be less than 0.02%. The potential for patient harm is also low given the nature of the defect and impact on product performance.

We are committed to patient health and safety in all that we do and have elected to take this voluntary recall (field removal).

■ Product name

- Radifocus Introducer II™
- Radifocus Introducer II M coat™
- Glidesheath Slender™

■ Affected products

Lot Numbers: Please refer to the attached document.

■ Risk to Patient Health

We cannot completely rule out any possibility of a health hazard related to this problem. However, the occurrence rate is 0.02%, which is very low. We are recalling the product because we have identified a potential loss of packaging integrity that could compromise sterility. As stated earlier, we are not aware of any customer complaints nor reported patient injuries related to this issue.

The end of the report

List of Product identifiers affected

RM*AF4J16SQW	161109
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