



■ VascoMed GmbH · Hertzallee 1 · D-79589 Binzen, Germany

To
our TC-115-Balloon Customers

Binzen, November 2018

Field Safety Notice TC-115-Balloon (catalogue number 356318)

Dear Customer,

We hereby inform you about a voluntary Field Safety Corrective Action concerning a limited amount of the TC-115-Balloon. Our records show that you are using "TC-115-Balloon" catheters for temporary pacing and electrophysiology. We kindly ask you for your support for the following field safety action.

Reason for this field safety action is a potentially incorrect labeling of the outer boxes of the product "TC-115-Balloon". The use before date (UBD) labeled on the outer box shows a one year later UBD than the UBD of the correctly labeled sterile pouch of the individual catheters inside the box. Apart from this labeling issue of the outer box the catheters are 100% tested and are in full compliance with the specifications.

No harm to a patient has been reported and is not expected to occur. However, there is a chance that catheters in your possession cannot be used due to an elapsed UBD.

Therefore, we recommend the following actions to complete the Field Safety Corrective Action:

1. LOT number verification:

- Check if TC-115-Balloons in your possession are affected according to the enclosed LOT number list.

2. For any affected open boxes and sterile pouches in your possession:

- Discard the outer box, if still existent.
- Check the sterile pouch of the individual catheters for a valid UBD.
- Check if the UBD recorded in your local hospital management system matches the correct UBD of the sterile pouches.
- Store sterile pouches with valid UBD together with the IFU in a container.

Remark: For storage please always follow the storage conditions (see Instructions for Use).

3. For any affected closed boxes in your possession:

- Return these boxes via your local sales representative
- If the return of the boxes is not desired (for example due to logistical reasons), open all boxes and follow the instructions under item 2.



VascoMed

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4. Acknowledgement:

- Acknowledge the receipt of this letter and the closure of the action using the attached acknowledgement form and return it to your sales representative without undue delay.

Your local sales representative will support you to identify affected catheters and in case of any questions.

The applicable National Competent Authorities have been advised of this Field Safety Notice.

May we take this opportunity to apologize for any inconvenience caused by this issue and thank you for all your support.

Yours sincerely,

VascoMed GmbH

Dr. Wolfgang Geistert
Managing Director
Medical Device Safety Officer

Acknowledgement Form

For Field Safety Notice "TC-115-Balloon" dated November 2018

Name _____
Hospital _____
Address _____

- The above mentioned Field Safety Notice has been read and understood.
- The inventory has been checked for affected TC-115-Balloon catheters
- There were catheters in our possession affected by the Field Safety Notice

yes no

- If "yes":

- I have followed the instructions of the Field Safety Notice for affected catheters
- Catheters with the following LOT numbers have been returned to the sales representative:

Date _____

Signature _____

PLEASE RETURN TO:
Your Local Sales Representative