



For preliminary information only (official letter for end-customers will follow soon)

Important Safety Information
Regarding
Scaled Guide Wires for use during Abdominal Aortic Aneurysm (AAA) procedures

June 23, 2017

Sender:

EPflex Feinwerktechnik GmbH
 Im Schwöllbogen 24
 72581 Dettingen/Ems
 Germany

Recipient:

Customers of our distribution partner Symbdrix GmbH, who have received the products below.

Identification of the affected products:

Brand Name: WiTrac® A.S. AAA Wire

Article Codes

<u>Reference</u>	<u>Global Order No.</u>
44011643	AA-035-260-30A
45011723	AA-035-260-20
45011744	AA-035-220-20

Description of the issue including the determined cause:

EPflex Feinwerktechnik GmbH is aware of its responsibility as a manufacturer of guide wires for various medical applications for the safe and efficient use of its products and for the welfare of the patients and users.

As of this we are informing our customers, who have received one of the aforementioned guide wires, on a mistakable advertising message for these products:

The cm-scaling on the product, which is visible under X-Ray, was mistakenly promoted as measuring instrument. This could have led to the fact, that the product was used for measuring the length of an aneurysm. We herewith constitute, that the product is not a medical device with measurement function. The scaling is not validated for measuring and therefore an adequate constancy and accuracy of the measuring values is not ensured. The only intended purpose of the scaling is to show the movement of the guide wire during an X-Ray and control it this way.

In our instructions for use the following note will be added:

“The scaling or scaled X-Ray markers on the guide wires are only serving for orientation. Measuring results have to be verified by other ways.”

Which actions does the recipient have to take?

- This is not a product recall! There is no need to return any products
- Read this safety information carefully
- Inform all person within your organization and hospital about this safety information so that anybody gets aware of it
- Acknowledge the receipt of this safety information by returning the attached reply form to EPflex Feinwerktechnik GmbH

Disclosure of the information described herein:

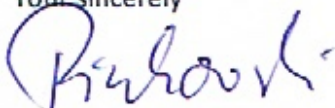
Please ensure, that in your organization all users of the aforementioned products and all other persons, who need to be notified, are informed about this notification. If the products were forwarded to any third party, please forward this notification or inform the contact person as stated below.

The Federal Institute for Drugs and Medical Devices in Germany (BfArM) has received a copy of this important safety notification.

Contact:

Dr. Wolfhard Pinkowski
Medical Device Safety Advisor
P: +49 7123 9784 67
M: +49 170 342 43 21

Your sincerely



Dr. Wolfhard Pinkowski

Reply Form

Herewith I confirm that I have read and understood the important safety notification on the use of scaled guide wires during AAA procedure.

Name: _____

Clinic/Organization: _____

Date: _____

Signature of the clinic's representative/user

Please return this form to:

Email: sicherheitsbeauftragter-mpg@epflex.com

Fax: +49 (0) 7123 9784-22