flexible solutions

For prellminary information only (official letter for end-customers wlll follow soon)

Important Safety Information
Reg.arding
Scaled Guide Wires tor use durlng Abdominal Aortic Aneurysm (AAA) procedures

June 23, 2017

Sender:
EPOex FeinwerktechnikGmbH
lm Schwöllbogen 24
72581Dettingen/ Ems
Germany

Retipient:
Customers of our distribution partner Symedrix GmbH, who have received the products below.

l dentifica ti on of the affectedproducts:
Brand Name: WiTrac" A.S. AAA Wire

Article Codes

Reference	Global Order No.
44011643	AA-035-260-30A
45011723	AA-035-260-20
45011744	AA-035· 220-20

Oescription of the issue including the determlned 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 *tor* the welfare of the patients and users.
As of this we *are* lnforming our customers, who have received one of the aforementio ned guide wires,on a mistakable advertising message for these products:

The cm-sealing on the product, which is visible under X·Ray, was mistakenly promoted as measuring instrument. This could have led to the tact, that the product was used for measuring the length of an aneurysm. We herewith constitute, that theproduct as nota medical device with measurement fun ction. The sçaling is not validated for measuring and therefore an adequate constancy and accuracy of the measuring *va*lues is n ot ensured. The only intended purpose of the sealing is to show the movement of the guide wire duringan X·Ray andcontrol it thisway.

In our instructions tor use the following note wil!beadded:

"The sealing 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 Isnotaproduct recall! There is no need to return any products
- Read this safety information carefully
- Inform all person within your organization and hospita! about this safety information so that anybody getsaware of it
- Acknowledge the receipt of thls safety information by returnine the attached reply form to EPflex Feinwerktechnik GmbH

Oisclosure of the information described herein:
Please ensure, that in your organization all usersof 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 fo:rward this notification or inform the contact perşo1as stated below.

The Federal Institute for Drugs and Medica! Oevices in Germany (BfArM} has received a topy of this Important safety notification.

Contact:
Or. Wolfhard Pinkowski
Medica! Device Safety Advisor
P: +49 71239784 67
M:+49 170 342 43 21

.....

Or. Wolfhard Pinkowski

flexible solutions

Reply Form

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

Name:_ _

Clinic/Organization:- - - - - - - - - - - - - -

Date: _

_____

Signature of the clinic's representative/user

Please returnthis form to:

Email: slchcrheitsbeau ftragter-mpg@epOex.com

Fax:+49 (0) 7123 9784-22