WITTENSTEIN | intens

Urgent Field Safety Notice

FITBONE® Receiver, REF 60001780
Event information 370 and 391
Device exchange

Date: 2020-02-21

Attention

Details on affected devices:

Receiver REF 60001780

Description of the problem:

Based on two events in the field concerning the Receiver REF 60001780, the FITBONE® user have to be informed about the following:
According to information from two FITBONE® user there were intermittent functional failures of the Receivers. The examination of the Receivers showed that unfavorable handling of the bipolar plug connection in the transition of the connection socket to the supply line could lead to a short circuit at this particular point.

Advise on action to be taken by the user:

A recall respectively an exchange of all receivers regarding REF 60001780 available in the consignment stocks or in the field for planned surgeries will be performed.

Transmission of this Field Safety Notice:

In case of distributors this Field Safety Notice needs to be passed to all of your FITBONE® physicians.

Contact reference person:

Roman Stauch
WITTENSTEIN intens GmbH
Walter-Wittenstein-Straße 1
97999 Igersheim

The signatory confirms that this notice has been notified to the appropriate Regulatory Agency

Roman Stauch
Managing Director and Safety Officer