

Assago, October 18th 2017

Field Safety Notice

Object. **Field Safety Notice regarding the Dynlock Stabilization System**

Ref. No. **FSCA 17/001**

Type of Action. **Product Recall**

Product Ref. **PLS-48NI65, PLS-49TN15060, PLS-233T30**

Lot numbers. **9347, 9423, 9441, 9296**

Dear Customer,

we have received some customers' complaints in which it is stated that the component Nitinol rod of the Dynlock Dynamic Stabilization System unexpectedly broke once implanted, during the normal functioning.

The clinical risk for patient instrumented with this system is the need for a revision surgery if the patient feels pain and the rod is found to be broken.

The issue has been investigating, but the information that Sintea Plustek was able to collect up to now are not believed sufficient for definitely excluding that these events could be device-related.

Therefore, Sintea Plustek decided for a voluntary recall of all the components of the system not implanted yet, until it will be able to investigate the root causes for these failures and, in case, perform proper corrective action to avoid the risk that such a event occurs again.

Sintea Plustek has already communicated this information to the Competent Authority of your country.

Sintea Plustek S.r.l.

**Sede commerciale,
amministrativa e legale:**
20090 Assago (MI) – Italy
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C. F. e P. IVA 04874470968
Capitale Sociale € 100.000,00 i.v.
R.E.A. Milano n. 1778805
sintea⁺plustek@alapec.it
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20021 Baranzate (MI) – Italy
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Several Corrective and Preventive Actions will be implemented in order to rectify this issue:

- a) a Field Safety Corrective Action has been initiated to recall all affected product from the market;
- b) an advice will be distributed to follow-up the patients who have the affected products already implanted;
- c) a corrective design modification will be tested and implemented, if the root cause analysis will show a device-related or a design-related error;
- d) an advice will be issued regarding the implantation of the device as an integration of the surgical technique, if the root cause analysis will show a surgery technique related error.

Our traceability system indicates you have received products affected by this FSCA. Please read the following detailed listing, by lot number, for these devices.

Code	Description	Lot number
PLS-48NI65	NITINOL rod Ø3 mm - L 65mm	9347
PLS-49TN15060	Hybrid Ti-NiTi rod - L 150x60 mm	9423
		9441
PLS-233T30	Cap for NITINOL rod	9296

In order to facilitate the fast resolution of this FSCA we ask that you:

- **Immediately identify and quarantine any affected devices as listed above**
- **Complete the attached customer response form and email/fax back to Sintea Plustek. Please complete and return this form even if you no longer have any affected devices in inventory.**
- **Inform Sintea Plustek immediately if you have further distributed any affected product to other organisations.**
- **Circulate this document internally to all interested parties.**

A Representative will then contact you in order to arrange for collection/replacement of any affected product, if appropriate.

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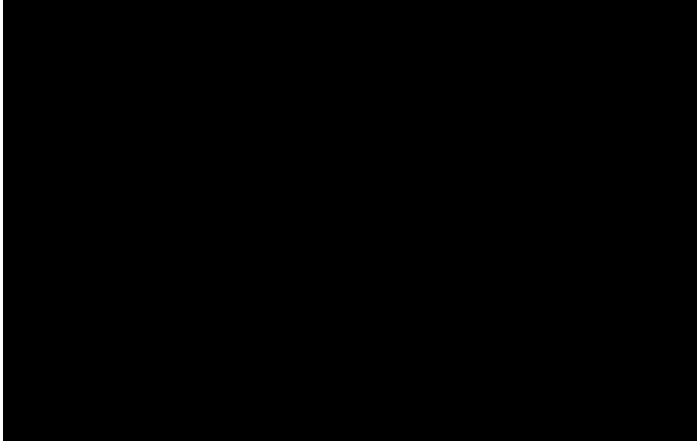
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Should you have any queries regarding this action in the meantime please do not hesitate to contact the undersigned.

Best regards,



Sintea PlusTek S.r.l.

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CUSTOMER REPLY FORM

Please complete this acknowledgment and send it back to us within 15 days by fax on +39 02 45 79 02 66 or by email to grosso@sinteaplustek.com

Institution / Company Name : _____
Name: _____
Position: _____
Address: _____

Telephone No: _____

By completing and returning this form, I confirm that I have received and read this Field Safety Notice and that I have undertaken the actions indicated by the Manufacturer in order to facilitate the FSCA resolution.

Date: _____ Signature: _____

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