

SUBJECT

## Field Safety Notice - PRODUCT RECALL

Reference procedure PR 95.12 TYPE CAN BE DISCLOSED

Product Name	Part No.	Lot No.	Quantity
ComposiTCP 30 Interference screw - D 7- L:25 mm; cannula 1.2m	110004605	190491	3 defects / 147 sent

Date: September 30, 2021.

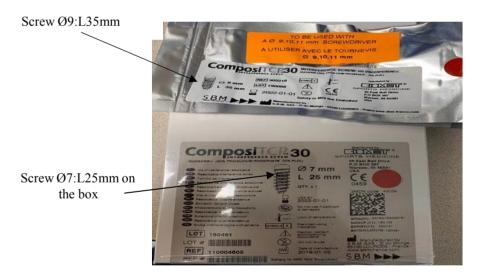
Attention: To all relevant parties within your organization or, where applicable, to any organization to which the medical device has been transferred and is affected by this measure.

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## **Description of the problem:**

SBM has initiated a voluntary product recall concerning a reference of ComposiTCP Interference screws. According to our traceability system, you have received at least one of the three devices mentioned above. You are therefore concerned by this action.

3 cases of: 1 screw Ø9/L35mm Lot 190068 inside a box for screw Ø7/L25mm Lot 190491. Date of manufacture: 2019-01-02; Use before: 2022-01-01.



Predicted risk to patient/users: Delay in surgery of more than 30mn - Potential impact on surgical technique.

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## Actions to be taken by the user:

Include, as appropriate:

- ⊠ Identifying and quarantining the medical device,
- ☐ Method of recovery, disposal or modification of device,
- ☐ Recommended patient follow up, e.g. implants,
- ☐ Timelines.
- ⊠ Confirmation form to be sent back to the manufacturer if an action is required (e.g. return products).

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#### **Transmission of this Field Safety Notice:**

This notice needs to be forwarded to all the interested parties within your organization or to any organization to which the device has been transferred (If appropriate).



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Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

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## **Contact reference person:**

## **Régine BAREILLES**

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#### **Anne COSPIN**

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