

Urgent Field Safety Notice

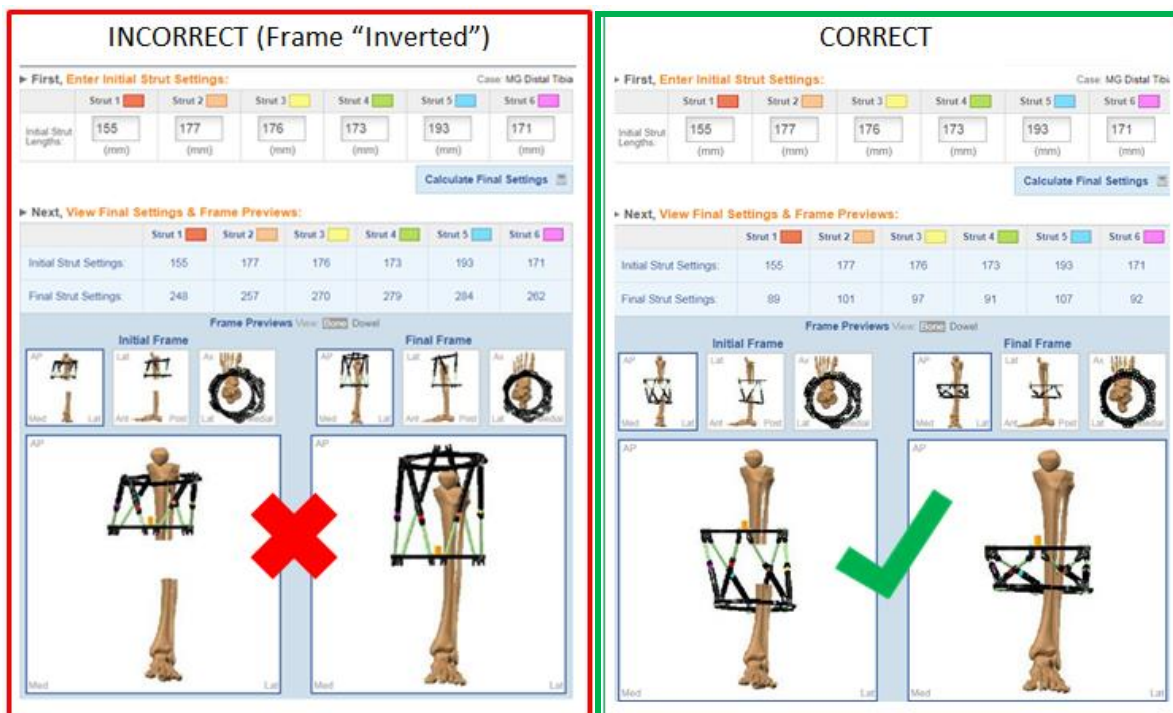
Affected Product: TAYLOR SPATIAL FRAME[®] WEBSITE SOFTWARE
FSCA reference: R-2017-40
Date: December 13, 2017
FSCA action: Advisory Notice
Details of affected product: See below

Dear Dr.

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary Field Safety Corrective Action (FSCA) to notify users of a potential SpatialFrame.com website software issue. We became aware that in rare circumstances, when surgeons use the software to plan the strut adjustment, an “inverted” image of the frame is generated by the software. This situation is easily recognizable; the frame will appear “inverted” in the preview images on the Strut Settings tab (see below). If the surgeon proceeds to print the patient prescription on the basis of the “inverted” frame, the strut adjustments on the prescription will be incorrect. An example of an inverted image is provided below.

This situation has a very low occurrence rate (0.005%) and Smith & Nephew is currently working to implement corrective measures to the software to resolve this issue. We are requesting that surgeons systematically verify images generated by the SpatialFrame.com software to confirm that all frame preview graphics match the frame on the patient clinically before providing a strut adjustment schedule to the patient.

In the unlikely event that you notice an inverted frame in the software, you should repeat the process for the same case and notify a Smith & Nephew representative.



Background

The SpatialFrame.com website is used to determine the strut adjustment schedule for Smith & Nephew's TAYLOR SPATIAL FRAME[°] External Fixator. TAYLOR SPATIAL FRAME devices are used to correct congenital deformities and post traumatic deformities.

Context and reasons for this FSCA

This FSN has been issued to inform you of this potential concern affecting the SpatialFrame.com software. It is requested that for each case being inputted using SpatialFrame.com you verify that the preview images match the frame on the patient.

Information relating to patient safety

In the event that a case with an inverted frame strut adjustment schedule was provided to the patient, the patient would be following incorrect instructions resulting in unanticipated movement of the bone segments. In one reported instance, this resulted in preconsolidation of the osteotomy which required surgical intervention.

Actions to be taken by the user

1. Complete the return slip and forward it to [the contacts highlighted below](#) to confirm receipt of this Field Safety Notice.
2. Ensure this safety information is passed on to all those who need to be aware of it within your organization.
3. Maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
4. Double check your planning's for strut adjustments and compare with the images printed as described above.

Affected Products

This FSCA is applicable to the following products:

Catalogue Number	Product Description	Batches/Lots
71070401	SPATIALFRAME.COM SOFTWARE	Version 5.2.5

Smith & Nephew is committed to distributing only products of the highest quality standards and to providing support to customers who use those products.

If you have any questions, please contact Daniel Ball on the following phone number: +1 410-350-1230 or by e-mail: daniel.ball@smith-nephew.com.

Yours sincerely,

Andy Weymann, MD
Chief Medical Officer

Smith & Nephew Advanced Surgical Devices UK & I
Email: greg.williams@smith-nephew.com
Sandeep.garcha@smith-nephew.com
Fax: + 44 (0)1480 423 201.

.....
Return Slip

Please complete and return this feedback information to the contact specified above to prevent repetitive enquiries.

We confirm the receipt of this Field Safety Notice.

Institution: _____ Reference: R-2017-40

Name: _____ Date/Signature: _____