Doc. Ref. FSN201801

TO WHOM IT MAY CONCERN

Urgent: Field Safety Notice ref. FSCA201801

Subject: **DOUBLE ROW FOOTPLATES, TL-HEX STERILE, ALL SIZES. Below is reported the list of codes and batches involved.**

Details of the FSCA			
Date	**January 23, 2018**		
Reference Contact	Orthofix Srl Customer Service department Orthofix Srl Via delle Nazioni, 9 - 37012 Bussolengo (Verona) Italy e-mail: customerservice@orthofix.it – tel. +39 045 6719000 – fax. +39 045 6719380		
Affected Products	**Product code**	**Batch number**	**Product Description**
	99-56-22000	V1374370	DOUBLE ROW FOOTPLATE, 120MM, TL-HEX STERILE
	99-56-22020	V1374298	DOUBLE ROW FOOTPLATE, 140MM, TL-HEX STERILE
	99-56-22040	V1374255	DOUBLE ROW FOOTPLATE, 160MM, TL-HEX STERILE
	99-56-22040	V1374374	DOUBLE ROW FOOTPLATE, 160MM, TL-HEX STERILE
	99-56-22040	R1065030	DOUBLE ROW FOOTPLATE, 160MM, TL-HEX STERILE
	99-56-22060	V1374259	DOUBLE ROW FOOTPLATE, 180MM, TL-HEX STERILE
	99-56-22080	V1374361	DOUBLE ROW FOOTPLATE, 200MM, TL-HEX STERILE
	99-56-22100	V1374373	DOUBLE ROW FOOTPLATE, 220MM, TL-HEX STERILE
Details of the FSCA	As of January 19, 2018, Orthofix has received a total of 8 complaints of incompatibility and dimensional interference between double row footplates manufactured in a limited period of the year 2014 and struts manufactured after September 2016. Orthofix Srl conducted an investigation by performing technical analysis, medical evaluations and a review of the risk analysis. The result of the investigation determined that some production batches of double row footplate, manufactured in a limited period of the year 2014, are now potentially not compatible with the current version of the TL-HEX struts. In detail, it is possible that the stud of the strut (picture A) cannot be inserted in the hole of double row footplate (picture B and C).		

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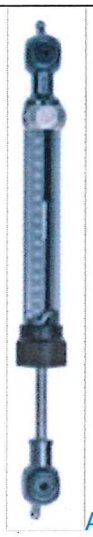
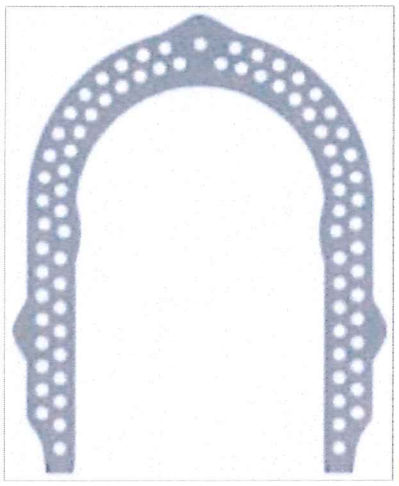
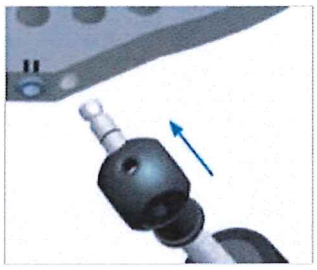

A


B


C

Risk for patient	The reported incompatibility was caused by a design problem for which the combination of tolerances of two parts (double row foot plate – struts) can generate interference with consequent difficulty to insert the stud of the strut in the hole of double row foot plate. This problem can be detected during: - pre-planning phase without effect on Patients. The pre-planning phase is recommended by Orthofix Srl in the Instruction for Use leaflet, ref. PQTLH. - intra-operative phase, causing a prolongation of surgery time. - Post-operative phase, in case of strut exchange, causing a prolongation of treatment. Orthofix determined that all footplates manufactured in a specific period of year 2014 be withdrawn from the market. The hazards identified are: - Delay of surgery; - Post-operative non-surgical intervention; - Additional surgery.
Immediate Actions Required – PLEASE REPLY WITHIN JANUARY 29TH, 2018	
For Distributors	Immediately identify the products in Your warehouse which are involved in this action, remove them from inventory and return to Orthofix Srl (see contact details above). Please ensure that all who received, or who may have received, affected units from You are provided immediately with this Field Safety Notice. Please fill in the **REPLY FORM** with all the above information and send to Orthofix.
For Hospitals	Do not use any products involved in this action and immediately return to your local distributor or directly to Orthofix Srl (see contact details above)
Products on patient	- For patients who have undergone fixation with a double row footplate, TL-HEX, code and lot number affected by this action, we recommend continuing their prescribed post-operative activities and follow-up. - In case of issue during the strut exchange step, please use the emergency tab following the instructions reported below.

Alternative procedures to complete the surgical intervention (1 – 2) and treatment (3)	**1)** The surgeon can use parallel external support (either footplate or ring) that do not have dimensional issues; **2)** The surgeon can complete fixation temporarily using non-hexapodal TrueLok connection elements. This solution requires post-operative non-surgical intervention: a) - The surgeon completes the TL-Hex frame with an additional parallel external support (either footplate or ring) that do not have dimensional issues; b) - The surgeon completes the frame for treatment using TrueLok non-hexapodal elements; **3)** In case the issue arises in a strut change during treatment, the surgeon can use an Emergency Tab Kit, as explained in the Attachment A.

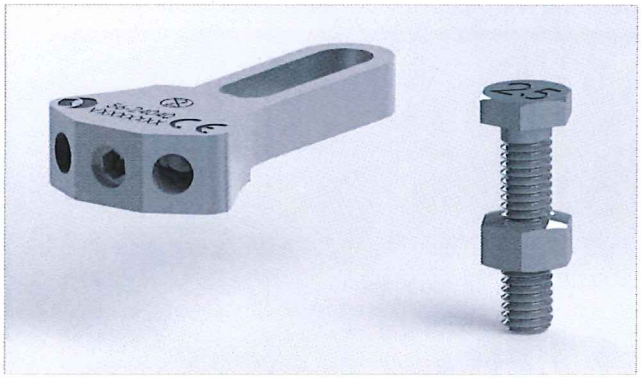
The undersigned confirms that this notice has been notified to the appropriate Regulatory Agencies.

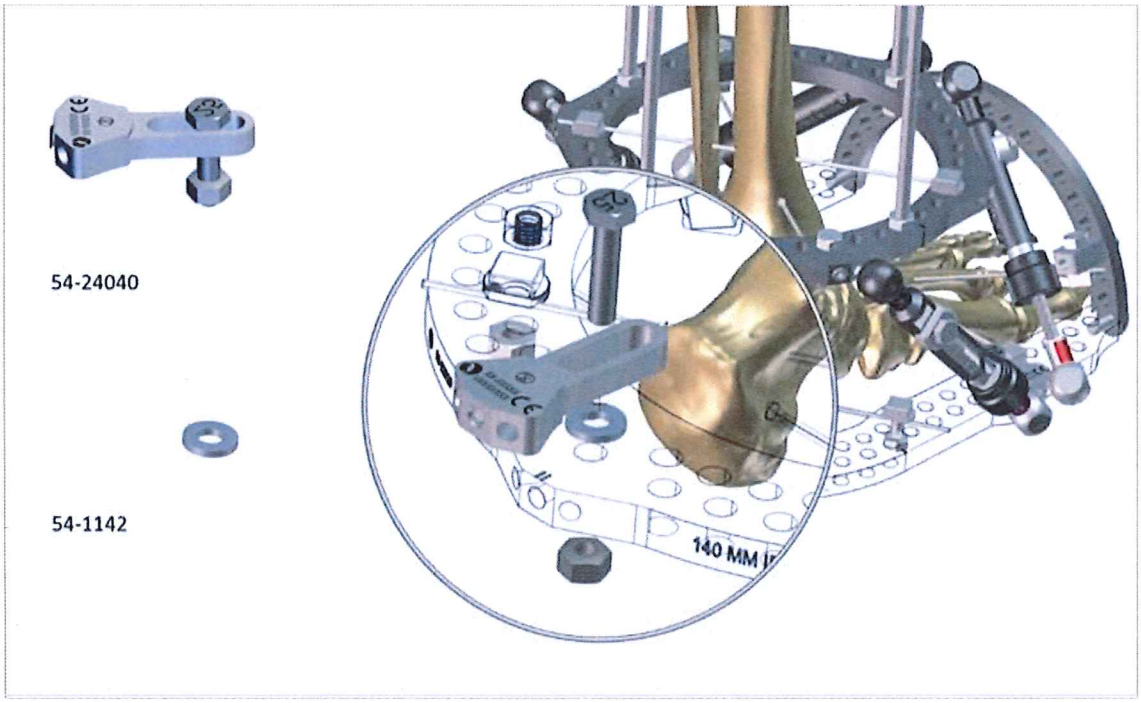
Respectfully,

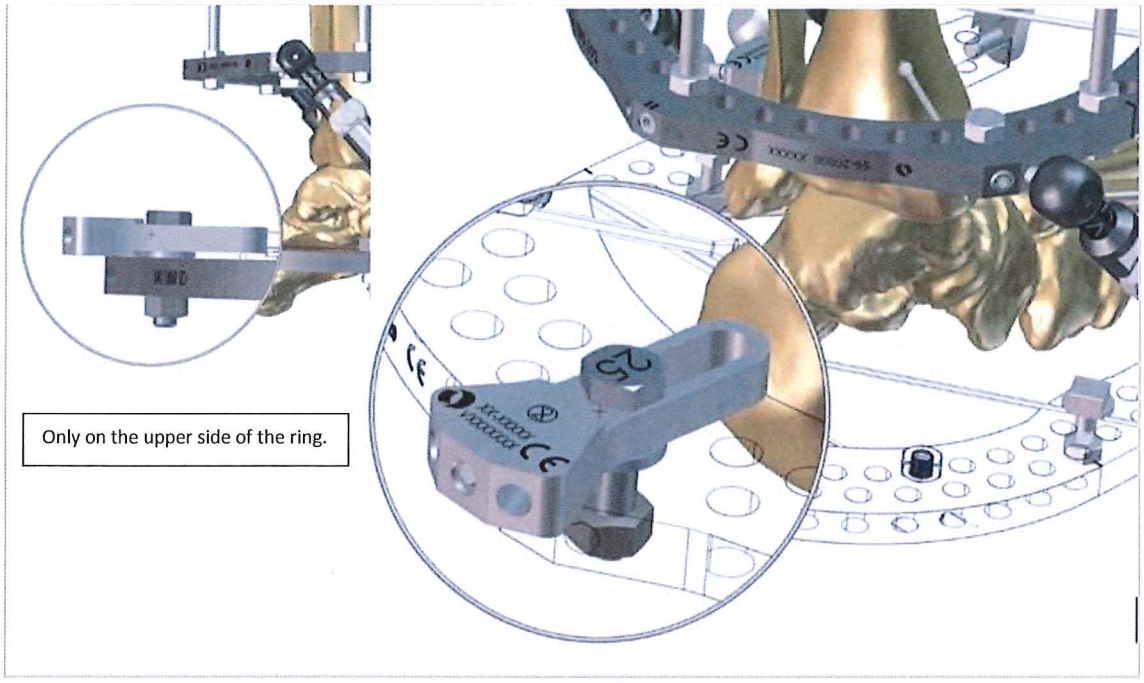
Roberto Donadello
Managing Director – VP Operations Intl
Orthofix Srl

ATTACHMENT A

Use of the emergency tab kit







Only on the upper side of the ring.

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