

## URGENT FIELD SAFETY NOTICE

### THOMAS SPLINT FIELD SAFETY NOTICE – INCORRECT CLEANING AND STERILISATION INSTRUCTIONS

July 2020

#### AFFECTED DEVICES

##### THOMAS SPLINT

Item No.	Description
TS1	THOMAS SPLINT PAED
TS2	THOMAS SPLINT ADULT
TSH1	THOMAS SPLINT HOOP COVER 150
TSH2	THOMAS SPLINT HOOP COVER 175
TSH3	THOMAS SPLINT HOOP COVER 200
TSH4	THOMAS SPLINT HOOP COVER 250
TSH5	THOMAS SPLINT HOOP COVER 300
TSH6	THOMAS SPLINT HOOP COVER 350
TSP1	THOMAS SPLINT PEARSON ATT PAED
TSP2	THOMASSPLINT PEARSON ATT ADULT
TSNPA	TS START PACK W/O PEARSON ADUL
TSNPP	TS START PACK W/O PEARSON PAED
TSSP1	THOMAS SPL STARTER PACK-PAED
TSSP2	THOMAS SPL STARTER PACK-ADULT

#### ATTENTION

Össur is committed to providing safe, high-quality medical devices to its customers. As such Össur is implementing a voluntary FSN (Field Safety Notice) in relation to the Thomas Splint device. It has been identified that the cleaning and sterilisation instructions contained a discrepancy in relation to the cleaning standards referenced. To ensure compliance the instructions have been updated to reflect the correct information.

The recommended actions outlined in relation to this case are outlined as follows:

## ACTION - ORGANISATIONS

**ACTION REQUIRED:** Please ensure the updated Instructions for Use are distributed to the necessary persons within the organisation and that the parameters within the instructions for cleaning and sterilisation are adhered to. A copy of the updated instructions accompanies this notice.

**ADDITIONAL ACTION REQUIRED:** Recipients of this notice should take the following actions:

1. Please pass this notice to those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.
2. Maintain awareness on this notice for an appropriate period.
3. If you have further distributed this product, please identify your customers, and notify them at once of this product alert. We recommend that you include a copy of this product safety notice.

## PICTURES OF THE AFFECTED DEVICE



This notice is to be communicated to all those within your organisation, and to any other organisation where affected devices may have been provided or serviced.

Please maintain awareness of this notice and recommended actions.

Please contact customer service on this phone number for further information and assistance:

Tel: +44 (0)8450 065 065



Hulda Hallgrímsdóttir  
Vice President, Quality & Regulatory

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