URGENT FIELD SAFETY NOTICE

J TONG PRODUCT SAFETY NOTICE
PRODUCT LABELING – MR CONDITIONAL STATEMENT

July 2020

AFFECTED DEVICES

J TONG

JT-100	J Tong Assembly MD/LG
JT-115	J Tong MD/LG - No App
JT-200	J Tong Assembly SM/MD
JT-215	J Tong SM/MD - No App
JT-400	J Tong Component Tray
JTP-0100	J Tong Medium/Large
JTP-0200	J Tong Small/Medium
JTP-0910	Sterile J Tong Base Tray M/L
JTP-0920	Sterile J Tong Base Tray S/M
JTP-0930	Sterile J Tong Component Tray

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 J TONG devices. Testing has confirmed the potential for a safety issue when using the product in accordance with the current MR Conditional guidance during Magnetic Resonance testing. Össur has not received any reports of incidents of injury related to the labeling issue.

The recommended actions are outlined below:

ACTION – ORGANISATIONS AND END USERS

ACTION REQUIRED: Please replace the Instructions for Use that are included with the product with the Instructions for Use that are attached to this Field Safety Notice. Contact Össur customer service if there are any questions. A list of the contact numbers is provided at the end of 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 of this notice until June 2025.

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 field safety notice.

RECOMMENDED MR LABELING FOR J-TONG

MRI Safety Information

Non-clinical testing has demonstrated that Össur J-Tong device is **MR Conditional**.
A patient with a J-Tong device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
- Landmarked at or below the torso.
- Maximum spatial field gradient of 2,500 G/cm (20 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4.0 W/kg.
- Maximum MR system reported, head specific absorption rate (SAR) of 3.2 W/kg.

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

Please maintain awareness of this notice and recommended actions.

Please contact customer service for further information and assistance. A list of the contact numbers is provided at the end of this notice.

Hulda Hallgrímsdóttir
Vice President, Quality & Regulatory

ÖSSUR CUSTOMER SERVICE CONTACT NUMBERS

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