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FIELD SAFETY NOTICE (FSN)

September 26, 2014

Commercial brand name: MAGEC® Spinal Bracing and Distraction System

<u>Models</u>	<u>Part Description</u>
RA002-4545SL	4.5mm Single Rod with 4.5mm Long Extension
RA002-4545SLR	4.5mm Single Offset Rod with 4.5mm Long Extension
RA002-5555SL	5.5mm Single Rod with 5.5mm Long Extension
RA002-5555SLR	5.5mm Single Offset Rod with 5.5mm Long Extension

FSCA-Identifier: FSCA14-09-001

Type of Action: Advisory Statement

Affected lot numbers: 110419-001 and 111209-007

Please note: This advisory notice affects only the specified lots in the attached list. No other product lots are affected with regard to your patients.

Dear Professor Dr. med.

Since the MAGEC® Spinal Bracing and Distraction System was introduced in November 2009, there have been design and performance changes made to the device. Specifically, Ellipse has made changes to the MAGEC weld inspection and welding manufacturing processes. These changes were made in March 2011 and March 2012, respectively.

A visual inspection is performed on every device after laser welding to evaluate the quality of the weld. Samples are rejected if the weld is discolored (i.e., brown or blue hue). In addition, the weld process has been modified from a pulsed laser weld to a continuous laser weld, in order to increase the robustness of the weld. Collectively, these changes represent a modification to the design and performance characteristics related to device safety and effectiveness. In short, the weld process improvement provides a more repeatable process and consequently a more robust weld.

Although there are no devices remaining in the field without these process enhancements, we are notifying you because our records indicate that one or more of your patients were implanted with the MAGEC rod of the earlier design (without process enhancements). These rods may be more prone to fracture at the welded actuator portion of the device. If the patients have not yet already completed their treatment with the MAGEC System and the devices are still implanted, these patients may require closer monitoring until the completion of their treatment.



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Advice on action to be taken by the user:

Please continue to closely monitor patients until the completion of treatment. Ellipse Technologies is not recommending replacement of these rods.

Transmission of this Field Safety Notice:

This notice has been sent to you as records indicate that your organization/hospital has received this device of the affect lot numbers referenced herein. This notice needs to be passed on to all those who need to be aware within your organization or to any organization where these products may have been transferred.

Please complete the attached Acknowledgement Form in its entirety. Fax or email the completed Form to the corresponding addresses stated on the form.

Please note that the relevant National Competent Authorities have been informed of this notice.

We sincerely apologize for any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter.

For any inquiries regarding this matter please contact:

Cora Sim
Regulatory Affairs Associate
E-mail: csim@ellipse-tech.com
Telephone no. +001 949 837 3600 ext. 221

Sincerely,

A handwritten signature in black ink, appearing to read "JRM", with a long horizontal flourish extending to the right.

John McIntyre
Vice President, Regulatory, Quality, and Clinical Affairs
Ellipse Technologies, Inc.