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URGENT FIELD SAFETY NOTICE

Re: **Cadisc® Device Information for Centres**

Product: **Cadisc®-L Total Disc Replacement Device**

Ref: **COM 0051**

Dear Customer

As you will be aware, Ranier Technology Limited issued a Field Safety Notice on the 22nd of May 2014 to provide information regarding the Cadisc®-L Artificial Spinal Disc. You are in receipt of this letter on the basis that you received a copy of that Field Safety Notice.

You will recall that it was brought to the company's attention that a number of devices within the DISCERN clinical trial had not performed as intended, and in a number of cases, the implanting surgeon had elected to undertake revision surgery.

The original Field Safety Notice indicated that the onset of performance deterioration became clinically significant between the 3 and 4 year follow-up after implantation, and was evident radiographically in most cases through a pronounced loss in disc height typically accompanied by some degree of visible migration of the radiographic markers.

The associated rate of revision related to this performance deterioration remains at 17.9%.

Subsequent to the issue of the original Field Safety Notice, Ranier Technology has reviewed the advice provided in relation to patient monitoring. As a consequence of this review, the company has taken the decision to revise the advice being issued, and proposes the following amendment as an appropriate programme for the patients who have received a Cadisc®-L device covered by the original Field Safety Notice:

Ranier Technology Limited, Greenhouse Park Innovation Centre, Newmarket Road, Cambridge CB5 8AA, UK
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Registered in England no. 3015156 at the above address

- For years 1 to 3 after implantation, all affected patients should be recalled for examination including Lateral and flexion/extension plain x-ray imaging of the lower back. The purpose of the form pose of this review is to identify whether there are any signs of device disruption or device migration and any elevated symptoms which may relate to the treated level.
- From year 4 until year 10 post-implantation, all affected patients should be recalled for examination including standing AP in addition to Lateral and flexion/extension plain x-ray imaging of the lower back. Again, the purpose of this review is to identify whether there are any signs of device disruption or device migration and any elevated symptoms which may relate to the treated level.
- If any of the patients show evidence of device disruption or migration, upon examination and a review of imaging, or have reported a return of symptomatic pain, then a full work up including CT and MRI should be undertaken and consideration should be given to continued monitoring, or to surgical intervention to either stabilise the device or explant it, as is considered appropriate by the treating clinician.

Attached to this Field Safety Notice is a Fax-back Form. The purpose of the form is to confirm receipt of the Notice, and either to confirm intent to comply with the above recommendations or to provide justification for an alternative course of action. Please complete the form and fax it to the number provided **within 1 week** of receipt of the Notice. A Ranier Technology Limited representative will then contact you in due course to agree on further action on the basis of the response provided.

Notification of this advice is being supplied to the relevant National Competent Authority and Notified Body in accordance with the Medical Device Directive 93/42/EEC, as amended by Directive 2007/47/EC.

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If you have any further questions arising from this note, or more general questions relating to this topic, please don't hesitate to contact me:

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With kind regards,

[redacted]

Parminder Kalle

Regulatory Affairs Manager

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