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Urgent Field Safety Notice

Precautionary Removal from Market

Date:
To: [redacted]

Att. <Name>

FSCA Ref: COM0051

Affected Products: **Product Name:** Cadisc®-L Artificial Spinal Discs

Product Code	Lot Number	Serial No.
130-S-10-06-01	130312-01	001
		003
		005
	130320-01	002
130-S-10-09-02	130110-02	002
	130318-02	001
	130318-02	003
	130318-02	005
130-S-10-12-03	111101-03	001
		002
	130917-03	001
		002
130-M-10-06-07	130314-07	001
		002
	130402-07	001
		002
130-M-10-09-08	130429-08	001
	130923-08	001
		002
		003
		004
130-M-10-12-09	111209-09	004
	130620-09	001
130-L-10-06-13	130423-13	001
130-L-10-09-14	131101-14	003
		005
130-L-10-12-15	110822-15R	002
	110907-15R	001

Ranier Technology Limited is implementing a Field Safety Corrective Action for specific lots of Cadisc®-L Artificial Spinal Discs as detailed above. The affected devices are to be blocked from sale and all users are to cease using the affected devices.

This is being undertaken in light of data generated from within a clinical trial involving the Cadisc®-L range of devices (ref. DISCERN) currently being conducted by Ranier Technology.

The DISCERN study commenced in 2009 and was planned with a 5 year follow-up. Its objective was to assess the safety and performance of the Cadisc®-L Total Disc Replacement therapy.

Recently, it has been brought to the company's attention that a number of devices within this clinical trial have not performed as intended, and in a number of cases, the implanting surgeon has elected to undertake revision surgery.

The onset of this performance deterioration appears to become clinically significant between the 3 and 4-year follow-up after implantation, and is 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 currently lies at 17.9%.

Whilst there is no evidence to indicate that the devices listed above are affected by the same issue, precluding these devices from sale and withdrawing them from the market is seen as an appropriate precautionary measure.

The cause of the issue within the clinical trial and the potential for cross-over into commercial CE marked stocks sold by the company is under investigation through a formal complaint (ref. COM0051. This investigation will result in appropriate corrective actions being implemented to address any root-cause issues identified. Discussions are planned with Ranier Technology Limited's Scientific Advisory Board to explore appropriate screening of patients who have received the above CE marked devices, purely as a precautionary measure. Any advice in this regard will be issued in further communication.

Our records indicate that you have received some of the affected product listed overleaf.

As our records indicate that you have received the Cadisc®-L lots listed overleaf, we would ask you to please complete the attached Fax-Back Form and return the device(s) to Ranier Technology Limited. Your local Ranier Sales Representative will contact you to facilitate this.

The address to return the devices to is:

Ranier Technology Limited
Greenhouse Park Innovation Centre
Newmarket Road, Teversham
Cambridge
Cambs.
U.K.
CB5 8AA

Attn: [redacted], Director of Quality and Regulatory Affairs

You may use TNT number 001556027 to send the product back.

Until such time as investigations are concluded, Ranier Technology Limited will not be in a position to issue replacement stock. Your local representative will provide any further information to you as it becomes available.

In all cases please confirm the quantities of affected devices that you hold in stock by the completion and return of the attached fax-back form.

It would be greatly appreciated if this could be completed as soon as possible but no later than the **8th April 2014.**

This notice needs to be passed on to all those who need to be aware within your organisation. However, it is a confidential document and should not be passed to anyone outside your organisation, without Ranier Technology Limited's prior agreement.

Ranier Technology Limited appreciates your cooperation and understanding of our efforts to assure the quality of our products. If you should have any further questions, please contact Ian Wilde (ian.wilde@ranier.co.uk) or [redacted] ([redacted]@ranier.co.uk) by email or on telephone number +44 (0)1223 505 045. Alternatively please contact the Country Manager, [redacted] on + [redacted]

Yours Sincerely

Ian Wilde
Director of Quality and Regulatory Affairs
Ranier Technology Limited