JRI Orthopaedics Limited
18 Churchill Way • 35A Business Park • Sheffield • S35 2PY
T: 0114 345 3200 • F: 0114 257 3204 • W: www.jri-ltd.co.uk

Urgent FIELD SAFETY NOTICE

Furlong® H-A.C Femoral Stem Size 8 - *Field Safety Corrective Action* – *PRODUCT RECALL*

Date: 12-December-2022
Reference: 2022/012/006/601/001

Details on affected devices:

Catalogue Reference	Product Description	UDI-DI / GTIN
81-08-05	Furlong H-A.C 140° CCD Angle Femoral Stem High Offset 8mm	05032982026100
81-08-08	Furlong H-A.C 140° CCD Angle Femoral Stem Standard Offset 8mm	05032982026094
81-08-30	Furlong H-A.C 133° CCD Angle Femoral Stem Standard Offset 8mm	05032982026124
81-08-35	Furlong H-A.C 133° CCD Angle Femoral Stem High Offset 8mm	05032982026216

Dear Customer,
JRI Orthopaedics Ltd. is initiating a voluntary medical device recall for all size 8 Furlong H-A.C Femoral Stems as listed in the affected devices table above.

Description of the problem:

JRI Orthopaedics Ltd. is initiating this voluntary medical device recall as the latest results of testing to ISO 7206-6:2013 have demonstrated that the size 8 femoral stems within the Furlong® H-A.C Femoral Stem range do not comply with the requirements.

Potential Risks

The potential risk associated with the problem described above are:

- Under certain circumstances of high patient load and high patient activity, there is a risk the neck of the stem could fail post operatively resulting in the patient requiring revision surgery.

Recommendations for patients already implanted with an affected device

Patients already implanted with an affected device should continue to be followed as per the normal protocol established by their healthcare professional. There are no recommended changes to the frequency of the standard follow-up care protocol.

Actions to be taken

Our records indicate that you have received at least one of the affected devices and you are therefore impacted by this FSN.

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We request that you read this notice carefully and complete the following actions:

1. Immediately check your internal inventory and quarantine all affected devices pending return to JRI Orthopaedics Ltd. Please contact your JRI Orthopaedics sales representative to organise the return.
2. Circulate this Field Safety Notice internally to all interested/affected parties.
3. Maintain awareness of this notice internally until all required actions have been completed within your facility.
4. Inform JRI Orthopaedics Ltd. if any of the subject devices have been distributed to other organizations.
    a. Please provide contact details so that JRI Orthopaedics Ltd. can inform the recipients appropriately.
    b. If you are a Distributor, note that you are responsible for notifying your affected customers. Each of your customers is then required to complete the Acknowledgement of Receipt form and return to JRI Orthopaedics Ltd.
5. Please inform JRI Orthopaedics Ltd. of any adverse events concerning the use of the affected devices.
    a. Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.
6. Return the completed Acknowledgement of Receipt form to regulatory@jri-ltd.co.uk

We request that you respond to this notice within **7 calendar days** from the date of receipt.

Transmission of this Field Safety Notice:

This notice must be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Contact reference person:

[redacted]
Senior Regulatory Affairs Specialist
JRI Orthopaedics Ltd, 18 Churchill Way, 35A Business Park, Chapeltown, Sheffield, United Kingdom, S35 2PY, regulatory@jri-ltd.co.uk

JRI are taking every measure to address the issues stated and are grateful for your understanding and cooperation. We thank you for working with us and for your continued trust in our company.

Yours faithfully,

[redacted]
Senior Regulatory Affairs Specialist

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Acknowledgement of Receipt

Please complete this acknowledgement of receipt and return to JRI Orthopaedics:

regulatory@jri-ltd.co.uk

Please complete the form even if you do not have inventory.

Affected Devices

Catalogue Reference	Product Description	UDI-DI / GTIN
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Customer Information

Hospital / Company Name			
Contact Name			
Function			
Address			
Phone Number		**Email**	

If you have affected devices within your inventory, please provide information below:

Catalogue Reference	LOT Number	Qty Quarantined	Qty returned to JRI

I hereby confirm that I have read and understand the instructions provided in this Field Safety Notice from JRI Orthopaedics, relating to the **Furlong® H-A.C Femoral Stem Size 8** and have distributed it to whom it may concern.

Date		**Signature**	