**Smith & Nephew**
Cardinal Park
Godmanchester
Huntingdon
Cambridgeshire
PE29 2SN

T 01480 423200
F 01480 423201
www.smith-nephew.com

We are smith&nephew

[Recipients Address]


08 August 2013

Dear Customer

**URGENT FIELD SAFETY NOTICE: Medical Device Field Safety Corrective Action / Recall**

Reference: FA2013-01

Concerned Devices: One batch of Durolane® Injectable Hyaluronic Acid (HA) Syringes

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary recall of one batch of Durolane® Injectable Hyaluronic Acid (HA) Syringes.

This field action has been reported to the relevant competent authorities.

| Product No. | Description | Batch No. |
|---|---|---|
| 1081110 | Durolane® Injectable Hyaluronic Acid (HA) Syringes | 12068-2 |

| | |
|---|---|
| **Product** | One batch of Durolane Injectable Hyaluronic Acid (HA) Syringes<br>(see article and lot information above). |
| **Reason for this Field Action** | As part of our routine vigilance and product monitoring, a higher than anticipated number of reports of post-injection knee pain and swelling and in some cases, an increase in the intensity of the symptoms reported has been received. |
| **Risks to Health** | Immediate – pain and swelling, stiffness may limit mobility or use of the limb. Recovery time might be increased and moderate to severe patient discomfort may result. Some patients may have swelling due to varying degrees of effusion and which may require aspiration.<br><br>Long term – most patients involved with the reported complaints recover within the listed time frame in the IFU and known from the clinical studies of the product. Few patients have a protracted recovery time beyond 3 weeks after the injection. |
| **Actions to be taken by the user** | 1. Locate and quarantine unused products of the affected batch immediately.<br>2. Return quarantined product to your national Smith & Nephew ASD as per above address.<br>3. Complete the return slip and fax it to your national Smith & Nephew ASD as per contact details below.<br>4. Please make sure this safety information is passed on to all those who need to be aware of it within your organization.<br>5. Please maintain awareness on this notice and resulting action until the Field Safety |

| | |
|---|---|
| | Corrective Action is terminated to ensure effectiveness of the action. |
| **Other Information** | Within the European Economic Area and Switzerland the field action is coordinated by Smith & Nephew Orthopaedics AG (Switzerland). |

Smith & Nephew is committed to distribute only products of the highest quality standards and to provide any required support. We regret that this has occurred and any inconvenience it may cause or has caused you, your patients, or your staff.

If you have any questions please feel free to contact us under the following contact details:

Yours sincerely

**Greg Williams – Quality & Regulatory Manager**
Smith & Nephew Advanced Surgical Devices
Email: greg.williams@smith-nephew.com
T: + 44 (0) 1480 423 200
F: + 44 (0) 1480 423 201

**DECLARATION**
**Please complete this declaration and return to Smith & Nephew Advanced Surgical Devices by fax: 01480 423 201, or email: greg.williams@smith-nephew.com or UK.ServiceOperations@smith-nephew.com**

**Return Slip**

**Please complete and return this feedback information to the contact specified above to prevent repetitive enquires.**

☐ We confirm the receipt of this Field Safety Notice.

☐ In our facility we have _____ concerned devices which we will return.

☐ _____ concerned devices have been consumed in our facility.

Please provide name and address of the physician who injected it

| Health Care Professional Name | Address | Qty |
|---|---|---|
| | | |
| | | |

Organisation /Hospital: _____ Reference: FA2013-01

Name: _____ Date / Signature: _____

Smith & Nephew Advanced Surgical Devices is part of T.J. Smith and Nephew Limited. Registered in England and Wales No. 00093994
Registered office: PO Box 81, 101, Hessle Road, Hull HU3 2BN