Initial Report Form
Field Safety Corrective Action

Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 6)

1. Administrative information
Destination

Name of national competent authority (NCA)

Address of national competent authority

Date of this report
1 April 2011

Reference number assigned by the manufacturer
PRA 2001-004

Incidence reference number and name of the co-ordinating national competent authority (if applicable)

Identify to what other national competent authorities this report was also sent
Belgium, France, Hungary, Italy, Slovenia, UK, Switzerland

2 Information on submitter of the report

Status of submitter

☐ Manufacturer

☒ Authorized representative within EEA

☐ Others (identify the role):

3 Manufacturer information

DePuy Spine
325 Paramount Drive
Raynham, MA 02767
USA

Manufacturer's contact person
Andrew Topoulos

Address
As above

Postal code **As above**	City **As above**
Phone **+1 508 828-2790**	Fax **N/A**
E-mail **N/A**	Country **As above**

4 Authorized representative information

Name of the authorized representative
DePuy International Ltd
St Anthony's Road
Leeds LS11 8DT
England

The authorized representative's contact person
Paul Arnott

Address
As above

Postal code **As above**	City **Leeds**
Phone **+44 (0) 7771 971 930**	Fax **+44 113 3876087**

E-mail **parnott@its.jnj.com**	Country **England**
5 National contact point information	
National contact point name **As above**	
Name of the contact person **As above**	
Address **As above**	
Postal code As above	City **As above**
Phone **As above**	Fax **As above**
E-mail **As above**	Country **As above**
6 Medical device information	

Class

☐	AIMD Active implants		
☐	MDD Class III	☐	IVD Annex II List A
☐	MDD Class IIb	☐	IVD Annex II List B
X	**MDD Class IIa**	☐	IVD Devices for self-testing
☐	MDD Class I	☐	IVD General

Nomenclature system (preferable GMDN)
GMDN Code = 12727

Nomenclature code

Nomenclature text
Intended Use of the Device:
The Confidence Needles are supplied sterile. They are used to place bone cement percutaneously at a desired location. They come in a variety of sizes (length and diameter) and configurations (Bevel tip, Diamond tip). The cement extrudes from the end of the cannulated needle with the exception of the side hole needle which extrudes cement from a portal on the side of the tube near the distal end. The needle is placed under fluoroscopy prior to cement delivery. The needle is also sometimes used in MIS cases to place the guide wire that is used to assist in the placement of the pedicle screw.

Commercial name/brand name/make
DePuy Spine Confidence® Introducer Needle

Catalogue Numbers / Description:

283903611 Confidence 11g x 6-inch Introducer Needle, Diamond Tip
283904413 Confidence 13g x 4-inch Introducer Needle, Side Hole

Lot Number**:**

HLPB4G & HLPB4F

Serial number(s) and/or lot/batch number(s)
As above

Software version number (if applicable)
N/A

Manufacturing date/expiry date (if applicable)
Not applicable

Accessories/associated device (if applicable)
Not applicable

Notified body (NB) ID- number
BSi – 0086

7 Description of FSCA

Background information and reason for the FSCA

The reason for this Field Safety Corrective Action and Field Safety Notice is that a lot which is properly labeled (11g x 6 inch) contains a 13g x 4-inch side hole needle with the sterile package. As the needle contained within the package is two inches shorter in length it could result in an inability to get the shorter needle to the desired location. If no additional 6-inch needles were on hand the procedure may be have to be aborted. The second lot was in production at the same time as the side fire needle which is also part of this field safety corrective action.

Description and justification of the action (corrective/preventive)

As above

Advice on actions to be taken by the distributor and the user

Recalled products identified above must not be used. Notify your DePuy Sales Representative or Account Manager as soon as possible.

Attached please find

x	Field Safety Notice (FSN) in English

Time schedule for the implementation of the different actions
Immediate

These countries within the EEA and Switzerland are affected by this FSCA

Within EEA and Switzerland:

Belgium, France, Hungary, Italy, Slovenia, UK, Switzerland

Candidate Countries:

These countries outside the EEA and Switzerland are affected by this FSCA

Australia, Malaysia, USA, South Africa, UAE

8 Comments

I affirm that the information given above is correct to the best of my knowledge.

Signature

Name	City	Date
Paul Arnott	**Leeds, UK**	**April 2011**

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorized representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.