

Customer
Address

URGENT – FIELD SAFETY NOTICE / PRODUCT RECALL
Medical Devices

Commercial name of the affected product(s): ODALYS Pedicular screws and blocking caps
FSCA-identifier: CAPA Système PAS-2015-0076_FSCA
Type of action: Product recall

Date: September 11th, 2015

Attention: Hospital Director, the local Medical Device Vigilance Correspondent and any other medical professionals of the concerned departments

Details on affected devices:

See annex 2

Intended use:

Posterior thoraco lumbar osteosynthesis system

Purpose of the notice:

KISCO INTERNATIONAL has recently pointed out the audits of the dose to be carried out in accordance with the 11137 standard have not been made during the period from August 2013 to August 2014. As a result, we can not demonstrate compliance of our sterilization process to the standard

Potential associated risks:

No incidents relating to sterilization have been reported since August 2013 to date. However KISCO INTERNATIONAL is not able to formally guarantee the sterility of the listed products.

Taken actions

As a precaution, KISCO INTERNATIONAL is undertaking a voluntary recall of all products listed in Annex 2. In addition, we recommend increased monitoring of patients implanted with lots of products in Annex 2.

Actions to be taken by the user:

Our records indicate that we have made available to your health establishment devices affected by this notification.

1. Identify all affected devices present in your establishment and place them in quarantine.
2. Our representative will visit you as soon as possible to proceed to an exchange of product.
3. Complete and return the attached form by which you confirm that you have read this safety information.

-REG-D-035 Rev. c

Transmission of this Field Safety Notice:

We ask you to follow the below procedure:

- Pass this information on to all those who need to be aware of it within your organization.
- Retain a copy of this information and make sure that it is regularly circulated in order to assure efficiency of this safety action.

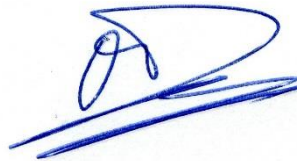
The concerned competent authorities have been informed of this action.

According to MEDDEV 2.12-1 Rev. 8, we kindly remind you that it is essential to report to the competent national authority and/or KISCO International all adverse events observed during the use of these medical devices.

Should you have any question, our Quality department can be reached by phone at +33(0)4 78 90 85 59 or by email: materiovigilance@kisco.fr.

We apologize for the inconvenience caused by this safety notice and we thank you for your comprehension and your cooperation.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'Olivier DEROO', with a horizontal line underneath.

Olivier DEROO
Medical Device Vigilance Correspondent

Acknowledgement and return form *Healthcare facility name*

**Field Safety Notice CAPA Système PAS-2015-0076_FSCA related to ODALYS
Pedicular screws and blocking caps**

We kindly ask you to complete and return this acknowledgement form within 7 days:
KISCO International, Quality and Regulatory Affairs Department
By email: materiovigilance@kisco.fr or by fax: +33(0)9 72 46 70 86

With this form, I confirm that:

- I have received the safety notice from KISCO International
- I have passed this information on to all those who need to be aware of it within my organization

In case of product recall:

- I do not have any device in stock within my facility.
- I would like to return the devices to KISCO International. The concerned references and batch numbers are listed the Table below:

Reference	Batch #	Quantity

Establishment

Signatory name:

Function:

Address:

Signature and date:

ANNEX 2

Reference	Description	lot #	Sterilization #	Qty
10MS0160	2x Monoaxial screws Ø6, L35 for rod Ø6	132269	S13013	19
10MS0170	2x Monoaxial screws Ø6, L40 for rod Ø6	132270	S13013	33
		130075	S14010	16
		140182	S14015	24
		140188	S14015	15
10MS0180	2x Monoaxial screws Ø6, L45 for rod Ø6	132271	S13013	31
		130076	S14010	47
10PS0020	2x polyaxial screws Ø5, L35 for rod Ø6	130084	S14015	30
		130085	S14015	5
10PS0030	2x polyaxial screws Ø5, L40 for rod Ø6	130086	S14014	50
		130087	S14014	12
10PS0040	2x polyaxial screws Ø5, L45 for rod Ø6	130088	S14015	18
		130089	S14015	10
10PS0070	2x polyaxial screws Ø6, L40 for rod Ø6	132305	S13016	50
		132306	S13016	46
		132307	S13016	5
		130092	S14014	30
		130093	S14014	6
		140189	S14014	4
		140190	S14014	3
		130090	S14014	27
10PS0110	2x polyaxial screws Ø7, L35 for rod Ø6	130094	S14010	15
		130095	S14010	16
10PS0120	2x polyaxial screws Ø7, L40 for rod Ø6	130096	S14014	8
10PS0130	2x polyaxial screws Ø7, L45 for rod Ø6	130097	S14010	18
		130099	S14010	18
		130098	S14010	16
10SS0070	2x polyaxial spondylolisthesis screws Ø7, L35 for rod Ø6	140124	S14018	19