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www.alphatecspine.com

FIELD SAFETY NOTICE
FSCA – lots recall

02 December 2015

Client Name
Adress

Reference ANSM : *201515554*
Destination : Scient'x customers, including Health Institution Directors, Local Materiovigilance Correspondents and all involved health practitioners and services
Action type : *Field Safety Corrective Action (FSCA) – lots recall*

Dear Madam, dear Sir,

You are receiving this Field Safety Notice (FSN) from Scient'x in order to inform you about a voluntary recall of the cervical cage Samarys ™(potentially affected references and lot numbers are listed below), notified to competent authorities.

Part Number	Lot Number
11CC2A15-45S	23MM+18457
	23MN+18457
	23TL+19029
	247A+19029
	248N-19196
	248O+19196
	248O-19196
11CC2A15-5S	23LJ-19196
	23SH+19029
	23TY+19029
	24KM+19949
11CC2A15-6S	22YN
	22YN+17547
	23ME+17547
11CC2A17-45S	23UL
11CC2A17-5	246E
11CC2A17-6S	23KY+19029
11CC2A17-7	24RP
11CC2A20-6S	23KX+19029
11CC2AC17-45S	23M4+17547
	23M4+19029
	23SK+17547
	246L+19029
	248M+19029

Part Number	Lot Number
11CC2AC17-5	23TT
	23TZ
	23UT
	23W7
	245X
	2465
	246M
	246W
	247G
	248L
	248R
	24L2
	24MT
	24RF
	24RFS1
11Cc2AC17-5S	246K+18457
	246M+18457
	246W+19029
	2479+19029
	247J+19029
	247P+19029
	248R+19196
	24KD+19949

Part Number	Lot Number
11CC2AC17-6	23M2
	23SG
	23SS
	23SW
	23TE
	23U4
	23W1
	2464
	246F
	246R
	247F
	247O
	248S
	24LL
	24MZ
	24PU
11CC2AC17-6S	246F+18457
	246P+18457
	248K+19029
11CC2AC17-8S	23TN+18457

All non-cited references, as well as the Samarys RF™ devices are not affected by this action.

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Description of the incident at the origin of the current FSN:
This action was initiated because of a random non-conformity relevant to the gold wires integral used as a position marker for the cervical PEEK cage Samarys™. The observed facts were that some devices within lots manufactured between April 2014 and November 2015 may have missing, improperly secured, and/or incorrectly positioned gold wire markers, which may protrude of 1-2 mm inside or outside the cage. However, no customer complaint has been recorded and no adverse event or incident was reported until now.

Potential associated risks :
A risk evaluation was performed, allowing to evaluate potential risks related to the use of a non-conforming device; they were considered significant, though the probability of their occurrence is extremely low. Thus, the gold wire absence may cause positioning errors during cage insertion at treated site which may result in neurological injury. Incorrectly positioned gold wires may cause local inflammation of the surrounding tissues being in contact with the wire, with however limited consequences given the biocompatibility of gold material and the small wire dimensions (diameter 0.55 mm, maximal length 2.70mm). In the case of improper fixation of the gold wire, though this hypothesis is very improbable, migration of these small dimensioned gold wires in the surrounding tissues is theoretically possible and it would be easily detected on the X-ray films that are routinely taken during patient follow-up.
For the patients that may have received the implant, the absence of gold wires(markers) at treated segment site or migration of these wires in the areas adjacent to the treated segment is a sign of using a non-conforming device that must be notified as AE (Adverse Event) related to the device by normal vigilance procedure.
Though no adverse event or incident was reported until now, we prefer to inform health practitioners on all the potential (even most improbable) risks in order to allow them take decisions with regard to the best follow up needed for the health and security of their patients.

Immediate measures to be implemented
Our registers show that some devices affected by this recall were delivered to your Health Institution by our distributor. We kindly ask you to immediate stop using devices cited in this letter and to please follow the following instructions:

1- **Stop using all devices identified in the current FSN**
2- **Inventory your stocks, identifying the affected devices and put them on hold**
3- **Forward this Product Field Safety Notification to all who may need to be aware and to maintain awareness within your organization until this field action is complete.**
4- **Complete the last page of this document and send it to your distributor, even if the device is no longer in your inventory.**
5- **As soon as your answer is received, our customer service or your local distributor will contact you for a removal of device and their rapid replacement**

Following the Meddev Vigilance Guidance 2.12-1 recommendations, we inform you that this recall action was notified to National Competent Authorities.
Do not hesitate to send any potential question to your distributor.

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Distributor contact informations (*distributor stamp)*

Please be reminded that this is a voluntary action and no adverse event or incident was notified until now. We apologize for this inconvenience and we thank you for your cooperation and patience as we implement this precautionary measure.

Best regards,

Sabina Champain (contact person for this vigilance)

Clinical research coordinator

Cell +33 6 46 34 09 36

On behalf of

Franck FASQUEL - *General Manager, France Operations*
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FIELD SAFETY NOTICE

FSCA – lots recall

Answer to be sent within 5 working days

Reference ANSM : *201515554*
Destination : Scient'x customers, including Health Institution Directors, Local Materiovigilance Correspondents and all involved health practitioners and services
Action type : *Field Safety Corrective Action – device recall*

We have reviewed our inventory and have determined the following regarding these parts:

☐ **The Product Name DOES NOT exist in our inventory. The devices have been previously consumed or discarded:**

☐ **The Product Name exists in our inventory, and will be returned immediately:**

☐ **Other:**

_____

☐ **This information was communicated to all persons who may need to be aware of**

Form filled by :			
Name		Health institution	
Adress		Title(function)	
		Telephone	
		Email	

By signing below, the undersigned certifies as to the accuracy of the statements above on behalf of the client center listed below.

Read and agreed:
By (First name Last name) :
Title : Health institution stamp

