

12 April 2013

Return Receipt Requested

URGENT NOTICE: MEDICAL DEVICE RECALL Synthes CMF MatrixNEURO Screws

Dear Sir/ Madam:

Synthes is initiating a voluntary recall of the below mentioned lots of the CMF MatrixNEURO due to the possibility that clips on the screws may be incorrectly etched with the wrong length.

Each screw is packaged in a "clip" that has a laser etch corresponding to the length of the screw. It has been reported that the etch on the clip does not correspond to the length of the screw. There have been instances in which the screw was longer than the specified etch, as well as the screw being shorter than the specified etch. Please note: there has not been any adverse event to patient reported with use of these screws. In all cases of complaints received, there was no patient involvement.

There is a remote probability that the presence of a screw that is packaged in the incorrect clip holder will result in a serious adverse event, including death. There is a remote probability that a medically reversible or transient adverse health event will result due to a screw being packaged in the incorrect clip holder. There is the potential specific to Matrix Neuro screws, where the incorrect screw length being utilized may result in a life-threatening event for population at greatest risk (Pediatric patients; Pediatric and adult patients with skull deformities/lesions; Patients with previous diseases of the bone or bone metabolism resulting in bone mass reduction).

Synthes is requesting that you please examine your inventory for all products with the Part numbers listed below. Synthes strongly urges you to return the identified devices and replacement product will be provided once it becomes available. However, due to the medical importance of these products and the potential lack of readily available alternative products, a secondary alternative is being provided. If returning them would adversely impact your ability to provide necessary medical care to patients you may measure your screws prior to use, using the measuring scale provided in the graphic case, and utilize them as needed. If sterile screws are measured prior to use, please re-sterilize the screws per SE_023827 AH.

FULL RECALLED PRODUCT LIST:

Part Description	Part Number	Lot Number
CMF Matrix NEURO Screws	See attached	See attached

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If you **DO have** any of the identified screws and intend to **return** them for credit, please take the following steps:

1. Please remove and return the above mentioned articles / lots from your inventory immediately.
2. Complete the attached reply form indicating your receipt of this letter and that you intend to return the screws. Return the completed form by fax or email to your local Synthes sales organisation.

If you **DO have** any of the identified screw and **intend to measure** them and use them or measure/re-sterilize and use them. Please take the following steps:

1. Complete the attached reply form indicating your receipt of this letter and that you re-measure/re-sterilize the screws. Return the completed form by fax or email to your local Synthes sales organisation.

If you **DO NOT** have the identified product, please take the following steps

1. Complete the attached reply form indicating your receipt of this letter. Return the completed form by fax or email to your local Synthes sales organisation.

We apologise for any inconvenience this may cause and thank you in advance for your attention and cooperation. Please contact your Synthes Sales Consultant for additional information as required.

Sincerely,

A blue ink signature of Claudia Allemann, consisting of a stylized 'C' followed by a horizontal line.

Claudia Allemann
Field Action Manager

A blue ink signature of Markus Wien, featuring a stylized 'M' and 'W'.

Markus Wien
Director Quality Assurance Operations



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Synthes CMF MatrixNEURO Screws

Verification Section

Part Description	Part Number	Lot Number
CMF MatrixNEURO Screws	See attached	See attached

I have located the identified product in stock; returned quantity for replacement is documented below.

I have located the identified product in stock and will re-measure/ re-sterilize if applicable prior to use.

I do not have any identified product in stock; returned quantity is zero.

RETURNED DEVICES (including quantity):

Name/Title (please print)

Phone Number:

Signature and Date:

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Affected articles and lots:

System	Affected Lots	Article Numbers																																																																													
MatrixNEURO (non-sterile)	<div style="border: 2px solid red; padding: 5px; text-align: center;"> <p>RETURN</p> <p>Lots less than ($<$) 7111955 must be returned.</p> </div>	04.503.103.01C 04.503.104.01C 04.503.105.01C 04.503.113.01C																																																																													
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