

12 April 2013

Return Receipt Requested

**URGENT NOTICE: MEDICAL DEVICE RECALL**  
**Synthes CMF MatrixMIDFACE, MANDIBLE and ORTHOGNATHIC Screws**

Dear Sir/ Madam:

Synthes is initiating a voluntary recall of the below mentioned lots of the CMF MatrixMIDFACE, MANDIBLE and ORTHOGNATHIC 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.

It is not likely that the presence of a screw that is packaged in the incorrect clip holder will result in a serious adverse event. 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.

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 MatrixMIDFACE, MANDIBLE and ORTHOGNATHIC 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 screws 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

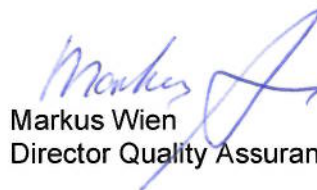
1. Complete the attached reply form indicating your receipt of this letter. Return the completed form by fax or email to your local Synthes sales organisation.

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 several fluid, overlapping strokes.

Claudia Allemann  
Field Action Manager

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

Markus Wien  
Director Quality Assurance Operations

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**URGENT NOTICE: MEDICAL DEVICE RECALL**  
**Synthes CMF MatrixMIDFACE, MANDIBLE and ORTHOGNATHIC**

**Verification Section**

Part Description	Part Number	Lot Number
CMF Matrix Mandible, Midface and Orthognathic 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):

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Name/Title (please print)

Phone Number:

Signature and Date:

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**Affected articles and lots:**

System	Lot Numbers	Article Numbers			
MatrixMIDFACE (non-sterile)	<b>RETURN</b> Lots less than (<) 7111955 must be returned.	04.503.203.01C	04.503.208.01C	04.503.224.01C	04.503.233.01C
	<b>KEEP</b> Non-affected lots can be used 6969490 7059606 7049532	04.503.203.04C	04.503.208.04C	04.503.224.04C	04.503.234.01C
MatrixMANDIBLE (non-sterile)	<b>RETURN</b> Lots less than (<) 7111955 must be returned.	04.503.204.01C	04.503.210.01C	04.503.225.01C	04.503.235.01C
	<b>KEEP</b> Non-affected lots can be used 6869915 7062757 6882168 7088960 6882169 7097254 6977107 7100140 6984029 7101798 7029754 7103852 7053418 7104996 7055260	04.503.204.04C	04.503.210.04C	04.503.225.04C	04.503.236.01C
		04.503.205.01C	04.503.212.01C	04.503.226.01C	04.503.238.01C
		04.503.205.04C	04.503.212.04C	04.503.226.04C	04.503.240.01C
		04.503.206.01C	04.503.223.01C	04.503.228.01C	04.503.242.01C
		04.503.206.04C	04.503.223.04C	04.503.228.04C	
		04.503.405.01C	04.503.442.01C	04.503.556.01C	04.503.642.01C
		04.503.405.04C	04.503.442.04C	04.503.556.04C	04.503.642.04C
		04.503.406.01C	04.503.444.01C	04.503.558.01C	04.503.644.01C
		04.503.406.04C	04.503.444.04C	04.503.558.04C	04.503.644.04C
		04.503.408.01C	04.503.446.01C	04.503.605.01C	04.503.646.01C
		04.503.408.04C	04.503.446.04C	04.503.605.04C	04.503.646.04C
		04.503.410.01C	04.503.448.01C	04.503.606.01C	04.503.648.01C
		04.503.410.04C	04.503.448.04C	04.503.606.04C	04.503.648.04C
		04.503.412.01C	04.503.465.01C	04.503.608.01C	04.503.668.01C
		04.503.412.04C	04.503.466.01C	04.503.608.04C	04.503.668.04C
		04.503.414.01C	04.503.468.01C	04.503.610.01C	04.503.670.01C
		04.503.414.04C	04.503.470.01C	04.503.610.04C	04.503.670.04C
		04.503.416.01C	04.503.472.01C	04.503.612.01C	04.503.672.01C
		04.503.416.04C	04.503.474.01C	04.503.612.04C	04.503.672.04C
		04.503.418.01C	04.503.476.01C	04.503.614.01C	04.503.674.01C
		04.503.418.04C	04.503.478.01C	04.503.614.04C	04.503.674.04C
		04.503.435.01C	04.503.506.01C	04.503.616.01C	04.503.676.01C
		04.503.435.04C	04.503.508.01C	04.503.616.04C	04.503.676.04C
		04.503.436.01C	04.503.546.01C	04.503.618.01C	04.503.678.01C
		04.503.436.04C	04.503.548.01C	04.503.618.04C	04.503.678.04C
		04.503.438.01C	04.503.554.01C	04.503.638.01C	
		04.503.438.04C	04.503.554.04C	04.503.638.04C	
		04.503.440.01C	04.503.555.01C	04.503.640.01C	
		04.503.440.04C	04.503.555.04C	04.503.640.04C	

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System	Affected Lots	Article Numbers			
Matrix ORTHOGNATHIC (non-sterile)	<b>RETURN</b> Lots less than (<) 7111955 must be returned.	04.511.204.01C	04.511.212.01C	04.511.225.01C	04.511.240.01C
	<b>KEEP</b> Non-affected lots can be used 7090634	04.511.204.04C	04.511.212.04C	04.511.225.04C	04.511.242.01C
Matrix ORTHOGNATHIC Lock (non-sterile)	<b>RETURN</b> Lots less than (<) 7111955 must be returned.	04.511.604.01C	04.511.614.01C	04.511.635.01C	04.511.664.01C
	<b>KEEP</b> Non-affected lots can be used 6666479 6871746 6678850 6874652 6679990 6876317 6679991 6876920 6681189 6878221 6683405 6883551 6684310 6884367 6686369 6884504 6688640 6886582 6688641 6886975 6688642 6887176 6694635 6891187 6758074 6891491 6855348 6894558 6856470 6895117 6870553 6896095 6870734 6896286 6871412	04.511.604.04C	04.511.616.01C	04.511.635.04C	04.511.664.04C

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System	Affected Lots	Article Numbers		
MatrixMANDIBLE (sterile)	<p><b>RETURN</b></p> <p>Lots less than (&lt;) 8363887 must be returned.</p>	04.503.506.01S	04.503.554.01S	04.503.556.01S
	<p><b>KEEP</b></p> <p>Non-affected lots can be used</p> <p>8318071    8338211</p>	04.503.508.01S	04.503.554.04S	04.503.556.04S
Matrix ORTHOGNATHIC Lock (sterile)	<p><b>RETURN</b></p> <p>Lots less than (&lt;) 8363887 must be returned.</p>	04.511.605.01S	04.503.555.01S	04.503.558.01S
	<p><b>KEEP</b></p> <p>Non-affected lots can be used</p> <p>8359198    8359278    8360460</p> <p>8359217    8359279    8360461</p> <p>8359223    8360408    8360462</p> <p>8359256    8360412    8360464</p> <p>8359261    8360421    8360471</p> <p>8359265    8360450    8360472</p> <p>8359270    8360451    8360473</p> <p>8359273    8360452    8360474</p>	04.511.604.01S	04.511.624.01S	04.511.640.01S
		04.511.604.04S	04.511.624.04S	04.511.640.04S
		04.511.605.04S	04.511.625.01S	04.511.642.01S
		04.511.605.04S	04.511.625.04S	04.511.642.04S
		04.511.606.01S	04.511.626.01S	04.511.644.01S
		04.511.606.04S	04.511.626.04S	04.511.646.01S
		04.511.608.01S	04.511.628.01S	04.511.648.01S
		04.511.608.04S	04.511.628.04S	04.511.664.01S
		04.511.610.01S	04.511.634.01S	04.511.664.04S
		04.511.610.04S	04.511.634.04S	04.511.665.01S
		04.511.612.01S	04.511.635.01S	04.511.665.04S
		04.511.612.04S	04.511.635.04S	04.511.666.01S
		04.511.614.01S	04.511.636.01S	04.511.666.04S
		04.511.616.01S	04.511.636.04S	04.511.668.01S
		04.511.618.01S	04.511.638.01S	04.511.668.04S
			04.511.638.04S	

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System	Affected Lots	Article Numbers
Matrix ORTHOGNATHIC (sterile)	<b>RETURN</b> Lots less than (<) 8363887 must be returned.	04.511.204.01S 04.511.214.01S 04.511.228.01S 04.511.204.04S 04.511.214.04S 04.511.228.04S 04.511.205.01S 04.511.216.01S 04.511.234.01S 04.511.205.04S 04.511.216.04S 04.511.235.01S 04.511.206.01S 04.511.218.01S 04.511.236.01S 04.511.206.04S 04.511.218.04S 04.511.238.01S 04.511.208.01S 04.511.224.01S 04.511.240.01S 04.511.208.04S 04.511.224.04S 04.511.242.01S 04.511.210.01S 04.511.225.01S 04.511.244.01S 04.511.210.04S 04.511.225.04S 04.511.246.01S 04.511.212.01S 04.511.226.01S 04.511.248.01S 04.511.212.04S 04.511.226.04S
	<b>KEEP</b> Non-affected lots can be used 8243289 8355945 8358438 8243291 8355949 8358440 8258806 8355950 8358441 8268433 8355991 8358444 8277818 8355992 8358452 8281606 8355993 8358454 8292130 8355994 8358456 8301234 8355998 8358463 8303161 8355999 8358464 8313290 8356000 8359187 8313291 8356002 8363828 8321602 8356003 8363829 8321603 8356004 8363830 8323956 8356005 8363831 8338333 8356006 8363845 8346378 8357589 8363846 8346379 8358409 8363847 8346380 8358410 8363848 8346383 8358411 8363849 8346435 8358412 8363851 8349862 8358413 8363852 8355905 8358414 8363853 8355906 8358415 8363854 8355907 8358418 8363855 8355939 8358423 8363882 8355940 8358430 8363883 8355941 8358432 8363885 8355942 8358433 8363886 8355943 8358434 8355944 8358435	