

27 March 2017

**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

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.

Yours sincerely,

Marinah Ahmad  
Regulatory Affairs Associate

cc: Chairman Medical Board  
Relevant Head of Departments

**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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Hospital name & Stamp: \_\_\_\_\_

Name/Title (please print) \_\_\_\_\_

Phone Number: \_\_\_\_\_

Signature and Date: \_\_\_\_\_

**Affected articles and lots:**

System	Lot Numbers	Article Numbers
MatrixMIDFACE (non-sterile)	<div> <b>RETURN</b>                      Lots less than                      (&lt;) 7111955                      must be                      returned.                 </div> <div> <b>KEEP</b>                      Non-affected                      lots can be                      used                      6969490      7059606                      7049532                 </div>	04.503.203.01C    04.503.208.01C    04.503.224.01C    04.503.233.01C 04.503.203.04C    04.503.208.04C    04.503.224.04C    04.503.234.01C 04.503.204.01C    04.503.210.01C    04.503.225.01C    04.503.235.01C 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
MatrixMANDIBLE (non-sterile)	<div> <b>RETURN</b>                      Lots less than                      (&lt;) 7111955                      must be                      returned.                 </div> <div> <b>KEEP</b>                      Non-affected                      lots can be                      used                      6869915      7062757                      6882168      7088960                      6882169      7097254                      6977107      7100140                      6984029      7101798                      7029754      7103852                      7053418      7104996                      7055260                 </div>	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

System	Affected Lots	Article Numbers			
Matrix ORTHOGNATHIC (non-sterile)	<div> <b>RETURN</b>                      Lots less than                      (&lt;) 7111955                      must be                      returned.                 </div>	04.511.204.01C 04.511.212.01C 04.511.225.01C 04.511.240.01C 04.511.204.04C 04.511.212.04C 04.511.225.04C 04.511.242.01C 04.511.205.01C 04.511.214.01C 04.511.226.01C 04.511.244.01C 04.511.205.04C 04.511.214.04C 04.511.226.04C 04.511.246.01C 04.511.206.01C 04.511.216.01C 04.511.228.01C 04.511.248.01C 04.511.206.04C 04.511.216.04C 04.511.228.04C 04.511.208.01C 04.511.218.01C 04.511.234.01C 04.511.208.04C 04.511.218.04C 04.511.235.01C 04.511.210.01C 04.511.224.01C 04.511.236.01C 04.511.210.04C 04.511.224.04C 04.511.238.01C			
	<div> <b>KEEP</b>                      Non-affected                      lots can be                      used                      7090634                 </div>				
Matrix ORTHOGNATHIC Lock (non-sterile)	<div> <b>RETURN</b>                      Lots less than                      (&lt;) 7111955                      must be                      returned.                 </div>	04.511.604.01C 04.511.614.01C 04.511.635.01C 04.511.664.01C 04.511.604.04C 04.511.616.01C 04.511.635.04C 04.511.664.04C 04.511.605.01C 04.511.618.01C 04.511.636.01C 04.511.665.01C 04.511.605.04C 04.511.624.01C 04.511.636.04C 04.511.665.04C 04.511.606.01C 04.511.624.04C 04.511.638.01C 04.511.666.01C 04.511.606.04C 04.511.625.01C 04.511.638.04C 04.511.666.04C 04.511.608.01C 04.511.625.04C 04.511.640.01C 04.511.668.01C 04.511.608.04C 04.511.626.01C 04.511.640.04C 04.511.668.04C 04.511.610.01C 04.511.626.04C 04.511.642.01C 04.511.610.04C 04.511.628.01C 04.511.642.04C 04.511.612.01C 04.511.628.04C 04.511.644.01C 04.511.612.04C 04.511.634.01C 04.511.646.01C 04.511.634.04C 04.511.648.01C			
	<div> <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                 </div>				

System	Affected Lots	Article Numbers
MatrixMANDIBLE (sterile)	<div> <b>RETURN</b>                      Lots less than                      (&lt;) 8363887                      must be                      returned.                 </div> <div> <b>KEEP</b>                      Non-affected lots can be                      used                      8318071    8338211                 </div>	04.503.506.01S    04.503.554.01S    04.503.556.01S 04.503.508.01S    04.503.554.04S    04.503.556.04S 04.503.546.01S    04.503.555.01S    04.503.558.01S 04.503.548.01S    04.503.555.04S    04.503.558.04S
Matrix ORTHOGNATHIC Lock (sterile)	<div> <b>RETURN</b>                      Lots less than                      (&lt;) 8363887                      must be                      returned.                 </div> <div> <b>KEEP</b>                      Non-affected lots can be                      used                      8359198    8359278    8360460                      8359217    8359279    8360461                      8359223    8360408    8360462                      8359256    8360412    8360464                      8359261    8360421    8360471                      8359265    8360450    8360472                      8359270    8360451    8360473                      8359273    8360452    8360474                 </div>	04.511.604.01S    04.511.624.01S    04.511.640.01S 04.511.604.04S    04.511.624.04S    04.511.640.04S 04.511.605.01S    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

System	Affected Lots	Article Numbers																																																																																								
Matrix ORTHOGNATHIC (sterile)	<div>RETURN</div> <div>Lots less than (<math>&lt;</math>) 8363887 must be returned.</div>	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																																																																																								
	<div>KEEP</div> <div>Non-affected lots can be used</div> <table><tr><td>8243289</td><td>8355945</td><td>8358438</td></tr><tr><td>8243291</td><td>8355949</td><td>8358440</td></tr><tr><td>8258806</td><td>8355950</td><td>8358441</td></tr><tr><td>8268433</td><td>8355991</td><td>8358444</td></tr><tr><td>8277818</td><td>8355992</td><td>8358452</td></tr><tr><td>8281606</td><td>8355993</td><td>8358454</td></tr><tr><td>8292130</td><td>8355994</td><td>8358456</td></tr><tr><td>8301234</td><td>8355998</td><td>8358463</td></tr><tr><td>8303161</td><td>8355999</td><td>8358464</td></tr><tr><td>8313290</td><td>8356000</td><td>8359187</td></tr><tr><td>8313291</td><td>8356002</td><td>8363828</td></tr><tr><td>8321602</td><td>8356003</td><td>8363829</td></tr><tr><td>8321603</td><td>8356004</td><td>8363830</td></tr><tr><td>8323956</td><td>8356005</td><td>8363831</td></tr><tr><td>8338333</td><td>8356006</td><td>8363845</td></tr><tr><td>8346378</td><td>8357589</td><td>8363846</td></tr><tr><td>8346379</td><td>8358409</td><td>8363847</td></tr><tr><td>8346380</td><td>8358410</td><td>8363848</td></tr><tr><td>8346383</td><td>8358411</td><td>8363849</td></tr><tr><td>8346435</td><td>8358412</td><td>8363851</td></tr><tr><td>8349862</td><td>8358413</td><td>8363852</td></tr><tr><td>8355905</td><td>8358414</td><td>8363853</td></tr><tr><td>8355906</td><td>8358415</td><td>8363854</td></tr><tr><td>8355907</td><td>8358418</td><td>8363855</td></tr><tr><td>8355939</td><td>8358423</td><td>8363882</td></tr><tr><td>8355940</td><td>8358430</td><td>8363883</td></tr><tr><td>8355941</td><td>8358432</td><td>8363885</td></tr><tr><td>8355942</td><td>8358433</td><td>8363886</td></tr><tr><td>8355943</td><td>8358434</td><td></td></tr><tr><td>8355944</td><td>8358435</td><td></td></tr></table>	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
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27 March 2017

**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



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.

Yours sincerely,

Marinah Ahmad  
Regulatory Affairs Associate

cc: Chairman Medical Board  
Relevant Head of Departments

**URGENT NOTICE: MEDICAL DEVICE RECALL**  
**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):

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Hospital name & Stamp: \_\_\_\_\_

Name/Title (please print) \_\_\_\_\_

Phone Number: \_\_\_\_\_

Signature and Date: \_\_\_\_\_

### Affected articles and lots:

System	Affected Lots	Article Numbers			
MatrixNEURO (non-sterile)	<div>RETURN</div> <div>Lots less than (&lt;) 7111955 must be returned.</div>	04.503.103.01C	04.503.104.01C	04.503.105.01C	04.503.113.01C
		04.503.103.04C	04.503.104.04C	04.503.105.04C	04.503.114.01C 04.503.115.01C
	<div>KEEP</div> <div>Non-affected lots can be used</div> <div><div><div>69074647032270</div><div>69456177033509</div><div>69463417033510</div><div>69483007033511</div><div>69496977034840</div><div>69522637050254</div><div>69531237051271</div><div>69592677051517</div><div>69623217052572</div><div>69630947052790</div><div>69630957053832</div><div>69633467055919</div><div>69717947055920</div><div>69725377056966</div><div>69725387056967</div><div>69910147058312</div><div>70046697058313</div><div>70099297059725</div><div>70118267059726</div><div>70135497060003</div><div>70168327060486</div><div>70179097061104</div><div>70188127062262</div><div>70226397063408</div><div>70226407064295</div><div>70237497065201</div><div>70237507066951</div><div>70249767067405</div><div>70249777068268</div><div>70260337069226</div><div>70262717071197</div><div>70271957071198</div><div>70277737071245</div><div>70280737071863</div><div>70291947076575</div><div>70298267072402</div><div>70308857072465</div><div>70308867073426</div><div>70312757074024</div></div></div>				