

# Medical Device Alert

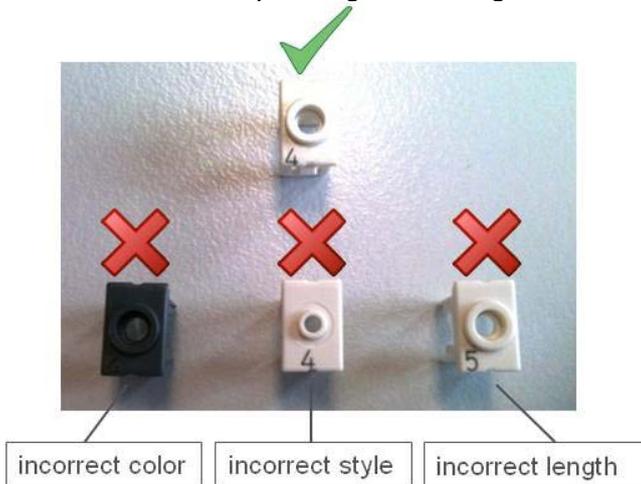
Ref: MDA/2013/044 Issued: 20 June 2013 at 15:30

Device
<p>Implantable screw: MatrixMANDIBLE, MatrixNEURO, MatrixMIDFACE and MatrixORTHOGNATHICS.</p> <p>Manufactured by Synthes GmbH.</p> <p>Specific lot numbers affected.</p>

Problem	Action
<p>Recall due to incorrectly etched screw size on the screw-holding clip (see picture).</p> <p>The use of an incorrectly sized screw could lead to clinical complications including dural injury, bleeding and failure of fracture fixation.</p>	<ul style="list-style-type: none"> <li>• Identify and quarantine any unimplanted affected devices using the list of lot numbers in the manufacturer's <a href="#">Field Safety Notice (FSN)</a></li> <li>• Return unused affected devices to the manufacturer.</li> <li>• If there are no alternatives and you need to use the affected screws you should confirm the length of the screw prior to use by measuring it on the measuring scale provided on the case.</li> <li>• The manufacturer advises that patients who have had procedures using the Synthes CMF Matrix Screws should be followed up using standard diagnostic evaluation and treatment protocols. If the follow-up reveals risk to vessels or dura, the potential for inadequate fixation or potential loss of fixation due to incorrect screw length, standard diagnostic evaluation and treatment protocols for these types of events should be followed.</li> </ul>
Action by	
<ul style="list-style-type: none"> <li>• Neurosurgeons</li> <li>• Oral / maxillofacial surgeons</li> <li>• Ophthalmic surgeons</li> <li>• Paediatric surgeons</li> <li>• Plastic surgeons</li> <li>• Supplies managers</li> <li>• Sterile services managers</li> <li>• Theatre managers</li> </ul>	
CAS deadlines	Contact
<p>Action underway: 04 July 2013 Action complete: 11 July 2013</p> <p><b>Note: These deadlines are for systems to be in place to take actions and not for the completion of patient follow-up.</b></p>	<p><b>Manufacturer</b> Claudia Allemann Synthes GmbH Tel: +41 32 720 72 24 Email: <a href="mailto:allemann.claudia@synthes.com">allemann.claudia@synthes.com</a></p>

## Device

The affected screws were first distributed in July 2007. Each screw is held within a clip that has a number etched on it, corresponding to the length of the screw.



## Problem

The manufacturer has received reports of instances where the number etched on the screw holder does not match the length of the screw. This includes screws being labelled as being longer or shorter than they actually are. However, the outer packaging of the device has the correct screw size.

The use of an incorrectly sized **MatrixMANDIBLE**, **MatrixMIDFACE** and **MatrixORTHOGNATHICS** screw could lead to inadequate fixation or loss of fixation.

The use of an incorrectly sized **MatrixNEURO** screw may result in a life threatening event for patients at greatest risk. If the screw is too long, the greatest risks are posed to paediatric patients, patients with skull deformities, and patients with face lesions because they are predisposed to having skulls that may not be as thick as the largest available screw (5mm). If a screw is longer than anticipated it may come into contact with the patient's dura and small vessels.

The manufacturer has recalled these devices and will be offering an alternative.

## Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams for information
- NHS trusts in England (chief executives)

### Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

### Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Neurosurgeons
- Oral / maxillofacial surgeons
- Ophthalmic surgeons

- Paediatric surgeons
- Plastic surgeons
- Risk managers
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Sterile services

## Independent distribution

### Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Hospitals in the independent sector
- Independent treatment centres

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: [safetyalerts@dh.gsi.gov.uk](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## Contacts

### Manufacturer

Synthes GmbH  
Luzernstrasse 21  
CH-4528  
Zuchwil  
Switzerland  
Tel: +41 32 720 72 24

Fax: +41 79 345 96 93

Email: [allemann.claudia@synthes.com](mailto:allemann.claudia@synthes.com)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/044** or **2013/004/019/291/014**

### Technical aspects

John McManus or Salma Husain  
Medicines & Healthcare products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 7226 / 6729

Fax: 020 8754 3965

Email: [john.mcmanus@mhra.gsi.gov.uk](mailto:john.mcmanus@mhra.gsi.gov.uk)  
[salma.husain@mhra.gsi.gov.uk](mailto:salma.husain@mhra.gsi.gov.uk)

### Clinical aspects

Carol Lowry or Kayleigh Purdon  
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151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 7248 / 7032

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[kayleigh.purdon@mhra.gsi.gov.uk](mailto:kayleigh.purdon@mhra.gsi.gov.uk)

## How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>

Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

## Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre

Health Estates Investment Group, Room 17, Annex 6, Castle Buildings, Stormont Estate,  
Dundonald BT4 3SQ

Tel: 02890 523 704 Fax: 02890 523 900 Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

## How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

## Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

Health Facilities Scotland, NHS National Services Scotland, Gyle Square, 1 South Gyle Crescent,  
Edinburgh EH12 9EB

Tel: 0131 275 7575 Fax: 0131 314 0722 Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

## Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team

Medical Directorate, Welsh Government, Cathays Park, Cardiff CF10 3NQ

Tel: 029 2082 3922 Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

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