

## To the ATTENTION of: Operating room manager

16 August 2013

### **URGENT MEDICAL DEVICE PRODUCT REMOVAL**

**Part Description / Part Number: see list at the end of this letter**

Dear Madam / Dear Sir,

Synthes is initiating a medical device removal regarding the below mentioned article and lot numbers of various MultiLoc, Locking and LISS Screws. Our records indicate that you have inventory that is impacted by this removal.

Description of problem:

Synthes received a complaint by a surgeon that a MultiLoc screw with a deformed cross-hole (recess) was identified in the Loan Office.

The root cause for this non-conformance is an employee who failed to follow established processes.

Patient risk:

The presence of a screw that is out of specification may be detected prior to insertion. In this situation it is likely that the surgical delay would be minimal while an alternative screw is located and inserted. The screw may also be difficult to insert and/remove due to the non-conformance. If the screw was inserted and the non-conformance was detected after implantation a surgical delay may result, during removal, exposing the patient to increased amounts of anesthesia and IV fluids.


If the non-conforming screw is not detected by the surgeon and the index procedure is completed there is the potential that the screw will not perform as anticipated during the post operative recovery period. Per information provided by manufacturing the non-conforming screw has a smaller outer diameter. There is an increased risk of screw loosening and backout in this scenario. This can result in prolonged healing, pain, and the need for an additional surgical intervention. Permanent impairment is not anticipated.

Customer immediate actions:

1. Immediately identify and quarantine all unused products listed below in a manner that ensures the affected products will not be used.
2. Review, complete, sign and return the attached reply form to your local Synthes sales organisation in accordance with the directions on the form within 5 business days of receipt of this notification.
3. Return any affected product within 30 business days. A credit note will be issued for the returned items.
4. Forward this notice to anyone in your facility that needs to be informed.
5. If any product listed below has been forwarded to another facility, contact that facility to arrange return.
6. Maintain awareness of this notice until all products listed below have been returned to Synthes GmbH.
7. Maintain a copy of this notice.

The applicable regulatory agencies are being notified. Synthes GmbH is voluntarily taking this action.

We apologise for any inconvenience that this product removal may create and appreciate your cooperation with our request. Should you have any queries please do not hesitate to contact your Synthes sales representative.

Synthes GmbH	
	
Claudia Allemann	Markus Wien
Field Action Manager	Director Quality Assurance Operations
Cc:	

Thank you for your attention and cooperation.



## NOTICE: MEDICAL DEVICE REMOVAL R2013531

### Verification Section

Part Number	Part Description	Lot Numbers
See list below	Locking Screws	See list below
See list below	MultiLoc™ Screw Ø 4.5 mm	See list below
422.396	LISS Screw Ø 5.0 mm, self-drilling, length 75 mm, Titanium Alloy (TAN)	2608172

- We have located the identified product in stock; returned quantity is documented below, and a copy of this letter is being retained for our records.
- We do not have any identified product in stock; returned quantity is zero. We have retained a copy of this letter for our records.

RETURNED DEVICES (including quantity) and/or COMMENTS:

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Hospital name: \_\_\_\_\_

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

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

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



List of affected articles and lots:

Part Number	Part Description	Lot Numbers
412.105	Locking Screw Stardrive® Ø 3.5 mm, self-tapping, length 18 mm, Titanium Alloy (TAN)	8096478
412.118	Locking Screw Stardrive® Ø 3.5 mm, self-tapping, length 42 mm, Titanium Alloy (TAN)	8191927
413.012	Locking Screw Ø 3.5 mm, self-tapping, length 12 mm, Titanium Alloy (TAN)	7959360
413.016	Locking Screw Ø 3.5 mm, self-tapping, length 16 mm, Titanium Alloy (TAN)	7942778, 7942780
413.018	Locking Screw Ø 3.5 mm, self-tapping, length 18 mm, Titanium Alloy (TAN)	7960597
413.022	Locking Screw Ø 3.5 mm, self-tapping, length 22 mm, Titanium Alloy (TAN)	8025620
413.024	Locking Screw Ø 3.5 mm, self-tapping, length 24 mm, Titanium Alloy (TAN)	8059925
413.026	Locking Screw Ø 3.5 mm, self-tapping, length 26 mm, Titanium Alloy (TAN)	7942961
413.028	Locking Screw Ø 3.5 mm, self-tapping, length 28 mm, Titanium Alloy (TAN)	7942970
413.052	Locking Screw Ø 3.5 mm, self-tapping, length 52 mm, Titanium Alloy (TAN)	7726637
413.314	Locking Screw Ø 5.0 mm, self-tapping, length 14 mm, Titanium Alloy (TAN)	2778859
413.326	Locking Screw Ø 5.0 mm, self-tapping, length 26 mm, Titanium Alloy (TAN)	8026431
413.330	Locking Screw Ø 5.0 mm, self-tapping, length 30 mm, Titanium Alloy (TAN)	2780937
413.332	Locking Screw Ø 5.0 mm, self-tapping, length 32 mm, Titanium Alloy (TAN)	2781981; 2787491; 2789949; 8060334; 8186508
413.334	Locking Screw Ø 5.0 mm, self-tapping, length 34 mm, Titanium Alloy (TAN)	2780175
413.336	Locking Screw Ø 5.0 mm, self-tapping, length 36 mm, Titanium Alloy (TAN)	2787481; 8026415; 8186512
413.338	Locking Screw Ø 5.0 mm, self-tapping, length 38 mm, Titanium Alloy (TAN)	2775053; 2781982
413.340	Locking Screw Ø 5.0 mm, self-tapping, length 40 mm, Titanium Alloy (TAN)	8026418
413.342	Locking Screw Ø 5.0 mm, self-tapping, length 42 mm, Titanium Alloy (TAN)	8026405
413.344	Locking Screw Ø 5.0 mm, self-tapping, length 44 mm, Titanium Alloy (TAN)	8060964

413.360	Locking Screw Ø 5.0 mm, self-tapping, length 60 mm, Titanium Alloy (TAN)	7909289
413.365	Locking Screw Ø 5.0 mm, self-tapping, length 65 mm, Titanium Alloy (TAN)	2784475; 7717554
413.375	Locking Screw Ø 5.0 mm, self-tapping, length 75 mm, Titanium Alloy (TAN)	2756450; 2780172
413.380	Locking Screw Ø 5.0 mm, self-tapping, length 80 mm, Titanium Alloy (TAN)	2755486; 2780173
413.385	Locking Screw Ø 5.0 mm, self-tapping, length 85 mm, Titanium Alloy (TAN)	2778637; 8059339
413.414	Locking Screw Ø 5.0 mm, self-drilling, length 14 mm, Titanium Alloy (TAN)	2764597
413.465	Locking Screw Ø 5.0 mm, self-drilling, length 65 mm, Titanium Alloy (TAN)	2759972; 8178395
04.019.030	MultiLoc™ Screw Ø 4.5 mm, length 30 mm, Titanium Alloy (TAN)	8200582
04.019.038	MultiLoc™ Screw Ø 4.5 mm, length 38 mm, Titanium Alloy (TAN)	8253142
04.019.040	MultiLoc™ Screw Ø 4.5 mm, length 40 mm, Titanium Alloy (TAN)	8187631
04.019.042	MultiLoc™ Screw Ø 4.5 mm, length 42 mm, Titanium Alloy (TAN)	8187613
04.019.046	MultiLoc™ Screw Ø 4.5 mm, length 46 mm, Titanium Alloy (TAN)	8187612
04.019.054	MultiLoc™ Screw Ø 4.5 mm, length 54 mm, Titanium Alloy (TAN)	8187631
413.040S	Locking Screw Ø 3.5 mm, self-tapping, length 40 mm, Titanium Alloy (TAN), sterile	8024323
413.044S	Locking Screw Ø 3.5 mm, self-tapping, length 44 mm, Titanium Alloy (TAN), sterile	7726973; 8187950
413.070S	Locking Screw Ø 3.5 mm, self-tapping, length 70 mm, Titanium Alloy (TAN), sterile	2614607
413.330S	Locking Screw Ø 5.0 mm, self-tapping, length 30 mm, Titanium Alloy (TAN), sterile	8184787
413.332S	Locking Screw Ø 5.0 mm, self-tapping, length 32 mm, Titanium Alloy (TAN), sterile	8060955
413.338S	Locking Screw Ø 5.0 mm, self-tapping, length 38 mm, Titanium Alloy (TAN), sterile	8186520
413.340S	Locking Screw Ø 5.0 mm, self-tapping, length 40 mm, Titanium Alloy (TAN), sterile	2780174
413.350S	Locking Screw Ø 5.0 mm, self-tapping, length 50 mm, Titanium Alloy (TAN), sterile	8184564
413.355S	Locking Screw Ø 5.0 mm, self-tapping, length 55 mm, Titanium Alloy (TAN), sterile	8184560
413.360S	Locking Screw Ø 5.0 mm, self-tapping, length 60 mm, Titanium Alloy (TAN), sterile	8186429