Synthes GmbH Luzernstrasse 21 4528 Zuchwil Switzerland
Tel. +41 32 720 40 60 Fax +41 32 720 40 61 http://www.depuysynthes.com/

02 March 2015

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2014189
Inserter f/TEN

Part Description, Part- and Lot Numbers

Part Description	Part Number	Lot Numbers
Inserter f/TEN	359.219	Please refer to Attachment 1 on page 4 of this notification

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of the Inserter for Titanium Elastic Nails (TEN) (part number 359.219), which is a part of the Stainless Steel and Titanium Elastic Nail Instrument and Implant set. The TEN Inserter is a handheld manual surgical instrument designed to facilitate the insertion and advancement of the TEN implant into the medullary canal of the bone. The nail is fixed in the chuck and driven in by hitting it on the back of the head with, at times, considerable force.

Our records indicate that you may have inventory that is impacted by this recall or have been using affected product(s) from a loan set.

Reason for the Recall:

The affected lots of the Inserter for Titanium Elastic Nails (TEN) may have the potential for breakage during use. It is important to note that the removal of the TEN Inserter would prevent the performance of emergency surgery, thus Synthes GmbH is not requiring an immediate return of affected product(s).

Potential hazard:

If an Inserter for Titanium Elastic Nails (TEN) breaks during use, there is the potential for surgical delay while an alternate trauma set is located to complete the procedure.

In a worst case scenario, if the Inserter for Titanium Elastic Nails (TEN) breaks during use, the breaking pieces may cause damage to surrounding structure and/or injury to user.
To manage the potential hazards involved with continued use, follow the below recommendations:

1. To prevent breaking of the cross/transversal bar of the TEN Inserter as the result of hammering, the DePuy Synthes technique guide (Document number 036.000.207 DSEM/TRM/0115/0290 01/15) specifies the following on page 20 of 64:

"Advance the nail manually up to the fracture site, using oscillating movements or with gentle blows to the impaction surface of the inserter using the slotted part of the combined hammer."

2. To prevent the chuck of the TEN Inserter from jamming, DePuy Synthes recommends (according to Function Control Manual 035.000.090 08/14):
    a. Inspecting the chuck of the TEN Inserter before and after each use. More information for preventing this occurrence can be found in the Function Control Manual (Chapter 2.40).
    b. Lubricating the chuck and the cannulation at the back of the instrument prior to sterilization with autoclavable DePuy Synthes oil (Chapter 2.40).
    c. Fully open and close the chuck without implants and check its frictionless function.

3. If the TEN Inserter breaks intraoperatively, the user may utilize optional T-Handle (part number 395.380) to complete the procedure. The T-Handle is capable of grasping the TEN and stainless steel elastic nails (listed as also available on page 57 of 306.000.207). Please note the T-Handle is not included in the Stainless Steel and Titanium Elastic Nail Instrument and Implant set.

The TEN Inserter is a reusable device. DePuy Synthes provides instruction clearly outlining the reprocessing steps and stating damaged and excessively worn products should not be used (Important Information with Cleaning and Sterilization Instructions Version SE_023827 AI).

Customer immediate actions:

We have record that your facility has received the product(s) subject to this recall. It is important to note that the removal of the product would prevent the performance of emergency surgery, thus Synthes GmbH is not requiring an immediate removal of affected product(s). Synthes GmbH is in the process of developing the replacement & recovery plan for indicated devices. Synthes GmbH will contact you as replacements become available.

1. Read the **Field Safety Notice** carefully.

2. Complete the **Verification Section** and pass it to your DePuy-Synthes representative or fax it to **6720 0750 within 2 business days.**

3. As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported as a complaint to Johnson & Johnson Medical Singapore following the usual procedure.

4. If your facility chooses to return the product(s) at this time, return any affected product within 30 business days. A credit note will be issued for the returned items.

5. Forward this notice to anyone in your facility that needs to be informed.

6. If any of the affected products has been forwarded to another facility, contact that facility to arrange return, if applicable.

7. Maintain awareness of this notice until all products listed below have been returned to DePuy Synthes.

8. Keep a copy of this notice.

The applicable regulatory agencies are being notified.

We apologize for any inconvenience that this product recall may create and appreciate your cooperation with our request. Should you have any inquiries please do not hesitate to contact your DePuy Synthes sales consultant.

Thank you for your attention and cooperation.

Yours sincerely,

Cherie Yip
Regulatory Affairs Specialist

Attachment 1: Part Description, Part and Lot Numbers subject to this recall

Product Description	Part Number	Lot Numbers								
Inserter f/TEN	359.219	1041381	1866386	3033461	3341163	3659645	7836658	8009427	8335585	8963230
		1044538	1870747	3033463	3354265	3697518	7841025	8009534	8391480	9005840
		1044543	1876261	3033464	3367964	3747212	7854778	8011027	8404433	9008515
		1049467	1883898	3051190	3382582	3747213	7881769	8011670	8435040	9025182
		1050163	1904339	3051192	3382583	3757845	7918165	8012109	8452527	9049487
		1054475	1909053	3054608	3410332	3799878	7938451	8012353	8472079	9060725
		1060406	1915684	3069566	3416289	3799879	7947886	8012925	8509639	9135455
		1067580	1929358	3084637	3421170	7502541	7978769	8013244	8523545	9154680
		1072252	1930996	3157118	3430483	7505411	8000136	8014068	8547587	9175932
		1076271	1984492	3163015	3439931	7528425	8001688	8014078	8567000	9175933
		1084477	3007469	3174430	3469282	7559128	8001981	8014654	8597291	9180263
		1095154	3009607	3191673	3481505	7565990	8002518	8015540	8603411	9256642
		1095607	3009608	3201613	3490699	7569265	8002635	8015605	8618461	A8LA417
		1121876	3009609	3212524	3493588	7579554	8003920	8015831	8641964	A8LA901
		1370583	3009705	3216811	3497030	7601112	8004538	8016063	8683130	A8MA648
		1641700	3012049	3232929	3500538	7613278	8004646	8024536	8715577	A8MB744
		1659298	3012051	3242298	3504996	7630964	8005179	8041357	8728731	A8NA025
		1806500	3015867	3242304	3505016	7638091	8005539	8073091	8752503	A8NA430
		1809277	3015868	3262318	3512716	7653257	8006103	8088552	8775453	A8NB079
		1811056	3015871	3279603	3512719	7676496	8006214	8119783	8808780	
		1811059	3020670	3301003	3522547	7676498	8007139	8192989	8820230	
		1813897	3024883	3309017	3582512	7715933	8007472	8204902	8820233	
		1813900	3024884	3318766	3614349	7742544	8008046	8214803	8820236	
		1822602	3024885	3325262	3614350	7742550	8008261	8225088	8831173	
		1833602	3028152	3325269	3626055	7774633	8008896	8232469	8857770	
		1840151	3030399	3325271	3658126	7791412	8009205	8277706	8878816	
		1849650	3030409	3325276	3658127	7810715	8009363	8311439	8902914	

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Inserter f/TEN

Please distribute this information to the appropriate personnel at your facility

Verification Section

Part Description / Part Number:

Part Description	Part Number	Lot Numbers
Inserter f/TEN	359.219	Please refer to Attachment 1 on page 4 of this notification

____ We have located the identified product in stock and acknowledge the potential hazards involved with continuing to use the product. Our facility will continue to use the TEN Inserter until replacement product becomes available. Please indicate the number of products and lot number above

____ We acknowledge receipt of this information. Our facility will not continue using the TEN Inserter and the quantity to return is listed above.

____ We acknowledge receipt of this information, but do not have any identified product in stock.

Record NUMBER OF DEVICES and Lot Number:

_____

_____

Please sign, date and stamp below. Your signature provides confirmation that you have received and understood this notification.

_____ _____

Customer Name Title

_____ _____

Signature & Date Stamp *(Stamp shall bear facility name)*

Please complete this **Verification Section** and return to your Depuy Synthes representative or fax it to +65 6720 0750 within **(2) two business days** of receipt of the Field Safety Notice.

Note: If the Verification Section is answered on behalf of more than one facility and/or individual, please clearly indicate the name and address of the facility and/or individual on this page of the notification.