Synthes GmbH
Luzernstrasse 21
4528 Zuchwil
Switzerland
Tel. +41 61 965 61 11
Fax +41 61 965 66 01
www.synthes.com

SYNTHES®

To the ATTENTION of:

- **Materials Management**
- **OR/Surgery**
- **Orthopedics**
- **Central Sterilization**
- **Reprocessing**
- **Infection Control**

22 April 2013

URGENT: MEDICAL DEVICE RECALL

Part Description / Part Number:

Part Description	Part Number	Lot Numbers
Handle, flexible, for No. 355.220	355.280	All lots (XXXXXXX) of the old handle

Dear Sir/Madam

Synthes is initiating a voluntary recall of the Handle, flexible, for No. 355.220 (Part Number 355.280), which is part of the Simplified Universal Nail System (SUN) and the Universal Nail System (UNI), due to the potential lack of the ability to thoroughly clean the instrument.

The Flexible Handle (355.280) is a mandatory device for the SUN and UNI surgical technique and is threaded onto the Hammer Guide (355.220). It may be used for insertion and is mandatory for removal of the nails.

There have been no complaints or adverse events reported with regards to this issue. The issue was discovered by Synthes internally. An evaluation of the potential risk to patient has been assessed to be remote.

Synthes is requesting that you please examine your inventory for this product(s) with the aforementioned part and lot numbers.

If you **DO have** any of the identified devices in your inventory, please take the following steps:

1. Complete the Verification Section at the end of this letter by checking the appropriate box indicating the affected product has been located. Also, please indicate the number of devices found. Please include your name, title, telephone number and signature in the spaces provided.

2. Return the Verification Form (page 4 of this letter) to your local Synthes Sales organisation.

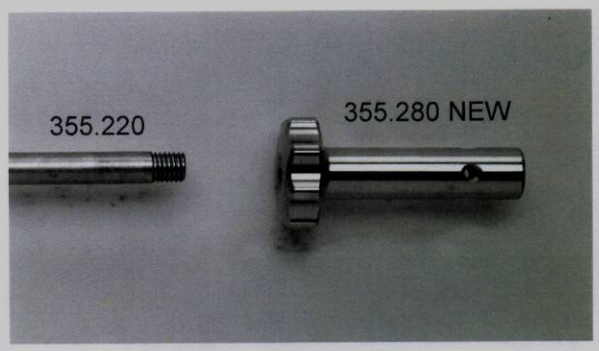
The Flexible Handle is mandatory also for removal of the nails. Therefore to allow you continuity please proceed as follows:

3. **Before returning the handles**, please **place your replacement order** with your Synthes Sales Representative under the same article number. You will receive one of the new replacement handles (please see picture below).

4. **Return** the identified old handles immediately **after reception of the new handles**.

Handle, flexible (355.280) old:

Handle (355.280) new:



If you **DO NOT** have the identified product in your inventory, please take the following steps:

- Complete the attached Verification Section at the end of this letter by checking the appropriate box indicating that no affected product has been located. Please include your name, title, telephone number and signature in the spaces provided. This return documentation acknowledges your receipt of medical device removal information.

- Return the document to your Synthes Sales organisation.

If you have any questions, please contact your Synthes Sales Representative.

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.

Synthes GmbH

Claudia Allemann
Field Action Manager

Markus Wien
Director Quality Assurance Operations

Cc:

SYNTHES®

11 April 2013 Return Receipt Requested

SYNTHES GmbH
Luzernstrasse 21
CH-4528 Zuchwil
Tel +41 32 720 40 60

URGENT NOTICE: MEDICAL DEVICE RECALL
Synthes Handle, flexible, for No. 355.220 355.280, all lots (XXXXXXX) of the old handle

Verification Section

Part Description

Part Description	Part Number	Lot Number
Handle, flexible, for No. 355.220	355.280	All lot numbers (XXXXXXX) of the old handle

☐ I have located the identified product in stock; returned quantity is documented below for replacement.

☐ I do not have any identified product in stock; returned quantity is zero.

RETURNED DEVICES (including quantity):

_____

_____

_____

_____

Name/Title: (please print)

Phone Number:

Signature and Date: