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:
Doctors using Synthes Mandible Distractor multiaxial

01 October 2012

URGENT: MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number:

Part Number	Part Description	Lot Number
487.931	Distractor Body, Titanium Alloy (TAV)	7895264 7793390 7583381 7583380 7528840 3708643 3683421 3683403 3560888
487.966	Mandible Distractor, multiaxial, right, Titanium Alloy (TAV)	7765627 7562081 7532790 3800757 3757207
487.967	Mandible Distractor, multiaxial, left, Titanium Alloy (TAV)	7834374 7662788 7562083 3757213 3739743

Dear Doctor

Synthes is initiating a Medical Device Product Removal related to the Synthes Mandible Distractor, mulitaxial.

This action is being initiated following a detailed investigation in response to a reported complaint of missing outer sheer pin. The inner diameter (for fixing the sheer pin) of the worm gear component was out of specification.

For patients who may be undergoing treatment with this device, it is advised to contact the patient to check if the device they have is one of the effected lots. If the patient is in the consolidation phase of treatment, a consolidation rod should be used according to the Surgical Technique, page 13.

If the patient is in the distraction phase of treatment and has one of these device lots, please follow the steps on page 13 of the Surgical Technique Guide which describes the application of a consolidation rod and removal of the device. Once the central body of the device has been removed as described, a new device can be put in its place and secured. The distraction arms can be preloaded by normal activation. The consolidation rod can then be removed.

To eliminate any risks Synthes decided to remove all potential affected parts from the field. Synthes is requesting that you immediately cease using the product and please examine your inventory for the above effected lot numbers and remove them. When in doubt, please remove the product and provide it to your Synthes Sales Representative.

Thank you for your attention and cooperation.

Synthes GmbH

Heinz Gribi
Manager Complaint Handling Unit

Markus Wien
Director Quality EMEA

Cc:

NOTICE: MEDICAL DEVICE RECALL

Mandible Distractor, multiaxial

Verification Section

Part Number	Part Description	Lot Number
487.931	Distractor Body, Titanium Alloy (TAV)	7895264 7793390 7583381 7583380 7528840 3708643 3683421 3683403 3560888
487.966	Mandible Distractor, multiaxial, right, Titanium Alloy (TAV)	7765627 7562081 7532790 3800757 3757207
487.967	Mandible Distractor, multiaxial, left, Titanium Alloy (TAV)	7834374 7662788 7562083 3757213 3739743

☐ We have located the identified product in stock; returned quantity is documented below, and have retained a copy of this letter for our records.

☐ We do not have any identified product in stock; returned quantity is zero, and have retained a copy of this letter for our records.

RETURNED DEVICES (including quantity):

_____

_____

_____

_____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____