

**To the ATTENTION of:
Operating room manager**

17 January 2013

URGENT: MEDICAL DEVICE FIELD SAFETY NOTICE

Part Description / Part Number: See attached list

Part Number	Part Description	Lot Numbers
05.001.012	Hand Switch, for Electric Pen Drive	AV19044; AV18166; AV20666

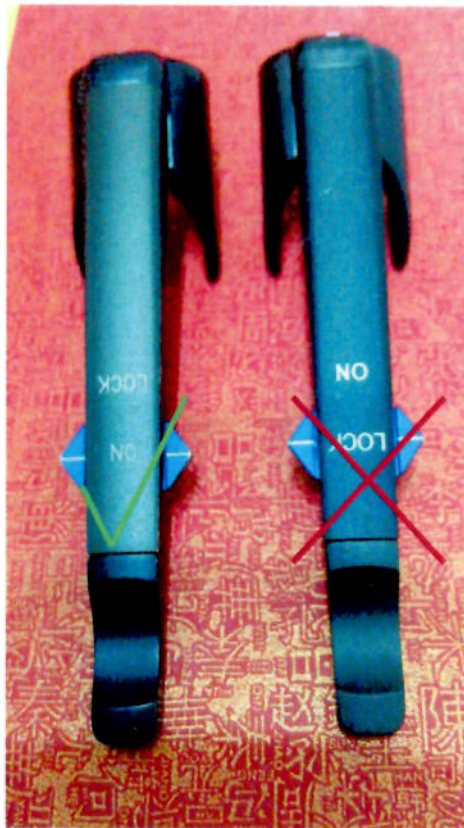
Dear Sir/Madam

Synthes is initiating a Medical Device Field Safety Notice related to the above mentioned medical device.

Synthes received one complaint about a Hand Switch, for Electric Pen Drive not labeled correctly ("on" and "lock" labels interchanged, see picture below).

Synthes requests you to immediately inspect your inventory for the above mentioned part numbers.

- Please confirm if you find correct parts in verification section below.
- If you have detected wrong parts, please send them back to Synthes immediately for replacement.



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

We apologize for the inconvenience caused.

Thank you for your attention and cooperation.

Synthes GmbH



Heinz Gribi
Manager Complaint Handling Unit



Markus Wien
Director Quality Assurance Operations

Cc:

URGENT: MEDICAL DEVICE FIELD SAFETY NOTICE

Hand Switch, for Electric Pen Drive Verification Section

Part Number	Part Description	Lot Numbers
05.001.012	Hand Switch, for Electric Pen Drive	AV19044; AV18166; AV20666

We have located the identified product in stock. Inspection of the device was done and the part was classified as correct.

We have located the identified product in stock. Inspection of the device was done and the part was classified as incorrect. The incorrect part is sent back to Synthes immediately.

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

RETURNED DEVICES (including quantity):

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____