

To the ATTENTION of: Operating room manager

21 February 2017

URGENT: MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number: See attached list

Part Number	Part Description	Lot Number
280.XXXS	DHS/DCS® Screw, Stainless Steel, sterile	see attached list (separate file)
480.XXXS	DHS/DCS® Screw, Titanium Alloy (TAN), sterile	see attached list (separate file)

Dear Sir/Madam

Synthes is initiating a medical device removal regarding the DHS/DCS® Screw, sterile. Our records indicate that you have inventory that is impacted by this removal.

Description of problem:

Synthes has two couplings in place for DHS/DCS® Screws: standard with teethed recess and octagonal recess. The pictogram on the labels of the above mentioned articles shows the wrong coupling. All the other information on the label is correct.

Customer immediate actions:

1. Please remove and return the above mentioned articles / lot numbers from your inventory immediately.
2. Complete the attached reply form indicating your receipt of this letter. Return the completed form by fax or email to your local Synthes sales organisation.

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.

Thank you for your attention and cooperation.

Synthes GmbH

Claudia Allemann
Field Action Manager

Markus Wien
Director Quality Assurance Operations

Cc:

NOTICE: MEDICAL DEVICE REMOVAL**DHS/DCS® Screw, sterile****Verification Section**

Part Description	Part Number	Lot Number
DHS/DCS® Screw, sterile	280.XXXS 480.XXXS see attached list (separate file)	see attached list (separate file)

- 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:

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____