

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

21 February 2017

URGENT: MEDICAL DEVICE FIELD SAFETY NOTIFICATION

Part Description / Part Number:

Part Number	Part Description	Lot Numbers
296.680	Transpedicular Schanz Screw Ø 5.0 mm, shaft Ø 5.0 mm, length 180/35 mm, Stainless Steel	see separate list
296.690	Transpedicular Schanz Screw Ø 6.0 mm, shaft Ø 5.0 mm, length 180/35 mm, Stainless Steel	see separate list
296.780	Transpedicular Schanz Screw Ø 7.0 mm, shaft Ø 5.0 mm, length 180/35 mm, Stainless Steel	see separate list
496.680	Transpedicular Schanz Screw Ø 5.0 mm, shaft Ø 5.0 mm, length 180/35 mm, Titanium Alloy (TAN), gold	see separate list
496.690	Transpedicular Schanz Screw Ø 6.0 mm, shaft Ø 5.0 mm, length 180/35 mm, Titanium Alloy (TAN), gold	see separate list
496.711	Transpedicular Schanz Screw Ø 5.0 mm with dual core, length 180/35 mm, Titanium Alloy (TAN), violet	see separate list
496.712	Transpedicular Schanz Screw Ø 5.0 mm with dual core, length 185/40 mm, Titanium Alloy (TAN), violet	see separate list
496.713	Transpedicular Schanz Screw Ø 5.0 mm with dual core, length 190/45 mm, Titanium Alloy (TAN), violet	see separate list
496.714	Transpedicular Schanz Screw Ø 5.0 mm with dual core, length 195/50 mm, Titanium Alloy (TAN), violet	see separate list
496.715	Transpedicular Schanz Screw Ø 5.0 mm with dual core, length 200/55 mm, Titanium Alloy (TAN), violet	see separate list
496.721	Transpedicular Schanz Screw Ø 6.2 mm with dual core, length 180/35 mm, Titanium Alloy (TAN), dark blue	see separate list
496.722	Transpedicular Schanz Screw Ø 6.2 mm with dual core, length 185/40 mm, Titanium Alloy (TAN), dark blue	see separate list
496.723	Transpedicular Schanz Screw Ø 6.2 mm with dual core, length 190/45 mm, Titanium Alloy (TAN), dark blue	see separate list
496.724	Transpedicular Schanz Screw Ø 6.2 mm with dual core, length 195/50 mm, Titanium Alloy (TAN), dark blue	see separate list
496.725	Transpedicular Schanz Screw Ø 6.2 mm with dual core, length 200/55 mm, Titanium Alloy (TAN), dark blue	see separate list
496.780	Transpedicular Schanz Screw Ø 7.0 mm, shaft Ø 5.0 mm, length 180/35 mm, Titanium Alloy (TAN)	see separate list

Dear Madam or Sir,

Synthes is initiating a Medical Device Field Safety Corrective Action related to the above mentioned medical devices.

Synthes received several complaints that the clamps could not be connected with the Transpedicular Schanz Screw, because in some cases, the shaft of the screw is too thick.

The presence of a Transpedicular Schanz Screw that will not allow a fracture clamp to slide into position is not likely to result in a serious adverse health consequence. There is a remote probability that a medically reversible health consequence could occur. In the presence of one non-conforming Transpedicular Schanz Screw a surgical delay that is not clinically significant will most likely result; less than 5 minutes would be required to exchange the offending screw. However, there is the potential for more than one screw to be non-conforming. In this situation a surgical delay that is clinically significant could result; greater than 15 minutes may be required to exchange the offending screws or replace the Transpedicular Schanz Screw system with an alternative pedicle screw construct.

Synthes advises you to take the following steps:

- Please examine your inventory for all products with the part numbers listed above.
- Before bringing the screws to the OR, please check if a clamp can be smoothly slid over the shaft of the Transpedicular Schanz Screws potentially affected.
- If the clamp can be slid over the shaft of the screw, the screw can be safely used.
- If the clamp cannot be slid over the shaft of the screw, please return the screw to your local Synthes sales organisation. Credit or replacement will be provided based on product availability.
- Review, complete, sign and return the attached reply form to your local Synthes sales organisation in accordance with the directions on the form.
- Forward this notice to anyone in your facility that needs to be informed.
- If any product listed above has been forwarded to another facility, contact that facility to arrange return.
- Maintain awareness of this notice until all products listed above have been checked.
- Please maintain a copy of this notice.

The applicable regulatory agencies are being notified. Synthes GmbH is voluntarily taking this action.

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

We apologise for any inconvenience this may cause you.

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Thank you for your attention and cooperation.

Synthes GmbH

Claudia Allemann
Field Action Manager

Markus Wien
Director Quality Assurance Operations

Cc:

URGENT: MEDICAL DEVICE FIELD SAFETY NOTIFICATION

Transpedicular Schanz Screw

Please see separate list for more details

Verification Section

We have located the identified product in stock:

- We have checked the screws and have found non-conforming screws. Returned quantity is documented below and a copy of this letter is being retained for our records.
- We have checked the screws and have not found any non-conforming screws. Returned quantity is zero 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:

Hospital name: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____