


Urgent Field Safety Notice


Product name: seleXys TH+ and seleXys TPS shells
FSCA ID no.: FSCA 15/02
Type of action: **Field Safety Notification due to higher than expected revision rate**

Bettlach, 15 September 2015

Issued by: Mathys Ltd Bettlach
Addressee: Orthopaedic Surgeons (users of seleXys TH+ and TPS)
CC: N/A

Affected products:

 seleXys TH+ shell	Item number	Item description	Batch numbers
	55.42.0142	seleXys TH+ shell 42/AA	all
	55.42.0144	seleXys TH+ shell 44/BB	all
	55.42.0146	seleXys TH+ shell 46/CC	all
	55.42.0148	seleXys TH+ shell 48/DD	all
	55.42.0150	seleXys TH+ shell 50/EE	all
	55.42.0152	seleXys TH+ shell 52/FF	all
	55.42.0154	seleXys TH+ shell 54/GG	all
	55.42.0156	seleXys TH+ shell 56/HH	all
	55.42.0158	seleXys TH+ shell 58/II	all
	55.42.0160	seleXys TH+ shell 60/JJ	all
	55.42.0162	seleXys TH+ shell 62/KK	all
55.42.0164	seleXys TH+ shell 64/KK	all	

 seleXys TPS shell	Item number	Item description	Batch numbers
	55.40.0042	seleXys TPS shell 42/AA	all
	55.40.0044	seleXys TPS shell 44/BB	all
	55.40.0046	seleXys TPS shell 46/CC	all
	55.40.0048	seleXys TPS shell 48/DD	all
	55.40.0050	seleXys TPS shell 50/EE	all
	55.40.0052	seleXys TPS shell 52/FF	all
	55.40.0054	seleXys TPS shell 54/GG	all
	55.40.0056	seleXys TPS shell 56/HH	all
	55.40.0058	seleXys TPS shell 58/II	all
	55.40.0060	seleXys TPS shell 60/JJ	all
	55.40.0062	seleXys TPS shell 62/KK	all
55.40.0064	seleXys TPS shell 64/KK	all	

Ladies and Gentlemen,

Mathys Ltd Bettlach hereby informs you of a voluntary Field Safety Corrective Action (FSCA) in relation to the seleXys TH+ and seleXys TPS acetabular shells. You were identified as being a former user of the system and are therefore subject to this safety-relevant action.

Description of the problem

A recent analysis of data derived from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) shows that the revision rates for the seleXys TH+ and seleXys TPS acetabular shells are higher than the revision rate of other acetabular cups/shells being used in Australia. The AOANJRR identifies loosening/lysis as the most significant reasons for revisions of the seleXys TH+ and TPS shells.

It is important to note that this Field Safety Notice does not relate to the seleXys PC acetabular shells which continue to have a satisfactory, equivalent revision rate when compared with other total hip replacement systems.

Information relating to patient safety

This Field Safety Notice does not change current practices for patient follow-up care for the seleXys TH+ and seleXys TPS systems. Mathys Ltd Bettlach is recommending that physicians maintain their routine follow-up protocol for patients who have undergone hip arthroplasty.

Patients who experience symptoms including limited mobility, pain, swelling, etc. may need to contact their treating physician. The need for any additional follow-up or revision surgery should be determined on a case-by-case basis following a detailed assessment of the patients' clinical circumstances.

Actions to be taken by the user:

- Read this Field Safety Notice carefully and make sure that all relevant departments and positions are informed of its content.
- Please complete the enclosed confirmation form (page 4) and return it to the address indicated or hand it over to your Mathys representative. *(This will stop Mathys from sending you further reminders concerning this FSCA.)*
- The present Field Safety Notice must be observed until the action has been completed within your organisation. Please keep a copy of this Field Safety Notice.
- For questions regarding this Field Safety Notice, please contact us at the following address: vigilance@mathysmedical.com

Information on materiovigilance:

The competent national authorities have been notified of this action.

Please notify Mathys Ltd Bettlach of any adverse event in connection with the seleXys TH+ or seleXys TPS system or any other Mathys product. You can report adverse events to Mathys at vigilance@mathysmedical.com or via your local Mathys office.

We very much regret the inconvenience caused to you. If you have any further queries, please do not hesitate to contact us.

Mathys Ltd Bettlach

Head Regulatory & Vigilance
Regulatory & Quality Management

Vigilance & Post Market Surveillance Manager
Regulatory & Vigilance

Confirmation form FSCA 15/02

Urgent Field Safety Notice

Product name: seleXys TH+ and seleXys TPS shells

FSCA ID no.: FSCA 15/02

Type of action: **Field Safety Notification**

Confirmation of receipt

Please complete:

Customer no. _____
Hospital _____
Post code, town _____
Contact _____
(Name/position)

By completing and returning the present form I confirm that I have received and read this Field Safety Notice:

Place/date: _____

Signature: _____

Please return this form by e-mail or fax to the following address:

e-mail:

fax: