
Urgent Field Safety Notice

Product name: RM Pressfit cup vitamys® and seleXys® inlay vitamys®
FSCA-ID-No.: FSCA 12/04
Type of action: Notification: Addendum to the instruction for using
(package insert)

Bettlach, February 16th 2012

Adresser: Mathys Ltd Bettlach

Addressee: Trust Chief Executives, General Manager, Surgery Management, Safety Delegate, OR staff.

Details regarding the affected product:

See appendix 1

Description of the problem:

Mathys Ltd Bettlach (Mathys) has initiated a Field Safety Corrective Action by issuing a revised instruction for using for hip prostheses.

The assessment of a market notification has revealed a certain insecurity in our markets regarding the correct removal of vitamys implants from the packaging. The three pouches and the sterile barrier are not clearly seen after removal of the cardboard box. This might lead to a handover to the sterile surgical staff after having opened the first pouch. As this first pouch does not represent the sterile barrier, in a worst case scenario there might be a contamination of the sterile surgical staff and surgical field. Please note that this is a hypothetical scenario as Mathys has not received any reports on an incident as described. There is no quality issue related to the product itself.

Potential hazards:

- The implant is handed over to the sterile surgical staff already after having opened the first pouch without recognizing an incorrect procedure. This might lead to the contamination of the sterile surgical field.

Based on our risk assessment, the results from vitamys studies and an analysis of the bioburden between the first and second pouch which demonstrates no clinically relevant contamination, there is no increased health risk to patients even when an incorrect opening procedure was performed.

Actions to be taken by the addressee:

- Read this notification and the addendum to the instruction for using carefully.
- Please make sure that all relevant positions will be informed of this Field Safety Notice within your hospital.
- Complete the response form attached and send it to the address specified:
(*You herewith avoid the delivery of further notifications through Mathys. Please also complete the form in case you do not have vitamys implants on stock anymore.*)

Instruction for using (IFU, reference 72838)

The chapter sterility was completed as follows (new version: 5/13):

Instruction regarding vitamys implants:

The implants are packed inside a cardboard box including the implant packed in three pouches. Please be aware that the outer pouch is a non-sterile protective pouch.

- 1) Remove the non-sterile protective pouch (1st layer, transparent pouch).
- 2) Open the first white pouch (2nd layer) by non-sterile surgical staff and remove the content by sterile surgical staff.
- 3) Open the second white pouch (3rd layer) by sterile surgical staff and remove the implant.

An illustration of the correct removal procedure has been added to this notification on the basis of the RM Pressfit cup vitamys.

Distribution of this Field Safety Notice:

Please ensure that all involved positions are informed off this Field Safety Notice within your organisation. Should affected devices have been passed on, make sure the corresponding organisations will be notified and instructed.

This Field Safety Notice should be kept until the action within your organisation has been terminated.

Contact reference person:

Stephan Affolter
Manager Vigilance
Regulatory Affairs & Vigilance
vigilance@mathysmedical.com

This notice has been notified to the corresponding competent authorities.

Mathys Ltd Bettlach



Director Risk Management
Member Management Board



Stephan Affolter
Manager Vigilance
Regulatory Affairs & Vigilance

Illustration: correct removal of RM Pressfit cup vitamys

Steps	Description	Illustration	Opening / Removal	Content
1	Cardboard box		Opened and removed by the non-sterile surgical staff.	<ul style="list-style-type: none"> • Non-sterile protective pouch with implant • Instructions for use (IFU) • Labels for patient record
2	Non-sterile protective pouch, transparent (1 st pouch)		Opened and removed by the non-sterile surgical staff.	<ul style="list-style-type: none"> • Implant packed in two pouches
3	White pouch (2 nd pouch)	 	Opened by the non-sterile surgical staff. Inner pouch removed by the sterile surgical staff and deposited in the sterile field.	<ul style="list-style-type: none"> • Implant packed in one pouch
4	Sterile, white pouch (3 rd pouch)	 	Opened by the sterile surgical staff. Implant removed by the sterile surgical staff in the sterile field.	<ul style="list-style-type: none"> • Implant

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Appendix 1

RM Pressfit cup vitamys:

Description	Article no.	Lot no.
RM Pressfit cup TiCP vitamys 44/28	52.34.0032	all
RM Pressfit cup TiCP vitamys 46/28	52.34.0033	all
RM Pressfit cup TiCP vitamys 48/28	52.34.0034	all
RM Pressfit cup TiCP vitamys 50/28	52.34.0035	all
RM Pressfit cup TiCP vitamys 52/28	52.34.0036	all
RM Pressfit cup TiCP vitamys 54/28	52.34.0037	all
RM Pressfit cup TiCP vitamys 56/28	52.34.0038	all
RM Pressfit cup TiCP vitamys 58/28	52.34.0039	all
RM Pressfit cup TiCP vitamys 60/28	52.34.0040	all
RM Pressfit cup TiCP vitamys 62/28	52.34.0041	all
RM Pressfit cup TiCP vitamys 64/28	52.34.0042	all
RM Pressfit cup TiCP vitamys 66/28	52.34.0043	all
RM Pressfit cup TiCP vitamys 68/28	52.34.0044	all
RM Pressfit cup TiCP vitamys 70/28	52.34.0045	all
RM Pressfit cup TiCP vitamys 48/32	52.34.0052	all
RM Pressfit cup TiCP vitamys 50/32	52.34.0053	all
RM Pressfit cup TiCP vitamys 52/32	52.34.0054	all
RM Pressfit cup TiCP vitamys 52/36	52.34.0067	all
RM Pressfit cup TiCP vitamys 54/36	52.34.0068	all
RM Pressfit cup TiCP vitamys 56/36	52.34.0069	all
RM Pressfit cup TiCP vitamys 58/36	52.34.0070	all
RM Pressfit cup TiCP vitamys 60/36	52.34.0071	all
RM Pressfit cup TiCP vitamys 62/36	52.34.0072	all
RM Pressfit cup TiCP vitamys 64/36	52.34.0073	all
RM Pressfit cup TiCP vitamys 66/36	52.34.0074	all
RM Pressfit cup TiCP vitamys 68/36	52.34.0075	all
RM Pressfit cup TiCP vitamys 70/36	52.34.0076	all

seleXys inlay vitamys:

Description	Article no.	Lot no.
seleXys inlay standard vitamys 28/AA	52.34.0130	all
seleXys inlay standard vitamys 28/BB	52.34.0131	all
seleXys inlay standard vitamys 28/CC	52.34.0132	all
seleXys inlay standard vitamys 28/DD	52.34.0133	all
seleXys inlay standard vitamys 28/EE	52.34.0134	all
seleXys inlay standard vitamys 28/FF	52.34.0135	all
seleXys inlay standard vitamys 28/GG	52.34.0136	all
seleXys inlay standard vitamys 28/HH	52.34.0137	all
seleXys inlay standard vitamys 28/II	52.34.0138	all
seleXys inlay standard vitamys 28/JJ	52.34.0139	all
seleXys inlay standard vitamys 28/KK	52.34.0140	all
seleXys inlay standard vitamys 28/LL	52.34.0141	all
seleXys inlay standard vitamys 32/DD	52.34.0150	all
seleXys inlay standard vitamys 32/EE	52.34.0151	all
seleXys inlay standard vitamys 32/FF	52.34.0152	all
seleXys inlay standard vitamys 32/GG	52.34.0153	all
seleXys inlay standard vitamys 32/HH	52.34.0154	all
seleXys inlay standard vitamys 32/II	52.34.0155	all
seleXys inlay standard vitamys 32/JJ	52.34.0156	all
seleXys inlay standard vitamys 32/KK	52.34.0157	all
seleXys inlay standard vitamys 32/LL	52.34.0158	all
seleXys inlay standard vitamys 36/FF	52.34.0165	all
seleXys inlay standard vitamys 36/GG	52.34.0166	all
seleXys inlay standard vitamys 36/HH	52.34.0167	all
seleXys inlay standard vitamys 36/II	52.34.0168	all
seleXys inlay standard vitamys 36/JJ	52.34.0169	all
seleXys inlay standard vitamys 36/KK	52.34.0170	all
seleXys inlay standard vitamys 36/LL	52.34.0171	all
seleXys Inlay, hooded, vitamys 28/AA	52.34.0240	all
seleXys Inlay, hooded, vitamys 28/BB	52.34.0241	all
seleXys Inlay, hooded, vitamys 28/CC	52.34.0242	all
seleXys Inlay, hooded, vitamys 28/DD	52.34.0243	all
seleXys Inlay, hooded, vitamys 28/EE	52.34.0244	all
seleXys Inlay, hooded, vitamys 28/FF	52.34.0245	all
seleXys Inlay, hooded, vitamys 28/GG	52.34.0246	all
seleXys Inlay, hooded, vitamys 28/HH	52.34.0247	all
seleXys Inlay, hooded, vitamys 28/II	52.34.0248	all
seleXys Inlay, hooded, vitamys 28/JJ	52.34.0249	all
seleXys Inlay, hooded, vitamys 28/KK	52.34.0250	all
seleXys Inlay, hooded, vitamys 28/LL	52.34.0251	all
seleXys Inlay, hooded, vitamys 32/DD	52.34.0260	all
seleXys Inlay, hooded, vitamys 32/EE	52.34.0261	all
seleXys Inlay, hooded, vitamys 32/FF	52.34.0262	all
seleXys Inlay, hooded, vitamys 32/GG	52.34.0263	all
seleXys Inlay, hooded, vitamys 32/HH	52.34.0264	all
seleXys Inlay, hooded, vitamys 32/II	52.34.0265	all
seleXys Inlay, hooded, vitamys 32/JJ	52.34.0266	all
seleXys Inlay, hooded, vitamys 32/KK	52.34.0267	all
seleXys Inlay, hooded, vitamys 32/LL	52.34.0268	all
seleXys Inlay, hooded, vitamys 36/FF	52.34.0275	all
seleXys Inlay, hooded, vitamys 36/GG	52.34.0276	all
seleXys Inlay, hooded, vitamys 36/HH	52.34.0277	all
seleXys Inlay, hooded, vitamys 36/II	52.34.0278	all
seleXys Inlay, hooded, vitamys 36/JJ	52.34.0279	all
seleXys Inlay, hooded, vitamys 36/KK	52.34.0280	all
seleXys Inlay, hooded, vitamys 36/LL	52.34.0281	all