Synthes GmbH
Luzernstrasse 21
4528 Zuchwil
Switzerland
Tel. +41 32 720 40 60
Fax +41 32 720 40 61
http://www.depuysynthes.com

DePuy Synthes
COMPANIES OF Johnson & Johnson

To the ATTENTION of:
Hospital Personnel

2 October 2015

URGENT NOTICE: MEDICAL DEVICE FIELD SAFETY NOTIFICATION - FSN2015122
Incorrect information relating to Precautions and Side Effects included in Instructions For Use (IFU)

Affected Parts and IFU

Part Description	Part Number	Lot Number
chronOS Inject Bone Void Filler	710.065S, 710.066S, 710.067S	All lots
Affected Labeling	**Incorrect Package Insert**	**Updated Package Insert**
SE_018720	SE_018720_AE	SE_018720_AF

Please note that this is a Medical Device Field Safety Notification only, it is not required to return products associated with the IFU listed above.

Dear Sir/Madam,

Synthes GmbH is initiating a Field Safety Notification (FSN) to inform you of incorrect information included in the IFU of the chronOS Inject Bone Void Filler. The Part Numbers associated with these IFUs are listed at the top of the letter.
chronOS Inject Bone Void Filler is intended to be used as bone void filler or augmentation material where cancellous or cortico-cancellous bone should be replaced. This includes the filling of bone defects in the upper and lower extremities and pelvis in non-load bearing indications only.
Our records indicate that you may have product with IFUs that are impacted by this Field Safety Notification.

Reason for the Field Safety Notification

The incorrect IFU was released instead of the approved IFU. The approved IFU features an expanded listing of Precautions and Possible Side Effects, Possible Adverse Effects and Potential Complications. Please refer to attachment 1 for comparison of the incorrect section of IFU SE_018720_AE and the updated section of IFU SE_018720_AF.

Potential hazard

The information provided in the approved IFU is intended to inform the treating physician and inform pre-operative and post-operative medical decision making. Key health risks communicated in the approved IFU are Local Adverse Tissue Reaction, Local Adverse Tissue Reaction (Transient) and Pain (Marginal). The omission of this information may lead to user dissatisfaction but the integrity of the product is intact and there is no increased risk to the user or patient at this time.

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Customer actions

We ask that you review the information contained in this Field Safety Notification and complete the following actions:

- Replace the listed IFU in this Accounts Letter with the updated IFU.
- Forward this Field Safety Notification to anyone in your facility that needs to be informed, especially personnel involved with Synthes Trauma Biomaterial systems.
- If the product has been forwarded to another facility, please contact that facility and provide them with a copy of this Field Safety Notification.
- Maintain awareness of this notice.
- Review, complete, sign and return the attached reply form on page 4 of this letter to your local DePuy Synthes sales organization in accordance with the directions on the form within 5 business days of receipt of this notification.
- If the Verification Form is answered on behalf of more than one facility and/or individual, please clearly indicate the name and address of the facility and/or individual on page 4.
- Keep a copy of this notice.

The applicable regulatory agencies are being notified.

We apologize for any inconvenience that this field safety notification may create and appreciate your cooperation with our request. Should you have any inquiries please do not hesitate to contact your DePuy Synthes sales consultant.

Thank you for your attention and cooperation.

Synthes GmbH

Paul Ames

Field Action Manager

Anne M. Brisson

Sr. QA Manager, Product Safety and Performance

Cc:

Account Name: _____

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Incorrect information relating to Precautions and Side Effects included in Instructions For Use (IFU)

Affected IFU and Parts

Part Description	Part Number	Lot Number
chronOS Inject Bone Void Filler	710.065S, 710.066S, 710.067S	All lots
Affected Labeling	**Incorrect Package Insert (IFU)**	**Correct Package Insert (IFU)**
SE_018720	SE_018720_AE	SE_018720_AF

Please note that this is a Medical Device Field Safety Notification only, it is not required to return products associated with the IFUs listed above.

☐ We acknowledge receipt of this information and have replaced the listed IFUs in the Accounts Letter with the updated IFUs.

☐ We acknowledge receipt of this information but do not have the listed IFUs at this facility.

Hospital name: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____

Please complete and return this page to your local DePuy Synthes sales organization.

Note: If the Verification Section is answered on behalf of more than one facility and/or individual, please clearly indicate the name and address of the facility and/or individual on this page of the notification.

Attachment 1. Comparison incorrect IFU (SE_018720_AE) and correct IFU (SE_018720_AF)

Incorrect	Correct	Correct
Precautions – Do not open the package until use. – Examine the packaging for damage before using the sterile bone substitute, as they might impair sterility. This applies to both the inner primary and the outer secondary peel-off package, In removing the implant from its package, strictly observe the instructions concerning aseptic procedures. – Do not attempt to re-sterilise the unused contents of an opened package, but dispose of it. Re –sterilization alters the chronOS inject powder blend and liquid components. – Do not use chronOS inject after expiration of the use-by date printed on the package. – When preparing the chronOS for implantation, use exclusively components from one and the same pack-age. Always mix the entire amount of powder mixture and liquid – chronOS inject must not be mixed with any additives that are not included in the package. – Always apply chronOS inject directly from the cartridge or use the delivery needle intended for the application. Never use delivery needle with a diameter inferior to 12GA. **Side Effects** No Side effects due to material have been reported to date. **Interactions** No negative interactions have been reported to date.	**Precautions** – An application of chronOS Inject in an enclosed defect with access to blood vessels can provoke an embolism and must be avoided. – Particular care is needed when applying chronOS Inject close to an open articular cavity. Avoid extravasations into the articular space. – Do not open the package until use. – Examine the package for damages before using the sterile bone substitute, as they might impair sterility. This applies to both the inner primary and the outer secondary peel-off package. In removing the implant from its package, strictly observe the instructions concerning aseptic procedures. – Do not attempt to re-sterilise the unused contents of an opened package, but dispose of it. Re-sterilization of the chronOS Inject Bone Void Filler powder blend and/or chronOS Inject liquid component can result in product not being sterile, and/or not meeting performance specifications and/or alters material properties. – Do not use chronOS Inject Bone Void Filler after expiration of the use-by date printed on the package. – When preparing chronOS Inject Bone Void Filler for implantation, use exclusively components from one and the same package. Always mix the entire amount of powder mixture and liquid. – chronOS Inject Bone Void Filler must not be mixed with any additives that are not included in the package. – Always apply chronOS Inject Bone Void Filler directly From the cartridge and use the delivery needle intended for the application. Never use delivery needles with a diameter inferior to 12 ga (gauge).	**Possible Side Effects, Possible Adverse Effects and Potential Complications** – Non union or delayed union, which may lead to a failure of the implant – Pain, discomfort, abnormal sensation, or palpability due to the presence of the device – Increased fibrous tissue response around fracture site and/or the implant Apart from these possible adverse effects there is also the risk of complications associated with any surgical procedure featuring bony defects such as, but not limited to, necrosis of bone, infection, nerve damage and pain which may not be related to the implant. In general, good tissue response of tricalcium phosphate/ brushite (dicalcium phosphate dihydrate) implants in bone is supported by experimental and clinical data. Nevertheless, the following complications are possible: – Fragment displacement as a result of use in inappropriate indications – Neurovascular injuries caused by surgical trauma – Foreign body reactions – Allergic reactions – Inflammatory reactions – Infections that can lead to failure of the procedure – General complications caused by invasive surgery