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

<table>
<thead>
<tr>
<th>Part Description</th>
<th>Part Number</th>
<th>Lot Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>chronOS Inject Bone Void Filler</td>
<td>710.065S, 710.066S, 710.067S</td>
<td>All lots</td>
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<tr>
<th>Affected Labeling</th>
<th>Incorrect Package Insert</th>
<th>Updated Package Insert</th>
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<tbody>
<tr>
<td>SE_018720</td>
<td>SE_018720_AE</td>
<td>SE_018720_AF</td>
</tr>
</tbody>
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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.
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:
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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.
### Incorrect

**Precautions**
- Do not open the package until use.
- Do not re-use or re-package the device after use.
- Do not re-sterilize the used content of an opened package.

**Side Effects**
No side effects due to materials have been reported to date.

**Interactions**
No negative interactions have been reported to date.

### Correct

**Precautions**
- An application of chronOS Inject in an enclosed device with accessible blood vessels can provoke an embolism and must be avoided.
- Particular care is needed when applying chronOS Inject close to an open arterial cavity. Avoid extravasations into the arterial space.
- Do not open the package until use.
- Do not re-use or re-package the device after use.
- Do not re-sterilize the used content of an opened package.

**Side Effects**
No side effects due to materials have been reported to date.

**Interactions**
No negative interactions have been reported to date.

### Possible Side Effects, Possible Adverse Effects and Potential Complications
- Hypersensitivity or delayed reaction, which may lead to a failure of the implant.
- Pain, discomfort, abnormal sensation, or instability due to the presence of the device.
- Increased immune 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, including:
- Bone defects such as, but not limited to, necrosis or bone, in infection, damage and pain which may not be related to the implant.
- In general, good tissue response of oricalum phosphate/brushite (calcium phosphate/hydroxyapatite) 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 indication.
  - Neurovascular injuries caused by surgical trauma.
  - Foreign body reactions.
  - Allergic reactions.
  - Infections that can lead to failure of the procedure.
  - General complications caused by invasive surgery.