August XX, 2013

URGENT: Field Safety Notice

FSCA identifier: Product Field Action **RA2013-111**

Type of Action: Field Safety Corrective Action: **Return to Supplier**

Description H.SEIDEL PLUG, 10MM DIA

Catalog #: 0930-9-010

Lot Code: L6238

Dear Distributor/ Risk Management/Surgeon:

On 19th July 2013, Stryker® Orthopaedics initiated a lot specific product recall for the products referenced above. Stryker Orthopaedics received a report from the field that a 12mm plug was identified in packaging associated with a 10mm plug.

Potential Hazards

Primary Total Hip Arthroplasty involving a Cemented Stem has progressed to a point where the surgeon, after trialing, desires to implant the Seidel Intramedullary 10mm cement plug.

The following potential hazards were identified:

1. Misinformation. A 12mm Seidel Intramedullary Cement Plug is packaged and labeled as a 10mm Seidel Intramedullary Cement Plug.

   The Seidel Intramedullary Cement Plug is retrieved and the surgical staff notices it is a size 12mm and not a 10mm.

   a. A replacement Cement Plug is obtained and implanted, or

   b. The surgeon decides to ream the femoral canal up to 13mm to accommodate the 12mm plug.

   The potential harm associated with the above scenarios is complications associated with an extended surgery time of less than 5 minutes.

2. Inadequate mating compatibility between 12mm Seidel Intramedullary Cement Plug and 8/10mm Plug Introducer.

   The Seidel Intramedullary Cement Plug is retrieved and the surgical staff does not notice it is a size 12mm and not a 10mm. The size 12mm plug cannot be assembled to the introducer

for the size 10mm plug. The surgical staff notices it is a size 12mm and not a 10mm. A replacement Cement Plug is obtained and implanted.

The potential harm associated with this scenario is complications associated with an extended surgery time of less than 5 minutes.

3. Mal-positioned implant. The 12mm Seidel Intramedullary Cement Plug does not seat to the required depth within the reamed femoral canal.

   The Seidel Intramedullary Cement Plug is retrieved and the surgical staff does not notice it is a size 12mm and not a 10mm. The size 12mm plug cannot be assembled to the introducer for the size 10mm plug. The surgical staff obtains the introducer for the size 12mm plug and proceeds with the surgery. The surgeon encounters difficulty seating the plug to the desired depth.

   a. Surgeon proceeds to remove the plug from the femoral canal. A replacement Cement Plug is obtained and implanted.

      The potential harm associated with this scenario is complications associated with an extended surgery time of less than 30 minutes.

   b. Surgeon proceeds to apply additional force to seat the plug at the desired depth within the femoral canal. Plug seats at the desired depth.

      The potential harm associated with this scenario is complications associated with an extended surgery time of less than 5 minutes.

4. Excessive stress/force on bone.

   The Seidel Intramedullary Cement Plug is retrieved and the surgical staff does not notice it is a size 12mm and not a 10mm. The size 12mm plug cannot be assembled to the introducer for the size 10mm plug. The surgical staff obtains the introducer for the size 12mm plug and proceeds with the surgery. The surgeon encounters difficulty seating the plug to the desired depth. Surgeon proceeds to apply impaction forces, to the inserter, to seat the 12 mm plug at the desired depth within the femoral canal. Intraoperative fracture occurs.

   The potential harm associated with this scenario is intraoperative fracture as a result of excessive force applied by the surgeon in order to implant a 12mm Cement Plug in a femoral cavity prepared for a 10mm Cement Plug.

Risk Mitigation Factors

This non-conformance will result in the inability to assemble the Seidel Intramedullary Plug (Size 12mm) to the Plug Introducer (For Plug sizes 8mm and 10mm), which is used to introduce the plug into the femoral canal. This would trigger the surgical staff to closely inspect the Plug and identify via visual inspection of the size marking on the device that it is, in fact, a 12mm Plug and not a 10mm as expected.

Regarding any H.Seidel Plug, 10mm Dia, Catalogue Number 0930-9-010, Lot L6238 that are in your possession, please follow the below advice:

1. Immediately check you internal inventory and quarantine all subject devices.

2. Circulate this Field Safety Notice internally to all interested/affected parties.

3. Maintain awareness of this notice internally until all required actions have been completed within your facility.

4. Inform Stryker if any of the subject devices have been distributed to other organisations. *(Please provide contact details so that Stryker can inform the recipients appropriately).*

5. Complete the attached customer response form. *(Please complete this form even if you do not have any product to return. This will preclude the need to Stryker to send any reminder notice)*

6. Please inform Stryker of any adverse events.

7. Return the completed form and any affected devices to your local Stryker Representative.

Stryker® Orthopaedics maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We apologize for any inconvenience this Field Corrective Safety Corrective Action may create and appreciate your cooperation with our request.

If you have any further enquiries, please contact your local Sales Representative.

Yours Sincerely,

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STRYKER® ORTHOPAEDICS
FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGMENT FORM

August XX, 2013

SURGEON

ADDRESS

CITY, STATE ZIP

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I have received the notification from Stryker® Orthopaedics dated Aug XX, 2013 stating that they initiated a Field Safety Corrective Action of the above referenced product.

_____ _____

Surgeon (Signature) Date

_____

Surgeon (Print)

_____

Please fax this signed and dated form to XXXX