September 13th, 2011

URGENT: Field Safety Notice

FSCA identifier: Product Field Action omt2011-1

Type of Action: Field Safety Corrective Action: Reportable Product Recall

Description: EIUS® Tibial (Keeled) and Femoral Implants

Catalog #: See attached List

Lot Code: All

Dear Distributor/Risk Management/Surgeon:

The intent of this letter is to inform you that two National Joint Registries suggest that the EIUS® Unicompartmental System is associated with a higher revision rate than unicompartmental devices generally. Collectively, these Registries report on outcomes for 492 surgical procedures, 60 of which were followed by a revision procedure associated with one or more of the following: femoral loosening, tibial loosening, pain, disease progression, infection, malalignment, dislocation, instability, and periprosthetic fracture.

The 2010 Annual Report of the National Joint Replacement Registry of the Australian Orthopaedic Association reported a 18.5% revision rate for EIUS® compared to 8.6% for other unicompartmental devices at 5 years post implantation.

The 2010 National Joint Registry for England & Wales reported data which corresponds to revision rates for EIUS® of 2.1%, 8.2% and 13.0% at 1, 3 and 5 years post implantation. This is compared to revision rates of 1.7%, 6.5% and 9.4% at these timepoints for unicompartmental devices generally.

Based on a medical opinion that omt GmbH has obtained on this matter, additional patient follow-up is not required.

Implant loosening, disease progress (up to 50% of all revisions) and procedure-related issues regarding critical surgical technique, the leading causes of revision with unicompartmental devices generally, are all accompanied by pain. Pain and swelling are natural and sensitive problem indicators. An absence of pain indicates that there is no problem with the performance of the implanted devices and no need for follow-up.

Furthermore, if an issue does exist, pain will become clinically manifest due to the intricate biomechanics involved and rapid symptomatology associated with unicompartmental devices generally. Where fundamental biomechanics are impacted, pain will be persistent and a patient will return to his or her surgeon who will then assess the patient for any abnormalities.

As implanting and treating surgeons are in a unique position to exercise medical judgment as it relates to individual patient experience with the EIUS® devices noted, this communication is intended to increase surgeon awareness of the results reported by the two registries. Surgeons should continue to follow patients according to their normal post-operative course of treatment for unicondylar devices generally.

Our records indicate that you have received and/or used the above referenced product(s). It is omt GmbH responsibility as the manufacturer to ensure that customers who may have received and/or used these affected products also receive this important communication.

Please note that your signature on the following form only confirms that you received this notification and does not obligate you to take any additional action beyond what is called for in this notification letter.

In the occurrence that any of the affected products are unused, please follow the below advice:

1. Immediately check your 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 omt/Stryker if any of the subject devices have been distributed to other organisations. *(Please provide contact details so that omt/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 omt/Stryker to send any reminder notice)
6. Please inform omt/Stryker of any adverse events.
7. Return the completed form and any affected devices to your local Stryker Representative.

Omt GmbH maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We apologize for any inconvenience this Field 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,

[redacted]

(Sicherheitsbeauftragter
für Medizinprodukte)

o·m·t
Oberflächen- und Materialtechnologie GmbH

Catalog Number	Description
T636-2-001	EIUS UNI XS FEM LM/RL
T636-2-002	EIUS UNI SML FEM LM/RL
T636-2-003	EIUS UNI MED FEM LM/RL
T636-2-004	EIUS UNI LRG FEM LM/RL
T636-2-005	EIUS UNI XL FEM LM/RL
T636-2-011	EIUS UNI XS FEM RM/LL
T636-2-012	EIUS UNI SML FEM RM/LL
T636-2-013	EIUS UNI MED FEM RM/LL
T636-2-014	EIUS UNI LRG FEM RM/LL
T636-2-015	EIUS UNI XL FEM RM/LL