URGENT FIELD SAFETY NOTICE

iTotal CR Cruciate Retaining Total Knee Replacement System
Important Update Regarding Instruction for Insertion of iTotal CR Tibial Poly Inserts

July 5, 2012

Dear [Surgeon Name],

We have identified the need to provide additional guidance for proper poly insertion into the tibial base plate for current iTotal CR devices. Affected product catalog numbers are referenced below.

Affected devices:
M57250600010 – iTotal CR, Left Knee
M57250600020 – iTotal CR, Right Knee

A small number of complaints have been received regarding improper poly insertion into the tibial base plate. Improper poly insertion may lead to the poly insert not fully seating in the tray prior to completion of surgery and may require replacement of the poly insert.

ConforMIS has confirmed that all distributed product meets design and manufacturing specifications. However, to reduce the risk of improper poly insertion, ConforMIS is providing additional instructions (reference Attachment 1) for proper poly insertion into the tibial base plate.

This notice needs to be distributed to all within your organization who are users of the iTotal device. Please maintain awareness of this notice to ensure effectiveness of the information provided.

All relevant National Competent Authorities have been advised of this notice.

If should have any questions regarding this notice, please contact your local ConforMIS representative or MDSS GmbH**,** Tel.: +49-511-62628630, info@mdss.com.

Sincerely,

[redacted]
VP, Regulatory and Quality Affairs