Corin

Field Safety Notice

Device: **Uniglide Unicondylar Knee, Femoral Component**
Part Number **514.0400, LOT Number KNRU, Quantity 7 units**
514.0300, LOT Number KNTK, Quantity 9 units

Type of action: **Voluntary device withdrawal**

Date: 14 April 2009

To:

Details on affected devices:
This Field Safety Notice concerns the above devices ONLY. The devices are size 3 & 4 femoral components used in a non-cemented total unicondylar knee arthroplasy. Our records indicate that you are in receipt of qty devices from the above affected lots.

No other devices within the range are affected. Only these two part number/lot number combinations are affected.

Description of the problem:
The nonconforming devices may have been comingled during the manufacturing process.

1. LOT number KNRU, there may be devices in unit boxes with labels stating the device to be size 4, the device itself marked as size 4 whereas the device is actually size 3.
2. LOT number KNTK, there may be devices in unit boxes with labels stating the device to be size 3, the device itself marked as size 3 whereas the device is actually size 4.

Clinical Implications
It is highly probable that a surgeon would identify this issue before implanting.

Outcome for a size 4 device located on a femur prepared for size 3:

The surgeon would find that despite the trial being a snug fit; the prosthesis would be loose with a significant gap between posterior cut and prosthesis. There would also be poor radial fit between the modelled surfaces of the femur and the prosthesis.

Outcome for a size 3 device located on a femur prepared for size 4:

The surgeon would find that, despite the trial being a good fit, the prosthesis would not seat on the femur

Instruction

1. Discontinue use of the above devices, remove them from your inventory and place in a quarantine area pending return to Corin Ltd.
2. Corin Ltd customer representatives shall contact you during the week starting 14th April regarding the removal of the incorrect device and arranging for a replacement device. Alternatively please contact us on the Customer Hotline Tel:++44(0)1285 649 231.
3. Please forward this safety notice to any health professional in your organisation that needs to be aware.

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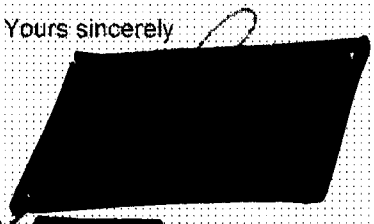
Your Competent Authority has been notified of this voluntary withdrawal.

If you have any questions or would like assistance with this issue please contact either your local Corin sales executive or the abovementioned customer services hotline.

Yours sincerely



Mr [redacted]
Quality Assurance Manager
Corin Ltd.