



Field Safety Notice

Device: ALPHAFIT PROXIMALLY MODIFIED STEM

Part Number 226.3095, 226.3110

Lot Number All devices with an expiry date of 2014-07 or earlier

Type of action: Voluntary device withdrawal

Date: 10 August 2009

To: Managing Director/Owner (International Distributors)
To: General Manager (Corin Germany)
To: Hospital, Clinical Director - Orthopaedics. (via Corin Germany)

Description of the problem:

Four of the two smallest size stems in the proximally modified (47mm offset) variant of the Alphafit Hip stem range have been reported as failing due to fatigue fracture, 2 - 4 years after implantation, (failure rate <1% for these size stems).

Corin Ltd has determined that the above devices shall be withdrawn from the market as a precautionary measure.

Our records indicate that your facility has received one or more of the above products. **All unimplanted devices with an expiry date of 2014-07 or earlier are being withdrawn.** All devices with an expiry date of 2014-08 or later will NOT be affected.

Instruction

1. Immediately discontinue use of the above devices, remove them from your inventory and place in a quarantine area pending return to Corin Ltd.
2. If you have products to return, please package them and contact Corin Ltd on the Customer Hotline Tel: ++44(0)1285 649 231 to arrange return.
3. Please forward this safety notice to any health professional in your organisation that needs to be aware.
4. So we can be assured that all unimplanted devices are recalled, we do ask that you return a letter stating that you have returned all stock (or that you have checked and have no stock). The address for this communication is to:

The devices have been distributed to Germany only. Your Competent Authority is being notified of this voluntary recall.

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

Corin
Yours sincerely

[Redacted]

Ms [Redacted]
Senior Quality Engineer
for

Mr [Redacted]
Quality Assurance Manager
Corin Ltd
Love Lane
Cirencester
Gloucestershire, GL7 1YJ
UK

Corin Limited
The Corinium Centre
Cirencester
Gloucestershire
GL7 1YJ

t: +44 (0)1285 659866
f: +44 (0)1285 658960
e: info@coringroup.com
www.coringroup.com