

March 14, 2007 / MS

Zimmer GmbH
P.O.Box
CH-8404 Winterthur

Phone +41 (0)52 262 [REDACTED]
Fax +41 (0)52 262 01 39
www.zimmer.com

Customer information on:

Alpha Durasul Inlay, neutral, GG/32
Reference number 01.00013.407, Lot 2339347

Alpha Durasul Inlay, neutral, HH/32
Reference number 01.00013.408, Lot 2340424

To whom it may concern:

We have discovered that two lots of the Alpha Durasul product line were commingled. The affected lots are: Alpha Durasul Inlay, neutral, GG/32 (Reference number 01.00013.407, Lot 2339347) and Alpha Durasul Inlay, neutral, HH/32 (Reference number 01.00013.408, Lot 2340424). These two inlays differ in the size of the outer diameter.

Possible consequences:

If an Alpha Durasul inlay HH/32 is implanted instead of size GG/32 in an Allofit or Fitmore shell 48mm, the surgeon would not be able to impact the inlay, the condition would be immediately apparent. Therefore no negative consequences for the patient would occur in this scenario. A correct size inlay has to be used.

If an Alpha Durasul inlay GG/32 is implanted instead of size HH/32 in an Allofit or Fitmore shell 50mm, the surgeon will not be able to achieve a stable fixation of the inlay within the shell. In most of the cases this would be realized by the surgeon when checking the stability of the inlay after impaction as prescribed in the surgical technique. A correct size inlay has to be used.

Corrective action:

As a measure of precaution we decided to recall all products of both affected lots 2339347 and 2340424 to prevent any further use of these lots.

We apologize for any inconvenience which might have been caused to you by this product recall. Please do not hesitate to contact your Zimmer representative if you have any questions or concerns.

Yours faithfully

Zimmer GmbH

[REDACTED]
Manager Product Surveillance