

Template for Dear Doctor letter

Regulatory Action Information

Date 24-May-05

Stryker RA Reference Number RA 2005-031

Regulatory Agency Reference No 0123

Contact Information

Contact Person Name of person within distribution site

Product Information

Product Description Gamma lag screw 12x85 and 12x95

Product Code/Catalogue No 12071285S and 12071295S

Lot Numbers to be filled individually

Quantities to be filled individually

Issue

Description of problem A side label on the outer packaging may indicate the wrong length of lagscrew. E.g. 95mm instead of 85mm or vice versa.

Potential Hazard In case of a lag screw being longer than expected, it may penetrate the femoral joint during introduction.

Communications/Attachments

Immediate Actions

- 1 Please quarantine affected product immediately
- 2 Your local sales representative will exchange affected items asap.
- 3 Please circulate internally to all affected parties
- 4 please immediately inform Stryker incase you have distributed product to other users.

Product Return Information

Please use "RA_2005_031" as Reference.

In case items have been in use, please issue a sterilisation certificate.