

ATTENTION: ADVISORY NOTICE

Effective Date:

RE: New precaution added to instructions for use

Product:	Calstrux™ (Previously known as TCP Complete)
Catalog Number:	400-05EU, 400-10EU, 400-15EU

Dear Doctor,

We are writing to inform you of a new precaution that has been added to the Calstrux™ instructions for use. This precaution has been added to ensure the safe use of the product in light of recent reported adverse events.

The new precaution is as follows:

Calstrux™ should be used precisely as directed. Do not exceed total liquid advised or over-fill the defect site with Calstrux™. The volume of Calstrux™ used should approximate the size of the defect since over-filling the defect site may create a risk of Calstrux™ migration. In addition, Calstrux™ should not be implanted in combination with other products. Adverse events including localized induration, swelling, inflammation, wound drainage, infection, and device migration have been reported when Calstrux™ has been used in such combination.

Please keep this new precaution in mind when you use Calstrux™.

A copy of the complete revised instructions for use is enclosed for your review.

Stryker Biotech continually monitors the safety of its marketed products and will keep you informed of any pertinent updates. If you have any questions regarding this communication or if your patients develop any adverse events, or experience a serious adverse event, please immediately notify me at 001 508-██████████ or Stryker Biotech's Pharmacovigilance representative at 001 508-██████████.

Sincerely,

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Vice President, Clinical and Medical Affairs
Stryker Biotech