

# Field Safety Notice

**Abutment Screw Diamond 1191, 1192**

**2017-10-19**

## **Details about affected Devices**

Products with reference numbers:

1191

1192

## **Description of the problem**

Integrum has identified during the investigation of post market issues with sudden Abutment Screw fractures a relationship between retightening and patients using Abutment Screw Diamond as a possible cause to the sudden Abutment Screw fracture.

## **Advice on Action to be taken by the User**

For patients using Abutment Screw Diamond (REF 1191, 1192) we recommend no retightening of the Abutment Screw to be performed.

## **Communication of this Field Safety Notice**

This message must be forwarded to anyone who needs to know the information within your organization or to any other organization where the potentially affected products have been transferred.



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## **Integrum contact person**

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The Undersigned confirms that this notice has been notified to the relevant Regulatory Authority.

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