
Urgent Field Safety Notice

Tava Surgical (from Elva BV only)
FSCA IT 2004545
Recall

Date: October 16, 2017

Attention: Tava Surgical saw blades and burs delivered by Elva BV.

Details on affected devices:
See attachment

Due to the lack of a correct CE-certification (CE-mark), all saw blades and burs as specified in the attachment to this letter, delivered by Elva B.V., are subject to a product recall. It regards a recall based on regulatory reasons. The product quality and safety to the patient are not at stake.

The products in stock must not be used and need to be sent back to the distributor before November 1, 2017. The distributor will send the products back to Elva B.V./Tava Surgical. The cost of the products and of the shipment will be reimbursed. This recall is limited to the products of Tava Surgical delivered by Elva B.V. as from March 1 2017.

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact (If appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate)

Elva BV/Tava Surgical
Strawinskylaan 701
1077 XX, Amsterdam
the Netherlands

The undersigned confirms that this notice has been notified the appropriate Regulatory Agency

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