

URGENT: MEDICAL DEVICE RECALL
Generation 1 Jasper Vektor

Leeds, 30th September 2018

Attention to Customer:

[INSERT CUSTOMER NAME/ADDRESS FIELDS]

Dear [INSERT CUSTOMER NAME],

Purpose of this letter:

The purpose of this letter is to advise you that TP Orthodontics, Inc. is voluntarily recalling Generation 1 Jasper Vektor Class 2 Correction Appliance. The Jasper Vektor is used for correcting class 2 malocclusions by applying light forces on the teeth using a tube, arch wire and stops.

Reason for the Voluntary Recall:

Generation 1 Jasper Vektor has broken in the patient's mouth during placement and usage.

- We have received reports of 106 device breakage reports from customers in our global distribution chain.
- One of these reports included a report of an injury; the injury was a minor irritation of the cheek.

Risk to Health:

The device breakage will have minimal if any effect on patient. Delays in treatment are not anticipated if the device is replaced soon after breakage, and injury is not anticipated.

How to recognize that the device may fail: Device breakage occurs due to stress overload and will be easily noticeable to the dental professional and patient as the device will be in two pieces and the spring will no longer be applying any corrective forces.

Actions to be taken by the Customer/User:

1. Locate any of the affected lots identified in the table below and quarantine the product.

- Return the Generation 1 Jasper Vektor for a replacement Jasper Vektor Generation 2 or refund, following the instructions below:

Contact TP Orthodontics, Inc. at **0044 (0)113 2539192** or [ReturnsEurope@tportho.com](mailto>ReturnsEurope@tportho.com) for a Return Authorisation Number and we will arrange collection of the returned goods.

- Email, mail, or fax the attached response letter to TP Orthodontics Europe. In addition to sending the letter back, you may call us with any questions or concerns.

EMAIL: [ReturnsEurope@tportho.com](mailto>ReturnsEurope@tportho.com)
FAX: **0044 (0)113 2539193**
MAIL: **TP Orthodontics Europe**
ATTN: Recall Coordinator
Fountain Court
12 Bruntcliffe Way
Morley, Leeds
LS27 0JG

- If you have any further questions or concerns after reviewing this notice, please contact TPO Customer Care Team **0044 (0)113 2539192** or TPEng@tportho.com

Product and Distribution Information:

Product and Distribution Information Table					
Product Names	Manufacturer's Product Number/Catalog Number	Lot Number	Manufacturing/Distribution Dates	Expiration Date (MM/DD/YYYY)	Quantity
Jasper Vektor	610-500	15915000, 17615000, 17715000, 18015000, 18115000, 18915000, 20315000, 23915000, 24515000, 25715000, 25815000, 26515000, 29415000, 29315000, 32915000	Manufactured from: 06/08/2015-12/01/2015 Distributed from: 06/8/2015- 02/19/2016	12/01/2020	132
Jasper Vektor	610-527	16015000, 18115000,	Manufactured from: 06/08/2015-12/01/2015	12/01/2020	31

		18815000, 25715000, 30215000	Distributed from: 06/8/2015- 02/19/2016		
Jasper Vektor	610-530	16015000, 17315000, 17715000, 18115000, 19515000, 24015000, 26515000, 30015000, 32315000, 32815000, 33515000	Manufactured from: 06/08/2015-12/01/2015 Distributed from: 06/8/2015- 02/19/2016	12/01/2020	154
Jasper Vektor	610-533	16015000, 17315000, 17715000, 18115000, 19515000, 24015000, 26515000, 30015000, 32315000, 32815000, 33515000	Manufactured from: 06/08/2015-12/01/2015 Distributed from: 06/8/2015- 02/19/2016	12/01/2020	143
Jasper Vektor	610-536	18915000, 19515000, 26515000, 30215000	Manufactured from: 06/08/2015-12/01/2015 Distributed from: 06/8/2015- 02/19/2016	12/01/2020	27
Jasper Vektor	610-527L	25715000	Manufactured from: 06/08/2015-12/01/2015 Distributed from: 06/8/2015- 02/19/2016	12/01/2020	10
Jasper Vektor	610-527R	25715000	Manufactured from: 06/08/2015-12/01/2015 Distributed from: 06/8/2015- 02/19/2016	12/01/2020	10
Jasper Vektor	610-530L	22015000, 25715000	Manufactured from: 06/08/2015-12/01/2015 Distributed from: 06/8/2015- 02/19/2016	12/01/2020	20
Jasper Vektor	610-530R	19515000, 25915000	Manufactured from: 06/08/2015-12/01/2015 Distributed from: 06/8/2015- 02/19/2016	12/01/2020	15

Jasper Vektor	610-533L	17515000, 25915000	Manufactured from: 06/08/2015-12/01/2015 Distributed from: 06/8/2015- 02/19/2016	12/01/2020	16
Jasper Vektor	610-533R	17515000, 17615000, 25915000	Manufactured from: 06/08/2015-12/01/2015 Distributed from: 06/8/2015- 02/19/2016	12/01/2020	16
Jasper Vektor	610-536L	25915000	Manufactured from: 06/08/2015-12/01/2015 Distributed from: 06/8/2015- 02/19/2016	12/01/2020	10
Jasper Vektor	610-536R	25915000	Manufactured from: 06/08/2015-12/01/2015 Distributed from: 06/8/2015- 02/19/2016	12/01/2020	10

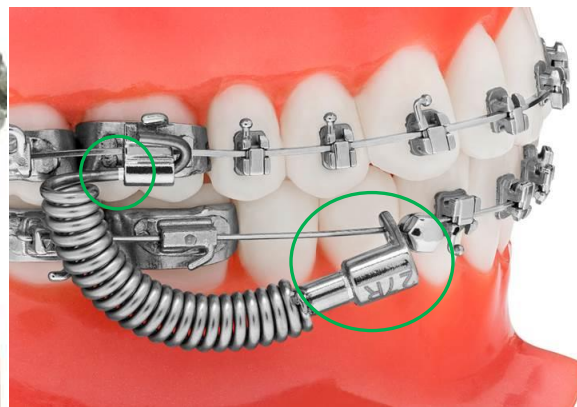
Type of Action by the Company:

The Jasper Vektor Generation 2 was modified to improve performance in the following manner:

- White line added to the straight tail section to indicate where the U-bend should be made with related modifications to the instructions for use.
- Improvements to the weld process.
- The key way has been replaced with boot design.



Generation 1 does not have a boot at the Mandibular wire connection.



Generation 2 has a boot at the Mandibular wire Connection and a visual marker for guidance.

Authorised by:

Deborah Lindsay
General Manager
TP Orthodontics Europe

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form
Response is Required

Customer Information:

Customer Name

Street Address

Town, Province, Postal Code

Jasper Vektor
(Generation 1)

Lot/Serial numbers:

I have read and understand the recall instructions provided in the **September 2018 Recall** letter.

Yes ___ No___

Any adverse events associated with recalled product? Yes ___ No ___

If yes, please explain:

Was this device placed in a patient? **(If yes, please specify the dates)**

Affected Product Information: Include information that is applicable for affected product.

Product Name	Manufacturer's Product Number/Catalog Number	Lot Number shipped to Customer	Quantity in inventory	Quantity destroyed/returned

Return Response Box:

<p>Please provide any additional information, if applicable.</p>
