Field Safety Notification
Recall of specific batches of the medical device
VENUS

26.06.2024

HumanTech Spine GmbH
Gewerbestrasse 5
D-71144 Steinenbronn

Addressee:
Users of the VENUS implant systems .

Identification of the affected medical devices:

Recall of the following affected batches of the VENUS implant system:

Item number	Item description	Affected batch number:
VL-RC-5-4	**Rod Ø5.5 mm / 40 mm curved**	**H1246QJ**
VL-RC-5-4	**Rod Ø5.5 mm / 40 mm curved**	**H1305QK**
VL-RC-5-5	**Rod Ø5,5 mm / 50 mm curved**	**H1330QJ**
VL-RC-5-6	**Rod Ø5.5 mm / 60 mm curved**	**H1137QJ**
VL-RC-5-7	**Rod Ø5.5 mm / 70 mm curved**	**H1409QI**
VL-RC-5-8	**Rod Ø5.5 mm / 80 mm curved**	**H1222QJ**
VL-RS-5-4	**Rod Ø5.5 mm / 40 mm straight**	**H1325QI**
VL-RS-5-5	**Rod Ø5.5 mm / 50 mm, straight**	**H1324QI**
VL-RS-5-9	**Rod Ø5.5 mm / 90 mm, straight**	**H1327QI**

Description of the problem including the identified root-cause:

- *During the manufacturing of the affected products, a deviation from the specified material was identified in a raw material batch. These products may have been produced with titanium grade 4 instead of titanium grade 5. The material properties of titanium grade 4 can have an impact on the mechanical performance of the products.*
- *As we cannot rule out that these deviating properties will affect the performance of these products, we are carrying out a product recall as a precautionary measure.*
- *Titanium Grade 4, like Titanium Grade 5, is suitable for long-term use in the body from a biocompatibility perspective and does not pose any additional risk in this regard.*
- *The implants listed do not have any other known technical defects that pose a risk to users, patients or third parties.*
- *However, the use of one of the affected implants may not lead to the desired treatment success due to the different biomechanical material properties.*
- *At this point in time, we assume that patients who have already had an affected product implanted will not suffer any serious disadvantages. However, we are still assessing the situation and will inform you of the result after the final analysis and provide you with an appropriate recommendation for action.*

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BW Bank Stuttgart
IBAN: DE05 6005 0101 0405 0933 06
BIC: SOLADEST600

Sitz der Gesellschaft Steinenbronn
Amtsgericht Stuttgart HRB 763517
Geschäftsführer: Harald Meyer, Katrin Faust, Gerd Stumpp
Ust-IdNr.: DE317214065 St.Nr. 99058/02198

What measures must the addressee take?

- *Our records indicate that you have received one or more implants from the affected batches.*
- *Please check your inventory immediately to determine if you have an implant of the lot number listed in this safety notification in your inventory.*
  Note: You can find the batch number either directly on the product label or via the laser marking on the product.
- *Regardless of whether or not you have affected products with one of the batch numbers listed in this safety notification, please complete and sign the attached **REPLY FORM** to confirm that you have received this safety notification. Please send a scanned copy of the completed form by email to vigilance@humantech-spine.de*
- *Please do the following as soon as possible:*

  1. Transfer all affected products into a restricted warehouse.

  *2. Please return all products together with the enclosed reply form by **July 26, 2024,** at the latest to:*
  HumanTech Spine GmbH, Gewerbestr. 5, 71144 Steinenbronn
  E-Mail: vigiliance@humantech-spine.de

  3. All returned products will be exchanged.

Forward the information described in this Field Safety Notification (FSN):

Please ensure in your organization that all users of the above products and other persons involved are informed of this FSN. If you have given the products to third parties, please forward a copy of this information. Please keep this information at least until the measure has been completed. The German national point of contact (BfArM) has received a copy of this FSN.

Please confirm receipt of this letter **immediately.**

Please confirm the implementation of the measures using the attached reply form by **July 05, 2024**, at the latest.

Please contact us for further information.

We thank you for your kind support and cooperation and apologize for all inconvenience that may be caused.

Best regards
HumanTech Spine GmbH

Appendix 1 – Reply form

HumanTech Spine GmbH
Gewerbestr. 5
71144 Steinenbronn

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Reply form

Please complete both pages of this form completely, where applicable, regardless of whether you are returning a product or not.

Please send the completed form by email until **July 05, 2024,** at the latest vigilance@humantech-spine.de

Contact details:

Name Customer / Company / Clinic / User	
Contact person Phone / E-Mail	
Address Street, City, Country	

I confirm that I have read and understood this Field Safety Notification for the recall of the affected products.

I have ensured that all affected recipients and users of the affected implants of batch numbers indicated on pages 1 and 2 of this Letter, have been notified accordingly.

_____

Signature Date

If you do not have an affected product, please check here: ☐

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Reply form

If you have affected products, please fill out the table below:

Affected batch number:	Quantity returned:	Return number (will be filled out by HumanTech)

Thank you in advance for your feedback.
Best regards

HumanTech Spine GmbH

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