HumanTech Spine

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Customer information on
Recall of specific batches of the medical device VENUS
- Extended risk assessment -

17.07.2024

HumanTech Spine GmbH
Gewerbestraße 5
D-71144 Steinenbronn

Addressee:
Users of the VENUS implant systems.

This letter contains **supplementary** information on the risk assessment carried out for the urgent safety information dated 26 June 2024.

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:

- *As you have already been informed in our Field Safety Notification that 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.*

- *For this reason, we are carrying out this product recall as a precautionary measure.*

Interim information on the current state of risk assessment for users:

As part of the extended risk assessment, which we carried out together with Prof. Dr Wilke, Institute for Trauma Surgical Research and Biomechanics, Centre for Trauma Research Ulm, there are currently no significant differences in the primary stability of the VENUS rods between titanium grade 4 and titanium grade 5.
Additional finite element analyses were used to simulate the range of motion/ RoM of the spine to assess the primary stability.

As a result, there are no further restrictions on the use of VENUS grade 4 titanium rods.

In order to further assess the risk of potential long-term failure of VENUS grade 4 titanium rods, the long-term behaviour under continuous load is currently being tested in accordance with ASTM F1717.

Possible clinical impact of long-term failure of the affected VENUS rods:
Longer treatment episode, revision surgery

Occurrence probability:
No clinical effects have been reported so far.

Preliminary recommendation for action:
Doctors who have used the affected VENUS rods during patient interventions should follow up these patients postoperatively in the usual manner.
At this time, there are no additional patient monitoring instructions related to the safety corrective action at hand that are recommended beyond your existing post-operative care plan.
If the system is functioning well and there is no new or worsening pain or symptoms, no further action is recommended.

After final analysis, we will inform you about the result and, if necessary, adapt the recommended action accordingly.

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Amtsgericht Stuttgart HRB 763517
Geschäftsführer: Harald Meyer, Katrin Faust
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.*
- *If you have not yet returned the affected products to us, we would like to remind you that you should continue to follow the procedure below:*

  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 note that the competent authorities will be kept informed of the measures taken and their progress on an ongoing basis. We would also like to inform you that the names of the notified user organisation will be sent to the competent authorities.

Please inform us if you notice any adverse events in connection with our products.

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

[redacted]

Best regards
HumanTech Spine GmbH