Urgent safety information

Corrective action
concerning
TRISTANflex – Anterior Cervical Interbody Fusion

To

xxx

Steinenbronn, 05.01.2018

Dear Sir or Madam,

HumanTech Germany GmbH is initiating a voluntary corrective action for the TRISTANflex product line with the articles listed below.

REF	Name
1503121405	TRISTANflex 12x14x05
1503121406	TRISTANflex 12x14x06
1503121407	TRISTANflex 12x14x07
1503121408	TRISTANflex 12x14x08
1503141605	TRISTANflex 14x16x05
1503141606	TRISTANflex 14x16x06
1503141607	TRISTANflex 14x16x07
1503141608	TRISTANflex 14x16x08

The instructions for use of this product contain a contraindication with the following wording: “Known hereditary or acquired brittleness of the bones or calcification problems”
When using the TRISTANflex to counteract this specified contraindication we point out the risk of dislocation of the cage. In a case where calcification problems are present, with associated hard endplates of the vertebral bodies, the spikes introduced into the TRISTANflex may under certain circumstances not penetrate sufficiently deeply into the endplates, which may lead to reduced primary fusion and subsequently to a dislocation of the cage.

In order to reduce the risk of dislocation, also in the case of use to counteract the contraindication mentioned above, we have already included instructions for compressing the vertebral bodies after inserting the cage in the surgical technique. Thus, the spikes can penetrate deeper into the endplate and in this way better primary fusion can be achieved. (The surgical technique is attached to this letter.)
Furthermore, the information in the instruction for use related to indication and contraindication in this context has been clarified. At the same time, a note is included in the instruction for use that an anterior plating should be used if insufficient primary fusion of the cage is to be expected, in order to prevent the cage from dislocating. The amended instruction for use is attached to this letter.
Tests have shown that through constructive measures the risk where the product is used to counteract the above mentioned contraindication can be reduced. We will implement these measures as soon as possible and inform you as soon as we have the corresponding products available. Upon request, the existing implant inventory in your possession can then be replaced.

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BW Bank Stuttgart
Konto: 4 272 401/BLZ 600 501 01
IBAN: DE55 6005 0101 0004 2724 01
BIC: SOLADEST600

Commerzbank Stuttgart
Konto: 624 2127 00/BLZ 600 400 71
IBAN: DE69 6004 0071 0624 2127 00
BIC: COBADEFFXXX

Sitz der Gesellschaft Steinenbronn
Amtsgericht Stuttgart HRB 731437
Geschäftsführer: Jochen Hutzel
USt-IdNr.: DE267786508 / St.Nr. 99058/18121

What measures should be taken by the addressee?

Description of safe use of the product

The application of the TRISTANflex is not intended for use on extremely hard vertebral body endplates and must not be used where there is such an indication without securing with anterior fusion.

When using TRISTANflex, please note the description of indications and contraindications as well as the important information for the operating surgeon in the instruction for use and the information in the surgical technique.

Recommendations for patients or treatment/follow-up of patients

If controls which would detect a dislocation of the cage after the intervention are routinely carried out in your establishment and no abnormalities are or have been detected, no further action is required.

If a routine inspection is not performed to detect cage dislocation, a review of patients who have or could have osteochondrosis Modic 3 or another calcification problem in the area of the bone bed should be undertaken as quickly as possible.

If a dislocation of the cage is detected then this must be examined to see to what extent this endangers the patient. On that basis, the measures to implement must be decided upon (e.g. correcting position, additional anterior plating).

Distribution of the information described here

Please ensure that all users of the above-mentioned products in your organisation and other persons who need to be informed are aware of this urgent safety information. If you have supplied the products to third parties, please forward a copy of this information or inform the contact person listed below.
Please retain this information at least until these measures have been undertaken.
The Federal Institute for Drugs and Medical Devices (BfArM, Germany) has received a copy of this "urgent safety information".

Contact person:

xxx
(Head of Quality Management)

xxx
(Safety Officer for Medical Devices)

Yours sincerely

HumanTech Germany GmbH

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