Absender:
Innovative Tomography Products GmbH
Universitätsstraße 136
D – 44799 Bochum
Telefon: +49 234 54621940
Telefax: +49 234 54622444
info@innotom.com
www.innotom.com
Datum: 20.04.2021

Urgent safety information
Product recall
Interventional cannulas KIR, KIM, BIM

Addresses:
All users and distributors

Problem description and identified cause:
The affected products may not have been properly sterilised at the sterilisation service provider, so that proper sterility cannot be guaranteed. The sterilisation service provider has knowingly falsified records over a long period of time. This problem affects a large number of medical device manufacturers across Europe.
The sterilisation service provider in question is no longer working for us.

The use of a possibly non-sterile product results in a risk of infection in patients. Patients treated with products containing the listed batches should be monitored according to standard medical practices.

We note in this regard that to date no complaints or incidents have been made to ITP regarding the possible non-sterility of the products.

Medical devices concerned:

KIR Interventional cannula:

KIR 23/05:	LOT: 2516, 5016, 1417, 0718, 3318, 4318, 3819, 1520
KIR 23/05N:	LOT: 0717, 5117, 0518, 4318, 1520
KIR 23/07:	LOT: 2516, 4216, 3617, 0718, 3318, 4318, 2119, 3819, 1520, 3320, 4420
KIR 23/07N:	LOT: 2916, 4516, 5016, 0717, 1618, 4318, 3819, 1520, 5220
KIR 23/10:	LOT: 2016, 2916, 4016, 5016, 0417, 0817, 0917, 1417, 2117A, 2117B, 3917, 4217, 4317, 4517,1618, 4118, 3318, 4818, 4318, 0319, 3319, 4119, 4619, 0520, 1620, 4420, 5220
KIR 23/15:	LOT: 0418, 3319, 2420
KIR 21/10:	LOT: 2916, 4016, 1417, 2117A, 2117B, 0418, 4318, 0719, 2119, 3519, 4619,1020, 1620, 5220
KIR 21/12:	LOT: 2116, 0717, 1618, 2119, 4619, 1020, 3820
KIR 21/15:	LOT: 3416, 0717, 1417, 0418, 3318, 4318, 3819, 1020, 3820
KIR 21/20:	LOT: 3617, 1020
KIR17/15:	LOT: 2417, 5117, 0918
KIR17/15:45:	LOT: 3616, 4216, 2317, 5117, 0918, 3919, 2720

KIM Interventional cannula, MRI-compatible:

KIM 22/05:	LOT: 3416, 5016, 0717, 1417, 4117, 4217, 0418, 2818, 2119, 4619A, 3819, 0220A, 0220B, 0220C, 2420, 3820
KIM 22/07:	LOT: 4216, 0717, 1417, 4918, 2119, 4619A, 4319, 0220A, 0220B, 3820
KIM 22/10:	LOT: 3616, 5016, 0717, 1417, 0418, 1118, 2818, 2119, 2419, 4619A, 0220A, 0220B, 0220C, 4319, 1220, 1020, 2720, 3520
KIM 22/15:	LOT: 1417, 2118,4319
KIM 20/10:	LOT: 4318
KIM 20/15:	LOT: 4318
KIM 18/10:	LOT: 0717, 4318

KIM 18/10T: LOT: 0217
KIM 18/15: LOT: 0717, 4318, 0920
KIM 18/15T: LOT: 4318
KIM 18/20: LOT: 4318

KIM 13/04T: LOT: 0817, 4318
KIM 13/09T: LOT: 0817, 4318
KIM 13/14T: LOT: 0817, 4318

KIM 15/04T: LOT: 2818
KIM 15/09T: LOT: 2818
KIM 15/14T: LOT: 2818

KIM 16/04T: LOT: 2818, 4820
KIM 16/09T: LOT: 2818, 4820, 5020
KIM 16/14T: LOT: 2818, 4820

KIM 14/20T: LOT: 2419

Semi-automatic biopsy needle, MRI-compatible:
BIM 18/10: LOT: 4918
BIM 18/15: LOT: 4017, 4918, 4719
BIM 18/20: LOT: 4017, 4918
BIM 16/10: LOT: 4918, 1119, 1219
BIM 16/15: LOT: 4918, 1119
BIM 16/20: LOT: 4918, 1119
BIM 14/10: LOT: 4918, 3019
BIM 14/15: LOT: 4918
BIM 14/20: LOT: 4918

Measures to be taken by users/distributors:
We request that you immediately check your stock of the products in question with the LOT numbers indicated.

Please complete the attached response letter and return it to the ITP..

Address: ITP GmbH
Rückrufunterlagen
Universitätsstraße 136
44799 Bochum
Germany

Contact person:
Dominik Främke
Tel.: +49 234 54621942
Fax: +49 234 54622444
E-Mail: fraemke@innotom.com

Upon receipt of the documents, we will contact you to retrieve and exchange the products..

Information sharing:
Please inform all persons within your company belonging to the circle of users about this urgent safety information.

The competent authority has been informed. They have received a copy of this letter.

An:
ITP GmbH
Rückrufunterlagen
Universitätsstraße 136
D-44799 Bochum

Reply form

We have received, read and understood the urgent safety information dated 19.04.2021:

Yes ___ No:___ (Please tick)

There are no affected products in our inventory:

Yes ___ No:___ (Please tick)

There are the following products in our inventory. These have been blocked:

Product (z.B. KIR 21/10)	LOT-Number	Quantity	Note

If there are several LOT numbers of one product, please enter them in separate lines.

We have also passed on the affected products to third parties.

Yes ___ No:___ (Please tick)

If yes:

The Urgent Safety Information has been forwarded to the third parties concerned:

Yes ___ No:___ (Please tick)

The third parties concerned have sent back letters of reply.

Yes ___ No:___ (Please tick)

The third parties concerned do not have any of the specified products in their inventory.

Yes ___ No:___ (Please tick)

The third parties concerned have blocked the following of the specified products in their inventory.

Yes ___ No:___ (Please tick)

Product (z.B. KIR 21/10)	**LOT-Number**	**Quantity**	**Note**

Filled in by:

Name Contact:		Institution:	
Signature:		Tel-number:	
Date:		E-Mail:	

Distributor data
(to be filled in if the distributor has arranged for the necessary forwarding of the safety information to third parties):

Name Contact:	
Institution:	
Tel-Number:	
E-Mail:	

We apologise for any inconvenience caused by this situation (which is not our fault).
Thank you for your support in implementing this safety measure.