

**ALPHATEC SPINE  
5818 El Camino Real  
92008 CARLSBAD  
USA**

L'Union, 14<sup>TH</sup> of October 2016

**For the attention of the General Manager and/or of the Medical Device Vigilance Manager**

Re: Product recall

Dear Sir or Madam,

Following a validation verification of our sterilization procedures on the premises of one of our providers, we wish to inform you that as a precautionary measure we are making a voluntary product recall concerning the following batches:

ARTICLE	REFERENCE	BATCH	QUANTITY
BONE X	OBX3PCBH55C	455/15.078	11
BONE X	OBX3PCBH55C	455/15.078	58
SAMARYS	11CCRF17-15-7S	251/14.265	6
SAMARYS	11CCRF20-15-7S	251/14.266	3
SAMARYS	11CCRF20-15-45S	251/14.266	7
SAMARYS	11CCRF17-15-7S	251/14.266	37
SAMARYS	11CCRF20-15-7S	251/14.267	6
SAMARYS	11CCRF20-15-45S	251/14.268	2
SAMARYS	11CCRF20-15-45S	251/15.267	11
SAMARYS	11CCRF17-13-6S	251/15.296	5
SAMARYS	11CCRF17-13-6S	251/15.297	5
SAMARYS	11CCRF17-13-7S	251/15.298	8
SAMARYS	11CCRF17-13-7S	251/15.299	2
SAMARYS	11CCRF17-13-7S	251/15.300	1
SAMARYS	11CCRF17-15-9S	251/15.301	1

We identified a risk in connection with sterilization conformity which could lead to infection in the days following surgery.

The cause of the incident is diagnosed and we have taken the necessary corrective steps to prevent recurrence.

In the context of this recall procedure, we are requesting a return of products from the batches quoted above to be sent to us at the following address:

KASIOS SAS  
18 chemin de la Violette  
31240 L'Union - FRANCE

As soon as we receive these products, they will be replaced free of charge.

Please address any queries concerning the recall to the KASIOS Medical Device Vigilance Unit:

Mr. Alain LERCH - Medical Device Vigilance Manager: [alain.lerch@kasios.com](mailto:alain.lerch@kasios.com) – +33(0)6.80.98.65.44

Mrs Adeline FRANCOIS - Medical Device Vigilance Deputy: [adeline.francois@kasios.com](mailto:adeline.francois@kasios.com) – +33(0)5 34.27.33.25

We much regret the inconvenience caused by this recall procedure. We wish to express our sincere apologies and the hope that we may look forward to enjoying your continued trust.

Yours sincerely,

Alain LERCH  
Medical Device Vigilance Manager

