kasios
BONE SUBSTITUTES

[redacted]

L'Union, 19TH 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
KAGE	KAG04	467/024-1	3
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KASIOS TCP	K43110G-E	431/14.179	5
RSF	RSF14-04P	486/039-14	3

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 – +33(0)6.80.98.65.44
Mrs Adeline FRANCOIS - Medical Device Vigilance Deputy: 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