

Urgent: SPIROTOME BIOPSY INSTRUMENT RECALL

September 16th 2014

MEDINVENTS NV
Bodemstraat 16/3
3830 Wellen – Belgium

to

COOK MEDICAL INC.
P.O. Box 4195
Bloomington, IN 47402-4195
U.S.A.



Dear Sir/Madame,

This is to inform you of a voluntary product recall involving:

SPIROTOME, biopsy instruments, with the following specifications and delivered between the 20th of June 2013 and the 26th of August 2014 :

RPN	GPN	Needle Gage	Needle Length (CM)
SS-08-06	G31987	8	6
SS-08-10	G31985	8	10
SS-08-15	G31998	8	15
SS-10-06	G32709	10	6
SS-10-10	G31988	10	10
SS-10-15	G32000	10	15
SS-14-06	G31993	14	6
SS-14-10	G31991	14	10
SS-14-15	G32752	14	15

This recall has been initiated due to a complaint of a customer (filed under PR103883 - QA_PAF_2014-07001) on July 24, 2014 that the protective caps were dislodged in one pouch. Further investigation disclosed potential dislodging of protective caps on the needle tips on other distributed needles. Use of affected products could create risk for non-sterile use or accidental puncture. Up to now, none of these events have occurred, and as manufacturer we take the quality of our products serious.

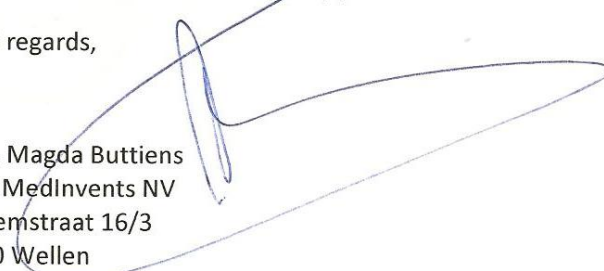
We began shipping this product conform to the specifications in June 2013 but were informed of the dislodging of the caps on August 28, 2014 after the cited customer (end-user) complaint and investigation of the complaint both in Cook Medical and in MedInvents.

Please examine immediately your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter. Customers are advised to return all products with the specification in the table to

Cook Medical. This recall should be carried out to the customer level. Your assistance is appreciated and necessary to prevent any patient harm.

If you have any questions, call Mrs. Magda Buttiens, CEO MedInvents on + 32 477 484734. As agreed during our conference call on the 8th of September Cook Medical will inform the Food and Drug Administration of this recall. A copy of this official notice will be sent to Medinvents.

Kind regards,



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