Lettix bv
medical supplies

November 14, 2019

To : Combimed

Subject: Medical device field safety notice – removal lot specific

Affected Product: Beenmergbioptie set 06

By a complaint report Lettix bv has discovered that the set composition was not correct for item 115T-10 BC.
Investigation of the complaint has discovered that the failure could be in two lot numbers

Our records indicate you may have received on or two affected products.
The affected products are distributed between 14/06/2019 until 14/11/2019.

Risks

Describe immediate health consequences (injuries or illness).	Most probable	Highest severity
	Extension of treatment < 30min (painful) No danger for the patient.	Extension of treatment < 30min (Painful) No danger for the patient
Describe long range health consequences (Injuries or illness)	Most probable	Highest severity
	None	None

Risk Manager Responsibilities:

1. Review this notification and ensure affected personnel are aware of the contents.
2. Distributer Combimed will be informed.
3. Distributer will be ordered to start recall for ref 115T-10BC with two lot numbers 2619010673 and 3019010673
4. Distributer will be asked to send Attachment 1 – certificate of acknowledgement to all his customers for this item.
    a. Return a digital copy to ls@lettix.nl and info@combimed.nl
5. If after reviewing this notice you have further questions or concerns please contact Combimed sales representative.

Other Information
This voluntary medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices.
Please keep Lettix bv informed of any adverse events associated with this product or any other Lettix bv product by emailing ls@lettix.nl or to your local Combimed contact.
The undersigned confirms that this notice has been delivered to the appropriate Competent Authorities, as per MEDDEV 2.12-1 revision 8.
We would like to thank you for your cooperation in advance and regret any inconveniences caused by this field action.
Sincerely,

H.L.J. Schrooten
QA manager Lettix bv

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ATTACHMENT 1

Certificate of Acknowledgement CBM19KLA.003

By signing below, I acknowledge that the required actions have been taken in accordance with the Field action Notice.

[ ] **Hospital Facility** [ ] **Surgeon** (Please check one as applicable)

Printed Name: _____ Signature: _____
Title: _____**Telephone:** ( ) ____-_____ **Date:**____/____/____
Facility Name: _____
Facility Address: _____
City:_____ **State:**_____ **ZIP:**_____
Note: This form must be returned to Lettix bv before this action can be considered closed for your account. It is important that you complete this form and email a copy to: ls@lettix.nl and info@combimed.nl.

Product reference	Lot number	Number of returned instruments
115T–10BC	2619010673	
115T-10BC	3019010673	