

Subject: Field Safety Notice for Lipivage batch number VN11852

Dear Partner,

Unfortunately, we have to inform you that our US manufacturer of our LipiVage® system has recently informed us that the CE-certificate for the disposable autologous fat transfer system (our article codes LipiVage 200-5/ 200-1/ 201-5 and 201-1) has meanwhile expired and up to now could not be renewed.

A CE-certificate is a prerequisite for placing a product on the market within the European Union. Unfortunately, we are currently unable to deliver the LipiVage® system, so we apologize for that.

The affected batch number is VN11852 / 2021-03, which has been sent out by mistake. Other batches are NOT concerned and can distributed and used.

We ask you for following measurements:

1. In the event that you still have the above-mentioned batch number in your stock, please do not sell them anymore to your customers!
2. Furthermore, please inform your Customers that they should not use this device. Please feel free to send existing stocks of this batch back to us.

Attached please find the letter, which we are using to inform our customers in Germany. This is intended as support and should be used as template to inform your customers.

We are currently investigating the situation with the manufacturer and working hard to find a solution. We will get back to you as soon as possible to inform you about further steps.

If you should have any regulatory questions please contact our regulatory colleague Mr. Wolfgang Henn: w.henn@polytechhealth.com. For commercial questions, please contact Vivian Thompson, our Senior Director Sales EMEA & Asia Pacific.

We kindly ask you to confirm the receipt of this notification and that you have execute the above-mentioned measurements not later than August the 10th. Your confirmation is essential for POLYTECH to complete this field safety action.

We regret this situation and hope that the impact on you and your work is manageable and we apologize for the inconvenience this may cause you.

We thank you for your trust in our products and are looking forward to a continued good cooperation.

Best regards,

