Field Safety Notice **Ref: Trsw**	Diffuplast S.r.L. Via Piave 48, 21057 Olgiate Olona (VA), Italia

11 May 2021

Dear Customer,

Diffuplast has been informed by its EO Sterilization supplier that, after an internal review, the sterilization certificates received by Diffuplast differs from the original raw data. The review performed by Diffuplast shows that only a few sterilization cycles were actually not acceptable in line with the validated sterilization cycles.

To ensure patient's safety, Diffuplast conducted the assessment to detect the affected batches, involved in deviations of the sterilization cycles.

In view of our conclusions and deductions of our assessment, Diffuplast had discussion with the Swiss competent authorities and Diffuplast decided that all unused medical devices impacted or potentially impacted by the wrong sterilization parameters should be recalled from the Swiss market.

The devices distributed in Switzerland are all batches starting with letter F, G, H, I, L and from batch M001 to batch M021.

All devices starting from batch number M022 onwards, are to be used normally with no issues and may be distributed to the Swiss market as required.

Below the list of article numbers distributed in Switzerland.

28010241	03MF	82.1302.0C	82.1430.6	E1340OLPF5
28010351	1302.0LP	82.1305.0	82.1440.6	E1350OLPF
28013011	1302.0S	82.1305.0C	82F.L84E	E1350OLPF5
28013021	1302.3	82.1305.3	82M.F84	E1401OD
28013051	1305.0LP	82.1310.0	82M.L84	E1401OD5
28013101	1305.0S	82.1310.0C	82S.L31	E1402OD
28013201	1305.3	82.1310.3	82S.NF29	E1402OD5
28013301	1310.0LP	82.1320.0	82S.NF30	E1405OD
28013401	1310.0S	82.1320.0C	B103	E1405OD5
28013501	1310.3	82.1320.3C	E1301OLPF	E1410OD
28014011	1320.0LP	82.1330.0	E1301OLPF5	E1410OD5
28014021	1320.0S	82.1330.0C	E1302OLPF	E1420OD
28014051	1320.3	82.1330.3	E1302OLPF5	E1420OD5
28014101	1330.0LP	82.1350.3	E1305OLPF	E1430OD
28014201	1330.0S	82.1402.0	E1305OLPF5	E1430OD5

28014301	1330.3	82.1402.0C	E1310OLPF	E1440OD
28014401	1335.0LP	82.1402.0C/5	E1310OLPF5	E1440OD5
28014501	6020V	82.1405.0C	E1320OLPF	E1450OD
28100651	82.0001F	82.1410.0C	E1320OLPF5	E1450OD5
28101331	82.1301.0	82.1420.0	E1330OLPF	F.F4202
28900076	82.1301.0C	82.1420.0C	E1330OLPF5	H9380003
28900077	82.1302.0	82.1430.0C	E1340OLPF	L.L.701

Diffuplast has not identified any reports of adverse events to date that could be associated to this field safety corrective action. No specific patient follow-up activities are required if the product has already been used.

To implement this recall, please perform the following actions:

1. Examine your inventory and quarantine the affected products.
2. Discontinue the use batch numbers listed above.
3. Inform Diffuplast of the quantity of affected medical devices in your stock according to Reply Form.
4. Please request your customers to return the affected devices and quarantine them.
5. If the bags are already in use on patients these can be left in use, however all other unused articles from the specified batches are to be recalled.

Diffuplast has sent an FSCA report to the relevant National Competent Authorities.

Your assistance is sincerely appreciated. Diffuplast apologizes for any inconvenience that this recall may cause to you and your staff.

If you have any question, please do not hesitate to contact us on number +390331640646 or write to info@diffuplast.it.

Giuseppe Vignati
Diffuplast S.r.l.

Reply Form

Please read in conjunction with FSN recall letter of 11 May 2021. Please return this form to info@diffuplast.it.

Company name:	
Address:	
Contact name:	
Email:	

☐ I confirm the receipt, the reading and understanding of the FSN

☐ I confirm that the following affected units have been returned

Code	Batch	Quantity

Signature and date: _____