

Rev 1: September 2018

FSN Ref: FSN 02/2021

FSCA Ref: FSCA 01/2021



Rev: 00

Date: 04/06/2021

Urgent Field Safety Notice

Dear Customer / Distributor,

As Manufacturer of Medical Devices, Gruppo Bioimpianti Srl hereby notify about the issue of a Field Safety Notice relating to the Medical Devices included in Annex 2.

Urgent Field Safety Notice (FSN) – Swiss Market ONLY

Purpose of this Field Safety Notice (FSN)

The purpose of this safety notice is to inform you that Gruppo Bioimpianti Srl is performing a new field safety notice **specific to the Swiss market** for specific batches of various types of polyethylene implantable medical devices for orthopaedics.

In particular, following the issue described in detail in the following paragraph of this FSN the Swiss Ministry of Health has requested to withdraw all products sterilised by Steril Milano and marketed in Switzerland, regardless of whether they were part of suspicious and therefore potentially non-compliant sterilization batches or not.

For the complete list of devices of interest please see Annex 2.

According to our traceability system, you have been supplied with one or more devices that may be impacted by the issue described below and therefore one or more of these devices may be in your inventory or those of your respective customers.

Reason for the Field Safety Notice (FSN)

Gruppo Bioimpianti Srl used the company Steril Milano for the outsourcing of the Ethylene Oxide (EO) sterilisation process for devices made of Polyethylene. The supplier Steril Milano Srl notified Gruppo Bioimpianti Srl of a possible compliance issue with some sterilization batches. Specifically, records of some process parameters for some sterilization cycles carried out over the last few years were falsified. The EO sterilization process was subjected to appropriate validation activity and the release on the market of the devices has always been carried out by Gruppo Bioimpianti in accordance with internal procedures, verifying the reports showing the process parameters, cycle graphics and cycle compliance shared by the supplier (parametric release) and verifying the results of the biological indicators. For this reason, Gruppo Bioimpianti was not able to identify this falsification having always received compliant reports from the supplier. Following the communications received from Steril Milano Srl concerning the falsification of process parameters relating to some sterilisation cycles involving batches of medical devices manufactured by Gruppo Bioimpianti Srl, the relevant Notified Body and the circulars of the Italian Ministry of Health, in order to ensure the safety and compliance of medical devices and patient health, appropriate investigations have been conducted in relation to all the sterilization cycles carried out by Steril Milano based on the analysis of the communications and raw data received from the Company in order to identify the presence of potential deviations from the validated cycle and their entity.

This investigation led to the identification of some suspected and therefore potentially non-compliant sterilization batches.

In parallel with this investigation, sterility tests were performed on sample devices from the various sterilization batches (compliant and non-compliant). All the sterility tests conducted on sample devices from the suspected and potentially non-compliant sterilization batches concluded with compliant results, i.e. sterility of the tested devices, except for one single sterilization batch which led to non-compliant results during the testing. This NC result led to the issue of FSCA 01-2021 and FSN 01-2021, which were shared with Italian MOH, and to the recall action of all the related material from the market. Parallel to the recall action, Gruppo Bioimpianti has carried out further sterility tests on other devices belonging to the same

sterilization batch and all the additional tests carried out concluded with compliant results, i.e. sterility of the tested devices.

Despite the fact that sterility analyses have been carried out on sample devices from the suspected and potentially non-compliant sterilization batches with compliant results, i.e. sterility of the tested devices, in addition to the recall of the devices belonging to the batch which obtained non-compliant sterility test result, it was considered necessary, in light of the above considerations, to recall from the market also all products considered potentially non-compliant on the basis of analyses conducted on the raw data.

Despite this recall action already implemented on products belonging to suspicious and potentially non-compliant sterilization batches for all distributors and end customers supplied by Gruppo Bioimpianti, this specific FSN has been required by Swiss Ministry of Health in order to recall all the devices sterilised by Steril Milano and marketed in Switzerland, regardless of whether they were part of suspicious and therefore potentially non-compliant sterilization batches or not.

Since all the devices belonging to the suspicious and therefore potentially non-compliant sterilization batches have already been recalled, a list of the remaining products sterilised by Steril Milano and still present in the Swiss market is provided in Annex 2 of this FSN in terms of code, description, lot and expiry date.

Hazards and risks arising from this FSN

The dangers and risks arising from the Steril Milano issue are those of the use of a possible non-sterile medical device for orthopaedics, with a consequent cause of infection for the patient. To date, Gruppo Bioimpianti Srl has never received any report of either infection or accident in relation to the devices that are involved in Steril Milano issue, considering that these may be sterilisation batches dating back as far as the beginning of 2018 since the company Steril Milano has stated that the non-conformities have been in place for several years. Furthermore, the devices listed in Annex 2 do not belong to suspected and potentially non-compliant sterilization batches on the basis of analyses conducted on the raw data.

Actions taken by the Manufacturer

Following the above reports and communications, Gruppo Bioimpianti Srl has:

- Carried out appropriate internal investigations in order to identify the suspected and therefore potentially involved sterilization batches and the related material list.
- Stopped the shipment of the potentially involved devices still in stock and informed all customers/distributors about the issue by means of a field safety notice and/or appropriate communications in order to allow the identification, quarantine and return of all potentially affected devices present in their warehouses.
- Coordinated the replacement of all potentially affected devices.
- Suspended any sterilization service by Steril Milano. The ethylene oxide sterilisation process is currently carried out by another Company certified ISO 13485, ISO 9001 and ISO 11135 which offers this type of service.

Furthermore, following the request received by the Swiss Ministry of Health, Gruppo Bioimpianti is currently conducting a recall of all remaining products sterilised by Steril Milano and still present in the Swiss market, even if these devices do not belong to the suspicious and therefore potentially non-compliant sterilization batches on the basis of analyses conducted.



Actions required by healthcare professionals who have not already done so

Gruppo Bioimpianti Srl and its staff are coordinating the removal and replacement of all medical device lots sterilised by Steril Milano from your inventory.

In particular, all potentially affected devices present in warehouses outside the Manufacturer's warehouse have been already recalled; the additional recall requested concerns devices considered compliant on the basis of the analyses conducted.

If you have not already done so, please:

- Identify within your own and/or your respective customer's warehouse the presence of any involved devices as per the list included within Annex 2;
- Proceed with their isolation and quarantine, all pending their return to Gruppo Bioimpianti Srl;
- Fill in Annex 1 and return it by e-mail to qualita@bioimpianti.it to start the process of returning and replacing the devices of interest, if this has not already been done.

If this has not already been done, the reference representative of Gruppo Bioimpianti will contact you to coordinate the return of any potentially impacted devices.

The action should be completed within 10 days.

For any request for clarification or information regarding the contents of this FSN or regarding the return and replacement of the devices, please contact your usual representative or directly Gruppo Bioimpianti Srl at qualita@bioimpianti.it.

Transmission of the Field Safety Notice (FSN)

Please proceed with the transmission of this Field Safety Notice to all those who need to be aware of it within your organisation or to any organisation to which the devices listed in Annex 2 have been delivered.

Please take the utmost care on this notice and the resulting action for an appropriate period of time to ensure the effectiveness of the corrective action.

Please report all incidents relating to devices to the manufacturer, distributor or local representative and, if appropriate, to the national competent authority as this provides important feedback.

There is no provision for a follow-up Field Safety Notice (FSN) for the issue in question.

General Information of the Manufacturer

Company:	Gruppo Bioimpianti Srl
Address:	Via Liguria 28, 20068 Peschiera Borromeo (MI), Italy
Telephone number:	+39 0251650371
E-mail:	qualita@bioimpianti.it
Website:	www.bioimpianti.it

Annexes

Annex 1: Customer / Distributor Reply Form

Annex 2: List of involved devices

Rev 1: September 2018

FSN Ref: FSN 02/2021

FSCA Ref: FSCA 01/2021



Thanking you for your kind cooperation and apologising for any inconvenience that this situation may have caused, Gruppo Bioimpianti is working diligently to resolve in the best possible way this problem.

Gruppo Bioimpianti Srl
CEO

Fabio Angelo Pietro Bedini

Gruppo Bioimpianti srl
Fabio Bedini
CEO

Annex 1 - Customer / Distributor Reply Form

Please send your reply by e-mail to:
qualita@bioimpianti.it

Please complete this form in full and tick the appropriate boxes.

- ☐ I confirm the receipt of this FSN 02/2021 and I have informed all relevant persons about the product recall and the procedure described.
- ☐ None of the devices listed in Annex II is in our warehouse.
- ☐ The following devices are present in our warehouse and have been promptly quarantined:

Code	Lot	Description	Expiry data	Quantity

Please do not return unrequested goods and contact the contact person to arrange the replacement of the material.

Name Hospital / Institute / Customer:	
Customer number:	
Address Hospital / Institute / Customer:	
Contact person: Function:	
Phone number:	

Annex 2 – List of involved devices

The following table shows the material for which you are asked to identify, isolate and return to Gruppo Bioimpianti Srl because EO sterilized by the Company Steril Milano Srl. Please check if there are devices in your warehouse which are part of the list below and follow the actions required in the FSN form by returning us the duly completed Annex 1.

Reference	Description	Lot	Expiration date
120704201E	K-MONO XLPE + VE INSERT RM/LL 8mm, size 1	AF2409	27/04/2030
120704202E	K-MONO XLPE + VE INSERT RM/LL 8mm, size 2	AF2410	29/04/2030
120704203E	K-MONO XLPE + VE INSERT RM/LL 8mm, size 3	AF2411	29/04/2030
120704204E	K-MONO XLPE + VE INSERT RM/LL 8mm, size 4	AF2412	29/04/2030
120704205E	K-MONO XLPE + VE INSERT RM/LL 8mm, size 5	AF2413	29/04/2030
120704206E	K-MONO XLPE + VE INSERT RM/LL 8mm, size 6	AF2414	27/04/2030
120704211E	K-MONO XLPE + VE INSERT RM/LL 9mm, size 1	AF2415	30/04/2030
120704212E	K-MONO XLPE + VE INSERT RM/LL 9mm, size 2	AF2416	30/04/2030
120704213E	K-MONO XLPE + VE INSERT RM/LL 9mm, size 3	AF2417	30/04/2030
120704214E	K-MONO XLPE + VE INSERT RM/LL 9mm, size 4	AF2418	30/04/2030
120704215E	K-MONO XLPE + VE INSERT RM/LL 9mm, size 5	AF2419	30/04/2030
120704216E	K-MONO XLPE + VE INSERT RM/LL 9mm, size 6	AF2420	30/04/2030
120704221E	K-MONO XLPE + VE INSERT RM/LL 10mm, size 1	AF2421	30/04/2030
120704222E	K-MONO XLPE + VE INSERT RM/LL 10mm, size 2	AF2422	30/04/2030
120704223E	K-MONO XLPE + VE INSERT RM/LL 10mm, size 3	AF2423	30/04/2030
120704224E	K-MONO XLPE + VE INSERT RM/LL 10mm, size 4	AF2424	30/04/2030
120704225E	K-MONO XLPE + VE INSERT RM/LL 10mm, size 5	AF2425	30/04/2030
120704226E	K-MONO XLPE + VE INSERT RM/LL 10mm, size 6	AF2426	30/04/2030
120704231E	K-MONO XLPE + VE INSERT RM/LL 12mm, size 1	AF2427	30/04/2030
120704232E	K-MONO XLPE + VE INSERT RM/LL 12mm, size 2	AF2428	30/04/2030
120704233E	K-MONO XLPE + VE INSERT RM/LL 12mm, size 3	AF2429	30/04/2030
120704234E	K-MONO XLPE + VE INSERT RM/LL 12mm, size 4	AF2430	30/04/2030
120704235E	K-MONO XLPE + VE INSERT RM/LL 12mm, size 5	AF2431	30/04/2030
120704236E	K-MONO XLPE + VE INSERT RM/LL 12mm, size 6	AF2432	30/04/2030
120704251E	K-MONO XLPE + VE INSERT RL/LM 8mm, size 1	AF2433	11/05/2030
120704252E	K-MONO XLPE + VE INSERT RL/LM 8mm, size 2	AF2434	11/05/2030
120704253E	K-MONO XLPE + VE INSERT RL/LM 8mm, size 3	AF2435	11/05/2030
120704254E	K-MONO XLPE + VE INSERT RL/LM 8mm, size 4	AF2436	11/05/2030
120704255E	K-MONO XLPE + VE INSERT RL/LM 8mm, size 5	AF2437	11/05/2030
120704256E	K-MONO XLPE + VE INSERT RL/LM 8mm, size 6	AF2438	11/05/2030
120704261E	K-MONO XLPE + VE INSERT RL/LM 9 mm, size 1	AF2439	11/05/2030
120704262E	K-MONO XLPE + VE INSERT RL/LM 9 mm, size 2	AF2440	11/05/2030

120704263E	K-MONO XLPE + VE INSERT RL/LM 9 mm, size 3	AF2441	11/05/2030
120704264E	K-MONO XLPE + VE INSERT RL/LM 9 mm, size 4	AF2442	11/05/2030
120704265E	K-MONO XLPE + VE INSERT RL/LM 9mm, size 5	AF2443	11/05/2030
120704266E	K-MONO XLPE + VE INSERT RL/LM 9mm, size 6	AF2444	11/05/2030
120704271E	K-MONO XLPE + VE INSERT RL/LM 10 mm, size 1	AF2445	12/05/2030
120704272E	K-MONO XLPE + VE INSERT RL/LM 10 mm, size 2	AF2446	12/05/2030
120704273E	K-MONO XLPE + VE INSERT RL/LM 10 mm, size 3	AF2447	12/05/2030
120704274E	K-MONO XLPE + VE INSERT RL/LM 10 mm, size 4	AF2448	12/05/2030
120704275E	K-MONO XLPE + VE INSERT RL/LM 10 mm, size 5	AF2449	12/05/2030
120704276E	K-MONO XLPE + VE INSERT RL/LM 10 mm, size 6	AF2450	12/05/2030
120704281E	K-MONO XLPE + VE INSERT RL/LM 12 mm, size 1	AF2451	15/05/2030
120704282E	K-MONO XLPE + VE INSERT RL/LM 12 mm, size 2	AF2452	15/05/2030
120704283E	K-MONO XLPE + VE INSERT RL/LM 12 mm, size 3	AF2453	15/05/2030
120704284E	K-MONO XLPE + VE INSERT RL/LM 12 mm, size 4	AF2454	23/06/2030
120704285E	K-MONO XLPE + VE INSERT RL/LM 12 mm, size 5	AF2455	15/05/2030
120704286E	K-MONO XLPE + VE INSERT RL/LM 12 mm, size 6	AF2456	15/05/2030
120700661	K-MOD UC FIXED INSERT, Size 1, TH. 10mm	AG0596	24/04/2030
120700662	K-MOD UC FIXED INSERT, Size 2, TH. 10mm	AG1359	04/08/2030
120700663	K-MOD UC FIXED INSERT, Size 3, TH. 10mm	AG2642R1	19/02/2031
120700664	K-MOD UC FIXED INSERT, Size 4, TH. 10mm	AG0879	15/06/2030
120700665	K-MOD UC FIXED INSERT, Size 5, TH. 10mm	AG0627	25/05/2030
120700666	K-MOD UC FIXED INSERT, Size 6, TH. 10mm	AF3357	12/11/2029
120700671	K-MOD UC FIXED INSERT, Size 1, TH. 12mm	AC1657	25/10/2027
120700672	K-MOD UC FIXED INSERT, Size 2, TH. 12mm	AB3340	30/05/2026
120700673	K-MOD UC FIXED INSERT, Size 3, TH. 12mm	AF1632	01/07/2029
120700674	K-MOD UC FIXED INSERT, Size 4, TH. 12mm	AG0343	08/04/2030
120700675	K-MOD UC FIXED INSERT, Size 5, TH. 12mm	AF0910	13/05/2029
120700676	K-MOD UC FIXED INSERT, Size 6, TH. 12mm	AC1665	17/01/2027
120700681	K-MOD UC FIXED INSERT, Size 1, TH. 14mm	AB1025	28/12/2025
120700682	K-MOD UC FIXED INSERT, Size 2, TH. 14mm	AC2165	21/06/2027
120700683	K-MOD UC FIXED INSERT, Size 3, TH. 14mm	AG0807	28/05/2030
120700684	K-MOD UC FIXED INSERT, Size 4, TH. 14mm	AE2576	22/10/2028
120700685	K-MOD UC FIXED INSERT, Size 5, TH. 14mm	AC1663	24/02/2027
120700686	K-MOD UC FIXED INSERT, Size 6, TH. 14mm	AB2216	28/06/2026
120700691	K-MOD UC FIXED INSERT, Size 1, TH. 16mm	AA1504	20/02/2025
120700692	K-MOD UC FIXED INSERT, Size 2, TH. 16mm	K2453	01/03/2023
120700693	K-MOD UC FIXED INSERT, Size 3, TH. 16mm	AB0932	28/06/2026
120700694	K-MOD UC FIXED INSERT, Size 4, TH. 16mm	AA0521	13/06/2024
120700695	K-MOD UC FIXED INSERT, Size 5, TH. 16mm	AA0539R2	29/10/2028
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120700713	K-MOD DC INSERT LEFT, Size 3, TH. 10mm	AG0141	28/02/2030

120700714	K-MOD DC INSERT LEFT, Size 4, TH. 10mm	AG2343R1	20/03/2031
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120700723	K-MOD DC INSERT LEFT, Size 3, TH. 12mm	AE3607	22/01/2029
120700724	K-MOD DC INSERT LEFT, Size 4, TH. 12mm	AG1752R1	18/02/2031
120700725	K-MOD DC INSERT LEFT, Size 5, TH. 12mm	AE0357	07/03/2028
120700726	K-MOD DC INSERT LEFT, Size 6, TH. 12mm	AE2867	12/11/2028
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120700732	K-MOD DC INSERT LEFT, Size 2, TH. 14mm	AF4060R1	18/03/2031
120700733	K-MOD DC INSERT LEFT, Size 3, TH. 14mm	AG0345R1	10/03/2031
120700734	K-MOD DC INSERT LEFT, Size 4, TH. 14mm	AF0175	01/03/2029
120700735	K-MOD DC INSERT LEFT, Size 5, TH. 14mm	AF4103R1	18/03/2031
120700736	K-MOD DC INSERT LEFT, Size 6, TH. 14mm	AE0614R1	25/03/2031
120700741	K-MOD DC INSERT LEFT, Size 1, TH. 16mm	AG0238R2	24/03/2031
120700742	K-MOD DC INSERT LEFT, Size 2, TH. 16mm	AG0346R1	10/03/2031
120700743	K-MOD DC INSERT LEFT, Size 3, TH. 16mm	AG0143R1	24/03/2031
120700744	K-MOD DC INSERT LEFT, Size 4, TH. 16mm	AG1753R1	18/02/2031
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120700753	K-MOD DC INSERT RIGHT, Size 3, TH. 10mm	AH0091	02/03/2031
120700754	K-MOD DC INSERT RIGHT, Size 4, TH. 10mm	AG2838	08/01/2031
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120700763	K-MOD DC INSERT RIGHT, Size 3, TH. 12mm	AF0009	08/02/2029
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120700765	K-MOD DC INSERT RIGHT, Size 5, TH. 12mm	AF0011	06/02/2029
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120700772	K-MOD DC INSERT RIGHT, Size 2, TH. 14mm	AG1328R1	18/02/2031
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120700775	K-MOD DC INSERT RIGHT, Size 5, TH. 14mm	AG0239	10/03/2030
120700776	K-MOD DC INSERT RIGHT, Size 6, TH. 14mm	AE2331	14/09/2028
120700781	K-MOD DC INSERT RIGHT, Size 1, TH. 16mm	AG0599R2	30/03/2031
120700782	K-MOD DC INSERT RIGHT, Size 2, TH. 16mm	AF3359R2	09/03/2031
120700783	K-MOD DC INSERT RIGHT, Size 3, TH. 16mm	AF4106	11/02/2030
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120704202E	K-MONO XLPE + VE INSERT RM/LL 8mm, size 2	AF2410	29/04/2030
120704203E	K-MONO XLPE + VE INSERT RM/LL 8mm, size 3	AF2411	29/04/2030
120704204E	K-MONO XLPE + VE INSERT RM/LL 8mm, size 4	AF2412	29/04/2030
120704205E	K-MONO XLPE + VE INSERT RM/LL 8mm, size 5	AF2413	29/04/2030
120704206E	K-MONO XLPE + VE INSERT RM/LL 8mm, size 6	AF2414	27/04/2030
120704211E	K-MONO XLPE + VE INSERT RM/LL 9mm, size 1	AF2415	30/04/2030
120704212E	K-MONO XLPE + VE INSERT RM/LL 9mm, size 2	AF2416	30/04/2030
120704213E	K-MONO XLPE + VE INSERT RM/LL 9mm, size 3	AF2417	10/07/2030
120704214E	K-MONO XLPE + VE INSERT RM/LL 9mm, size 4	AF2418	30/04/2030
120704215E	K-MONO XLPE + VE INSERT RM/LL 9mm, size 5	AF2419	30/04/2030
120704216E	K-MONO XLPE + VE INSERT RM/LL 9mm, size 6	AF2420	30/04/2030
120704221E	K-MONO XLPE + VE INSERT RM/LL 10mm, size 1	AF2421	30/04/2030
120704222E	K-MONO XLPE + VE INSERT RM/LL 10mm, size 2	AF2422	30/04/2030
120704223E	K-MONO XLPE + VE INSERT RM/LL 10mm, size 3	AF2423	30/04/2030
120704224E	K-MONO XLPE + VE INSERT RM/LL 10mm, size 4	AF2424	30/04/2030
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120704226E	K-MONO XLPE + VE INSERT RM/LL 10mm, size 6	AF2426	30/04/2030
120704231E	K-MONO XLPE + VE INSERT RM/LL 12mm, size 1	AF2427	30/04/2030
120704232E	K-MONO XLPE + VE INSERT RM/LL 12mm, size 2	AF2428	30/04/2030
120704233E	K-MONO XLPE + VE INSERT RM/LL 12mm, size 3	AF2429	30/04/2030
120704234E	K-MONO XLPE + VE INSERT RM/LL 12mm, size 4	AF2430	30/04/2030
120704235E	K-MONO XLPE + VE INSERT RM/LL 12mm, size 5	AF2431	30/04/2030
120704236E	K-MONO XLPE + VE INSERT RM/LL 12mm, size 6	AF2432	30/04/2030
120704251E	K-MONO XLPE + VE INSERT RL/LM 8mm, size 1	AF2433	11/05/2030
120704252E	K-MONO XLPE + VE INSERT RL/LM 8mm, size 2	AF2434	11/05/2030
120704253E	K-MONO XLPE + VE INSERT RL/LM 8mm, size 3	AF2435	11/05/2030
120704254E	K-MONO XLPE + VE INSERT RL/LM 8mm, size 4	AF2436	11/05/2030
120704255E	K-MONO XLPE + VE INSERT RL/LM 8mm, size 5	AF2437	11/05/2030
120704256E	K-MONO XLPE + VE INSERT RL/LM 8mm, size 6	AF2438	11/05/2030
120704261E	K-MONO XLPE + VE INSERT RL/LM 9 mm, size 1	AF2439	11/05/2030
120704262E	K-MONO XLPE + VE INSERT RL/LM 9 mm, size 2	AF2440	11/05/2030
120704263E	K-MONO XLPE + VE INSERT RL/LM 9 mm, size 3	AF2441	11/05/2030
120704264E	K-MONO XLPE + VE INSERT RL/LM 9 mm, size 4	AF2442	11/05/2030
120704265E	K-MONO XLPE + VE INSERT RL/LM 9mm, size 5	AF2443	11/05/2030
120704266E	K-MONO XLPE + VE INSERT RL/LM 9mm, size 6	AF2444	11/05/2030
120704271E	K-MONO XLPE + VE INSERT RL/LM 10 mm, size 1	AF2445	12/05/2030
120704272E	K-MONO XLPE + VE INSERT RL/LM 10 mm, size 2	AF2446	12/05/2030
120704273E	K-MONO XLPE + VE INSERT RL/LM 10 mm, size 3	AF2447	12/05/2030
120704274E	K-MONO XLPE + VE INSERT RL/LM 10 mm, size 4	AF2448	12/05/2030
120704275E	K-MONO XLPE + VE INSERT RL/LM 10 mm, size 5	AF2449	12/05/2030



120704276E	K-MONO XLPE + VE INSERT RL/LM 10 mm, size 6	AF2450	12/05/2030
120704281E	K-MONO XLPE + VE INSERT RL/LM 12 mm, size 1	AF2451	15/05/2030
120704282E	K-MONO XLPE + VE INSERT RL/LM 12 mm, size 2	AF2452	15/05/2030
120704283E	K-MONO XLPE + VE INSERT RL/LM 12 mm, size 3	AF2453	15/05/2030
120704284E	K-MONO XLPE + VE INSERT RL/LM 12 mm, size 4	AF2454	23/06/2030
120704285E	K-MONO XLPE + VE INSERT RL/LM 12 mm, size 5	AF2455	15/05/2030
120704286E	K-MONO XLPE + VE INSERT RL/LM 12 mm, size 6	AF2456	15/05/2030
120700733	INSERT DC SIZE 3 TH.14 LEFT	AE1441	29/05/2028
120700765	K-MOD FIXED INSERT DC SIZE 5 TH.12 RIGHT	AE1445	29/05/2028
120700781	K-MOD FIXED INSERT DC SIZE 1 TH.16 RIGHT	AE1493	05/06/2028
120700721	K-MOD FIXED INSERT DC SIZE 1 TH.12 LEFT	AE1479	08/06/2028
120700726	K-MOD FIXED INSERT DC SIZE 6 TH.12 LEFT	AE1480	08/06/2028
120700785	K-MOD FIXED INSERT DC SIZE 5 TH.16 RIGHT	AE1484	08/06/2028
120700741	K-MOD FIXED INSERT DC SIZE 1 TH.16 LEFT	AE2368	10/10/2028
120700732	K-MOD FIXED INSERT DC SIZE 2 TH.14 LEFT	AE3346	14/12/2028
120700784	K-MOD FIXED INSERT DC SIZE 4 TH.16 RIGHT	AF0177	01/03/2029
120700755	K-MOD FIXED INSERT DC SIZE 5 TH.10 RIGHT	AF1006	13/05/2029
120700762	K-MOD FIXED INSERT DC SIZE 2 TH.12 RIGHT	AF1007	09/09/2029
120700722	K-MOD FIXED INSERT DC SIZE 2 TH.12 LEFT	AF3644	03/12/2029
120700764	K-MOD FIXED INSERT DC SIZE 4 TH.12 RIGHT	AF2876	12/12/2029
120700712	K-MOD FIXED INSERT DC SIZE 2 TH.10 LEFT	AF3926	20/01/2030
120700716	K-MOD FIXED INSERT DC SIZE 6 TH.10 LEFT	AF4005	31/01/2030
120700735	K-MOD FIXED INSERT DC SIZE 5 TH.14 LEFT	AF4103	31/01/2030
120700723	K-MOD FIXED INSERT DC SIZE 3 TH.12 LEFT	AF4059	04/02/2030
120700756	K-MOD FIXED INSERT DC SIZE 6 TH.10 RIGHT	AG0053	25/02/2030
120700731	K-MOD FIXED INSERT DC SIZE 1 TH.14 LEFT	AG0142	03/03/2030
110362356	XLPE INSERT FOR FIN CUP 56/58 INT.36 0°	100043	09/04/2030
120700751	K-MOD FIXED INSERT DC SIZE 1 TH.10 RIGHT	AG0476	24/04/2030
120704202E	K-MONO INSERT XLPE+VE RM/LL 2x8	AF2410	29/04/2030
120704205E	K-MONO INSERT XLPE+VE RM/LL 5x8	AF2413	29/04/2030
120704251E	K-MONO INSERT XLPE+VE RL/LM 1x19	AF2433	11/05/2030
120704252E	K-MONO INSERT XLPE+VE RL/LM 2x20	AF2434	11/05/2030
120704254E	K-MONO INSERT XLPE+VE RL/LM 4x19	AF2436	11/05/2030
120704263E	K-MONO INSERT XLPE+VE RL/LM 3x22	AF2441	11/05/2030
120704264E	K-MONO INSERT XLPE+VE RL/LM 4x22	AF2442	11/05/2030
120704286E	K-MONO INSERT XLPE+VE RL/LM 6x27	AF2456	15/05/2030
120700713	K-MOD FIXED INSERT DC SIZE 3 TH.10 LEFT	AG0680	15/06/2030
120700714	K-MOD FIXED INSERT DC SIZE 4 TH.10 LEFT	AG0955	15/06/2030
120700753	K-MOD FIXED INSERT DC SIZE 3 TH.10 RIGHT	AG0628	15/06/2030
120700752	K-MOD FIXED INSERT DC SIZE 2 TH.10 RIGHT	AG1271	16/06/2030
120700754	K-MOD FIXED INSERT DC SIZE 4 TH.10 RIGHT	AG0809	19/06/2030
120704224E	K-MONO INSERT XLPE+VE RM/LL 4x10	AF2424	23/06/2030
120704224E	K-MONO INSERT XLPE+VE RM/LL 4x10	AF2424	23/06/2030

120704282E	K-MONO INSERT XLPE+VE RL/LM 2x23	AF2452	23/06/2030
120704282E	K-MONO INSERT XLPE+VE RL/LM 2x27	AF2452	23/06/2030
120704285E	K-MONO INSERT XLPE+VE RL/LM 5x23	AF2455	23/06/2030
120704285E	K-MONO INSERT XLPE+VE RL/LM 5x25	AF2455	23/06/2030
120704222E	K-MONO INSERT XLPE+VE RM/LL 2x10	AF2422	29/06/2030
120704222E	K-MONO INSERT XLPE+VE RM/LL 2x10	AF2422	29/06/2030
120704232E	K-MONO INSERT XLPE+VE RM/LL 2x23	AF2428	29/06/2030
120704232E	K-MONO INSERT XLPE+VE RM/LL 2x25	AF2428	29/06/2030
120704235E	K-MONO INSERT XLPE+VE RM/LL 5x23	AF2431	29/06/2030
120704235E	K-MONO INSERT XLPE+VE RM/LL 5x25	AF2431	29/06/2030
120704271E	K-MONO INSERT XLPE+VE RL/LM 1x21	AF2445	29/06/2030
120704271E	K-MONO INSERT XLPE+VE RL/LM 1x23	AF2445	29/06/2030
120704276E	K-MONO INSERT XLPE+VE RL/LM 6x21	AF2450	29/06/2030
120704276E	K-MONO INSERT XLPE+VE RL/LM 6x23	AF2450	29/06/2030
120704221E	K-MONO INSERT XLPE+VE RM/LL 1x10	AF2421	30/06/2030
120704221E	K-MONO INSERT XLPE+VE RM/LL 1x10	AF2421	30/06/2030
120704223E	K-MONO INSERT XLPE+VE RM/LL 3x10	AF2423	30/06/2030
120704223E	K-MONO INSERT XLPE+VE RM/LL 3x10	AF2423	30/06/2030
120704236E	K-MONO INSERT XLPE+VE RM/LL 6x23	AF2432	30/06/2030
120704251E	K-MONO INSERT XLPE+VE RL/LM 1x21	AF2433	30/06/2030
120704252E	K-MONO INSERT XLPE+VE RL/LM 2x22	AF2434	30/06/2030
120704255E	K-MONO INSERT XLPE+VE RL/LM 5x21	AF2437	30/06/2030
120704261E	K-MONO INSERT XLPE+VE RL/LM 1x21	AF2439	30/06/2030
120704261E	K-MONO INSERT XLPE+VE RL/LM 1x23	AF2439	30/06/2030
120704264E	K-MONO INSERT XLPE+VE RL/LM 4x20	AF2442	30/06/2030
120704265E	K-MONO INSERT XLPE+VE RL/LM 5x22	AF2443	30/06/2030
120704265E	K-MONO INSERT XLPE+VE RL/LM 5x24	AF2443	30/06/2030
120704272E	K-MONO INSERT XLPE+VE RL/LM 2x21	AF2446	30/06/2030
120704272E	K-MONO INSERT XLPE+VE RL/LM 2x23	AF2446	30/06/2030
120704273E	K-MONO INSERT XLPE+VE RL/LM 3x21	AF2447	30/06/2030
120704273E	K-MONO INSERT XLPE+VE RL/LM 3x23	AF2447	30/06/2030
120704283E	K-MONO INSERT XLPE+VE RL/LM 3x25	AF2453	30/06/2030
120700761	K-MOD FIXED INSERT DC SIZE 1 TH.12 RIGHT	AG0682	03/07/2030
120704202E	K-MONO INSERT XLPE+VE RM/LL 2x8	AF2410	08/07/2030
120704204E	K-MONO INSERT XLPE+VE RM/LL 4x8	AF2412	08/07/2030
120704203E	K-MONO INSERT XLPE+VE RM/LL 3x8	AF2411	10/07/2030
120704203E	K-MONO INSERT XLPE+VE RM/LL 3x8	AF2411	10/07/2030
120704205E	K-MONO INSERT XLPE+VE RM/LL 5x8	AF2413	10/07/2030
120704212E	K-MONO INSERT XLPE+VE RM/LL 2x9	AF2416	10/07/2030
120704212E	K-MONO INSERT XLPE+VE RM/LL 2x9	AF2416	10/07/2030
120704213E	K-MONO INSERT XLPE+VE RM/LL 3x9	AF2417	10/07/2030
120704213E	K-MONO INSERT XLPE+VE RM/LL 3x9	AF2417	10/07/2030
120704253E	K-MONO INSERT XLPE+VE RL/LM 3x19	AF2435	10/07/2030

120704253E	K-MONO INSERT XLPE+VE RL/LM 3x23	AF2435	10/07/2030
120704262E	K-MONO INSERT XLPE+VE RL/LM 2x21	AF2440	10/07/2030
120704262E	K-MONO INSERT XLPE+VE RL/LM 2x23	AF2440	10/07/2030
120704263E	K-MONO INSERT XLPE+VE RL/LM 3x24	AF2441	10/07/2030
120700715	K-MOD FIXED INSERT DC SIZE 5 TH.10 LEFT	AG1327	21/07/2030
120704206E	K-MONO INSERT XLPE+VE RM/LL 6x8	AG1323	17/08/2030
120704216E	K-MONO INSERT XLPE+VE RM/LL 6x9	AF2642	17/08/2030
120704216E	K-MONO INSERT XLPE+VE RM/LL 6x9	AF2642	17/08/2030
120704225E	K-MONO INSERT XLPE+VE RM/LL 5x10	AF2647	17/08/2030
120704225E	K-MONO INSERT XLPE+VE RM/LL 5x10	AF2647	17/08/2030
120704226E	K-MONO INSERT XLPE+VE RM/LL 6x21	AF2648	17/08/2030
120704231E	K-MONO INSERT XLPE+VE RM/LL 1x24	AF2649	17/08/2030
120704233E	K-MONO INSERT XLPE+VE RM/LL 3x24	AF2651	17/08/2030
120704234E	K-MONO INSERT XLPE+VE RM/LL 4x25	AF2652	17/08/2030
120704236E	K-MONO INSERT XLPE+VE RM/LL 6x25	AF2654	17/08/2030
120704256E	K-MONO INSERT XLPE+VE RL/LM 6x21	AF2660	17/08/2030
120704281E	K-MONO INSERT XLPE+VE RL/LM 1x23	AF2673	17/08/2030
120704281E	K-MONO INSERT XLPE+VE RL/LM 1x25	AF2673	17/08/2030
120704284E	K-MONO INSERT XLPE+VE RL/LM 4x25	AF2676	17/08/2030
120704284E	K-MONO INSERT XLPE+VE RL/LM 4x27	AF2676	17/08/2030
120704215E	K-MONO INSERT XLPE+VE RM/LL 5x9	AF2641	24/08/2030
120704255E	K-MONO INSERT XLPE+VE RL/LM 5x23	AF2659	24/08/2030
120704266E	K-MONO INSERT XLPE+VE RL/LM 6x20	AF2666	24/08/2030
120704266E	K-MONO INSERT XLPE+VE RL/LM 6x22	AF2666	24/08/2030
120704274E	K-MONO INSERT XLPE+VE RL/LM 4x22	AF2670	25/08/2030
120704274E	K-MONO INSERT XLPE+VE RL/LM 4x24	AF2670	25/08/2030
120704204E	K-MONO INSERT XLPE+VE RM/LL 4x8	AF2634	22/10/2030
120704283E	K-MONO INSERT XLPE+VE RL/LM 3x23	AF2675	26/10/2030
120704286E	K-MONO INSERT XLPE+VE RL/LM 6x25	AF2678	26/10/2030
120704226E	K-MONO INSERT XLPE+VE RM/LL 6x23	AF2648	28/10/2030
120704234E	K-MONO INSERT XLPE+VE RM/LL 4x23	AF2652	28/10/2030
120704275E	K-MONO INSERT XLPE+VE RL/LM 5x21	AF2671	29/10/2030
120704275E	K-MONO INSERT XLPE+VE RL/LM 5x23	AF2671	29/10/2030
120704211E	K-MONO INSERT XLPE+VE RM/LL 1x9	AF2637	04/11/2030
120704214E	K-MONO INSERT XLPE+VE RM/LL 4x9	AF2640	04/11/2030
120704254E	K-MONO INSERT XLPE+VE RL/LM 4x21	AF2658	04/11/2030
120704256E	K-MONO INSERT XLPE+VE RL/LM 6x19	AF2660	26/11/2030
120704206E	K-MONO INSERT XLPE+VE RM/LL 6x8	AF2636	11/12/2030
120704201E	K-MONO INSERT XLPE+VE RM/LL 1x8	AF2631	18/01/2031

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It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.
Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.