



Rev 1: September 2018
FSN Ref: 01/2021 - finale

FSCA Ref: 01/2021 - finale

Date: 15/07/2021

Urgent Field Safety Notice

Dear Customer,

Following the previous safety warnings sent, we hereby inform you of the issue of the final Field Safety Corrective Action related to the products described (Annex 1).

Explanation of the problem

Adria S.r.l. is a manufacturer of class IIa, IIb medical devices.

The devices are marketed in sterile form, after being subjected to sterilization by ethylene oxide by Steril Milano S.r.l.

ethylene oxide sterilization process performed by the company Steril Milano S.r.l.

We have received communication from the same sterilizer about the falsification of the parameters of process parameters of the sterilization cycles.

After conducting a thorough investigation accompanied by sterility tests and ethylene residue, and after initiating the recall and sending the previous safety notices to quarantine the goods and get information about the stocks, we inform you that we are proceeding with the destruction of the reported products.

We therefore ask you to proceed as reported below for the devices (listed in Annex 1) in stock at our distributors. As far as hospitals and health services are concerned, we request instead the immediate return to the reference distributors or to Adria S.r.l. of the devices listed in Annex 1 previously quarantined.

In Annex 1 you can find the extract of the impacted lots.

Clinical Impact

The use of non-sterile devices may involve an increased risk of patient infection.

We would like to specify that Adria S.r.l. has never been notified of any adverse events or damage to patients potentially attributable to the problem object of this report.

There are no specific follow-up actions for patients on whom the product has already been used.

All batches of potentially non-sterile devices, supplied to your company, are listed in Attachment 1 "List Impacted batches".

Actions required to distributors and traders

1 - Return to Adria S.r.l. all products quarantined and withdrawn from hospitals/healthcare facilities, which fall within the lots reported in Annex 1 "List of Impacted batches",

OR

2 - Directly send the quarantined products withdrawn from hospitals/clinics, which are among the batches indicated in attachment 1 "List of Impacted batches", to the destruction/maceration.

3 - Notify Adria S.r.l. of the destruction by providing written confirmation by e-mail to qa@adriamedical.com indicating lot and number of pieces.

4 - Adria S.r.l. will replace the goods as soon as possible.

ADRIA S.r.l. – Società Unipersonale

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Warehouse and logistics: via San Francesco d'Assisi 15, 46020 Pegognaga (MN) - Italy

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Actions required to hospitals and health care facilities

Send the quarantined products to your reference distributor or to Adria S.r.l. who will arrange for their destruction/maceration.

Corrective Actions

We are proceeding with the destruction of the reported devices.
The new supplier of the sterilization service has been approved by our Notified Body, so we can resume production and the products will be replaced as soon as possible.

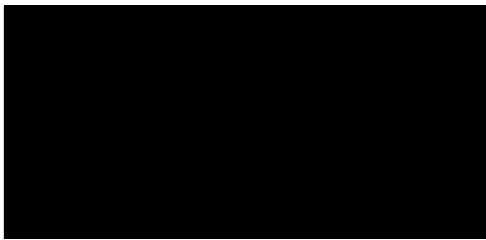
Contacts

For further information about this FSN please contact Adria S.r.l. at the number +39 3472441014 or by e-mail at qa@adriamedical.com or export@adriamedical.com or your distributor.


We confirm that the relevant authorities have been informed of the actions described herein.

We would like to signify that the safety of our devices is a primary objective for us, in issuing this FSN we wanted to maintain a prudent and cooperative approach, we trust that we will handle the actions in the best possible way.

Thank you for the cooperation and we are available for any clarification.



Yours faithfully


QA/RA Manager
Adria S.r.l.

Product	Lot #	Note
49225	AD0366/20	Vertebroplasty needles kit
49225	ZU0226	Vertebroplasty needles kit
49225	ZV0697	Vertebroplasty needles kit
49225	ZU0226	Vertebroplasty needles kit
49225	ZU0226	Vertebroplasty needles kit
49225	ZV0697	Vertebroplasty needles kit
49225	AD0366/20	Vertebroplasty needles kit
49225	ZU0226	Vertebroplasty needles kit
49225	ZV0697	Vertebroplasty needles kit
49225	AD0366/20	Vertebroplasty needles kit
49225	ZV0697	Vertebroplasty needles kit
49225	ZU0226	Vertebroplasty needles kit
49225	ZU0226	Vertebroplasty needles kit
49225	ZU0226	Vertebroplasty needles kit
495041123	ZV0500	Cement Injection Cannula kit
495041123	AD0215/20	Cement Injection Cannula kit
495041123	AD0424/20	Cement Injection Cannula kit
495041123	AD0584/20	Cement Injection Cannula kit
495041123	AD0653/20	Cement Injection Cannula kit
495041123	AD0847/20	Cement Injection Cannula kit
495041123	ZU0470	Cement Injection Cannula kit
495041123	ZV0021	Cement Injection Cannula kit
495041123	ZV0124	Cement Injection Cannula kit
495041123	AD0653/20	Cement Injection Cannula kit
495041123	ZU0146	Cement Injection Cannula kit
495041123	ZV0874	Cement Injection Cannula kit
495041123	ZV0500	Cement Injection Cannula kit
495041123	ZV0124	Cement Injection Cannula kit
495041123	ZU0146	Cement Injection Cannula kit
495041123	ZV0500	Cement Injection Cannula kit
495041123	AD0215/20	Cement Injection Cannula kit
495041123	ZV0500	Cement Injection Cannula kit
495041123	ZV0874	Cement Injection Cannula kit
495041123	AD0215/20	Cement Injection Cannula kit
495041123	AD0424/20	Cement Injection Cannula kit
495041123	AD0584/20	Cement Injection Cannula kit
495041123	AD0653/20	Cement Injection Cannula kit
495041123	AD0847/20	Cement Injection Cannula kit
495041123	ZV0021	Cement Injection Cannula kit
495041123	ZU0146	Cement Injection Cannula kit
495041123	ZU0146	Cement Injection Cannula kit
495041123	AD0584/20	Cement Injection Cannula kit
495041123	AD0847/20	Cement Injection Cannula kit
495041123	AD0424/20	Cement Injection Cannula kit
495041123	AD0653/20	Cement Injection Cannula kit
495041123	AD0847/20	Cement Injection Cannula kit
495041123	ZU0470	Cement Injection Cannula kit
495041123	ZV0124	Cement Injection Cannula kit
495041123	ZV0124	Cement Injection Cannula kit

495041123	ZV0874	Cement Injection Cannula kit
495041123	ZV0124	Cement Injection Cannula kit
BMH 1507	AD0437/20	Biopsy needle
BMH 1507	ZV0888	Biopsy needle
BMH 1507	ZV0066	Biopsy needle
BMH 1507	ZU0313	Biopsy needle
BMH 1510	AD0612/20	Biopsy needle
BMH 1510	AD0588/20	Biopsy needle
BMH 1512	AD0606/20	Biopsy needle
BMH 1512	AD0606/20	Biopsy needle
BMH 1512	AD0606/20	Biopsy needle
BMH 1512	AD0606/20	Biopsy needle
BMH 1512	ZU0318	Biopsy needle
IST 1501	AD0814/20	Biopsy needle
IST 1501	AD0778/20	Biopsy needle
IST 1501	AD0685/20	Biopsy needle
IST 1501	AD0617/20	Biopsy needle
IST 1501	AD0329/20	Biopsy needle
IST 1501	AD0329/20	Biopsy needle
IST 1501	AD0241/20	Biopsy needle
IST 1501	AD0207/20	Biopsy needle
IST 1501	ZV0843	Biopsy needle
IST 1501	ZV0295	Biopsy needle
IST 1501	ZV0139	Biopsy needle
IST 1501	ZV0131	Biopsy needle
IST 1501	ZV0115	Biopsy needle
IST 1501	ZU0566	Biopsy needle
IST 1501	ZU0342	Biopsy needle
IST 1501	ZU0307	Biopsy needle
IST 1501	ZU0088	Biopsy needle
IST 1501	ZU0047	Biopsy needle
IST 1501	ZU0041	Biopsy needle
IST 1501	ZT 0170	Biopsy needle
IST 1503	AD0815/20	Biopsy needle
IST 1503	AD0780/20	Biopsy needle
IST 1503	AD0686/20	Biopsy needle
IST 1503	AD0686/20	Biopsy needle
IST 1503	AD0618/20	Biopsy needle
IST 1503	AD0585/20	Biopsy needle
IST 1503	AD0428/20	Biopsy needle
IST 1503	AD0330/20	Biopsy needle
IST 1503	AD0330/20	Biopsy needle
IST 1503	AD0242/20	Biopsy needle
IST 1503	AD0197/20	Biopsy needle
IST 1503	AD0071/20	Biopsy needle
IST 1503	AD0053/20	Biopsy needle
IST 1503	ZV0892	Biopsy needle
IST 1503	ZV0892	Biopsy needle
IST 1503	ZV0553	Biopsy needle
IST 1503	ZV0511	Biopsy needle

IST 1503	ZV0269	Biopsy needle
IST 1503	ZV0116	Biopsy needle
IST 1503	ZV0062	Biopsy needle
IST 1503	ZU0409	Biopsy needle
IST 1503	ZU0350	Biopsy needle
IST 1503	ZU0320	Biopsy needle
IST 1503	ZU0275	Biopsy needle
IST 1503	ZU0094	Biopsy needle
IST 1503	ZU0049	Biopsy needle
IST 1503	ZU0038	Biopsy needle
IST 1503	ZU0021	Biopsy needle
RDS 0810	AD0832/20	Biopsy needle
RDS 0810	ZV0972	Biopsy needle
RDS 0810	AD0777/20	Biopsy needle
RDS 0810	AD0619/20	Biopsy needle
RDS 0810	AD0482/20	Biopsy needle
RDS 0810	AD0315/20	Biopsy needle
RDS 0810	AD0315/20	Biopsy needle
RDS 0810	AD0213/20	Biopsy needle
RDS 0810	ZV0877	Biopsy needle
RDS 0810	ZV0877	Biopsy needle
RDS 0810	ZV0877	Biopsy needle
RDS 0810	ZV0542	Biopsy needle
RDS 0810	ZV0513	Biopsy needle
RDS 0810	ZV0513	Biopsy needle
RDS 0810	ZV0513	Biopsy needle
RDS 0810	ZV0426	Biopsy needle
RDS 0810	ZV0426	Biopsy needle
RDS 0810	ZV0257	Biopsy needle
RDS 0810	ZV0209	Biopsy needle
RDS 0810	ZV0001	Biopsy needle
RDS 0810	ZU0511	Biopsy needle
RDS 0810	ZU0471	Biopsy needle
RDS 0810	ZU0304	Biopsy needle
RDS 0810	ZU0271	Biopsy needle
RDS 0810	ZU0263	Biopsy needle
RDS 0810	ZU0203	Biopsy needle
RDS 0810	ZU0100	Biopsy needle
RDS 0810	ZU0035	Biopsy needle
RDS 0815	ZV0974	Biopsy needle
RDS 0815	AD0593/20	Biopsy needle
RDS 0815	AD0593/20	Biopsy needle
RDS 0815	ZV0774	Biopsy needle
RDS 0815	ZU0576	Biopsy needle
RDS 0815	ZU0164	Biopsy needle
RDS 0815	ZU0101	Biopsy needle
RDS 0815	ZU0034	Biopsy needle
RDS 0815	ZT 0206	Biopsy needle
RDS 0910	AD0679/20	Biopsy needle
RDS 0910	AD0621/20	Biopsy needle

RDS 0910	AD0440/20	Biopsy needle
RDS 0910	AD0276/20	Biopsy needle
RDS 0910	AD0199/20	Biopsy needle
RDS 0910	ZV0940	Biopsy needle
RDS 0910	ZV0839	Biopsy needle
RDS 0910	ZV0219	Biopsy needle
RDS 0910	ZV0219	Biopsy needle
RDS 0910	ZU0565	Biopsy needle
RDS 0910	ZU0565	Biopsy needle
RDS 0910	ZU0193	Biopsy needle
RDS 0910	ZU0167	Biopsy needle
RDS 0910	ZU0149	Biopsy needle
RDS 0910	ZU0136	Biopsy needle
RDS 0910	ZU0108	Biopsy needle
RDS 0910	ZT 0152	Biopsy needle
RDS 0915	ZV0987	Biopsy needle
RDS 0915	AD0277/20	Biopsy needle
RDS 0915	AD0200/20	Biopsy needle
RDS 0915	AD0103/20	Biopsy needle
RDS 0915	ZV0514	Biopsy needle
RDS 0915	ZV0342	Biopsy needle
RDS 0915	ZV0208	Biopsy needle
RDS 0915	ZV0208	Biopsy needle
RDS 0915	ZV0208	Biopsy needle
RDS 0915	ZU0555	Biopsy needle
RDS 0915	ZU0333	Biopsy needle
RDS 1110	AD0776/20	Biopsy needle
RDS 1110	AD0680/20	Biopsy needle
RDS 1110	AD0663/20	Biopsy needle
RDS 1110	AD0622/20	Biopsy needle
RDS 1110	AD0582/20	Biopsy needle
RDS 1110	AD0381/20	Biopsy needle
RDS 1110	AD0218/20	Biopsy needle
RDS 1110	AD0124/20	Biopsy needle
RDS 1110	ZV0864	Biopsy needle
RDS 1110	ZV0672	Biopsy needle
RDS 1110	ZV0515	Biopsy needle
RDS 1110	ZV0339	Biopsy needle
RDS 1110	ZV0270	Biopsy needle
RDS 1110	ZU0613	Biopsy needle
RDS 1110	ZU0613	Biopsy needle
RDS 1110	ZU0613	Biopsy needle
RDS 1110	ZU0613	Biopsy needle
RDS 1110	ZU0613	Biopsy needle
RDS 1110	ZU0613	Biopsy needle
RDS 1110	ZU0410	Biopsy needle
RDS 1110	ZU0268	Biopsy needle
RDS 1110	ZU0111	Biopsy needle
RDS 1110	ZU0046	Biopsy needle
RDS 1110	ZT 0198	Biopsy needle

RDS 1110	ZT 0204	Biopsy needle
RDS 1115	AD0787/20	Biopsy needle
RDS 1115	AD0583/20	Biopsy needle
RDS 1115	AD0583/20	Biopsy needle
RDS 1115	ZV0915	Biopsy needle
RDS 1115	ZV0915	Biopsy needle
RDS 1115	ZV0330	Biopsy needle
RDS 1115	ZV0330	Biopsy needle
RDS 1115	ZU0514	Biopsy needle
RDS 1115	ZU0228	Biopsy needle
RDS 1115	ZU0147	Biopsy needle
RDS 1310	AD0788/20	Biopsy needle
RDS 1310	AD0681/20	Biopsy needle
RDS 1310	AD0681/20	Biopsy needle
RDS 1310	ZV0775	Biopsy needle
RDS 1310	ZV0331	Biopsy needle
RDS 1315	AD0682/20	Biopsy needle
RDS 1315	ZV0332	Biopsy needle
RDS 1315	ZU0610	Biopsy needle
RDT 0910	AD0514/20	Biopsy needle
RDT 1110	AD0515/20	Biopsy needle
SMA 1815	ZU0204	Biopsy needle
SMAC 1810	AD0662/20	Biopsy needle
SMAC 1810	AD0649/20	Biopsy needle
SMAC 1810	AD0056/20	Biopsy needle
SMAC 1810	ZV0080	Biopsy needle
SMAC 1810	ZV0080	Biopsy needle
SMAC 1810	ZU0367	Biopsy needle
SMAC 1810	ZU0279	Biopsy needle
SMAC 1810	ZU0279	Biopsy needle
SMAC 1815	ZU0605	Biopsy needle
SMAC 1815	ZU0269	Biopsy needle
SMAC 1816	AD0650/20	Biopsy needle
SMAC 1816	AD0650/20	Biopsy needle
SMAC 1816	AD0057/20	Biopsy needle
SMAC 1816	ZV0925	Biopsy needle
SMAC 1816	ZV0844	Biopsy needle
SMAC 1816	ZV0844	Biopsy needle
SMAC 1816	ZV0673	Biopsy needle
SMAC 1816	ZV0609	Biopsy needle
SMAC 1816	ZV0341	Biopsy needle
SMAC 1816	ZV0223	Biopsy needle
SMAC 1816	ZU0312	Biopsy needle
SMAC 1816	ZU0312	Biopsy needle
SMAC 1816	ZU0273	Biopsy needle
SMAC 1816	ZU0273	Biopsy needle
SMAC 1820	AD0058/20	Biopsy needle
SMAC 1820	ZV0610	Biopsy needle
SMAC 1820	ZU0437	Biopsy needle
SMAC 1820	ZU0437	Biopsy needle

SMAC 1820	ZU0272	Biopsy needle
SMAC 1820	ZU0272	Biopsy needle
SMAC 1820	ZU0272	Biopsy needle
SMAC 1820	ZU0272	Biopsy needle
SMAC 1820	ZU0272	Biopsy needle
T060430	AD0404/20	Vertebroplasty needle
T060431	AD0447/20	Vertebroplasty needle
T060434	AD0239/20	Vertebroplasty needle