



Nyon, April 14th, 2021

## URGENT MEDICAL DEVICE RECALL

### Box SmartFibers and SmartFibers Power used with Swiss LaserClast FIELD SAFETY NOTICE CAPA-2021-0004

This letter contains important information which require **your immediate attention**.

Dear Valued Customer,

We, E.M.S. Electro Medical Systems S.A., are conducting a Field Safety Corrective Action to remove all lots of distributed laser fibers since 2016:

**Single use Swiss LaserClast SmartFibers / SmartFiber Power:**

*FR-177\*, FR-179\*, FR-181\*, FR-185\*, FR-272\*, FR-273\**

**Reusable Swiss LaserClast SmartFibers / SmartFiber Power:**

*FR-178\*, FR-180\*, FR-182\* FR-186\*, FR-275\*, FR-276\**

See Appendix 1 for full list of all impacted products you received.

#### Explanation of the issue

We, E.M.S. Electro Medical Systems S.A. recently discovered improper sterilization process of at supplier sterilizing E.M.S SmartFibers and SmartFibers Power.

We have immediately investigated and determined that we are unable to guarantee the primary sterility of the devices listed in the attached appendix. However, sterility testing of available laser fiber batches and a comprehensive review of post-market surveillance showed no direct negative safety findings. Because the safety of our customers is our top priority and as a precautionary measure, we are voluntarily recalling all our sterile laser fibers from the market.

As the failure impact the primary sterilization process only unused and original packed devices are concerned. Fibers already in use and resterilized by the customer are safe and not affected by this recall.

#### Clinical Impact

The use of non-sterile devices in the clinical setting could lead to an increased risk of infection which may cause serious harm or life-threatening conditions.

E.M.S. has not identified any reports of adverse events or serious patient harm 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.

#### Action required by Distributors / Economic operators

1. Circulate this Field Safety Notice to all those in your organization, that need to be made aware. If you have further distributed the product, please identify those facilities, and forward this notification to them immediately.
2. All distributors / economic operators must **quarantine and return** the affected devices to E.M.S.:



- a. **Quarantine** any units in stock of the impacted lots.
- b. **Collect** and **quarantine** any unit coming back from your customers.
- c. Complete the customer response form on pages 3 & 4 and return to **vigilancemailbox@ems-ch.com** as soon as possible or **no later than May 15<sup>th</sup>, 2021**. **EMS will contact you to organize the return.**

EMS will replace the products as soon as product is available. Please inform us if an alternative solution is required.

### Action required by Hospitals

1. **Cease use and quarantine** SmartFibers and SmartFibers Power unused and still in their original sterile pouch in your possession (refer of references/batches listed in Appendix 1).
2. **Only if the hospital has the necessary equipment according to FB-554 (chapter 5) delivered with the fibers:** Use the reprocessing process described in chapter 5 of the FB-554 to re-package and re-sterilize the fibers in stock before use. This additional sterilization can be done on single use and reusable fibers and will not affect the remaining number of uses.
3. **If sterilization is not possible on site or if the hospital has not the necessary equipment,** return the fibers unexpired and still in their original sterile pouch to your local distributor.
4. Complete the customer response form on pages 3 & 4 and return to **vigilancemailbox@ems-ch.com copying your distributor** as soon as possible or no later than May 10<sup>th</sup>, 2021.

Until E.M.S. can resume shipments, E.M.S. recommends contacting your local representative to discuss possible product alternatives.

### Corrective Actions by EMS

E.M.S. is working to qualify an alternate sterilization facility for its Laser Fibers.

### Contact Reference Person

If you have any question about this Field Action, please contact your local EMS representative/distributor or **vigilancemailbox@ems-ch.com**

We confirm that the appropriate regulatory agencies have been informed of these actions.

EMS considers patient safety and customer satisfaction our top priorities. Our primary objectives are patient safety and user safety and providing you with quality products. We apologize for the inconvenience this situation may cause and thank you in advance for helping E.M.S. to resolve this matter as quickly and effectively as possible.

Sincerely,

T. Deblock  
Head of Quality

J. Blondeau  
Marketing Manager Urology



## Customer Response Form

### URGENT: FIELD SAFETY NOTICE Product recall

#### Box SmartFibers & SmartFibers Power used with Swiss LaserClast

Please read in conjunction with Field Safety Notice CAPA-2021-0004 and return completed and signed form as soon as possible or **no later than the 15th May 2021** to [vigilancemailbox@ems-ch.com](mailto:vigilancemailbox@ems-ch.com)

**I confirm this notice has been read, understood and that all recommended actions have been implemented as required.**

*Tick the appropriate box below*

- We have already used and disposed of the impacted devices as listed in Appendix 1

Product Reference	Batch number	Quantity

- We have re-sterilized before use the impacted devices as listed in Appendix 1 in our possession (for Hospital only)

Product Reference	Batch number	Quantity

- We have the units of the impacted devices as listed in Appendix 1 in our possession and I confirm that the following units have been quarantined. (Please contact E.M.S. for the organization of the products' return).

Product Reference	Batch number	Quantity



Comments (if any):

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**Name of Trust / Organisation :**

**Your Facility Address :**

**Postcode :**

**Country :**

**Telephone number :**

**E-mail address :**

**Name of your supplier for this product (if not direct from EMS) :**

**Name, title and signature of person completing form:**

**Please list all Facilities / Hospitals covered by your response (e.g. other hospitals within your Trust)**

Facility / Hospital Name	Postcode	Country

*This form must be returned to EMS before this action can be considered closed for your account. Please return your completed and signed Response Form to [vigilancemailbox@ems-ch.com](mailto:vigilancemailbox@ems-ch.com)*

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**Appendix 1: PRODUCT RECALL - CAPA-2021-0004** List of impacted products

<b>Invoice</b>	<b>Reference</b>	<b>Quantity</b>	<b>Batch number on the pack of 5 fibers</b>	<b>Batch number on each individual pouch</b>	<b>Expiry date</b>
FC-16-3915	FR-180#A/001	1	OF-88-38706-1	B162070	2021.04
FC-16-3932	FR-186#A/001	2	OF-88-38775-1	B162060	2021.04
FC-16-3932	FR-180#A/001	2	OF-88-38774-1	B162070	2021.04
FC-16-4117	FR-186#A/001	1	OF-88-39012-1	B162060	2021.04
FC-16-4117	FR-180#A/001	1	OF-88-39013-1	B162070	2021.04
FC-16-4251	FR-182#A/001	1	OF-88-39236-1	B162030	2021.04
FC-16-5666	FR-182#A/001	2	OF-88-41231-1	B162720	2021.05
FC-16-5666	FR-186#A/001	2	OF-88-41230-1	B162380	2021.05
FC-16-5666	FR-180#A/001	1	OF-88-41232-1	B162350	2021.05
FC-16-6695	FR-186#A/001	1	OF-88-42710-1	B163080	2021.06
FC-16-6876	FR-180#A/001	1	OF-88-42967-1	B163000	2021.06
FC-16-6876	FR-178#A/001	1	OF-88-42966-1	B163800	2021.08
FC-16-8340	FR-182#A/001	1	OF-88-45401-1	B163040	2021.06
FC-16-8340	FR-186#A/001	2	OF-88-45399-1	B163750	2021.08
FC-16-8340	FR-178#A/001	1	OF-88-45400-1	B163850	2021.08
FC-17-00198	FR-182#A/001	1	OF-88-45936-1	B163935	2021.08
FC-17-00198	FR-178#A/001	1	OF-88-45938-1	B163850	2021.08
FC-17-00198	FR-180#A/001	1	OF-88-45937-1	B163660	2021.07
FC-17-00198	FR-186#A/001	1	OF-88-45935-1	B163750	2021.08
FC-17-00764	FR-180#A/001	2	OF-88-46562-1	B163660	2021.07
FC-17-01886	FR-177#A/001	2	OF-88-48305-1	B170170	2021.12
FC-17-01886	FR-179#A/001	2	OF-88-48306-1	B163670	2021.07
FC-17-01886	FR-185#A/001	2	OF-88-48304-1	B164240	2021.09
FC-17-02211	FR-179#A/001	8	OF-88-48676-1	B163850	2021.08
FC-17-02211	FR-185#A/001	20	OF-88-48673-1	B164600	2021.10
FC-17-02211	FR-181#A/001	5	OF-88-48674-1	B162330	2021.05
FC-17-02211	FR-185#A/001	3	OF-88-48677-1	B164240	2021.09

FC-17-02211	FR-177#A/001	8	OF-88-48675-1	B170170	2021.12
FC-17-02342	FR-180#A/001	2	OF-88-48989-1	B163840	2021.08
FC-17-02342	FR-186#A/001	2	OF-88-48990-1	B163800	2021.08
FC-17-02342	FR-178#A/001	2	OF-88-48988-1	B164200	2021.09
FC-17-03603	FR-186#A/001	2	OF-88-50839-1	B163850	2021.08
FC-17-03603	FR-180#A/001	1	OF-88-50840-1	B163850	2021.08
FC-17-05405	FR-272#A/001	1	OF-88-53516-1	B372410	2022.05
FC-17-05405	FR-275#A/001	1	OF-88-53514-1	B372790	2022.06
FC-17-05405	FR-276#A/001	1	OF-88-53515-1	B372790	2022.06
FC-17-05405	FR-273#A/001	1	OF-88-53513-1	B372410	2022.05
FC-17-06358	FR-180#A/001	1	OF-88-54908-1	B163900	2021.08
FC-17-06358	FR-186#A/001	1	OF-88-54910-1	B164600	2021.10
FC-17-06358	FR-178#A/001	1	OF-88-54909-1	B164290	2021.09
FC-17-07126	FR-177#A/001	2	OF-88-56120-1	B172070	2022.04
FC-17-07126	FR-179#A/001	2	OF-88-56121-1	B172300	2022.05
FC-17-07301	FR-180#A/001	3	OF-88-56408-1	B163900	2021.08
FC-17-07778	FR-177#A/001	12	OF-88-57320-1	B173700	2022.08
FC-17-07778	FR-185#A/001	6	OF-88-57319-1	B172560	2022.05
FC-17-07778	FR-179#A/001	8	OF-88-57318-1	B173700	2022.08
FC-18-00202	FR-186#A/001	2	OF-88-58104-1	B164600	2021.10
FC-18-00202	FR-178#A/001	2	OF-88-58103-1	B170170	2021.12
FC-18-01120	FR-275#A/001	1	OF-88-60003-1	B372700	2022.06
FC-18-01120	FR-276#A/001	1	OF-88-60004-1	B372890	2022.07
FC-18-02403	FR-182#A/001	2	OF-88-61615-1	B173700	2022.08
FC-18-04532	FR-180#A/001	1	OF-88-64393-1	B171840	2022.04
FC-18-04625	FR-178#A/001	1	OF-88-64786-1	B171860	2022.04
FC-18-04625	FR-186#A/001	1	OF-88-64787-1	B164670	2021.10
FC-18-06553	FR-178#A/001	1	OF-88-67434-1	B172380	2022.05
FC-18-06553	FR-186#A/001	1	OF-88-67435-1	B180900	2023.01
FC-18-06692	FR-276#A/001	1	OF-88-67733-1	B372890	2022.07
FC-18-06692	FR-275#A/001	1	OF-88-67734-1	B372700	2022.06
FC-18-07468	FR-276#A/001	1	OF-88-68838-1	B372790	2022.06
FC-18-07468	FR-273#A/001	5	OF-88-68839-1	B374450	2022.10
FC-18-07559	FR-186#A/001	1	OF-88-67435-1	B180900	2023.01
FC-18-07559	FR-178#A/001	1	OF-88-67434-1	B172380	2022.05
FC-18-08450	FR-180#A/001	1	OF-88-70371-1	B172500	2022.05
FC-19-00304	FR-273#A/001	2	OF-88-71499-1	B384924	2023.11
FC-19-02123	FR-273#A/001	1	OF-88-74426-1	B384924	2023.11
FC-19-02123	FR-273#A/001	8	OF-88-74378-1	B390721	2024.01
FC-19-02123	FR-273#A/001	2	OF-88-74432-1	B390722	2024.01
FC-19-02123	FR-179#A/001	2	OF-88-74425-1	B182410	2023.05
FC-19-02123	FR-273#A/001	2	OF-88-74423-1	B390723	2024.01
FC-19-02123	FR-177#A/001	2	OF-88-74424-1	B182401	2023.05
FC-19-02352	FR-186#A/001	2	OF-88-74777-1	B182408	2023.05
FC-19-02712	FR-178#A/001	1	OF-88-75385-1	B173700	2022.08
FC-19-03689	FR-180#A/001	1	OF-88-76906-1	B180950	2023.01

FC-19-04324	FR-179#B/001	2	OF-88-77903-1	B191205	2024.02
FC-19-04324	FR-272#A/001	2	OF-88-77902-1	B381550	2023.03
FC-19-04509	FR-276#A/001	2	OF-88-78118-1	B372790	2022.06
FC-19-05147	FR-178#A/001	1	OF-88-79239-1	B173700	2022.08
FC-19-05147	FR-182#A/001	1	OF-88-79238-1	B182403	2023.05
FC-19-05147	FR-180#A/001	1	OF-88-79237-1	B180950	2023.01
FC-19-05147	FR-186#A/001	1	OF-88-79236-1	B184927	2023.11
FC-19-05314	FR-179#B/001	2	OF-88-79497-1	B191205	2024.02
FC-19-06125	FR-272#A/001	2	OF-88-80692-1	B381550	2023.03
FC-19-06125	FR-180#A/001	1	OF-88-80683-1	B180950	2023.01
FC-19-06125	FR-180#A/001	1	OF-88-80671-1	B181550	2023.03
FC-19-06125	FR-272#A/001	2	OF-88-80691-1	B381550	2023.03
FC-19-07042	FR-179#B/001	2	OF-88-82081-1	B191426	2024.02
FC-19-07042	FR-272#A/001	2	OF-88-82092-1	B392711	2024.05
FC-19-07042	FR-272#A/001	1	OF-88-82093-1	B392711	2024.05
FC-19-08051	FR-273#A/001	4	OF-88-83505-1	B392713	2024.05
FC-19-08051	FR-179#B/001	5	OF-88-83504-1	B191427	2024.02
FC-19-08689	FR-272#A/001	3	OF-88-84401-1	B392711	2024.05
FC-20-01027	FR-273#A/001	2	OF-88-87237-1	B392713	2024.05
FC-20-01027	FR-186#B/002	1	OF-88-87305-1	B191204	2024.02
FC-20-01027	FR-272#A/001	3	OF-88-87306-1	B393503	2024.07
FC-20-01913	FR-180#B/001	1	OF-88-88562-1	B182413	2023.05
FC-20-01913	FR-272#A/001	4	OF-88-88563-1	B393503	2024.07
FC-20-02252	FR-273#A/001	1	OF-88-88986-1	B392713	2024.05
FC-20-02567	FR-273#A/001	1	OF-88-89437-1	B392713	2024.05
FC-20-02567	FR-272#A/001	2	OF-88-89436-1	B381550	2023.03
FC-20-02669	FR-178#B/002	1	OF-88-89584-1	B192006	2024.04
FC-20-02839	FR-179#B/001	1	OF-88-89754-1	B191427	2024.02
FC-20-02930	FR-273#A/001	2	OF-88-89872-1	B392713	2024.05
FC-20-03151	FR-178#B/002	2	OF-88-90196-1	B190814	2024.01
FC-20-03339	FR-178#B/002	1	OF-88-90322-1	B192006	2024.04
FC-20-03662	FR-276#A/001	1	OF-88-90679-1	B373910	2022.08
FC-20-03835	FR-273#A/001	1	OF-88-90905-1	B394817	2024.10
FC-20-04355	FR-273#A/001	2	OF-88-91450-1	B394817	2024.10
FC-20-04513	FR-186#B/002	2	OF-88-91699-1	B194820	2024.10
FC-20-04678	FR-273#A/001	1	OF-88-91860-1	B401127	2025.03
FC-20-04678	FR-275#A/001	1	OF-88-91861-1	B372700	2022.06
FC-20-04678	FR-276#A/001	1	OF-88-91862-1	B372790	2022.06
FC-20-04678	FR-180#B/001	2	OF-88-91859-1	B201132	2025.03
FC-20-04995	FR-272#A/001	2	OF-88-92172-1	B402714	2025.06
FC-20-04995	FR-273#A/001	1	OF-88-92171-1	B394817	2024.10
FC-20-05236	FR-179#B/001	3	OF-88-92467-1	B193506	2024.07
FC-20-05236	FR-179#B/001	2	OF-88-92466-1	B193506	2024.07
FC-20-05236	FR-179#B/001	3	OF-88-92467-1	B193506	2024.07
FC-20-05389	FR-180#B/001	1	OF-88-92690-1	B182413	2023.05
FC-20-05389	FR-182#B/001	1	OF-88-92691-1	B182404	2023.05

FC-20-05389	FR-178#B/002	1	OF-88-92689-1	B194015	2024.08
FC-20-05389	FR-186#B/002	1	OF-88-92692-1	B194819	2024.10
FC-20-05389	FR-179#B/001	2	OF-88-92688-1	B193506	2024.07
FC-20-06660	FR-273#A/001	1	OF-99-00133-1	B401127	2025.03
FC-20-06660	FR-272#A/001	1	OF-99-00139-1	B402714	2025.06
FC-20-07235	FR-273#A/001	3	OF-99-00905-1	B403615	2025.08
FC-20-07235	FR-272#A/001	1	B381550	B381550	2023.03
FC-21-00083	FR-182#B/001	1	OF-99-01795-1	B192417	2024.05
FC-21-00083	FR-180#B/001	1	OF-99-01762-1	B201132	2025.03
FC-21-00083	FR-186#B/002	1	OF-99-01763-1	B194820	2024.10
FC-21-00510	FR-272#A/001	2	B402714	B402714	2025.06
FC-21-00510	FR-180#B/001	2	OF-99-02279-1	B182413	2023.05
FC-21-00510	FR-182#B/001	1	OF-99-02275-1	B192417	2024.05
FC-21-00510	FR-179#B/001	4	OF-99-02278-1	B205012	2025.12
FC-21-00510	FR-272#A/001	2	B402714	B402714	2025.06
FC-21-00510	FR-273#A/001	1	B403615	B403615	2025.08
FC-21-00510	FR-273#A/001	1	B403615	B403615	2025.08
FC-21-00510	FR-273#A/001	1	B403615	B403615	2025.08
FC-21-00510	FR-273#A/001	1	B403615	B403615	2025.08
FC-21-00510	FR-273#A/001	1	B403615	B403615	2025.08
FC-21-00510	FR-273#A/001	1	B403615	B403615	2025.08
FC-21-00510	FR-273#A/001	1	B403615	B403615	2025.08
FC-21-00510	FR-186#B/002	1	OF-99-02280-1	B201129	2025.03
FC-21-00510	FR-186#B/002	1	OF-99-02272-1	B201129	2025.03
FC-21-00510	FR-272#A/001	2	B402714	B402714	2025.06
FC-21-00510	FR-272#A/001	2	B402714	B402714	2025.06
FC-21-00510	FR-272#A/001	2	B402714	B402714	2025.06
FC-21-00510	FR-272#A/001	1	B402714	B402714	2025.06
FC-21-00510	FR-272#A/001	1	B402714	B402714	2025.06
FC-21-00510	FR-272#A/001	1	B402714	B402714	2025.06
FC-21-00510	FR-272#A/001	1	B402714	B402714	2025.06
FC-21-00510	FR-272#A/001	1	B402714	B402714	2025.06
FC-21-00510	FR-272#A/001	2	B402714	B402714	2025.06
FC-21-00510	FR-272#A/001	2	B402714	B402714	2025.06
FC-21-00510	FR-272#A/001	2	B402714	B402714	2025.06
FC-21-00510	FR-272#A/001	2	B402714	B402714	2025.06
FC-21-00510	FR-272#A/001	2	B402714	B402714	2025.06
FC-21-00510	FR-272#A/001	2	B402714	B402714	2025.06
FC-21-00814	FR-272#A/001	3	B402714	B402714	2025.06
FC-21-00814	FR-272#A/001	3	B402714	B402714	2025.06
FC-21-00814	FR-272#A/001	3	B402714	B402714	2025.06
FC-21-00814	FR-272#A/001	3	B402714	B402714	2025.06
FC-21-00814	FR-272#A/001	3	B402714	B402714	2025.06
FC-21-00814	FR-273#A/001	3	B403615	B403615	2025.08
FC-21-00814	FR-273#A/001	3	B403615	B403615	2025.08
FC-21-00814	FR-273#A/001	3	B403615	B403615	2025.08



