



FSN Ref: Anika ref number

FSCA Ref: Anika ref number

Date:  May 2021

**URGENT FIELD SAFETY NOTICE  
POTENTIAL NON-STERILIZATION RISK  
HYALOGLIDE® ANTI-ADHESION GEL/ HYALOBARRIER® GEL/  
HYALOBARRIER® GEL ENDO  
PRODUCT DESTRUCTION**

For Attention of: [Identify either by name or role]

Contact details of local representative (name, e-mail, telephone, address etc.)

[Distributor or local branch. To be added at the appropriate stage in the different local languages.]

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### Information on Affected Devices

This notice is provided voluntarily to inform you of the requirement for urgent product destruction of the following hyaluronic acid solutions for post-surgical adhesion prevention:

**HYALOBARRIER® GEL  
HYALOBARRIER® GEL ENDO  
HYALOGLIDE® ANTI-ADHESION GEL**

#### Product codes:

| PRODUCT                                  | SKU     |
|--|---------|
| Hyalobarrier gel 3SYR                    | 130012F |
| Hyalobarrier gel 1SYR SKU                | 130035F |
| Hyalobarrier gel endo 10mL-5cm GCC       | 130250F |
| Hyalobarrier gel endo 6mL-5cm GCC        | 130270F |
| Hyalobarrier gel endo 3mL-5cm GCC        | 130280F |
| Hyalobarrier gel 1SYR NORDIC PHARMA      | 130003F |
| Hyalobarrier gel 3 Syr Israele           | 130011F |
| Hyalobarrier Gel, 3 Syr, Malesia         | 130021F |
| Hyaloglide, 1 mL, with 10 cm PVC cannula | 130400F |
| Hyaloglide, 2 mL, with 13 cm PVC cannula | 130500F |

We are requiring immediate destruction of all lots of these products at this time.

### Reason for Field Safety Corrective Action (FSCA)

#### Description of the product problem

As a result of a failure in a third-party sterilisation plant, the cannulas supplied with each of the above listed products are at risk of not meeting the required level of sterility and/or having higher than normal residual levels of ethylene oxide or ethylene chlorohydrin (ECH). Anika has been informed that ethylene oxide sterilization cycles performed by the third-party on the cannulas included in the above listed products were potentially not performed in accordance with validated processes as set out by the International Organisation for Standardisation. Anika is requiring immediate destruction of all lots of the above listed products.

#### Hazard giving rise to the FSCA

There are no reports of patient adverse events or injury related to this issue, however it is possible that infection and/or toxicity may result in patients treated using these products. No specific patient follow-up activities are required if the product has already been used.

### Action to be taken to mitigate the risk

1. Read this Field Safety Notice carefully and ensure that affected persons, such as appropriate clinical staff are aware of its contents.



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2. Please complete the Acknowledgement Form within 10 business days of receiving this Field Safety Notice. Even if you hold no stock of the affected products, you must still complete the Acknowledgement Form and return it via email to [SafetyNotice@anika.com](mailto:SafetyNotice@anika.com).
3. Identify your own stock of the affected products.
4. Immediately remove all affected products from circulation and destroy according to your local operating procedures.
5. No patient follow-up or notification is necessary.
6. Inform Anika, using the Acknowledgement Form, of any destroyed products.
7. If you have further distributed the affected products, please identify those customers to Anika, and forward this notification to them immediately.
8. Retain a copy of the Acknowledgement Form with your field action records in the event of a compliance audit of your facility's documentation.

Anika will continue to monitor the issue in the field and will notify you if additional information is uncovered. Anika is treating this issue seriously and patient care remains our priority at all times during this process.

## General Information

### Manufacturer information

- |                           |   |
|---------------------------|---|
| <b>a. Company Name</b>    | Anika Therapeutics, S.R.L.  |
| <b>b. Address</b>         | Corso Stati Uniti 4/U<br>35127 Padova (PD) – Italy                                  |
| <b>c. Website address</b> | <a href="https://www.anikatherapeutics.com/">https://www.anikatherapeutics.com/</a> |

We recognise that this situation is a potential disruption to your normal operations. Anika is committed to providing quality products and we apologise for any inconvenience this may have caused. Thank you for your immediate assistance in this matter.

**The Competent (Regulatory) Authority of your country has been informed about this communication.**

**This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected products have been transferred.**

**Please transfer this notice to other organisations on which this action has an impact.**



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Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to Anika, and the national Competent Authority if appropriate, as this provides important feedback.



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HYALOBARRIER® GEL ENDO  
PRODUCT DESTRUCTION**

**Acknowledgement Form**

Date: DD:MMM:YYYY

[Details of recipient(s)  
Name  
Address  
City/state/country/zip]

This letter is being returned to confirm that we have read and understood the information provided to us in the Field Safety Notice dated 14 May 2021 related to the destruction of Hyaloglide® Anti-adhesion Gel/ Hyalobarrier® gel/ Hyalobarrier® Gel Endo.

We have removed all our inventory of these product from circulation and destroyed them.

We have shared this information with all persons and organisations who have received the affected products from us. .

Location:

Print name/role:

Signature:

Date:

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**Confirmation of Product Destruction**

Note: Please indicate "NONE" if you do not currently hold any inventory of the affected products.

| Device model and number | Lot number | Quantity destroyed |
|-------------------------|------------|--------------------|
|                         |            |                    |
|                         |            |                    |
|                         |            |                    |
|                         |            |                    |

Please return this signed letter immediately to Anika at [SafetyNotice@anika.com](mailto:SafetyNotice@anika.com).

## Annex 1 to ANIKA FSICA

| Srl P/N    | Description                              | Finished goods Lot number (add six zeros to front) | exp date  | Release date |
|------------|--|--|-----------|--------------|
| 130003F    | Hyalobarrier Gel, Nordic                 | 0000005241   | 6-Oct-23  | 21-Dec-20    |
| 130003F    | Hyalobarrier Gel, Nordic                 | 0000004872   | 15-Jul-23 | 2-Sep-20     |
| 130003F    | Hyalobarrier Gel, Nordic                 | 0000002014   | 7-Jan-22  | 23-Apr-19    |
| 130003F    | Hyalobarrier Gel, Nordic                 | 0000003079   | 28-Jun-22 | 4-Feb-20     |
| 130011F    | HYALOBARRIER GEL 3 ISRAELE               | 0000002015   | 7-Jan-22  | 3-Feb-20     |
| 130012F    | Hyalobarrier Gel, 3 pack                 | 0000005242   | 5-Oct-23  | 12-Feb-21    |
| 130012F    | Hyalobarrier Gel, 3 pack                 | 0000001273   | 13-Jul-21 | 10-Jul-19    |
| 130012F    | Hyalobarrier Gel, 3 pack                 | 0000004353   | 18-Jun-21 | 22-May-20    |
| 130012F    | Hyalobarrier Gel, 3 pack                 | 0000001275   | 13-Jul-21 | 31-Oct-18    |
| 130012F    | Hyalobarrier Gel, 3 pack                 | 0000002015   | 7-Jan-22  | 3-Feb-20     |
| 130012F    | Hyalobarrier Gel, 3 pack                 | 0000003080   | 28-Jun-22 | 24-Sep-19    |
| 130012F/EA | Hyalobarrier Gel 3 syr                   | 0000001275   | 13-Jul-21 | 22-Nov-18    |
| 130021F    | Hyalobarrier Gel, 3 Syr, Malesia         | 0000002015   | 7-Jan-22  | 3-Feb-20     |
| 130021F    | Hyalobarrier Gel, 3 Syr, Malesia         | 0000001275   | 13-Jul-21 | 31-Oct-18    |
| 130035F    | Hyalobarrier Gel, 1 PK, 10mL             | 0000001273   | 13-Jul-21 | 31-Oct-18    |
| 130035F    | Hyalobarrier Gel, 1 PK, 10mL             | 0000004873   | 15-Jul-23 | 12-Nov-20    |
| 130035F    | Hyalobarrier Gel, 1 PK, 10mL             | 0000004354   | 11-Mar-23 | 11-Sep-20    |
| 130035F    | Hyalobarrier Gel, 1 PK, 10mL             | 0000003079   | 28-Jun-22 | 4-Feb-20     |
| 130035F    | Hyalobarrier Gel, 1 PK, 10mL             | 0000003081   | 28-Jun-22 | 29-Nov-19    |
| 130035F    | Hyalobarrier Gel, 1 PK, 10mL             | 0000002337   | 26-Feb-22 | 31-Jul-19    |
| 130035F    | Hyalobarrier Gel, 1 PK, 10mL             | 0000002446   | 26-Feb-22 | 2-Sep-19     |
| 130035F    | Hyalobarrier Gel, 1 PK, 10mL             | 0000003698   | 24-Oct-22 | 5-Dec-19     |
| 130035F    | Hyalobarrier Gel, 1 PK, 10mL             | 0000004119   | 27-Jan-23 | 30-Mar-20    |
| 130035F    | Hyalobarrier Gel, 1 PK, 10mL             | 0000002016   | 7-Jan-22  | 2-May-19     |
| 130035F    | Hyalobarrier Gel, 1 PK, 10mL             | 0000001083   | 3-May-21  | 17-Sep-18    |
| 130250F    | Hyalobarrier Gel Endo 10 mL 5cm Korea    | 0000003935   | 27-Nov-22 | 19-Mar-20    |
| 130250F    | Hyalobarrier Gel Endo 10 mL 5cm Korea    | 0000001828   | 6-Dec-21  | 22-Feb-19    |
| 130270F    | Hyalobarrier Gel Endo, 6 ml, Korea, 5 cm | 0000005136   | 20-Aug-23 | 23-Nov-20    |
| 130270F    | Hyalobarrier Gel Endo, 6 ml, Korea, 5 cm | 0000005063   | 20-Aug-23 | 23-Nov-20    |
| 130270F    | Hyalobarrier Gel Endo, 6 ml, Korea, 5 cm | 0000005114   | 19-Aug-23 | 23-Nov-20    |
| 130270F    | Hyalobarrier Gel Endo, 6 ml, Korea, 5 cm | 0000005062   | 19-Aug-23 | 22-Oct-20    |
| 130270F    | Hyalobarrier Gel Endo, 6 ml, Korea, 5 cm | 0000003938   | 4-Dec-22  | 19-Mar-20    |
| 130270F    | Hyalobarrier Gel Endo, 6 ml, Korea, 5 cm | 0000001868   | 17-Dec-21 | 22-Feb-19    |
| 130280F    | Hyalobarrier Gel Endo, 3 ml, Korea       | 0000004996   | 11-Aug-23 | 17-Sep-20    |
| 130280F    | Hyalobarrier Gel Endo, 3 ml, Korea       | 0000001694   | 30-Nov-21 | 17-Dec-18    |
| 130310F    | HYALOGLIDE MINI ML 10 Pack               | 0000001669   | 15-Nov-21 | 2-May-19     |
| 130310F    | HYALOGLIDE MINI ML 10 Pack               | 0000003245   | 26-Jul-22 | 25-Sep-19    |
| 130400F    | Hyaloglide, 1 ml                         | 0000004990   | 30-Jul-23 | 17-Sep-20    |
| 130400F    | Hyaloglide, 1 ml                         | 0000005202   | 30-Jul-23 | 12-Nov-20    |
| 130400F    | Hyaloglide, 1 ml                         | 0000004934   | 31-Jul-23 | 2-Sep-20     |
| 130400F    | Hyaloglide, 1 ml                         | 0000003742   | 4-Nov-22  | 7-Apr-20     |
| 130400F    | Hyaloglide, 1 ml                         | 0000003247   | 29-Jul-22 | 1-Oct-19     |
| 130400F    | Hyaloglide, 1 ml                         | 0000001670   | 13-Nov-21 | 13-Dec-18    |
| 130400F    | Hyaloglide, 1 ml                         | 0000001710   | 31-Oct-21 | 2-May-19     |
| 130500F    | Hyaloglide, 2 ml                         | 0000004704   | 1-Jun-23  | 12-Nov-20    |
| 130500F    | Hyaloglide, 2 ml                         | 0000003741   | 5-Nov-22  | 10-Dec-19    |
| 130500F    | Hyaloglide, 2 ml                         | 0000003246   | 26-Jul-22 | 24-Sep-19    |
| 130500F    | Hyaloglide, 2 ml                         | 0000000703   | 4-May-21  | 18-Jun-18    |