
Urgent Field Safety Notice - Update
Recall
regarding
Hysteromat E.A.S.I
200829959
Update to field safety notice from November 25, 2020
[2021-02-23]

Sender:
KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen, Germany

Addressee:
Representatives for medical product safety, users, operators, distributors

Name/identification of the medical devices concerned:
Suction/irrigation pump - Hysteromat E.A.S.I., article number: 26340020-1
Serial number: All

A. Description of the problem including the identified cause:
During review of the technical documentation, it was determined that KARL STORZ currently does not have sufficient clinical evidence to demonstrate fully the basic requirements of the HYSTEROMAT E.A.S.I. in respect to certain performance characteristics in combination with the associated tubing set. In particular, the pressure value displayed by the device could differ from the actual intracavitary pressure value. In this connection, it cannot be proven at this point in time that the device meets the indicated specifications and certain basic performance characteristics.
The time requirement identified for generating the required clinical data cannot be represented with reasonable outlay.

B. Description of the corrective action:
Recall of Hysteromat E.A.S.I.
For alternative therapies, please contact your responsible KARL STORZ representative.

C. Risks for patients/users/third parties if the products are used again:
The displayed pressure value could differ from the actual intracavitary pressure value. There is a risk that a patient may be exposed to a higher pressure than intended. Due to the possibly increased pressure, the general risks of hysteroscopy are more likely to occur than when comparable pump systems are used.
The Hysteromat E.A.S.I. should not be used further.

No incidents have been reported in connection with the the problem described above – the corrective action (recall) is a preventive measure.

D. Risks for patients who have already been treated with affected products:
No incidents have been reported in connection with the above-described problem in patients who have already been treated with the affected products – the corrective action (recall) is a preventive measure.

E. What measures are to be taken by the addressee?
Do not use the Hysteromat E.A.S.I. anymore.
Remove the pumps so that they are inaccessible to users.
Contact your KARL STORZ representative to reverse the transaction.
Please respond by March 19, 2021.

F. Transmission of the urgent field safety notice:
This **urgent field safety notice** must be passed on to all users of the products listed above and all other persons who need to be aware within your organization. If you have transferred these products to third parties, please transmit a copy of this notice or alert the contact listed below.
Please keep this notice at least until the corrective action has been fully implemented.
The competent supervisory authority has received a copy of this urgent field safety notice.

We thank you for your cooperation and understanding for this measure.

G. Contact:
KARL STORZ SE & Co. KG
Robert Herz
Tel.: +49 (0)7461 708 7348 (during business hours)
Fax: +49 (0)7461 708 45581.

Sincerely,

KARL STORZ SE & Co. KG

p.p. Robert Herz
- Abteilungsleiter Vigilance -

Feedback form

Field safety notice: 200829959

This is a product recall!

We hereby confirm that the safety information has been received and, where applicable, passed on.
We have passed on affected products to the following facilities:

_____
Contact details for facility

Hospital
or organization (stamp):

I confirm that I have read and understood the safety information and that I have implemented it accordingly.

Name: _____

Title/position: _____

Signature: _____

Date: _____

Please send this form to:
vigilance@karlstorz.com

or

Fax: +49 (0)7461 708 45581

or by mail to

KARL STORZ SE & Co. KG
Attn. Robert Herz
- Abteilungsleiter Vigilance -
Dr. Karl-Storz-Str. 34
78532 Tuttlingen