
Urgent Field Safety Notice

Product: Warming Solution Set 205
Warming Kit 102
Vitrification Solution Set 110
Vitrification Kit 101

FSCA identifier : 20190521

Type of action : The return of a medical device to the supplier

Date: May 23, 2019

Attention:

Details on affected devices:

- Warming Solution Set 205 (Solutions)
- Warming Kit 102 (Solutions + Plate)
- Vitrification Solution Set 110 (Solutions)
- Vitrification Kit 101 (Solutions + Plate + Cryotec)

<http://reprolife.jp/global/cryotech/>

See the lot numbers of the affected products.

Description of the problem:

Unapproved Class III device called Solution was placed in a kit containing a Class IIa devices and sold in the EU market.

The product named Solution is used for vitrification and is a Class III medical device. Solution has not been reviewed or approved by Notified Body; however, it was sold in the EU market as a kit with approved Class IIa devices. Below are potential risks of the unapproved product use to the patient and user.

- mistreatment
- delayed diagnosis
- delayed treatment
- inappropriate treatment and/or
- transfusion of inappropriate materials

Advise on action to be taken by the user:

- identifying and quarantining the device
- disposal of device
- send the device back to REPROLIFE

Transmission of this Field Safety Notice:

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

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

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

Contact reference person:

Ryuta Sato
Regulatory Affair, REPROLIFE Inc.
2-5-3 9F Shinjuku, Shinjuku-ku, Tokyo, 160-0022, Japan
sato.r@reprolife.jp
+81-3-5925-8931

The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

REPROLIFE is committed to patient safety and will prevent recurrence of this type of problem.

Signature

