
Urgent Field Safety Notice – MDV15-005

Commercial Name of the Affected Product: CryOmega

CryoConcepts Ref Number: 100-1001

Distribution: CryoConcepts EU Distributors and End Users

Implementation: Immediate

Type of Action: Advice Regarding the Activation of the CryOmega Device

Date: 07 April 2015

Attention: Distributors and End Users

Details on affected devices:

CryOmega® Multi-Use Disposable Cryosurgical Device

REF Number: 100-1001

Description of the problem:

When performing the activation step to begin using a new CryOmega® device, an incident occurred where the user did not fully pressing the activation lever into place. If activation is not properly performed and the lever is not locked in place, upon actuation (spraying the device) there is a potential for the rear caps to move out of position resulting in the cylinder of the device escaping out the rear of the device. The cylinder is under pressure and therefore can discharge at a very high speed and therefore there is a potential for injury if the lever has not been locked in place during activation.

Advise on action to be taken by the user:

Procedural Direction: Users must **firmly and completely press** the CryOmega® device activation lever into the locked position prior to dispensing cryogen. The instructions below outline the steps.



Move the lever firmly from its extended position to its closed position on top of the device.



Press the end of the lever firmly with both thumbs into the device opening. A click will be felt and heard on both sides of the lever. If done properly, the lever is locked and cannot be moved back. The unit is now activated and ready for use. **Warning:** once activated the unit is under pressure. Do not attempt to open or disassemble!



Once the lever is "clicked" into place on both sides of the lever the unit is completely activated and cryogen may be sprayed by **firmly and completely** depressing the thumb print area until a steady stream of cryogen is dispensing from the nozzle.

Transmission of this Field Safety Notice:

This Field Safety Notice needs to be distributed to those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please complete and return the Field Safety Notice Acknowledgement to CryoConcepts to indicate receipt and transmission of this Field Safety Notice to customers/users in your organisation.

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

Contact reference person:

Name/Organization:

Gloria M. Ferko, Quality/Regulatory Management
CryoConcepts, LP

Address:

205 Webster St.
Bethlehem, PA 18015
USA

Email: gloria@cryoconcepts.com

Tel: +1 855-355-2796

CryoConcepts is committed to providing quality products and apologizes for any inconvenience this situation may cause. If you have any questions, please contact the CryoConcepts contact reference person listed above.

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

Yours sincerely,



Gloria M. Ferko
Quality/Regulatory Management

Field Safety Notice Acknowledgement

Please read in conjunction with Field Safety Notice MDV15-005, complete the following fields and return via e-mail to gloria@cryoconcepts.com.

By signing below and returning this form you are:

- confirming receipt of this Field Safety Notice and;
- confirming transmission of the Field Safety Notice to all applicable customers/users in your organisation.

Organisation / Distributor:	
Department (if applicable) :	
Address :	
Postcode :	City :
Contact Name :	
Position Title :	
Contact Telephone Number :	
Contact E-mail Address :	
Signature :	Date :