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## Urgent FIELD SAFETY NOTICE

### Vitrectomy TDC kit 1-step 23 G

FSCA Identifier: 02546/17

FSCA type: Return of device (by customer)

Dear Customer,

According to our information you have received the product this Field Safety Notice concerns.

We are providing you important information regarding an issue with this product. Please review this information with relevant members of your staff and pass it on to all those who need to be aware of it (including other organisations who may have received this product from you).

Please remain aware for at least the specified period.

If you need any further information or support concerning this issue, please contact our Customer Service Center on +31 181 45 80 80 at [csc@dorc.eu](mailto:csc@dorc.eu)

This action has also been reported to the relevant Regulatory agencies.

D.O.R.C. Dutch Ophthalmic Research Center (International) B.V. apologizes for any inconvenience caused by this problem.

Kind regards,





## Urgent FIELD SAFETY NOTICE

### Vitrectomy TDC kit 1-step 23 G

FSCA Identifier: 02546/17

FSCA type: Return of device (by customer)

<b>Affected product, commercial name</b>	Vitrectomy TDC kit 1-step 23 G
<b>Affected product, article number</b>	6272.G1T
<b>How to identify affected products</b>	LOT 2000382693
<b>Reason for FSCA</b>	In one case within this Lot, a manufacturing error lead to the possibility for air pressure to enter the eye during Vitrectome use.
<b>Risk of continued use</b>	Pressurized air can enter the eye, which could lead to damage to eye.
<b>Risks of previous use</b>	None
<b>Customer actions</b>	Quarantine items from the potentially affected Lot, and return to DORC for replacement.
<b>Manufacturer actions</b>	Advise customers who received the potentially affected Lot of necessary actions. Complete Root Cause Investigation, and implement necessary corrective actions.

Productieordernummer: \_\_\_\_\_

Artikelnummer: \_\_\_\_\_

Ordergrootte: \_\_\_\_\_ Stuks

Deellevering: Ja / Nee

Checklist:	Testapparatuur /methode	Criteria <waarde>	Aantal Goed	Aantal Fout
Check op juistheid geleverde vitrectoom volgens DMR	Visuele controle			
Check gebruik correcte slangenset volgens DMR	Visuele controle			
Check plaatsing slangenset aan vitrectoom volgens DMR	Visuele controle			
Check wel/geen extension volgens DMR	Visuele controle			
Check extension vast/los volgens DMR	Visuele controle			
Check naald onbeschadigd in tray	Visuele controle			

Opmerking:

Te controleren aantal:	Paraaf:
Afgekeurd product aantal:	Vernietigd: Herstelaantal:

Naam: \_\_\_\_\_

Handtekening: \_\_\_\_\_

Datum: \_\_\_\_\_



# RETURN FORM

## Vitrectomy TDC kit 1-step 23 G

FSCA Identifier: 02546/17  
FSCA type: Return of device (by customer)

Dear sir, madam,

With regards to your Field Safety Notice, we have checked our current product inventory.

I hereby declare that, if present, any potentially affected items from lot 2000382693 were quarantined. The quarantined items will be shipped back to D.O.R.C. International as soon as possible.

Potentially affected items in inventory?	<input type="checkbox"/> Yes; ____ items <input type="checkbox"/> No
Potentially affected items returned to D.O.R.C.?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Track & Trace number	

Yours sincerely,

(Name and signature of customer representative and date)