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

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**

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<table>
<thead>
<tr>
<th>Affected product, commercial name</th>
<th>Vitrectomy TDC kit 1-step 23 G</th>
</tr>
</thead>
<tbody>
<tr>
<td>Affected product, article number</td>
<td>6272.G1T</td>
</tr>
<tr>
<td>How to identify affected products</td>
<td>LOT 2000382693</td>
</tr>
</tbody>
</table>

**Reason for FSCA**  
In one case within this Lot, a manufacturing error lead to the possibility for air pressure to enter the eye during Vitrectome use.

**Risk of continued use**  
Pressurized air can enter the eye, which could lead to damage to eye.

**Risks of previous use**  
None

**Customer actions**  
Quarantine items from the potentially affected Lot, and return to DORC for replacement.

**Manufacturer actions**  
Advise customers who received the potentially affected Lot of necessary actions. Complete Root Cause Investigation, and implement necessary corrective actions.
Productieordernummer: ____________

Artikelenummer: ____________

Ordergrootte: ____ Stuks

Deellevering: Ja / Nee

<table>
<thead>
<tr>
<th>Checklist:</th>
<th>Testapparatuur/methode</th>
<th>Criteria &lt;waarde&gt;</th>
<th>Aantal Goed</th>
<th>Aantal Fout</th>
</tr>
</thead>
<tbody>
<tr>
<td>Check op juistheid geleverde vitrectoom volgens DMR</td>
<td>Visuele controle</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Check gebruik correcte slangenset volgens DMR</td>
<td>Visuele controle</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Check plaatsing slangenset aan vitrectoom volgens DMR</td>
<td>Visuele controle</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Check wel/geen extension volgens DMR</td>
<td>Visuele controle</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Check extension vast/los volgens DMR</td>
<td>Visuele controle</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Check naald onbeschadigd in tray</td>
<td>Visuele controle</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Opmerking:

Te controleren aantal: Paraaf:

Afgekeurd product aantal: Vernietigd:

Naam: ____________

Handtekening: ____________

Datum: ____________
RETURN FORM

Vitrectomy TDC kit 1-step 23 G

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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.

<table>
<thead>
<tr>
<th>Potentially affected items in inventory?</th>
<th>☐ Yes; _____ items</th>
<th>☐ No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potentially affected items returned to D.O.R.C.?</td>
<td>☐ Yes</td>
<td>☐ No</td>
</tr>
</tbody>
</table>

Track & Trace number

Yours sincerely,

(Name and signature of customer representative and date)