

Field Safety Notice

"23/25/27G Two Dimensional Cutter - 20k CPM" in the following called "TDC VELOCE™"

9311.XXK01, 9311.XXK02, 9311.XXK03, 9311.XXG01, 9311.XXG02, 9268.VITXX, 9623.K0201, 9623.G0201, 9625.G0201, 9627.G0201, 9623.G0202, 9627.G0101, 9311.23G01-00, 9311.27G01-00

FSN Identifier SA-2026-0004

Att: <name customer>
<address customer>
<postal code, city>
<country>

Dear Customer,

The purpose of this letter is to inform you about a potential safety risk concerning the TDC VELOCE™, disposable pneumatic vitrectome. The Products impacted are packs, kits and standalone Products including a TDC VELOCE vitrectome with the following article numbers. **According to our information you have received <indicate number> box(es) of the Product lots that are affected. <adapt as needed>**

9268.VIT23
9268.VIT25
9268.VIT27
9311.23G01
9311.23G02
9311.23K01
9311.23K02
9311.23K03
9311.25G01
9311.25G02
9311.25K01
9311.25K02
9311.25K03
9311.27G01
9311.27G02
9311.27K01
9311.27K02
9311.27K03
9623.G0201
9623.G0202
9623.K0201
9625.G0201
9627.G0101
9627.G0201
9311.23G01-00
9311.27G01-00

Please review the attached Field Safety Notice as soon as possible with relevant members of your staff and pass it on to all those who need to be aware of it, including other locations and organizations who might have received this Product through you.

If you need any further information or support concerning this Issue, please contact your local DORC representative, call the Customer Technical Service Center of DORC on +31 181 45 80 80, or sent an email to FCA@dorcglobal.com

Once you have completed the requested actions, please complete, sign and return the attached Field Action Acknowledgement Form with the instructions provided on this form.

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

Kind regards,
 Evgeny Shchedin
 Global Director Commercial Operations
 D.O.R.C. Dutch Ophthalmic Research Center (International) B.V

TDC VELOCE™

Outer Shaft becomes loose from handle

1 INFORMATION ON AFFECTED DEVICES	
1.1. Product Device Type(s)	<i>Disposable pneumatic vitrectome</i>
1.2. Commercial Product name(s)	<i>TDC VELOCE™ (23/25/27G Two Dimensional Cutter - 20k CPM)</i>
1.3. Clinical Purpose	<i>Vitreous Aspirating and Cutting Instrument</i>
1.4. Product Code(s)	<i>9311.23K01, 9311.25K01, 9311.27K01, 9311.23K02, 9311.25K02, 9311.27K02, 9311.23K03, 9311.25K03, 9311.27K03, 9311.23G01, 9311.25G01, 9311.27G01, 9311.23G02, 9311.25G02, 9311.27G02, 9268.VIT23, 9268.VIT25, 9268.VIT27, 9623.K0201, 9623.G0201, 9625.G0201, 9627.G0201, 9623.G0202, 9627.G0101, 9311.23G01-00, 9311.27G01-00</i>
1.5. Affected software version	<i>NA</i>
1.6. Affected Product Serial or LOT Number range	<i>See attachment</i>

2 REASON FOR FIELD SAFETY CORRECTIVE ACTION (FSCA)	
2.1 Description of the Product problem	<i>The outer knife may become loose during use in the patient eye.</i>

<p>2.2 Hazard giving rise to the F(S)CA</p>	<p>The immediate health consequences that Using of a vitrectome with a loosened outer knife may lead to uncontrolled tissue interaction. This may result in retinal tears, progression of cataract, retinal and/or choroidal hemorrhage, and in severe cases retinal detachment. These complications may require additional surgical intervention and may lead to temporary or permanent visual impairment.</p>
<p>2.3 Probability of Product Issue arising</p>	<p>The probability of the outer knife becoming loose has been estimated as low, based on complaint data received to date: 27 reports out of 34,931 units distributed (approximately 0.08%). In the majority of reported cases, the issue was detectable intraoperatively through abnormal device behaviour, allowing the surgeon to discontinue use before patient harm occurred. To date, no patient harm has been reported.</p>
<p>2.4 Background on Issue</p>	<p><i>The Product Issue was reported due to customer complaints. Surgeons reported that the outer knife became loose during use, which could potentially affect patient safety. Root cause investigation concluded that the use of oil in the sub assembly could negatively impact the bond of the outer knife to the handle sub assembly. Therefore, the use of oil was removed in this sub assembly step per 16 October 2025.</i></p>

3 TYPE OF ACTION TO MITIGATE THE RISK

<p>Actions to take by the Product User</p>	<ul style="list-style-type: none"> • Review this information as soon as possible with relevant members of your staff. • Pass this FSN as soon as possible on to all those who need to be aware of it, including other locations, organizations and/or customers who might have received the impacted Product(s) through you. • <i>Check the attached list of affected lots and Products and if you still have remaining boxes and individual Products from this list in your inventory, please scrap them.</i> • Follow the instructions on how to complete and submit the Field Action Acknowledgement Form that is provided with this FSN. • Please report all Product related incidents to DORC, and the National Authority, if appropriate.
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<p>Actions Being Taken by the Manufacturer</p>	<ul style="list-style-type: none"> We have decided to inform our customers and distributors and related National Authorities about the observed situation and the actions to take to prevent potential patient harm or inconvenience. about the observed situation and the actions to take to prevent potential patient harm or inconvenience.
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<p>4 GENERAL INFORMATION</p>	
<p>4.1 FSN Type</p>	<p>New</p>
<p>4.2 Further advice or information already expected in follow-up FSN?</p>	<p>No</p>
<p>4.3 Manufacturer Information</p>	<p>D.O.R.C. Dutch Ophthalmic Research Center (International) B.V. Scheijdelveweg 2 3214 VN Zuidland The Netherlands</p>
<p>4.4 Contact in case of questions</p>	<p>Contact for questions on this FSN your local DORC representative; alternatively, you can send an email to FCA@dorcglobal.com</p>
<p>4.5 Authority Notification</p>	<p>The responsible competent Authority of your country has been informed about this Field Safety Notice.</p>

Kindly find attached the affected lots and products:



Veloce Lots
Evaluation (List_2026)