STAXS®
CONTAMINATION CONTROL EXPERTS

Urgent Field Safety Notice

DOTCH® Puru® Syringes
FSCA-identifier: <vul hier het FSCA-nummer in>
Advisory

Date: 8-2-2021

Subject: Advisory on possible risks relating to intraocular use with 1ml syringe

Dear customer,

Description of the problem
The DOTCH® Puru® 1ml Syringes consists of 1ml syringes manufactured by BD. Through a product notification BD informed STAXS® about a potential risk in case the product is used for other than the intended use. STAXS® has become aware that the intraocular use of sterile, BD branded syringes have been associated with events such as "floaters" and endophthalmitis (inflammation of the interior of the eye). BD issued a Field Safety Notice containing the following information: *"When syringes and needles are used for intraocular injections, the potential exists for "floaters" in patients' eyes which are believed to be due to silicone. (Note: Syringes and needles manufactured by BD have silicone applied to the inside of the barrels to provide lubrication for the plunger stopper, allowing it to move easily). The potential hazard is deposition of silicone oil (SO) droplets in the vitreous. The potential harm could be symptomatic "floaters" in the patient's field of vision which, normally, are tolerable and resolve over a few months. However, if sufficiently bothersome, floaters may lead to a vitrectomy for their removal. BD became aware of other potential risks associated with intraocular injections, such as endophthalmitis (inflammation of the interior of the eye), which may be associated with failure modes not previously identified by BD. To reduce this risk of silicone floaters and inflammation or irritation that may occur, HCPs can use the syringes and needles provided with ocular medications that are specifically designed and labeled for intravitreal injection".*

For STAXS® the safety of patients and users is of highest priority. STAXS® wants to emphasize that these syringes are intended for general purpose injection/aspiration of fluids and injection/aspiration of fluids below the surface of the skin. STAXS® has not validated the syringe for specific purposes, such as intraocular use. STAXS® will revise the datasheets for the affected products presented in table 1 to further emphasize the intended use and will therefore explicitly mention the intraocular use being specific use. Customers should reconsider the use of this syringe for intraocular purposes.

Details on affected devices
The following Dotch® Puru® Syringe article codes are affected.

Article code	Product description	Batchnumber
SYS-0001-10	DOTCH® Puru® Syringe, polycarbonate syringe, Luer-Lock™ ,1ml, double bagged in LLDPE, 10 pcs/double bag, 10 double bags/box, sterile	n/a
SYS-0001-25	DOTCH® Puru® Syringe, polycarbonate syringe, Luer-Lock™ ,1ml, double bagged in LLDPE, 25 pcs/double bag, 10 double bags/box, sterile	n/a
SYS-0001-50	DOTCH® Puru® Syringe, polycarbonate syringe, Luer-Lock™ ,1ml, double bagged in LLDPE, 50 pcs/double bag, 5 double bags/box, sterile	n/a
SYS-1001-10	DOTCH® Puru® Syringe, polycarbonate syringe, Luer-Lock™, 1ml, double bagged in Al/LLDPE, 10 pcs/inner bag, 1 inner bag/outer bag, 10 outer bags/box, sterile	n/a
SYS-1001-25	DOTCH® Puru® Syringe, polycarbonate syringe, Luer-Lock™, 1ml, double bagged in Al/LLDPE, 25 pcs/inner bag, 1 inner bag/outer bag, 8 outer bags/box, sterile	n/a

Table 1: List of impacted products

Advise on action to be taken by the user

1. Ensure the contents of this Field Safety Notice, including the contraindications, are read and understood by those within your organization who may use the DOTCH® Puru® Syringes, listed in Table 1 above.
2. Please complete and return the customer response form on the next page

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:

In case you have any questions please contact us by phone or e-mail.

Telephone: +31 (0)513 677 076
E-mail: RO@Staxs.eu

René Ouwerkerk (QA Officer)
Businesspark Friesland-West 1
8447 SL Heerenveen
The Netherlands

The undersigned confirms that this Field Safety Notice has been notified to the appropriate Regulatory Agency.

Our sincere apologies for any inconvenience this may have caused you.

Yours sincerely,

STAXS the Netherlands B.V.

xxx xxx

Appendix: Customer Response Form

STAXS®
CONTAMINATION CONTROL EXPERTS

Customer Response Form

Appendix to Urgent Field Safety Notice <vul hier FSCA-nummer in>

Advisory on Dotch® Puru® Syringes

Date: 8-2-2021

Company name: **<Vul hier bedrijfsnaam klant in>**

Address: _____

_____

_____

We declare to have received the Urgent Field Safety Notice from STAXS The Netherlands B.V. We confirm to have passed this notice on all those who need to be aware within our organization and, if applicable, to any other organization where the potentially affected devices have been transferred.

The result from our stock assessment is as follows (if applicable):

☐ After a thorough check, we did not found any stock
☐ After a thorough check, we have found the following stock;
☒ Not applicable

Article code	Product	Batchnumber	Amount

Date: _____

Filled in by: _____

Function: _____

Telephone: _____

E-mail: _____

Signature: _____

Please return this form no later than 19-3-2021 to:

- **By E-Mail: QA@staxs.eu**
- **By mail: STAXS The Netherlands BV, Businesspark Friesland-West 1, 8447 SL HEERENVEEN**