FSN Reference number: 463 CAPA N C21-003_FSN
Revision: 02

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**Urgent Field Safety Notice**

**Commercial name:** Metal semi rigid injection needle facette tip indicated for Vantris VUR Treatment (RINS).
**FSCA -ref. MDD21.199**
**Type of action:** Update on Instructions for Use

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**Date:** August 8th, 2021.
Promedon S.A issues this Field Safety Notice (FSN) to inform users about a reportable incident regarding Injection Needles used to VANTRIS VUR Treatment.

**Details on affected devices:**

Commercial name: Metal semi rigid injection needle facette tip indicated for Vantris VUR Treatment.

Nomenclature text: Endoscopic injection needle 3,6 Fr x 22 G x 350 mm. The injection needle is intended for the endoscopic implantation of tissue bulking agents for the treatment of vesicoureteral reflux and female urinary incontinence.

Model number: 3,6 Fr metal semi rigid injection needle facette tip

Catalogue number: RINS

**Manufacturer information:**

Promedon S.A.
Av. Gral. Manuel Savio Lote 3 - Manzana 3
X5925XAD- Parque Industrial Ferreyra
Córdoba- Argentina

**Description of the problem**:

An incident report from the National Organization for Medicines (NOM) was received on March 8th, 2020.
The issue was related to the metal semi rigid injection needle facette tip indicated for Vantris VUR treatment (Ref.: RINS). During Vantris VUR injection with STING method on a female patient

and after the submucosal injection with the needle RINS, the final tip of the needle was disconnected from the shaft of the needle, resulting the detached part of the needle to remain inside the patient on the bladder neck. There was no major damage on the patient as the detached tip was retrieved with a grasper transurethral.

In this case, the incident did not lead to death or serious deterioration in health, due to the intervention of healthcare personnel.

As a corrective action for this reported incident, an instruction for use of the injection needle has been updated and incorporated, because the needle should not fail if it is used correctly.The risk would be mitigated by precise information on the use of the injection needle (such as using a straight cystoscope and avoiding bending the needle during surgery), and by the precautions and warnings mentioned in the IfU:

- This device should only be used by qualified surgeons experienced in endoscopic practices and trained in bulking agent injection procedures.
- Patients and/or their legal representatives should be informed of the details of the surgery, as well as of all risks and potential complications which may result in harm to the patient.
- DO NOT USE if the pouch containing the needle is OPENED OR DAMAGED.
- Carefully inspect the needle prior to use in order to verify that there is no external mechanical damage or other failures. Do not use the needle if damage is found.
- Make sure that the needle diameter is compatible with the substance to be injected and with the working channel of the endoscope to be used.
- Use a cystoscope with a straight working channel of 4 Fr or more, according to the needle chosen.
- Pay attention to the indicator marks printed on the needles.
- Endoscopic injection needles have been designed to be used only ONCE. The needles are disposable devices and may not be REUSED, REPROCESSED, or RESTERILIZED.
- Any site, physician or third-party that reprocesses, restores, remakes, resterilizes or reuses these disposable devices shall be fully responsible for their safety and efficacy.
- Promedon has not designed these injection needles to be reprocessed or reused; therefore, it cannot be determined whether reprocessing can clean and/or sterilize or maintain the structural integrity of the needles to ensure patient/user safety.
- Do not bend the tip of the needle when checking if the bulking agent is flowing out since it could become irreversibly damaged.
- If the needle cannot be retracted through the endoscope channel, DO NOT TRY to remove it from the instrument. It may be removed together with the endoscope.

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**Advise on action to be taken by user:**

- Read Instructions for Use (IfU) carefully before use.

**Transmission of this Field Safety Notice:**

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations 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:**

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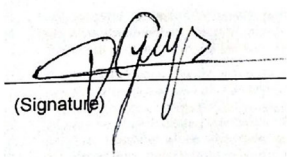
The undersigned confirms that this notice has been notified the appropriate Regulatory Agency.




Veronica Grupe
Head of Regulatory Affairs