

*Date: 25/12/2020*

**Medical Device Safety Advisory Notice**

**Subject:** Advisory notice regarding the BfArm, Germany with the case no. 01274/20 new amendment reference no.20750/20- Cystostome 10 Fr.

<b>Product reference no.</b>	<b>Description</b>
SE-CY-10	Cystostome 10 Fr

**For the Attention of:**

- **Customers using Cystostome 10 Fr**
  1. MANDEL + RUPP MEDIZINTECNIC Gmbh (Distributor)
  2. RMS MEDICAL DEVICE BVA (Distributor)
  3. COUSIN ENDOSURG SARL (Distributor)

**Product Advisory Notice**

Shaili Endoscopy has received complaints regarding Cystostome 10 Fr.

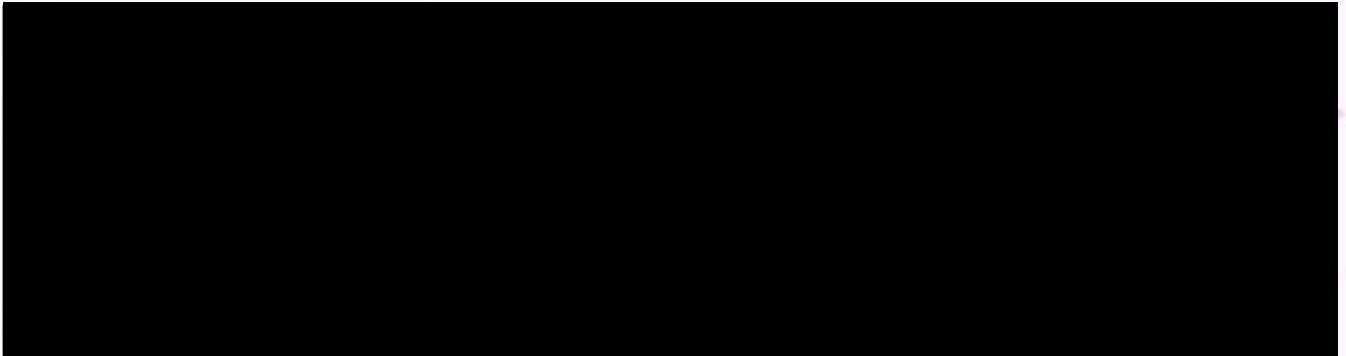
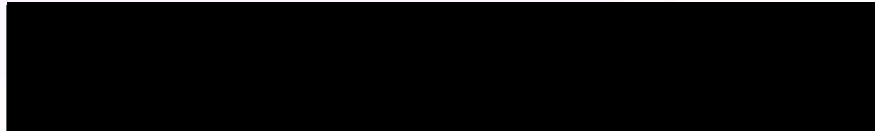
**Nature of the complaint:** during endoscopic procedure, while passing the Cystostome over a guide wire, the tip of the Cystostome peeled off the cover of the guide wire. So, the channel of the endoscope was clogged and the rest of the cover material had to be taken out of the stomach of the patient.

**Possible risk to the patient:** Not applicable.

**Root cause of the problem:** The root cause has been determined. It was observed that the cap of Cystostome has burrs leading to peeling of the guide wire cover.

**Corrective action:** Rectified the manufacturing process of the cap of Cystostome & 'Finishing' of the metal tip. An additional step of 'Finishing' of the metal tip was introduced in the manufacturing process sequence. Procedure for manufacturing of Cystostome Doc.no. SE/PRD/SOP-55 is revised.

**Immediate correction:** Field Safety Notice (FSN) has been issued to all distributors to recall the batches of the affected product:



**YOU NEED TO TAKE THE FOLLOWING ACTIONS:**

1. Please distribute this information to anyone who uses or orders Cystostome 10 Fr as per tabulated lot no. Additionally, please ensure that a copy of this letter is provided to any other organisation where affected devices have been transferred.
2. For 10 Fr Cystostome 0.025" guide wire use for double stenting and for single stenting only 0.035" guide wire use.
3. Please complete Advisory Notice Response and return it by email to [drparesh@shailiendoscopy.com](mailto:drparesh@shailiendoscopy.com), mail or fax immediately.

**CONTACT DETAILS**

