Rev 1: September 2018

FSN Ref: FSN-BSMTI-26001-Rev00 FSCA Ref: FSCA-BSMTI-26001-Rev00

Date: 27/10/2026

Urgent Field Safety Notice

(Kit) IMP Tumorstent, (Kit) Innoflex Mono-J, (Kit) Innoflex Ureteral stent, (Kit) Innosoft Mono-J, (Kit) Innosoft Ureteralstent, (Kit) Innostar Ureteralstent, (Kit) Percudrain 2 step nephrostomy, (Kit) Percudrain 3, (Kit) Percusoft 3 step drainage, (Kit) Percusoft 3 step nephrostomy set, Balloon 2 step Nephrostomy

For Attention of*:Distributors and healthcare facilities who may be in possession of affected products nominated hereafter.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Procedure Pack Assembler: BS Medical Tech Industry (BS-MTI), quality@bs-mti.com, 2 rue de l'Avenir, 67470 Niederrœdern, France

Urgent Field Safety Notice (FSN)
(Kit) IMP Tumorstent, (Kit) Innoflex Mono-J, (Kit) Innoflex Ureteral stent, (Kit) Innosoft Mono-J, (Kit) Innosoft Ureteralstent, (Kit) Innostar Ureteralstent, (Kit) Percudrain 2 step nephrostomy, (Kit) Percudrain 3, (Kit) Percusoft 3 step drainage, (Kit) Percusoft 3 step nephrostomy set, Balloon 2 step Nephrostomy
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The IMP ureteral stent kits (single-loop and double-loop) are procedure packs placed on the market by BS-MTI. Each kit contains a ureteral stent set, sterilized by BS-MTI, for which BS-MTI is the legal manufacturer, and a guidewire, packaged and sterilized by EPflex, for which EPflex is the legal manufacturer. The IMP nephrostomy kits are procedure packs placed on the market by BS-MTI. Each kit contains systematically a nephrostomy set, sterilized by BS-MTI, for which BS-MTI is the legal manufacturer, and a guidewire, packaged and sterilized by EPflex, for which EPflex is the legal manufacturer.
1.	2. Commercial name(s)
	(Kit) IMP Tumorstent, (Kit) Innoflex Mono-J, (Kit) Innoflex Ureteral stent, (Kit) Innosoft Mono-J, (Kit) Innosoft Ureteralstent, (Kit) Innostar Ureteralstent, (Kit) Percudrain 2 step nephrostomy, (Kit) Percudrain 3, (Kit) Percusoft 3 step drainage, (Kit) Percusoft 3 step nephrostomy set, Balloon 2 step Nephrostomy
1.	3. Unique Device Identifier(s) (UDI-DI)
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1.	4. Primary clinical purpose of device(s)*
	IMP Ureteral stent kits: Ureteral stents are intended for urine drainage from kidney through the ureter. Guidewire is used on ureteral stent placement. Nephrostomy sets: Nephrostomy catheters are intended for percutaneous urine derivation of the upper urinary track. Guidewire is used on nephrotomy catheters placement.
1.	5. Device Model/Catalogue/part number(s)*
	Cf Appendix: FSN-BSMTI-26001-Appendix1-Rev00
1.	6. Software version
	Not Applicable
1.	7. Affected serial or lot number range
	ALL lot number affected
1.	8. Associated devices
	Not Applicable

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	EPflex Feinwerktechnik GmbH, the legal manufacturer of the guidewires included in certain BS-MTI Procedure Packs, has identified the following product problem: “The sterile packaging of the products failed the microbial barrier test after five years of real-time aging. Therefore, there is no evidence that the sterile packaging can maintain product

	sterility over a shelf life of five years.", as described in its Field Safety Notice (FSN_260001), dated 23 October 2026.
2.	2. Hazard giving rise to the FSCA*
	As described in EPflex, the legal manufacturer of the guidewires, Field Safety Notice (FSN_260001), dated 23 October 2026: "Sterile packaging must maintain a product's sterility throughout its entire shelf life. If it does not, there is a risk that a non-sterile product may be used. This may lead to infections in patients." The risk associated with the use of the affected guidewires can therefore be prevented, if procedure packs containing them are identified, quarantined and returned.
2.	3. Probability of problem arising
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2.	4. Predicted risk to patient/users
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2.	5. Further information to help characterise the problem
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2.	6. Background on Issue
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2.	7. Other information relevant to FSCA
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	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Distributors and healthcare facilities are requested to: - Immediately stop distribution and use of the affected BS-MTI Procedure Packs. - Identify and quarantine all affected Procedure Packs in their possession. - Inform relevant downstream customers, where applicable. - Arrange the return of the affected Procedure Packs in their entirety to BS-MTI or the relevant distributor, in coordination with BS-MTI or the relevant distributor.	
3.	2. By when should the action be completed?	Return should be completed by 2026/12/31
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. Provide further details of patient-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes

3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	
3	6. By when should the action be completed?	--
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	--
4.	**3.** For Updated FSN, key new information as follows:	
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4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
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4	6. Anticipated timescale for follow-up FSN	--
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	BS Medical Tech Industry (BS-MTI)
	b. Address	2 rue de l'Avenir, 67470 Niederrœdern, France
	c. Website address	--
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	9. List of attachments/appendices:	Appendix: FSN-BSMTI-26001-Appendix1-Rev00
4.	10. Name/Signature	

	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. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.