N° TVA : FR85440880706
RCS Toulon 440 880 706

Safety action Ref.231003 concerning a product recall

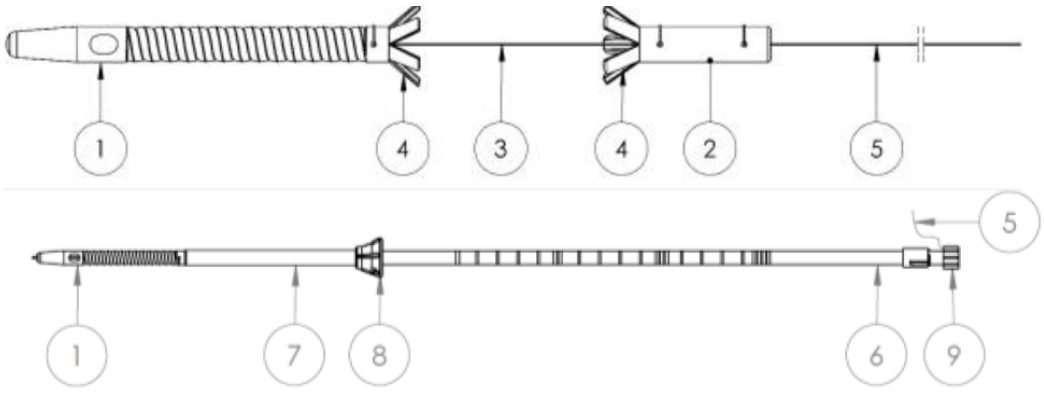
Dear customer,

We are performing a safety action on the EXIME device.

Device concerned

Reference: ROFV2200ST
Designation: EXIME
Batch numbers: all
Product description:
The Rocamed Urethral Stent is a sterile, single-use device consisting of two tubular silicone parts joined by a connecting wire. The stent allows the drainage of urine from the bladder. The two parts of the stent have fins to ensure its stability on each side of the striated sphincter and to avoid its migration. The stent is delivered mounted on its insertion device.

The Rocamed Urethral Stent is intended for single use (30 days maximum).



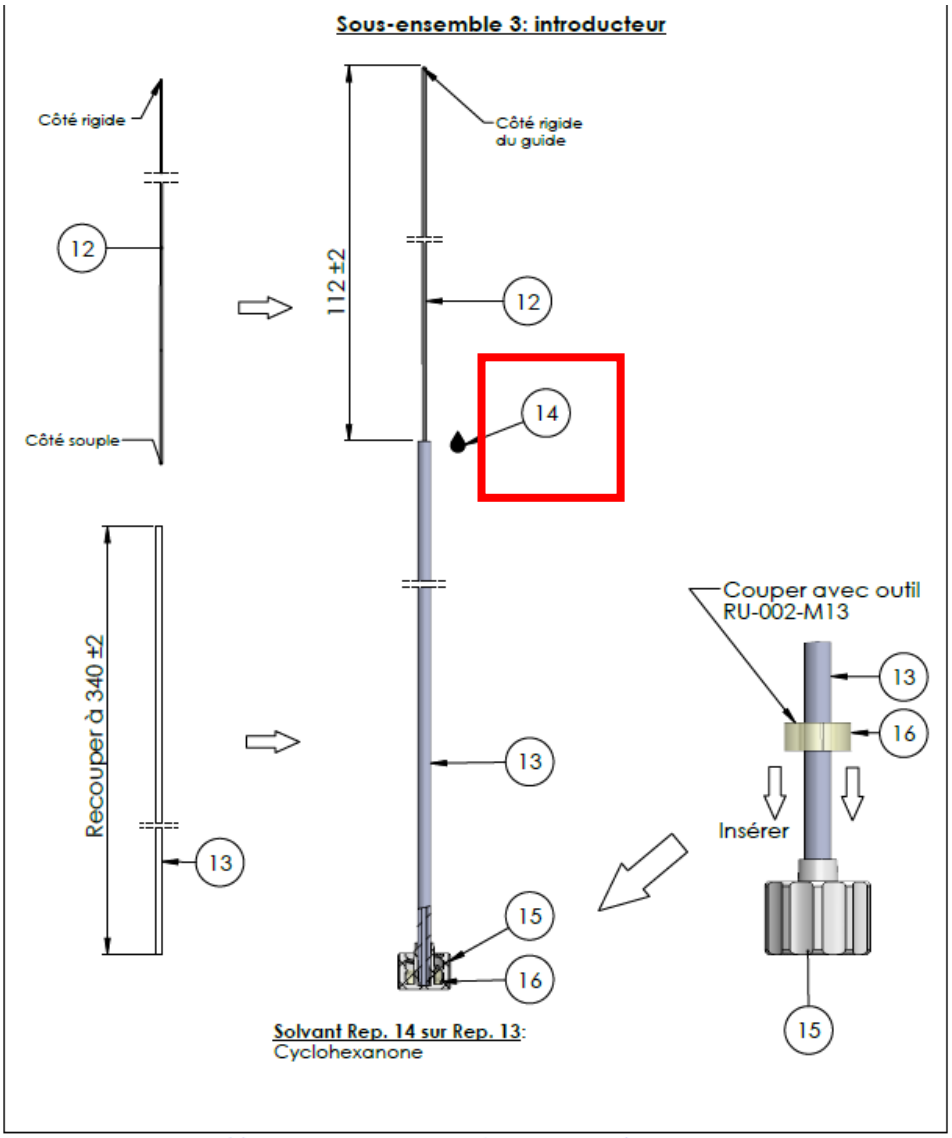
1. Partie urétrale prostatique
2. Partie urétrale bulbaire du tuteur
3. Fil de connexion entre les deux parties
4. Ailettes stabilisatrices
5. Fil de sécurité et de retrait
6. Tube pousseur
7. Tube rabatteur des ailettes
8. Butée du tube rabatteur
9. Connexion Luer entre tube pousseur et stylet d'alignement.

Reason for FSCA:

N° TVA : FR85440880706
RCS Toulon 440 880 706

We are withdrawing the devices from the market as a precautionary measure because we have received a feedback stating that the alignment of the pusher stylet of the product has become detached during insertion.
The reason for this is that the bonding between the semi-rigid grey plastic segment and the metal nitinol guide is weak and breaks.

The bonding in question is represented by mark 14 in the plan below. This bonding is made at the junction between the end of the grey tube (which is not connected to the glow wire) and the nitinol wire.

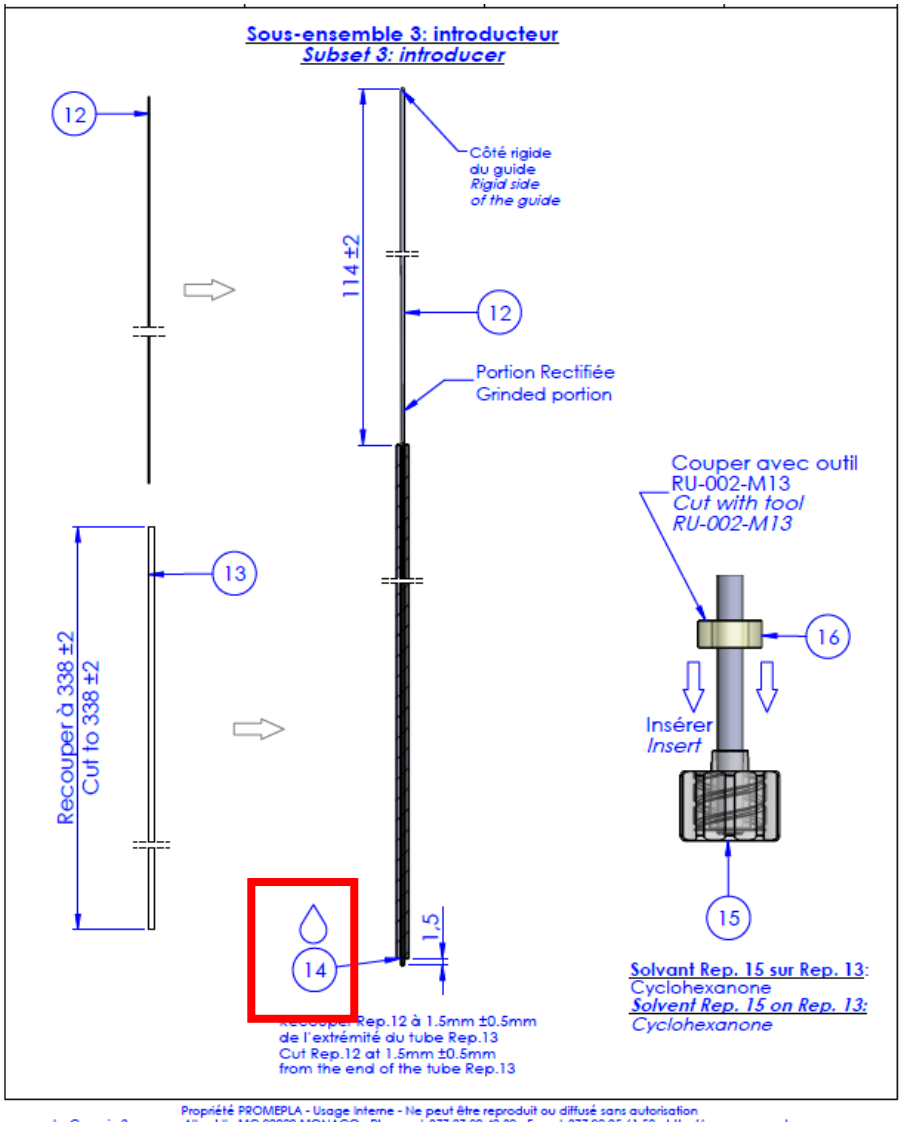


Propriété PROMEPLA - Usage Interne - Ne peut être reproduit ou diffusé sans autorisation
Le Copori - 9, avenue Albert II - MC 98000 MONACO - Phone : + 377.97.98.42.32 - Fax : + 377.92.05.61.50 - http://www.promepla.com

11	ABB17300	LUER LOCK FEMELLE PVC DEHP FREE TRANSP. POUR TUBE ØE 6.8mm - GAMMA
12	ROWP3599	Fil Guide Nitinol d'introduction 0.035" Stiff
13	PRO095270C420PU	COUPE DE TUBE PU-BASO4 GRIS 0.95 x 2.70 x 420mm

The purpose of returning the products is to check them to ensure that the bonding is correct.

In parallel, an improvement of the product is being studied to increase the reliability of this bonding. Thus, the nitinol wire would become longer and would pass completely through the grey tube, so that the bonding is carried out between the end of the grey tube and the wire at the level of the glow as indicated in mark 14 of the specification below.



Propriété PROMEPLA - Usage Interne - Ne peut être reproduit ou diffusé sans autorisation
Le Copori - 9, avenue Albert II - MC 98000 MONACO - Phone : + 377.97.98.42.32 - Fax : + 377.92.05.61.50 - http://www.promepla.com

11	ABB17300	LUER LUG FEMELLE A AILETTES POUR TUBE ØE 6.8mm - PVC RAD. DEHP FREE
12	PSM070500260	NITINOL GRINDED WIRE 0.7/0.5mm x 500mm
13	PRO095270C420PU	COUPE DE TUBE PU-BASO4 GRIS 0.95 x 2.70 x 420mm
14	TLO3921SG25ML	ADHESIF ACRYLIQUE U.V LOT LE + LOIN

N° TVA : FR85440880706
RCS Toulon 440 880 706

Patient risk associated with this defect:

This detachment makes it impossible to use the device.

No patient safety risk.

Action to be taken by NSF recipients:

Return product to inventory.

No risk to product already in use as this stylet is only used for device placement.

This FSN shall be communicated to all users and persons who might have used the product.

List of informed competent authorities: Competent authorities are informed.

Who to contact

If you have any questions about this safety action, please contact ROCAMED's quality department by phone at +377 97 98 41 93 or by email at mr@promepla.com.

Once again, we confirm that our main objective is to guarantee the safety of patients and users.

In issuing this FSCA, we are aware that we have taken a conservative approach to the issue and we rely on your understanding and full support to ensure that our safety action is followed up quickly and effectively.

We apologize for any inconvenience this situation may cause you and your customers and remain at your disposal for any further recommendations or requests.

Sincerely.

Mohamed Rekik
Quality / Regulatory Manager

ROCAMED
N° TVA : FR85440880706
RCS Toulon 440 880 706

Appendix 1 - Acknowledgement letter for hospitals and health care facilities

Please read Ref.231003 and return this completed and signed schedule as soon as possible or within 5 days of receipt to mr@promepla.com. **Check all that apply**	
☐	I confirm that this notice has been read, understood and that all recommended actions have been implemented as required.
☐	I have checked my stock and quarantined the affected products
☐	The number of devices I am referring to is ..... devices
☐	We confirm that all products that we are not able to return have been used.

Name of the organization:	
Address:	
Postal code:	**Country:**
Phone number:	**Email address:**
Name, title and signature of the person who completed the document:	