Date: 29/11/2023

Manufacturer's FSN Ref. No.: AFSN/01/2023-00 Manufacturer's FSCA Ref. No.: AFSCA/01/2023-00

FIELD SAFETY NOTICE

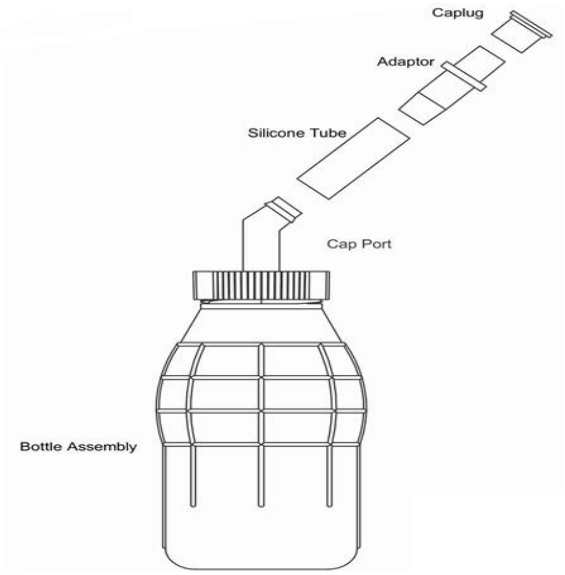
SAFETY INFORMATION for ACE BLADDER EVACUATOR

For Attention of: Distributor and User of ACE Bladder Evacuator

Contact Details of local representative	
Name and Address	Coloplast A/S Holtedam 1, 3050 Humlebæk, Denmark Coloplast Manufacturing France, 9, avenue Edmond Rostand, CS 70218, 24206 Sarlat la Canéda cedex, France
Email Id:	Vigilance@coloplast.com

SAFETY INFORMATION - ACE BLADDER EVACUATOR

Risk addressed by FSN

A	**Information related to concerned device**	
1.	Device Type	Non-invasive suction device. Brief description: The Ace Bladder Evacuator consists of a Bottle with a pre-attached cap and filter, Silicone Tube, Nozzle Adaptor for Storz / Wolf / Olympus / ACMI resectoscope and a Caplug (Endcap). This device is supplied Sterile and is intended for Single use only. It is a non- invasive class 1 (sterile) medical device. Device Photograph: 
2.	Commercial Name	ACE BLADDER EVACUATOR
3.	Unique Device Identifiers (UDI-DI)	Basic UDI-DI: 890414810BECL
4.	Primary Clinical Purpose of the device	The ACE BLADDER EVACUATOR is intended to be used for evacuating irrigation solutions, blood clots, tissue collection and/or straining functions during prostate surgery or bladder surgery.

5.	Device Catalogue/ REF No.	ABVac
6.	Lot Number range	Batches of Bladder Evacuator supplied by ACE.
7.	Associated device	None

Competent authority ANSM aware of the incident, Incident reference no. R2323072.

B	**Reason for FSCA**	
1.	Device Problem description	Field Safety Notice (FSN) is to reinforce instructions for use. Rare Potential Complications may be involved with the use of Bladder Evacuator.
2.	Hazard giving rise to the FSCA/ Description of risk	Bladder Rupture which may lead to patient/user death. Rare but Potential complication associated with the use of Bladder Evacuator. The Doctors should be aware of these complications before use of the device.
3.	Probability of problem arising	Rare
4.	Primary Clinical Purpose of the device	Non- Invasive device intended to be used for evacuating irrigation solutions, blood clots, tissue collection and/or straining functions during prostate surgery or bladder surgery.
5.	Predicted risk to patient/users	Probability: Low, Severity: High.
6.	Further information to help characterise the problem	Urologist must be aware of the Potential complications associated with the use of the device.
7.	Background on Issue	ANSM Incident reference No. R2323072 wherein patient died due to bladder rupture after use of the device.

C	**Type of Action to mitigate the risk**
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

2.	Particular considerations for: Is follow-up of patients or review of patients' previous results recommended? NOT APPLICABLE	
3.	Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No.
4.	Action Being Taken by the Manufacturer ☐ Product Removal ☐ On-site device modification/inspection ☐ Other ☐ Software upgrade ☒ IFU or labelling change ☐ None	
5.	By when should the action be completed?	For all orders post 01/ 01/2024, IFUs will be updated.
6.	Is the FSN required to be communicated to the patient /lay user?	NO. The complication is very rare. Doctors should be aware of it.
7.	If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Not Applicable	

D	**General Information**	
1.	FSN Type*	NEW
2.	For updated FSN, reference number and date of previous FSN	-
3.	For Updated FSN, key new information added	-
4.	Further advice or information already expected in follow-up FSN?	None
5.	If follow-up FSN expected, what is the further advice expected to relate to:	
	None identified.	
6.	List of attachments/appendices:	Draft Copy of IFU (English) updated to specify the potential complications and additional instructions associated with the use of the device. Will also be updated in other languages and implemented.
7.	Name	Anuja Khidse, Manager QA and Regulatory. Email id.: regulatory@acemedicaldevices.com

F. Acknowledgement of receipt of the FSN			
Recipient Name	Sign/Date	Position/Designation	Feedback