FSN Ref: FSN_Philips Bougies_06042021 FSCA Ref: FSCA_Philips Bougies_06042021

Date: 22 April 2021

Urgent Field Safety Notice – Recall of specific Item and lot numbers AG5416 lot 7694143 and AG5420 7748119
Philips Bougies female metric thread

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

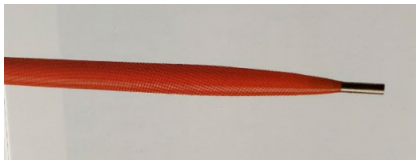
Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

Urgent Field Safety Notice (FSN)
Philips Bougies female metric thread
Risk addressed by FSN

1. Information on Affected Devices*

1.1. Device Type(s)*

This FSN concerns the Philips Bougies Ch16 and Ch20. Philips bougie is a connectable bougie of 34 cm length. The shaft is made of Neoplex® and the tip of the bougie bears a female metric thread, intended to be screwed onto the complementary male metric thread glued to the proximal end of a Filiform bougie.



1.2. Commercial name(s)

Philips Bougies female metric thread

1.3. Primary clinical purpose of device(s)*

The Philips Bougies are intended for the management of urethral stenosis.

1.4. Device Model/Catalogue/part number(s)*

AG5416, AG5420

1.5. Affected lot number range

Item number	Lot n°	Expiry date
AG5420	7748119	11/11/2025
AG5416	7694143	07/10/2025

2 Reason for Field Safety Corrective Action (FSCA)*

2.1. Description of the product problem*

Following discrepancies between packaging labels and contents due to inversion of two batches, Coloplast initiates a voluntary recall.

2.2. Hazard giving rise to the FSCA*

A difference in size of bougie (Ch20 instead of Ch16 and vice versa) was identified and reported by five hospitals. None of these incriminated bougies have been used in patient. However, failure to identify the issue may lead to a prolonged procedure for changing the size. Moreover, inadvertent forceful maneuvers exerted on a Ch20 dilator – instead of a Ch16 – by a non-trained user may lead to urethral bleeding and possible need for surgeon re-intervention.

2.3. Background on Issue

No clinical consequence was reported by the complaining hospitals. A review of the complaints database was carried out on reference AG5420 and AG5416 and no similar case has been reported since CE marking until these current cases.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☒ Identify Device ☒ Return Device The customers affected by this recall are kindly advised to return any unused product covered by the list above to the address mentioned below: Distribution Center of Coloplast Champlan Recall Bougie Service Retour 2 bis route du Chemin Blanc ZAC du Clotais 91160 CHAMPLAN France	
3.	2. By when should the action be completed?	June 30 2021
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes

	4. General Information*	
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Coloplast A/S**
	b. Address	**Holtedam 1** **3050 Humlebæk** **Denmark**
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	5. List of attachments/appendices:	**Customer Reply Form**
4.	6. Name/Signature	Insert Name and Title here and signature below Lone Zacho Vigilance Specialist 

	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. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) 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.