FSN Ref: FSN_ Titan Pump_20230215 FSCA Ref: FSCA_ Titan Pump_20230215

Date: 02.23.2023

Urgent Field Safety Notice – Recall of specific lot numbers
Titan Inflatable Penile Prosthesis

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)
Titan Inflatable Penile Prosthesis
Risk addressed by FSN

1. Information on Affected Devices*

1.1. Device Type(s)*

This FSN concerns the Titan Inflatable Penile Prosthesis (IPP) pumps, which are part of a Titan IPP hydraulic system. The Titan implant consists of two inflatable Bioflex® penile cylinders that are implanted in the corpora cavernosa of the penis. The cylinders are attached to a pump, which is placed in the patient's scrotum, and the pump is connected to a fluid reservoir that is implanted underneath the abdominal muscles. The fluid reservoir contains a Lock-Out™ valve, which is intended to minimize the opportunity for auto-inflation. The fluid reservoir is filled with a sterile saline solution.
Repetitive squeezing of the pump bulb transfers fluid from the reservoir to the cylinders in the penis. As the penile cylinders fill with fluid, the penis enlarges and becomes erect, thereby facilitating intercourse.
The Titan IPP is a three-piece inflatable penile prosthesis (IPP) consisting of a pump, cylinder assemblies and reservoir. The pump and cylinders are pre-connected, and the reservoir is connected to the pump inlet tubing prior to implantation, using components of the assembly kit.

1.2. Commercial name(s)

Titan Inflatable Penile Prosthesis

1.3. Primary clinical purpose of device(s)*

The Titan IPP is a self-contained hydraulic system designed to be surgically implanted for the management of erectile dysfunction. This implant provides the patient with voluntary control over the erect and flaccid states of the penis.

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

ES2918, ES2922, ES2920, EN2814, ES2916, EN2816, ES2914, EN2911, EN2918

1.5. Affected serial or lot number range

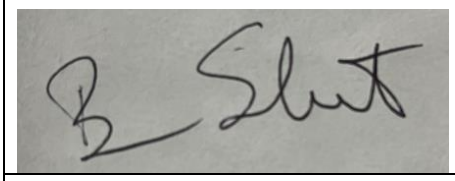
Lot Serial Number	Item Number	Expiration Date
8812159	ES29181022	Oct 5, 2027
8840683	ES29221022	Oct 12, 2027
8812162	ES29201022	Oct 6, 2027
8849596	ES29221022	Nov 3, 2027
8852985	ES29181022	Oct 24, 2027
8852984	ES29181022	Oct 24, 2027
8887598	EN28141022	Nov 16, 2027
8849590	ES29181022	Oct 27, 2027
8840681	ES29161022	Oct 12, 2027
8812163	ES29201022	Oct 6, 2027
8812164	ES29221022	Oct 6, 2027
8812161	ES29201022	Oct 6, 2027
8812160	ES29201022	Oct 6, 2027
8849612	ES29201022	Nov 6, 2027
8812165	ES29221022	Oct 6, 2027
8849568	ES29161022	Oct 20, 2027

	8849594	ES29201022	Nov 3, 2027
	8849593	ES29201022	Nov 3, 2027
	8840682	ES29181022	Oct 12, 2027
	8849607	ES29161022	Oct 31, 2027
	8853029	ES29201022	Oct 24, 2027
	8895171	EN28161022	Nov 17, 2027
	8849597	ES29221022	Nov 3, 2027
	8849595	ES29201022	Nov 3, 2027
	8840680	ES29141022	Oct 12, 2027
	8849608	ES29181022	Nov 6, 2027
	8849583	EN29111022	Oct 26, 2027
	8849567	ES29161022	Oct 20, 2027
	8849574	EN29181022	Oct 24, 2027
	8849592	ES29181022	Nov 3, 2027
	8849610	ES29201022	Nov 6, 2027
	8849613	ES29221022	Nov 6, 2027
	8849591	ES29181022	Nov 3, 2027
	8812158	ES29181022	Oct 5, 2027
	8849611	ES29201022	Nov 6, 2027

	2 **Reason for Field Safety Corrective Action (FSCA)***
2.	1. Description of the product problem*
	Coloplast has identified that Titan Touch Pumps manufactured between September 17, 2022 through December 2, 2022 have a decreased wall thickness (compared to the current standard) and are therefore, subject to this voluntary recall. A decreased wall thickness may result in difficulty inflating and/or deflating the device, pump failure, or a fracture of the pump.
2.	2. Hazard giving rise to the FSCA*
	Pump failure may present as a fracture of the pump wall and may compromise or prevent device function. In the event of a pump fracture, solution used to fill the IPP device may leak. This fluid is physiological saline (sterile, isotonic, pyrogen-free Sodium Chloride U.S.P. Solution for Injection) and is not a source of risk or harm in the case of leakage within the body. Temporary swelling may follow the fracture. Additional potential risks from pump fracture are those associated with replacement surgery if this is the course of action determined by you and your patient.Pump failure may present as the inability to inflate or deflate the device due to loss of the fill solution or weakened wall. If you suspect a patient has a device affected by this issue, it is recommended that you manage the patient as you would in the normal course of clinical practice. If a replacement is necessary, please report the issue immediately to FRcomplaints@coloplast.com and return the explanted device.
2.	3. Probability of problem arising
	This voluntary recall is a proactive measure conducted by Coloplast. There have been no reports of pump failure directly related to this issue as of now. Pump longevity is impacted by the number of inflate/deflate cycles the device undergoes over its lifespan, which may vary by user. Testing confirms Titan Touch pumps manufactured prior to September 17, 2022, and after December 2, 2022, are not affected.
	4. Background on Issue

2.	The mold utilized in building the Titan Touch pump shifted during production. This resulted in a build of material in the core of the mold, which decreased wall thickness of the pump. A decrease in wall thickness has the potential for a premature pump failure, compared to a pump with standard wall thickness, based on the number of interactions with the pump to inflate and deflate the penile prosthesis.

	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 must return any unused product covered by the list above to the address mentioned below: Centre De Distribution Coloplast Le Plessis Pate Attn: FSCA_ Titan Pump_20230215 2 Rue Jacqueline Auriol Le Plessis-Pate Essonne, FR 9122	
3.	2. By when should the action be completed?	April 14, 2023
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? **No** If you suspect a patient has a device affected by this issue, it is recommended that you manage the patient as you would in the normal course of clinical practice. If a replacement is necessary, please report the issue immediately to Coloplast and return the explanted device.	
3.	4. Is customer Reply Required? * (Response Form included with FSN required)	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. *	
4.	5. List of attachments/appendices:	**Customer Reply Form**
4.	6. Name/Signature	Brian Schmidt Head of Regulatory Affairs 

	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.