CHRISTEYNS France

NC 621
Rev 1: September 2018

FSN Ref: FSN _Dynacide PA_20190926

FSCA Ref: N° Dynacide PA 2019-09-26

Date: 26/09/2019

Urgent Field Safety Notice
Dynacide PA
Réf: P60000

For Attention of*: Dynacide PA
ANSM/ BFARM (Allemagne), URPL (Pologne), MSP libanais, SUKL (Tchèque)/GMED

Contact details of local representative (name, e-mail, telephone, address etc.)*
[redacted] **Christeyns FRANCE** 31 rue de la Maladrie - 44120 VERTOU T = +33 (0)2 40 80 27 27 F = +33 (0)2 40 03 09 73 W = www.christeyns.com

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Urgent Field Safety Notice (FSN)
Dynacide PA
Réf: P60000
Risk addressed by FSN

1.	1. Device Type(s)*
1.	2. Commercial name(s)
	Dynacide PA
1.	3. Unique Device Identifier(s) (UDI-DI)
	Not currently available
1.	4. Primary clinical purpose of device(s)*
	How the device(s) is/are used in the clinical setting/intended use.
1.	5. Device Model/Catalogue/part number(s)*
	02322
1.	6. Software version
	Not relevant
1.	7. Affected serial or lot number range
	N° Lot: 280101; 280201; 280301; 290401 EXP 2019-12
1.	8. Associated devices

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Peracetic Acid Generating Powder for High Level Disinfection of medical, surgical, thermosensitive instrumentation and endoscopy equipment.
2.	2. Hazard giving rise to the FSCA*
	We sell a high-level disinfectant product for cold disinfection of thermosensitive medical surgical and instrumentation and material endoscopy: the Dynacide PA.Dynacid PA is allows the generation of peracetic acid about 1900 ppm in 60.5 g (weight of the dose), according to the stability ratio of the product, the amount of peracetic acid decreases with time.After checking two batches available in stock batch: 280101 and 280301, manufactured in 01/2018 and will expire in 3 months (December 2019). The batches were below the 1900 ppm peracetic acid specification: Lot 280301: 1749ppm and Lot 280401: 1799 ppm.A Cause Analysis has been established to determine the cause of this Non-compliance, we found that product can not pass 4 microbiological performance standards. Therefore, it is no longer possible to guarantee the performance of the Dynacide PA medical device.
2.	3. Probability of problem arising
	No data available, There is no incident declared until now
2.	4. Predicted risk to patient/users
	There is a patient risk therefore the product Dynacide PA has been suspended from sale with batch recall.
2.	5. Further information to help characterise the problem
	Not relevant

2.	6. Background on Issue
	Not relevant
2.	7. Other information relevant to FSCA
	This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.

	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	
3.	2. By when should the action be completed?	Upon receipt of the FSN and the explanatory letter, the actions must be implemented immediately.
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No	
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?	FSN customer information and mail
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?	
	No 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:	
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:	
	Not relevant	
4	6. Anticipated timescale for follow-up FSN	Not relevant
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	[redacted]

	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.