

FSN : CBS_FSN-2022.001

URGENT : SAFETY NOTICE (FSN)

COBES COMPANY PRODUCTS

Date : 14/04/2022

To the attention of : Dear Sir or Madam Safety officer

Contact information for the manufacturer's local representative	
Name :	DISPOMED SAS European Representative
Address :	29 rue de Bassano 75008 PARIS
Phone :	+33(0)1 47 22 22 90
Fax :	+33(0)1 47 22 22 92
Contact :	M. Elie SCETBON President
e-mail :	elie_scetbon@yahoo.com

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1. Information on the medical device

1.1.	Name or trade name :
	<ul style="list-style-type: none"> - Surgical Kit - Isolation Gowns - Surgical Gowns - Medical Cap - Surgical drapes - Suits
1.2.	Model, reference of the medical device :
	Orthopedic surgery pack (SC85044).
	General surgery package (SC81004IE, SC81005).
	Surgical gown (S71652E, S71653E, S71654E, S71655E, S71852E, S71853E, S71854E, S71855E, S71752E, S71753E, S71754E, S71755E, S7175XE).
	Surgical gown (5570392, 5570393, 5570395N, 5570396, 5570397, 5570398N).
	Surgical Drapes (S722XX, S72206, S72XXX, S72XXX, S57XXX).

2. Reason for Field Safety Corrective Action (FSCA)

2.1.	Description of the product problem :
	During an inspection of the CE marking technical files, documentary non-conformities were highlighted.
2.2.	Hazard giving rise to the FSCA :
	Documentary non-conformities don't affect the safety and performance of the products. The products must be isolated and must not be put on the market until COBES Manufacturer deliver the corrected documents.

3. Type of action to mitigate risk

3.1.	Action to be taken by the user:
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	<input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None		
3.2.	<table border="1" style="width: 100%;"> <tr> <td style="background-color: #e6f2ff;">Is customer response required ?</td> <td>Yes, the response letter to be completed and returned by the distributor is attached to this notice.</td> </tr> </table>	Is customer response required ?	Yes, the response letter to be completed and returned by the distributor is attached to this notice.
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4. General Information

4.1.	Type of safety notice	New Field Safety Notice
4.2.	ther advice or information already expected in the FSN follow-up?	Non-applicable
4.3.	The competent authority in your country has been informed of this safety notification.	

5. Date, name and quality

2022/04/20
 Elie SCETBON
 President

Transmission of this field safety notice

This field safety notice should be sent to all persons who need to be informed within your company and to any organization where the potentially affected devices have been transferred.

Please report any incidents related to the device to the manufacturer Cobes Industries(Hefei) Co.,Ltd, the local representative DISPOMED S.A.S, European Representative, and the competent national authority ANSM if applicable.