

Rev 1: September 2018  
FSN Ref: 19-001



FSCA Ref: 19-001

Date: 10.31.2019

**Urgent Field Safety Notice**  
**Axiom Medical Inc.**

For Attention of: European Axiom Medical Customers

Contact details of local representative (name, e-mail, telephone, address etc.)*
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See Appendix B
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**Urgent Field Safety Notice (FSN)**  
**Axiom Medical Inc. Sumps, Drains, Catheters and Accessories**  
**Product has been distributed without a valid CE Mark**

<b>1. Information on Affected Devices</b>	
1.	1. Device Type(s) Sterile sumps, drains, catheters, and accessories for general, plastic, cardiovascular, and thoracic surgery.
1.	2. Commercial name(s) See Appendix B
1.	3. Primary clinical purpose of device(s) Axiom products are intended to be placed at surgical or wound sites for fluid drainage.
1.	4. Device Model/Catalogue/part number(s) See Appendix B
1.	5. Affected serial or lot number range: All lot numbers that are in expiry date are affected.

<b>2. Reason for Field Safety Corrective Action (FSCA)</b>	
2.	1. Description of the product problem Axiom products have been distributed in the EU without a valid CE Mark.
2.	2. Hazard giving rise to the FSCA There have been no hazards.

<b>3. Type of Action to mitigate the risk</b>	
3.	<b>1. Action To Be Taken by the User</b> <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input checked="" 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. By when should the action be completed? Upon receipt of this FSN
3.	3. Is customer Reply Required? (If yes, form attached specifying deadline for return)                      Yes

3.	<b>4. Action Being Taken by the Manufacturer</b>  <input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None  No further product will be distributed to the EU until a CE mark is properly obtained.	
3.	5. Is the FSN required to be communicated to the patient /lay user?	No

<b>4. General Information</b>	
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 Axiom Medical, Inc.
	b. Address 19320 Van Ness Ave, Torrance, CA, 90501
	c. Website address Axiommed.com
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.
4.	5. List of attachments/appendices: <b>Appendix A-Customer Reply Form, Appendix B-Products in Distribution &amp; Contacts</b>
4.	6. Name/Signature Valerie Ramsay, Director of Operations
	<p>Valerie Ramsay  <i>Valerie Ramsay</i> 30 Oct 2019 15:11:053-0700            REASON: I am approving this document.            3bc079ea-286c-4bd1-9201-50ac51c0bab7</p>

<b>Transmission of this Field Safety Notice</b>	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.</p>

### Appendix A-End User Reply Form

<b>1. Field Safety Notice (FSN) information</b>	
FSN Reference number	19-001
FSN Date	10/31/2019
Product/Device name	See Appendix B
Product Code(s)	See Appendix B
Lot Numbers	All lots in shelf-life

<b>2. Customer Details (to be completed by customer)</b>	
Account Number	
Name	
Address	
Shipping Address if different to above	
Contact Name	
Title of Function	
Telephone Number	
Email	

<b>3. Customer action undertaken</b>		
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant	Customer to complete or enter N/A



	users and executed.				
<input type="checkbox"/>	I have no product in my possession.	Customer to complete or enter N/A			
<input type="checkbox"/>	I have destroyed affected devices-enter catalogue number, number of devices returned, lot/serial number, and date returned. Add an attachment if needed.	Catalogue #	Qty:	Lot/Serial #	Date Destroyed
Print Name					
Signature					
Date					
<b>4. Return acknowledgement to sender</b>					
Email		See Attachment B			
Address		“			
Fax		“			
Deadline for returning the customer reply form		Jan 30, 2020			

### Appendix B-Products in Distribution and Contact Information

<b>Austria</b>	
<b>National Contact Point:</b> C. Brady	
<b>Address:</b>	
<b>Phone:</b>	
<b>Fax:</b>	
<b>Email:</b>	
Item Number	Item Name
100020ATSC	Thoracic Silicone Catheter, 20FR, Straight, Scale, Double-Pouched
100024SC	Thoracic Silicone Catheter, 24FR, Straight, Scale, Double-Pouched
100028ATSC	Thoracic Silicone Catheter, 28FR, Straight, Scale, Double-Pouched
100028SC	Thoracic Silicone Catheter, 28FR, Straight, Scale, Double-Pouched
111016ATSC	Thoracic Silicone Catheter, 16FR, Angle, Scale, Double-Pouched
111124ATSC	Thoracic Silicone Catheter, 24FR, Angle, Scale, Double-Pouched
111128ATSC	Thoracic Silicone Catheter, 28FR, Angle, Scale, Double-Pouched
111198AT	Silicone Dual-Sump, 20", 8.5 I.D., Large Eye
200MAT	Petite Wound Drain, 11FR, Special Size
201AT	Petite Wound Drain, 7FR
202AT	Petite Wound Drainage Kit, 11FR
3611	CWV Reservoir, 150cc
3626AT	CWV Flat Drain, 10mm
3631	CWV Flat Drain, 7mm
<b>Denmark</b>	
<b>National Contact Point:</b> Kebomed A/S	
<b>Address:</b>	
<b>Phone:</b>	
<b>Fax:</b>	
<b>Email:</b>	
Item Number	Item Name
100036AT	Thoracic Silicone Catheter, 36FR, Straight
111136AT	Thoracic Silicone Catheter, 36FR, Angle
111176	Silicone Uni-Sump, 18", 6.5mm I.D. Small Eye
111186	Filtered Dual-Sump, 20", 8.5mm I.D., Small Eye
111189	Filtered Dual-Sump, 18", 6.5mm I.D., Large Eye
111198	Silicone Dual-Sump, 20", 8.5 I.D., Large Eye
300	Lig-A-Boots, White
<b>Germany</b>	
<b>National Contact Point:</b> Axiom GmbH	
<b>Address:</b>	
<b>Phone:</b>	
<b>Fax:</b>	
<b>Email:</b>	
Item Number	Item Name
100020	Thoracic Silicone Catheter, 20FR, Straight
100020AT	Thoracic Silicone Catheter, 20FR, Straight
100024	Thoracic Silicone Catheter, 24FR, Straight
100024AT	Thoracic Silicone Catheter, 24FR, Straight
100028	Thoracic Silicone Catheter, 28FR, Straight

100028AT	Thoracic Silicone Catheter, 28FR, Straight
111016SC	Thoracic Silicone Catheter, 16FR, Angle, Scale, Double-Pouched
111059AT	Mediastinal Drain, 5mm, Eyes on Top & Bottom
111099AT	Mediastinal Drain, 9mm, Eyes on Top & Bottom
111119AT	Mediastinal Drain, 9mm, Eyes on Top & Bottom
111120SC	Thoracic Silicone Catheter, 20FR, Angle, Scale
111132	Thoracic Silicone Catheter, 32FR, Angle, Scale
111132AT	Thoracic Silicone Catheter, 32FR, Angle
111166	Silicone Hacienda Sump, 28FR
111188AT	Filtered Dual-Sump, 20", 8.5mm I.D., Large Eye
111198	Silicone Dual-Sump, 20", 8.5 I.D., Large Eye

**Ireland**

**National Contact Point:** Fitzwilliam Hosp Sup

**Address:**

**Phone:**

**Fax:**

**Email:**

Item Number	Item Name
100014	Thoracic Silicone Catheter, 14FR, Straight
100016AT	Thoracic Silicone Catheter, 16FR, Straight
100024	Thoracic Silicone Catheter, 24FR, Straight
100028S	Thoracic Silicone Catheter, 28FR, Straight, Scale
100032AT	Thoracic Silicone Catheter, 32FR, Straight
100032NS	Thoracic Silicone Catheter, 32FR, Straight, Non Sterile
111132	Thoracic Silicone Catheter, 32FR, Angle

**Slovenia**

**National Contact Point:** Pre-Gem D.O.O.

**Address:**

**Phone:**

**Fax:**

**Email:**

Item Number	Item Name
100032AT	Thoracic Silicone Catheter, 32FR, Straight
100036AT	Thoracic Silicone Catheter, 36FR, Straight
100040AT	Thoracic Silicone Catheter, 40FR, Straight