Synaptive

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www.synaptivemedical.com

FSN & FSCA Ref: CAP-00332- Synaptive Trackable Suction

Date: 30-APR-2021

Urgent Field Safety Notice
Synaptive™ Trackable Suction

Contact details of Manufacturer:

Synaptive Medical Inc.
555 Richmond St. W Unit #800
Toronto, Ontario M5V 3B1
Canada

Dear Biomedical Department,

Synaptive Medical Inc. is writing to inform you that we are voluntarily recalling **Synaptive™ Trackable Suction**. This recall impacts all released lots and serial numbers.

This device is a vacuum-powered body fluid suction apparatus that is used to remove fluids and small solid masses from the surgical site through aspiration.

Please find all relevant information in the attached Field Safety Notice on Page 2 of this document and follow the given instructions. For further information regarding Synaptive™ Trackable Suction, please contact Synaptive Medical Inc. using the contact information provided in this field safety notice.

We apologize for any inconvenience caused. We are committed to providing quality products and are working diligently to correct this issue and ensure that it does not recur.

Sincerely,

Carly Desmond
Regulatory Affairs Manager
Synaptive Medical Inc.

Synaptive

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Urgent Field Safety Notice (FSN)
Synaptive™ Trackable Suction
Risk of Residual Burrs/Metal Filings

RE: Potential presence of manufacturing residuals (burrs/metal filings) to remain affixed within the suction tube inner perimeter.

1. Information on Affected Devices
1. Device Type(s)
Suction cannula, reusable 
2. Commercial Name(s)
Synaptive™ Trackable Suction
3. Unique Device Identifiers (UDI-DI)
For complete list of UDI-DI's, see Appendix A
4. Primary clinical purpose of device(s)
Synaptive Trackable Suction is a vacuum-powered body fluid suction apparatus that is used to remove fluids and small solid masses from the surgical site through aspiration. It is powered by an external source of vacuum. The device can be used to provide surgical suction for procedures while optionally allowing a localization system to track its position in 3D space. The tracked position of the suction tool may be then used to focus a surgical camera at the tip of the suction tool. Typical users of the device are medical professionals such as surgeons and other Operating Room staff. Synaptive Trackable Suction is designed to be used in conjunction with Modus V™, Synaptive's Robotic Digital Microscope.

5. Device model/catalogue/part numbers

Suction Sets	
CODE	ITEM DESCRIPTION
SYN-0657	**TRACKABLE SUCTION - SUCTION SET STANDARD**
SYN-0783	**TRACKABLE SUCTION - SUCTION SET MALLEABLE**

For a complete list of product codes for individual suction tubes and replacement packs, see Appendix A.

6. Affected serial or lot number range

All serial and lot numbers of the suction tubes are affected by this FSCA.

2. Reason for Field Safety Corrective Action (FSCA)

1. Description of the product problem

After an in-house inspection on a selection of suction tubes, multiple samples were identified with visible burrs/metal filings affixed along the suction tube inner perimeter. Further investigation has determined that the defect is related to a deficiency in the supplier production process.

2. Hazard giving rise to the FSCA

With sufficient force, the metal filings/burrs present within the suction tube could become dislodged and fall onto the patient and/or surgical site during a surgical procedure. Rough edges created by the burrs could also impact the ability of these instruments to be properly cleaned and sterilized.

While the likelihood of the burrs becoming dislodged during normal use is low and the potential for serious health consequences is considered remote, the use of the defective device associated with this recall could result in serious injuries and/or deaths. To date, there have been no complaints and no known patient or user injuries related to this issue.

3. Type of Action to mitigate the risk

1. Action To Be Taken by the Customer/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

1. Quarantine and discontinue use of all Synaptive Trackable Suction devices.
2. Contact Synaptive Recall Support at +1 647 243 3111 or by email at RecallSupport@synaptivemedical.com. Customer service will schedule an on-site inspection of each device. If this is not possible, arrangements will be made to have all impacted units returned to Synaptive.
3. Once on-site inspection or return of your stock has been arranged, please complete and return the attached *Acknowledgement and Receipt Form*. All forms should be submitted by email to RecallSupport@synaptivemedical.com.

   Note: If you are in North America and your account is supported by a Synaptive Clinical Applications Specialist (CAS), then a company representative may have already visited your site and conducted the necessary inspections. If so, we kindly ask that you still complete the Acknowledgement and Receipt Form for our records.
4. Upon inspection, all units will be graded as pass or fail. Units that pass meet normal specifications and are safe for continued use. These devices will be returned and released back into circulation. Failing (i.e. defective) units will be removed immediately and replaced by Synaptive at no cost.

2. By when should the action be completed?	Within 10 business days
3. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes; return attached acknowledgment form within 10 business days

4. Action Being Taken by the Manufacturer

☐ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change

☒ Other ☐ None

	If defective product is identified during inspection, impacted units will be removed from the field and arrangements will be made for replacement at no cost. Synaptive has identified the root cause of this issue and will taking corrective action to prevent future recurrence.	
	5. Is the FSN required to be communicated to the patient /lay user?	No

4. **General Information**		
	FSN Type	New
	Further advice or information already expected in follow-up FSN?	No
	The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
	List of attachments/appendices:	1) Appendix A – Affected Product Codes and UDIs 2) Customer Acknowledgement and Response Form
	Name/Signature	Name: Carly Desmond Title: Regulatory Affairs Manager 

Transmission of this Field Safety Notice	
	This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred including the chairman of medical board and/or head of the department. Please transfer this notice to other organisations on which this action has an impact. 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 and the national Competent Authority if appropriate, as this provides important feedback.

Appendix A – Affected Product Codes and UDIs

SETS AND COMPONENTS		
CODE	ITEM DESCRIPTION	UDI-DI
SYN-0657	**TRACKABLE SUCTION - SUCTION SET STANDARD**	00670082000184
SYN-0783	**TRACKABLE SUCTION - SUCTION SET MALLEABLE**	00670082000382

CONSUMABLES			
CODE			
3 Pack	Individual Tube	ITEM DESCRIPTION	UDI-DI
SYN-0663	SYN-0651	**NON-MALLEABLE SUCTION TUBES** 160 mm Working Length 30° Bend Angle French Size: 6	Package: 10670082000150 Direct Mark: 00670082000153
SYN-0664	SYN-0652	**NON-MALLEABLE SUCTION TUBES** 160 mm Working Length 30° Bend Angle French Size: 10	Package: 10670082000204 Direct Mark: 00670082000207
SYN-0665	SYN-0653	**NON-MALLEABLE SUCTION TUBES** 160 mm Working Length 30° Bend Angle French Size: 12	Package: 10670082000211 Direct Mark: 00670082000214
SYN-0666	SYN-0654	**NON-MALLEABLE SUCTION TUBES** 160 mm Working Length 90° Bend Angle French Size: 6	Package: 10670082000228 Direct Mark: 00670082000221
SYN-0667	SYN-0655	**NON-MALLEABLE SUCTION TUBES** 160 mm Working Length 90° Bend Angle French Size: 10	Package: 00670082000238 Direct Mark: 10670082000235
SYN-0668	SYN-0656	**NON-MALLEABLE SUCTION TUBES** 160 mm Working Length 90° Bend Angle French Size: 12	Package: 10670082000242 Direct Mark: 00670082000245

SYN-0759	SYN-0671	**MALLEABLE SUCTION TUBES** 80 mm Working Length 30° Bend Angle French Size: 4	Package: 10670082000273 Direct Mark: N/A
SYN-0761	SYN-0672	**MALLEABLE SUCTION TUBES** 80 mm Working Length 30° Bend Angle French Size: 6	Package: 10670082000280 Direct Mark: N/A
SYN-0763	SYN-0673	**MALLEABLE SUCTION TUBES** 80 mm Working Length 30° Bend Angle French Size: 8	Package: 10670082000297 Direct Mark: N/A
SYN-0765	SYN-0674	**MALLEABLE SUCTION TUBES** 80 mm Working Length 30° Bend Angle French Size: 10	Package: 10670082000303 Direct Mark: N/A
SYN-0760	SYN-0675	**MALLEABLE SUCTION TUBES** 120 mm Working Length 30° Bend Angle French Size: 4	Package: 10670082000310 Direct Mark: 00670082000313
SYN-0762	SYN-0676	**MALLEABLE SUCTION TUBES** 120 mm Working Length 30° Bend Angle French Size: 6	Package: 10670082000327 Direct Mark: 00670082000320
SYN-0764	SYN-0677	**MALLEABLE SUCTION TUBES** 120 mm Working Length 30° Bend Angle French Size: 8	Package: 10670082000334 Direct Mark: 00670082000337
SYN-0766	SYN-0678	**MALLEABLE SUCTION TUBES** 120 mm Working Length 30° Bend Angle French Size: 10	Package: 10670082000341 Direct Mark: 00670082000344

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Field Safety Notice Customer Reply Form

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	CAP-00332 – Synaptive Trackable Suction
FSN Date	2020-04-22
Product/ Device name	Synaptive Trackable Suction
Product Code	SYN-0657 – Suction Set, Standard SYN-0783 – Suction Set, Malleable *including all replacement suction tubes

2. Customer Details	
Healthcare Organisation Name	
Organisation Address	
Department/Unit	
Contact Name	
Title or Function	
Telephone number	
Email	

Please select from the following three options:
◯ We do not have any of the suction tubes subject to this recall.
◯ We do have stock of the suction tubes subject to this recall, and we have contacted Synaptive for further instruction. How many individual suction tubes are located at your site?: _____
◯ We do have stock of the suction tubes subject to this recall, but we are not interested in pursuing inspection. We understand that these units are not safe for continued use and commit to having them destroyed. We recognize that no replacement will be provided. How many individual tubes have been located and destroyed?: _____

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3. Customer action undertaken on behalf of Healthcare Organisation		
Yes ☐	No ☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.
Yes ☐	No ☐	I performed all actions requested by the FSN.
Yes ☐	No ☐	The information and required actions have been brought to the attention of all relevant users and executed.
Print Name		
Signature		
Date	YYYY – MM - DD	

4. Return acknowledgement to sender	
Email	RecallSupport@synaptivemedical.com
Deadline for returning the customer reply form	10 business days

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Note: Please contact Synaptive's Product Support FSN Line at +1 647 243 3111 to request assistance