

Rev 1: September 2018



UNIMAX Medical Systems Inc.

FSN Ref: FSN-ST20001

FSCA Ref: FCA-ST20001

Date: 2020/12/21

Urgent Field Safety Notice
Hasson Trocar

For Attention of*: Theatre Manager

Contact details of local representative (name, e-mail, telephone, address etc.)*



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Urgent Field Safety Notice (FSN)
Hasson Trocar

1. Information on Affected Devices*	
1	<p>1. Device Type(s)*</p> <p>Components:</p>  <p>Components: Hasson trocar 12mm Transp. Cannula 10cm, Component code: 899307</p>
1	<p>2. Commercial name(s)</p> <p>Hasson Trocar</p>
1	<p>3. Unique Device Identifier(s) (UDI-DI)</p> <p>07323190273140</p>
1	<p>4. Primary clinical purpose of device(s)*</p> <p>A trocar consists of an obturator and a cannula that are assembled and locked together during insertion through the abdominal wall tissue layers to create a port to the abdominal cavity. The Hasson trocar is a sterile single patient use instrument consisting of an obturator with a blunt tip and a cannula with an anchoring device. The Hasson Trocar is designed for laparoscopic surgery with open-entry technique to the fascia. Upon entry into a free space in the abdominal or chest cavity, the blunt tip aids in reducing the potential risk for injury to internal structures.</p>
1	<p>5. Device Model/Catalogue/part number(s)*</p> <p>899307</p>
1	<p>6. Affected serial or lot number range</p> <p>6292002020</p>

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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)
	a. Company Name
	b. Address
	c. Website address
4.	4. The Competent (Regulatory) Authority communication to customers. *
4.	5. Name/Signature

Transmission of this Field Safety Notice	
	<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>

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.



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2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	The protective flanges come away from trocar cannula. No patient harm has been reported
2	2. Hazard giving rise to the FSCA*
.	The reported incidence is potentially serious to patients as the disconnected flanges could cause a delay to surgery. When not retrieved, it can be left in the patient. So there is a possibility of potential risk of injury to the patient.
2	3. Predicted risk to patient/users
.	The reported incidence is potentially serious to patients as the disconnected flanges could cause a delay to surgery. When not retrieved, it can be left in the patient. So there is a possibility of potential risk of injury to the patient.
2	4. Background on Issue
.	Unimax Medical Systems, Inc. has, through our product complaint system, become aware of situation where the protective flanges come away from trocar cannula. No patient harm has been reported. Unimax Medical Systems, Inc. is initiating a Field Safety Corrective Action on specific batch of the Hasson Trocars

3. Type of Action to mitigate the risk*	
3.	1. Action To Be Taken by the User* <input checked="" 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. Is customer Reply Required? * (within 10 business days)
	Yes

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN-ST20001
FSN Date*	2020/12/11
Product/ Device name*	Hasson Trocar
Product Code(s)	899307
Batch/Serial Number (s)	6292002020

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation										
<input type="checkbox"/>	<ul style="list-style-type: none"> I confirm receipt of the Field Safety Notice and that I read and understood its content. 									
<input type="checkbox"/>	<ul style="list-style-type: none"> I performed all actions requested by the FSN. I did not perform all or some actions requested by the FSN No action is applicable to me 									
<input type="checkbox"/>	<ul style="list-style-type: none"> The information and required actions have been brought to the attention of all relevant users and executed. The information and required actions have NOT been brought to the attention of all relevant users and NOT executed. No action is applicable to me 									
<input type="checkbox"/>	I have identified/collected the affected devices as mentioned on the right side table	<table border="1"> <thead> <tr> <th>Quantity</th> <th>Lot/Batch Number</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> </tr> <tr> <td></td> <td></td> </tr> <tr> <td>N/A</td> <td>Comment:</td> </tr> </tbody> </table>	Quantity	Lot/Batch Number					N/A	Comment:
Quantity	Lot/Batch Number									
N/A	Comment:									
<input type="checkbox"/>	I have destroyed affected devices as mentioned on the right side table	<table border="1"> <thead> <tr> <th>Quantity</th> <th>Lot/Batch Number</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> </tr> <tr> <td></td> <td></td> </tr> </tbody> </table>	Quantity	Lot/Batch Number						
Quantity	Lot/Batch Number									

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3. Customer action undertaken on behalf of Healthcare Organisation			
		N/A	Comment
<input type="checkbox"/>	No affected devices are available for identify and destroy		
<input type="checkbox"/>	Other Action (Define):		
<input type="checkbox"/>	I do not have any affected devices.		
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product).		
Print Name*			
Signature*			
Date*			

4. Return acknowledgement to sender	
Email	
Customer Helpline	
Postal Address	
Web Portal	
Fax	
Deadline for returning the customer reply form	

Mandatory fields are marked with *

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.