

FSN Ref: 10/31/2019-002-R

FSCA Ref: Manufacturer's ref number:10/31/2019-002-R

Date: December 04, ,2019


Urgent Field Safety Notice
CapsoCam Plus (SV-3)

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

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

<i>See attached list of Distributer's with contact information. Refer to attachment A</i>

Urgent Field Safety Notice (FSN)
CapsoCam Plus (SV-3) Capsule Endoscopy System
Risk addressed by FSN

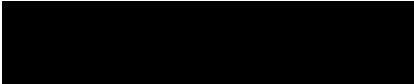
1. Information on Affected Devices*	
1.	<p>1. Device Type(s)*</p> <p><i>CapsoCam Plus (SV-3) capsule is a single-use, ingestible video capsule that acquires and stores video images in on-board memory while moving through the gastrointestinal tract, propelled by natural peristalsis. The patient retrieves the capsule using the provided retrieval kit and returns it to the physician who downloads and reviews the images on a computer. The capsule is typically excreted within 3 to 30 hours after swallowing.</i></p> 
1.	<p>2. Commercial name(s)</p> <p>CapsoCam Plus</p>
1.	<p>3. Unique Device Identifier(s) (UDI-DI)</p> <p><i>See attached serial number list. Refer to Attachment B</i></p>
1.	<p>4. Primary clinical purpose of device(s)*</p> <p><i>CapsoCam Plus (SV-3) Capsule Endoscopy capsules, indicated for visualization of the small bowel mucosa in patients in patients ages 2 and above. It may be used as a tool in the detection of abnormalities of the small bowel.</i></p>
1.	<p>5. Device Model/Catalogue/part number(s)*</p> <p>SV-3</p>
1.	<p>6. Software version</p> <p>CapsoView (CVV)-3.4.2</p>
1.	<p>7. Affected serial or lot number range</p> <p><i>Lot # 01-19-0058 & 0058R and 01-19-0069. See attached serial number list. Refer to Attachment B</i></p>
1.	<p>8. Associated devices</p> <p>N/A</p>

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	<p>1. Description of the product problem*</p> <p><i>This recall is being initiated due to the discovery of a defect present in the window of the capsule that may be stressed through the production process and in the final package, which could cause the housing of the capsule to crack and leak when ingested.</i></p>
2.	<p>2. Hazard giving rise to the FSCA*</p>

	<i>Although, there is no serious impact on the device user's health, however, there is a risk that due to the crack, fluid from the patient could leak in to the capsule. This may damage the components inside the capsule and the patient data may not be retrieved, therefore the patient may need to repeat the exam.</i>
2.	3. Probability of problem arising <i>No data for OUS yet to calculate the probability. To date 2 related complaints were reported but no analyses have been performed to confirm the failure.</i>
2.	4. Predicted risk to patient/users <i>Hazards associated with this failure are as follows: delay of diagnosis, data loss, patient may need to retake the exam (including dietary prep), unintended exposure to substances from capsule components.</i>
2.	5. Further information to help characterise the problem <i>To date, investigations for 15 units were initiated. Physical crack defect on the capsules were found during processing of used capsules from the Download Center service. For each capsule, the entirety of the data was able to be downloaded; however, some capsules had incomplete procedure (stopped capturing prior to exiting the small bowel).</i>
2.	6. Background on Issue <i>Tight package may stress the window and make an existing crack bigger over time. Reviewed all production processes, specifically AR coating process, capsule sealing, window molding, and in-process shipping method. Re-inspected units from Inventory and used capsules from the Download Center. Tested the final packaging trays with magnet and capsule to check how tightly it fits. Investigation is ongoing.</i>
2.	7. Other information relevant to FSCA <i>This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.</i>

	3. Type of Action to mitigate the risk*	
3.	1. Action To Be Taken by the User*	
	<input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input checked="" 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	
	<i>Users were requested to ship back the affected capsules, list of serial numbers was provided with RMA form, FedEx account number and customer recall letter with details of the shipping instruction.</i>	
3.	2. By when should the action be completed?	Specify where critical to patient/end user safety <i>Immediately/ as soon as the notification is received by the users.</i>

3.	3. Particular considerations for: Diagnostic Imaging device Is follow-up of patients or review of patients' previous results recommended? No <i>However, if the data retrieved is insufficient, the patient may need to repeat the exam.</i> Provide further details of patient-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * <i>(If yes, form attached specifying deadline for return)</i>	Yes
3.	5. Action Being Taken by the Manufacturer <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 <i>CapsoVision to provide the list of affected units to the users and request them to be shipped back as soon as possible. We will follow up as needed to ensure that all affected product is returned and accounted for.</i>	
	6. By when should the action be completed?	<i>Immediately/ as soon as the notification is received by the users.</i>
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 Provide reference and date of previous FSN if relevant
4.	3. For Updated FSN, key new information as follows: Summarise any key difference in devices affected and/or action to be taken.
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: Eg patient management, device modifications etc
4	6. Anticipated timescale for follow-up FSN For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name CapsoVision, Inc.
	b. Address 18805 Cox Avenue Suite 250, Saratoga CA 95070 USA
	c. Website address www.capsovision.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes
4.	9. List of attachments/appendices: List of distributor's and serial numbers
4.	10. 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>

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