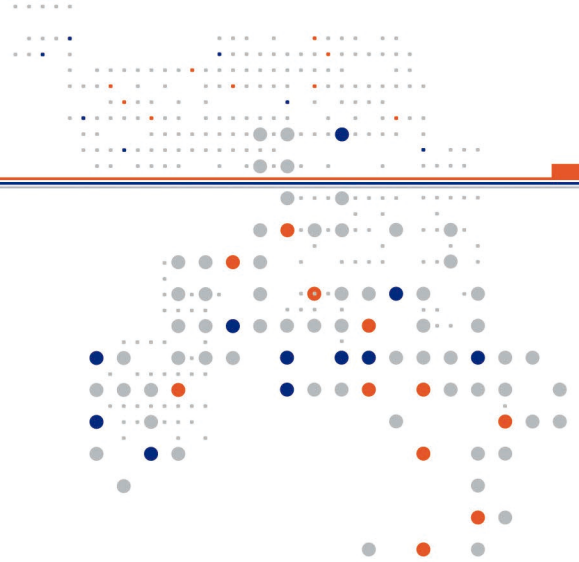




FSN Ref: CAPA C26100_FSN (Revision: 01)

FSCA Ref: CAPA C26100

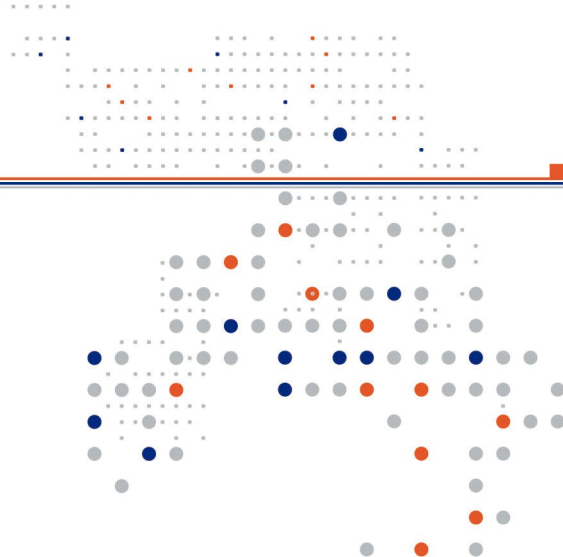
Date: August 26th, 2026.

Urgent Field Safety Notice
VICTO

For Attention of*:

- 1) European Union Importer
- 2) Distributors in the EEA
- 3) Distributor in Switzerland
- 4) Customers

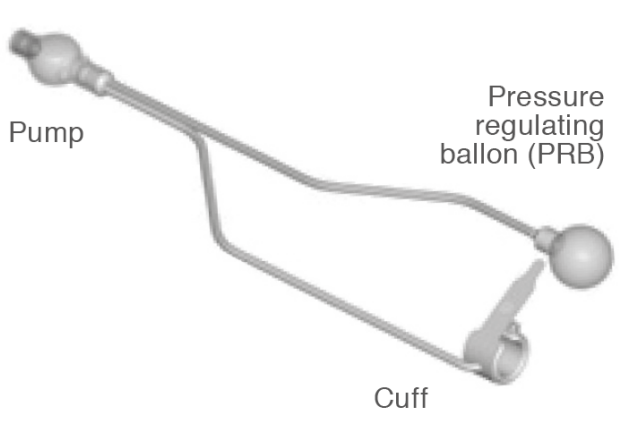
Contact details of local representative (name, e-mail, telephone, address etc.) *
Promedon GmbH Name of the contact person: Andreas Spicker Address: An der Alten Spinnerei 5 Postcode: 83059; City: Kolbermoor Country: Germany Phone: +49 8031 900 400 E-mail: andreas.spicker@promedon.com

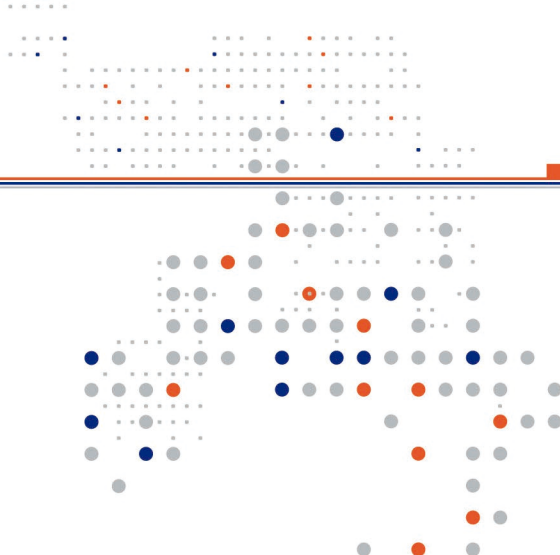


FSN Ref: CAPA C26100_FSN (Revision: 01)

FSCA Ref: CAPA C26100

Urgent Field Safety Notice (FSN)**VICTO****Risk addressed by FSN**

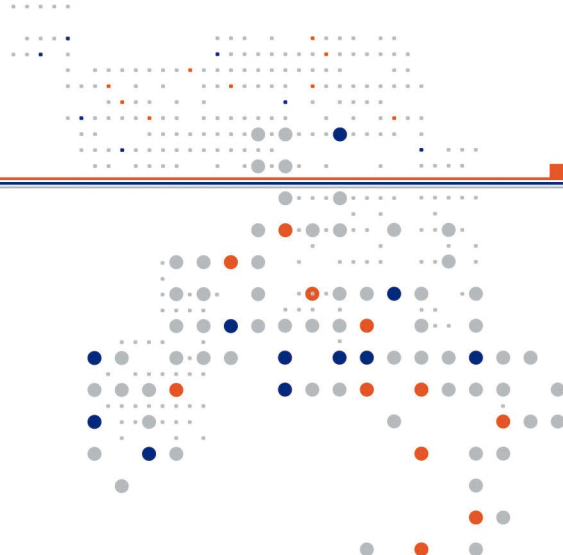
1. Information on Affected Devices*	
1.	1. Device Type(s)* VICTO is an adjustable artificial urinary sphincter (AUS). It has been developed to maintain continence. The device keeps the urethra closed by means of an urethral cuff which prevents the passage of urine. The pressure in the cuff is regulated by a small silicone balloon (pressure regulating balloon- PRB). When the patient wishes to void the cuff, it can be deflated by manual operation of the control pump which is placed in the scrotum. The fluid in the cuff is transferred to the PRB allowing the urine pass through the urethra. The cuff automatically re-inflates through a slow bleed valve in the control pump. In addition, it can be manipulated for fast re-inflation. The base of the control pump contains a self-sealing port which enables the device to be adjusted percutaneously, injecting extra fluid to increase the pressure of the system. This device is supplied sterile. 
1.	2. Commercial name(s)
	VICTO
1.	3. Unique Device Identifier(s) (UDI-DI)



FSN Ref: CAPA C26100_FSN (Revision: 01)

FSCA Ref: CAPA C26100

	<table><tr><th>Catalogue number</th><th>UDI-DI</th></tr><tr><td>KIT-VICTO-37</td><td>7798121803343</td></tr><tr><td>KIT-VICTO-40</td><td>7798121803350</td></tr><tr><td>KIT-VICTO-45</td><td>7798121803367</td></tr><tr><td>KIT-VICTO-50</td><td>7798121803374</td></tr><tr><td>KIT-VICTO-55</td><td>7798121803381</td></tr></table>	Catalogue number	UDI-DI	KIT-VICTO-37	7798121803343	KIT-VICTO-40	7798121803350	KIT-VICTO-45	7798121803367	KIT-VICTO-50	7798121803374	KIT-VICTO-55	7798121803381																																																																																																																				
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1.	4. Primary clinical purpose of device(s)* VICTO is an adjustable artificial urinary sphincter (AUS) used to treat male stress urinary incontinence. caused by intrinsic sphincter deficiency (ISD) in cases such as post-prostatectomy incontinence.																																																																																																																																
1.	5. Device Model/Catalogue/part number(s)* Product catalogue numbers: KIT-VICTO-37; KIT-VICTO-40; KIT-VICTO-45; KIT-VICTO-50; KIT-VICTO-55.																																																																																																																																
1.	6. Affected serial or lot number range <u>Lot numbers affected:</u> <table><tr><th>Catalogue number</th><th>Lot number</th><th>Catalogue number</th><th>Lot number</th><th>Catalogue number</th><th>Lot number</th><th>Catalogue number</th><th>Lot number</th></tr><tr><td>KIT-VICTO-37</td><td>064575</td><td>KIT-VICTO-40</td><td>065164</td><td>KIT-VICTO-45</td><td>065606</td><td>KIT-VICTO-50</td><td>067612</td></tr><tr><td>KIT-VICTO-37</td><td>064709</td><td>KIT-VICTO-40</td><td>065909</td><td>KIT-VICTO-45</td><td>065638</td><td>KIT-VICTO-50</td><td>067613</td></tr><tr><td>KIT-VICTO-37</td><td>065908</td><td>KIT-VICTO-40</td><td>065975</td><td>KIT-VICTO-45</td><td>065977</td><td>KIT-VICTO-50</td><td>067808</td></tr><tr><td>KIT-VICTO-37</td><td>065973</td><td>KIT-VICTO-40</td><td>065976</td><td>KIT-VICTO-45</td><td>066227</td><td>KIT-VICTO-50</td><td>069226</td></tr><tr><td>KIT-VICTO-37</td><td>065974</td><td>KIT-VICTO-40</td><td>066226</td><td>KIT-VICTO-45</td><td>066547</td><td>KIT-VICTO-50</td><td>069247</td></tr><tr><td>KIT-VICTO-37</td><td>066225</td><td>KIT-VICTO-40</td><td>066266</td><td>KIT-VICTO-45</td><td>066558</td><td>KIT-VICTO-50</td><td>069517</td></tr><tr><td>KIT-VICTO-37</td><td>066265</td><td>KIT-VICTO-40</td><td>066546</td><td>KIT-VICTO-45</td><td>066815</td><td>KIT-VICTO-50</td><td>069568</td></tr><tr><td>KIT-VICTO-37</td><td>066545</td><td>KIT-VICTO-40</td><td>066557</td><td>KIT-VICTO-45</td><td>066863</td><td>KIT-VICTO-55</td><td>065161</td></tr><tr><td>KIT-VICTO-37</td><td>066813</td><td>KIT-VICTO-40</td><td>066814</td><td>KIT-VICTO-45</td><td>067238</td><td>KIT-VICTO-55</td><td>065163</td></tr><tr><td>KIT-VICTO-37</td><td>067236</td><td>KIT-VICTO-40</td><td>067237</td><td>KIT-VICTO-45</td><td>067551</td><td>KIT-VICTO-55</td><td>065345</td></tr><tr><td>KIT-VICTO-37</td><td>067274</td><td>KIT-VICTO-40</td><td>067550</td><td>KIT-VICTO-45</td><td>067805</td><td>KIT-VICTO-55</td><td>065608</td></tr><tr><td>KIT-VICTO-37</td><td>067275</td><td>KIT-VICTO-40</td><td>067804</td><td>KIT-VICTO-50</td><td>064704</td><td>KIT-VICTO-55</td><td>065972</td></tr><tr><td>KIT-VICTO-37</td><td>067549</td><td>KIT-VICTO-40</td><td>067883</td><td>KIT-VICTO-50</td><td>065162</td><td>KIT-VICTO-55</td><td>066816</td></tr><tr><td>KIT-VICTO-37</td><td>067610</td><td>KIT-VICTO-40</td><td>068291</td><td>KIT-VICTO-50</td><td>065353</td><td>KIT-VICTO-55</td><td>067240</td></tr><tr><td>KIT-VICTO-37</td><td>067803</td><td>KIT-VICTO-40</td><td>068331</td><td>KIT-VICTO-50</td><td>065607</td><td>KIT-VICTO-55</td><td>067280</td></tr></table>	Catalogue number	Lot number	Catalogue number	Lot number	Catalogue number	Lot number	Catalogue number	Lot number	KIT-VICTO-37	064575	KIT-VICTO-40	065164	KIT-VICTO-45	065606	KIT-VICTO-50	067612	KIT-VICTO-37	064709	KIT-VICTO-40	065909	KIT-VICTO-45	065638	KIT-VICTO-50	067613	KIT-VICTO-37	065908	KIT-VICTO-40	065975	KIT-VICTO-45	065977	KIT-VICTO-50	067808	KIT-VICTO-37	065973	KIT-VICTO-40	065976	KIT-VICTO-45	066227	KIT-VICTO-50	069226	KIT-VICTO-37	065974	KIT-VICTO-40	066226	KIT-VICTO-45	066547	KIT-VICTO-50	069247	KIT-VICTO-37	066225	KIT-VICTO-40	066266	KIT-VICTO-45	066558	KIT-VICTO-50	069517	KIT-VICTO-37	066265	KIT-VICTO-40	066546	KIT-VICTO-45	066815	KIT-VICTO-50	069568	KIT-VICTO-37	066545	KIT-VICTO-40	066557	KIT-VICTO-45	066863	KIT-VICTO-55	065161	KIT-VICTO-37	066813	KIT-VICTO-40	066814	KIT-VICTO-45	067238	KIT-VICTO-55	065163	KIT-VICTO-37	067236	KIT-VICTO-40	067237	KIT-VICTO-45	067551	KIT-VICTO-55	065345	KIT-VICTO-37	067274	KIT-VICTO-40	067550	KIT-VICTO-45	067805	KIT-VICTO-55	065608	KIT-VICTO-37	067275	KIT-VICTO-40	067804	KIT-VICTO-50	064704	KIT-VICTO-55	065972	KIT-VICTO-37	067549	KIT-VICTO-40	067883	KIT-VICTO-50	065162	KIT-VICTO-55	066816	KIT-VICTO-37	067610	KIT-VICTO-40	068291	KIT-VICTO-50	065353	KIT-VICTO-55	067240	KIT-VICTO-37	067803	KIT-VICTO-40	068331	KIT-VICTO-50	065607	KIT-VICTO-55	067280
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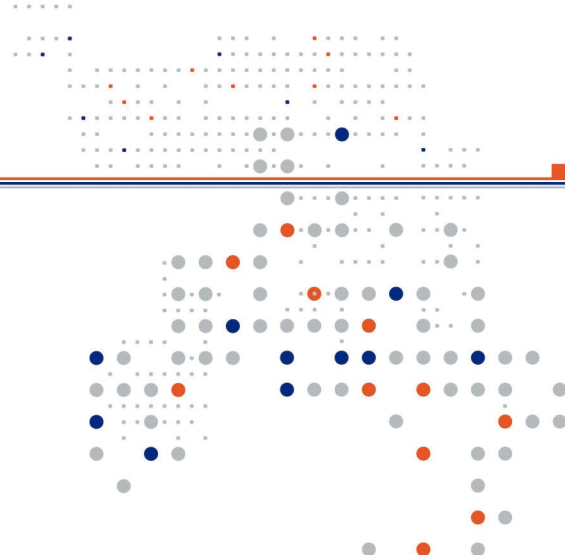


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FSCA Ref: CAPA C26100

	KIT-VICTO-37	067884	KIT-VICTO-40	068602	KIT-VICTO-50	065971	KIT-VICTO-55	067553
	KIT-VICTO-37	067885	KIT-VICTO-40	068858	KIT-VICTO-50	066228	KIT-VICTO-55	067809
	KIT-VICTO-37	068290	KIT-VICTO-40	069224	KIT-VICTO-50	066559	KIT-VICTO-55	068294
	KIT-VICTO-40	064710	KIT-VICTO-45	064576	KIT-VICTO-50	066560	KIT-VICTO-55	068605
	KIT-VICTO-40	064723	KIT-VICTO-45	064711	KIT-VICTO-50	067239	KIT-VICTO-55	068861
	KIT-VICTO-40	064724	KIT-VICTO-45	065167	KIT-VICTO-50	067277	KIT-VICTO-55	069518
	KIT-VICTO-40	064725	KIT-VICTO-45	065350	KIT-VICTO-50	067552	KIT-VICTO-55	069961

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem* Internal monitoring revealed a potential increase in the time required for the product's automatic recovery in the medium term.
2.	2. Hazard giving rise to the FSCA* Potential product performance issue that could potentially lead to a gradual loss of Victo's performance in the medium term, affecting the level of continence achieved.
2.	3. Probability of problem arising Low, as it has only been observed in bench testing and not in clinical use.
2.	4. Predicted risk to patient/users The situation identified in the affected lots does not require the implementation of any proactive follow-up or review of patients who have already been implanted by the physician. Because urinary incontinence is a multifactorial condition, recurrence or worsening of symptoms after AUS implantation may result from factors other than device performance, including progression of the underlying condition, patient-specific characteristics, comorbidities, or changes in urinary tract function. Therefore, the return of incontinence should not be interpreted as evidence of device failure alone. In this situation, a follow-up appointment is appropriate. If the expert considers that it may be related to the issue described in this FSN, the description below shall be used.
2.	5. Further information to help characterise the problem PATIENT MANAGEMENT GUIDANCE TO BE PERFORMED BY THE PHYSICIAN: 1. Identify the Control Pump located in the patient's scrotum. The Control Pump should be filled and should be compressible when pressed between two fingers. Note: If it is coaptated, use the rapid refill system until the Control Pump is filled.

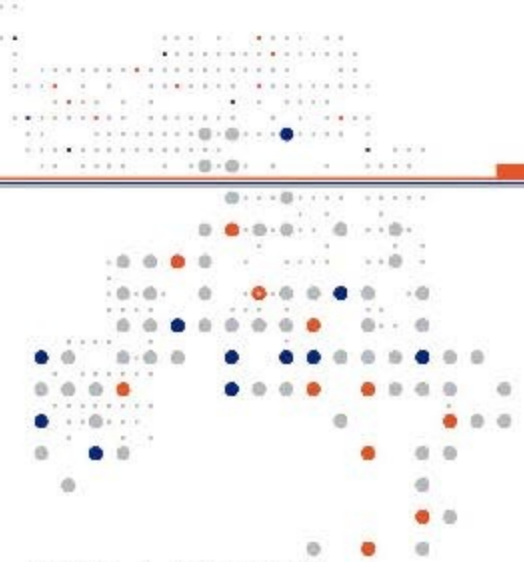


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	2. Squeeze the Control Pump once, in the same way as educated the patient, until the control pump is completely flat/collapsed, allowing the urethral cuff to deflate. 3. Observe and feel the Control Pump after squeezing. Under normal conditions fluid should return and the Control Pump should progressively refill and return to its initial shape. 4. If the Control Pump does not refill after 3 minutes and remains completely flat/collapsed, the urethral cuff may not re-inflate as intended and the patient may experience deterioration or loss of urinary continence. This finding is considered consistent with the mechanical issue described in this Field Safety Notice. If this happens, the physician must train the patient, as indicated in the IFU, to re-inflate the cuff by squeezing the top of the control pump. Doing this, the system works "manually". The subsequent course of action should be judged on a patient-by-patient basis. 5. If the Control Pump refills and returns to its initial shape as expected, the issue described in this Field Safety Notice is not suspected as the cause of the patient's deterioration in urinary continence.
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	3. Type of Action to mitigate the risk*	
3.	1. Action To Be Taken by the User* Identify Devices Quarantine Devices Return Devices Affected product in stock, must immediately be identified and segregated as nonconforming product in accordance with your internal quality procedures. If any of these products have been sold to a customer, the customer shall be contacted accordingly. If the products have not been implanted, you must arrange for their return with your Promedon contact.	
3.	2. By when should the action be completed?	Implementation of the actions described in this FSN should begin immediately upon receipt.
3.	3. Is customer Reply Required? *	Yes



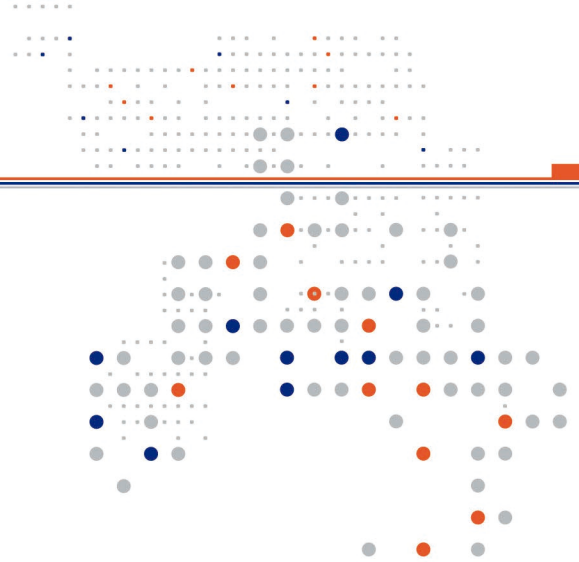
FSN Ref: CAPA C26100_FSN (Revision: 01)

FSCA Ref: CAPA C26100

	Reply form must be sent no later than 2026/09/03
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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 refer to page 1 of this FSN)
	a. Company Name Promedon S.A.
	b. Address Av. Gral. Manuel Savio s/n Lote 3, Manzana 3 Parque Industrial Ferreyra X5925XAD Córdoba Argentina SRN (Single Registration Number): AR-MF-000023348
	c. Website address www.promedon-upf.com
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes
4.	5. List of attachments/appendices: Annex I: Importer reply form Annex II: Distributor reply form Annex III: Customer Reply form
4.	6. Name/Signature Juan Pablo Gigli Person Responsible for Regulatory Compliance

Transmission of this Field Safety Notice	
	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)

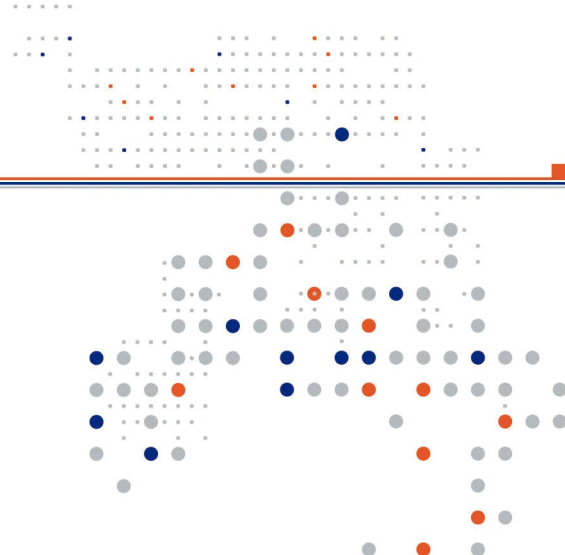


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	Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.
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Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.



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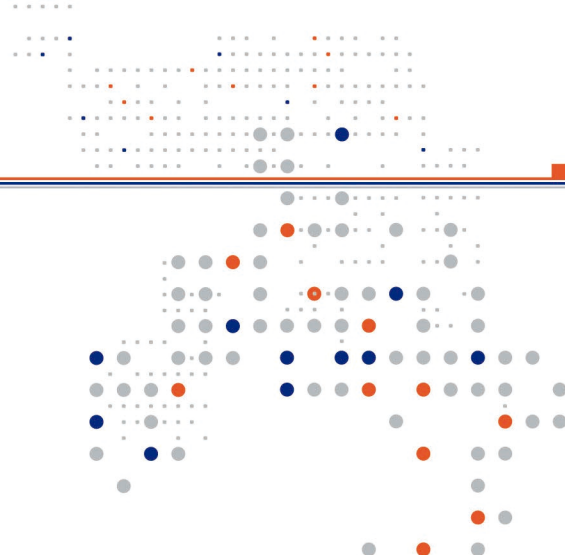
Field Safety Notice - Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	CAPA C26100_FSN
FSN Date	August 21 st , 2026
Product/ Device name	VICTO
Product Code(s)	
Batch/Serial Number (s)	

2. Importer Details	
Company Name	
Account Number	
Address	
Shipping address if different to above	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Return acknowledgement to Sender	
Email	Veronica.fernandez@promedon.com
Importer Helpline	Verónica Fernandez
Postal Address	Av. Gral. Manuel Savio - Lote 3 - Manzana 3 – Cordoba – Argentina – Postcode X5925XAD
Web Portal	https://www.promedon-upf.com
Deadline for returning the Importer reply form	August 28 th , 2026

4. Importers (Tick all that apply)		
☐	I confirm the receipt, the reading and understanding of the Field Safety Notice.	Importer to complete or enter N/A
☐	I have checked my stock and quarantined inventory	Importer to enter quantity and date
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	



FSN Reference number: CAPA C26100_FSN

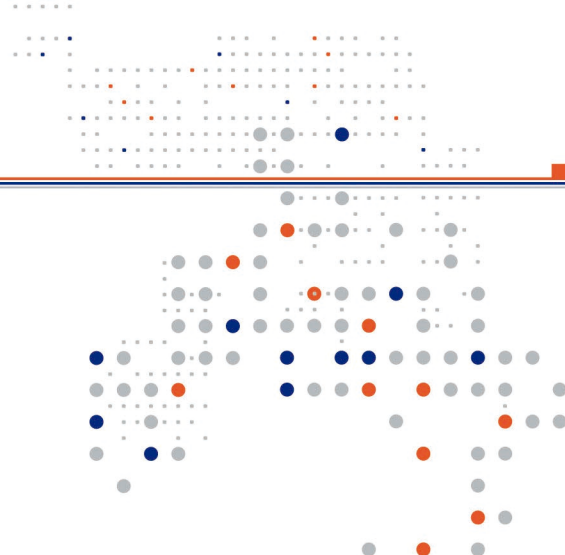
Revision: 01

☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form)
☐	Neither I nor any of my customers has any affected devices in inventory	
Print Name		Importer print name here
Signature		Importer sign Here
Date		

Note: If all requested information is not available by the deadline due to pending responses, please return the form with the information currently available. Any outstanding items may be marked as pending. A follow-up process will be carried out to collect the missing information.

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

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



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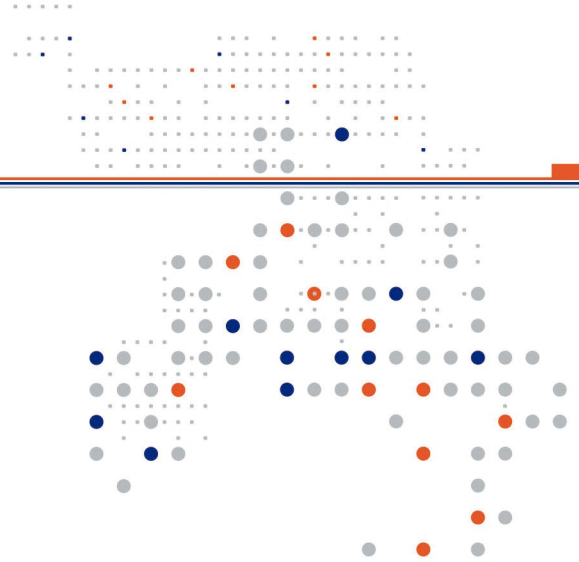
Field Safety Notice - Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	CAPA C26100_FSN
FSN Date	August 27 th , 2026
Product/ Device name	VICTO
Product Code(s)	Complete before sending to distributor
Batch/Serial Number (s)	

2. Distributor Details	
Company Name	Complete before sending to distributor
Account Number	Complete before sending to distributor
Address	Distributor to complete
Shipping address if different to above	Distributor to complete
Contact Name	Distributor to complete
Title or Function	Distributor to complete
Telephone number	Distributor to complete
Email	Distributor to complete

3. Return acknowledgement to Sender	
Email	Pre-filled by sender/requester
Distributor Helpline	Pre-filled by sender/requester
Postal Address	Pre-filled by sender/requester
Web Portal	Pre-filled by sender/requester
Deadline for returning the Distributor reply form	1 week since the FSN reception date

4. Distributors (Tick all that apply)		
☐	I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor to complete or enter N/A
☐	I have checked my stock and quarantined inventory	Distributor to enter quantity and date
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	



FSN Reference number: CAPA C26100_FSN

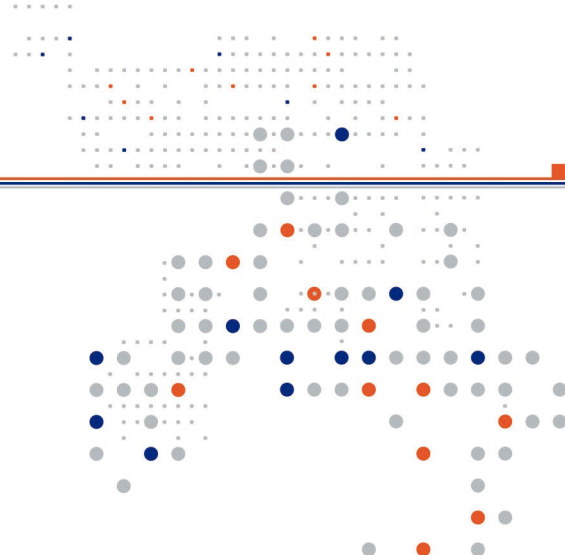
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☐	I have informed the identified customers of this FSN	Date of communication:
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☐	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form)
☐	Neither I nor any of my customers has any affected devices in inventory	
Print Name		Distributor print name here
Signature		Distributor sign Here
Date		

Note: If all requested information is not available by the deadline due to pending responses, please return the form with the information currently available. Any outstanding items may be marked as pending. A follow-up process will be carried out to collect the missing information

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

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



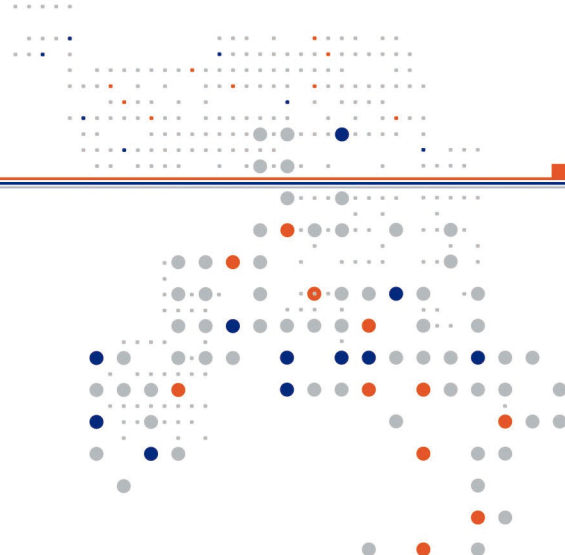
FSN Reference number: CAPA C26100_FSN
Revision: 01

Field Safety Notice - Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	CAPA C26100_FSN
FSN Date	Distributor to complete
Product/ Device name	VICTO
Product Code(s)	Distributor to complete
Batch/Serial Number (s)	Distributor to complete

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

3. Customer action undertaken on behalf of Healthcare Organisation			
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A	
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A	
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number: Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number: Date Returned (DD/MM/YY):
		N/A	Comments:



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☐	No affected devices are available for return	Customer to complete or enter N/A
☐	Other Action (Define):	
Print Name		Customer print name here
Signature		Customer sign here
Date		

4. Return acknowledgement to sender	
Email	Pre-filled by sender
Customer Helpline	Pre-filled by sender
Postal Address	Pre-filled by sender
Web Portal	Pre-filled by sender
Fax	Pre-filled by sender
Deadline for returning the customer reply form	1 week since the FSN reception date

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

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