


<b>Urgent Field safety Notice</b>		
Document: <b>QFB099</b>	Revision: <b>04</b>	
Document type: <b>QualiMed Formblatt (QFB)</b>	Effective Date: 15.07.2021	

**From,**

**Quality Manager**  
**QualiMed Innovative Medizinprodukte GmbH**  
 Boschstraße 16, 21423 Winsen, Germany

### **Urgent Field Safety Notice**

Product	Peripheral Vascular Self Expanding Stent System
FSCA-identifier	FSCA2023-01
Type of action	Return to manufacturer

Date: 28/04/2023

Attention (Name of Distributor/customer/end user):

#### **Details on affected devices:**

Peripheral Vascular Self Expanding Stent System  
 Refer Lot Numbers mentioned in Appendix 1: List of impacted lots

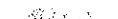
#### **Description of the problem:**

We have reason to believe that some lots of our products 'Peripheral Vascular Self Expanding Stent System' (refer Appendix 1), may pose a risk to consumers due to an issue with a raw material lot (inner sheath lot 17929-01) used as a component for manufacturing of these lots. During investigation for an internal CAPA (CAPA2022-11-0038), it was found during the product testing (simulated use) that the inner sheath used in these lots can break during application of the product. While we have not received any reports of injuries related to this issue, we take responsibility for the patient and urge you to stop using the product immediately.

Please note that within these lots, the issue is limited only to inner sheath component and there is no issue with the stent itself. Therefore, there is no need to take any action if the stent has been implanted successfully.

#### **Advise on action to be taken by the user:**

- identifying and quarantining the devices from lot numbers mentioned in Appendix 1.
- Notify QualiMed if any product is available for possible return.

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**Transmission of this Field Safety Notice:**

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations 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.

**Contact reference person:**



QualiMed Innovative Medizinprodukte GmbH  
Boschstraße 16, 21423 Winsen, Germany

Direct

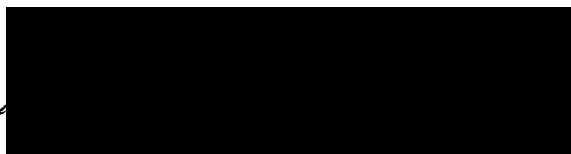
Mob

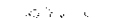
Mail



The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

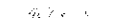
Signature:



Urgent Field safety Notice		 <b>QualiMed.</b> <small>Intervetna Marketingstruktura GmbH</small>
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Appendix 1: List of impacted lots

Delivery Note	Delivery Note-Date	Article Description	Lot Number	Expiry	qty
2100029	15.01.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 6x40mm Stent 80cm Usable Catheter Length	N403577A	12.2023	2
2100029	15.01.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 6x40mm Stent 80cm Usable Catheter Length	N404674A	12.2023	1
2100029	15.01.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 6x40mm Stent 80cm Usable Catheter Length	N404674B	12.2023	1
2100279	22.02.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 6x40mm Stent 80cm Usable Catheter Length	N408113A	12.2023	1
2100279	22.02.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 6x40mm Stent 80cm Usable Catheter Length	N408113B	01.2024	1
2100348	26.02.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 6x60mm Stent 80cm Usable Catheter Length	N408729A	12.2023	1
2100279	22.02.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 6x80mm Stent 80cm Usable Catheter Length	N408730A	01.2024	2
2100107	28.01.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 7x60mm Stent 80cm Usable Catheter Length	N405534A	12.2023	2
2100195	07.02.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 7x60mm Stent 80cm Usable Catheter Length	N408732A	12.2023	1
2100195	07.02.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 7x80mm Stent 80cm Usable Catheter Length	N408114A	11.2023	1
2100195	07.02.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 7x80mm Stent 80cm Usable Catheter Length	N408114B	12.2023	1
2100107	28.01.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 7x80mm Stent 80cm Usable Catheter Length	N408733A	11.2023	1
2100279	22.02.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 8x40mm Stent 80cm Usable Catheter Length	N405536A	01.2024	5

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2100279	22.02.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 8x40mm Stent 80cm Usable Catheter Length	N405536B	01.2024	1
2100279	22.02.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 8x40mm Stent 80cm Usable Catheter Length	N406365A	01.2024	5
2100279	22.02.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 8x40mm Stent 80cm Usable Catheter Length	N408115A	01.2024	3
2100279	22.02.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 8x40mm Stent 80cm Usable Catheter Length	N408115B	01.2024	3
2100107	28.01.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 8x60mm Stent 80cm Usable Catheter Length	N405537A	12.2023	1
2100107	28.01.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 8x60mm Stent 80cm Usable Catheter Length	N405537B	12.2023	5
2100107	28.01.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 8x60mm Stent 80cm Usable Catheter Length	N406366A	12.2023	4
2100107	28.01.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 8x60mm Stent 80cm Usable Catheter Length	N408116A	12.2023	1
2100195	07.02.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 8x60mm Stent 80cm Usable Catheter Length	N408116B	12.2023	1
2100195	07.02.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 8x60mm Stent 80cm Usable Catheter Length	N408116C	12.2023	4
2100107	28.01.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 8x80mm Stent 80cm Usable Catheter Length	N405538A	12.2023	1
2100107	28.01.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 8x80mm Stent 80cm Usable Catheter Length	N405538B	12.2023	3
2100107	28.01.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 8x80mm Stent 80cm Usable Catheter Length	N406367A	12.2023	4
2100195	07.02.2021	Polaris Pin Pull Peripheral Vascular Self Expanding Stent System 8x100mm Stent 80cm Usable Catheter Length	N408118A	12.2023	2