


06th June 2025

Urgent Field Safety Notice

regarding

Mini PCNLNephroscopy Sheath

<p>Originator:</p>	<p>TROKAMED GmbH Kleine Breite 17 78187 Geisingen Germany</p>
<p>Recipient:</p>	<p>Users, operators and distributors of the product</p>
<p>Identification of affected medical devices:</p>	<p>Sheath, 20 Fr., 130 mm (REF: WA2PS20S) Sheath, 20 Fr., 160 mm (REF: WA2PS20L) Sheath, 18 Fr., 130 mm (REF: WA2PS18S) Sheath, 18 Fr., 160 mm (REF: WA2PS18L)</p> 
<p>Description of the problem including the identified cause:</p>	<p><u>Problem:</u> There has been an event with decreased outflow resulted in increased intrarenal pressure, kidney rupture and death. There were no more complaints.</p> <p><u>Cause:</u> Some of the instructions have been written using terms that may be misunderstood by users. The IFU does not describe clearly that the sheath is not for suction and irrigation and outflow is through gravity drainage. The IFU does not describe that the nephroscope has to be removed temporarily from the shaft to clear it and flush out the fragments. If the inflow speed is too quick, it could result in reduced outflow through the shaft due to blood, tissue fragments and kidney stone fragments, and quickly build up of intrarenal pressure.</p> <p>We would like to inform you that our sheaths have been manufactured according to the specifications and there was no malfunction of the medical device.</p> <p><u>Risks to Health:</u></p> <ul style="list-style-type: none"> • Improper use of the device: Due to ambiguous language, users may misinterpret instructions, leading to incorrect setup or application of the device. The IFU does not describe clearly that the sheath is not for suction and irrigation and the outflow is

	<p>through gravity drainage. The IFU does not describe that the nephroscope has to be removed temporarily from the shaft to clear it and flush out the fragments.</p> <ul style="list-style-type: none"> • Increased Risk of Adverse Events: If users fail to follow the instructions correctly, there is a heightened risk of adverse events occurring. <p>If reduced outflow through the shaft occurs due to blood, tissue fragments and kidney stone fragments, there can be an increased intrarenal pressure when the inflow speed is too quick, which can lead to kidney rupture or death.</p> <ul style="list-style-type: none"> • Users have to pay attention to the inner diameter of the shaft and watch for the outflow. Users have to remove the nephroscope temporarily from the shaft and clear it and flush out the fragments.
<p>What measures are to be taken by the recipient?</p>	<ul style="list-style-type: none"> • Inform the medical personnel using the product about this Field Safety Notice. • Replace your current Instructions for Use for this device with the updated version provided (W9229406_01). This is not a product removal action. You may continue to use the device as following this letter and the updated Instruction for Use. • Acknowledge receipt according to the instructions provided by your local distributor.

Disclosure of the information described herein:

Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this **Urgent Field Safety Notice**. If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.

Please keep this information at least until the action has been completed.

TROKAMED has informed your National Competent Authority of this Field Safety Notice.

We apologize for any inconvenience this may cause you. If you have any questions or concerns about this notification, please contact your local distributor.



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Vigilance reference number: 2024_VIG_105610_Mini-PCNL

REPLY FORM – QIL FY25-EMEA-27-FY25-901-F Trokamed IfU update

Facility Name	
Facility Address	
Contact Name	
Additional Customer Requests (Indicate if you have any additional requests to support this action)	
Quantity of TROKAMED Mini-PCNL sheaths Instructions for Use hard copies or electronic pdf document required	

I acknowledge receipt of this notification. I confirm that I have further communicated to any affected departments.

Completed By:		
		Click or tap to enter a date.
<i>Name</i>	<i>Signature</i>	<i>Date (YYYY-MM-DD)</i>

Please send the completed form to ra@olympus-mea.com by date 04.07.2025.