

Due to missing information your complaint cannot be processed accordingly and without delay. Therefore, please complete your data by answering following questions.

Date sent to Rudolf Medical:

Your contact information

Your company name:

Address:

Contact person (Name and E-Mail):

Product information

Your internal complaint number:

Item Number (One item no. per form):

Item Description:

Lot/Serial No.:
(one lot, batch, serial no. per form)

Affected quantity:

Invoice:

Date:

Purchase order:

Date:

Failure description

When did the problem occur?

- During product training / demonstration (not in use during treatment or procedure on a patient).
- During incoming inspection
- During functional test prior first use
- During reprocessing respectively functional testing of the instrument/device
- During the surgical procedure
- During post cleaning at the operating table

Describe the quality issue and/or event in detail (who, what, where, when, how):

This problem was reported to you by:

- discovered in our company
- Hospital/Health Care Institution
- Distributor
- OEM Customer
- Sales Rep
- Other describe:

Please fill in the event information when the device was in use

Date you were informed:

Event date:

Institution Name where event occurred:

Address:

E-Mail:

Was there an injury?

Yes No

Was there a death?

Yes No

Could it have resulted in injury or death?

Yes No

Was there a delay in surgical procedure?

Yes, how much? _____ No

Did an additional medical procedure needed to be performed due to the product issue? Yes No

Was the event reported to a competent authority? Yes, Date:

Competent authority:

No

Please note decontamination statement on page two!

Decontamination certificate

We confirm that the returned parts are free of contamination and have been cleaned, disinfected and sterilized prior to their shipment.

Handling fee

In case the article cannot be repaired and we decide to return it to our company, we acknowledge and accept the associated handling fee of 25.- EUR per instrument.

YES NO (The article will be scrapped)

Date		Signature	
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Return information

For returns from **Germany** or the **European Community** please indicate **Address B**.
For the **rest of world** please indicate **Address A**.

<p>A DHL Global Forwarding C/O Rudolf Medical Industriestr. 15 D-78647 Trossingen / Station Code: VSS Phone: +49 (0) 7425 223 600 Facsimile: +49 (0) 7425 220 250</p>	<p>B <i>RUDOLF Medical GmbH + Co. KG</i> <i>Zollerstraße 1</i> <i>78567 Fridingen</i> <i>Tel: +49 (0) 7463 – 99560</i> <i>Fax: +49 (0) 7463 – 995656</i></p>
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Important: Please fill in the RQI form and enclose it in the shipment