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| [Date](http://dict.leo.org/%22%20%5Cl%20%22/search%3Ddate%26searchLoc%3D0%26resultOrder%3Dbasic%26multiwordShowSingle%3Don) send to Rudolf Medical:       |
| **Is this Report based on an Reportable Event (Injury or Death)?**[ ]  **Yes** (If Yes complete sections 1, 2 and 3) [ ]  **No** (If No complete sections 1 and 2) |
| 1. **Product information:**
 |
| Item Number (One item no. per form): |       |
| Lot/Serial No.: (one lot, batch, serial no. per form)  |       |
| Affected quantity: |       |
| **Describe the quality issue or event in detail:**[ ]  During incoming inspection or during review of inventory on hand [ ]  Prior to use on a patient during inspection/functionality testing (not during incoming inspection or inventory check) [ ]  Post cleaning/reprocessing during inspection of the device[ ]  During product training/demonstration (not in use during treatment or procedure on a patient).[ ]  During an Operation [ ]  Not applicable**Description (explain who, what, where, when, how):**                 |
| 1. **Your contact information:**
 |
| **You are a (Please choose one):**[ ] Hospital/Health Care Institution [ ] Distributor [ ] OEM customer [ ]  Sales Rep [ ]  Other describe:       |
| Your company name:  |       |
| City, State, Zip: Country:  |       |
| PO#/Invoice# :  |       |
| E-Mail:  |       |
| 1. **Describe event sections 1 and 2 before continuing below with section 3.**

**Please read and answer all questions!** |
| Date you were informed:       | Event date:       |
| **This event was reported to you by (choose one):**[ ] Hospital/Health Care Institution [ ] Distributor [ ] OEM Customer [ ]  Sales Rep [ ]  Other describe:       |
| Institution Name:       | PO No. / Invoice No. / Ref. No.:       |
| City, State, Zip, Country:       | E-Mail:       |
| 1. Reportable event information:
	* + - Was there a death? [ ]  Yes [ ]  No
			- Was there an injury? [ ]  Yes [ ]  No
			- If known, what is the patient's current condition?       [ ]  Unknown
			- Has a medical professional confirmed that the device contributed to the reported event? [ ]  Yes [ ]  No
			- Did an additional medical procedure needed to be performed due to the product issue? [ ]  Yes [ ]  No
* If yes, explain the medical procedure performed:       [ ]  Procedure performed but details are unknown
	+ - * Name/ describe treatment/ medical procedure being performed when defect was detected:
			* Was the event reported to a competent authority? [ ]  Yes [ ]  No Date:      Competent authority:
1. Was the device used or re-sterilized/reprocessed prior? [ ]  Yes [ ]  No
* If yes, how often was the product used prior to discovery of the defect/ event?
1. Was the product repaired or refurbished prior to discovery of this alleged defect/ event? [ ]  Yes [ ]  No
* If yes, provide: Company       Approx. Date       Company/Date Unknown but was serviced [ ]
 |
| **PLEASE SEND THIS COMPLETED FORM TO COMPLAINT@RUDOLF-MED.COM** |

After receiving this form we or the Rudolf Medical Representative will send you an RMA number. Please do not return the Item, before you have received this RMA number.
Please write the RMA number on the outside of the package you return.

**If we do not receive the Item with RMA number within 30 days after you received the RMA number from us, the RMA number will be cancelled automatically.**