References:

AMD-0393 Complaint Handling Directive
AMD-0498 Complaints management for distributors

Instruction:

Please fill in this report and send it by e-mail to the address below. The e-mail address is the same for all of Atos Medical Group (AMG). The report should preferably be filled in together with an AMG or Coloplast Group employee. The complaint form can be used by the Complaint Originator to collect further information and/or samples from the customer.

Make sure not to submit any patient/end user identification, use an anonymous unique patient/customer ID from the CRM system such as SalesForce. According to the GDPR, which applies to countries in EEA, when a customer contacts AMG to submit a complaint, they must be informed that their personal data will be stored and will be used to comply with regulatory requirements. A written confirmation including the mandatory privacy information must be sent to the complainant.

If a product return is requested due to investigation, then return the product (and its package, if available) clearly marked with the assigned complaint number when requested according to the instruction given by the confirmation e-mail. To protect our employees as well as all handlers of potentially contaminated goods the following must apply:

- Only devices that are, to the best of the complaint's knowledge, contaminant free may be returned. No device that has been exposed to a known communicable disease may be returned.
- All products returned must be placed in double (x2), clean, clear, sealable plastic bags, preferably of Ziploc type.
- All products returned must be packaged to prevent further damage, preferably in a padded envelope or wrapped in shock absorbing material in a cardboard box. As a safety precaution, protective gloves shall always be used when handling returned devices.

Ensure that any decision taken not to return the device due to potential contamination risk is explained in the form.

Atos Medical AB Att: Complaint Investigator Kraftgatan 8 SE-242 35 Hörby SWEDEN **TRACOE medical GmbH** Att: Complaint Investigator Reichelsheimer Str. 1 / 3 55268 Nieder-Olm GERMANY	Telephone: Int.+46 (0)415-198 00 Web: www.atosmedical.com Email: **complaint.se@atosmedical.com** Telephone: Int. +49 6136 91690 Web: www.tracoe.com Email: **complaint.se@atosmedical.com**	Complaint Registration number filled in by Atos Medical AB: **Complaint no.**

Reporters contact information

Distributor/subsidiary/hospital (if applicable):	Complainant or Healthcare professional, provide an **anonymous** unique patient/customer ID from the CRM system such as SalesForce:
Contact person within Coloplast Group:	
Address: E-mail:	
Country:	
Tel:	

Customer relation

Warranty product given to customer? ☐ **Yes** ☐ **No**	Is follow-up requested by customer? ☐ **Yes** ☐ **No**

Product

REF No:	Product name:	LOT or Serial No:
Manufacturer: ☐ Atos Medical AB ☐ TRACOE Medical GmbH ☐ Kapitex Healthcare Ltd ☐ Other (3PP):		Complaint Quantity:

Event info

NOTE! Complaints must be sent to **complaint.se@atosmedical.com** without delay due to vigilance reporting requirements!

Date when **company representative** was made aware of event (by mail, phone call, personal meeting etc):	
Date when the event occurred (per information received from customer):	
Country where the event happened:	

Did the event lead to death or serious injury? ☐ **No** ☐ **Yes** (Describe in detail below) Was medical intervention required? ☐ **No** ☐ **Yes** (Describe in detail below) Any residual adverse effect on patient? ☐ **No** ☐ **Yes** (Describe in detail below)	Patient was injured, frightened, or experienced discomfort ☐ (Describe in detail below) or Product complaint only ☐
Has the product been used? How long has the **actual** product been used by the patient?	Has the product been used according to instructions? ☐ **Yes** ☐ **No** **IFU used** (REF & edition)
Has the patient/user experienced this problem previously? ☐ **Yes**, if so, when? ☐ **No**	Is the product available for examination? ☐ **Yes** ☐ **No** If no, are products from same LOT/carton available? ☐ **Yes** ☐ **No**
Are images of the device or the alleged problem available?	☐ **Yes** (attach to email) ☐ **No**
Have other products/medicines been used together with the product? If so, please list here	

Event description

Please include a detailed description of what is considered wrong with the product and/or what happened to the patient. Feel free to uses as many pages as necessary. The more information the better. Don't forget to take pictures if possible.

Initial reporter within Atos Medical Group organization: