

Purpose

This document describes the procedure to be followed in the event of a serious hazard situation.

Scope of application

Partners of 3TO GmbH and their clients.

1. Data relating to the incident

1.1 Occurrence of an incident

Has an incident occurred? YES → please fill out this form completely.

Incidents are malfunctions, failures, or changes in the characteristics or performance of a medical device, or inadequacies in the labeling or instructions for use of a medical device, which have led, could have led, or could lead directly or indirectly to the death or serious deterioration in the health of a patient, user, or other person.

1.2 Time of the incident and persons affected

Date of the incident (if known): _____

Date on which the incident became known: _____

Place/country of occurrence: _____

Participants:

▪ **PATIENT** Patient name and address: _____

Date of birth: _____

▪ **USER** User name and address: _____

User phone number: _____

Which of the above parties involved in the incident suffered damage?

PATIENT USER

1.3 Classification of the incident

Impact of the hazardous situation:

- Immediate DEATH Immediate SERIOUS INJURY
 Indirect DEATH Indirect SERIOUS INJURY



Notification of Incident (english version)

Dok.-Nr.: 1-1-2-13

Typ: INSTRUCTION/FORM

1.4 Description of the incident

Cause and precise description of the hazardous situation (as far as known): _____

1.5 Recording of the incident

Please send this completed form by email to 3TO GmbH as soon as possible.: info@3to.de

Note for internal processing

→ Die Bearbeitung bei der 3TO GmbH erfolgt anhand Dokument 1-1-2-12 – „Besonderes Vorkommnis“, beginnend bei Punkt 2.