UriCap Medical Device Report – Adverse Event (AE) Form

The following questionnaire is part of a monitoring process required by the authorities where the device is sold. Please fill it out in case of any adverse reaction, ASAP after the reaction is observed, in order to maintain patient's safety.

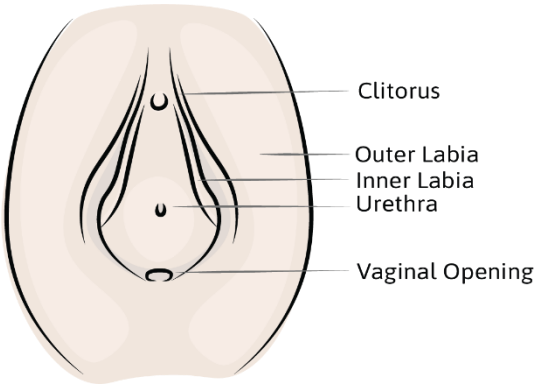
Patient name/ID_____

AE onset Date: _____ AE outcome Date: _____

Adverse Event Description :

Local rash \ Itching\ Irritation\ Wound\ Bleeding\ Redness \ Injury \ Device Malfunction\ Other, please specify: _____

Please check the right place in the picture →



- Intensity:

  Mild \ Moderate \ Severe

- Adverse Event Outcome:

  Resolved / Partially resolved / Not resolved.

- Treatment Required:

  None / Medication / Local treatment / Other, please specify: _____

- Adverse Event Relation to UriCap device:

  Not related / Possibly Related / Strongly related

- Action taken regarding UriCap device (e.g. device removal, device replacement):

Yes / No. If Yes, please specify _____

Please answer the following questions:

- How many days had the patient been using the device? _____ days
- How long was the device installed at the last installation? _____hours
- Was the device application performed according to instructions? Yes / No
- Has the patient any known medical history of Gynecological or Urine System disorders? Yes/No
- Did the size of the UriCap seem suitable for this patient? Yes / no
- Has any UriCap "pulling out" event by patient or medical staff occurred? Yes / no

Date of report: _____

By, Name and position_____

Signature _____