

# ERN eUROGEN registry FAQ 2.1 AMS800

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## 1. QUESTIONS

### Complications within 6 weeks after surgery

#### 8.4 ITEM: Local pain at prosthesis site

**Question:** Is local pain without intervention (e.g., use of painkillers) also considered a complication?

**Answer:** Yes, any type of pain in the affected area is a complication.

**Question:** Can I register complications beyond 6 weeks after surgery anywhere?

**Answer:** Yes, but only if the AMS800 was activated 6 weeks after surgery (ITEM 8.8).

### Complications within 3 months after activation

#### 8.9.2 ITEM: Local pain at prosthesis site

**Question:** Is local pain without intervention (e.g., use of painkillers) also considered a complication?

**Answer:** Yes, any type of pain in the affected area is a complication.

#### 8.9.5 ITEM: Mechanical failure

**Question:** Is mechanical failure due to an incorrect fit of the cuff (e.g., too loose, too big) considered a complication?

**Answer:** Yes.

**Question:** How do I complete the section on complications within 3 months after surgery if a patient has had a revision within that period?

**Answer:** You can select what the patient was suffering from which led to the revision.

**Question:** Is it correct that there is no item on retention in the section Complications within 3 months after surgery?

**Answer:** Yes, this is correct. Retention is no longer expected after activation of the AMS800 device.

### Last visit evaluation

#### 8.12 ITEM: Revision

**Question:** The patient has had multiple revisions, is it possible to register more than one?

**Answer:** Yes. After having registered the first revision, the Snapshot will ask you if another revision has taken place. You can register up to 5 revisions.





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