

Appendix 1: Adverse Event Recording and Reporting

All AEs should be reported, even if they share a related cause. For example, wound disruption that is caused by an infection should be reported as two AEs: infection and wound disruption. All AEs must be recorded and include time, type, and severity.

MOST COMMON TYPES OF AEs RELATED TO MC, NOT INCLUDING PAIN:

Bleeding related:	Infection related:	
<ul style="list-style-type: none"> Excessive bleeding Haematoma 	<ul style="list-style-type: none"> Infection Wound disruption 	<ul style="list-style-type: none"> Abscess formation Scarring/disfigurement from infection
<i>Bleeding and infection cause over 95% of non-pain AEs reported.</i>		

Time	Type	Severity
<p>FOR SURGERY</p> <p>A = Procedure (during surgery or prior to discharge from clinic)</p> <p>B = Early post-operative period (1-6 days after surgery and discharge from clinic)</p> <p>C = Late post-operative period (≥7 days after surgery and discharge from clinic)</p> <p>FOR DEVICE</p> <p>A = Placement (during device placement or prior to clinic discharge)</p> <p>B = In-situ (while wearing device after clinic discharge up to device removal)</p> <p>C = Removal (device removal by a provider)</p> <p>D = Post-removal</p>	<p>AN = Problem with Anaesthesia</p> <p>BL = Excessive Bleeding</p> <p>DD = Device Displacement*</p> <p>IN = Infection</p> <p>OT = Occupational Exposure</p> <p>PA = Pain</p> <p>SD = Scarring/Disfigurement/Poor Cosmetic Result; Insufficient Skin Removal; Excess Skin Removal; Penile Torsion; Injury to Glans or Shaft of Penis</p> <p>SX = Sexual Dysfunction/Undesirable Sensory Changes</p> <p>WD = Wound Disruption</p> <p>OA = Other AEs (Including Excess Swelling of Penis/Scrotum, Haematoma, Difficulty Urinating, Other)</p> <p>*DD is only for devices</p>	<p>Mild</p> <p>Moderate</p> <p>Severe</p>

Example of Coding: An AE coded **A-PA-Moderate** indicates moderate pain during the procedure: **A** = during procedure, **PA** = pain, **moderate**.