

Appendix 4: Adverse Event Classifications and Definitions: Post-Operative Period After Discharge from VMMC Clinic or While Wearing Device or During or After Device Removal

ADVERSE EVENT	MILD	MODERATE	SEVERE
BL: Bleeding			
Surgery	B/C-BL: Blood-stained dressings or underwear, no active bleeding. Small amount of bleeding from minor clot disruption when changing dressings that is controllable with new dressings or 5–10 minutes of manual pressure measured on a clock.	B/C-BL: Bleeding that is not controlled by new dressings or 5–10 minutes of manual pressure measured on a clock, and requires a special return to the clinic for a pressure dressing or additional skin sutures without surgical re-exploration of the wound.	B/C-BL: Bleeding that requires surgical re-exploration, hospitalization, or transfer to another facility; or any case where blood transfusion or intravenous fluid is necessary.
Device	B/C/D-BL: Small amount of bleeding from wound with no active bleeding and is controllable with new dressings or 5–10 minutes of manual pressure.	B/C/D-BL: Bleeding that is not controlled by new dressings or 5–10 minutes of manual pressure or requires a special return to the clinic for a pressure dressing or additional skin sutures without surgical re-exploration of the wound.	B/C/D-BL: Bleeding that requires surgical re-exploration, hospitalization, or transfer to another facility; or any case where blood transfusion or intravenous fluid is necessary.
DD: Device displacement			
Device	B-DD: Displacement of the device after which no other treatment needed beyond routine post-removal wound care. <u>Do not include self-removals or displacements due to external trauma</u> (these should all be at least moderate severity). This category should primarily include clients whose ring detached later in their post-operative course, but prior to day 7, and whose circumcision wound has healed similar to what is expected on post-operative day 7.	B-DD: Displacement of the device that requires any treatment more than routine post-operative wound care but does not meet severe criteria. This is the lowest level of severity for classifying self-removals or displacements secondary to external trauma (such as resumption of sexual activity with the ring in place or the ring getting caught on something and pulled away).	B-DD: Displacement of the device, including intentional movement of device by the client and/or self-removal, that requires surgical intervention, hospitalization, or transfer to another facility to clinically manage.

ADVERSE EVENT	MILD	MODERATE	SEVERE
IN: Infection			
Surgery (B/C-IN) and Device (B/D-IN)	B/C/D-IN: Erythema or traces of serous discharge or infective process noted at wound margin. No intervention other than improved wound hygiene.	B/C/D-IN: Discharge from the wound, painful swelling with erythema, or elevated temperature that requires use of oral antibiotics.	B/C/D-IN: Cellulitis or abscess of the wound, or infection severe enough to require surgical intervention, hospitalization, or intravenous or intramuscular antibiotics.
PA: Pain			
Surgery	B/C-PA: Client complaints of pain, not requiring more than standard post-operative analgesics and considered within normal thresholds associated with surgery.	B/C-PA: Pain serious enough to result in disability (as evidenced by loss of work or cancellation of normal activities) that lasts for at least 1 day after surgery.	B/C-PA: Pain serious enough to result in disability (as evidenced by loss of work or cancellation of normal activities) lasting 2 or more days after surgery.
Device	B/C/D-PA: Client complaints of pain, not requiring more than standard post-operative analgesics and considered within normal thresholds associated with surgery.	B/C/D-PA: Pain serious enough to result in disability (as evidenced by inability to work or perform activities of daily living) lasting for at least 1 day after device placement or removal. For programmes that utilize a visual analogue scale (VAS) for rating severity, a VAS score of 5–7 (on a 1–10 scale).	B/C/D-PA: Pain serious enough to result in disability (as evidenced by inability to work or perform activities of daily living) lasting 2 or more days after device placement or removal. For programmes that utilize a VAS for rating severity of pain, a VAS score of 8–10 (on a 1–10 scale).
SD: Scarring/disfigurement/poor cosmetic result; torsion; insufficient skin removal; excess skin removal; injury to penis			
Scarring/disfigurement/poor cosmetic result; excess skin removal Surgery (C-SD) and Device (D-SD)	<i>Scarring</i> —complaints by client in the absence of discernible abnormal scarring/disfigurement. <i>Torsion of penis</i> —torsion present but does not cause pain or discomfort. <i>Insufficient skin removal</i> —prepuce extends over the coronal margin but less than one-third of the glans is covered in flaccid state.	<i>Scarring</i> —Discernible but re-operation not required. Usually noticed first by the client and reported to the provider. <i>Torsion of penis</i> —torsion present that causes mild pain or discomfort with erection but does not require surgery to correct. <i>Insufficient skin removal</i> —prepuce partially covers glans when flaccid but surgical correction is not necessary.	<i>Scarring</i> —Discernible and requires re-operation or referral/transfer to another facility. <i>Torsion of penis</i> —torsion present. Erections are painful and client cannot tolerate the appearance, discomfort, or pain. Surgery needed for correction. <i>Insufficient skin removal</i> —prepuce covers most of the glans when flaccid and

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			surgical correction is necessary.
Injury to penis Surgery	B/C-SD: <i>Injury to penis</i> —bruising or abrasion, or limited superficial laceration, or burn injury not requiring additional dressings.	B/C-SD: <i>Injury to penis</i> —significant laceration or burn injury requiring either prolonged follow-up care and attention, or repeated or additional dressings, but not requiring surgical correction or hospitalization.	B/C-SD: <i>Injury to penis</i> —significant injury including laceration or severed portion of glans; damage to the urethra or shaft laceration with ongoing bleeding that requires hospitalization, development of a fistula, transfer or transfusion; or significant burn injury leading to significant tissue necrosis/loss. Laceration or severed tissue should be evident at the time of surgery but severe diathermy burns or even coagulation of blood in the whole penis may not be evident until a day or two later. In the case of diathermy urethral injury, leakage of urine through the circumcision wound may occur some days later.
Injury to penis Device	B/C/D-SD: Limited superficial injury not requiring additional intervention.	B/C/D-SD: Bruise, abrasion or small laceration of the glans or shaft requiring pressure dressing, but surgical repair is not required.	B/C/D-SD: Injury that requires surgical intervention to stop bleeding or to repair. Severing of the glans or shaft, injury to urethra or development of a fistula is also considered a severe AE.
Excess skin removal Surgery	B/C-SD: <i>Excess skin removal</i> —slight tightening of the skin observed; no surgical correction needed.	B/C-SD: <i>Excess skin removal</i> —pulling of scrotal skin onto the penile shaft, wound disruption or disruption of sutures due tension on stitches.	B/C-SD: <i>Excess skin removal</i> —wound appearance is such that the wound has gaping edges or large or deep defects such that without revision, there would be significant scar formation.

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Excess skin removal Device	D-SD: <i>Excess skin removal</i> —slight tightening of the skin observed; no surgical correction needed.	D-SD: <i>Excess skin removal</i> —pulling of scrotal skin onto the penile shaft and wound disruption.	D-SD: <i>Excess skin removal</i> —wound appearance is such that the wound has gaping edges or large or deep defects such that without revision, there would be significant scar formation.
SX: Sexual effects/undesirable sensory changes			
Surgery (C-SX) and Device (D-SX)	C/D-SX: Occasional inability to have erection or dissatisfaction with sexual performance, no psycho-behavioural consequences.	C/D-SX: Post-operative changes that consistently impair or preclude sexual function for 3 to 6 months after surgery not present prior to surgery.	C/D-SX: Post-operative changes that consistently impair or preclude sexual function for greater than 6 months after surgery that were not present prior to surgery.
WD: Wound disruption			
Surgery	B/C-WD: Wound disruption but not extensive enough to require suturing for wound closure (<1.0 cm).	B/C-WD: Wound disruption extensive enough to require suturing or other clinical intervention but not surgery, (\geq 1.0 cm).	B/C-WD: Surgical re-exploration or repair is required, or referral/transfer to another facility or hospitalization is required.
Device	D-WD: Wound disruption but not extensive enough to require suturing for wound closure.	D-WD: Muco-cutaneous gap \geq 1.0 cm in width, but no exposure of deeper tissue	D-WD: Wound disruption exposing tissue deeper than subcutaneous tissue or requiring surgical intervention such as suturing or debridement.

ADVERSE EVENT	MILD	MODERATE	SEVERE
OA: Other AEs, excess swelling of penis/scrotum including haematoma; difficulty urinating; other			
Surgery (B/C-OA) and Device (B/D-OA)	<p><i>Excess swelling</i>—mild swelling without signs of ongoing bleeding.</p> <p><i>Other</i>—N/A.</p>	<p><i>Excess swelling</i>—symptoms/signs that require clinical intervention, but not surgical exploration.</p> <p><i>Other</i>—other adverse events related to surgery that result in disability (as evidenced by loss of work or cancellation of normal activities) lasting for at least 4 days after surgery but not more than 7 days.</p>	<p><i>Excess swelling</i>—surgical exploration required to control bleeding or remove haematoma or symptoms/signs so extraordinary as to cause disability (as evidenced by loss of work or cancellation of normal activities) lasting for at least 8 days after surgery or device placement or removal as pertinent.</p> <p><i>Other</i>—other AE(s) related to the surgery that result in disability (as evidenced by loss of work or cancellation of normal activities) lasting for at least 8 days after surgery or device placement or removal, or result in hospitalization or referral/transfer to another facility.</p>
Difficulty urinating Surgery	NA	B/C-OA: Obstruction requiring a special return to the clinic but not surgical intervention or placement of a catheter (transient difficulty urinating that resolves on its own would not be considered an AE).	B/C-OA: Complete obstruction and/or requires placement of a catheter, referral for treatment, or surgery to correct.
Difficulty urinating Device	NA	B/D-OA: Symptoms that resolve with removal/repositioning of the device or dressing (transient difficulty urinating that resolves on its own would not be considered an AE).	B/D-OA: Complete obstruction and/or requires placement of a catheter, referral for treatment or surgery to correct.