

APPENDIX 5: ADVERSE EVENT CLASSIFICATION AND GRADING

Adverse Event (AE) Type (abbreviation code noted below each type)	Timing of Initial Diagnosis (Check only one box.)	Severity of Initial Diagnosis		
		Mild (1)	Moderate (2)	Severe (3) ***
Excessive bleeding (BL)	Bleeding was diagnosed: <ul style="list-style-type: none"> Intra-operative or immediately post-operative (prior to discharge from clinic) = Code A After discharge from clinic and up to 30 days post-operative = Code B Greater than 30 days post-operative = Code C 	<ul style="list-style-type: none"> Bleeding that requires minimal intra-operative attention? Bleeding that requires less than 10 minutes of direct pressure to control? 	<ul style="list-style-type: none"> Bleeding that requires significant intra-operative effort to control? Bleeding that requires extra pressure dressing to control? Unscheduled return to the clinic for medical attention? (not just for reassurance) 	<ul style="list-style-type: none"> Surgical re-exploration for ligation or cauterization of bleeding vessels? Hospitalization? Transfer to another facility? Transfusion? Any hemodynamic instability?
Infection (IN)	Infection was diagnosed: <ul style="list-style-type: none"> Within the 30 days post-operative = Code B Greater than 30 days post-operative = Code C 	<ul style="list-style-type: none"> Mild erythema and minimal serous discharge from wound Only topical antibiotics used Infected area less than 1 cm in length 	<ul style="list-style-type: none"> Purulent discharge from wound Oral or IV antibiotics needed Infected area greater than 1 cm in length 	<ul style="list-style-type: none"> Abscess Severe cellulitis Wound necrosis Severe wound disruption Tissue loss
Pain (PA)	Pain was noted: <ul style="list-style-type: none"> Intra-operative or immediately post-operative (prior to discharge from clinic) = Code A After discharge from clinic and up to 30 days post-operative = Code B Greater than 30 days post-operative = Code C 	<ul style="list-style-type: none"> Mild discomfort 	<ul style="list-style-type: none"> Moderate discomfort Pain requiring interruption of operation for additional local anesthetic Pain resulting in inability to work or cancellation of normal activities lasting for four to seven days after surgery 	<ul style="list-style-type: none"> Pain resulting in early termination of VMMC or administration of general anesthesia Pain severe enough to result in inability to work or cancellation of normal activities lasting at least eight days after surgery
Swelling of penis/ scrotum, including hematoma (SH)	Swelling was noted: <ul style="list-style-type: none"> After discharge from clinic and up to 30 days post-operative = Code B Greater than 30 days post-operative = Code C 	<ul style="list-style-type: none"> Significant circumferential swelling along incision line (without bleeding) that resolves with time 	<ul style="list-style-type: none"> Localized swelling associated with some bleeding, resolves spontaneously (with or without pressure dressing) 	<ul style="list-style-type: none"> Surgical re-exploration for drainage of hematoma? Hospitalization? Transfer to another facility? Transfusion?

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		Mild (1)	Moderate (2)	Severe (3) ***
Anesthesia reaction or complication (AN)	Reaction was diagnosed: <ul style="list-style-type: none"> Intra-operative or immediately post-operative (prior to discharge from clinic) = Code A 	<ul style="list-style-type: none"> Palpitations, vasovagal reaction, or emesis managed with observation at VMMC clinic? 	<ul style="list-style-type: none"> Symptoms requiring medical intervention at clinic? 	<ul style="list-style-type: none"> Client transferred or referred to another facility for anaphylaxis or other anesthetic reaction? Client hospitalized for anaphylaxis or other anesthetic reaction?
Wound disruption/dehiscence (WD)	Disruption was noted: <ul style="list-style-type: none"> After discharge from clinic and up to 30 days post-operative = Code B Greater than 30 days post-operative = Code C 	<ul style="list-style-type: none"> Disruption involving less than 1 cm 	<ul style="list-style-type: none"> Disruption involving up to 2 cm, but no surgical intervention 	Wound disruption requiring additional surgery? <ul style="list-style-type: none"> Transfer to another facility? Hospitalization?
Damage to penis (DP)	Injury was noted: <ul style="list-style-type: none"> Intra-operative or immediately post-operative (prior to discharge from clinic) = Code A After discharge from clinic and up to 30 days post-operative = Code B Greater than 30 days post-operative = Code C 	<ul style="list-style-type: none"> Superficial burn or laceration 	Significant laceration or burn requiring: <ul style="list-style-type: none"> Prolonged intra-operative attention to treat Extra pressure dressing Additional clinic follow-up care 	Severe injury (amputation, laceration, urethral injury, significant tissue loss, or severe burn) requiring: <ul style="list-style-type: none"> Additional surgery? Transfer to another facility? Hospitalization? Transfusion?
Torsion of penis—new onset (TP)	Torsion was noted: <ul style="list-style-type: none"> After discharge from clinic and up to 30 days post-operative = Code B Greater than 30 days post-operative = Code C 	<ul style="list-style-type: none"> Torsion visible, but does not cause discomfort 	<ul style="list-style-type: none"> Torsion causes mild discomfort with erection, but no surgery needed 	<ul style="list-style-type: none"> Severe symptomatic torsion requiring re-operation

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Excessive skin removed (ES)	Excessive skin removal noted: <ul style="list-style-type: none"> Intra-operative or immediately post-operative (prior to discharge from clinic) = Code A After discharge from clinic and up to 30 days post-operative = Code B Greater than 30 days post-operative = Code C 	<ul style="list-style-type: none"> Intra-operative recognition of excess removal noted, but not enough to warrant additional surgical steps Post-operatively, client complains of tightening, but physical exam is normal 	<ul style="list-style-type: none"> Intra-operative recognition of excess removal noted, requiring either: <ul style="list-style-type: none"> Mobilization of skin near wound margin Placement of extra sutures for reinforcement Post-operatively, tightening of the skin is discernible, but re-operation not required 	<ul style="list-style-type: none"> Additional surgery required? Transfer to another facility? Hospitalization?
Insufficient skin removed (IS)	<ul style="list-style-type: none"> Intra-operative or immediately post-operative (prior to discharge from clinic) = Code A After discharge from clinic and up to 30 days post-operative = Code B Greater than 30 days post-operative = Code C 	<ul style="list-style-type: none"> Prepuce (foreskin) extends over the coronal margin, but less than one-third of the glans is covered at rest in flaccid state 	<ul style="list-style-type: none"> Between one- and two-thirds of glans is covered by residual prepuce at rest in flaccid state 	<ul style="list-style-type: none"> Greater than two-thirds of glans is covered by residual prepuce at rest in flaccid state
Voiding problems (difficulty urinating) (VO)	Voiding problems noted: <ul style="list-style-type: none"> After discharge from clinic and up to 30 days post-operative = Code B Greater than 30 days post-operative = Code C 	<ul style="list-style-type: none"> Resolves spontaneously or with loosening of dressing 	<ul style="list-style-type: none"> Requires treatment in clinic—such as transient catheterization 	<ul style="list-style-type: none"> Requires surgical re-exploration for urethral injury or blockage Requires placement of suprapubic tube
Device application difficulty (DA)	<ul style="list-style-type: none"> Intra-operative or immediately post-operative (prior to discharge from clinic) = Code A 	<ul style="list-style-type: none"> Could not apply device, changed to surgical method of VMMC 	<ul style="list-style-type: none"> Device caused mild bleeding or other mild AE, requiring change to surgical method of VMMC 	<ul style="list-style-type: none"> Device caused significant bleeding or other significant AE, requiring change to surgical method of VMMC
Device displacement or spontaneous detachment (DD)	<ul style="list-style-type: none"> After discharge from clinic and up to 30 days post-operative = Code B 	<ul style="list-style-type: none"> Post-operative device displacement and bleeding, three or fewer sutures required 	<ul style="list-style-type: none"> Displacement or detachment and bleeding, more than three sutures required 	<ul style="list-style-type: none"> Device displacement or detachment, penile damage present

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Occupational exposure of health care provider (OT)	<ul style="list-style-type: none"> ▪ Intra-operative or immediately post-operative (prior to discharge from clinic) = Code A ▪ After discharge from clinic and up to 30 days post-operative = Code B ▪ Greater than 30 days post-operative = Code C 	<ul style="list-style-type: none"> ▪ Blood splashes on intact skin 	<ul style="list-style-type: none"> ▪ Needle stick ▪ Blood splatters in eye ▪ No illness as a result 	<ul style="list-style-type: none"> ▪ Any seroconversion or illness attributed to exposure
Other AE (describe) (OA) _____ _____	<ul style="list-style-type: none"> ▪ Intra-operative or immediately post-operative (prior to discharge from clinic) = Code A ▪ After discharge from clinic and up to 30 days post-operative = Code B ▪ Greater than 30 days post-operative = Code C 		<ul style="list-style-type: none"> ▪ AE resulting in inability to work or cancellation of normal activities lasting for four to seven days after surgery 	<ul style="list-style-type: none"> ▪ AE severe enough to result in inability to work or cancellation of normal activities lasting for at least eight days after surgery ▪ Transfer to another facility? ▪ Hospitalization?

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