

Appendix 3: Adverse Event Classifications and Definitions: During Surgery or Prior to Discharge from VMMC Clinic, or During Device Placement or Prior to Discharge from VMMC Clinic

ADVERSE EVENT	MILD	MODERATE	SEVERE
AN: Anaesthetic-related problem			
Surgery (A-AN) and Device (A-AN)	Mild localized allergic reaction at injection site without swelling and systemic reaction.	Reaction to anaesthetic including light-headedness, nervousness, dizziness that resolves spontaneously and not requiring use of medicines or equipment from the emergency cart/kit/list of emergency commodities at VMMC site and no transfer to another facility or admission to hospital.	Symptoms of severe systemic allergic reaction to local anaesthetic including rash, urticaria, angioedema, and shortness of breath, or symptoms of overdose of local anaesthetic including light-headedness, nervousness, confusion, dizziness, drowsiness, ringing of ears, blurred or double vision, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression, bradycardia, or hypotension requiring use of medicines or equipment from the emergency cart/kit/list of emergency commodities or hospitalization to manage.
BL: Bleeding			
Surgery	A-BL: Intra-operative bleeding that is more significant than usual or post-operative spotting of the bandage with blood; both easily controlled.	A-BL: Intra-operative bleeding or bleeding that occurs prior to discharge that requires a pressure dressing to control, or that requires additional skin sutures without surgical re-exploration of the wound.	A-BL: Intra-operative bleeding requiring blood transfusion, transfer to another facility, or hospitalization; or post-operative bleeding that requires surgical re-exploration, hospitalization, or transfer to another facility.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Device	A-BL: Bleeding during placement that is more significant than usual or spotting of the bandage or clothing with blood prior to clinic discharge; both easily controlled.	A-BL: Bleeding during placement or prior to discharge that requires a pressure dressing to control without surgical re-exploration of the wound or removal of the device.	A-BL: Bleeding during placement that requires blood transfusion, transfer to another facility, or hospitalization; or bleeding prior to discharge that requires surgical exploration, removal of device, placement of sutures, hospitalization, or transfer to another facility.
PA: Pain			
Surgery	A-PA: Client expresses discomfort, however is able to remain still and cooperate for the procedure. No additional local anaesthetic is required.	A-PA: Pain requiring additional local anaesthesia.	A-PA: Pain not responsive to additional local anaesthesia.
Device	A-PA: Client expresses discomfort, however is able to remain still and cooperate for the procedure.	A-PA: Client expresses discomfort and is not able to cooperate well with procedure.	A-PA: Client rates pain as very severe.
SD: Scarring/disfigurement/poor cosmetic result; excess skin removal; injury to penis			
Surgery	<p>A-SD: <i>Excess skin removal</i>—tightness of skin discernible but additional sutures or mobilisation of skin not needed for skin closure.</p> <p>A-SD: <i>Injury to penis</i>—limited superficial laceration or burn injury not requiring additional dressings.</p>	<p>A-SD: <i>Excess skin removal</i>—tightness of the skin discernible and additional sutures or skin mobilisation needed for wound closure, but no other intervention needed.</p> <p>A-SD: <i>Injury to penis</i>—abrasion or small laceration of glans or shaft or small burn injury requiring prolonged intra-operative attention to treat or pressure dressing, but surgical repair not required.</p>	<p>A-SD: <i>Excess skin removal</i>—provider unable to close wound; referral to another facility required.</p> <p>A-SD: <i>Injury to penis</i>—severe laceration or severing of the glans or shaft, damage to the urethra that requires additional surgery to repair the injury, significant diathermy burn injuries.</p>
Device	<p><i>Excess skin removal</i>—NA</p> <p>A-SD: <i>Injury to penis</i>—limited superficial injury not requiring additional intervention.</p>	<p><i>Excess skin removal</i>—NA</p> <p>A-SD: <i>Injury to penis</i>—abrasion or small laceration of the glans or shaft requiring pressure dressing, but surgical repair is not required.</p>	<p><i>Excess skin removal</i>—NA</p> <p>A-SD: <i>Injury to penis</i>—injury that requires surgical intervention to stop bleeding or repair.</p>

ADVERSE EVENT	MILD	MODERATE	SEVERE
DD: Device displacement			
Device			A-DD: Displacement of the device during placement or prior to discharge from clinic, 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.