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CLINICAL EXAM TOOL: DAY 2

Clinician
(initials)

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Today's Date

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D	D	M	M	Y	Y	Y	Y

ADVERSE EVENTS			
<p>Instructions: The following table lists adverse events that may occur at this time, and provides definitions of severity. Inspect the client's penis and determine the severity of present signs and symptoms based upon the definitions provided. Relationship of the adverse event to the circumcision procedure should also be recorded. The following definitions should be used:</p> <p><u>Not likely related:</u> A complication has occurred that is clearly explained by a cause other than the circumcision procedure</p> <p><u>Possibly related:</u> A complication has occurred during or after surgery that could be explained by the circumcision procedure, but can equally or more likely be explained by other causes</p> <p><u>Probably related:</u> A complication has occurred during or after surgery that is most likely due to the circumcision procedure, but could be explained by other causes</p> <p><u>Definitely related:</u> A clear complication of the procedure has occurred either during or after the procedure</p>			
	DESCRIPTION OF ADVERSE EVENT	SEVERITY	RELATED TO CIRCUMCISION
HEMATOMA		<input type="checkbox"/> NOT PRESENT	<input type="checkbox"/> NOT LIKELY <input type="checkbox"/> POSSIBLE <input type="checkbox"/> PROBABLE <input type="checkbox"/> DEFINITELY
	More swelling than usual, but no significant discomfort	<input type="checkbox"/> MILD	
	Significant tenderness & discomfort, but surgery not required	<input type="checkbox"/> MODERATE	
	Surgical re-exploration required to correct	<input type="checkbox"/> SEVERE	
BLEEDING		<input type="checkbox"/> NOT PRESENT	<input type="checkbox"/> NOT LIKELY <input type="checkbox"/> POSSIBLE <input type="checkbox"/> PROBABLE <input type="checkbox"/> DEFINITELY
	Dressing soaked through with blood at a routine follow-up visit	<input type="checkbox"/> MILD	
	Bleeding that requires a special return to the clinic for medical attention	<input type="checkbox"/> MODERATE	
	Bleeding that requires surgical re-exploration	<input type="checkbox"/> SEVERE	
INFECTION		<input type="checkbox"/> NOT PRESENT	<input type="checkbox"/> NOT LIKELY <input type="checkbox"/> POSSIBLE <input type="checkbox"/> PROBABLE <input type="checkbox"/> DEFINITELY
	Erythema more than 1cm beyond incision line	<input type="checkbox"/> MILD	
	Purulent discharge from wound	<input type="checkbox"/> MODERATE	
	Cellulitis or wound necrosis	<input type="checkbox"/> SEVERE	
PAIN		<input type="checkbox"/> NOT PRESENT	<input type="checkbox"/> NOT LIKELY <input type="checkbox"/> POSSIBLE <input type="checkbox"/> PROBABLE <input type="checkbox"/> DEFINITELY
	3-4 on pain scale	<input type="checkbox"/> MILD	
	5-6 on pain scale	<input type="checkbox"/> MODERATE	
	7 and greater on pain scale	<input type="checkbox"/> SEVERE	
DAMAGE TO PENIS		<input type="checkbox"/> NOT PRESENT	<input type="checkbox"/> NOT LIKELY <input type="checkbox"/> POSSIBLE <input type="checkbox"/> PROBABLE <input type="checkbox"/> DEFINITELY
	Mild bruising or abrasion, no further treatment necessary	<input type="checkbox"/> MILD	
	Bruise or abrasion to the glans or shaft requiring pressure dressing or additional surgery to control	<input type="checkbox"/> MODERATE	
	Portion or all of the glans or shaft of penis severed	<input type="checkbox"/> SEVERE	

National Safe Male Circumcision Program in Botswana:
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	DESCRIPTION OF ADVERSE EVENT	SEVERITY	RELATED TO CIRCUMCISION
EXCESSIVE SKIN REMOVED		<input type="checkbox"/> NOT PRESENT	<input type="checkbox"/> NOT LIKELY <input type="checkbox"/> POSSIBLE <input type="checkbox"/> PROBABLE <input type="checkbox"/> DEFINITELY
	No discernible abnormality, but client concerned	<input type="checkbox"/> MILD	
	Skin is tight, but no further surgery necessary	<input type="checkbox"/> MODERATE	
	Requires operation or transfer to another facility to correct problem	<input type="checkbox"/> SEVERE	
	Participant circumcised with PrePex device that is still intact	<input type="checkbox"/> NOT APPLICABLE	
INSUFFICIENT SKIN REMOVED		<input type="checkbox"/> NOT PRESENT	<input type="checkbox"/> NOT LIKELY <input type="checkbox"/> POSSIBLE <input type="checkbox"/> PROBABLE <input type="checkbox"/> DEFINITELY
	Prepuce partially covers the glans only when extended	<input type="checkbox"/> MILD	
	Prepuce still partially covers glans and operation is required to correct	<input type="checkbox"/> MODERATE	
	Not applicable	<input type="checkbox"/> SEVERE	
	Participant circumcised with PrePex device that is still intact	<input type="checkbox"/> NOT APPLICABLE	
DELAYED WOUND HEALING		<input type="checkbox"/> NOT PRESENT	<input type="checkbox"/> NOT LIKELY <input type="checkbox"/> POSSIBLE <input type="checkbox"/> PROBABLE <input type="checkbox"/> DEFINITELY
	Healing taking longer than usual, but no extra treatment necessary	<input type="checkbox"/> MILD	
	Additional non-surgical treatment required	<input type="checkbox"/> MODERATE	
	Requires surgery to correct	<input type="checkbox"/> SEVERE	
ANESTHETIC-RELATED EVENT		<input type="checkbox"/> NOT PRESENT	<input type="checkbox"/> NOT LIKELY <input type="checkbox"/> POSSIBLE <input type="checkbox"/> PROBABLE <input type="checkbox"/> DEFINITELY
	Palpitations, vaso-vagal reaction or emesis	<input type="checkbox"/> MILD	
	Reaction to anesthetic requiring medical treatment in study clinic but not transfer to another facility	<input type="checkbox"/> MODERATE	
	Anaphylaxis or any reaction requiring transfer to another facility	<input type="checkbox"/> SEVERE	
VOIDING PROBLEMS		<input type="checkbox"/> NOT PRESENT	<input type="checkbox"/> NOT LIKELY <input type="checkbox"/> POSSIBLE <input type="checkbox"/> PROBABLE <input type="checkbox"/> DEFINITELY
	Transient complaint that that resolves without treatment	<input type="checkbox"/> MILD	
	Requires a special return to the clinic, but no additional treatment	<input type="checkbox"/> MODERATE	
	Requires referral to other facility or specialist for management	<input type="checkbox"/> SEVERE	
EARLY REMOVAL	Did the participant return with the device components intact and request early removal of the device before the scheduled removal day?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NOT APPLICABLE	<input type="checkbox"/> NOT LIKELY <input type="checkbox"/> POSSIBLE <input type="checkbox"/> PROBABLE <input type="checkbox"/> DEFINITELY
DEVICE DISPLACEMENT	Is the device displaced or partially detached?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NOT APPLICABLE	<input type="checkbox"/> NOT LIKELY <input type="checkbox"/> POSSIBLE <input type="checkbox"/> PROBABLE <input type="checkbox"/> DEFINITELY
SELF REMOVAL OF DEVICE	Was the device removed by the participant?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NOT APPLICABLE	<input type="checkbox"/> NOT LIKELY <input type="checkbox"/> POSSIBLE <input type="checkbox"/> PROBABLE <input type="checkbox"/> DEFINITELY
DEVICE MALFUNCTION	Did any of the components of the device malfunction?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NOT APPLICABLE	<input type="checkbox"/> NOT LIKELY <input type="checkbox"/> POSSIBLE <input type="checkbox"/> PROBABLE <input type="checkbox"/> DEFINITELY
DIFFICULTY IN REMOVING DEVICE	Was there difficulty with removal of the device?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NOT APPLICABLE	<input type="checkbox"/> NOT LIKELY <input type="checkbox"/> POSSIBLE <input type="checkbox"/> PROBABLE <input type="checkbox"/> DEFINITELY
Is the client currently experiencing an <u>adverse event</u>? <i>YES=at least one moderate or severe adverse event is present</i> <i>NO=the healing and symptoms are within normal range</i>		<input type="checkbox"/> YES <input type="checkbox"/> NO	NOTIFY STUDY COORDINATOR IMMEDIATELY

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STI ASSESSMENT		
Instructions: <i>Examine the penis and document in the table below whether the client exhibits any of the following conditions.</i>		
• Temp > 38°C	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• Urethral discharge	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• Genital sore or ulcer	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• Vesicles	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• Abdominal mass	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• Rebound tenderness, guarding	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• Scrotal swelling, pain	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• Elevated/rotated testes	<input type="checkbox"/> YES	<input type="checkbox"/> NO