



WHO guidance on devices for medical male circumcision for HIV prevention

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MALE CIRCUMCISION FOR HIV PREVENTION

Many devices marketed for adolescent and adult male circumcision

<p>1a. Collar Clamp</p>	 <p>ShangRing</p>	 <p>Kirve clamp</p>	 <p>Sunathrone</p>	
<p>1b. Vice Clamp</p>	 <p>Alis Klamp</p>	 <p>Tara Klamp</p>	 <p>Ismail Clamp</p>	 <p>Smart Clamp</p>
<p>2. Elastic collar compression</p>	 <p>PrePex</p>	<p>3. Ligature</p>	 <p>Zhenxi Ring</p>	

WHO guidance on device use as a method for male circumcision:

- Prequalification programme information
- Guideline on use of devices



WHO Prequalification of Male Circumcision Devices Programme, established 2011

Objective:

- Facilitate access to safe, appropriate, good quality male circumcision devices

Assessed according to international standards:

- Technical characteristics of device and its performance
- Manufacturer's quality management system
- Evidence on clinical efficacy and safety



Key information when a device is 'prequalified'

Information:

- List of 'prequalified' devices for male circumcision for HIV prevention
- 'Public Report' with technical information on each prequalified device

Used for procurement decisions by:

- Member States, UN, and other purchasers including Global Fund, PEPFAR

Not WHO 'approval' as approval is the sole prerogative of each national government



Status of devices in WHO Prequalification Programme

Product name	Manufacturer name	Application	Letter of Agreement	Product dossier including clinical data	Manufacturer site inspections	Prequalification Status
PrePex	Circ Med Tech Limited					Prequalified : 31 May 2013
ShangRing	Wuhu Snnda Medical Treatment Appliance Technology Co., Ltd.					
Alisklamp Disposable Circumcision Device	ABAGROUP Healthcare Services Co. Ltd.					
Tara KLamp	Taramedic Corp.					



WHO guideline on use of devices

Purpose:

to provide **recommendations** and **considerations** on introduction and use of devices as a method for adolescent and adult male circumcision in HIV prevention programmes

Process for development

- obtain inputs from diverse individuals
- review of clinical evidence and literature
- consider balance of benefits and harms, acceptability, resource use
- consider implications for programmes and services



Guideline (1): DRAFT key points

- prequalified devices: efficacious and safe method of MC
- among healthy males 18 years and older
- **WHEN**
 - used by health care providers who are adequately trained and competent with use of the specific device
 - in settings where urgent or immediate surgical back-up facilities and skills, appropriate to the specific device, are available



Guideline (2): DRAFT programmatic considerations

- Phased approach to introduction
 - with broad stakeholder engagement
 - pilot projects in routine settings
- Policies & regulations:
 - pre-market approvals in country
 - health care providers authorized to use device
- Monitoring, evaluation and reporting
 - safety monitoring
 - active follow up of the first 1000 clients in routine settings with ongoing monitoring after safety demonstrated
 - uptake and rates of return at removal visit



Guideline (3): DRAFT considerations

- Service delivery: many considerations
 - uniqueness of settings and each device
 - training includes observation to assess competence
 - 2 visits required - placement and removal
- Communications
 - accurate client and partner information; informed providers
- Procurement, supply management
 - good forecasting for a sufficient stock of full range of device sizes and appropriate accessories for placement and removal

Continue to offer minimum package of HIV prevention services and assure service quality



WHO

- *Framework for clinical evaluation of male circumcision devices*
- *Technical Advisory Group Report on evaluation of two devices*

<http://www.who.int/hiv/topics/malecircumcision/en/>

- *Beginning with the end in mind*

[www.who.int/reproductive health/publications](http://www.who.int/reproductive_health/publications)

- Prequalification: list of products and public reports

[http://www.who.int/diagnostics_laboratory/evaluations/prequalification male circumcision devices](http://www.who.int/diagnostics_laboratory/evaluations/prequalification_male_circumcision_devices)

Clearinghouse on Male Circumcision

<http://www.malecircumcision.org>