# WHO guidance on devices for medical male circumcision for HIV prevention

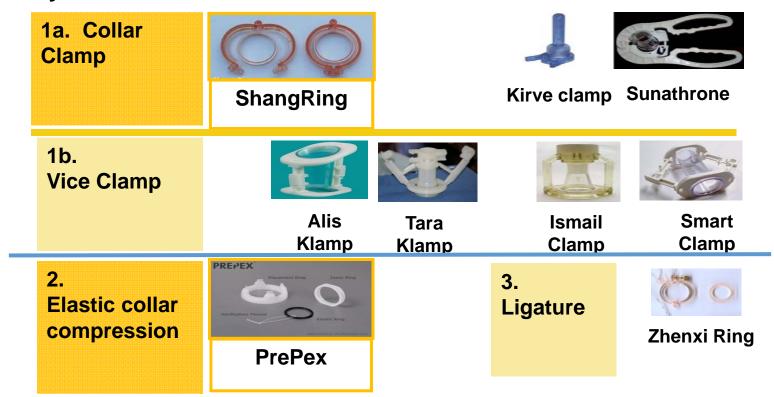
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#### Many devices marketed for adolescent and adult male circumcision



#### 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



#### MALE CIRCUMCISION FOR HIV PREVENTION

# Status of devices in WHO Prequalification Programme

Product	Manufacturer	Application	Letter of	<b>Product dossier</b>	Manufacturer	Prequalification
name	name		Agreement	including clinical		Status
				data	inspections	
PrePex	Circ Med Tech					Prequalified: 31
	Limited					May 2013
ShangRing	Wuhu Snnda					
	Medical Treatment					
	Appliance					
	Technology Co.,					
	Ltd.					
Alisklamp	ABAGROUP					
Disposable	Healthcare					
Circumcision	Services Co. Ltd.					
Device						
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/reprodutive health/publications
- Prequalification: list of products and public reports http://www.who.int/diagnostics laboratory/evaluations/prequal ification male circumcision devices

# Clearinghouse on Male Circumcision

http://www.malecircumcision.org

