World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

11 June 2015

Information on ShangRing™ (Generation II, self-locking model) device for voluntary medical male circumcision for HIV prevention

ShangRing™ (PQMC reference number 003-003-00) with the following product codes was prequalified by WHO on 5 June 2015, and added to the WHO list of prequalified male circumcision devices.

Product	Size*	Product codes
ShangRing™ (4.0cm)	A4	SR-II-40
ShangRing™ (3.9 cm)	A3	SR-II-39
ShangRing™ (3.8 cm)	A2	SR-II-38
ShangRing™ (3.7 cm)	A1	SR-II-37
ShangRing™ (3.6 cm)	A	SR-II-36
ShangRing™ (3.5 cm)	B	SR-II-35
ShangRing™ (3.4 cm)	C	SR-II-34
ShangRing™ (3.3 cm)	D	SR-II-33
ShangRing™ (3.2 cm)	E	SR-II-32
ShangRing™ (3.1 cm)	F	SR-II-31
ShangRing™ (3.0 cm)	G	SR-II-30
ShangRing™ (2.9 cm)	H	SR-II-29
ShangRing™ (2.8 cm)	I	SR-II-28
ShangRing™ (2.6 cm)	K	SR-II-26
ShangRing™ (2.4 cm)	M	SR-II-24
ShangRing™ (2.2 cm)	O	SR-II-22
ShangRing (2.0 cm)	Q	SR-II-20
ShangRing™ (1.8 cm)	S	SR-II-18

*** Sizes A4 – S can be used on both adolescents and adults.**

Background:

1. Since 2007, programmes in priority countries of East and Southern Africa are scaling-up voluntary medical male circumcision (VMMC) as an additional HIV prevention intervention.

2. Innovations in male circumcision methods have emerged that promise to make the procedure simpler, less resource intensive, usable by non-physician health care providers, acceptable to clients and providers, and have the potential to expand coverage thus maximizing prevention.

3. While a number of devices for VMMC are on the market, until recently scientifically robust and independent evidence on the quality and safety was not available. In response:
    a. WHO established the Prequalification of Male Circumcision Devices programme to provide Member States and other agencies with technical information about the quality and safety of specific medical devices for VMMC. These status for products undergoing WHO prequalification assessment can be found at: http://www.who.int/diagnostics_laboratory/evaluations/PQMCdevices_list/en/index.html

World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

b. In 2013 WHO issued the "*Guideline on the use of devices for adult male circumcision for HIV prevention"* which recommends the use of WHO prequalified devices given the assurance that the device meets global standards of quality, safety and efficacy.

Update:

4. On 5 June 2015, WHO prequalified the ShangRing™ device for the purpose of VMMC for HIV prevention. The term "prequalified" means the device has been assessed and meets international standards for three components: (1) the review of the regulatory dossier of the device, (2) the inspection of the quality management system under which the product is manufactured, and (3) clinical studies on efficacy and safety in settings of intended use, have been satisfactorily completed.

5. The use of the ShangRing™ device was demonstrated to be efficacious in male circumcision and safe for use among healthy adolescent and adult males ages 13 years and above when used by trained medical professionals which includes medical doctors, nurses and clinical officers. Skills and surgical facilities should be available, at the time of placement or soon after, to safely convert failures of device placement, such as foreskin slippage, to conventional procedures. The performance profile was similar for males 13 to 18 years as for males aged 18 years and older, however, only the minimal required data was available to evaluate efficacy and safety.

6. Introduction of a new device into public health HIV programmes should be implemented in a phased manner with careful monitoring of the type and frequency of complications outside of controlled study settings. It must also be accompanied by post-market surveillance to capture safety issues that permits to identify, record and report adverse events by health authorities and by the manufacturer as part of ongoing risk management. Specifically for males 13 to 18 years, it is advised that use occurs only under active surveillance for adverse events until safety has been further demonstrated on larger number of adolescents.

7. Male circumcision using the ShangRing™, a collar clamp device:
   - requires a sterile field and standard surgical skin preparation, local injectable anaesthesia, but does not require sutures;
   - required less time to perform than conventional surgery, but must be worn for one week to ten days and thus requires two visits to a provider - one for placement and a second for removal;
   - takes about one week longer to heal than by conventional surgery as healing is by secondary intention;
   - must include effective education and counselling in line with the WHO minimum service package for VMMC.

More information on voluntary medical male circumcision is available at
http://www.who.int/hiv/topics/malecircumcision/en/
The WHO Prequalification Public Report for ShangRing™ is available at
http://www.who.int/diagnostics_laboratory/evaluations/150605_pqmc_0003_003_00_pq_public_report_v2_adult_and_ado.pdf?ua=1