

WHO Prequalification of Male Circumcision Devices PUBLIC REPORT

Product: ShangRing

WHO reference number: PQMC 0003-003-00

ShangRing (Generation II, self-locking model) manufactured by Wuhu Snnda Medical Treatment Appliance Technology Co. Ltd., **Rest of World** regulatory version, was accepted for the WHO list of prequalified male circumcision devices and was listed on 03 June 2015.

Summary of prequalification status for ShangRing

	Date	Outcome
Status on PQ list	5-Jun-2015	listed
Dossier assessment	15-Jan-2015 and 4-May-2015	MR
Inspection status	15-Oct-2019	MR
Clinical study	15-Jan-2015	MR

MR: Meets Requirements

Report amendments and/or product changes

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

Public report amendment	Summary of amendment	Date of report amendment
2.0	1. No-Flip or Non-eversion of the Foreskin 2. Use of Topical in addition to Injectable Anesthetic 3. Allow for Spontaneous Detachment of the ShangRing 4. Eligibility for Use Approved to 10 years of age from the Current 13 5. Making Available and Using Every Other ShangRing Size	3-Jul-2018
3.0	Notification of CE marking of the product and Rest of the World Regulatory version	22-Mar-2019

4.0	Change in the image of the ShangRing device in the IFU and fulfillment of commitments to prequalification.	29-Aug-2019
5.0	Acceptance of manufacturer's responses to nonconformities raised during 2019 re-inspection	22-Oct-2019

Intended use:

According to the manufacturer *"The ShangRing device is indicated for male circumcision, defined as removal or excision of the foreskin or prepuce. The ShangRing is indicated for use in adolescent and adult males, specifically:*

- *ages ≥ 13 years with the flip technique or the no-flip technique, and*
- *ages 10 – 12 years only with the no-flip technique.*

Local anaesthesia is necessary for all clients. Topically applied EMLA cream is an alternative to injectable anaesthesia, but only in clients who do not have foreskin conditions (phimosis and/or adhesions) and only with the no-flip technique"

Mode of operation:

According to the manufacturer *"ShangRing device is only for professional use by health care providers. Healthcare providers are medical professionals and can include medical doctors, nurses and clinical officers.*

The ShangRing, manufactured by Wuhu SNDA Medical Treatment Appliance Technology Co., LTD., Wuhu, Anhui Province, China, is a sterile, single use, disposable male circumcision device that consists of two concentric plastic rings, the inner of which is lined by a silicone pad. The ShangRing is available in 32 sizes (A4 to Z2), with inside diameters of 40mm to 9mm (see Table 1). Hemostasis is achieved by the pressure applied by the interlocking rings which minimizes bleeding and eliminates the need for sutures.

Measuring tape is supplied with the ShangRing device. Bandages, removal cutter, and removal key opener are sold separately. Although bandages can be purchased from Wuhu SNDA for use with the ShangRing, any general surgical dressing can be used. General hospital supplies (e.g., gloves, gowns, etc.), local anesthetic, and instruments (e.g., hemostatic clamps, surgical scissors) are not supplied with the ShangRing.

The plastic disposable measuring tape is a single-use item that is used to select the appropriately sized ShangRing device. The measuring tape is supplied non-sterile and does not need to be sterilized prior to patient use.

The instruments used for placement of the ShangRing (e.g. hemostatic clamps, surgical scissors) must be cleaned and sterilized prior to each patient use.

The removal cutter and removal key opener are used to remove the ShangRing, if necessary. The removal cutter is a blunt-end scissor and the removal key opener is similar to a 1/8 inch (or 3mm) flat bladed screwdriver. Both the removal cutter and removal key opener (sold separately) are reusable. These removal tools must be cleaned and sterilized or cleaned and disinfected prior to each patient use”.

Product contents and codes

Table 1: ShangRing sizes and product codes

Shang Ring size	Product Code	Inner diameter of inner ring (mm)	Shang Ring size	Product Code	Inner diameter of inner ring (mm)
A4	SR-II-40	40	M	SR-II-24	24
A3	SR-II-39	39	N	SR-II-23	23
A2	SR-II-38	38	O	SR-II-22	22
A1	SR-II-37	37	P	SR-II-21	21
A	SR-II-36	36	Q	SR-II-20	20
B	SR-II-35	35	R	SR-II-19	19
C	SR-II-34	34	S	SR-II-18	18
D	SR-II-33	33	T	SR-II-17	17
E	SR-II-32	32	U	SR-II-16	16
F	SR-II-31	31	V	SR-II-15	15
G	SR-II-30	30	W	SR-II-14	14
H	SR-II-29	29	X	SR-II-13	13
I	SR-II-28	28	Y	SR-II-12	12
J	SR-II-27	27	Z	SR-II-11	11
K	SR-II-26	26	Z1	SR-II-10	10
L	SR-II-25	25	Z2	SR-II-9	9

Accessories required**Table 2: ShangRing accessories provided**

Accessory	Description
Bandages	1400 pieces will be provided with each order of 200 ShangRing units. Additional pieces can be purchased separately.
Removal Cutter and Removal Key	4 sets will be provided with each order of 200 ShangRing units. Additional sets can be purchased separately.
Measuring Tape	200 pieces will be provided with each order of 200 ShangRing units. Additional units can be purchased separately.

Items required but not provided

- General Hospital Supplies
- Local Anesthetic
- Povidone-Iodine
- Instruments

Storage:

- Store the ShangRing in its original package under controlled environmental conditions with $\leq 80\%$ relative humidity.
- 5 to ≤ 50 °C.

Shelf-life:

3 years.

Warnings:

- Do not use if the patient is allergic to silicone or Lexan (polycarbonate).
- The ShangRing is supplied sterile and is intended for single use. Do not reuse.
- Do not use if the package has been opened, damaged or broken. Do not re-sterilize.
- Do not use the ShangRing if the date of use is beyond the expiration date printed on the packaging.
- While the ShangRing is in place or after its removal all patients should be advised to contact the health care provider in the event of any of the following to prevent the occurrence of serious post-operative complications:

- Severe penile edema
 - Any bleeding
 - Difficulty urinating
 - Increasing pain or redness
 - Bruising (discoloration of the area around the wound); in general, bruising or discoloration will gradually fade after removal of the ShangRing.
 - Fever or the appearance of pus or discharge from the wound.
- Additionally, patients should be advised not to apply ointment or cream, or any traditional medicines/home remedies such as soil, ashes or animal dung on or around the circumcised area.

Special warnings:

- This device is only intended for single use, and any negative medical consequences due to its reuse are not the liabilities of the manufacturer.
- This device has been sterilized by gamma-irradiation and has a shelf life of three years.
- This device is protected by international patent law. Any unauthorized reproduction or counterfeit will be prosecuted.

Precautions:

- The patient should not remove or try to reposition the ShangRing
- Strenuous physical activity and all sexual activity (including masturbation) should be avoided while the ring is in place. Sexual activity (including masturbation) should be avoided for six weeks after the ShangRing has been removed in order to allow time for complete healing.
- The penis and genitalia should be kept clean and dry while the ShangRing is in place. After the day of circumcision, the patient may shower while the ShangRing is in place as long as the penis and ShangRing are carefully dried afterwards. Swimming and washing in a bathtub should be avoided.

Contraindications:

- The ShangRing should not be used if any of the following conditions are present: urinary tract infection, active genital infection (including warts on the glans or the inner surface of the foreskin), anatomic abnormalities of the penis (including moderate/severe hypospadias and epispadias), known bleeding diathesis, or any other condition precluding genital surgery.
- The ShangRing can be used in males with adhesions, tight foreskin or frank phimosis but only with injectable anesthesia. A dorsal slit may be required in order to permit

insertion of the inner ring, and/or eversion of the foreskin over the inner ring in case of flip technique.

For more details, please refer to the current version of manufacturer's instructions for use.

Prioritization for prequalification

Based on the established eligibility criteria, ShangRing device was given priority for WHO prequalification assessment.

Product dossier assessment

Wuhu Snnda Medical Treatment Appliance Technology Co. Ltd. submitted a product dossier for ShangRing as per the *"Instructions for compilation of a product dossier"* (PQMC_018 v1). The information submitted in the product dossier was reviewed by WHO staff and external experts (assessors) appointed by WHO in accordance with the *"Internal report on the screening and assessment of a product dossier"* (PQMC_009 v1). Based on the product dossier screening and assessment findings, a recommendation was made to accept the product dossier for ShangRing for prequalification.

Commitments for prequalification:

1. Conduct real time stability studies (at 5 °C and 50 °C) that will start January 2015 for 4 years. An annual status report will be submitted to PQ commencing January 2016, and within one month of finalization of the study.
2. Transportation studies must be undertaken. A status report will be submitted to PQ commencing January 2016, and within one month of finalization of the study. Evidence of the study implementation is under review.

All the commitments were fulfilled and closed.

Manufacturing site inspection

A comprehensive inspection was performed at the site of manufacture (4F Overseas Student Pioneer Park Science Innovation Center Economic & Technology Zone North Yinhu Road Wuhu, China) of the ShangRing male circumcision devices between 19-21 June 2019 as per the *'Information for manufacturers on prequalification inspection procedures for the sites of manufacture of male circumcision devices'* (PQDx_014 v4).

The inspection found that the manufacturer had an acceptable quality management system and good manufacturing practices in place that ensured the consistent manufacture of a

product of good quality. The manufacturer's responses to the nonconformities found at the time of the inspection were accepted on 15 October 2019.

Clinical study

The WHO Technical Advisory Group (TAG) on Innovations in Adult Male Circumcision concluded that the range and scope of clinical studies met the WHO requirements for evaluation of a new device; and demonstrated that, for the purposes of HIV prevention, the ShangRing device can efficaciously and safely circumcise healthy males aged 13 years and over, when used by suitably trained providers, and when skills and surgical facilities are available to safely convert technical failures of device placement to surgical procedures. Effective training resources for health care providers should be available. Men and adolescents (and caregivers) should receive accurate information on safe device use and care while wearing. This conclusion is time-limited and must be reassessed in one – two years when more experience with use of the device in non-research settings and data are generated to further inform safe use.

Studies reviewed:

Five studies from 3 African countries satisfactorily met the criteria in the “*WHO Framework for Clinical Evaluation of Devices*”; these studies included only healthy males 18 years and older and the device was placed successfully on 1983 eligible men. Two additional studies from Kenya and Uganda provided data on use of the ShangRing among 13 – 17 year old males. The 354 placements in adolescents exceeded the minimum sample size of bridging studies defined in the “*Framework*”.

The manufacturer of the ShangRing device requested changes to the placement procedure which included the no-flip technique as an alternative to the standard method of everting the foreskin during device placement, use of topical as an alternative to injectable anaesthesia, extending use down to age 10 years from the current lower age limit of 13 years, and reducing the number of device sizes. The changes were supported by clinical evidence from two study phases conducted under a single protocol ‘Simplifying the ShangRing Technique for Circumcision of Men and Boys’ conducted in Kenya.

Assessment of data supporting the no-flip technique indicated that the technique has similar efficacy, safety and acceptability as the standard technique, and may offer some advantages in terms of ease of placement and simplicity of training.

Device use:

Eligible: ages ≥ 13 years with the flip technique or the no-flip technique, and ages 10 – 12 years only with the no-flip technique; without contraindications to conventional male circumcision surgery, and additionally, without contraindications specific to ShangRing device such as minor foreskin abnormalities (for example short frenulum). Among males on whom the device was placed, 99% had a successful circumcision. The resulting wound line for all men was without suture marks. Some clients with moderate or severe phimosis required a small dorsal slit to be made in the foreskin to facilitate eversion over the inner ring of the device.

Requirements for device use:

At least two visits are required - one to place and one to remove the device.

- Placement: adequate supply of device sizes plus accessory supplies and two trained providers; sterile procedure; injectable anesthesia; and facilities and staff experienced in standard surgical circumcision immediately available on site, together with appropriate instruments and supplies to safely convert to and complete a conventional surgical circumcision in rare cases when device placement cannot be completed.
- While wearing the device for 1 week: analgesia as needed, and access to health care to manage device problems.
- Removal: requires a clean setting and accessory equipment. The ShangRing opener is included in the manufacturer's supplies, however, other accessory supplies and equipment are provided by the manufacturer. Tools and equipment should be reprocessed or discarded as per manufacturer instructions for use. If the device is not removed as scheduled at seven days, the device begins to detach spontaneously and may come off without removal by a medical provider. As such partial detachments appear to be painful and can cause discomfort or bleeding if the partially detached device snags or causes tearing of tissue, the device should ideally be removed at seven days.

Healing, safety and discomforts:

Healing occurs by secondary intention. Healing time appears to be about one week longer than following conventional surgical circumcision. In a small number of men (<1%) in whom the device placement procedure was started, it could not be completed; in this instance the procedure was immediately converted to conventional surgical circumcision by appropriately skilled, on-site providers.

Adverse events:

All adverse events observed in studies were reviewed and classified by the TAG in a uniform manner, guided by internationally recognized principles and definitions of adverse events

(AEs) and serious adverse events (SAEs) (Global Harmonization Task Force) which differed somewhat from the definitions and classification used by study investigators. AEs associated with ShangRing procedures were rare. In a total of 2337 successful device placements, there were no deaths or SAEs. The most common AEs were related to pain and a small number of wound disruptions, swelling or bleeding events. All AEs were managed with, at most, minor intervention and resolved with no long-term sequelae. The AE rate was lower among men who had ShangRing circumcision than among men who had conventional surgery, but this difference was not statistically significant.

Client information must clearly indicate that once placed, the device must remain for seven days; in case a client desires to remove the device, clients should be instructed to return to the clinic. Clients must also be instructed on safe behaviours while the device is worn, including avoidance of sexual activity and masturbation and the possibility of pain while wearing the device.

Labelling

- 1. Labels**
- 2. Instructions for use¹**

¹ English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages

Instructions for use

Instructions for Use of ShangRing™

Model: Generation II, Self-locking

Version 2.0 (Outside the U.S.A.)

Release Date: August 28, 2019

Regulatory Statement

CAUTION: For professional use only.

Indications for Use

The ShangRing™ device is indicated for male circumcision, defined as removal or excision of the foreskin or prepuce. The ShangRing is indicated for use in adolescent and adult males, specifically:

- ages ≥ 13 years with the flip technique or the no-flip technique, and
- ages 10 – 12 years **only** with the no-flip technique.

Local anaesthesia is necessary for all clients. Topically applied EMLA cream is an alternative to injectable anaesthesia, but only in clients who do not have foreskin conditions (phimosis and/or adhesions) and only with the no-flip technique.

Intended Users

Healthcare providers are medical professionals and can include medical doctors, nurses and clinical officers.

Device Description

The ShangRing™, manufactured by Wuhu SNNDA Medical Treatment Appliance Technology Co., LTD., Wuhu, Anhui Province, China, is a sterile, single use, disposable male circumcision device that consists of two concentric plastic rings, the inner of which is lined by a silicone pad. The ShangRing™ is available in 32 sizes (A4 to Z2), with inside diameters of 40mm to 9mm (see Table 1). Hemostasis is achieved by the pressure applied by the interlocking rings which minimizes bleeding and eliminates the need for sutures.

The figures below show the ShangRing™ in the open position and Micro-dots, Figure 1, and in the closed/locked position, Figure 2.

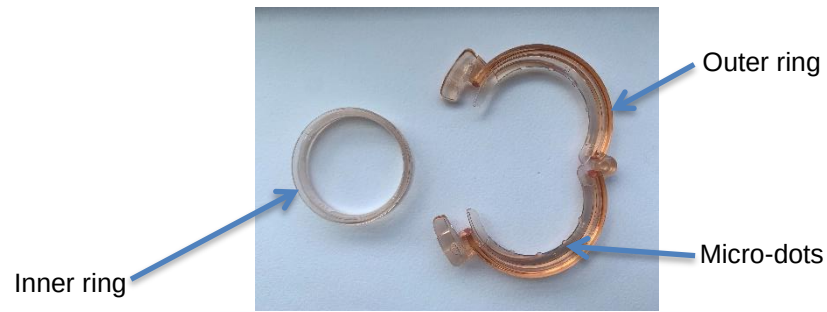


Figure 1

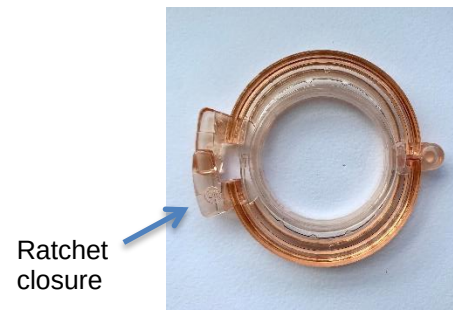


Figure 2

Table 1: ShangRing Sizes

Shang Ring size	Product Code	Inner diameter of inner ring (mm)	Shang Ring size	Product Code	Inner diameter of inner ring (mm)
A4	SR-II-40	40	M	SR-II-24	24
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K	SR-II-26	26	Z1	SR-II-10	10
L	SR-II-25	25	Z2	SR-II-9	9

A summary of accessories and equipment to be used with the ShangRing is provided below in Table 2.

Table 2: ShangRing Accessories

Accessory	Provided/Not provided
Bandages	1400 pieces will be provided with each order of 200 ShangRing units. Additional pieces can be purchased separately.
Removal Cutter and Removal Key	4 sets will be provided with each order of 200 ShangRing units. Additional sets can be purchased separately.
Measuring Tape	200 pieces will be provided with each order of 200 ShangRing units. Additional units can be purchased separately.
General Hospital Supplies	Not provided
Local Anesthetic	Not provided
Povidone-Iodine	Not provided
Instruments	Not provided

The measuring tape is supplied with the ShangRing™ device. Bandages, removal cutter, and removal key opener are sold separately. Although bandages can be purchased from Wuhu SNDA for use with the ShangRing™, any general surgical dressing can be used. General hospital supplies (e.g., gloves, gowns, etc.), local anesthetic, and instruments (e.g., hemostatic clamps, surgical scissors) are not supplied with the ShangRing.

Figure 3 shows the removal cutter and removal key opener.

Figure 4 shows the measuring tape.

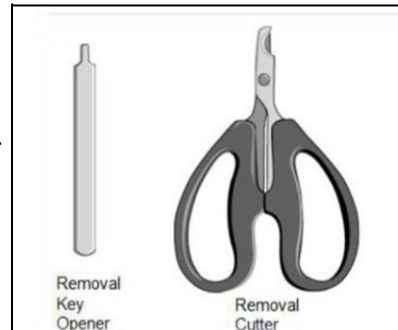


Figure 3

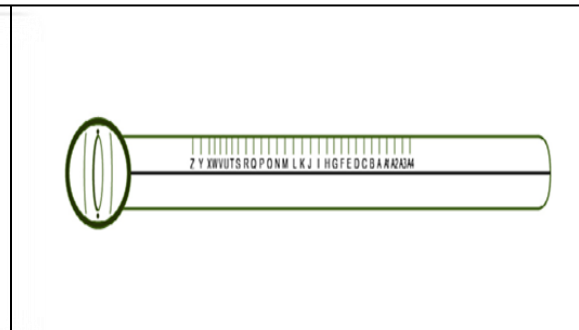
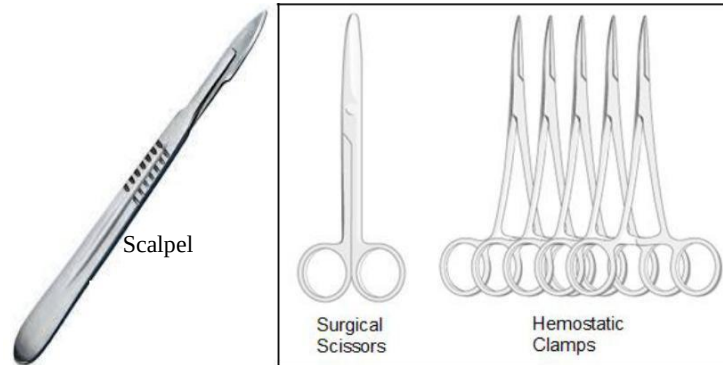


Figure 4

Figure 5 shows the surgical scissors, hemostatic clamps, and scalpel.

Figure 5



The plastic disposable measuring tape is a single-use item that is used to select the appropriately sized ShangRing™ device. The measuring tape is supplied non-sterile and does not need to be sterilized prior to patient use.

The instruments used for placement of the ShangRing™ (e.g., hemostatic clamps, surgical scissors) must be cleaned and sterilized prior to each patient use.

The removal cutter and removal key opener are used to remove the ShangRing™, if necessary. The removal cutter is a blunt-end scissor and the removal key opener is similar to a 1/8 inch (or 3mm) flat bladed screwdriver. Both the removal cutter and removal key opener (sold separately) are reusable. These removal tools must be cleaned and sterilized or cleaned and disinfected prior to each patient use.

Possible Side Effects

Mild to moderate penile edema may be experienced while the ShangRing is in place, usually restricted to the skin adjacent to the ShangRing. In general, this should be managed conservatively (i.e. without antibiotics) since the swelling resolves after removal of the ShangRing.

Wound separation may be seen before or after removal of the ShangRing. In most cases, this should be managed conservatively (i.e. without antibiotics or suturing). A mean healing time of 43 days post-device placement was observed in clinical evaluation of adults.

If active bleeding is noted upon placement or after removal of the ShangRing, pressure can be applied on the bleeding point, and if necessary, a suture can be applied for hemostasis.

Bruising, or discoloration of the area around the wound, may be observed. In general, bruising or discoloration will gradually fade after removal of the ShangRing.

Infection – surgical site infection is rare, and the risk is minimized by proper sterile technique. Exudate may build up around the wound during the healing process.

Circumcision has been associated with a number of serious anaerobic infections such as cases of *Clostridium tetani* which can result in serious complications.

In case of serious side effects; all events will be reported to the manufacturer and appropriate medical authorities.

Warnings

Do not use if the patient is allergic to silicone or Lexan (polycarbonate).

The ShangRing™ is supplied sterile and is intended for single use. Do not reuse.

Do not use if the package has been opened, damaged or broken. Do not re-sterilize!

Do not use the ShangRing™ if the date of use is beyond the expiration date printed on the packaging.

While the ShangRing™ is in place or after its removal all patients should be advised to contact the health care provider in the event of any of the following to prevent the occurrence of serious post-operative complications:

- Severe penile edema
- Any bleeding
- Difficulty urinating
- Increasing pain or redness
- Bruising (discoloration of the area around the wound); in general, bruising or discoloration will gradually fade after removal of the ShangRing™.
- Fever or the appearance of pus or discharge from the wound.

Additionally, patients should be advised not to apply ointment or cream, or any traditional medicines/home remedies such as soil, ashes or animal dung on or around the circumcised area.

Precautions

The patient should not remove or try to reposition the ShangRing™. Strenuous physical activity and all sexual activity (including masturbation) should be avoided while the ring is in place. Sexual activity (including masturbation) should be avoided for six weeks after the ShangRing™ has been removed in order to allow time for complete healing. The penis and genitalia should be kept clean and dry while the ShangRing™ is in place. After the day of circumcision, the patient may shower while the ShangRing™ is in place as long as the penis and ShangRing™ are carefully dried afterwards. Swimming and washing in a bathtub should be avoided.

Contraindications

The ShangRing™ should not be used if any of the following conditions are present: urinary tract infection, active genital infection (including warts on the glans or the inner surface of the foreskin), anatomic abnormalities of the penis (including moderate/severe hypospadias and epispadias), known bleeding diathesis, or any other condition precluding genital surgery. The ShangRing™ can be used in males with adhesions, tight foreskin or frank phimosis **but only with injectable anesthesia**. A dorsal slit may be required in order to permit insertion of the inner ring, and/or eversion of the foreskin over the inner ring in case of flip technique.

Storage

Store the ShangRing™ in its original package at 5 °C to 50 °C, humidity up to 80%. Do not expose the ShangRing™ to temperatures above 50 °C.

Determining ShangRing Size

Penile circumference is measured using the ShangRing™ measuring tape to determine the appropriate ShangRing™ size needed. The measuring tape is intended for single use and should be discarded following use on a single patient. To measure the correct size of the ring, the measuring tape is wrapped around the shaft of the penis, just below the level of the coronal sulcus. The size is read through a window on the tape. Note: The penis should be measured in the flaccid state (**Figure 6**).

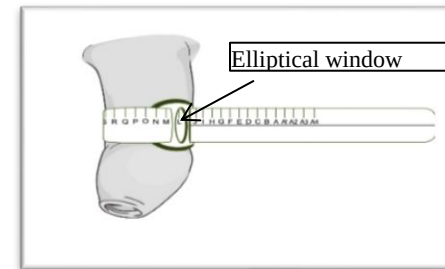


Figure 6

The measuring tape was designed for use with the flip ShangRing technique, where the inner ring is on the outside of the foreskin. With the no-flip technique, the inner ring is placed inside the foreskin. To avoid having to retract the foreskin to determine the correct ShangRing size for the no-flip technique, the provider must subtract one size from what is measured, using the next smallest size.

Take care not to make the fit too tight or too loose. Should the reading through the window on the tape fall between two sizes, the smaller size should be chosen. Note: Choosing the correct size can help minimize pain from nocturnal erections. A randomized controlled trial in 2016 has demonstrated that it is safe to use one size smaller than the measured size, so in circumstances where stock out occurs, using one size down has been shown to be safe and acceptable and could be used as an alternative when the best measured size is not available. Be careful to record the best measured size and the actual size used for the particular client and report to the manufacturer any adverse events which occur with that client.

Preparing for ShangRing Placement

The following measures must be carefully followed to minimize the risk of infection and to ensure proper infection control:

All healthcare providers to be involved in the procedure **must practice hand hygiene by using alcohol hand rub or another suitable method**. Sterile gloves should be worn; however, there is always a possibility that a glove will be accidentally punctured. If this happens during an operation, promptly remove the glove, rinse the hand with antiseptic, and put on a new sterile glove.

If the glove has leaked as a result of the puncture, re-scrub before putting on new gloves (WHO, 2009).

Before eating and after using a restroom, wash hands with a non-antimicrobial soap and water or with an antimicrobial soap and water (CDC, 2002).

Standard surgical protocol on skin preparation (i.e. disinfection of the genital area) should be carried out prior to performing the procedure and after carefully following the measures above.

Patient Preparation

After taking all appropriate infection control measures and hand hygiene has been completed, prepare the patient for placement of the ring by administering local anesthesia.

Local anesthesia:

Local anesthesia may be administered using either an injectable anesthetic or a topical anesthetic cream. The choice of which type of local anesthesia to use should be guided by local Ministry of Health guidelines, organization policies, and product availability. Instructions for each method are described below.

1. Topical anesthesia:

- Only to be used with the no-flip technique.
- Only to be used in clients who do not have adhesions and/or phimosis.

Anesthetic cream containing 2.5% lidocaine and 2.5% prilocaine provides safe and effective local anesthesia when used with the no-flip technique. To date, topical anesthesia has not been studied with other topical agents. The anesthetic cream should be liberally applied around and inside the foreskin (**Figure 7**), as well as over the glans if the foreskin can be retracted (**Figure 8**).

If available, a “dolphin nose” adapter can be used to ensure proper application of the cream inside the foreskin (**Figure 9**).

If one is not available, anesthetic cream can be put into a small syringe (without a hypodermic needle), which will facilitate application inside the foreskin (**Figure 10**).

Anesthetic cream should be applied to the outside of the penis from the tip of the foreskin all the way down to the base of the shaft (**Figure 11**). After application, the provider’s glove may be left inside-out over the penis and the anesthetic should be left for at least 25-30 minutes before beginning to test for anesthetic effectiveness.

In the case topical anesthesia did not provide a sufficient anesthetic effect, injectable anesthetic may be used to achieve a full effect. **Supplemental injectable anesthesia must always be available when using topical anesthesia.**

Once the desired anesthetic effect has been achieved, remaining anesthetic cream should be wiped off, and standard surgical protocols on skin preparation should be used.

- Disinfection of the genital area, the penis and the area under the retracted foreskin with an appropriate disinfectant (e.g. povidone-iodine), unless allergy is known, with at least 3 skin paint applications; waiting 2 minutes before device placement.

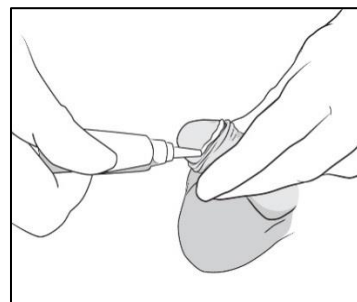


Figure 7

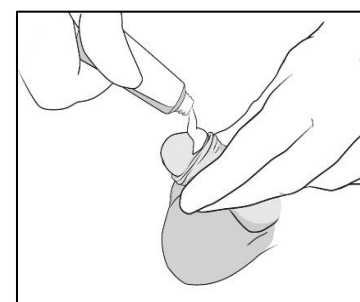


Figure 8

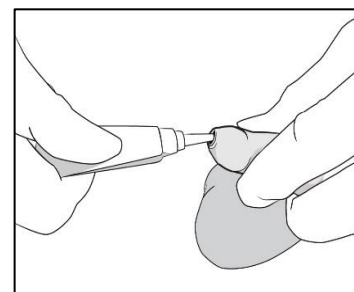


Figure 9

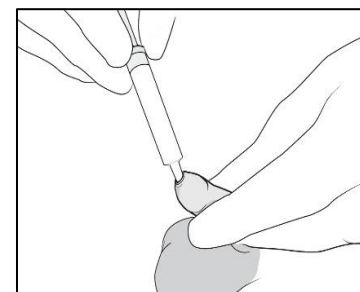


Figure 10

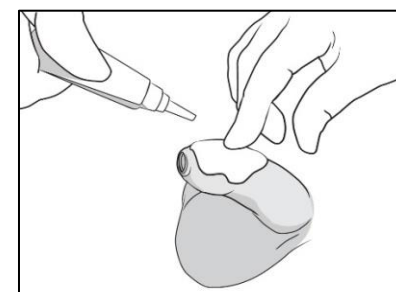


Figure 11

2. Injectable anesthesia:

Before the anesthetic is injected, standard surgical protocols on skin preparation should be used.

- Disinfection of the genital area, the penis and the area under the retracted foreskin with an appropriate disinfectant (e.g. povidone-iodine), unless allergy is known, with at least 3 skin paint applications; waiting 2 minutes before device placement.

The solution used for injectable anesthesia can be either plain lidocaine or a mixture of lidocaine and bupivacaine. See Table 3 below, extracted from the Manual for male circumcision under local anaesthesia and HIV prevention services for adolescent boys and men. Geneva: WHO; 2018, for dosage recommendations for plain lidocaine solution without epinephrine for adolescent and adult males). After administering the local anesthetic, massage around the base of the penis to facilitate spread and uptake. Wait 3-5 minutes, and then test all 4 quadrants for pain before starting the procedure to ensure effective anesthesia.

Table 3: Examples of Starting and Maximum Safe Volume of Plain Lidocaine*

Patient (Weight)	1% Lidocaine (10 mg per ml**)		2% Lidocaine (20 mg per ml**)	
	Starting volume	Maximum safe volume	Starting volume	Maximum safe volume
20-29 kg	4 ml	Additional 2 ml to TOTAL of 6 ml	2 ml	Additional 1 ml to TOTAL of 3 ml
30-39 kg	6 ml	Additional 3 ml to TOTAL of 9 ml	3 ml	Additional 1 ml to TOTAL of 4 ml
40-50 kg	8 ml	Additional 4 ml to TOTAL of 12 ml	4 ml	Additional 2 ml to TOTAL of 6 ml
More than 50 kg	10 ml	Additional 5 ml to TOTAL of 15 ml	5 ml	Additional 2 ml to TOTAL of 7 ml

*starting dose 2 mg/kg body weight; maximum safe dose 3mg/kg body weight

** 1 ml = 1 cc

A 50-50 mixture of 2% lidocaine and 0.5% bupivacaine without epinephrine can also be used. Independent of the type of anesthetic chosen for local anesthesia, epinephrine (adrenaline) should NOT be included. See the Manual for male circumcision under local anaesthesia and HIV prevention services for adolescent boys and men. Geneva: WHO; 2018, for complete dosage recommendations and warnings.

There are two primary techniques for the administration of injectable local penile anesthesia: the dorsal penile nerve block and the circumferential ring block.

- For the penile nerve block technique, the anesthetic is injected at the 1 o'clock and 11 o'clock positions, along the dorsal penile nerves to achieve a penile block.
- For the circumferential ring block technique, the anesthetic is injected circumferentially around the base of the penis, between the superficial (dartos) fascia and deep (Buck's) fascia. To achieve good anesthesia, it is necessary to ensure that a complete circumferential block is achieved (**Figure 12**).

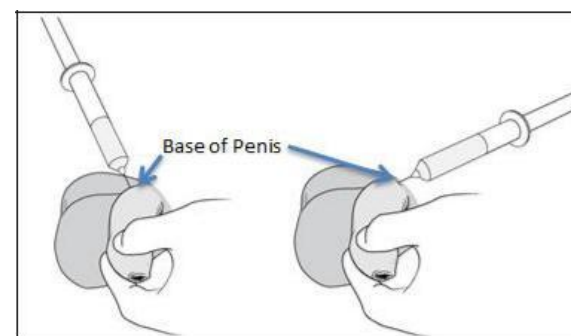


Figure 12

Flip ShangRing technique

Placing the ShangRing:

After the local injectable anaesthesia has taken effect, the inner ring is placed below or proximal to the level of the coronal sulcus. Using clamps at the 3, 6, 9, and 12 o'clock positions, the foreskin is then everted (turned inside out) over the inner ring, see Figures 13-16.

Figure 17 shows the completion of the placement of the inner ring.

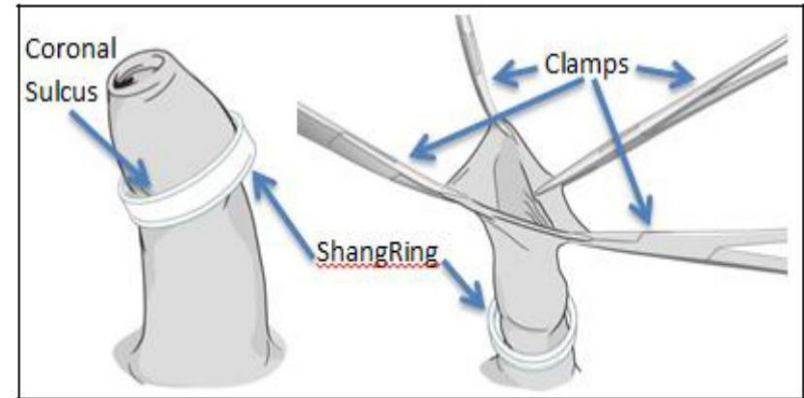


Figure 13

Figure 14

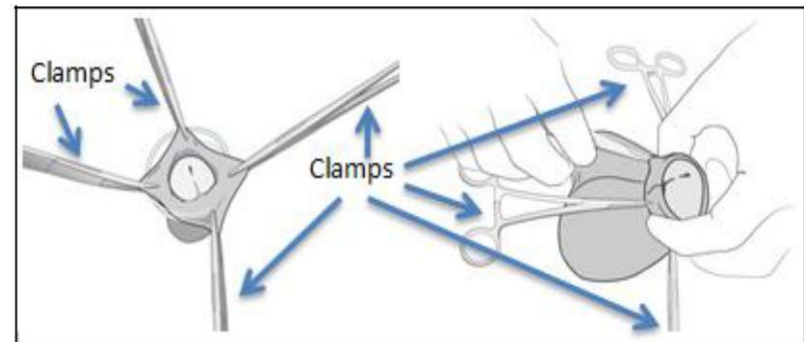


Figure 15

Figure 16

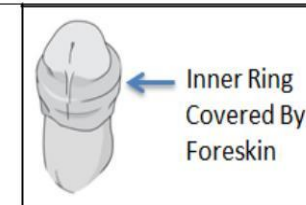


Figure 17

For men with a tight foreskin or frank phimosis, a dorsal slit may be required in order to permit eversion of the foreskin over the inner ring (**Figure 18**). Prior to cutting the skin, brief application of a clamp to crush the skin where the cut is to be made should be performed to minimize bleeding.

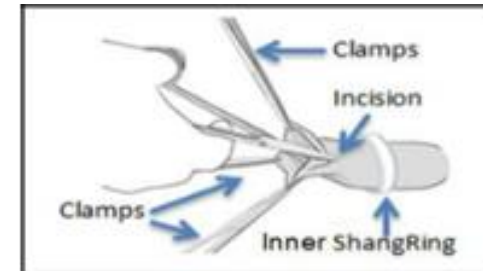


Figure 18

The outer ring is then secured over the inner ring, sandwiching the foreskin in-between the two rings (**Figure 19**). After engaging the first ratchet of the outer ring, the position of the foreskin may be adjusted to ensure the proper placement of the device.



Figure 19

Before engaging the second ratchet, gently pull on the skin of the shaft of the penis, and then gently pull on the foreskin, to make sure that there are no extra folds of skin caught between the two rings that might result in cutaneous pinches. Make sure that the inner ring is still in the proper location, which is right under the coronal sulcus.

The second ratchet of the outer ring is then engaged to complete the closure of the outer ring (**Figure 20**)



Figure 20

Excess foreskin is excised using a scalpel (**Figure 21**). Make 6 to 10 nicks on the incision line (**Figure 22**) using the scalpel to prevent formation of a constricting circumferential scab while the ShangRing is in place and to allow for adequate elastic expansion of the scab during erections after removal of the ShangRing.

After excising the foreskin, inspect the underside of the ShangRing interface in order to identify any extraneous skin that may be pinched between the rings. If pinched skin is identified, gently pull on the skin below the ring to free the pinched skin.

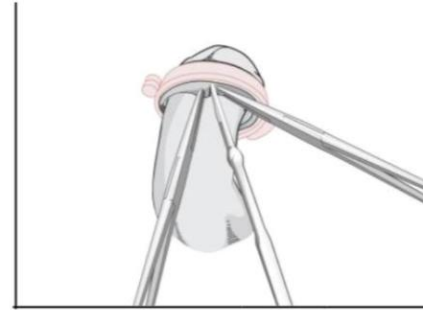


Figure 21

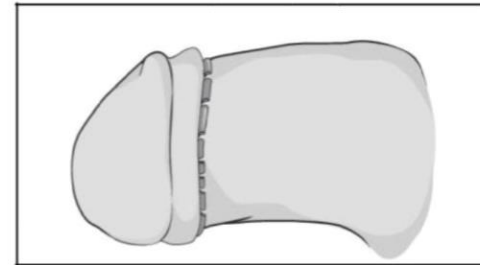


Figure 22

No-Flip ShangRing Technique

Placing the ShangRing:

It may be first necessary to break down adhesions, between the glans penis and the inner surface of the foreskin. If necessary, adhesions can be carefully broken down by inserting a closed hemostat between the foreskin and glans, and then spreading open the blades of the hemostat (**Figure 23**). This can only be done with the use of injectable anaesthesia. If adhesions and phimosis are present, then topical anaesthesia should not be used

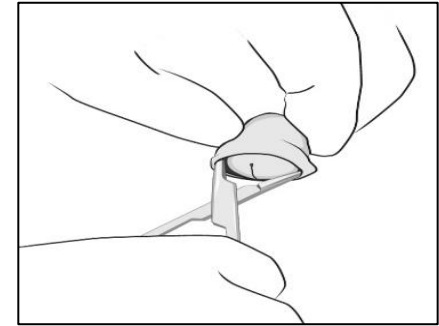


Figure 23

Working with an assistant, grasp the foreskin with hemostat clamps at the 3 o'clock and 9 o'clock positions, approximately 0.5 to 1cm from the edges of the foreskin (**Figure 24**).

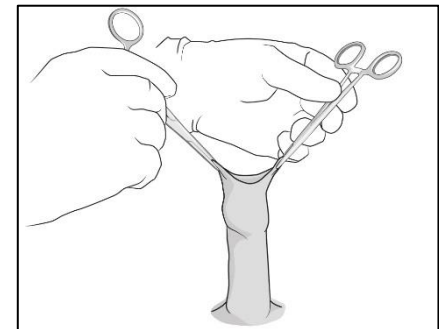


Figure 24

For boys and men with a tight foreskin or frank phimosis, a dorsal incision of about 1 cm may be required in order to permit insertion of the inner ring. Prior to cutting the skin, brief application of a clamp to crush the skin where the cut is to be made should minimize bleeding (**Figures 25 & 26**).

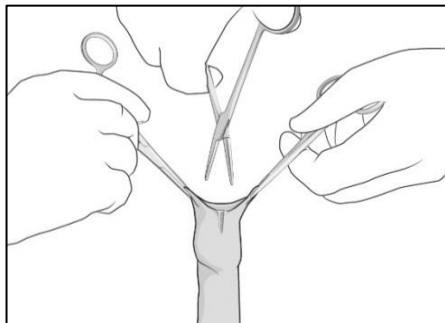


Figure 25

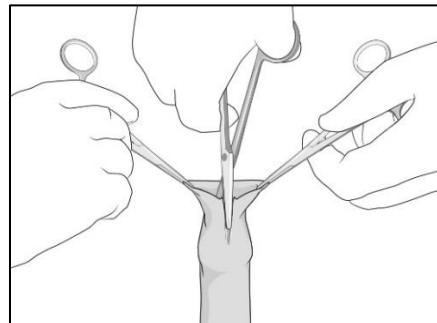


Figure 26

Once glandular adhesions have been broken down if necessary, the inner ring of the ShangRing is inserted under the foreskin, at a 45-degree angle (**Figure 27**), side view (**Figure 28**). The inner ring should be adjusted to have a horizontal position near the frenulum (**Figure 29**).

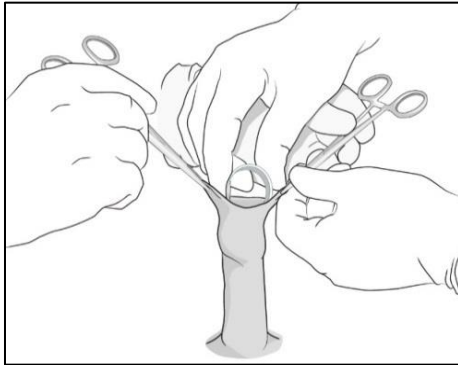


Figure 27

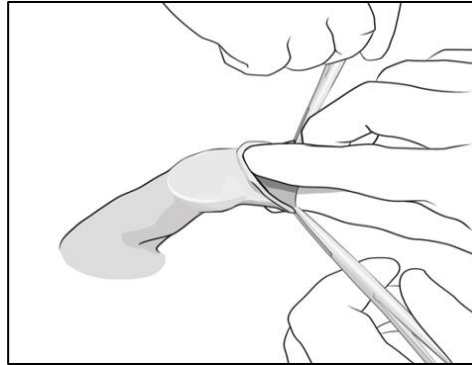


Figure 28

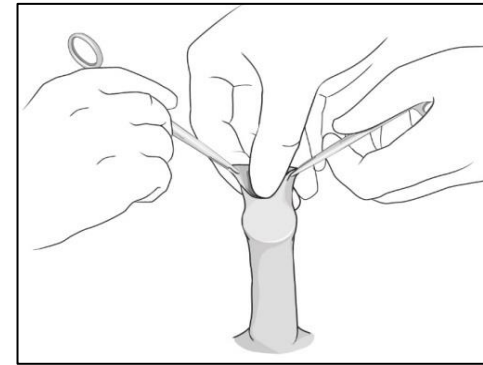


Figure 29

The outer ring is then placed over the inner ring, sandwiching the foreskin in-between the two rings (**Figure 30**). After engaging the first ratchet of the outer ring, the position of the foreskin may be adjusted to ensure the proper placement of the device.

Make sure that the inner ring is still in the proper location, which is right under the coronal sulcus.

Once the provider is satisfied with positioning, the outer ring is clamped to its second position, to close the ring, securing a hemostatic occlusion of the foreskin between the inner and outer rings.



Figure 30

The foreskin distal to the ShangRing™ is then excised using curved iris scissors, with care taken to protect the glans. The assistant should place gentle tension on the foreskin as it is being excised (**Figure 31**).

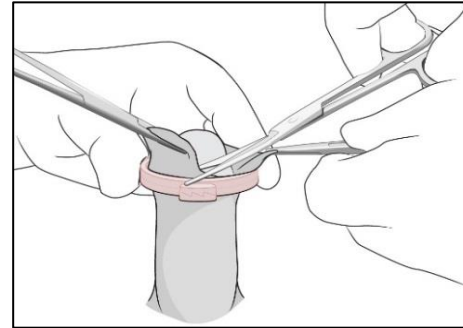


Figure 31

The wound should be cleaned with povidone iodine (**Figure 32**) and checked to ensure there is hemostasis.

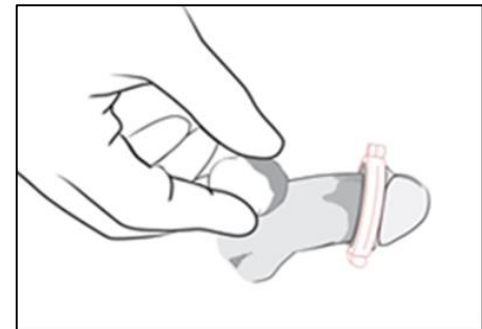


Figure 32

Figure 33 shows the completed ShangRing™ circumcision procedure.

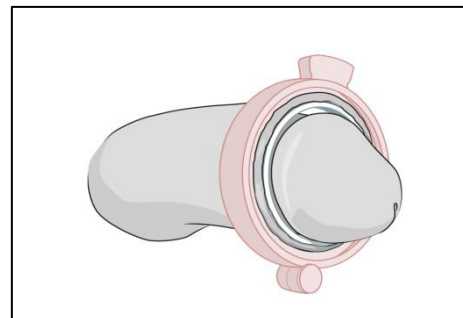


Figure 33

Removing the ShangRing

- It is recommended and is the standard of care that the ShangRing device is removed by the healthcare provider 7-10 days following circumcision.
- However, in circumstances where the client did not return for removal, evidence shows that the device will safely detach on its own within 21 days of circumcision.

A clean pair of examination gloves should be used by the healthcare provider during this procedure. Before initiating the removal of the outer ring, spray 1%-2% lidocaine (**Figure 34**) to the area around the wound and leave for approximately 1-2 minutes to take effect. Alternatively, normal saline solution can be used to moisten the area around the wound.

Break the ratchet closure of the outer ring using the removal key opener. Insert the tip of the removal key opener into the 'key hole' located on the hinge of the outer ring and twist or bend the removal key opener while firmly holding the outer ring (**Figure 35**). This will break the ratchet, allowing for easy removal of the outer ring (**Figure 36**).

Before removing the inner ring, 1%-2% lidocaine or normal saline solution may again be sprayed to the area around the wound.

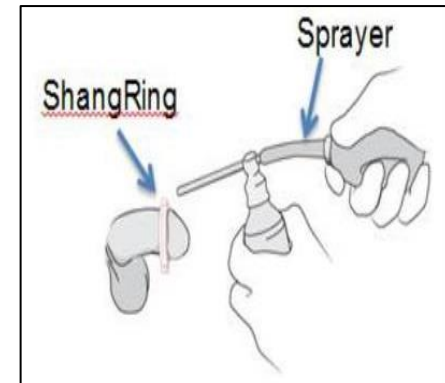


Figure 34

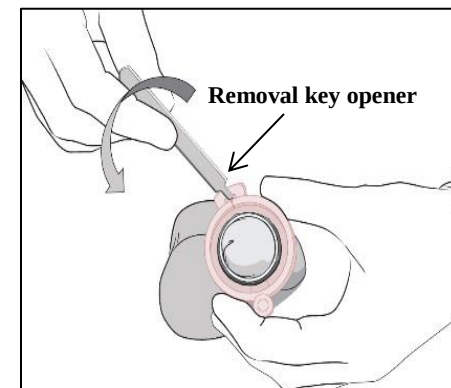


Figure 35

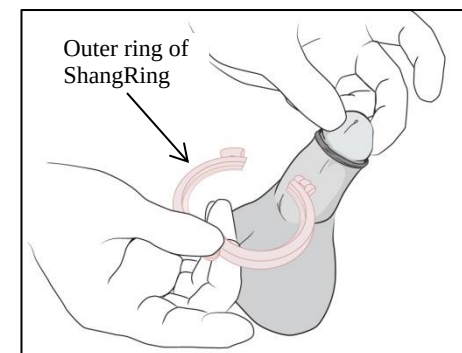


Figure 36

To remove the inner ring, grasp the edge of the inner ring firmly with toothed tissue forceps or your fingers and gently pull the inner ring back from the edge of the wound (**Figure 37**). Be gentle, as this may cause some brief discomfort and pain.

In most cases, it is not necessary to cut the inner ring when removing the ShangRing after a no-flip circumcision as the inner ring easily slips over the glans and off the penis.

Alternatively, the inner ring is cut at two points opposite each other, e.g. the 6 and 12 o'clock positions, using the removal cutter (**Figure 38**). Once cut, the inner ring should be disposed of.

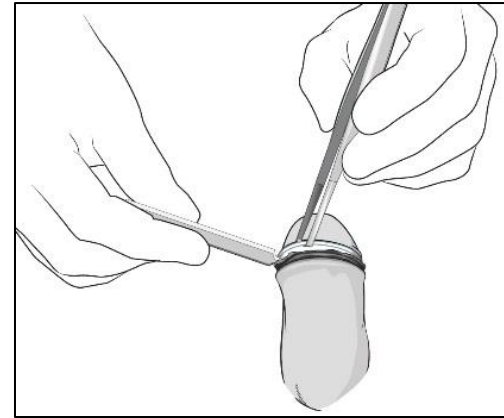


Figure 37

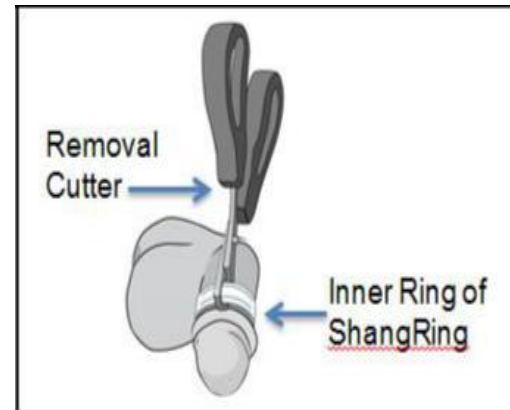


Figure 38

Post-Removal of Device

The healthcare provider should cover the wound with a bandage (**Figure 45**). Additional bandages should be provided to the patient to take home.

The health care provider should instruct the patient as follows: Keep the bandage clean and dry. Keep the circumcised area clean and dry and maintain good hygiene. In the event that the bandage does get wet, replace the bandage immediately. Replace with a new bandage in the morning and repeat for one additional day. On the third day, wash the penis and the wound area normally.

Finally, the healthcare provider should provide a copy of the “Post-Operative Instructions” for the patient to take home.

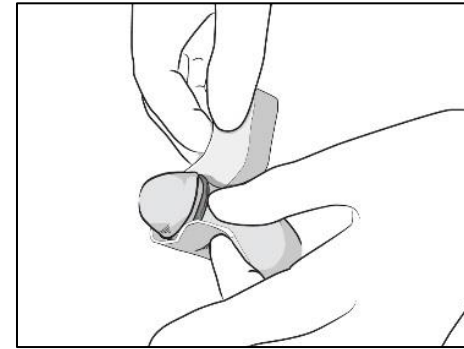


Figure 39

Cleaning and Disposal of the ShangRing and Other Equipment

Cleaning: Reusable surgical instruments used during the procedure must be cleaned and sterilized prior to each patient use. The removal cutter, removal key opener used during the removal procedure must be cleaned and disinfected prior to each patient use.

Disposal: The measuring tape and the ShangRing should be disposed of after use. Please follow your healthcare facility’s instructions for disposing of hazardous medical waste. If there are no such policies, please dispose in designated waste containers.

References

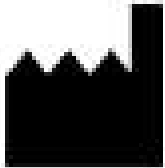
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Additional Instructions for Health Care Providers

Device Malfunctions and Adverse Events

Please report any device malfunctions, complaints, problems using the device, and any serious or unexpected adverse events to the manufacturer as soon as possible. Make sure to follow your national medical device adverse event reporting requirements.

Manufacturer



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Technology Co., Ltd. 4F Overseas Student
Pioneer Park
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E-mail: admin@snnda.com

Postoperative Instructions

Health Care Providers to Instruct Patients

Note to the health care provider: Please provide a copy of the instructions for the patient to take home.

Wearing the ShangRing™

1. It is recommended that you rest at home until you have gotten used to the ShangRing being in place.
2. Do not try to remove or reposition the ShangRing™ yourself, and keep the penis clean and dry.
3. After the day of circumcision, you may shower while the ShangRing™ is in place as long as afterwards you carefully dry by gentle dabbing the penis and ShangRing. Do not go swimming or wash in a bathtub.
4. Do not take part in any intensive activities to avoid the dislocation of the ring. In the case of heavy sweating, be sure to keep the penis and surrounding area dry.
5. DO NOT HAVE SEX (INCLUDING MASTURBATION) while the ShangRing™ is in place.
6. Try not to allow your penis to dangle freely. Tightly fitted briefs are recommended in order to keep the penis facing up and to keep the ring in place and avoid skin abrasion.
7. In the event that you experience mild pain (including during an erection), especially in the first few days after the circumcision, over-the-counter pain medications such as paracetamol (acetaminophen), naproxen or ibuprofen can be used for pain relief. If the pain is excessive, contact your health care provider for further advice.
8. Keep the circumcised area clean and dry. This will promote proper healing. When urinating, use a piece of toilet paper or cloth to prevent urine from seeping into the circumcision area, possibly resulting in infection.
9. Do not apply ointment or cream, or any traditional medicines/home remedies such as soil, ashes or animal dung on or around the circumcised area.
10. If your health care provider advises, you may clean any secretions around the ShangRing™ with povidone iodine or other iodophore, and gently dry the circumcised area, before going to bed at night. This may prevent the wound tissue adhesion against the outer ring and reduce the pain when the ring is removed by the health care provider.
11. You may experience slight swelling around the ShangRing™. This is normal as long as it does not cause you too much discomfort. Wearing tightly fitted briefs to keep the penis facing up should help prevent swelling.
12. Return to your health care provider to have the device removed in seven days. Do not try to remove or reposition the ShangRing yourself.

After Removal of the ShangRing

1. Keep the bandage clean and dry and remove the bandage before going to sleep. In the event that the bandage does get wet, replace the bandage immediately. Replace the bandage in the morning after ring removal and repeat for one additional day. On the third day, you can wash the penis and the wound area normally.

2. Do not apply ointment or cream, or any traditional medicines/home remedies such as soil, ashes or animal dung on or around the wound after removal of the ShangRing.
3. DO NOT HAVE SEX (INCLUDING MASTURBATION) after the device is removed or falls off on its own until the wound is healed, which usually takes about seven weeks after ShangRing circumcision. If sexual intercourse is resumed before then, a condom is essential to protect the healing wound and prevent HIV transmission. Your health care provider will advise you about this during your follow-up visits. The World Health Organization recommends that you should use a condom when you have sexual intercourse to protect the circumcision wound for six months, even after it appears completely healed.

At Any Time

While wearing the ShangRing™ or after removal, contact your healthcare provider or visit the clinic --

1. If you notice bleeding from around the ShangRing™ or from the wound after ShangRing removal.
2. If you experience difficulty passing urine.
3. If you experience painful swelling, increasing redness, bruising (discoloration of the area around the wound), fever or appearance of pus or discharge from the wound.
4. If there is severe swelling around the ShangRing™, or around the area in which the ShangRing was placed which causes you discomfort.
5. If you experience excessive pain (including during an erection) while the ring is still in place.
6. If the ShangRing is damaged or comes off accidentally (partially or completely).

If you have any further inquiries, contact your health care provider at: _____.

Special Warnings

1. This device is only intended for single use, and any negative medical consequences due to its reuse are not the liabilities of the manufacturer.
2. This device has been sterilized by γ -ray and has a shelf life of three years.
3. This device is protected by international patent law. Any unauthorized reproduction or counterfeit will be prosecuted.

Device Malfunctions and Adverse Events

Please report any device malfunctions, complaints, problems using the device, and any serious or unexpected adverse events to your health care provider as soon as possible.

Index of Symbols

Symbol	Meaning
	Manufacturer
	Date of manufacture
	CE Mark
	Sterilized using irradiation
	Do not re-use
	Consult Instructions for Use
	Catalogue number.
	Temperature limitation
	Batch code (Lot)
	Do not use if package is damaged
	EC Representative
	Caution, consult accompanying documents
	Use by date