

WHO Prequalification of Male Circumcision Devices PUBLIC REPORT

Product: ShangRing™
Number: PQMC 0003-003-00

Abstract

ShangRing™ (Generation II, self-locking model) with product codes:

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.

manufactured by Wuhu Snnda Medical Treatment Appliance Technology Co. Ltd., USFDA 510(k) clearance regulatory version, was accepted for the WHO list of prequalified male circumcision devices and was listed on 3 June May 2015.

The ShangRing™ device is indicated for male circumcision, defined as circumferential excision of the foreskin or prepuce at or near the level of coronal sulcus. The ShangRing™ is indicated for use in adolescent and adult males ages 13 years and above.

The ShangRing™ 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 18 sizes (A4 to S), with inside diameters of 4.0 cm to 1.8 cm. Hemostasis is realized by the pressure applied by the interlocking rings which minimizes bleeding and eliminates the need for sutures.

The measuring tape is supplied with the ShangRing™. Bandages, removal cutter, and removal key opener, are sold separately. Although bandages can be purchased from Wuhu Snnda 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 assist in selecting the appropriate size ShangRing™. 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™. The removal cutter is a blunt end scissor and the removal key opener is similar to a 3 mm 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.

Storage:

Store the ShangRing™ in its original package under controlled environmental conditions with ≤80% relative humidity.

Do not expose the ShangRing™ to temperatures above 50 °C.

Shelf-life:

3 years.

Summary of prequalification status for ShangRing™

	Initial acceptance	
	Date	Outcome
Status on PQ list	5 June 2015	listed
Dossier assessment	15 January 2015 and 4 May 2015	MR
Inspection status	5 December 2014	MR
Clinical study	15 January 2015	MR

MR: Meets Requirements

NA: Not Applicable

ShangRing™ was accepted for the WHO list of prequalified male circumcision devices on the basis of data submitted and publicly available information.

Background information

Wuhu Snnda Medical Treatment Appliance Technology Co. Ltd. submitted an application for prequalification of ShangRing. Based on the established prioritization criteria, ShangRing™ was given priority for prequalification.

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.

Manufacturing site inspection

A comprehensive inspection and a follow-up inspection were 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 in February 2014 and August 2014 as per the Information for manufacturers on prequalification inspection procedures for the sites of manufacture of male circumcision devices (PQDx_014 v1). 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 5 December 2014.

Commitments for prequalification:

N/A

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*”.

Device use

Eligible: males 13 years and older; 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 (AEs) 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.

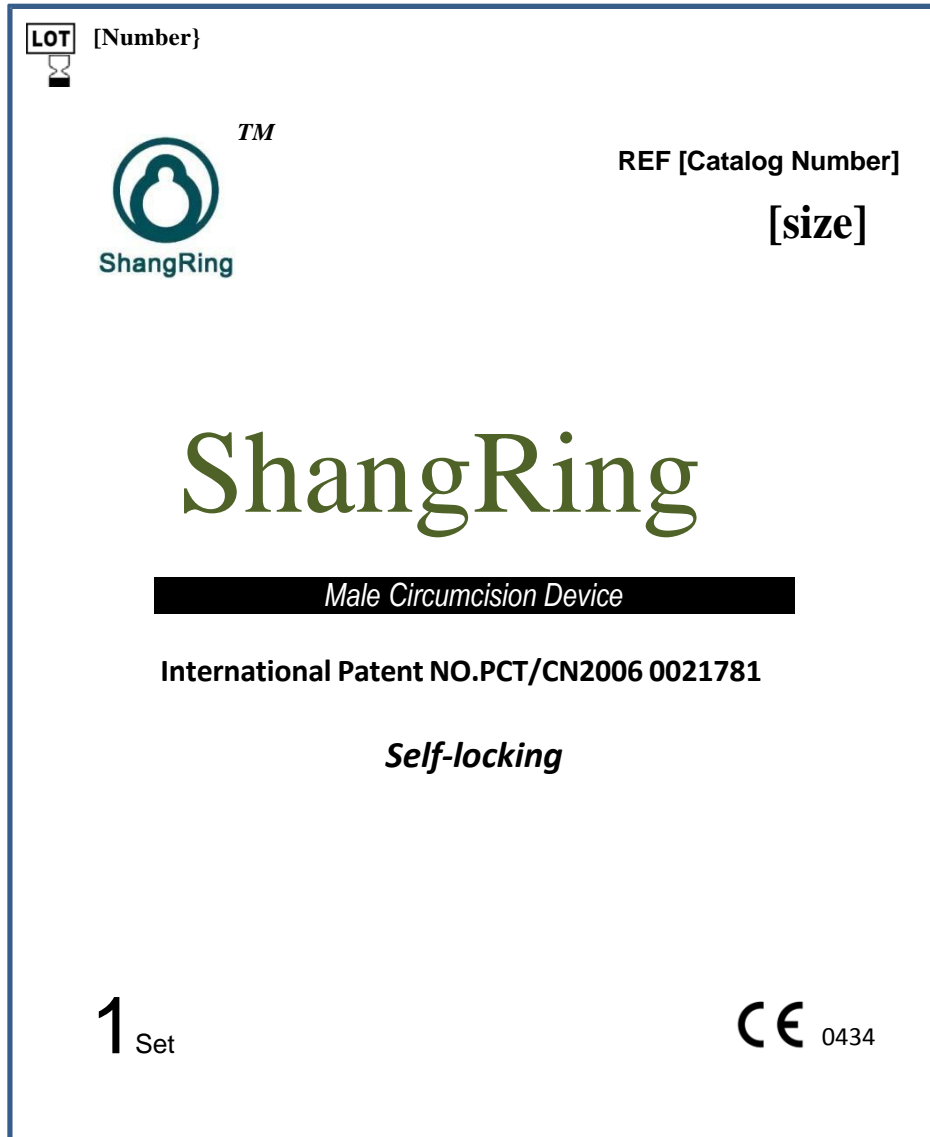
Client information must clearly indicate that once placed, the device must remain for seven days; in case a client desires to remove the device, clients should be instructed to return to the clinic. Clients must also be instructed on safe behaviours while the device is worn, including avoidance of sexual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

Labelling

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

1. Labels

FOIL POUCH - FRONT



FOIL POUCH - BACK

REF [Catalog Number]

[Size chart and product codes]

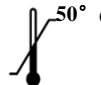


Damaged package is prohibited in use

bar code



5°
C



SNNDA

EC REP

Wuhu Snnda Medical Treatment Appliance Technology Co., Ltd.
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[Name and contact information of the distributor]

Version1.0



ShangRing

REF [Catalog Number]

[size]

[Size chart and product codes]

LOT [Number]

[DD-MM-YYYY]

[MM-YYYY]

bar code



Damaged package is prohibited in use

STERILE R



5° C



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EC REP

Version 1.0

Bar code

REF [Catalog Number]

[size]

ShangRing

Male Circumcision Device

Self-locking

Picture of the ring

1 Set

CE 0434

International Patent
No.: PCT/CN2006 002178

ShangRing



EC REP

ShangRing

BOX of 1 set



ShangRing

REF [Catalog Number]

[size]

[Size chart and product codes]

LOT [Number]

[DD-MM-YYYY]

[MM-YYYY]

bar code



Damaged package is prohibited in use

STERILE R



5° C



Wuhu Snnda Medical Treatment Appliance Technology Co., Ltd.
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EC REP

Version 1.0

Bar code

REF [Catalog Number]

[size]

ShangRing

Male Circumcision Device

Self-locking

Picture of the ring

10 Sets

CE 0434

International Patent
No.: PCT/CN2006 002178



EC REP

ShangRing

BOX of 10 sets

Shipping box – will use English print only

注意事项Caution

温度 Temperature	湿度 Humidity	层高 Stacking Layers
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Caution

Temperature ≤ 50°C	Humidity ≤80% RH	Stacking Layers 5
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Packing List

名称 Description	数量 Quantity
Shangring	200只 pcs
创可贴 Band-Aid	1400片 pcs
周径尺 Measuring tape	200条 pcs
下环工具 Removal tool	4套 set

总重量 Gross Weight:
KG

Packing List

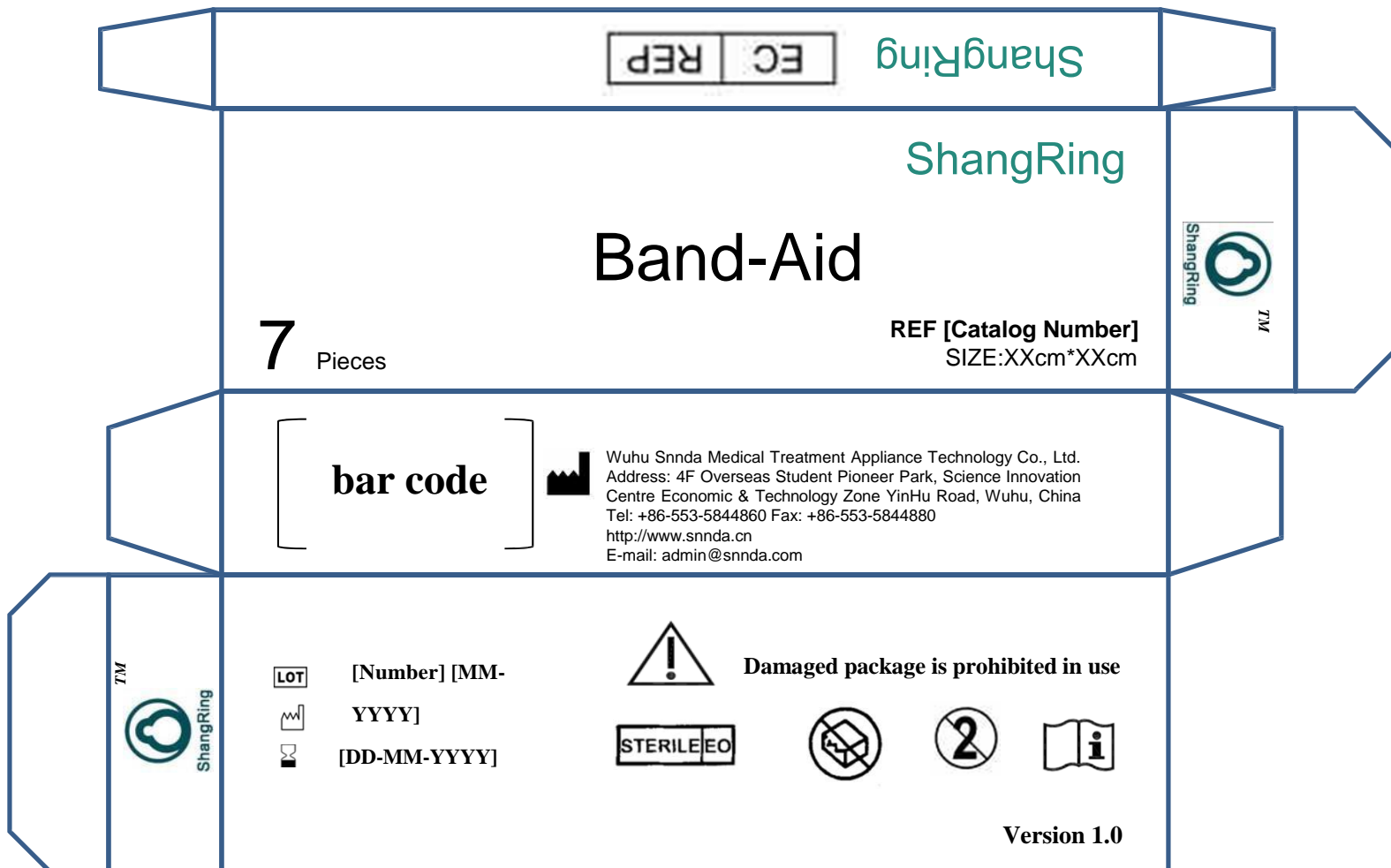
Description	Quantity
Shangring	200 Sets
Band-Aid	1400 Sets
Measuring tape	200 Pieces
Removal tool	4 Sets

Gross weight: KG

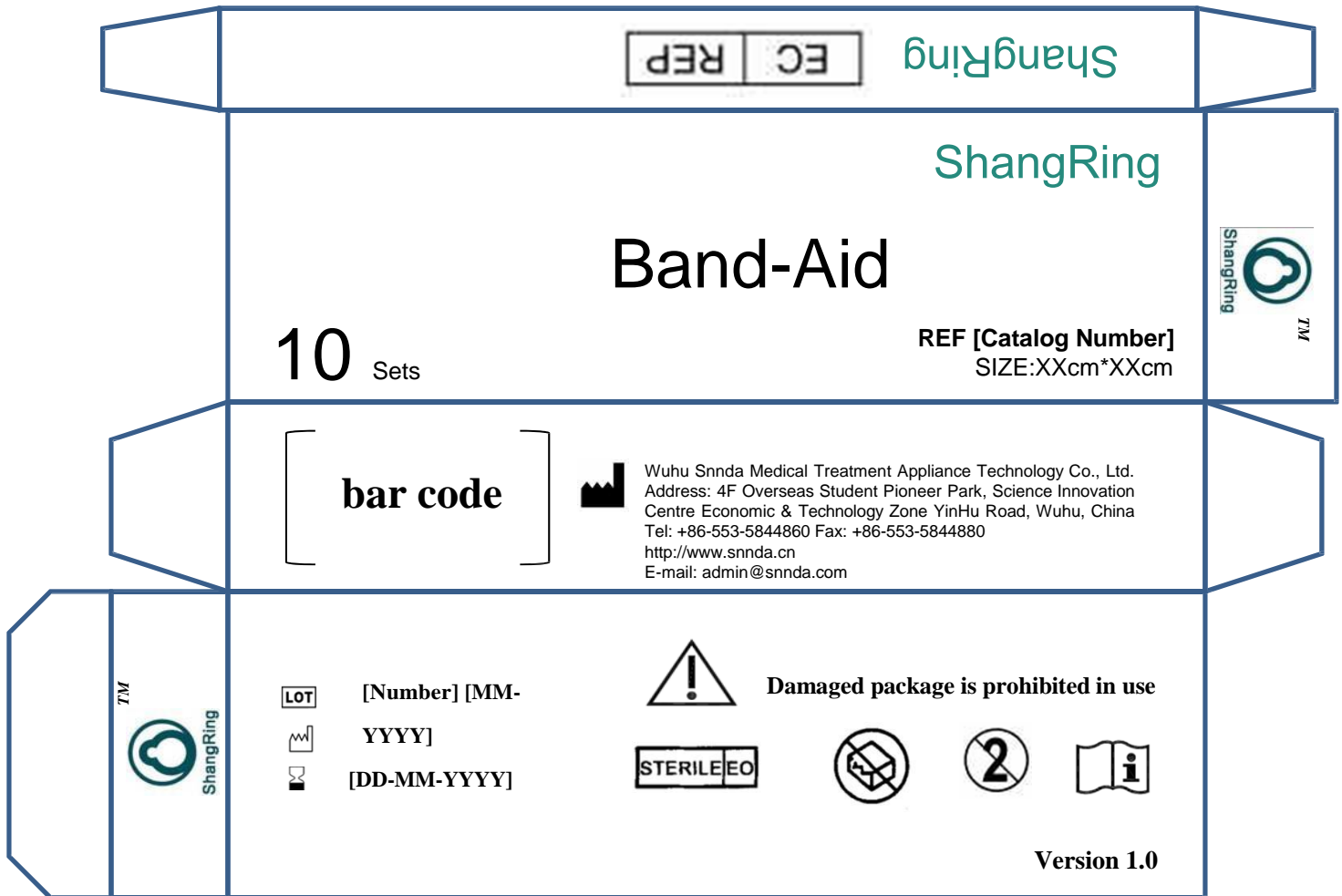
装箱清单 Packing List

名称 Name	数量 Quantity	包装规格 Packing Configuration
Shangring	200只 pcs	Single pack: 1 pcs Middle box: 10 single packs Shipping box: 20 middle box
创可贴 Band-Aid	1400片 pcs	Single pack: 7 pcs Middle box: 10 single packs Shipping box: 20 middle box
周径尺 Measuring tape	200条 pcs	Single pack: 10 pcs Middle box: 20 single packs Shipping box: 1 middle box
下环工具 Removal tool	4套 set	Single pack: 1 pcs Middle box: 4 single packs Shipping box: 1 middle box
总重量:		KG

Bandage box-single pack



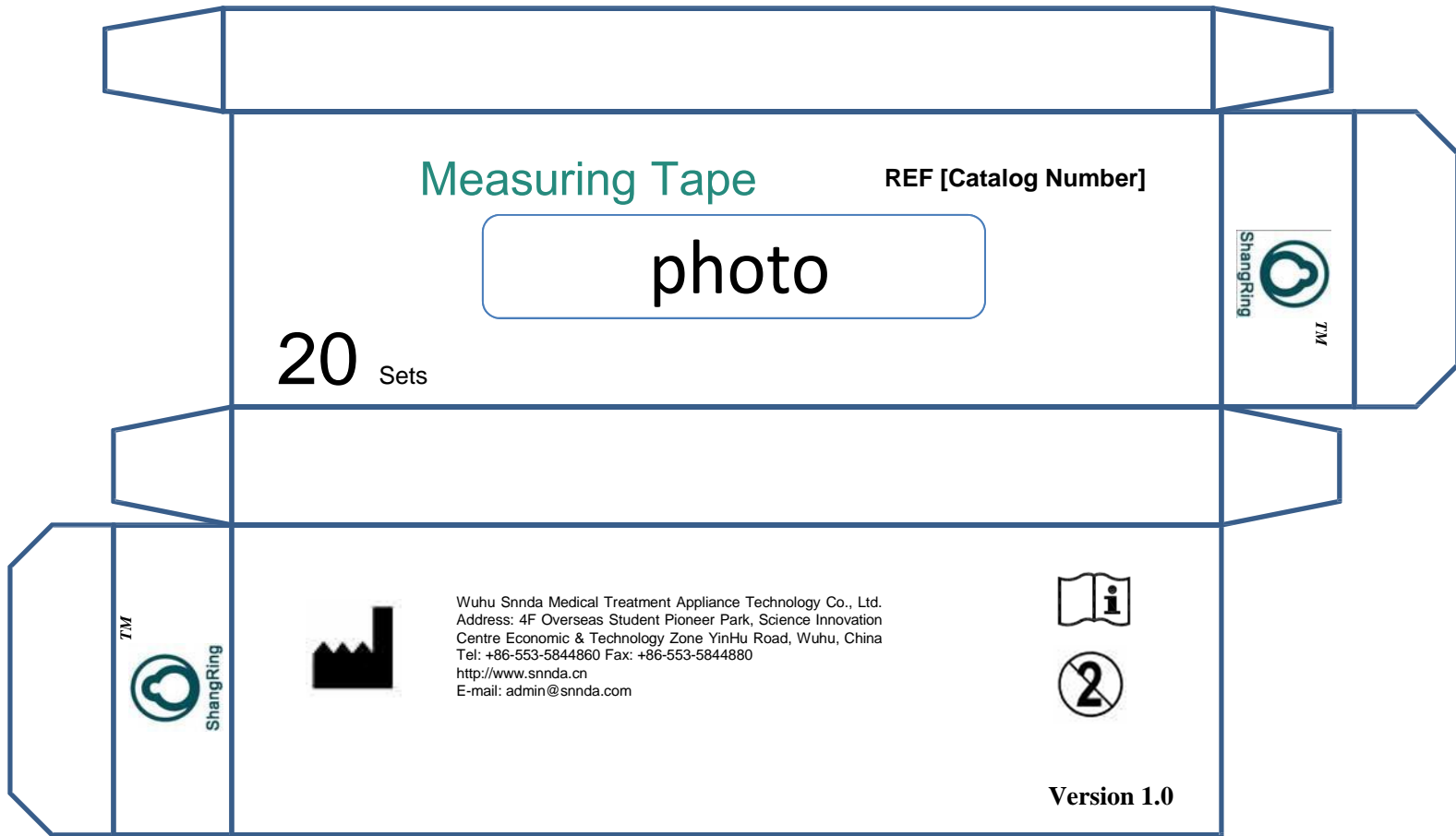
Bandage – middle box



Measuring Tape –Single pack, plastic pouch



Measuring Tape-Middle Box



Removal Tool-Single pack II

FRONT



ShangRing

Removal Tool


REF [Catalog Number


Cutter : 1 Piece

Key Opener : 1 Piece

BACK

Manufactured For:





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Version 1.0

Removal Tool-Middle Box

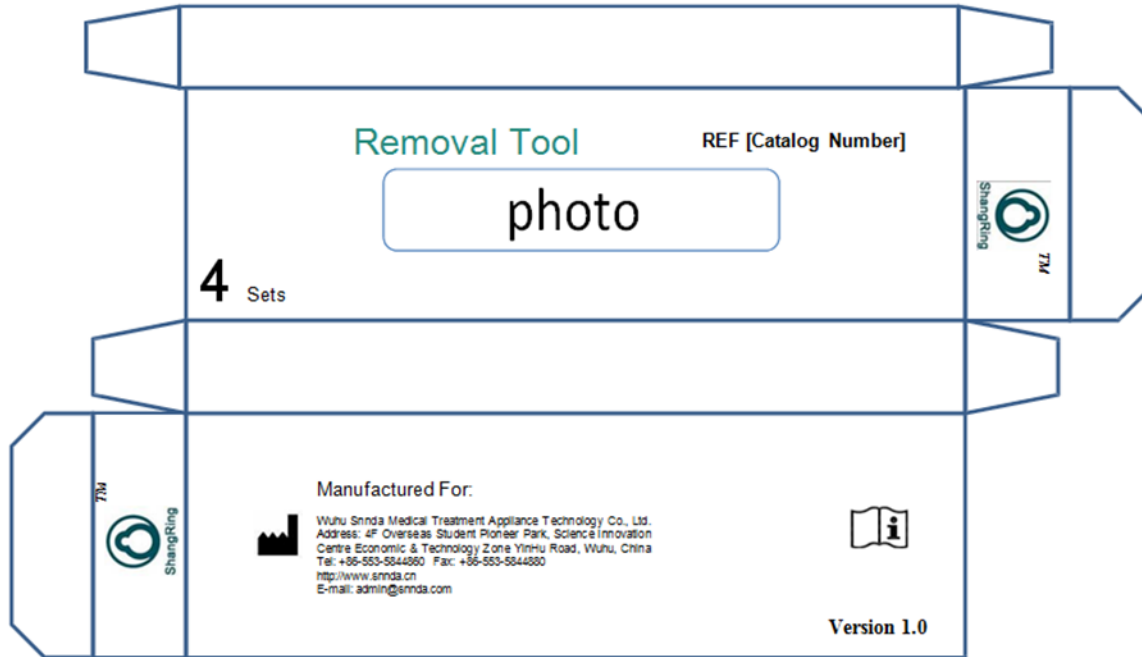


Table 1: ShangRing Sizes and Catalogue Numbers*

Product	Size	Product Number	Units Supplied Per Order
ShangRing (4.0 cm)	A4	SR-II-40	200 units
ShangRing (3.9 cm)	A3	SR-II-39	200 units
ShangRing (3.8 cm)	A2	SR-II-38	200 units
ShangRing (3.7 cm)	A1	SR-II-37	200 units
ShangRing (3.6 cm)	A	SR-II-36	200 units
ShangRing (3.5 cm)	B	SR-II-35	200 units
ShangRing (3.4 cm)	C	SR-II-34	200 units
ShangRing (3.3 cm)	D	SR-II-33	200 units
ShangRing (3.2 cm)	E	SR-II-32	200 units
ShangRing (3.1 cm)	F	SR-II-31	200 units
ShangRing (3.0 cm)	G	SR-II-30	200 units
ShangRing (2.9 cm)	H	SR-II-29	200 units
ShangRing (2.8 cm)	I	SR-II-28	200 units
ShangRing (2.6 cm)	K	SR-II-26	200 units
ShangRing (2.4 cm)	M	SR-II-24	200 units
ShangRing (2.2 cm)	O	SR-II-22	200 units
ShangRing (2.0 cm)	Q	SR-II-20	200 units
ShangRing (1.8 cm)	S	SR-II-18	200 units
Bandage (for use with ShangRing sizes larger than M)	Large (172mm×33mm)	SR-A-01	1400 pieces
Bandage (for use with ShangRing sizes M and smaller)	Small (120mm×25mm)	SR-A-02	1400 pieces
Removal Cutter and Removal Key	Not applicable	SR-A-03	4 sets
Measuring Tape	Not applicable	SR-A-04	200 pieces

*With each ShangRing order of 200 units, customers will be supplied with bandages (1400 pieces), removal tools (4 sets) and measuring tapes (200 pieces). If additional accessories are needed, please place orders separately.

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 purchases 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 including the Lidocaine Spray	Not provided
Povidone-Iodine	Not provided
Instruments	Not provided

The measuring tape is supplied with the ShangRing. Bandages, removal cutter, and removal key opener, are sold separately. Although bandages can be purchased from Wuhu Snnda 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, removal key opener and measuring tape.

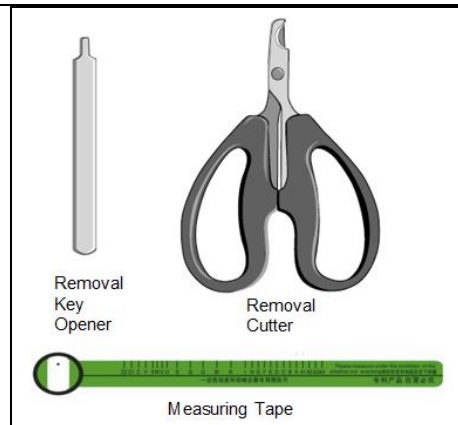


Figure 3

Figure 4 shows the surgical scissors, hemostatic clamps, and scalpel.

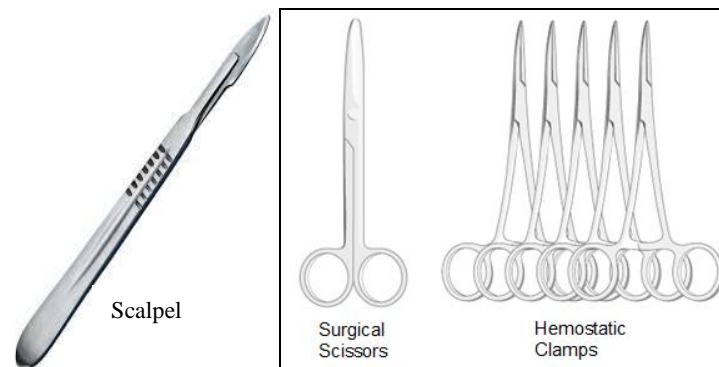


Figure 4

The plastic disposable measuring tape is a single use item that is used to assist in selecting the appropriate size ShangRing. 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. 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 foreskin remnant 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 evaluations.
- 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 – such infections that are associated with anaerobic bacteria, such as *Clostridium tetani* that may manifest as tetanus and lead to serious disorder.

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, the patient should be advised to contact his health care provider in the event of severe penile edema, any bleeding, difficulty urinating, increasing pain, increasing redness, bruising (discoloration of the area around the wound), fever or appearance of pus or discharge from the wound. In general, bruising or discoloration will gradually fade after removal of the ShangRing.

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 hypospadias and epispadias), known bleeding diathesis, or any other condition precluding genital surgery.
- The ShangRing can be used in males with tight foreskin or frank phimosis. However, a dorsal incision may be required in order to permit eversion of the foreskin over the inner ring.

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 wound 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 5).

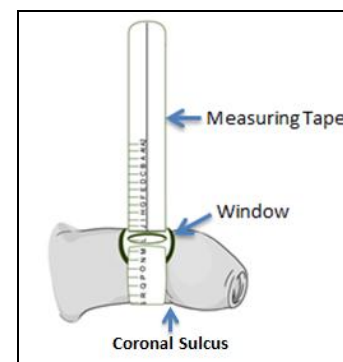


Figure 5

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 larger size should be chosen. Note: Choosing the right size can help minimize pain from nocturnal erections.

Preparing for ShangRing Placement

All health care providers, to be involved in the procedure, must practice hand hygiene by using alcohol hand rub or other suitable method. 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).

Patient Preparation:

After hand hygiene has been completed, prepare the patient for placement of ring by administering a local anesthetic solution. The solution can be either plain lidocaine or a mixture of lidocaine and bupivacaine. See Table 3 below, extracted from the WHO Manual for Male Circumcision under Local Anesthesia (WHO, 2009), for dosage recommendations for plain lidocaine solution without epinephrine for adolescent and adult males. Wait 15-20 minutes after administering the local anesthetic solution before starting the procedure.

Table 3: Examples of Maximum Safe Volume of Plain Lidocaine (3 mg per kg body weight)

Patient (Weight)	1% lidocaine (10 mg per ml*)	2% lidocaine (20 mg per ml*)
Boy (40 kg)	12 ml or 12 cc	6 ml or 6 cc
Man (70 kg)	21 ml or 21cc	10.5 ml or 10.5cc

* 1 ml = 1 cc

A 50-50 mixture of 2% lidocaine and 0.5% bupivacaine, without epinephrine, can also be used. Whichever type of anesthetic (lidocaine and/or bupivacaine) or concentration is used for local anesthesia, epinephrine (adrenaline) should NOT be included.

Following anesthesia, standard surgical protocols on skin preparation should be used.

- Personal cleanliness, including cleaning of the genital area and under the foreskin with soap and water prior to VMMC procedure to remove any dirt and debris prior to placement.
- Disinfection of the genital area, the penis and the area under the retracted foreskin with appropriate disinfectant with povidone-iodine, unless allergy is known, with at least 3 skin paint applications; waiting 2 minutes before device placement.

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

- For the penile nerve block technique the solution 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 solution is injected circumferentially around the base of the penis, between the superficial (Darto's) fascia and deep (Buck's) fascia. To achieve good anesthesia, it is necessary to ensure that a complete circumferential block is achieved (Figure 6).

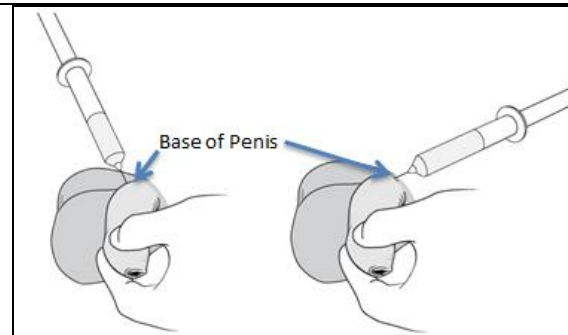


Figure 6

Placing the ShangRing

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 7-10.

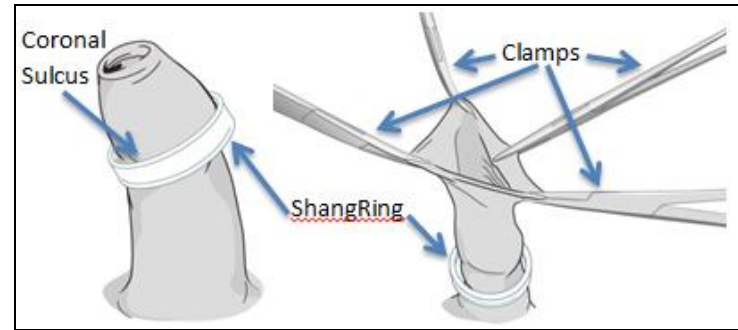


Figure 7

Figure 8

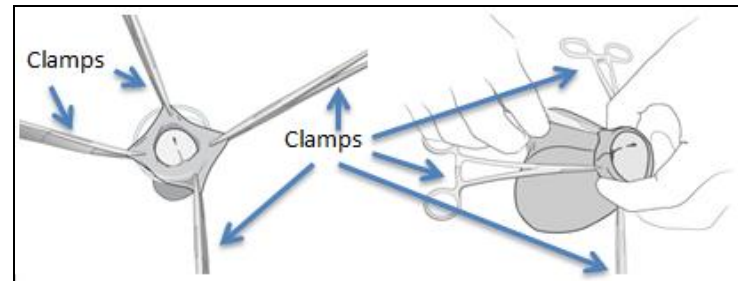


Figure 9

Figure 10

Figure 11 shows the completion of the placement of the inner ring.

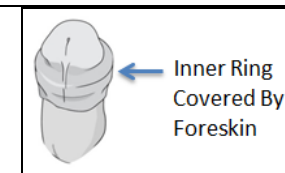


Figure 11

For men with a tight foreskin or frank phimosis, a dorsal incision of about 1 cm may be required in order to permit eversion of the foreskin over the inner ring (Figure 12). Prior to cutting the skin, brief application of a clamp to crush the skin where the cut is to be made, should minimize bleeding.

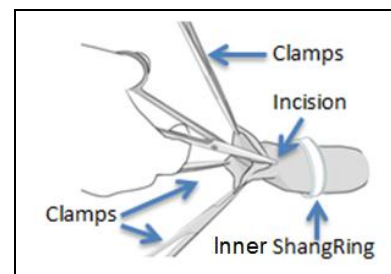


Figure 12

The outer ring is then secured over the inner ring, sandwiching the foreskin in-between the two rings (Figure 13). 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.

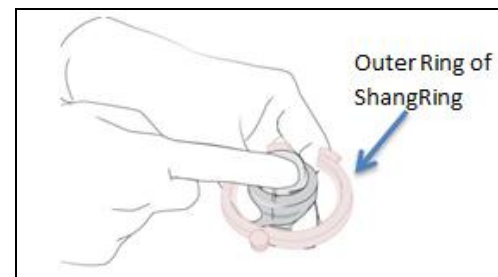


Figure 13

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.

Then the second ratchet of the outer ring is engaged to complete the closure of the outer ring (Figure 14).

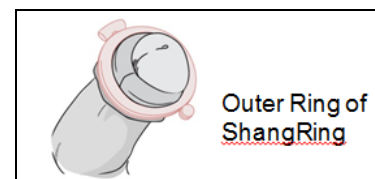


Figure 14

Excess foreskin is excised using a scalpel (Figure 15). Make 6 to 10 nicks on the incision line (Figure 16) 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.

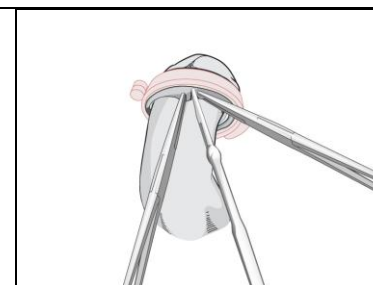


Figure 15

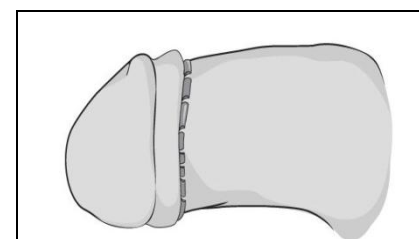
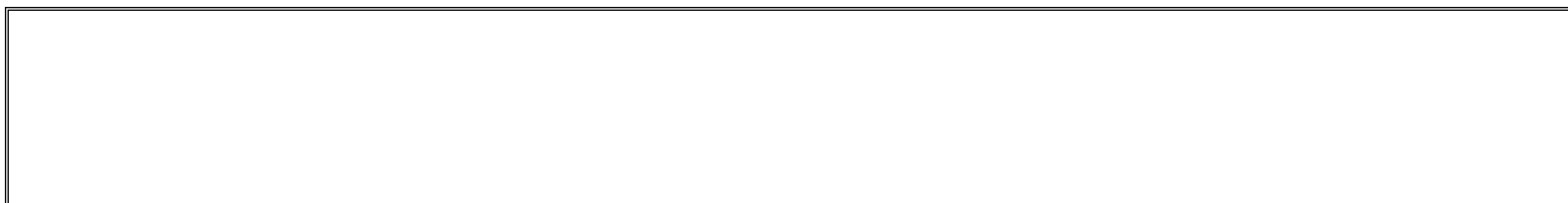


Figure 16

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 pinch to free the pinched skin.



Removing the ShangRing

The health care provider should remove the ShangRing 7 to 10 days after circumcision. A clean pair of examination gloves should be used by the health care provider during this procedure. Before initiating the removal of the outer ring, spray 1%-2% lidocaine (Figure 17) to the area around the wound and leave for approximately 1-2 minutes to take effect. Do not leave for more than 2 minutes.

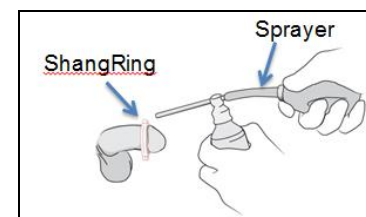


Figure 17

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 (Figure 18 and 19) and twist or bend the removal key opener while firmly holding the outer ring. This will break the ratchet, allowing for easy removal of the outer ring (Figure 20). A close up drawing of the removal key opener is provided in Figure 21.

Gently pull the inner ring back from the edge of the wound using a clamp (Figure 22). This may cause some brief pain.

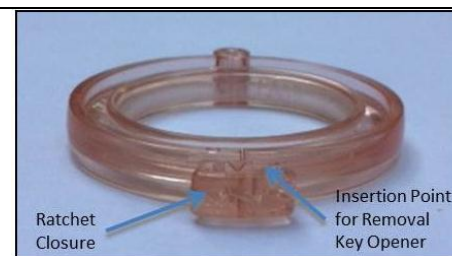


Figure 18

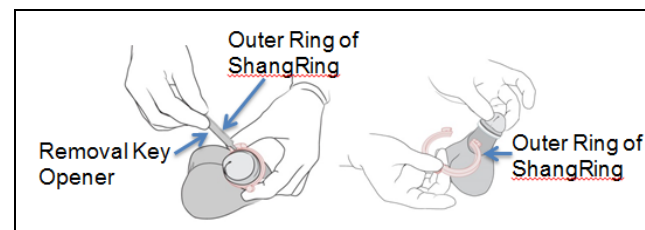


Figure 19

Figure 20

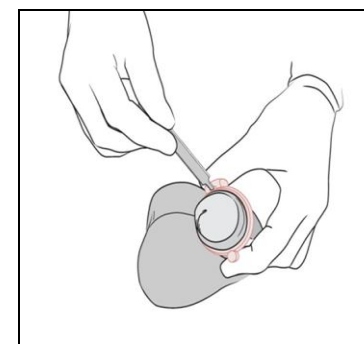


Figure 21

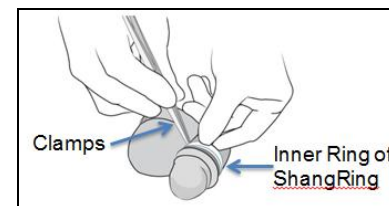


Figure 22

Cut the inner ring at two points opposite each other, e.g. the 6 and 12 o'clock positions, using the removal cutter (Figure 23). Once cut, the inner ring should be disposed of.

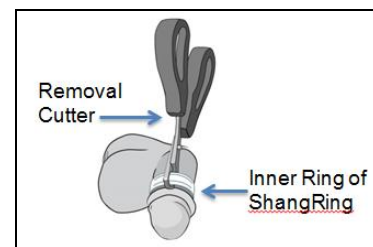


Figure 23

Post-Removal of Device

The health care provider should cover the wound with a bandage. 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.

The health care provider should instruct the patient to return to the clinic urgently when signs and symptoms suggestive of infection with tetanus arise.

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

Cleaning and Disposal of the ShangRing and Other Equipment

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

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Post-Operative 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, back at home, you rest 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 you carefully dry the penis and ShangRing afterwards. 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 on or around the circumcised area because it may slow the healing process.
10. If your health care provider so 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. Seven to ten days after your circumcision, return to your health care provider's office to have the ShangRing removed. 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 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 on or around the wound after removal of the ShangRing until the wound is completely healed because it may slow the healing process.
3. **DO NOT HAVE SEX (INCLUDING MASTURBATION)** within the 6 weeks after your circumcision or until the wound has healed completely. Your health care provider will advise you about this during your follow-up visits. The World Health Organization recommends that you should use condoms to protect the circumcision wound (as well as to reduce the transmission of HIV and other infections) for six months, even after it appears completely healed (WHO, 2009).

At Any Time

While wearing the ShangRing or after removal, contact your health care 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.







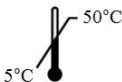


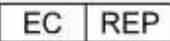


Additional Instructions for Health Care Providers**Device Malfunctions and Adverse Events**

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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E-mail: admin@snnda.com

Index of Symbols

Symbol	Meaning
	Manufacturer
	CE Mark
	Sterile – Method using irradiation
	Do no reuse
	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