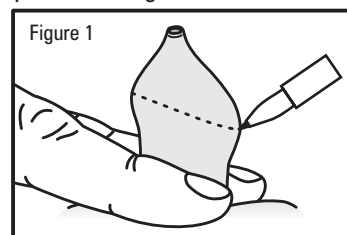


Instructions for Use

1. Procedure Preparation

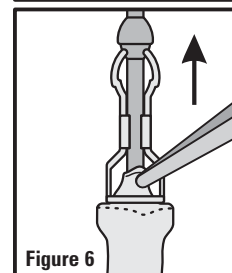
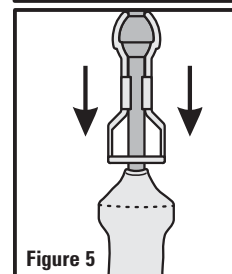
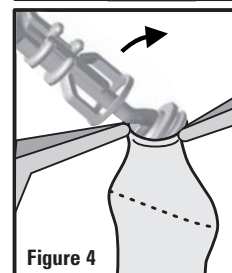
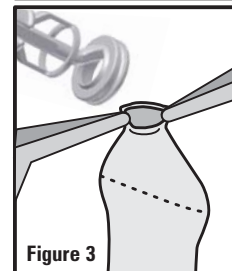
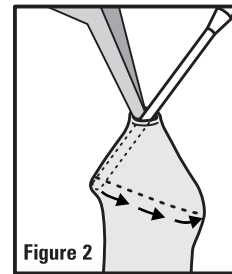
- Obtain informed consent from parents and/or the legal guardians of the infant.
- Ensure infant has had nothing by mouth for one hour prior to the procedure.
- Position the infant in a warm room using an assistant or an appropriate infant restraint.
- Inspect the penis and the urethral meatus for any abnormalities (e.g. hypospadias).
If the anatomy is abnormal, abort the procedure and consult a urologist. Proceed only if the anatomy can be visualized and is normal.
- Using hospital protocol, determine the size of the penis and select the AccuCirc™ device with the corresponding size.
- Consider using analgesia as recommended by the American Academy of Pediatrics.
- After analgesia is obtained, use an appropriate antiseptic solution to prepare the entire penis and a one-inch area surrounding the penis.
- Wearing sterile gloves, place a fenestrated drape and proceed using sterile technique.
- Apply light pressure to the suprapubic fat pad at the base of the penis to assess the true anatomic positioning of the foreskin overlying the glans. While maintaining the true anatomic position of the foreskin, use a surgical pen to mark the foreskin at the coronal margin (Figure 1).



2. Probe Placement

- Lightly grasp the tip of the foreskin with a hemostat.
- Using the top, blunt end of the probe, apply a small amount of sterile lubricant and carefully insert the tip of the probe in between the glans and the foreskin, removing by blunt dissection any adhesions, and thus freeing the foreskin down to the surgical pen mark (level of the coronal margin).
Note: Care should be taken to ensure the blunt probe is not forced past the level of the corona. Blunt dissection using the probe should be done carefully so as to explore the complete space between the preputial epithelium and the glans, but not injure the surrounding tissue (Figure 2).
- **NO DORSAL CRUSH AND SLIT ARE MADE.**
The AccuCirc™ is designed to perform neonatal circumcision without requiring a dorsal crush and slit.
- Once the adhesions have been removed to a level below the surgical mark, use both hemostats to lightly grasp the foreskin at the 3 o'clock and 9 o'clock positions.
- Inspect the probe to ensure that the foreskin holder is in the up position along the shaft, above the ring.
- Holding the probe at an angle in the dominant hand like a pencil, insert the ring into the foreskin that is being held open by the hemostats (Figure 3).
- As the ring is inserted it can be pushed down to rest on top of the glans beneath the foreskin (Figure 4).
- Once the ring is in the desired position, advance the foreskin holder down onto foreskin (Figure 5). The foreskin holder maintains a steady force against the ring and holds foreskin in place.
- Use the hemostats to gently position the foreskin (being held by the foreskin holder) so that the pen mark is circumferentially aligned on the top of the ring (Figure 6).

Note: If the ring cannot be easily inserted into the preputial space, or if the surgical mark cannot be easily aligned on the top of the ring, the procedure should be abandoned.



3. Clamp Placement and Foreskin Cut

- Once the foreskin is in the desired position and being held securely by the foreskin holder, place the AccuCirc™ clamp over the probe (Figure 7).

Note: The clamp should only be applied when the surgical mark is aligned on the top of the ring, and the foreskin is securely held in place by the foreskin holder.

- As the clamp is being placed over the probe, the probe will extend through the top of the clamp. Hold the probe to facilitate full application of the clamp.

Note: Care should be taken to avoid injury (e.g. to the eyes) by keeping the pointed end of the probe away from the face of the infant and any clinical personnel.

- When the probe is secured in place inside the clamp, an audible click will be heard and the clamp will lock into place on the probe (Figure 8). Ensure the circular line on the probe is visible above the clamp.

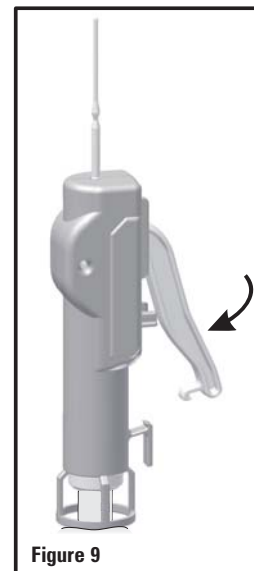
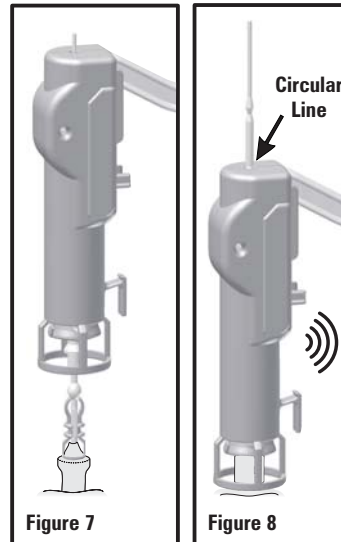
- If the clamp does not slide easily and completely over the probe, stop the procedure and check for damaged parts.

Note: For safety reasons, the probe should not be removed from the clamp once it is locked in place. Aborting the procedure at this time requires lifting the foreskin holder with a hemostat and removing the probe from the foreskin while the clamp remains attached to the probe. The clamp, with the probe locked in place, should be discarded and should not be used to perform another attempt at the procedure.

- After the AccuCirc™ clamp is locked into place on the probe, check again that the pen mark is correctly aligned, and then use one hand to activate the lever arm down against the clamp housing (Figure 9). As the lever arm is activated, a sleeve is pushed down over the movable arms causing the clamping action and simultaneously delivering the internally protected circular blade that makes the incision just above the area being crushed.

- The lever arm can only be activated when the probe is correctly locked in place. The lever arm should never require a large force. If the probe is not in place, the lever arm will remain locked.

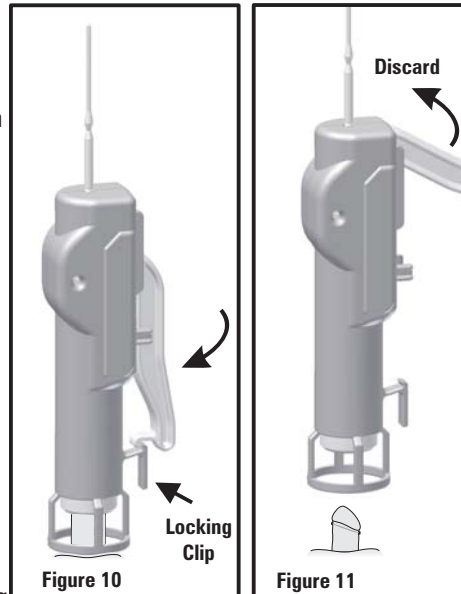
- If a large force is applied to the lever arm in this locked position, the internal gears of the clamp will not engage, disabling the lever arm and clamp, protecting the infant and user from inappropriately using the clamp. In this unlikely event, the disabled clamp and its associated probe should be discarded.



- Continue activating the lever arm downward until it locks into place against the clamp housing. As the lever arm is activated, the AccuCirc™ device will crush and cut the foreskin, timed and executed by the device itself (Figure 10).
- Keep the clamp in the closed and locked position for at least a full five minutes to ensure hemostasis.

Note: Once the lever arm is locked against the clamp housing, the device, without being held, will continue to maintain an adequate clamping pressure indefinitely until the lever arm is lifted and the clamping arms are released.

- Push in on the locking clip, release the lever arm, and lift the lever arm back to the up position. This releases the clamping arms and allows the probe and clamp to be removed together (Figures 10 & 11).



Warning: Some bleeding may occur following the procedure. Be prepared to manage this with appropriate surgical technique, if required.

4. Procedure Completion

- Evaluate to ensure adequate hemostasis. Follow institutional protocol or local standard of care to control bleeding. **DO NOT use silver nitrate or electrocautery to control bleeding.**
- Following the procedure, use the provided sterile moist towelette to remove the antiseptic solution from the skin of the patient to avoid allergic or delayed reaction to the antiseptic solution.
- Once hemostasis is ensured, petrolatum gauze can be used to wrap the site.
- Consider analgesia per institutional protocol to help with post-procedure pain.
- Monitor the infant for a minimum of one hour following the procedure to ensure continued hemostasis.
- Discard the used probe and clamp. Never reuse the device or any part of the device. The device is designed to be single use to avoid complications caused from used, worn parts and infection.
- If, in the rare event the clamp cannot be released, no emergent action is needed. The device is designed to allow for the flow of urine in the clamped or closed position. Immediately consult a urologist or the manufacturer for assistance in removing the clamp.

Made in the USA
Patents Pending

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