



Applicable catalog numbers:	
Number	Weight
ZF-F-XS	< 2.5 kg
ZF-F-S	2.5 - 6 kg
ZF-F-M	6-8.5 kg
ZF-F-L	> 8.5 kg
Sizes are estimates based on General weight – use best judgement	

ZORRO-FLOW®

INSTRUCTIONS FOR USE

FEMALE EXTERNAL URINE COLLECTION DEVICE

Product Description:

Zorro-Flow® is an external urine collection device designed with neonates, infants, and small children in mind.

Zorro-Flow® cup is created using 100% silicone to optimize urine collection. It is soft and comfortable.

Zorro-Flow® kit includes silicone-based adhesive liquid and tape strips that will adhere the cup to the baby’s sensitive skin.

Zorro-Flow® is easily removed using a silicone-based adhesive removal pad (not supplied).

Zorro-Flow® urine collection bag enables the approximation of urine volume.

Indications for Use:

Zorro-Flow® is intended for use by trained medical personnel for inpatient or outpatient settings.

Zorro-flow® is intended to be placed externally in the perineal area for urine collection for up to 24 hours.

Contraindications:

Do not use if patient’s perineal area skin integrity is poor, discolored, or not intact.

Precautions:

1. Discard any unused materials in accordance with regulations governing the disposal of medical waste.
2. This device is not designed for children with urogenital malformations.
3. This device should only be used by medically trained personnel.
4. Only use if perineal skin is healthy and intact. Do not use if perineal skin is damaged or infected.
5. Intended for EXTERNAL urine collection use only.
6. Do not use it if the package is opened or damaged.
7. Do not reuse.
8. Do not use alcohol pads or other chemicals to clean the perineal area.

Cautions:

1. **Read ALL instructions before beginning application.**
2. Use only as directed.
3. Follow the directions in the sequence provided.
4. Select size based on patient’s weight/body size. These are approximate, use best judgement.
5. Adhere device to skin only with the supplied adhesive silicone gel and silicone tape. Do not adhere device with other products. (Check for adherence periodically over the 24-hour period of use)
6. Do not allow liquid adhesive to flow into the vagina.
7. Discard after single use, do not reuse.
8. Check infant periodically for device adherence and inspect for any signs of irritation.
9. If silicone adhesive is not in liquid form do not use.

Warnings:

1. Accurate measurement of urine output cannot be guaranteed.
2. Assure that all tubing and the urine collection bag are below the level of the bladder to assure good flow.
3. Secure tubing and urine collection bag so that it does not pull on the device that is bonded to the patient and check that there are no kinks in tubing.
4. Do not let the tubing wrap around patient’s body parts or allow it to get pinched by medical equipment.

Troubleshooting:

If no urine (or less urine than expected) is collected, consider the following troubleshooting steps:

1. Determine if the urine is leaking into the diaper by inspecting to see if the diaper is wet.

2. Evaluate tubing for kinks or disconnections.
3. Assure that tubing is not pinched by medical equipment.
4. Assure that the urine cup has not been dislodged from the tubing.
5. Assure that the male and female luers are connected appropriately.
6. Assure that the tubing and urine collection bag are below the level of the bladder.
7. Assure that the valve on the urine collection bag is closed.

How the Zorro-Flow® external urine collection device is supplied:

Zorro-Flow® is an external urine collection device, supplied as a single patient use disposable item that contains 2 pouches.

- The device pouch contains the urine collection cup/tubing and the urine collection bag which are sterile.
- The accessory pouch contains the following ancillary components that are non-sterile:
 - ✓ Silicone adhesive liquid – used to adhere the inside rim of the collection cup to the patient’s skin.
 - ✓ 2 silicone tape strips – used to secure the outside part of the collection cup to the patient’s skin.
 - ✓ 2 hook and loop straps – used to secure the urine collection bag to the crib/bed.

Materials needed but not supplied:

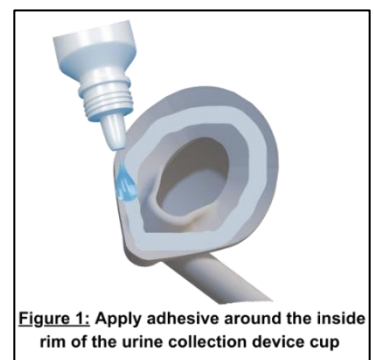
- Disposable diaper and diaper wipes.
- Silicone-based adhesive removal pads similar to Uni-solve or Medline.
- Alcohol wipes to clean before reconnecting an uncapped luer.

Sterilization:

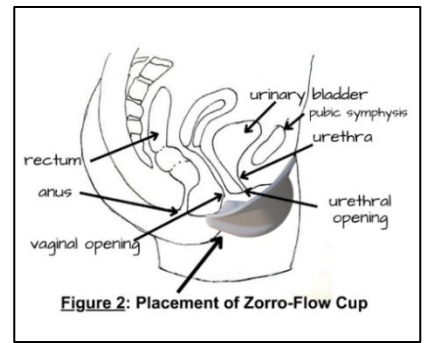
- The contents of the device pouch are sterile.
- The contents of the accessory bag are non-sterile.
- **Do not sterilize or re-sterilize any part of the Zorro-Flow®.**

Instructions for Use:

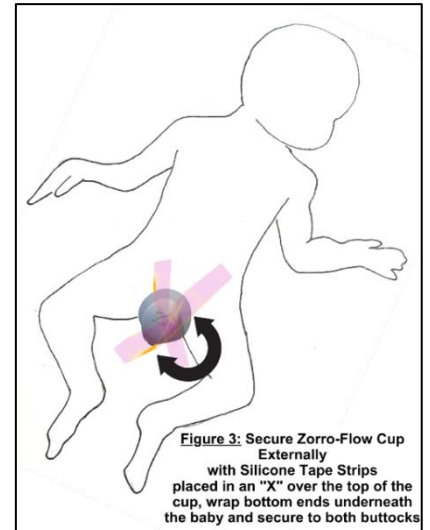
1. Evaluate the skin of the patient around the perineal area. If the skin is discolored, has poor skin integrity or is abnormally swollen, do not use device.
2. Preparation:
 - a. Open the bag, identify components.
 - i. Device Pouch (contains cup with tubing connected to the urine collection bag)
 - ii. Accessory Pouch (contains 1 adhesive liquid container, 2 adhesive strips, and 2 straps to hang bag)
 - b. Open accessory pouch and remove the components.
 - c. Uncap the silicone adhesive liquid container. **DO NOT TOUCH the open end of the container** with your fingers.
 - d. Using aseptic technique, open the device pouch. Don sterile gloves and be careful to avoid contamination of the cup.
3. Application: If a sterile sample is needed, follow aseptic technique.
 - a. Apply liquid adhesive around the inside rim of the urine collection device cup. (See Figure 1.)
 - i. Use enough liquid adhesive to cover the entire rim of the device but not too much that it spills over.
 - ii. **LET LIQUID ADHESIVE DRY FOR 3-5 MINUTES BEFORE APPLYING TO PATIENT**
This will optimize adhesion and prevent the liquid adhesive from flowing into vagina.
 - iii. **DO NOT PLACE LIQUID ADHESIVE DIRECTLY ON THE PATIENT, PLACE ONLY ON THE DEVICE.**
 - b. While the liquid skin adhesive is drying:
 - i. Clean the perineum of the patient with disposable baby wipes (not supplied).
 - ii. Change the diaper (not supplied) and discard gloves.
 - iii. Failure to change a wet diaper prior to starting will limit the ability to assess for a urine leak.



- c. **After the adhesive liquid has dried for 3-5 minutes**, spread the labia of the patient and position the urine collection cup starting with the tip of the ramp at the posterior vaginal opening. (See Figure 2.)
 - If a sterile sample is desired, aseptic technique will reduce chance of contaminants.
- d. Press firmly for 30 – 60 seconds to secure the device.
- e. Secure the device to the patient with the 2 silicone tape strips. (See Figure 3.)
 - i. If the patient is small, cut the tape strip to the approximate length (from the waist to back of the thigh).
 - ii. Remove the blue liner of tape to expose the sticky silicone adhesive side of the tape.
 - iii. Place each tape strip on top of the cup to secure the cup to the patient.
 - iv. Remove the white liner of the silicone tape.
 - v. The 2 tape strips will form “x” pattern over cup to hold it to reduce the potential for leaks.



4. Secure the urine collection bag and tubing:
 - a. Assure that there is no tension (no stretching) on the tube.
 - b. **MAKE SURE THAT THE TUBING AND URINE COLLECTION BAG ARE BELOW THE LEVEL OF THE PATIENT'S BLADDER TO PREVENT URINE FROM FLOWING BACK TO THE PATIENT.**
 - c. If tubing cannot be secured below the level of the bladder:
 - i. Raise the head of the crib and place the urine collection bag at the foot of the crib.
 - d. When the tubing and collection bag is positioned continuously below the level of the bladder, then:
 - i. Thread the 2 hook and loop straps included in the accessory pouch through the slits on the top of the urine collection bag.
 - ii. Secure the bag to the side of the crib/bed/isolette using the 2 straps to prevent the weight of the urine collection bag from putting tension on the patient's skin.
 - iii. If it is required to disconnect the luer to place the collection bag through the crib rail or isolette port, clean both connections of the luer with an alcohol wipe prior to reattachment.



5. Empty urine from collection bag:
 - a. Drain the urine by opening the valve switch at the base of the urine collection bag. To open, pull the blue valve stop down away from the bag. (See Figure 4)
 - b. After emptying urine, close the valve by pushing blue valve stop back up.
 - c. **Never let the bag overflow.**



Figure 4







6. Collect urine sample:
 - a. To collect a fresh urine sample, start the collection with an empty bag.
 - b. Clean end of valve with an alcohol pad to prevent contamination.
 - c. Collect the urine by pulling the valve down away from the collection bag to the “OPEN” position as shown in Figure 4.
 - d. After urine has been emptied, push the valve stop back up toward the collection bag “CLOSED” position as shown in Figure 4.

7. If a sterile sample is desired use aseptic technique and consider the following:
 - a. The Device Pouch contents are sterile.
 - b. False positives cannot be guaranteed.
 - c. Use aseptic technique:
 - i. Wear Sterile gloves.
 - ii. Clean baby with proper antiseptic that will not damage skin (e.g. betadine)
 - iii. Do not contaminate the field.
 - iv. Wipe the drain valve with an alcohol pad prior to sample collection.

v. If the luer must be disconnected for any reason, clean both ends with alcohol before reconnecting.

8. Removal of the device:

- a. Use a silicone based adhesive remover pad, similar to Uni-solve or Medline Adhesive Removal Pad (not supplied).
- b. Carefully apply adhesive removal pad and gently separate the edge of the device cup from the skin.
- c. Start at the top closest to the belly. Repeatedly apply adhesive remover around the edges of the collection cup until it has sufficiently loosened from the skin to easily remove the device.
- d. If the cup is not easily removed after using the silicone adhesive remover, do not aggressively pull device or skin may tear or become irritated. Use additional adhesive remover to gently peel away cup from skin.
- e. **Do not remove without a silicone based adhesive remover (not supplied) to avoid skin irritation or breakdown.**

	Read Instructions for Use		Applicable Catalog Reference # ZF-F-XS, ZF-F-S, ZF-F-M, ZF-F-L
	Sterilized by Ethylene Oxide Gas		Single Patient Use – Do Not Reuse
	Store between 15-25 °C (59- 77 °F)		Do not use if open or damaged

ZORRO-FLOW, Inc.
 1500 1st Avenue North (H102)
 Birmingham, AL 35223
 Ph: 1-205-289-7432
 Email: info@zorro-flow.com
www.zorro-flow.com



Manufactured by: Infus Medical Co. Ltd.
 Samutprakarn, Thailand
 For Zorro-Flow, Inc.

Product is not made with natural rubber latex.

Silicone Skin Adhesive, 3 mL made for Zorro-Flow® Woodland, CA. (Skinister® is a Class 1 Medical Device)

Ingredients: Hexamethyldisiloxane, Trimethylated Silica treated with Dimethylsiloxane

For more information go to www.skinister.com

FLAMMABLE WHILE IN LIQUID FORM, KEEP BOTTLE AWAY FROM SOURCES OF IGNITION.

DISCARD REMAINING BOTTLE OF LIQUID SKIN ADHESIVE IN THE APPROPRIATE MEDICAL WASTE CONTAINER.

LG-IFU-01 February 2024