

ZORRO-FLOW®  
INSTRUCTIONS FOR USE



[www.Zorro-Flow.com](http://www.Zorro-Flow.com)



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 weight – use best judgement.	

## FEMALE EXTERNAL URINE COLLECTION DEVICE

### Product Description:

Zorro-Flow® is an external urine collection device designed for neonates, infants and children.

Zorro-Flow® is made with silicone-based materials to optimize safety and efficacy.

Zorro-Flow® assembly includes silicone-based adhesive and tape which are easily removed with silicone adhesive removal pads (not supplied).

Zorro-Flow® urine collection bag enables sample analysis and approximation of urine volume.

### Indications for Use:

Zorro-flow® is intended for urine collection using an external collection system for up to 24 hours.

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

### Contraindications:

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

Do not use for patients with bladder dysfunction or bladder obstruction.

### 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.
5. Do not use if perineal skin is damaged or infected.
6. Do not use alcohol pads or other chemicals to clean the perineal area.
7. Do not reuse.
8. Do not re-sterilize.
9. Do not use if the package is opened or damaged.
10. Intended for EXTERNAL urine collection use only.
11. ENSURE that the Tube and Bag are BELOW the level of the Bladder to provide for the flow of urine.
12. ENSURE slack on the Tube to prevent tension on the Cup by the urine bag.

### Cautions:

1. Federal law restricts this device to sale by or on the order of a physician.
2. Read ALL instructions before beginning application and use only as directed.
3. Follow the directions in the sequence provided.
4. Adhere device only with supplied adhesive and tape. Do not use other products.
5. Check adherence periodically and inspect for any signs of skin irritation.
6. Do not allow adhesive to flow into the vagina.
7. Discard after single use, do not reuse.
8. If adhesive is not in liquid form do not use.

### Warnings:

1. A false positive urine test result cannot be guaranteed.
2. Accurate measurement of urine output cannot be guaranteed.
3. Ensure that all tubing and the bag are below the level of the bladder to ensure good flow.

4. Secure tubing and bag so that it does not pull on the cup and check that there are no kinks in tubing.
5. Do not let the tubing wrap around patient's body parts or allow it to get pinched by medical equipment.
6. The Skinister skin adhesive is flammable while in liquid form. Keep bottle away from sources of ignition.

**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 Zorro-Flow® device.

**Zorro-Flow® is single disposable unit that contains:**

- **Sterile device pouch**
  - Urine collection bag (with valve)
  - Female and male luer
  - Tubing
  - Cup which features a Ramp, Rim and Port
    - **Ramp** holds urine from leaking
    - **Rim** is the contact area for adhesive
    - **Port** is where the tube connects
- **Non-sterile accessory bag**
  - Hook and loop straps
  - Silicone-based adhesive liquid
  - Silicone-based adhesive tape

**Materials needed but not supplied:**

- Disposable diaper and diaper wipes.
- Silicone adhesive removal pads (e.g., Uni-solve)
- Aseptic cleaner if aseptic technique desired.
- Alcohol wipes to wipe luer and valve if needed.

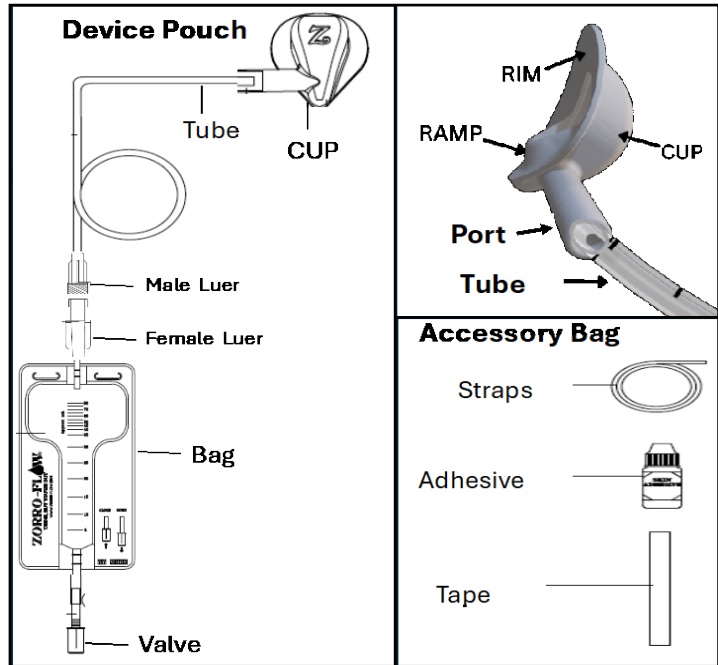


Figure 1. Parts of the Zorro-Flow Device

## INSTRUCTIONS FOR PLACEMENT OF THE ZORRO-FLOW® FEMALE EXTERNAL URINE COLLECTION DEVICE

**Step 1: Evaluate Skin Around Perineal Area**

- If the skin is discolored, has poor skin integrity or is abnormally swollen, do not use device.

**Step 2: If aseptic technique is desired, keep the following in mind:**

- Follow aseptic technique throughout placement of the catheter.
- Use an antiseptic (not supplied) that will not damage skin.
- Set up all sterile materials using aseptic technique.
- Keep one hand donned with a sterile glove on the cup, while the other can be used to open adhesive bottle and hold patient.
- When handling the adhesive BE CAREFUL not to touch the bottle tip.
- A false positive urine test result cannot be guaranteed.
- Wipe the drain valve with an alcohol pad prior to sample collection.

**Step 3: Preparation for application**

- Select size based on patient's weight/body size. These are approximate, use best judgement.
- Open the bag, accessory bag and device pouch. Identify components and set up.

**Step 4: Apply a small amount of adhesive around Rim of Cup (Figure 2).**

- **DO NOT** place adhesive directly on the patient.
- Use enough adhesive to cover the rim but not so much that it spills over.
- **LET ADHESIVE DRY FOR 3-5 MINUTES BEFORE PLACING ON PATIENT!**

**Step 5: Clean area with wipes (not supplied) and change diaper.**

- Failure to change a wet diaper will limit ability to assess urine leakage.

**Step 6: Place the cup on perineum.**

- **Carefully spread the labia and place cup starting with RAMP, which is placed at the lowest part of the vaginal opening (Figure 3).**
- Remember to wait 3-5 minutes for adhesive to dry.
- Press firmly for 30 – 60 seconds to secure the cup to the patient's skin.

**Step 7: Secure cup to the patient with the 2 tape strips (Figure 4).**

- Depending on the patient's size, tape strip may be cut for best length.
- Peel and discard blue liner.
- Secure the first strip to the pelvis/abdomen over the cup and behind thigh on the opposite side.
- Repeat previous steps with second strip using a crisscross pattern (Figure 4).

**Step 8: Secure the urine collection bag and tubing:**

- ENSURE that the Tubing and Bag are BELOW the level of the Bladder.
- Secure the bag with the straps provided to the side of crib / bed / isolette.
- ENSURE slack on Tubing to prevent tension on Cup by the urine bag.

**REMOVING the ZORRO-FLOW®**

- **DO NOT** remove cup or tape without a silicone based adhesive remover (not supplied).
- Gently separate the edge of cup from skin by applying adhesive removal. Continue until it can be easily removed.
- **NEVER** pull device with force as this could cause skin damage or irritation.

**KEEP THE FOLLOWING IN MIND WHEN THE USING ZORRO-FLOW®**

- **NEVER** let the bag overfill.
- Pull DOWN on valve to OPEN position to drain the urine (Figure 5).
- Push UP on valve to CLOSED position to collect the urine (Figure 5).
- To collect a fresh urine sample:
  - Clean end of valve with an alcohol pad to prevent contamination.
  - Start the collection with an empty bag.

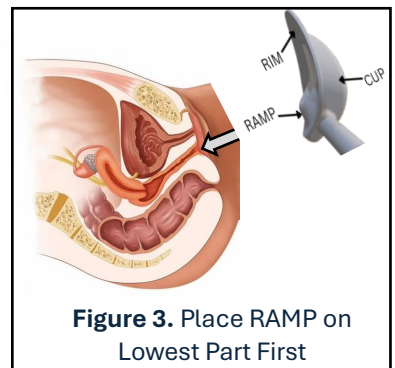
**TROUBLESHOOTING LOW URINE OUTPUT:**

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

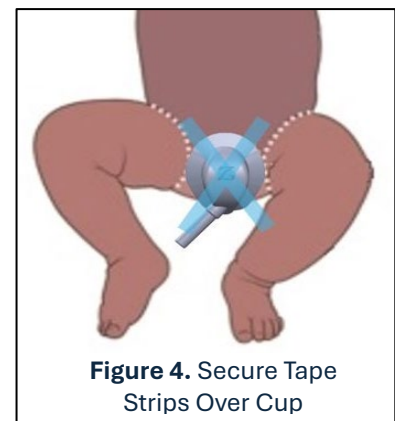
1. Determine if urine is leaking into diaper by evaluating if the diaper is wet.
2. Ensure that there are no tubing kinks or disconnections.
3. Ensure that tubing is not pinched by equipment.
4. Ensure that cup has not been dislodged from tubing.
5. Ensure that male and female luers are connected.
6. Ensure that the tubing and bag are below the bladder.
7. Ensure that the valve on the bag is closed.



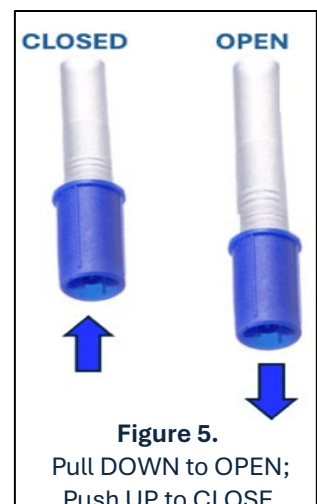
**Figure 2.** Apply adhesive around the inside rim of cup














**Figure 3.** Place RAMP on Lowest Part First



**Figure 4.** Secure Tape Strips Over Cup



**Figure 5.** Pull DOWN to OPEN; Push UP to CLOSE

	Consult instructions for use		Catalogue Number
	Sterilized using Ethylene Oxide		Do Not Reuse
	Do not resterilize		Do not use if package is damaged
	Use by date		Non-sterile
	Batch Code		Caution
	Manufacturer		

**Manufactured by:**

INFUS MEDICAL (THAILAND) CO., LTD  
Samutprakarn, Thailand  
For Zorro-Flow, Inc.

**ZORRO-FLOW, Inc.**

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Patent Pending

**Product is not made with natural rubber latex.**

**Silicone Skin Tape, DermaHug®** is a silicone gel tape that has a napped elastic fiber face and is supplied with a 100 micron blue matte polyethylene liner made by Ultra Wound Care LLC for Zorro-Flow® Inc. For more information go to [www.dermahug.net](http://www.dermahug.net).

**Silicone Skin Adhesive, 3 mL** made by Skinister Medical for Zorro-Flow® Inc.  
Ingredients: hexamethyldisiloxane, trimethylated silica treated with dimethylsiloxane.  
For more information go to [www.skinister.com](http://www.skinister.com).

**FLAMMABLE WHILE IN LIQUID FORM, KEEP BOTTLE AWAY FROM SOURCES OF IGNITION.  
DISCARD IN THE APPROPRIATE MEDICAL WASTE CONTAINER.**