



# ZORRO-FLOW® INSTRUCTIONS FOR USE

Proud Sponsor of the NKC



Catalog #	Width	Length
ZF-F-XS	2.4 cm	2.8 cm
ZF-F-S	3.2 cm	3.7 cm
ZF-F-M	4.1 cm	4.7 cm
ZF-F-L	5.1 cm	5.9 cm
Approximate size		

## FEMALE EXTERNAL URINE COLLECTION DEVICE

### Product Description:

Zorro-Flow® is an external urine collection device designed for neonates, infants and children. Zorro-Flow® cup is made with silicone-based materials to optimize safety and efficacy. 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 the skin integrity in the patient's perineal area is poor, discolored or not intact. Do not use for patients with bladder dysfunction or bladder obstruction.

## DESCRIPTION OF ZORRO-FLOW ASSEMBLY

### Sterile device pouch

- 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
- Tubing
- Female and male luer
- Urine collection bag (with valve)

### Non-sterile accessory bag

- Silicone-based adhesive liquid
- 1 x Silicone-based **RING** Seal
- 2 x Silicone-based **U-shaped** Tape
- 2 x Hook and loop **straps**

### Materials which may be needed (not supplied):

- Disposable diaper wipes.
- Aseptic cleaner (if aseptic technique is desired).
- Alcohol wipes to wipe luer and valve.
- Silicone-based adhesive removal pads.
- Consider the use of Cavillon™ Advanced Skin Protectant film barrier to protect skin.

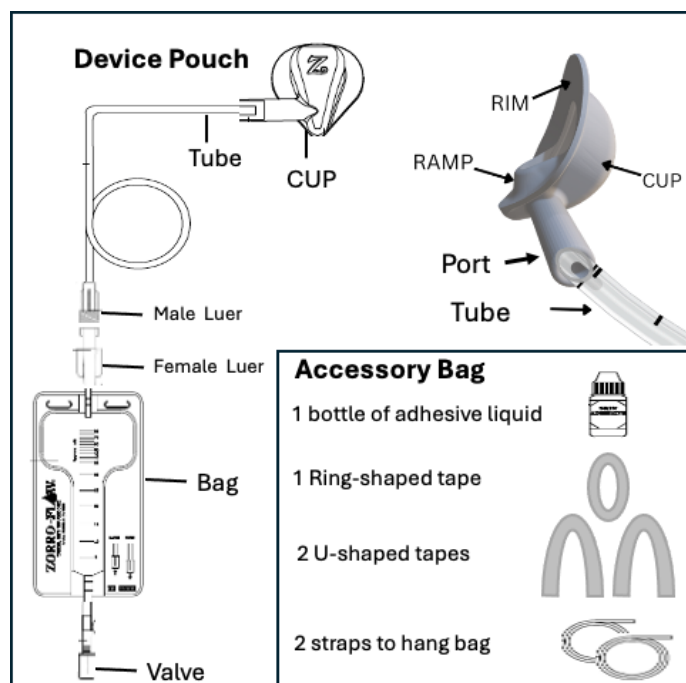


Figure 1: Parts of ZF – Female Assembly

## PLACEMENT INSTRUCTIONS FOR 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.

### Step 2: If aseptic technique is desired, consider the following:

- Set up all sterile materials using aseptic technique.
- Follow aseptic technique throughout placement of the cup.
- Use an antiseptic (not supplied) that will not damage skin.

- Keep one hand donned with a sterile glove on the cup, while the other can be used hold patient.
- A false positive urine culture result cannot be guaranteed.
- Wipe the drain valve with an alcohol pad prior to sample collection.

**Step 3: Preparation for application.**

- Select size of cup to match the width and length of the perineal area.
- Open the bag, accessory bag and device pouch.
- Identify all components and set up.

**Step 4: Secure the Adhesive Ring to the Rim of the Cup.**

- **DO NOT PLACE ADHESIVE DIRECTLY ON PATIENT**
- Apply **SMALL** line of liquid around the Rim (Figure 2a).
- Let Adhesive **DRY FOR 3-5 MINUTES.**
- Secure the **LIGHT BLUE SOFT SIDE** of the RING onto the adhesive liquid
- **Press Firmly for 30-60 seconds** (Figure 2b).
- The **DARK BLUE LINER** will be visible and face outwards.
- If desired, may cut RING with scissors.

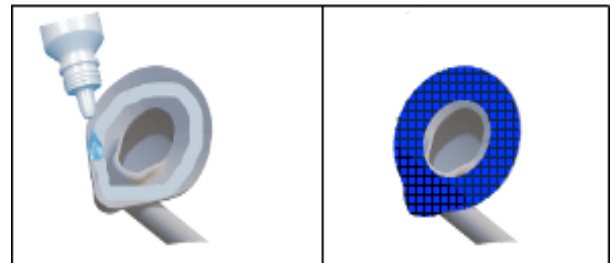


Figure 2a. Apply adhesive around the inside rim of cup

Figure 2b. Secure the Ring Tape to the Rim

**Step 5: Clean perineal 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.**

- Remove dark blue liner of the Ring to expose the adhesive
- Spread the labia and place cup (**starting with RAMP**) at the lowest part of the vaginal opening (Figure 3).
- **Press Firmly for 30 – 60 seconds** to secure the cup to the skin.

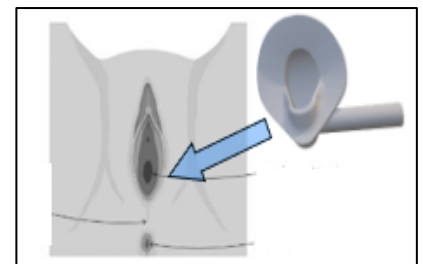


Figure 3: Place Ramp inside the Bottom of the vaginal opening.

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

- Peel and discard dark blue liner.
- Secure **BOTTOM U-shaped tape FIRST** and secure it to each thigh.
- Secure **TOP U-shaped SECOND** and secure to each buttock.
- If desired, may cut tape with scissors.



Figure 4: First, place 1st U-shaped tape at bottom of cup and secure to thighs. Next, place 2nd U-Shaped tape at top of cup and secure to buttocks.

**Step 8: Secure 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.
- Ensure ample overlap (at least 6 cm) of the strap when hanging bag.

**REMOVING THE ZORRO-FLOW®**

- Gently separate the adhesive tape from skin.
- **NEVER pull device with force** as this could dame or irritate skin
- If needed, use a silicone-based adhesive removal pad.

**KEEP the FOLLOWING IN MIND WHEN 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.

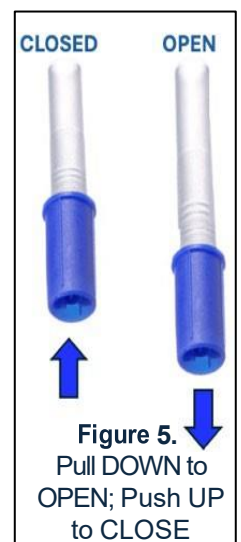


Figure 5. Pull DOWN to OPEN; Push UP to CLOSE

## **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.

### **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 skin around perineal area is healthy and intact.
5. Do not use if skin around perineal area is damaged or infected.
6. Do not use alcohol pads or other chemicals to clean the pelvic 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 use adhesive liquid if not in liquid form.
7. Do not apply liquid adhesive directly on skin.
8. Discard after single use, do not reuse.

### **Warnings:**

1. A false positive urine culture 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:**

1. The contents of the device pouch are sterile.
2. The contents of the accessory bag are non-sterile.
3. Do not sterilize or re-sterilize any part of Zorro-Flow<sup>®</sup> device.

	Consult instructions for use		Catalogue Number
	Sterilized using Ethylene Oxide		Do Not Reuse
	Do not re-sterilize		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.**

3508 Springhill Road  
Birmingham, AL 35223, USA  
Ph: 1-205-907-6048  
Email: [info@zorro-flow.com](mailto:info@zorro-flow.com)  
[www.zorro-flow.com](http://www.zorro-flow.com)

**PATENTED:**

US Patent Number 12,402,865  
Canada Patent Number 3,157,318  
Japan Patent Number 7539980

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

**Silicone-based 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-based 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.**