

# Haematuria Catheter 3-way COUVELAIRE tip Instruction for use

#### **INDICATIONS**

Used to provide good drainage to the bladder in the presence of blood clots.

#### **HOW SUPPLIED**

The Set is sterilized using irradiation. Contents are sterile, non-pyrogenic in unopened undamaged package. Do not use device if package has been damaged or has been opened.

#### **STORAGE**

Store at 5°C to 30°C. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that the articles are used prior to expiration date on the package label.

#### **WARNING**

- Do not use device if package has been damaged or opened.
- The balloon should be re-inflated at least every two weeks with the stated nominal fill volume.
- If the balloon cannot be deflated with syringe, use sharp scissors to cut side arm below the valve.
- Use water soluble lubricants on catheter shaft. Do not use petroleum based lubricant.
- Never clamp the catheter. Catheter can be damaged by clamp.
- Fill balloon with sterile water only. Do not use syringe with needle.
- Do not collect urine sample through directly from catheter shaft.
- Disposal of the device shall be made in accordance with applicable national regulations for biologically hazardous waste. - Do not expose the product to high temperature, humid air and ultraviolet ray during storage.
- Do not re-sterilize the product to avoid any potential risk of infection.

#### **COMPLICATIONS**

If difficulty is encountered aspirating the balloon with the syringe, a rare and infrequently reported event, the limb of the catheter with the valve should be cut with sharp scissors at the bifurcation, or the balloon ruptured according to established procedures reported in medical literature. Should it be necessary to rupture the balloon, care must be taken to remove all fragments from the patient. Inflation of the urethral mucosa, blockage of the catheter due to encrustation and catheter induced infections are documented complication with some catheter materials and patients. The patient should be routinely monitored in accordance with accepted procedures and the catheter removed after a suitable interval as determined by a physician.



#### **INSTRUCTION FOR USE**

#### Preparation for Use

Remove the catheter from its pouch using aseptic technique. Visually inspect the catheter for any mechanical damage.

Check the balloon before application, after checking, the balloon must be emptied completely. Only sterile water should be used to fill the balloon.

## Direction for Use

Lubricate the urethra using a water based lubricant or gel (with or without local anaesthetic, as required). Using sterile technique, as indicated in published literature, insert the catheter fully into the urethra ensuring that the balloon is beyond the bladder neck. For Hydrophilic catheters we recommend moisturizing the catheters before use.

A Luer syringe may be used to inflate the balloon with sterile water. The capacity of the balloon is indicated on the funnel of the catheter or on the label of the packaging. Do not over inflate. Ensure function by checking for urine for urine from the drainage funnel.

To deflate the balloon prior to removal, insert a Luer syringe as appropriate. Aspirate the syringe gently to remove the inflation fluid. Do not use excessive aspiration during syringe deflation as this may cause a vacuum collapse of the inflation lumen which may impair normal drainage.

The inflated balloon hold the catheter in the bladder. If the balloon loses the liquid, e.g. by diffusion of the filling liquid through the balloon membrane, the catheter can, with time, especially with silicone catheters, which are inflated with sterile water, because of the particular material characteristics of silicone. In order to prevent this risk, the infusion liquid should be withdrawn from the catheter at least one a week and the balloon should then be immediately re-inflated with the stated volume of infusion liquid.

#### **SPECIFICATIONS**

- Available from 18Fr to 24Fr
- Length 40cm
- · Couvelaire Tip
- Balloon size 60ml
- Made of Silicone Elastomer
- Indwelling time 7 to 15 days

#### ARTICLE NUMBERS

9395-1860, 9395-2060, 9395-2260, 9395-2460

## PRODUCT SAFE DISPOSAL

Used products should be disposed in sanitary container to prevent possible contamination and cross infection



# **TABLE OF SYMBOLS**

Symbol	Description
	Do not reuse
	Use by
LOT	Lot Number
	Date of manufacture
STERILE R	Sterilized using irradiation
REF	Catalogue number
<u> </u>	Caution
	Manufacturer
	Temperature limitation
	Consult instruction for use
类	Keep away from sunlight
<b>*</b>	Keep dry
LATEX	Contains or presence of natural rubber latex
$\mathbb{X}$	Non pyrogenic
	Do not use if package is damaged
(€	CE Mark

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