



**INSTRUCTIONS FOR USE
SINGLE USE ONLY
100% Silicone Supra-pubic
Catheter/
Puncture Set/
Exchange Set**

INTENDED USE:

The Supra-pubic Catheter is intended for drainage of bladder catheterizing in patients with impaired bladder function, and for urine balance studies and diagnosis. Anyone who cannot empty their bladder may need a catheter. A supra-pubic catheter may be chosen because it is more comfortable and less likely to give you an infection than other catheters. Supra-pubic catheters are sometimes used for the following reasons:

1. Urethral trauma (damage that has been caused to the urethra - the tube where urine comes out)
2. People who require long-term catheterization and are sexually active
3. After some gynaecological operations for stress incontinence
4. Some wheelchair bound people find this method simpler
5. People who cannot perform self- catheterization

Long-term catheterization for incontinence. Although this is not recommended, sometimes medical staff feel it appropriate to avoid skin problems or other medical complications. The Supra-pubic Catheter enters the bladder through a small cut in the lower abdomen and is held in place by a small balloon which is inflated inside the bladder.

FEATURES:

1. Transparent tube with X-ray opaque line. It allows for easy visual inspection and fluid observation. It also allows for confirmation of intubated tubes using X-ray.
2. Integrated balloon for smooth insertion through split cannula or surgical procedure.
3. The split cannula helps the catheter to puncture into the bladder immediately and is easily withdrawn by bending the wings.
4. The guide wire conducts the catheter to be replaced conveniently.
5. Soft and uniformly inflated balloon makes the tube sit well against the bladder.
6. Smooth round shaft can minimize trauma during insertion and withdrawal.

CONTENTS:

Silicone Supra-Pubic Catheter

Ordinary Balloon Cat. No.	Integrated Balloon Cat. No.	Size	Balloon	Length	Description
1890-0210	--	10FR	2cc	420mm	Depth marking Catheter spigot
1890-0212	4890-0212	12FR	5cc		
1890-0214	4890-0214	14FR			
1890-0216	4890-0216	16FR			
1890-0218	4890-0218	18FR			

Silicone Supra-Pubic Catheter

Ordinary Balloon Cat. No.	Integrated Balloon Cat. No.	Size	Balloon	Length	Description
1890-0220	4890-0220	20FR	5cc	500mm	Pigtall pattern Depth marking Catheter spigot
1890-0222	4890-0222	22FR			
1890-0224	4890-0224	24FR			
1857-0212	--	12FR			
1857-0214	--	14FR			
1857-0216	--	16FR			

Silicone Supra-Pubic Catheter Puncture Set

Cat. No.	Size	Balloon	Length	Description
4890-9212	12FR	5cc	420mm	Integrated balloon Split cannula Depth marking Catheter spigot Catheter clamp
4890-9214	14FR			

Silicone Supra-Pubic Catheter Exchange Set

Ordinary Balloon Cat. No.	Integrated Balloon Cat. No.	Size	Balloon	Length	Description
1890-8210	--	10FR	2cc	420mm	Depth marking Catheter spigot Catheter clamp - PTFE coated guide wire 0.035"
1890-8212	4890-8212	12FR	5cc		
1890-8214	4890-8214	14FR			
1890-8216	4890-8216	16FR			
1890-8218	4890-8218	18FR			
1890-8220	4890-8220	20FR			
1890-8222	4890-8222	22FR	5cc	500mm	Pigtall pattern Depth marking Catheter spigot Catheter clamp PTFE coated guide wire 0.035"
1890-8224	4890-8224	24FR			
1857-8212	--	12FR	5cc	500mm	Pigtall pattern Depth marking Catheter spigot Catheter clamp PTFE coated guide wire 0.035"
1857-8214	--	14FR			
1857-8216	--	16FR			

CONTRAINDICATIONS:

- Contracted bladder
- Microhaematuria
- Coagulopathies
- Tumours of the lower abdomen
- Pregnancy
- Recent surgical scars on the lower abdomen
- Severe skin changes in the area to be punctured
- Recent surgery to the bladder or prostate

PROCEDURE:

Puncture:

1. Ensure that the bladder is sufficiently full by bladder percussion.
2. Assemble all equipment: catheter, sterile gloves, cleaning supplies, syringe with water to inflate the balloon, drainage receptacle.
3. Exclude all contraindications. Shave widely and disinfect the puncture site, in the median line 2-3 cm above the pubic symphysis. Administer local anaesthesia if required.
4. Connect the catheter to the urine drainage system. Introduce the catheter into the split cannula as far as the first mark on the tube and make sure the first mark with the same position of the wings of split cannula.
5. Perform the skin incision.
6. The direction of the puncture should be perpendicular to the abdominal wall.
7. If puncture has been successful, urine appears in the catheter. If the solution does not easily return, you may not have the catheter far enough in the bladder.
8. Move the catheter steadily to the second mark from the puncture track.
9. Balloon catheters should be fixed by filling the balloon with the volume indicated.
10. Withdraw the split cannula by bending the wings, pull apart and remove.
11. Fix the catheter in place by using adhesive tape.

Exchanging the catheter:

1. Check bladder is adequately filled. Prepare another catheter you want to change.
2. At first introduce the guide wire through the existing catheter until reaching the adequate position.
3. Attach a small syringe to the inflation port on the side of the catheter. Draw out all the fluid until you are unable to withdraw any more fluid.
4. Slowly pull the existing catheter out from the bladder along the previously positioned guide wire, and then introduce the new catheter in the position through the guide wire.
5. Balloon catheters should be fixed by filling the balloon with the volume indicated.
6. Remove the guide wire and secure the catheter in place by using adhesive tape.

Note:

During puncture the integrated balloon catheter is only suggested for use but both of the integrated and ordinary balloon are applied to exchange.

INSTRUCTIONS ON ACCESSORIES:

Spigot: A plastic stopper for catheters; provided as individual sterilized package.

WARNINGS:

1. The puncture should not be made lateral to the midline of the body.
2. The catheter should not be withdrawn inside the split cannula (due to the risk of separating the catheter tip or damaging the balloon).
3. When exchanging the catheter, the flexible tip of the guide wire should always be introduced into the bladder.
4. Fix the catheter in place with adhesive tape. Do not suture direct to any part of the catheter - damage may occur.
5. The catheter must be regularly checked.

CAUTION:

1. Following aseptic catheterization. Inflate the retention balloon by a syringe without a needle with sterile water.
2. Inflate the balloon slowly and according with the volume indication.
3. If a balloon does not deflate, do not cut the balloon port proximal to the inflation valve. Urological consultation is recommended if non-deflation persists.

4. STORAGE:

The product should be kept in dryness and coolness only.

STERILIZATION:

1. The Silicone Supra-pubic Catheter is a single use item and supplied sterile.
2. Sterile by E.O. Gas, indicated on the label.
3. Please see the label on the sterilized peel pouch for expiration time.
4. Do Not re-sterilize or reuse. To reuse the device may lead to the risk of inflammation reaction and bacterial infection.
5. Sterile only if package is not opened, damaged or broken.



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