DOUBLE LOOP URETERAL STENT
Guides & Instruction for use

CAUTION: Federal law (USA) restricts this device to sale by or on the order of physician.

INDICATION:
1. Relieve of ureteric or renal pelvis obstruction whether organic or functional obstruction.
2. Stenting the ureter after operative intervention (renal or ureteric).
3. Stenting the ureter pre- extra corporeal shock wave lithotripsy.
4. Ureteric dilatation.
5. Preoperative before major vascular surgery.
6. Following extensive ureteral manipulation to avoid ureteral stricture.
7. Relieve of urinary tract infection as a result of ureteric obstruction.

HOW SUPPLIED:
The devices are sterilized by ethylene oxide. Contents are sterile, do not use if package has been damaged or has been opened.

STORAGE:
Store at room controlled temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to expiration date on the package label.

WARNING:
- For single product and patient use only.
- Do not use if any sign of product damage is visible.
- Do not re-use, reprocess or re-sterilize. Reuse may lead to infection. Reprocessing or Re-sterilization may damage the product and affect its integrity which when re-used may lead to possible deterioration in health and safety of patients.

COMPLICATIONS:
- Perforation or ureteric injury during application.
- Infection.
- Hematuria.
- Irritative lower urinary tract symptoms.
- Encrustation with long time implantation.
- Obstruction.
- Migration.
- Delayed effect: stricture.

CONTRAINDICATIONS:
The major contraindication to ureteral stents is an active and untreated urinary tract infection. A relative contraindication is uncorrected bleeding diathesis.

PRECAUTIONS:
- The methods of application are variable, and could be modified by the endoscopist according to his own experience.
- Short term catheter should not left inside the body for more than 30 days otherwise use Amecath long term stent.
- Market sound and follow up of Amecath long term double loop stent revealed that the accepted period of implantation is 90 day. Longer periods of implantation is not guaranteed Yet.
- The endoscopist should inform the patient of the presence of the catheter and the possible complications especially with negligence of withdrawing the catheter from the body within a suitable time.
- The proper size selection for stent size and length is the responsibility of the physician.
- Don’t connect the pusher to the catheter while the guide wire out.
INSTRUCTION FOR PHYSICIAN:
In general, the ease of processing and high strength of polyurethane makes them the material of choice in medical devices. Polyurethanes pass the tests of biocompatibility and chemical stability. They can be easily loaded with radiopaque material for X-ray detection. However, the major advantage of polyurethane are their thermo liability that makes them very soft inside the body, minimizing the sense of discomfort associated with implantable foreign body. AMECATH double loop catheter is made of tecoflex, which has the maximum degree of softening inside the body. It has a wide range of hardness extending from very soft to very hard with different sizes and length according to the physician specification.

METHODS OF APPLICATION:
*The methods of application are variable and could be modified by the endoscopist according to his own experience.

(1) Application of opened tip stent
- Insert the guide wire with its soft end inside the ureter under endoscopic guidance.
- Slide the catheter over the guide wire with its tapered end toward the kidney.
- Slide the pusher after the catheter then connect the upper part of the pusher to the distal end of the catheter.
- Push the catheter and the pusher under fluoroscopic guidance.
- Gradually, withdraw the guide wire to ensure presence of the upper coil in the renal pelvis.
- Withdraw the guide wire completely.
- Ensure the presence of the lower coil inside the bladder.
- Disconnect the pusher from the catheter by unlocking of the touhy piece from the male luer end.
- Withdraw the pusher completely.

(2) Application of closed tip stent
- Pass the guide wire with its rigid end through the lower end of the stent.
- Advance the wire till it reaches the upper closed end of the stent which now becomes straight.
- Advance the pusher over the wire.
- Connect the pusher with the lower end of the stent.
- Now, advance the whole system through the cystoscope to the ureteric orifice.
- Advance the stent under fluoroscopic guidance till it reaches the renal pelvis.
- Gradually withdraw the guide wire to ensure presence of the upper coil in the renal pelvis.
- Withdraw the guide wire completely.
- Ensure the presence of the lower coil inside the bladder.
- Disconnect the pusher from the catheter by unlocking of the touhy piece from the male luer.
- Withdraw the pusher completely.

(3) Advantages of Hydrophilic Coated Double Loop Stent
- Easy applicability over the guide wire during insertion.
- Smooth introduction inside the ureter.

INSTRUCTION FOR THE PATIENTS:
Stent is hollow tube, made of a flexible material that is placed in the ureter the length of the stents used in adult patients varies from 24 to 30cm, although there are different types of stents, all of them serve the same purpose. The stents are designed to stay in the urinary system by having both the ends coiled. The top end coils in the kidney and the lower end coils inside the bladder to prevent its displacement. The stents are flexible enough to withstand various body movements. Usually, a stent is placed under a general anesthetic using a special telescope (cystoscope) which is passed through the urethra into the bladder. The stents are then placed in the ureter and kidney via the opening of the ureter in the bladder. The stent may be inserted as an additional part of an operation on the ureter and kidney (e.g. ureteroscopy). Occasionally they are placed from the kidney down to the bladder using special x-ray techniques. The correct position of a stent is checked by taking x-ray film. There is no hard and fast rule about this. The stent has to be kept in place as long as necessary, i.e. until the obstruction is relieved. This depends on the cause of obstruction and the nature of its treatment. In the majority of patients, the stents are required for only a short period from a few weeks to a few months. However, a stent in the right position can stay in for up to three months without the need to replace it. When the underlying problem is not a kidney stone, the stent can stay in even longer. There are special stents, which may be left in for a much longer time.
HOW IS A STENT REMOVED?
This is a short procedure consists of removal of the stent using a cystoscope, usually under local anesthesia.

LIVING WITH A URETERIC STENT
Ureteric stents are designed to allow people to lead as normal a life as possible. However, they may not be without side effects. In placing a stent, there is a balance between its advantages in relieving the obstruction and any possible disadvantages in the form of side effects. Most side effects are not a danger to your health or your kidneys, although they can be a nuisance. Below, we have described all the possible side effects associated with a self-retained ureteric stent. You may experience none, some occasionally or a few of them. Many patients do not experience problems with the stents. In the majority of the patients experiencing side effects they are minor and tolerable. However, sometimes they can be moderate to severe in nature.

COMMONLY NOTED SIDE EFFECTS ARE:
The majority of patients with a stent in place will be aware of its presence most of the time.

**Urinary symptoms**
There might be:
- An increased frequency of passing urine. The need to rush to pass urine
- A small amount of blood in the urine. This is quite common and the situation can improve with a greater fluid intake.
- The stents can also result in a sensation of incomplete emptying of the bladder. Very occasionally, especially in women, there is a slight risk of incontinence episodes.
- These effects are possibly due to the presence of the stent inside the bladder causing mechanical irritation. These effects resolve when the stent is removed.

Discomfort or pain: stents can cause discomfort or pain, commonly in the bladder and kidney (loin) area, but sometimes in other areas such as the groin, urethra and genitals. The discomfort pain may be more noticeable after physical activities and after passing urine.

Complete understanding of these side effects and their causes is not clear at present. It has also not been possible to predict, before placement of a stent, which patients are likely to experience side effects and what they will be. There is some evidence that some of the symptoms, such as pain while passing urine and blood in the urine, may improve with time. However, this remains unpredictable.

It has been reported that around 20 - 70% of patients with a stent experience 1 or more of these side-effects. Medical science and the stent manufacturers are working to develop a stent that will cause the least possible side effects. You can carry on with various physical activities, while the stent is in place provided the underlying kidney condition and your health allows you to do it. However, you may experience some discomfort in the kidney area and passing of bloody urine, especially if sports and strenuous physical activities are involved. Sometimes side effects associated with a stent can make you feel more tired than normal.

You can continue to work normally with the stent inside your body. However, if the work involves lot of physical activities, you may experience more discomfort. Occasionally, side effects, such as urinary symptoms and pain associated with the stent, may make you feel tired. Repeatable urination may causes disturbance with your manager and colleagues temporary adjustments can be made at your work place. The presence of a stent should not affect this in a significant way. In case you get urinary symptoms such as, increased frequency and urgency, you may need to use public toilets more frequently while taking part in outdoor activities. Occasionally you may need a little more help from family members or colleagues, because of any pain or tiredness you may feel. There are no restrictions on your sexual habits due to the presence of a stent. Few patients experience discomfort during sexual activities. Occasionally the side effect associated with the stent may have an effect on the sexual desire. If you have a stent with a thread coming outside the body through the urethra, sexual activities may be difficult. Care will also be required so as not to dislodge the thread, which could then in turn displace the stent. Occasionally, a stent may develop a crystal coating on its surface. Usually, this is not a significant problem. Very occasionally, a stent may get displaced, usually slipping towards the bladder, and it may even fall out.

If this happens, you should contact the hospital or your GP.

IS THERE A POSSIBILITY OF A URINARY TRACT INFECTION?
The presence of a stent, along with the underlying kidney problem, makes it more likely that you could get a urinary tract infection. Some of the symptoms that you may experience if you get a urinary tract infection are raised temperature, increased pain or discomfort in the kidney or bladder area, a burning sensation while passing urine and feeling unwell. This usually requires treatment with antibiotics.
WHAT CARE DO I NEED TO TAKE?
It is essential that you drink at least 1.5 to 2 litters (approximately four pints) of fluids, mainly water, per day. This will help
to cut down the risk of getting an infection & will reduce the amount of blood in the urine. It will also help in the treatment
of stones. If you experience bother some pain you can take painkillers for relief, on the advice of a doctor. If you have got a
stent with a thread coming down from the urethra outside the body, then more care will be needed so as not to dislodge
the thread. If in any doubt please seek medical help.

DEVICE DESCRIPTION:
Stent is hollow tube, made of a flexible material that is placed in the ureter, the length of the stents used in adult patients
varies from 24 to 30cm, although there are different types of stents, all of them serve the same purpose. The stents are
designed to stay in the urinary system by having both the ends coiled. The top end coils in the kidney and the lower end
coils inside the bladder to prevent its displacement. The stents are flexible enough to withstand various body movements

PACKAGE INCLUDES:
- Stent
- Guide Wire
- Pusher

CODE KEY: DLU-XX-YY-PP-TTT-S/S-K-W-C

DLU:  Double loop stent.
XX :  Size in Fr.
YY :  Length in cm. (MM for Multilength (24-34 cm).
PP :  Type of pusher. (SP) For simple Pusher or (CP) For coaxial pusher.
TTT:  Type of stent and colour. (STB) For short term blue, (STY) For short term yellow or
      (LTT) For long term white.
S/S :  Both end tip. (O/O) For open/open, (O/C) For open/closed or (C/C) For
      closed/closed.
K :  Kit (stent, wire and pusher) or (0) for separate stent.
W :  Type of wire. (T) for PTFE, (H) for hydrophilic, (N)For nitinol or (Z) for zebra.
C :  Type of coating:  (0) for no coating, (H) for hydrophilic coating.

Note: For Double loop stent with strings add (S) at the end of the code

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