

## Information to the patient with an implantable device

Madam, Sir,

You have been implanted with a Vortek® hydro-coated double loop ureteral stent or a Vortek® double loop ureteral stent for treatment purpose. Please read carefully the below information for optimal follow-up.

### How to manage follow-up of my implanted device?

- It is recommended to maintain a good fluid intake after surgery and, if needed, to follow specific diet as advised by your physician.
- You have been supplied an implant card completed by your physician. This card mentions your name, your implantation date, your healthcare institution/provider and its address together with information on the implanted device and the manufacturing company.
- This card must be kept with you for the whole implantation duration to inform any other healthcare professionals of your implanted device.
- This stent is purported to stay in your body for a certain while, from a few days to several months (maximum 12 months), depending on your disease and as prescribed by your physician. You are advised to not forget your removal date.
- You are advised to consult your physician for regular monitoring of your stent as planned after the procedure to evaluate the treatment efficacy and check for any complication. The monitoring schedule greatly depends on the intended implantation duration and if you have a history of urinary stone.

### What is "Vortek® hydro-coated double loop ureteral stent" or "Vortek® double loop ureteral stent"?

- A double loop ureteral stent is a hollow tube equipped with a loop at each tip. It is implanted in your ureter to allow urine drainage between the kidney and the bladder.
- "Vortek® double loop ureteral stent" is made of:
  - Tube: Mix blend of Polyether block amide (>66%), Bismuth oxide (<34%), Phthalocyanin dye (<0.2%), Organic Antioxidant (<0.2%).
  - Ink: Organic dye (<0.1%), Cetonic solvent (<0.1%).
  - If thread: Homopolymer, Pigment (Phthalocyanin dye).
- "Vortek® hydro-coated double loop ureteral stent" is made of:
  - Tube: Mix blend of Polyether block amide (>64%), Bismuth oxide (<33%), Phthalocyanin dye (<0.2%), Organic Antioxidant (<0.2%).
  - Ink: Organic dye (<0.1%), Cetonic solvent (<0.1%).
  - Coating: Polyvinylpyrrolidone (<2%), Propyl alcohol (<0.1%).
  - If thread: Homopolymer, Pigment (Phthalocyanin dye).
- In some cases, if the stent is planned for short term less than 7 days, it may be equipped with a green thread which you can see outside the urinary natural orifice. This thread is for removal purpose.

### Which precautions should I take?

- Inform your physician in case of any allergy known to one of the above components.
- This device may act as a foreign body and be associated with inconveniences: some of them are mild and temporary like limited and transient pain, discomfort when urinating or during physical activities, frequent or urgent need to urinate, or possible sexual dysfunction.
- In some cases, complications like infection, stent migration, obstruction or breakage of the stent, may need urgent care: In case of any abnormal feeling like sustained pain, cloudy urine, bladder irritation, blood in the urine or any difficulty with urination, you are advised to immediately inform your physician.

- In case of a removal green thread remaining at your urinary orifice, you are advised not to pull this thread to avoid unintended removal of the device. This procedure must be done by your physician within 7 days after stent implantation.
- The practice of violent sports or strenuous physical activities is not recommended. The practice of sport should be evaluated by your physician.

I have an implanted "Vortek® double loop ureteral stent" or "Vortek® hydro-coated double loop ureteral stent". Can I safely pass medical imaging exams or airport security?

- In case of any medical, surgical or exploratory procedure, you are advised to inform the attending physician of your implanted device and show him your implant card.
- There is no contraindication to perform a MRI scan and no interference with any external equipment.

Be aware that:

- This device is for single use and should not be re-used.
- After removal, this device is dirty and should be discarded according to the hospital policy.