## **TELEFLEX** Patient Information Document

## Ureteral Stents – Superglide Stents with or without DD coupling and/or Valve

#### What is a Ureteral Stent?

A ureteral stent is a narrow, soft, tube. It is placed in the ureter, which is the muscular tube that drains urine from the kidney to the bladder. Each end of the stent is shaped like a pigtail. One end of the tube sits inside the kidney, and one end sits in the bladder.

#### Why do I have a Ureteral Stent?

Your Healthcare Professional has inserted a Ureteral Stent into you. Ureter Stents are intended for use following ureteric surgery or lithotripsy for ureter stone treatment for example. A stent is inserted into the ureter to treat or prevent blockage that prevents the flow of urine from the kidney to the bladder. It is important to maintain urine flow and to avoid your kidney(s) becoming damaged due to urinary obstruction.

# What are the potential complications with a Ureteral Stent?

- Irritation of the bladder Since the stent is a foreign body it may irritate your bladder which can cause frequent and / or uncomfortable urination.
- Injury of the orifice of the ureter During insertion the longer section of the stent passes the orifice of the ureter and then a short section remains continuously in the orifice. This may lead to an injury.
- Irritation and perforation of the ureter The stent may irritate the mucosa of the ureter and / or perforate it.
- Mucosal damage The mucosa of the urinary system may get damaged by the stent.
- Blockage of the stent due to encrustation Encrustation is the deposition of mineral crystals (which are normal in urine) onto the surface and lumen of a ureteral stent which can cause a blockage of the stent.
- Discomfort There can be flank, side, or back pain due to the presence of the stent.
- Infections The presence of a stent in your ureter may increase the possibility of a urinary infection.
- Calculus formation Mineral crystals in the urine may crystalise together to form urinary stones.
- Vesicoureteral reflux That means urine flows back from the bladder to the kidney.
- Bladder perforation There is the possibility that the ureteral stent may perforate your bladder wall.
- Haematuria This is the presence of blood in the urine.
- Stent migration It may happen that the stent moves from its position even after it has been appropriately positioned.

Any serious incident that occurs in relation to the device should be reported to the manufacturer (Teleflex) and to the Therapeutic Goods Administration www.tga.gov.au

# Contact your Urologist or Healthcare Provider

### immediately if:

- You do not pass any urine or very little urine
- You have severe pain in your abdomen
- You have bleeding from the urethra
- You have blood clots in your urine, or it is bright red
- You have a fever
- You need to urinate very often or feel like you need to pass urine even if you
  do not actually pass any
- Your symptoms get worse or you develop additional symptoms that your urologist has warned you about

#### What material is my Ureteral Stent made of?

| Substance                      | %           | Role/Notes                      |  |
|--------------------------------|-------------|---------------------------------|--|
| Polyurethanes                  | Balance     |                                 |  |
| Barium Sulfate                 | 29,1 - 39,5 | Radiopacity agent               |  |
| Polyamide                      | 0,0 - 2,9   | Retraction thread               |  |
| Amylodextrin Starch            | 0,0 - 0,6   | Surface treatment               |  |
| Ester Gum                      | 0,1         | Colorant (Black)                |  |
| Butadiene-Styrene<br>Copolymer | <0,1        |                                 |  |
| Carbon Black                   | <0,1        | Colorant (Black) / Printing Ink |  |
| Water                          | 0,2         | Hydrophilic coating             |  |
| Polyvinylpyrrolidone           | <0,1        |                                 |  |
| Poly(methyl methacrylate)      | <0,1        | Printing Ink                    |  |

#### What you need to know:

The stent may stay in for several weeks or longer, depending on the advice of your urologist. It may need to be replaced within a certain period of time. You will need regular follow-up visits with your urologist as long as you have a stent to make sure it works properly.

Please carry your Teleflex Implant Card with you at all times. If required, it will inform medical staff about the details of the stent and its features. Please have also the MR information in place.

Drink liquids as directed: Liquids will help flush your urinary tract and may help prevent infection. Ask your Doctor how much liquid to drink daily and which are the best liquids for you.

#### Can I have a MRI with the stent in situ?

An MRI can be safely performed.

#### How is the Ureteral Stent removed?

The stent is removed by cystoscopy, usually as an outpatient procedure. Your doctor will provide you details about that procedure.

In some instances, your doctor may decide to leave a thread on the stent. The thread is attached to the stent and it comes out of the urethra (the hole where urine exits the body). You should avoid pulling on the thread because the stent will easily come out with it.

# How to read and interpret your Implant Card?

Your International Implant Card includes the following information:



|    | <b>n</b> ?                      | <b>₩</b>                                 | 31           |  |
|----|---------------------------------|--|--------------|--|
| en | Patient Name                    | Healthcare<br>Institution                | Implant Date | Patient<br>Information<br>Website                      |
| de | Patientenidenti-<br>fikation    | Medizinische Einrich-<br>tung oder Arzt  | Datum        | Informationswebsite<br>für Patienten                   |
| fr | Identification de patient       | Centre de soins ou<br>médecin            | Date         | Site Web d'informa-<br>tions destinées aux<br>patients |
| es | ldentificación del<br>paciente  | Centro sanitario o<br>médico             | Fecha        | Sitio web de<br>información para el<br>paciente        |
| it | Identificazione del<br>paziente | Struttura sanitaria o<br>medico          | Data         | Sito web di informazi-<br>oni per il paziente          |
| pt | Identificação do<br>doente      | Centro de cuidados de<br>saúde ou médico | Data         | Página da Internet<br>de informação para<br>o doente   |
| sv | Patientidentifiering            | Vårdcentral eller<br>läkare              | Datum        | Webbplats med<br>patientinformation                    |
| n  | Patiëntidentificatie            | Zorginstelling of arts                   | Datum        | Website met patiëntin-<br>formatie                     |
| da | Patientidentifikation           | Lægecenter eller læge                    | Dato         | Websted med patientinformation                         |
| p  | Hasta kimliği                   | Sağlık hizmetleri<br>merkezi veya doktor | Tarih        | Hasta bilgilendirme<br>web sitesi                      |
| tr | ldentyfikator pacjenta          | Placówka opieki<br>zdrowotnej lub lekarz | Data         | Strona internetowa<br>z informacjami dla<br>pacjenta   |

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|    | REF                 |                   | MD                          | LOT        | UDI                           |
|----|---------------------|-------------------|-----------------------------|------------|-------------------------------|
| en | Catalogue<br>Number | Manu-<br>facturer | Medical<br>Device           | Batch code | Unique Devi-<br>ce Identifier |
| de |                     |                   | Medizinpro-<br>dukt         |            |                               |
| fr |                     |                   | Dispositif<br>médical       |            |                               |
| es |                     |                   | Producto<br>sanitario       |            |                               |
| it |                     |                   | Dispositivo<br>medico       |            |                               |
| pt |                     |                   | Dispositivo<br>médico       |            |                               |
| sv |                     |                   | Medicintek-<br>nisk produkt |            |                               |
| n  |                     |                   | Medisch<br>hulpmiddel       |            |                               |
| da |                     |                   | Medicinsk<br>udstyr         |            |                               |
| tr |                     |                   | Tıbbi Cihaz                 |            |                               |
| P  |                     |                   | Wyrób<br>medyczny           |            |                               |