Olympus Ureteral Stent

Brand Name(s): *Sof-Curl, LithoStent, Lubri-Flex, Quadra-Coil Multi-Length, Classic Double PigTail, Double J, Single J Urinary Diversion, Uro-Guide, Multi-Flex, Classic Closed Tip*

Patient Information Leaflet (PIL)

This leaflet contains important information about your implant. **You should speak to your doctor if you have any concerns or questions.**

All implantable medical devices have risks and benefits. Follow the advice from your healthcare team, even if it differs from the information contained in this leaflet. Please read this information carefully and keep it for future reference.

The name and number of your implant can be found on the patient implant card that has been provided by your doctor.


OLYMPUS Patient Implant Card

Device name

Model number

Batch / Lot number

Manufactured by

Intended Use

The Olympus Ureteral Stent is a support structure, placed in the ureter to hold it open, and provide drainage from the kidney to the bladder, or the outside stoma.

Implant Description

The Olympus Ureteral Stent is available in a variety of lengths and shapes. Your doctor has selected a stent based on your specific requirements. It may be made from silicone or Tecoflex®, a medical-grade polyether polyurethane:

Silicone:

- Double-J®
- Single J®
- Uro-Guide™
- Classic Closed Tip

Tecoflex®:

- Sof-Curl™
- LithoStent™
- Lubri-Flex®
- Multi-Flex™
- Quadra-Coil®
- Classic Double PigTail

Information for Safe Use

This device can only be inserted by your doctor.

You should follow your doctor's advice after your treatment. Discuss any questions or concerns with your doctor.

This device can be used with other surgical implants. You should always let your doctor know about any previous surgeries and treatments.

Expected Lifetime and Follow Up

The stent is not intended as a permanent implant. Your doctor will determine the length of time the stent will remain in place. It is recommended that the time in place does not exceed 365 days.

Periodic follow up with your doctor is recommended to evaluate device efficiency and check for possible complications.

Adverse Effects and Reporting

Your doctor will provide information about the benefits, risks and side effects of your treatment. Please talk to your doctor if you have concerns.

Possible adverse effects may include:

- Migration of the device
- Stone formation or encrustation of the device
- Compromised urine flow
- Urinary tract infection
- Leakage of urine
- Perforation of the kidney, renal pelvis, ureter, or bladder
- Stent breakage requiring removal

Reporting adverse effects

If you wish to report any adverse effects you believe are a result of your treatment with this implant, please speak with your medical team or report the information to the Olympus Quality and Regulatory Department:

Email: oaz-ra@olympus.com

Phone: 1300 132 992

You may also wish to contact the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

Australian Sponsor

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Patient Information:

https://www.olympus.com.au/company/en/home/patient-information-leaflets.html