

## Comparative Assessment of Ureteral Stent Biomaterial Encrustation

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The study compares the long-term in vitro encrustation of five materials widely used in the manufacture of ureteral stents: silicone, Percuflex, silitek, polyurethane, and hydrogel-coated polyurethane. This method was used to carefully control conditions and eliminate interexperimental variation.

### ABSTRACT

Long-term use of ureteral stents is hindered by the inherent problem of biomaterial encrustation which may lead to stone formation and attendant problems. The wide variety of polymeric biomaterials currently used for stent fabrication suggests that no single material is significantly superior to the others at resisting encrustation. A model representing upper urinary tract conditions was employed to compare the long-term struvite and hydroxyapatite encrustation of five materials currently used in the fabrication of ureteral stents. Silicone was least prone to struvite encrustation, followed by polyurethane, silitek, Percuflex and hydrogel-coated polyurethane, in rank order. Similarly, silicone was least prone to hydroxyapatite encrustation, followed by silitek, polyurethane, Percuflex and hydrogel-coated polyurethane. This study has shown that the problem of encrustation may limit the long-term use of ureteral stent biomaterials and suggests directions for improvement of biomaterials in this regard.

## COLOPLAST KEY TAKEAWAYS

- All materials examined in the study developed some encrustation, however, there were differences in the rates at which materials became encrusted.
- Significant differences were observed in the amount of calcium deposited on each material. Silicone was least prone to encrustation deposited in the form of calcium, followed by polyurethane, silitek, Percuflex, and HPU in rank order.
- Significant differences were observed in the amount of magnesium deposited on each material. Silicone was least prone to encrustation deposited in the form of magnesium, followed by silitek, polyurethane, Percuflex, and HPU in rank order.
- At 6 weeks, scanning electron microscopy (SEM) showed that surfaces of HPU, silitek, and Percuflex were completely covered by a thick deposit of encrustation while silicone and polyurethane were not.
- At 10 weeks, silicone was the least prone to encrustation, having 31% less surface coverage compared to all other materials which were completely covered.

### Indications

Drainage of the upper urinary tract over fistulas or ureteral obstacles (e.g. periureteral tumor). Healing of the ureter.

### Warnings

Reuse of this single use product may create a potential risk to the user. Reprocessing, cleaning, disinfection, and sterilization may compromise product characteristics which in turn create an additional risk of physical harm to or infection of the patient.

### Precautions

The following events have been reported although their occurrence greatly depends on medical conditions of patient: infection, encrustation, obstruction, rupture, migration, bladder irritation symptoms, pain, hematuria, erosion.

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

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