

trans urethram

Sterile lubricants in urology

Instillagel®

Endosgel®



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Serving urology

A comparison of the product charac

The use of lubricants in urological diagnostic testing and therapy has been a standard procedure for a long time. The decision to use a suitable lubricant not only makes the investigations and surgical procedures easier but also contributes considerably to their lasting success.

With the development of urology as a specialist field and the ever more complex possibilities for investigation and treatment there is also an increase in the requirements for lubricant functions and properties.

The preparations **Instillagel®** and **Endosgel®** were developed specifically for transurethral surgery and investigations. They are manufactured according to the highest quality standards and perform all the functions required of this particular, highly sensitive field of application.

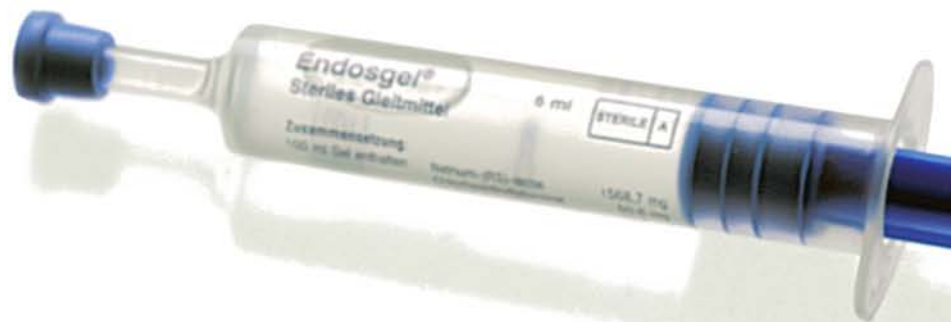
Making investigations and surgical procedures easier

Instillagel® and **Endosgel®** are lubricants on a hydroxyethylcellulose gel base. They have very good lubricant properties and adhere especially well to the mucosa. Through the addition of propylene glycol, which prevents rapid drying out of the gel, **Instillagel®** also has particularly long-lasting lubricant properties.

Protection against injuries by preparing the urethra



Application of **Instillagel®** and **Endosgel®** in the form of a ready-to-use syringe permits direct instillation into the urethra. By coating the urethra evenly and completely with the lubricant, the urethra, which would otherwise be collapsed to a star-shaped form, is gently dilated and kept open for the procedure that is about to be performed. The resulting lubricated cylinder shape reduces the friction between the urethra and the



teristics of Instillagel® and Endosgel®

instrument considerably. Injury to the sensitive mucous membrane and subsequent urethral stricture and via falsa is avoided as far as possible.

Safety in procedures that use electric current

Instillagel® and **Endosgel®** have been used successfully in many years of practice for all currently employed electroresection and coagulation procedures and for bipolar electroresection.

Reducing the risk of infection...

...due to their sterility

Instillagel® and **Endosgel®** are sterile lubricants packed under sterile conditions. The sterility of the substance and packaging means that they can be used for surgical procedures and they offer the best possible protection against the introduction of bacteria.

... and their antiseptic effect

Instillagel® and **Endosgel®** have a rapid, comprehensive, experimentally and clinically proven antiseptic effect, based on a combination of the active substances chlorhexidine digluconate, methyl- and propyl-4-hydroxybenzoate. The additional eradication of any bacteria present considerably reduces the risk of infection.

Pain relief through the anaesthetising effect

Instillagel® contains as active ingredient lidocaine hydrochloride, which anaesthetises the mucosa. The onset of its broad effect is only 5 minutes after instillation of the gel. The patient experiences no pain in investigations and surgical procedures and is thus more relaxed. Possible iatrogenic injuries that could occur, e.g. if the patient tenses up or jerks are avoided.



When do I choose which lubricant?

Instillagel® and **Endosgel®** are both suitable for virtually all indications in the specialist field of urology. If both products are available the circumstances can be a real help in making the decision. The following illustrates which factors can play a decisive role in the choice of preparation:

Indications in the specialist field of urology	Product recommendation					
	... in conscious patients with intact sensory function...	–	–	... in patients under general anaesthesia or with absence of sensory function...	–	–
Catheterisation and ISC	Instillagel®	6 ml	11 ml	Endosgel®	6 ml	11 ml
All forms of endoscopy	Instillagel®	6 ml	11 ml	Endosgel®	6 ml	11 ml
Transurethral and transvaginal endoscopic procedures	Instillagel® *	11 ml		Endosgel®	6 ml	11 ml
Stricturotomies	Instillagel® *	11 ml		Endosgel®	11 ml	20 ml
Electroresections and coagulations				Endosgel®	11 ml	20 ml
As a dressing following circumcision	Instillagel® *	6 ml				
Changing fistula catheters	Instillagel®	6 ml		Endosgel®	6 ml	



* If after the anaesthesia wears off a local anaesthetic effect is needed to dull the initial symptoms

Cystoscopy with sterile and disinfecting lubricants

How do I use Instillagel® and Endosgel® correctly?

In the field of urology, cystoscopy is a routine investigation that is frequently carried out but which must always be performed carefully and under sterile conditions. As with any transurethral surgery cystoscopy also involves the risk of bacteria being introduced into the urinary tract. The resulting inflammatory complications may be serious especially if residual urine is formed in the bladder. To prevent this happening the use of a sterile and disinfecting lubricant such as **Instillagel®** or **Endosgel®** is recommended.

Preparation

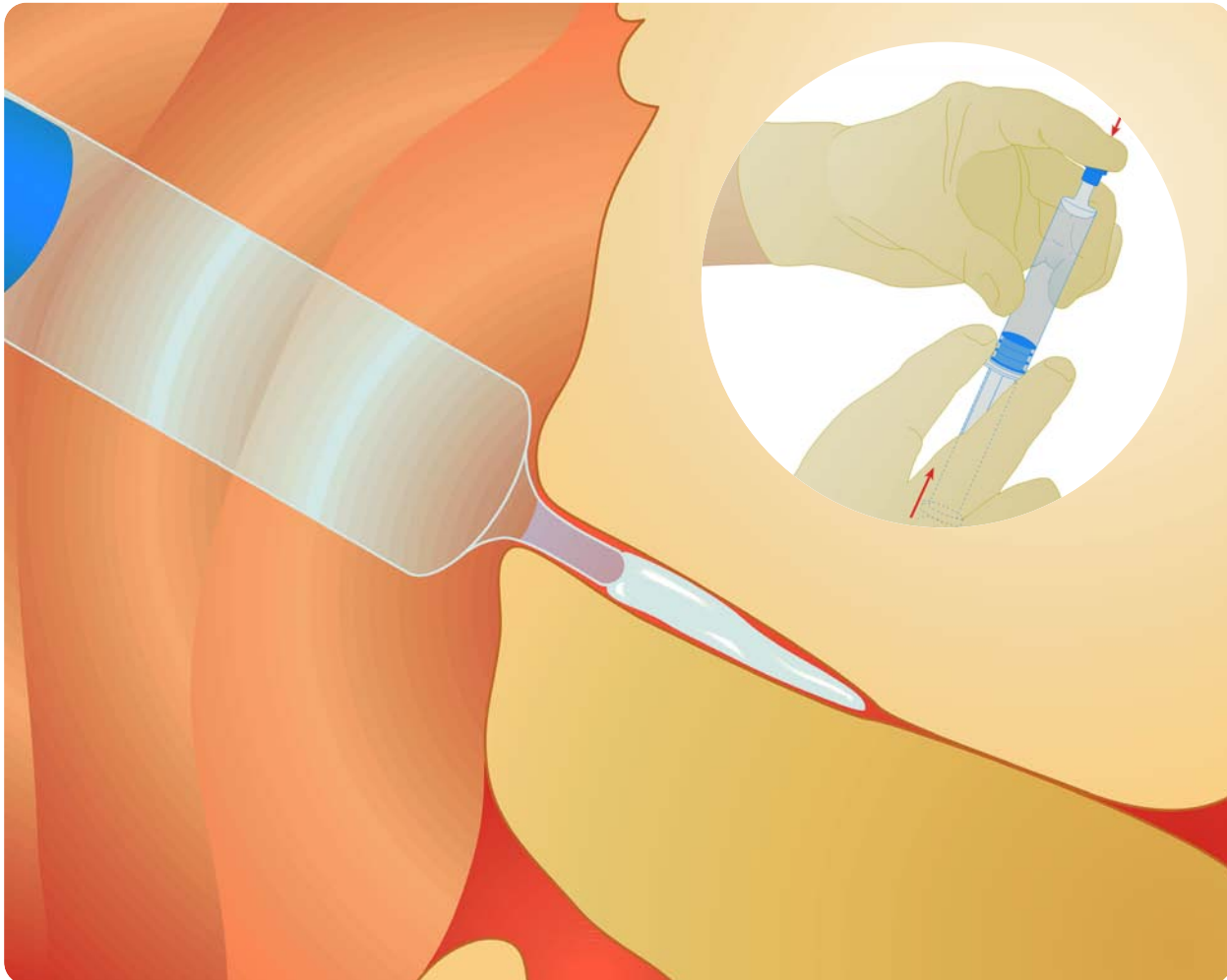
It is best for cystoscopy to be carried out in the gynaecological position. A disposable mat under the buttocks is recommended in all cases as a protection against wetting. The materials required for catheterisation should be held ready on a sterile pad or on the opened ready-to-use kit (on the right for right-handers and on the left for left-handers).

After appropriate preparation of the patient and disinfection of the genitals the lubricant is instilled.

A little pressure is exerted on the syringe plunger before removing the seal cap to release the piston (the resistance giving way is clearly felt), the rubber cap can then be carefully removed. At first a few drops of the lubricant are dropped onto the orifice. The rounded cone of the syringe can then be inserted more easily and securely.

Application

Instillagel® and **Endosgel®** are supplied in the form of a piston syringe which offers optimal, simple handling: the gel can be instilled into the urethra slowly, evenly and without using pressure.



Application of **Instillagel®** and **Endosgel®**.

Dosage

In women 6 ml gel is enough to coat the urethra evenly and completely. The average volume for use in the urethra in men is 11 ml.

As there is no resuction effect during instillation using the piston syringe no tiny bubbles are able to form, thus enabling the glass-clear gel to provide a perfect view for the imminent investigation.

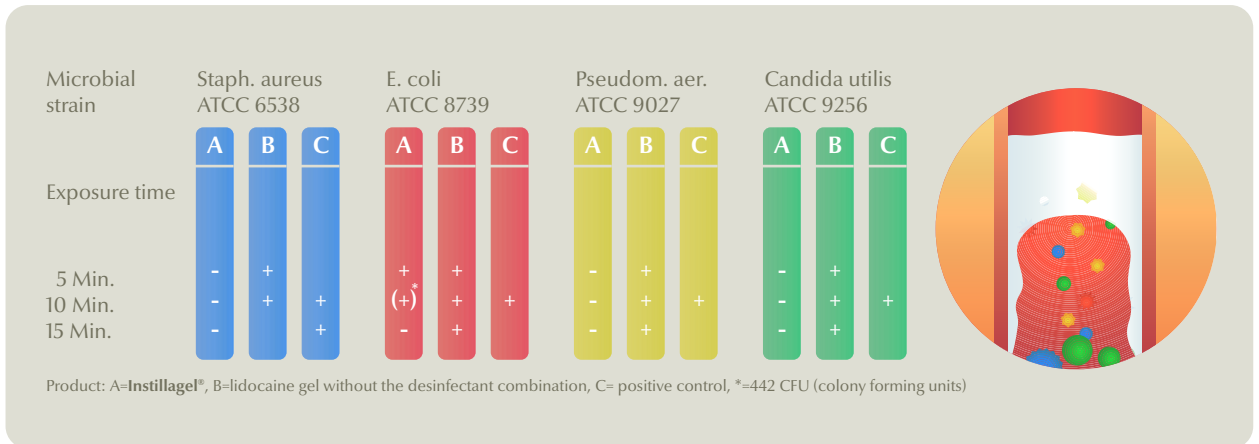
CAUTION!

When using **Instillagel®** the investigation should not be started until 5-10 minutes after instillation of the gel to allow the anaesthetising effect to develop fully. In male patients the use of a penis clamp is recommended to prevent the gel flowing out during the waiting period.

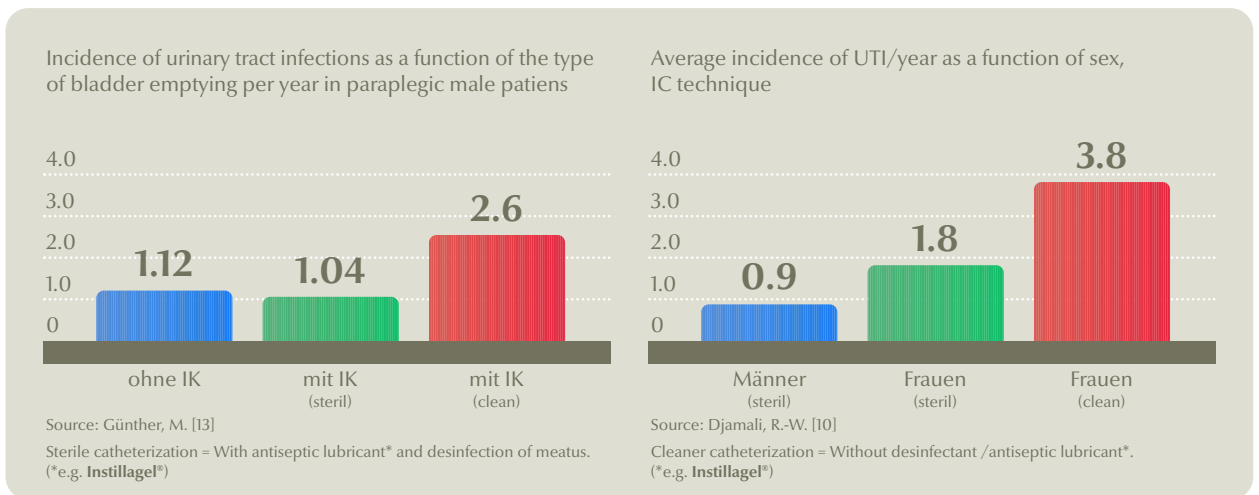
Positive effects of Instillagel® and Endosgel® on the progress and lasting success of the investigation

Antiseptic efficacy

Before, during and after the investigation **Instillagel®** and **Endosgel®**, because of their good adhesion to the urethra, act like an antiseptic protective shield against all present and ascending bacteria. Through the active substance combination of chlorhexidine digluconate, methyl- and propyl-4-hydroxybenzoate virtually all relevant problem bacteria are eradicated within a short space of time.



The rapid and pronounced antimicrobial action of **Instillagel®** has been demonstrated in vitro in wide-ranging studies.



Incidence of urinary tract infections (left), Average incidence of UTI/year (right).

Economic effectiveness

Proven data confirm the economic importance of a disinfecting lubricant with optimal lubricant properties. **Instillagel®** and **Endosgel®** because of their special properties contribute considerably to the prevention of postinstrumental urinary tract infections and urethral injuries. The low investment for the one-off application is balanced directly against the enormous cost involved in treating preventable secondary conditions.

At a glance

The most important product properties and advantages

Using this checklist ascertain simply and quickly that **Instillagel®** and **Endosgel®** meet your requirements for a lubricant for transurethral procedures !

Product characteristics	Instillagel®	Endosgel®
Sterility of substance and pack	●	●
Lubricant properties	●	●
Good adhesion to the mucosa	●	●
Disinfecting effect	●●	●●
Anaesthetising effect	●	
Conductivity	●	●●
Tolerability		
Low active substance absorption	●	●
Latex-free	●	●
Product safety / Handling		
Application form: piston syringe	●●	●●
Special, rounded syringe cone	●●	●●
No resuction effect	●●	●●
No fragment particles	●●	●●
No impairment of view		
Economic effectiveness	●●	●●
Avoidance of sequelae	●●	●●
Accurate dosing (men/women)	●●	●●
Use of the syringe for sterile irrigation	●●	●●
Reimbursement possibility*		
As surgery (clinic/consultation) requirement	●	●
On SHI drug prescription form	●	●



*these statements refer solely to Germany

●● = direct competitive advantage

Final summary:

As the substance and pack are sterile Instillagel® and Endosgel® are excellent for use in the field of sterile surgery, in clinical practice and in the home environment. They offer the doctor and patient a high degree of comfort and safety for all transurethral investigations and procedures and are of considerable economic significance.

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Prof. Dr. M. Exner, Direktor des Hygiene-Institutes der Universität Bonn: Gutachten zur antimikrobiellen Wirksamkeit des Fertigarzneimittels Instillagel®, 13.01.2000
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Instillagel® Composition: 6 ml/11 ml gel contain as active substances : Lidocaine hydrochloride 1 H₂O 125.40 mg/230.00 mg, Chlorhexidine digluconate 3.14 mg/5.75 mg, Methyl-4-hydroxybenzoate 3.76 mg/6.90 mg, Propyl-4-hydroxybenzoate 1.57 mg/2.87 mg. **Therapeutic indications:** As a gel for the disinfection of mucous membrane and for local anaesthesia, e.g. during catheterisation, probing, including intraoperative, all types of endoscopy, changing fistula catheters, intubation, including during patient ventilation, for the prevention of iatrogenic injuries to the rectum and colon, and in paediatrics. **Contraindications:** **Instillagel®** must not be used in cases of known hypersensitivity to lidocaine and other amide-type local anaesthetics, in patients with severe disorders of the impulse conduction system, if there is hypersensitivity (allergy) to methyl- and propyl-4-hydroxybenzoate, chlorhexidine or any of the other ingredients of **Instillagel®**. Use during pregnancy and breast-feeding: Lidocaine should only be used during the first three months of pregnancy if absolutely necessary. It is not known whether lidocaine passes into the breast milk, so breast-feeding should not take place until approximately 12 hours after administration. **Side effects:** Despite the proven large safety range of **Instillagel®**, undesired effects of the local anaesthetic, lidocaine, are possible in the case of severe urethral injuries. In very rare cases, allergic reactions (anaphylactic shock in the most severe cases) may be caused by an amide-type local anaesthetic. In very rare cases, chlorhexidine and/or methyl- or propyl-4-hydroxybenzoate may cause hypersensitivity reactions, including late reactions. **Pack sizes:** 1 x 6 ml/11 ml N1; 10 x 6 ml/11 ml N2; 100 x 6 ml/11 ml N3. **MA-No.:** 33660.00.00/15827.00.00 (**Instillagel®** 6 ml/11 ml)

Endosgel® 100 ml of gel contain: Chlorhexidine Digluconate 50.6 mg, Methyl Hydroxybenzoate 60.7 mg, Propyl Hydroxybenzoate 25.3 mg, Sodium Lactate 1568.7 mg. **Excipients:** Hydroxyethylcellulose, Purified Water. **Indications:** Electro-resection and electro-coagulation. Transurethral endoscopic surgery. Transvaginal endoscopic surgery. Stricturectomy. Resection of the neck of the bladder (prostate resection). Tumor coagulation. Resection of the bladder. Intermittent catheterization (6 or 11 ml). Endourological surgery. Rectal surgery. **Contraindications:** Must not be used in patients who are hypersensitive to alkyl hydroxybenzoates (parabens), chlorhexidine or any of the other constituents. **Side effects:** Hypersensitivity may result in skin symptoms; in very rare cases, contact dermatitis or irritation of the bladder may occur. **Pack sizes:** 10 x 6 ml/11 ml/20 ml, 100 x 6 ml/11 ml/20 ml. CE0197



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