REFERENCES
Prevention of healthcare-associated infection in primary and community care: NICE clinical guideline 2, June 2005
Lower urinary tract symptoms: NICE clinical guideline 16th June 2010
Multiple Sclerosis: Full Guidelines 2003
Huxley S. Importance of lubricants in transurethral manipulations. Urology 1991;31:133-135

CLASSIFICATION
1. What classification is OptiLube Active™?
OptiLube Active™ is a Class II Medical Device under the Medical Devices Directive 93/42/EEC
2. Why is OptiLube Active™ a Medical Device?
OptiLube Active™ is a Class II Medical Device in view of its primary function as a lubricating jelly, with the secondary use being the anaesthetic and antiseptic effects.

3. What are the benefits of being a Medical Device?
• The product can be advertised freely within the EU.
• The product can be freely distributed by DMCs/home delivery services into the community.

4. What is the CE Mark?
The CE Mark is the symbol used by manufacturers to show that a medical device meets the relevant requirements of the Regulations and that it is fit for its intended purpose. In the EU all medical device must be CE Marked.

5.  Why is OptiLube Active™ a Medical Device?
OptiLube Active™ is a sterile lubricating jelly which contains a local anaesthetic (Lidocaine 2%) and an antiseptic (Chlorhexidine Gluconate 0.25%).
OptiLube Active™ is a sterile lubricating jelly containing local anaesthetic (Lidocaine 2%) and antiseptic (Chlorhexidine Gluconate 0.25%). OptiLube Active™ is available in both 6ml and 11ml pre-filled syringes, each presented in a sterile package. OptiLube Active™ is used for the insertion of catheters and instruments into the body cavity. The jelly provides optimum lubrication, while the local anaesthetic minimises pain and the antiseptic properties reduce the risk of infection.

**HOW TO USE THE OPTILUBE ACTIVE™ STERILE LUBRICATING JELLY FOR URETHRAL CATHETERISATION USING ASEPTIC TECHNIQUE**

- Remove the syringe from the sterile pouch by tearing away the backing paper.
- Gently press the plunger on the end of the syringe.
- Remove the blue cap.
- Apply a small amount of OptiLube Active™ around the urethral opening.
- Gently insert the nozzle into the urethra.
- Apply even pressure to the syringe, slowly releasing the lubricating jelly in an equal flow.
- OptiLube Active™ will fill and numb the urethra.

**WHAT CAN I USE OPTILUBE ACTIVE™ FOR?**

- Urethral and suprapubic catheterisation
- Cystoscopy
- Intra-uterine sterile insertion
- Gynaecological investigations
- Rectal examinations and investigations

**Composition (in each 100g)**

- Purified Water 68.00g
- Lidocaine Hydrochloride 2.000g
- Chlorhexidine Gluconate 0.250g
- Methyl Hydroxybenzoate 0.060g
- Propyl Hydroxybenzoate 0.025g
- Hydroxyethylcellulose Propylene Glycol

**LATEX FREE**

**OMS Code**

- 1160

**NHS Code**

- FST652

**PIP Code**

- 366-2061

**Product Description**

- 6ml Syringe

**Brand**

- OptiLube Active™

**Pack size**

- Pack of 10

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**Latex free bung on end of syringe**

**Latex free plunger**

**Measuring facility on side of syringe enables precise application of a controlled volume of jelly**

**Outer blister pack is rupture resistant and protects syringe, even if stored outside original box**

**The packaging allows minimal syringe handling, maintaining an aseptic and ‘gold standard’ procedure for both patient and clinician.**

**Manufacturing, Expiry and LOT numbers are printed on each individual syringe’s tear off strip and are easily retained for accurate recording in patient records.**

**Syringe format is familiar to clinicians and easy to use.**

**Syringe falls easily from protective tray enabling gold standard Aseptic Non Touch Technique (ANTT) when preparing a sterile field.**

**Syringe is easy to prime.**