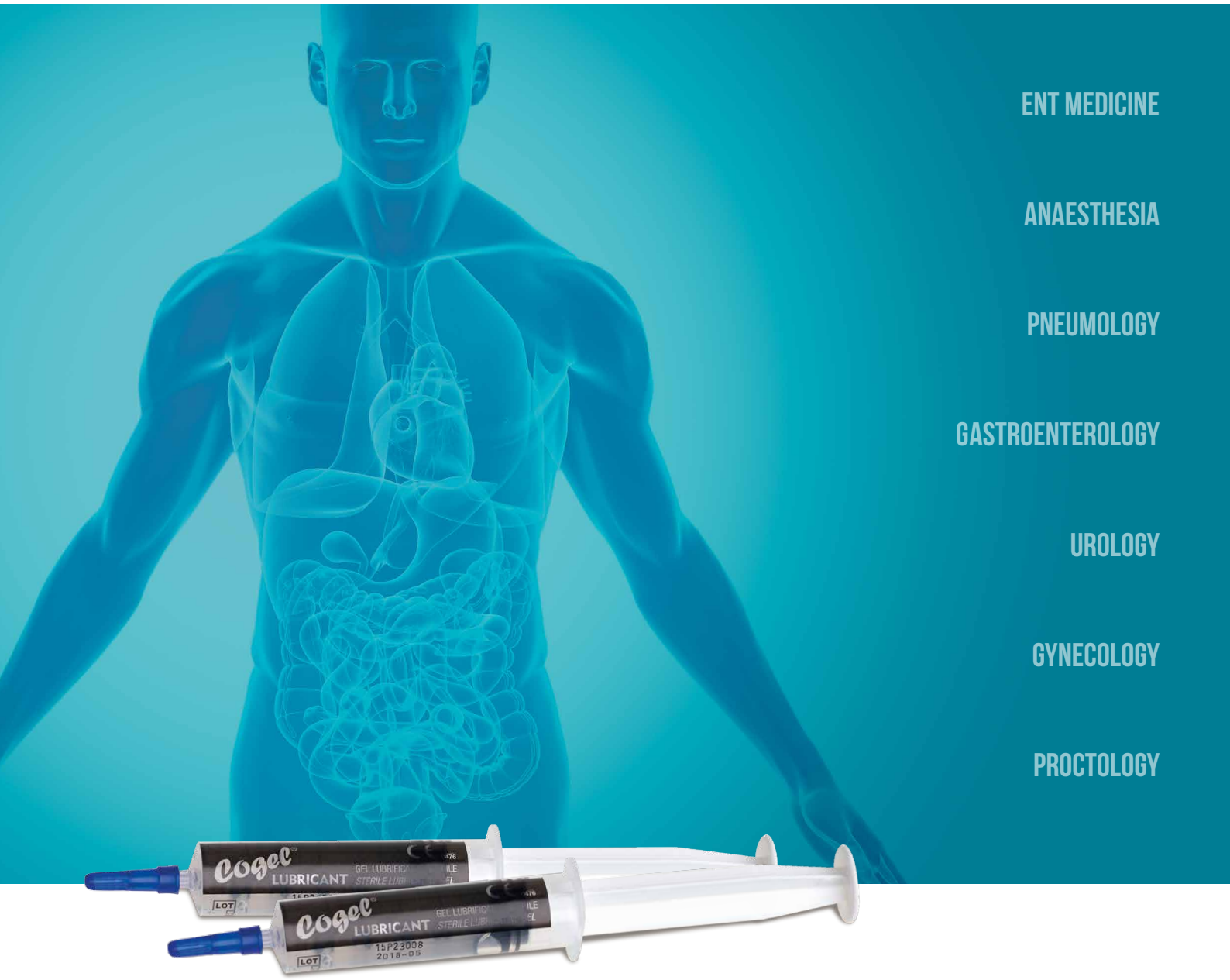
Comedical®

Cogel®



COGEL LUBRICANT

Sterile lubricant gel in syringe

Single-use medical device, latex free

The use of Cogel Lubricant is recommended in diagnostic and surgical medical applications as adjuvant in the insertion of endoscopes, tubes, probes and catheters because it reduces the friction on the mucosae, facilitating the sliding.
The product is normally used as lubricant in urologic procedures, yet thanks to its composition, sterility and practicality it is suitable also for other uses, such as the introduction in cavities of endotracheal tubes and cannulae, of catheters for nutrition and removal with nasogastric positioning, of rectal probes and gloved fingers during digital inspective monoeuvres.
The special chemical-physical characteristics of the gel offer very high efficiency, keeping the lubricating properties active for a long time.

STERILE

Device sterilized in autoclave by moist heat

Medical Device
Made in Italy

RELEVANT SPECIFICATIONS, QUALITY AND SAFETY ASPECTS

The water-based gel in the syringe is sterile, active substances free, is water-soluble, fats and proteins of latex free. All raw materials used are contained in the official pharmacopoeia.
Cogel Lubricant is well biocompatible, therefore it is suitable for Subjects who do not tolerate some active substances - usually disinfectants and anaesthetics - contained in some lubricants.
Cogel Lubricant is a product with CE mark class IIb and compliant with the Directive 93/42 EEC on manufacture, commercialization and use of medical devices.

THE STERILISATION PROCEDURE BY MOIST HEAT GUARANTEES STERILITY TO THE WHOLE DEVICE AND THEREFORE ALSO TO THE LUBRICATING GEL IN THE SYRINGE. MOREOVER THERE ARE NO MODIFICATIONS OF THE GEL CHEMICAL-PHYSICAL CHARACTERISTICS THAT ARE IN THIS CASE THYPICAL OF THE γ-RAYS STERILISATION METHODS.

CHEMICAL-PHYSICAL CHARACTERISTICS OF THE GEL

Composition:	gelled hydropolyhydrosilic solution
Contents:	Aqua, Propylene Glycol, Sodium Carbomer, Hydroxypropyl Methylcellulose, Methylparaben
Colour:	colourless
Density:	1 ± 0,05 g/ml
Water solubility:	soluble
Viscosity:	43.000 (35.000 - 51.000) mps
Ph:	6,7 ± 0,2

MAIN ADVANTAGES OF A LUBRICANT IN STERILE SINGLE-USE PREFILLED SYRINGE:

- no preparation of the device and therefore safety and time-saving
- absence of parts to be broken during the opening phase, which frequently cause plastic non-visible splinters or fragments
- atraumaticity of the spout, necessary most of all when the gel is instilled
- overall cheapness
- asepticity guarantee during each procedure (differently from lubricants in tube)
- familiarity with the execution of operations with only one hand
- easy disposal

CHARACTERISTICS OF THE MEDICAL DEVICE

Definition:	prefilled syringe with water-soluble lubricating gel for single-use
Primary packaging:	medical paper bag / film with easy opening
Constituting materials of the syringe:	polypropylene, hard natural rubber, synthetic rubber
Sterilisation:	the procedure is carried out in autoclave by moist heat complying with the norm UNI EN ISO 17665 - 1:2007.
Allergen:	the device is latex free

PRODUCT AND PACKAGING CODE

REF	Primary packaging	Contents	Secondary packaging
PAG09NA1Q	Sterile lubricating gel in syringe	10 ml	50 pieces

BIBLIOGRAPHY

- Woodward S. “Use of lubrificant in female urethral catheterization.” Br J Nurs. 2005 Oct 27-Nov 9;14(19):1022-3
- Tanabe P., Steinmann R., Anderson J., Johnson D., Metcalf S., Ring-Hurn E. “Factors affecting pain scores during female urethral catheterization.” Acad Emerg Med. 2004 Jun;11(6):699-702
- Park P.G., Choi G.J., Kim W.J., Yang S.Y., Shin H.Y., Kang H., Baek C.W., Jung Y.H., Kim J.Y., Kang M.S. “A comparative study among normal saline, water soluble gel and 2% lidocaine gel as a SLIPA lubrificant.” Korean J Anesthesiol. 2014 Feb;66(2):105-11
- O’Rourke M., Levan P., Khan T. “Current Use of Ultrasound Transmission Gel for Transesophageal Echocardiogram Examinations: a survey of Cardiothoracic Anesthesiology Fellowship Directors.” J Cardiothoracic vasc Anesth. 2014 Jul 11.pii:S1053-0770(14)00024-X

Retailer or Area Agent

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