



- Unexplained infertility
- Sperm motility
- Comfortable environment in vagina (sperm survival)

Medical Device



MADE IN ITALY

INFERTILITY

DESCRIPTION

XY GEL formulation, based on sugars, mineral salts, creatine, carnitine, hyaluronic acid and lactic acid is studied to:

- Create an optimal environment for spermatozoa
- Help in maintain a suitable pH for natural conception
- Obtain a seminal fluid-compatible osmolality.



XY GEL should be used during the ovulation phase 5 minutes before sexual intercourse.

THERAPEUTIC INDICATIONS

- **Unexplained infertility**
- **Reduced cervical mucus receptivity**
 - **Low production**
 - **Abnormal pH**
- **Low sperm survival**

PRESENTATION

Each box of **XY GEL** contains 6 single dose applicators of 5 mL each one.

INGREDIENTS

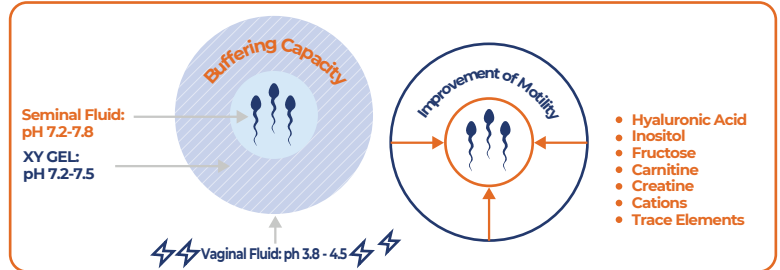
Aqua, Glucose, Fructose, Sodium Hyaluronate, Magnesium Citrate, Calcium Piruvate, Sorbitol, Lactic Acid, Citric Acid, Inositol, Potassium Citrate, Sodium Bicarbonate, Zinc Gluconate, Carnitine, Creatine, Sodium Chloride, DMDM Idantoin, Sodium hydroxide, Phenoxyethanol, Ethilexyglycerin, Hydroxyethylcellulose

REGULATORY STATUS

- Class IIA
- Free sale certificate
- Certificate of origin (at the time of invoicing)
- ISO 13485 certificate
- US FDA registration

PLUS

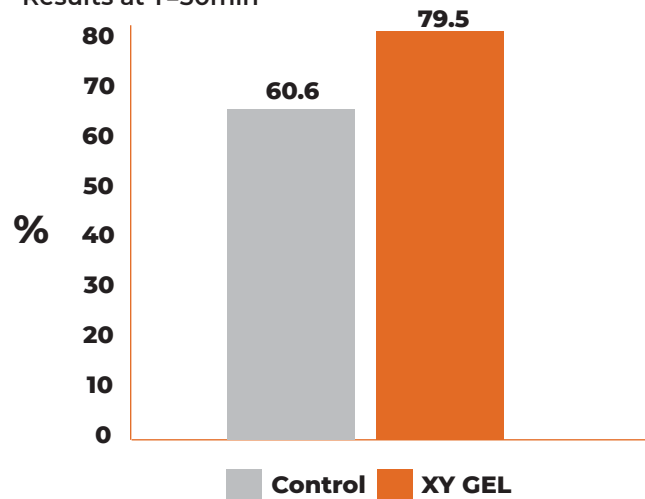
XY GEL mimics seminal fluid composition generating a comfortable environment for spermatozoa and giving adequate energy for sperm motility



CLINICAL TEST FOR SPERM MOTILITY IMPACT OF XY GEL

Motility PR (*sperm that are swimming in a mostly straight line or large circle*):
% of spermatozoa

Results at T=30min



Control → without gel
XY GEL → XY GEL : Semen=1:1

CLINICAL TEST

- **RISK ANALYSIS** - according to UNI CEI EN ISO 14971
- **BIOCOMPATIBILITY** - according to UNI EN ISO 10993:
- **CYTOTOXICITY** for DIRECT CONTACT - according to ISO 10993-5:2009
- **DELAYED HYPERSENSIVITY TEST (GPMT)** - according to ISO 10993-10:2010
- **VAGINAL IRRITATION TEST** - according to ISO 10993-10:2010
- **CLINICAL EVALUATION** - according to MEDDEV 2.7-1
- **STABILITY** - according to ICH Guidelines
- **ACCELERATED STABILITY STUDY**

CLINICAL TRIAL

XY AQUAGEL: a product based on Sodium hyaluronate



CLINICAL TRIAL ENDPOINTS



Sperm Motility

STUDY



30 sperm donors



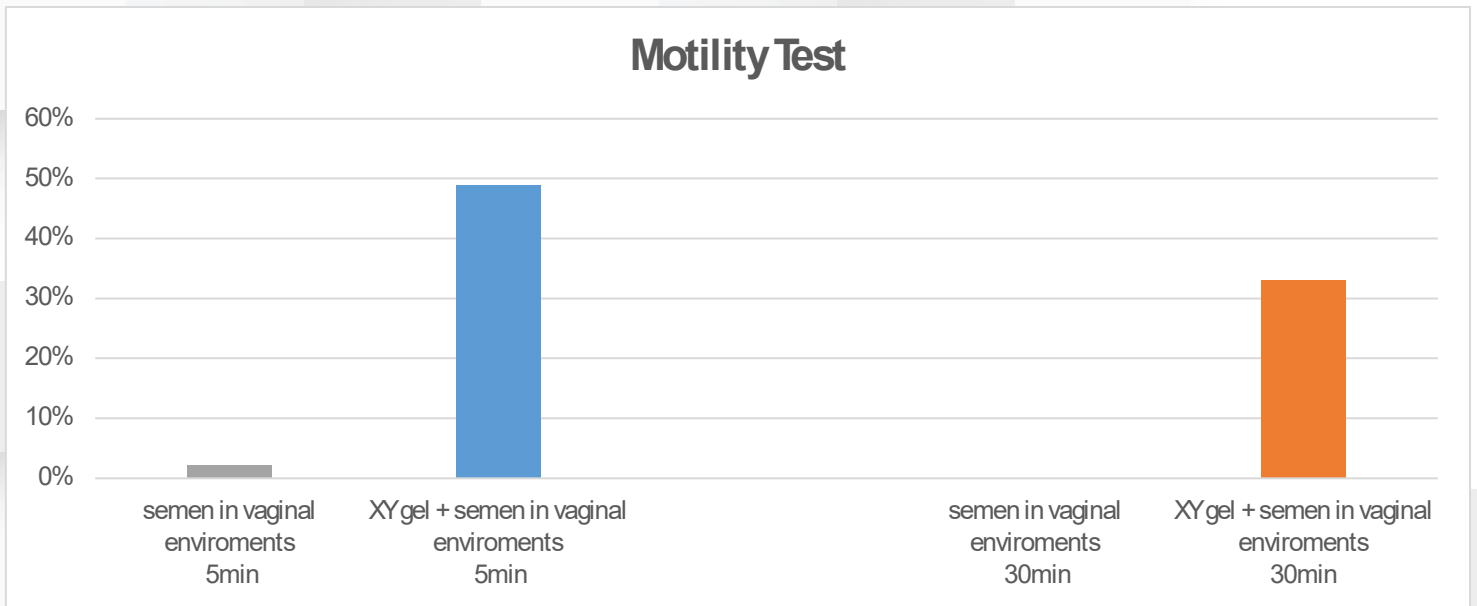
Conditions with and without the use of xy aquagel

**EVALUATION OF SPERM MOTILITY
(Progressive + Rectilinear)**

Through

Microscopic Observation

RESULTS OF THE TRIAL



Sperm Motility (progressive + rectilinear) with XY AQUAGEL increase from 5% to around 50%

- Semen + XY AQUAGEL after 5 min
- Semen + XY AQUAGEL after 30 min
- Semen alone after 5 min
- Semen alone after 30 min

Sperm Motility (+48% After 5min / +33% After 30min)

