Gynko®

Sterile single-use sheath for rigid endoscopes

EN

Please read these instructions for use carefully before each use and keep them easily accessible for interested users.
Please refer to the specific information on intended use, indication and contraindications.
Read these instructions for use carefully. Improper use of the products may result in serious injury to the patient, the user or third parties. Cover Srl rejects any liability for damage to property or persons in the event that maneuvers other than those described in this instruction sheet are carried out and the device is not used by qualified personnel.

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The **Gynko®** device is a sterile sheath to be used on the optical instrument called a rigid endoscope or hysteroscope. The sheath is equipped at the distal end with a lens to allow the gynecological doctor to view with the optical instrument during clinical activity. It consists of a sheath of medical grade material and a camera cover sheath (Please note Codes with W at the end do not have a camera cover sheath).

INTENDED USE AND CLINICAL BENEFITS

The sterile diagnostic optics sheath is used for the protection of optical instruments during inpatient or outpatient endoscopic examinations. In particular, **Gynko®** is used in the gynecological field, on the instrument known as the rigid endoscope or hysteroscope. The purpose of **Gynko®** is to prevent cross-infection between patients and users due to the use of the instrument on several people during diagnostic examinations.

FEATURES

The **Gynko®** rigid endoscope cover sheath is available in various sizes suitable for use with the most popular rigid endoscopes or hysteroscopes on the market. The nominal diameters of the **Gynko®** sheath refer to intact cystoscopes and/or in any case corresponding to the specifications provided by the respective manufacturers. Equipped with an operating channel allows the introduction of forceps, scissors, for biopsy samples.
The **Gynko®** cover sheath for rigid endoscopes is a valuable system for simultaneously ensuring:

- Complete sterility of the rigid endoscope or hysteroscope during each use
- Drastically reduced recovery time between examinations
- Reduction of procedural time

The **Gynko®** device is practical and simple to use: it is easily inserted on the endoscope before use and, thanks to the reduced thickness and high elasticity of the material used, is easily tolerated by the patient. The high transparency of the lens and its design guarantee clear and distortion-free vision.
The device is supplied STERILE and is DISPOSABLE.

INSTRUCTIONS

The use of the **Gynko®** sheath is indicated for the performance of endoscopic examinations using rigid endoscopes in inpatient and/or outpatient settings and is restricted to properly trained and qualified medical personnel.
It can be used on adult patients according to the size or article code chosen.

CONTRAINDICATIONS

- **Gynko®** only applies to the brand and model of endoscope described on the label. The device and/or endoscope may be damaged if an attempt is made to use an unsuitable **Gynko®** model.
- Do not use the **Gynko®** sheath with damaged endoscopes.
- Using an unsuitable **Gynko®** sheath can damage the instrument.
- Do not introduce lubricants or detergents into/on the **Gynko®** sheath
- Do not force the endoscope into the **Gynko®** sheath, the device may be damaged during insertion.
- **Gynko®** is designed to be inserted and removed from the endoscope quickly and easily, without applying any force. In the event of assembly difficulties ARREST THE PROCEDURE and contact the company distributing the product.

WARNINGS AND PRECAUTIONS

- Standard Precautions, recommended by the Centers for Disease Control (CDC), require the use of appropriate protection (masks, gloves, eyewear and gowns) by the operator when handling endoscopes and/or sheaths contaminated with patient fluids and tissue.
- Before use, check the integrity of the primary packaging (envelope). Quality and sterility can only be guaranteed for sealed, intact packages. If the primary packaging is opened or damaged, discard the product and use a new one.
- Check the expiry date on the label before use and do not use after the expiry date.
- Single-use device. Reuse may cause cross-contamination for patient and operator.
- Do not re-sterilize. Re-sterilization may cause cross-contamination for patient and operator.
- Do not disinfect. Disinfection of the device before use cannot guarantee that the initial chemical and physical characteristics are maintained.
- Before use, make sure you have a sheath suitable for the instrument to be covered.
- Once the instrument is covered with the sheath, visually check that there are no obvious cuts or holes.
- Do not heat the endoscope before applying the device.

INSTRUCTIONS FOR USE

Before inserting the endoscope into the **Gynko®** device, thoroughly clean the distal part of the optics with suitable solutions and dry with suitable materials to avoid loss of filaments.

1. Make sure the tube and the distal end of the endoscope are completely dry.
2. Prepare the endoscope and connect the light source
3. Insert the endoscope inside the device until contact is made between endoscope lens and device lens. Rotate the attachment clip until the connection between endoscope and device is locked.
4. Join the camera with the endoscope and unroll the camera cover, if present.
5. Join the irrigation tube with the Y delivery hose coupling of the sheath.
6. Insert the eventual operational tools in the dedicated channel.
7. Make the examinations.
8. Disconnect the irrigation tube, unlock the camera, gently rotate endoscope and gently pull **Gynko®** from the distal lens.
9. After the procedure, verify that the optic system is dry. Otherwise, replace or re-sterilize the used optics.
10. Remove **Gynko®** and dispose of as follows.

SERIOUS INCIDENT REPORTING

It is recommended that the user and/or patient report any serious incidents occurring in relation to the device to the manufacturer and to the competent authority of the Member State where the user and/or patient are located.

STORAGE

If stored in the original packaging, the medical device is valid for 5 years. The medical device can be stored and transported in a dry place in its original packaging. Also protect from sunlight, heat and handle with care.

DISPOSAL METHODS

Disposable medical device. After use, dispose of the product in the appropriate hospital containers and according to the protocols of the healthcare facility where the product is used. Do not dispose of in the environment.

SYMBOLS USED ON PRODUCT LABELS

	Do not reuse - Disposable		Manufacturer	REF	Product reference
MD	Medical Device		Manufacturing date	LOT	Lot number
	Expiry date	STERILE EO	Sterilized by ethylene oxide. Sterile single-layer barrier system		Do not re-sterilize
	Do not use if the envelope is open or damaged		Refer to the instructions for use	CE 0477	Medical Device under EU Regulation 2017/745
	Keep away from light and heat sources		Keep dry		Warning