TECHNICAL SPECIFICATIONS
SHEATH FOR RIGID HYSTEROSCOPES

Manufacturer:	Xmed S.r.l.
Trade Name:	Endoshaft Cover® G.D.K. - Ginecolo*gy Disposable Kit*
Product Code:	800/XXXXX 850/XXXXX
Manufactured by:	Xmed S.r.l. Via Statale Sud 151/a 41036 - Medolla Italy
Distribuited by:	Xmed S.r.l.
C.E. Certificate **Classification according to EU Directive**	CE 0123 IIa
GMDN:	44711 - A device/material used as a physical barrier for protection against the effects of environmental exposure and/or to maintain the required hygienic level of a flexible endoscope. This protection provides a sterile barrier, typically for the insertion part of the endoscope, which is pulled over this end of the endoscope prior to use reducing the risk of cross-contamination/infection between patients and increases the effective time for reuse of the endoscope between patients. This device will typically be equipped with an optical clear window at the distal end to not restrict the field of vision and is single-use

INTENDED USE

The device ENDOSHAFT-COVER ® G.D.K. is indicated for diagnostic tests performed with rigid hysteroscopes.

TECHNICAL FEATURES

ENDOSHAFT-COVER ® G.D.K. is a sterile, disposable protective coating for rigid hysteroscopes, made of medical – grade materials.

ENDOSHAFT-COVER ® G.D.K. fits over the instrument in an easy and quick way. The lens on the tip of the device is designed to fit perfectly on the hysteroscope's distal end, keeping a complete optical integrity. Thus, the lens is not blurred and ensures perfect vision.
The complete device provides a quick and effective way to increase the productivity of the department and ensures sterility during each procedure. Predominant feature of the line of sheaths ENDOSHAFT-COVER ® G.D.K. is to provide an effective barrier to microorganisms (tested for Bacillus subtilis, MS2 virus and BSE prion).
The device is a latex-free.

With ENDOSHAFT-COVER ® GDK, a high-level disinfection of the hysteroscope with peracetic acid, glutaraldehyde and the like is NOT REQUIRED, as the sheath itself is a sterile device that acts as a barrier between patient and instrument.

The sheaths are important both for the patient, since the investigation is surely being conducted in a sterile manner, and for the tool, since it is not being stressed with chemical materials. By so doing, it preserves the instrument's functional features, ensuring a longer useful life and allowing to purchase fewer hysteroscopes..

In addition, the nursing staff is not subject to inhalation of toxic gases (eg, glutaraldehyde), which are possible causes of malaise.

ENDOSHAFT-COVER® G.D.K. is realized in the diagnostic version to perform examinations of hysteroscopy. Thanks to the external jacket it helps protect the optical system from mechanical stress and from infection, in addition to allowing the passage of fluids (water and CO2).

There's a version equipped with a camera cover (identification code 850/xxxxx), in order to preserve from contamination also the image capture device connected to the instrument.

After the use of the ENDOSHAFT-COVER ® line, prescriptions for the disposal of special waste aren't required.

VERSIONS

The versions available are shown in the table below. We can manufacture customized devices according to the customers' requirements.

STORZ – TYPE CONNECTION			
HYSTEREOSCOPE DIAMETER	***TYPE OF HYSTEROSCOPE***	***VIEW ANGLE***	***CODES***
2.7	Diagnostic	0°	800/2700
2.7	Diagnostic	30°	800/2730
2.7	Diagnostic with camera cover	0°	850/2700
2.7	Diagnostic with camera cover	30°	850/2730
3.0	Diagnostic	0°	800/3000
3.0	Diagnostic	30°	800/3030
3.0	Diagnostic with camera cover	0°	850/3000
3.0	Diagnostic with camera cover	30°	850/3030

WOLF – TYPE CONNECTION			
HYSTEREOSCOPE DIAMETER	**TYPE OF HYSTEROSCOPE**	**VIEW ANGLE**	***CODES***
2.7	Diagnostic	0°	800/2700w
2.7	Diagnostic	30°	800/2730w
2.7	Diagnostic with camera cover	0°	850/2700w
2.7	Diagnostic with camera cover	30°	850/2730w
3.0	Diagnostic	0°	800/3000w
3.0	Diagnostic	30°	800/3030w
3.0	Diagnostic with camera cover	0°	850/3000w
3.0	Diagnostic with camera cover	30°	850/3030w

WEIGHT It depends on the model

CONNECTIONS Wolf and Storz rigid connectors for connection to the hysteroscope.
Universal docking connector to the external jacket.

MAXIMUM DURATION OF USE Single use

DISPOSABLE Do not re-sterilize and / or reuse

STERILIZATION Sterilized with ethylene oxide

MAXIMUM DURATION OF STERILITY 5 years

Each lot is submitted to the following tests required by the Official Italian Pharmacopoeia for all products sterilized with ethylene oxide:

1) sterility check on strips spore,
2) validation of the sterilization process, according to the validation protocol with determination of ETO residual (less than 4 mg as required by the Official Italian Pharmacopoeia).
3) release of the device at the end of the quarantine period provided by the validation protocol with detection of the curve of measurement of the residual gas of ethylene oxide.

The customer may request certificates of analysis of the lot in his / her possession.

QUALITY CHECK — Performed on 100% of production

All the devices for Xmed s.r.l. are assembled in a factory certified and during the assembling phase each device is tested at a pressure of 200 cm/H2O to verify patency and tightness.

The Quality System of Xmed complies with the requirements of Quality Assurance provided by the European Directive 93/42/EEC modified according to the 2007/47/EC DL and to ISO 9001, ISO 13485 with CE certification..

MATERIALS

COMPONENT	ENDOSHAFT-COVER® G.D.K. MATERIAL
INNER SHEATH	PVC
INNER SHEATH CONNECTOR	PVC
LENS	PET
PROTECTIVE TUBE	PP
EXTERNAL JACKET	PVC
EXTERNAL CONNECTOR	ABS
RETAINING LOCK	ABS
CAMERA – COVERING SHEATH	PE

All materials used for the realization of the device have been approved during the certification process. The materials used are latex – free and conform to be used with light sources.

REGISTRATION

The device Endoshaft-Cover ® G.D.K. is CE 0123 certified, class IIa.

PACKAGING

The device Endoshaft-Cover ® G.D.K. is packaged with envelopes made by coupling medical paper and polyester film / polyethylene..

The polyester / polyethylene is composed of a film of a special type of laminate, adhesive, solvent free, oriented polyester and low-density polyethylene. The product has been developed for medical applications, it's disposable and is designed to be used with machines for thermal welding. It can be thermally welded, alone or with other suitable substrates giving origin to a integral combination, which can be sterilized with ethylene oxide and gamma radiation.

GENERAL FEATURES

1. Excellent visibility of the lens.
2. Total microbiological barrier.
3. Excellent sealing characteristic.
4. Resistance to mechanical stress.

PHYSICAL FEATURES

Adhesion strength:	interlayer adhesion strength of 300g – 25 mm / minute.
Separation speed:	instron jaw 200 mm / minute.
Tensile strength:	min. 25 N / 15 mm MD
Separation speed:	instron jaw 100 mm / minute.
Burst strength:	min. 240 KN/mq.
Thermal welding:	it can produce an hermetic seal when thermally welded alone, and a strippable or peelable seal when it is welded with other substrates adjusted to 150 ° C, 1 sec, 200KN/mq with a laboratory thermal welding machine.

QUALITY GUARANTEE

All specifications meet the highest standards and undergo strict quality control..

CONFORMITY F & DA

Polyester "O"	Section 21 CFR 177/1630 " Polyethylene Phthalate Polymers "
Solvent-free adhesive	Section 21 CFR. 175/105
Polyethylene L.D.	Section 21 CFR. 177/1520 " Olefin polymers"

The paper consists of bleached wood pulp, free of impurities, odors and toxic substances when it is both damp and wet. The paper does not release color or toxic materials. The medical grade paper is used for the production of envelopes compliant with the norms British BS 6256 and German DIN 58953T2. The characteristics of porosity of the paper allows it to be gas sterilized, thus ensuring an excellent bacteriological protection.
The quality control is followed throughout the production phase..
Grammage 70 g/Mq.

MAXIMUM TEMPERATURE OF STORAGE	+ 45°C
TEMPERATURE OF STORAGE	-15/+45°C
SHELF LIFE	5 years

From the point of view of physical and chemical stability, the product and the material of which it is made are not affected in time. Exposure to sunlight or artificial sources of light do not vary the structure of the product, provided the integrity of the package. The product also does not show incompatibility towards the substances with which it comes into contact during normal use. During the thermodestruction, the material does not release toxic substances.

USE OF THE DEVICE

The instructions for use of the Endoshaft GDK-Cover ® device are clearly described in the "Instructions for use" and therefore we refer to them.

USE AND MAINTENANCE OF THE FIBERSCOPES

For the use and maintenance of the fiberscopes, you should follow the European guidelines and those prescribed by the manufacturer.
Recommended operations: a proteolytic enzyme detergent wash, followed by drying and relocation in the special container.
It does not require any high-level disinfection.

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