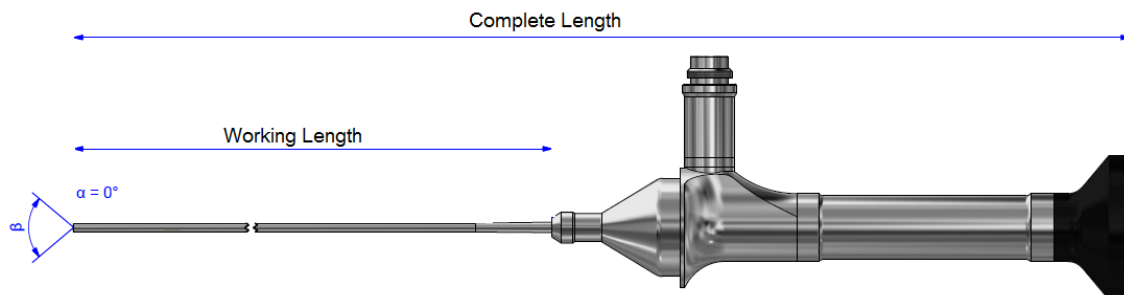


Specification

1. Picture

GMS40A



2. Product name /Trademark

Gimmi ® AlphaScope GMS40A

3. Technical specifications

Working Length/ Scope length:	282 mm/ 410,4 mm
Diameter:	1,85 mm
Direction of view /Field of view:	$\alpha = 0^\circ / \beta = 80^\circ$
Pixel:	40.000 Pixel
Ocular:	0 ° straight view
Light conductor connection:	fixed: ACMI additional: Storz/Olympus and Wolf
Material	Scope body + sheath, Light post: stainless steel Eypiece housing: PEEK Distal and proximal window: sapphire glass Distal and proximal glue: Epoxide, Polyepoxide

For further Information see under Point "Material composition"

4. Intended use

Endoscopes are intended for endoscopic visualization of internal anatomical structures of the patient. Hysteroscopes are used to diagnose, treat or relieve uterine disorders. The endoscopic sheath is inserted into the body through the vagina (invasive). The endoscope is gently pushed forward to the uterine cavity with the aid of an operation tube. This enables a view on the surgical area considering a maximum protection of the surrounding tissue structures.

5. Product description

The ALPHASCOPE™ Hysteroscope is a small diameter, fiberoptic hysteroscope intended for hysteroscopic procedures. The ALPHASCOPE Hysteroscope consists of an outer stainless steel sheath, inner illumination fibres, and an imaging fiber bundle. At the distal end of the imaging bundle is the objective lens and at the proximal end is the eyepiece. Endoscopic light sources are connected to the light post of the hysteroscope through compatible 3.5 mm light cables. The eyepiece can be connected through a focusing optical coupler to a camera head that carries the image by cable to the camera.

The ALPHASCOPE Hysteroscope (GMS40A) is intended for use only with the GYNECARE VERSASCOPE™ Sheath (GMS805).

6. Indications for Use:

NOTE: Hysteroscopes are used as tools for access to the uterine cavity and are not, in and of themselves, a method of surgery.

The ALPHASCOPE Hysteroscope is used to permit viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

Generally recognized indications for diagnostic and operative hysteroscopy include:

Diagnostic Hysteroscopy	Operative Hysteroscopy
Abnormal Uterine Bleeding	Directed Biopsy
Infertility & Pregnancy Wastage	Removal of Submucous Fibroids and Large Polyps
Evaluation of Abnormal Hysterosalpingogram	Submucous Myomectomy
Intrauterine Foreign Body	Transection of Intrauterine Adhesions
Amenorrhea	Transection of Intrauterine Septa
Pelvic Pain	Endometrial Ablation

7. Contraindications

Absolute contraindication to hysteroscopy is acute pelvic inflammatory disease (PID). Relative contraindications include:

- Hysteroscopy may be contraindicated by the following conditions, depending on their severity or extent:

Inability to distend the uterus	Cervical Stenosis
Cervical/Vaginal Infection	Uterine Bleeding or Menses
Known Pregnancy	Invasive Carcinoma of the Cervix
Recent Uterine Perforation	Medical Contraindication or Intolerance to Anesthesia

➤ CONTRAINDICATIONS TO ENDOMETRIAL ABLATION

Hysteroscopic endometrial ablation, whether by laser or electrosurgery, should not be undertaken without adequate training, preceptorship, and clinical experience. Additionally, endometrial biopsy should be performed prior to any ablation. The following are clinical conditions that can significantly complicate hysteroscopic endometrial ablation:

Adenomatous Endometrial Hyperplasia	Uterine Leiomyoma
Severe Adenomyosis	Pelvic Pain (Subtle PID)
Uterine Anomalies	

➤ CONTRAINDICATIONS TO HYSTEROSCOPIC MYOMECTOMY

Hysteroscopic myomectomy should not be undertaken without adequate training, preceptorship, and clinical experience. The following are clinical conditions that can significantly complicate hysteroscopic myomectomy: Severe Anemia or inability to circumnavigate a myoma due to myoma size (e.g., predominantly intramural myomas with small submucous components)

8. Cleaning and disinfection

Single use / Reusable:	Reusable
Sterile / Nonsterile:	Nonsterile
Sterilization:	Autoclavable, max. 137° C/ 2,0-2,3 bar/ min. 4 min (max. 35 min)

9. Packaging information

Packaging unit:	1 pc. Including 2 different adaptors for connection to light cables
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10. Further information

Manufacturer:	Gimmi GmbH, Carl-Zeiss-Strasse 6 D-78532 Tuttlingen, Germany
Classification 93/42/EEC:	II a
UMDNS-code:	12081

11. Reference No for Accessories for Alphascope

Ref-No.	Description
GMS710A	TRAY FOR ALPHASCOPE HYSTEROSCOPE
GMS805	GYNECARE VERSASCOPE™ Sheath

12. Additional information

Material Composition

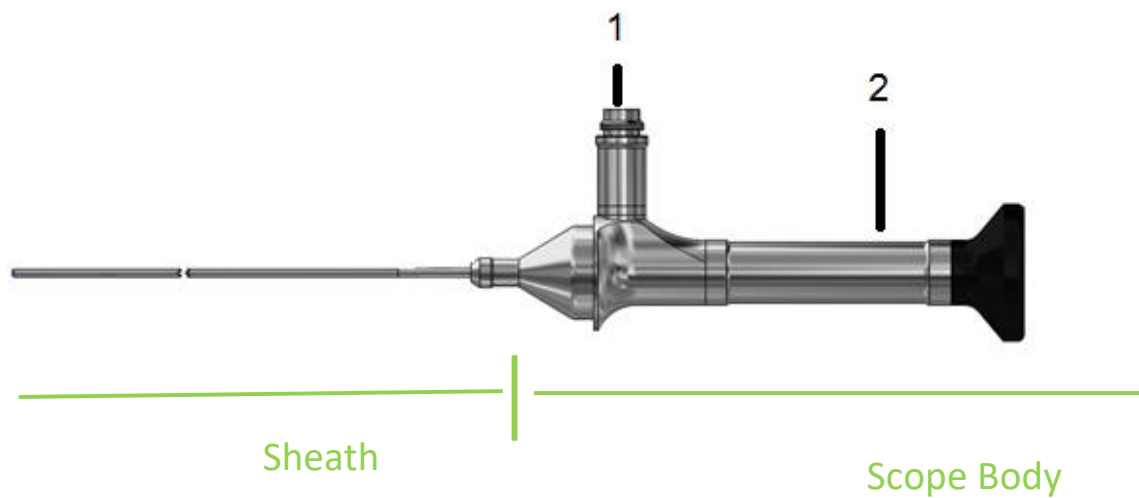
Part	Material	Short Name			Material Group	Specific Standard	DC	BC
		DIN	AISI	UNS				
Endoscope body	VA 1.4305	X8CrNiS 18-9	303	S30300	Stainless steel	EN ISO 7153-1 and DIN EN 10088-1		✓
Lightpost	VA 1.4305	X8CrNiS 18-9	303	S30300	Stainless steel	EN ISO 7153-1 and DIN EN 10088-1		✓
Closing Cap	VA 1.4305	X8CrNiS 18-9	303	S30300	Stainless steel	EN ISO 7153-1 and DIN EN 10088-1		✓
Eyepiece housing	Polyetheretherketon	PEEK			Thermoplast			✓
Outer tube	VA 1.4301	X5 CrNi 18-10	304	S30400	Stainless steel	EN ISO 7153-1 and DIN EN 10088-1	✓	✓
Distal window	Sapphire				Al ₂ O ₃	Mineral IV/C.4-10	✓	✓
Proximal window	Sapphire				Al ₂ O ₃	Mineral IV/C.4-10		✓
Light fibers	Different optical glasses/ Glassfibers				Glass	IEC 60793	✓	✓
Distal glue	Epoxide, Polyepoxide				Thermosetting epoxy polymer	USP Class VI	✓	✓
Proximal glue	Epoxide, Polyepoxide				Thermosetting epoxy polymer			

DC: Direct Contact (must be viewed critically)

→All materials, which are in direct contact with the human body (stainless steel, glass, epoxy adhesives) are biocompatible

BC: Biocompatible (evidence exists)

Diagram



1 Light post (for connection to light guide cable)

2 Ocular