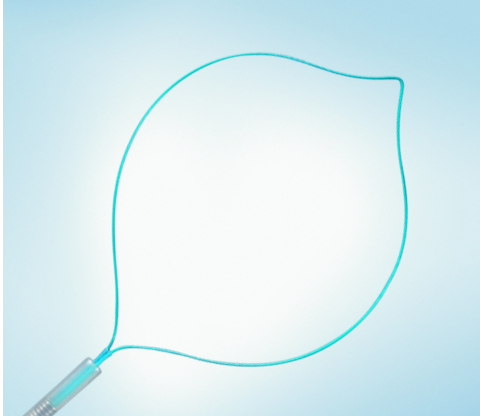


Product-Information-Sheet

Polypectomy, EMR and ESD

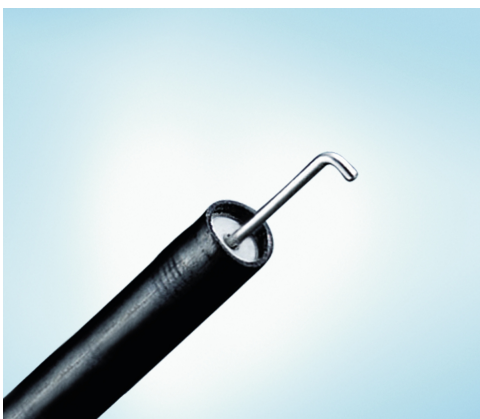
Cold and Hot
Snares



- For polyp ligation prior to polypectomy
- Prevents postpolypectomy bleeding
- Preloaded loop, ready to use with handle
- Nylon-loop ligation keeps tissue damage to a minimum
- Opening diameter of 30 mm enables ligation of large polyps



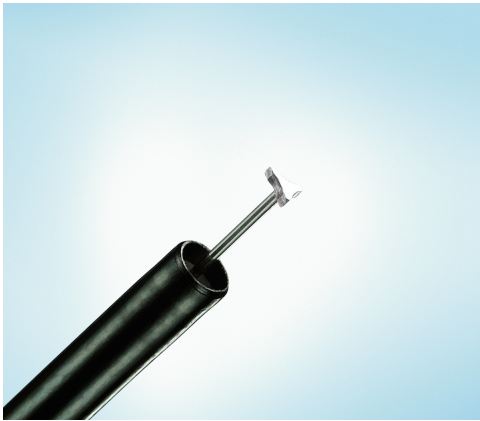
Article number	Article Name	Quantity value	Min. working channel ø value	Working length value	Loop ø	Area Compatibility
N5382130	HX-400U-30	5	● 2.8	2300 mm	30 mm	



- L-shaped hook for incision and dissection in longitudinal and lateral directions
- To minimise invasion, the use of a distal attachment is recommended (D-201 series) to help maintain the field of view
- Rotatable



Article number	Article Name	Quantity value	Min. working channel ø value	Working length value	Knife length value	Features	Area Compatibility
N3046130	KD-620UR	1	● 2.8	2300 mm	4.5 mm	Hook length: 1.3 mm; rotatable	




- Triangle-tipped knife for marking, incision and dissection
- Conductive triangle tip for cutting the mucosa
- No need to rotate the knife; cutting can be performed in any direction
- Tip design suitable for controlling moderate bleeding
- To ensure a clear field of view, a distal attachment (D-201 series) may be used



Article number	Article Name	Quantity value	Min. working channel \varnothing value	Working length value	Knife length value	Features	Area Compatibility
N2119630	KD-640L	1	● 2.8	1650 mm	4.5 mm	Triangle-tip plate length: 0.4 mm	

EU - KONFORMITÄTSERKLÄRUNG EC - DECLARATION OF CONFORMITY

Unternehmen: <i>Company</i>	Olympus Winter & Ibe GmbH Kuehnstr. 61 22045 Hamburg, Germany P.O.Box 70 17 09 22017 Hamburg, Germany Telefon: +49 (40) 6 69 66-0 Telefax: +49 (40) 6 69 66-2109			
Hiermit erklären wir, dass das Produkt <i>We herewith declare that the product</i>				
Produktname: <i>Product name:</i>	Siehe angehängte Produktliste / <i>see attached List of Related Items</i>			
Katalog Nr./ Modellname: <i>Catalog No./ Modelname:</i>	Siehe angehängte Produktliste / <i>see attached List of Related Items</i>			
Beginnend mit Seriennummer / Lot: <i>Beginning with Serial-No / Lot:</i>	Siehe angehängte Produktliste / <i>see attached List of Related Items</i>			
Produktfamilie: <i>Product Family:</i>	PF013 - KNIVES			
Produktklassifizierung: <i>Product classification:</i>	IIa			
die Anforderungen der Medizinprodukte Richtlinie 93/42/EEC erfüllt <i>complies with the requirements of the Medical Device Directive 93/42/EEC.</i>				
Diese Erklärung bezieht sich auf: <i>This declaration is based on:</i>	Anhang II Annex II			
Notifizierte Stellen für Produkte der Klasse Is, Im, IIa, IIb <i>Notified Body for products of class Is, Im, IIa, IIb:</i> TÜV Rheinland LGA Products GmbH – Tillystr. 2 – 90431 Nürnberg, Registration- Nr/No: 0197				
	Funktion <i>Function</i>	Name <i>Name</i>	Datum <i>Date</i>	Unterschrift <i>Signature</i>
Genehmigt <i>Approved by</i>	GM Q&R	Martin Peters	2015 -10- 09	

PRODUKTLISTE LIST OF RELATED ITEMS

Diese EG-Konformitätserklärung gilt für nachfolgende Produkte

This Declaration of Conformity covers following items:

PF013 – KNIVES

Produkt Name/ Product Name	REF:	Beginnend mit: Beginning with: Serial-No / Lot
Messer, Wellenschliff, gerade / Knife, corrugated, straight	WA35057A	157W
Messer, lanzettförmig, gerade / Knife, lancet type, straight	WA35055A	157W
Messer, halbrund, mit 5 Ch. Kanal, für A3523 / Knife, semi-circular, with 5 Fr. channel, for A3523	O3526	95W
Messer, lanzettförmig, für A3523 / Knife, lancet type, for A3523	O3525	96W
Messer, halbrund, für A2523 / Knife, semi-circular, for A2523	O3524	96W
Messer, gerade, für A37014A, steril, zur Einmalverwendung / Knife, straight, for A37014A, sterile, for single use	A37010A	16W 01
Messer, Haken, für A37014A, steril, zur Einmalverwendung / Knife, hook, for A37014A, sterile, for single use	A37009A	99277
Messer, rund, für A37014A, steril, zur Einmalverwendung / Knife, round, for A37014A, sterile, for single use	A37008A	991592
Messer, Wellenschliff, für A3573 / Knife, corrugated, for A3573	A3577	92W 01
Messer, halbrund, 4 Ch. Kanal, für A3573/ Knife, semi-circular, 4 Fr. channel, for A3573	A3576	92W 01
Messer, lanzettförmig, für A3573/ Knife, lancet type, for A3573	A3575	96W 01
Messer, halbrund, für A3573/ Knife, semi-circular, for A3573	A3574	94W 01
Messer, halbrund, flexible Spitze, für A3550/ Knife, semi-circular, flexible tip, for A3550	A3559	154W 01
Messer, halbrund, für A3550/ Knife, semi-circular, for A3550	A3558	158W
Messer, Wellenschliff, für A3550/ Knife, corrugated, for A3550	A3557	159W
Messer, halbrund, 4 Ch. Kanal, für A3550/ Knife, semi-circular, 4 Fr. channel, for A3550	A3556	158W
Messer, lanzettförmig, für A3550/ Knife, lancet type, for A3550	A3555	157W
Ersatz-Messer, für A3328/ Spare knife, for A3328	A3329	9YW
Messer, geführt/ Knife, guided	A3328	152W
Messer, flexible Spitze, lang, 2 x 355 mm/ Knife, flexible tip, long, 2 x 355 mm	A2588	7YW
Messer, 24-28 Ch., 12° und 30°, Steril, Einmalverwendung, 12 Stk./ Knife, 24-28 Fr., 12° and 30°, sterile, single use, 12 pcs.	A22265C	1YW
Kürette, 24-28 Ch., 12° und 30°/ Curette, 24-28 Fr., 12° and 30°	A22261A	1ZW

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60149405 0001

Report No.: 12018179 053

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo
192-8507 Japan

Products: Design and Development, Manufacture of Medical Endoscopy
Systems, Diagnostic, Operation and Treatment Products

(see attachments for products included)

Replaces Approval, Registration No.: HD 60144066 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-05-12

Date: 2020-05-12



Notified Body

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60149405 0001
Report No.: 12018179 053

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo
192-8507 Japan

Products included:

Medical Endoscopy Systems:

- Endoscopes
- Endotherapy Devices
- Imaging Processors
- Pumps for Endoscopy
- Light Sources
- Position Detecting Units
- Electrothermal Cautery Units
- Integrated Endosurgery Systems
- Endoscopic Regulation/Control Units
- Electrosurgical Equipment
- Probes and Transducers for Ultrasonic Lithotriptors
- Laparoscopic Insufflators
- Ultrasound Surgical Equipment
- Ultrasonic Surgical System generator
- Ultrasonic Surgical System transducer
- Hard-tissue ultrasonic surgical system holder/tip
- Disinfecting Units
- Capsule Endoscopes and Systems
- Ultrasound Diagnostic Imaging Systems

Date: 2020-05-12

Notified Body

M. Aihara
M.Sc. M. Aihara

