

OLYMPUS STONE MANAGEMENT

Premium Devices for Efficient and Convenient Stone Treatment



OLYMPUS STONE MANAGEMENT

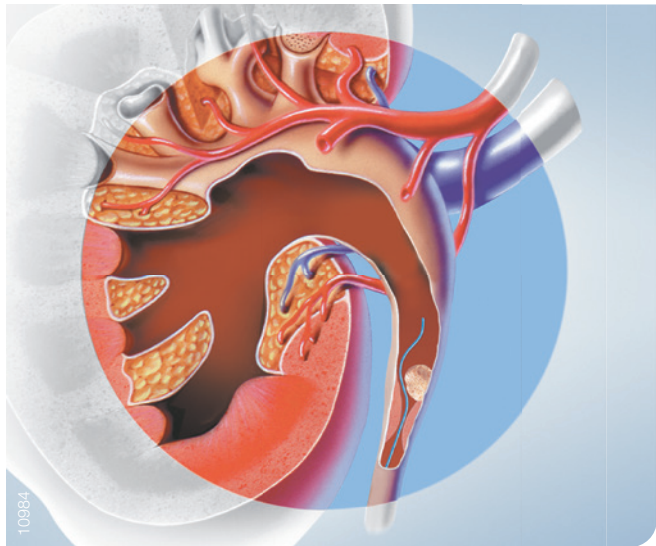
Having a long history in supporting physicians' needs in stone management through the provision of rigid and flexible ureteroscopes and the related video equipment, Olympus is well aware of the additional procedural requirements in terms of single-use instruments as well as holmium lasers and lithotriptors.

Olympus now offers a complete portfolio of stone management solutions in order to facilitate stone management procedures using premium-quality and innovative instruments as much as possible.

Olympus is constantly redefining total procedural solutions that enable you to achieve greater clinical success, improve patient safety and meet the financial goals of your practice. Olympus is your partner for your ureteroscopy needs and ensures that you will be at the forefront of See & Treat technology.



ACCESS

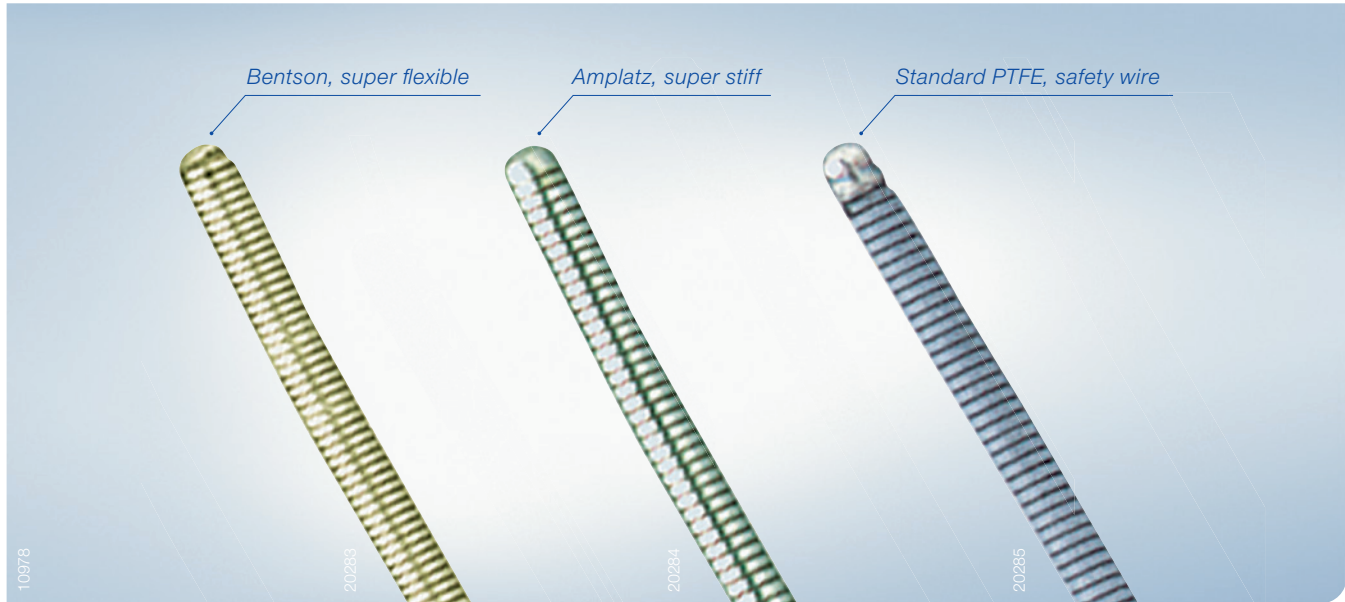


Getting access to the ureter or kidney is essential for every urologist treating stone burdens. Olympus recognizes the importance of achieving this access in a safe and time-efficient manner. Therefore, we provide a comprehensive lineup of nitinol and PTFE guidewires with various tip configurations to incorporate anatomical differences.



E-Z Grip Torque Device
The E-Z Grip Torque Device is a little tool adding convenience to your procedures. When mounted on an angled guidewire, turning this to access the ureteral orifice becomes extremely comfortable.

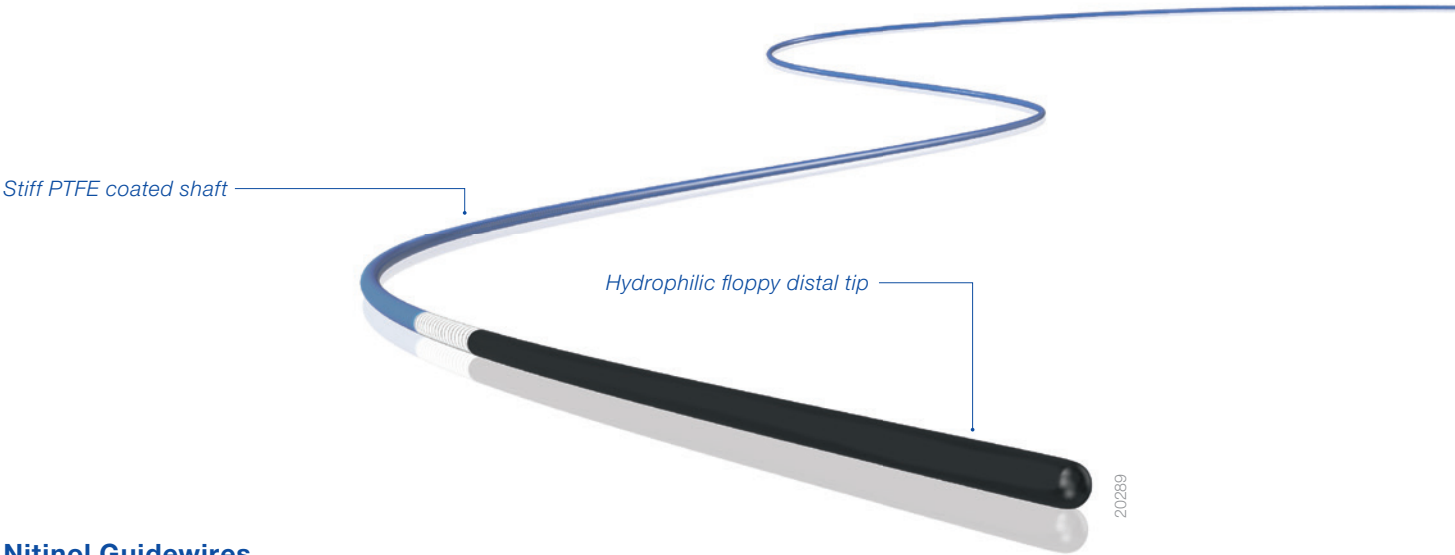
PTFE Guidewires



Hybrid Guidewires

UltraTrack – Hybrid Guidewire

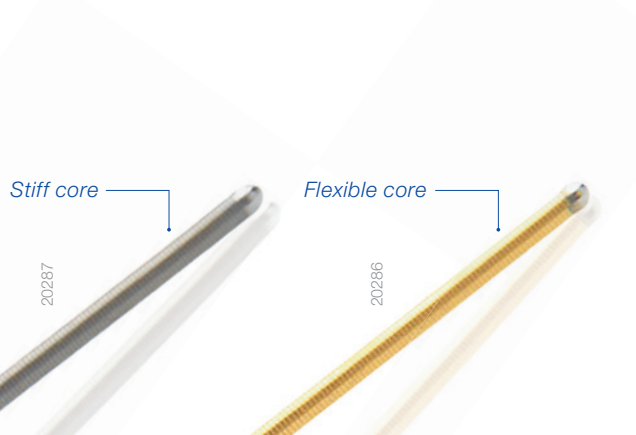
- Nitinol core with hydrophilic floppy tip and PTFE coated stiff shaft
- Hydrophilic floppy distal tip facilitates smooth and easy navigation through strictures and stone obstructions
- PTFE coated stainless steel coil optimizes grip and positioning
- Introducer coil allows for easy and safe surgeon controlled advancement of the wire
- Flexible proximal tip facilitates back loading of endoscopes



Nitinol Guidewires

Quattro – Two-in-One Guidewire

- Two tip characteristics aimed at accommodating different patient anatomies in one guidewire
- Flexible golden tip for accessing challenging anatomies
- Stiff silver tip for fast and easy access
- Extremely well differentiated during fluoroscopy due to tungsten tips

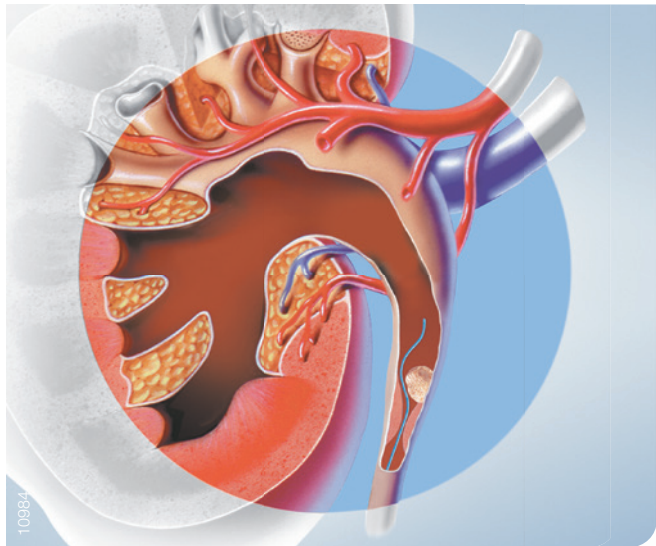


SureGlide – The Everyday Guidewire

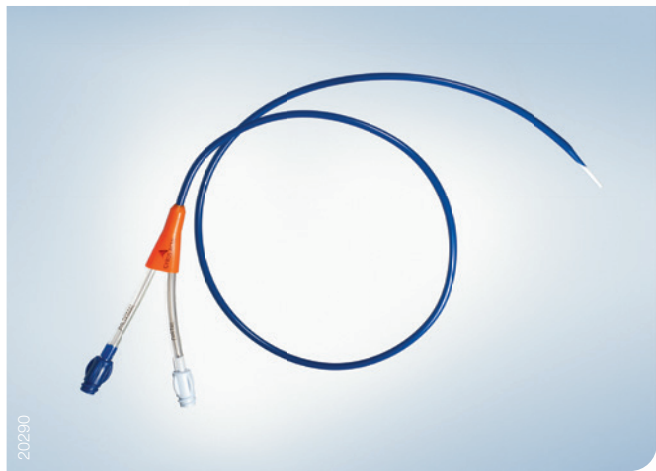
- Smooth, easy tracking through tortuous anatomy
- Nitinol core with hydrophilic coating facilitates initial access
- Features radiopaque jacket for clear visibility and easy positioning



ACCESS AND DILATION



Advancements in Olympus ureterscope technology have delivered smaller profile shafts and lubricious atraumatic tips that reduce ureteroscopic dilation needs. To complement the advanced scope technology, we have designed a range of single-use dilation solutions, from guidewires to balloon dilators and access sheaths.



Catheter

Next to a standard open-end catheter, Olympus provides the option of having a dual lumen catheter to facilitate safety guidewire placement and contrast injection during ureteroscopy:

- Color-coded Luer lock connectors to match the distal and proximal lumens for intuitive guidewire placement
- 6 Fr flexible tip gradually transitions to 10 Fr body for atraumatic dilation of the ureteral orifice

Atraumatic tip dilation from 6–10 Fr

Stainless-steel reinforced sheath prevents kinking to avoid the ureterscope getting stuck



EZDilate Balloon

EZDilate Balloon Dilators are available in multiple sizes to allow for safe ureter dilation and stricture relief as well as safe access during percutaneous surgery with minimized patient trauma.

Hydrophilic and silicone coating for low-friction single-step dilation

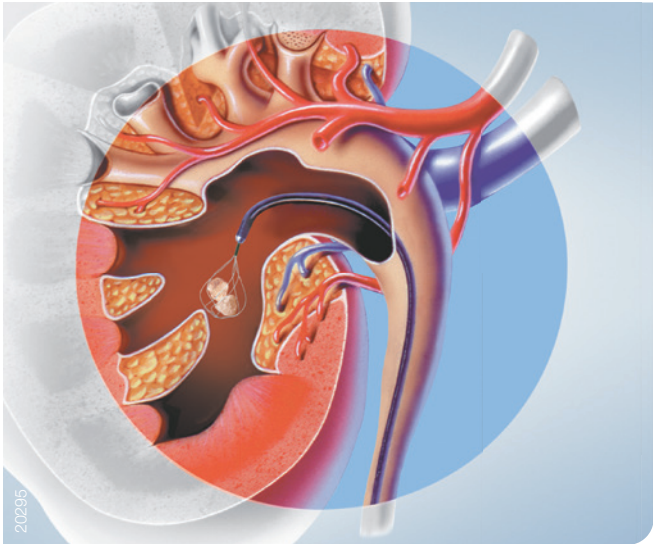
Radiopaque tip ensuring safe visualization prior to inflation

Tapered sheath for atraumatic insertion

UroPass Access Sheath

- Available from 10/12 to 13/15 Fr
- Establishes a conduit for atraumatic multiple instrument passage
- Stainless-steel reinforced sheath prevents kinking and resists sidewall collapse
- Hydrophilic coating reduces friction and facilitates passage

VISUALIZATION



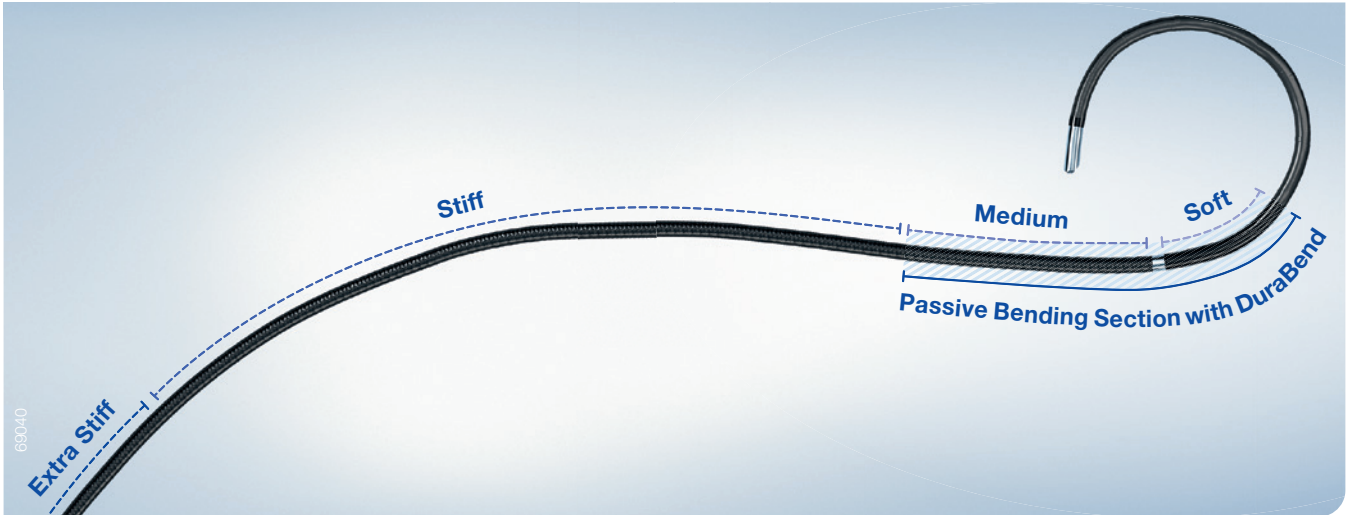
See what you have never seen before – the CCD imaging sensor in the distal end of the videoscope provides a bright, moiré-free image with high color reproduction without the need for a camera head.

This imaging portfolio is further strengthened by single-use accessories that facilitate the procedure.

Flexible Ureteroscopy

URF-V3 - High Image Quality and Durability in Superslim 8.4 Fr.

- Olympus's unique DuraBend insertion-tube design reduces stress on the bending section during insertion in the narrow renal pelvis by passive bending, which increases the durability of the URF-V3.
- 8.4 Fr slim URF-V3 fits into 10/12 Fr access sheath, allowing access in tight ureters.
- Deflection capabilities of 275° up and down allow for visualization of lower renal calyces as well as upper and middle calyces.
- The 120° rotation function allows the operator to change the shaft's angle by rotating a ring on the handle. This potentially allows for longer laser activation, making treatment of large stone burdens feasible.
- Large, distortion-free digital image with even illumination allows the surgeon to provide thorough and efficient treatment.



Olympus DuraBend Design

Fiberoptic Ureteroscopes

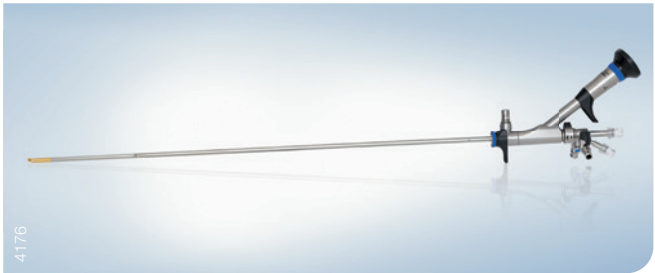
Olympus is known as an innovator in optical technology, which can also be seen in the high image quality of the fiber optic ureteroscopes.

The new URF-P7 with DuraBend design also facilitates renal access in difficult anatomy due to the extra-slim diameter of 7.95 Fr. The 4.5 Fr evolution tip allows for a smooth passage even without a ureteral access sheath.

The semi-rigid ureteroscopes equipped with up to 50,000 fibers and an atraumatic tip design, ensuring safe access and great visualization for procedures in the ureter.

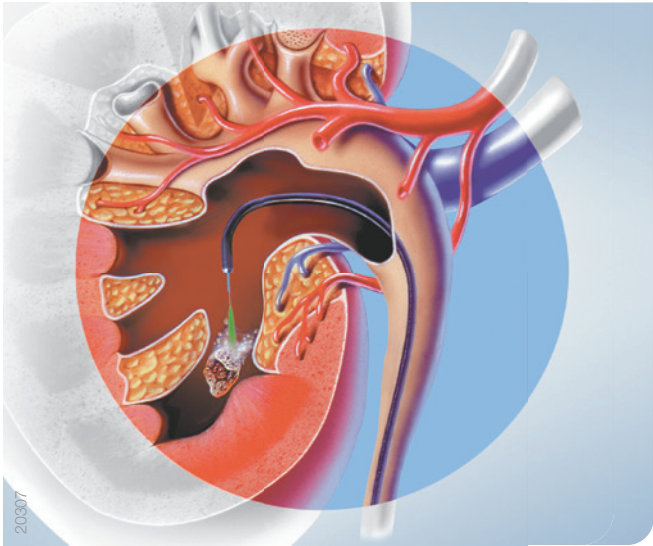
Accessories

Olympus's accessories are designed to provide additional convenience for your stone procedures. Our port seals ensure a safe fit for laser fibers and reduce leakages. With the manual irrigation system Irri-Flo the surgeon can manually control the flow of irrigation for higher visualization.



Irrigation delivery system and biopsy port seals

LITHOTRIPSY



Successful stone fragmentation depends largely on the ability to accurately apply the appropriate level of energy at the correct impact frequency to the exact target area of the stone. Olympus offers powerful advanced lithotripsy technology options for the fragmentation and removal of kidney, ureteral, and bladder stones regardless of the size, composition, or location.

ShockPulse-SE Lithotripter

The ShockPulse-SE lithotripter utilizes a single probe set which produces ultrasonic and mechanical impact action to fragment the hardest stone burdens efficiently. It is designed with a large lumen to fragment and remove stones with speed and safety as never seen before. The fact that it can be operated using the handpiece with one hand makes it extremely convenient for daily work. Its versatility in terms of probe variety for rigid ureteroscopy and PCNL is outstanding.



OLYMPUS EMPOWER H Laser Portfolio – H35, H65 and H100

The OLYMPUS EMPOWER H Laser Portfolio offers a full range of Holmium: YAG lasers and fibers to meet the diverse lithotripsy challenges physicians face each day.

- Wide range of setting capabilities for convenient stone treatment
- Treatment modes: Lithotripsy, soft tissue, and BPH for the H65 and H100
- Higher frequency affords greater versatility
- Wide range of laser fibers including 200 μm, 275 μm, 375 μm, 550 μm, 1000 μm, and 200 Series ball tip fiber
- Higher frequency facilitates dusting

Usability and User Interface

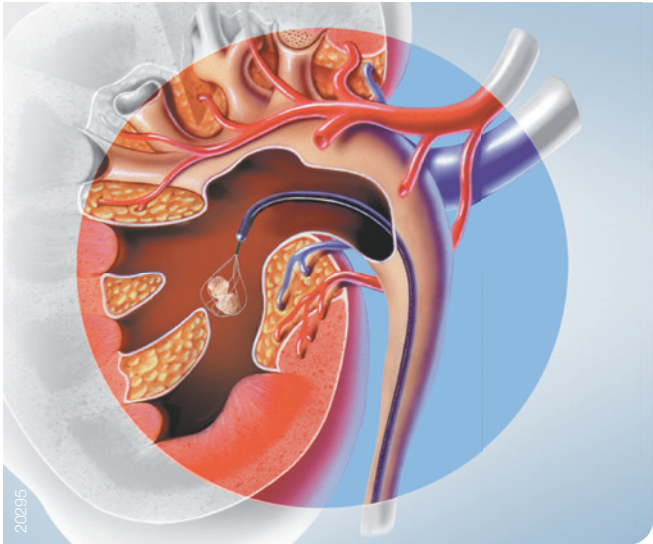
An intuitive user interface facilitates easy transition between emission modes and offers a simple selection of settings for convenient laser treatment. The option to save an individual setting selection enables the user to work with preferred treatment parameters.

Stabilization Mode

The OLYMPUS EMPOWER H65 and H100 offer a stabilization mode which creates a path of vapor between the fiber tip and the stone to stabilize the stone during dusting, resulting in a reduced retropulsion effect. The long pulse modulation allows a more efficient and precise treatment of stones due to reduced movement.



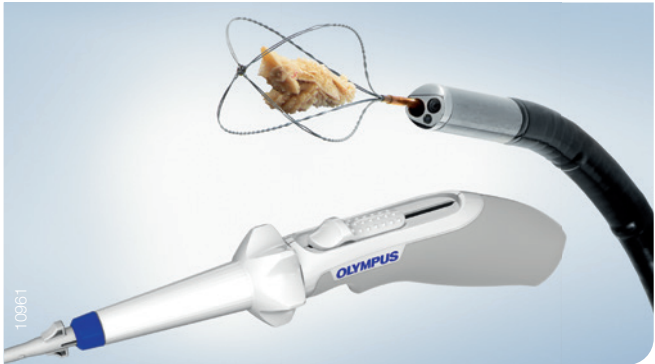
STONE RETRIEVAL



Olympus has focused on developing retrieval technology that simplifies the removal of stone fragments and tissue of all shapes and sizes in all anatomical situations while also minimizing patient trauma and reducing procedure times.

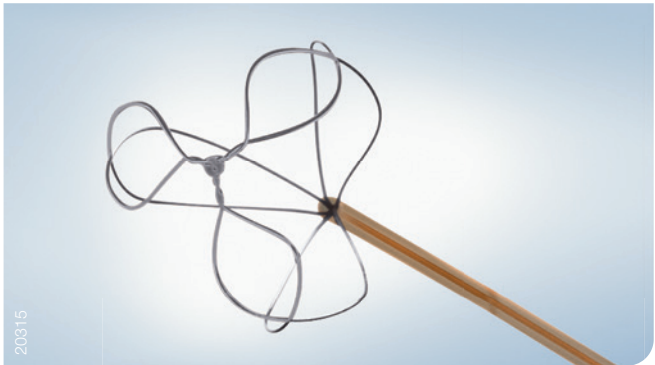
No-Tip Nitinol Baskets

The simple four-wire basket design allows for easy capture and release of stones. The no-tip design with round wires is safe for intrarenal use and minimizes tissue trauma during manipulation. The torque-responsive shaft and ergonomic handle provide the control and security to ensure safe and effective stone removal. Olympus offers a full range of no-tip nitinol baskets to ensure a safe stone removal.



Ultra-Catch Four-Wire No-Tip Nitinol Basket

A single-handed rotation and actuation thanks to the innovative rotation wheel combined with a patented distal-disc design to ensure an atraumatic stone retrieval. The twisted wire construction provides radial strength for manipulation in anatomical structures where movement can be restricted. The Ultra-Catch is equipped with a highly ergonomic gel-like handle.



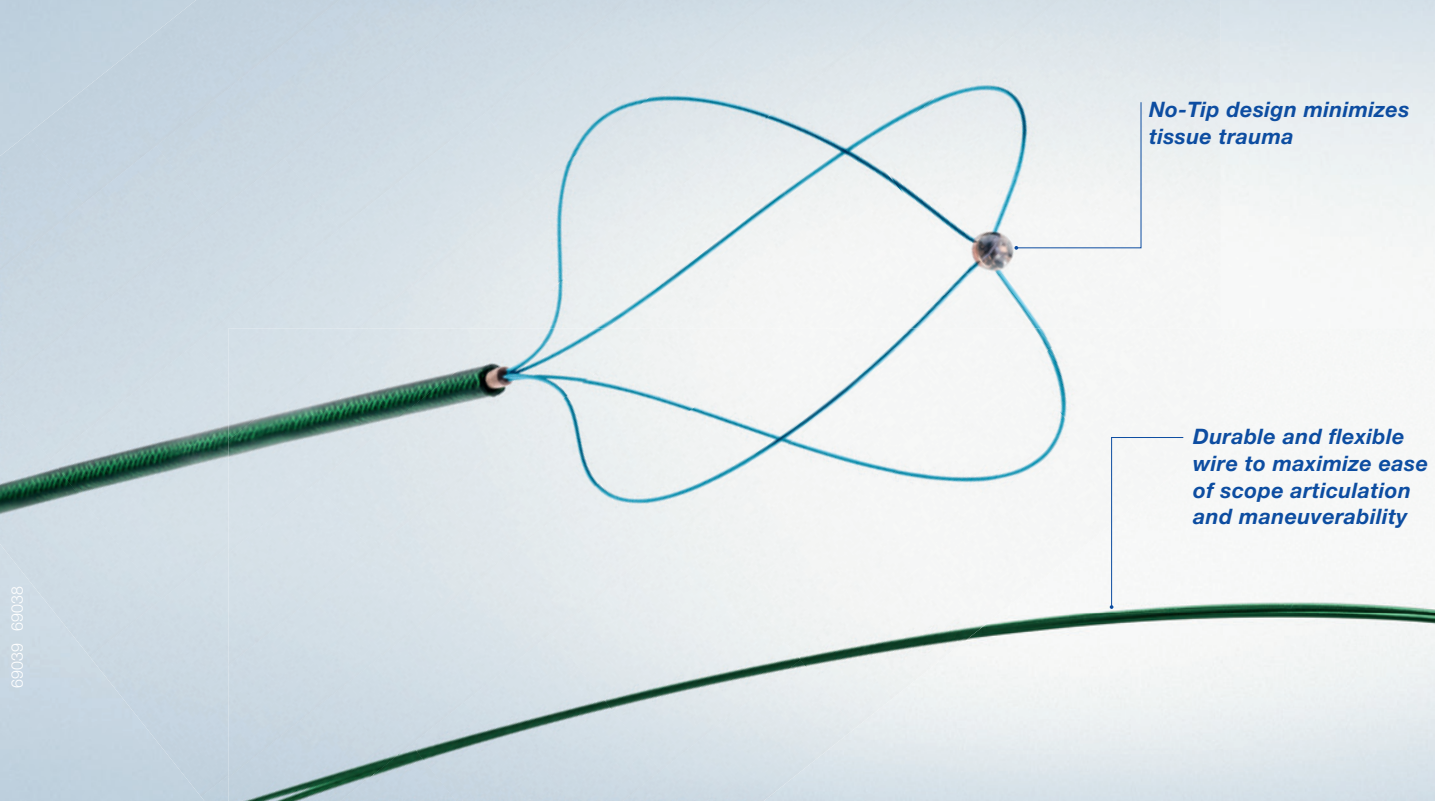
Additional Basket Shapes for Your Clinical Needs

X-Catch Six-Wire No-Tip Nitinol Basket

Paired construction enables capture of several small stones at once to save time.

Stainless Steel Basket Lineup

Available with four-wire, helical, and grasping forceps shape to adjust to stone characteristics and location.



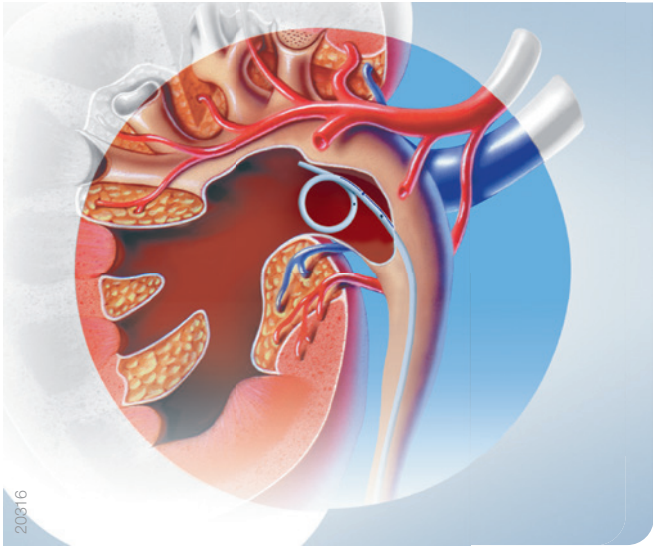
Flex Catch 1.9 Fr. Basket

The Flex Catch is designed to gradually open to capture and release stones of varying sizes in the lower and upper urinary tract.

- Soft nitinol cage and atraumatic tip design to conform to the patient anatomy also in most challenging procedures.
- The small 1.9 Fr shaft size allows for improved irrigation and visibility through smaller working channels.
- Flexible composite sheath allows for maximum scope deflection and smooth scope passage even in the lower pole.
- Gradual basket opening allows for control over basket.



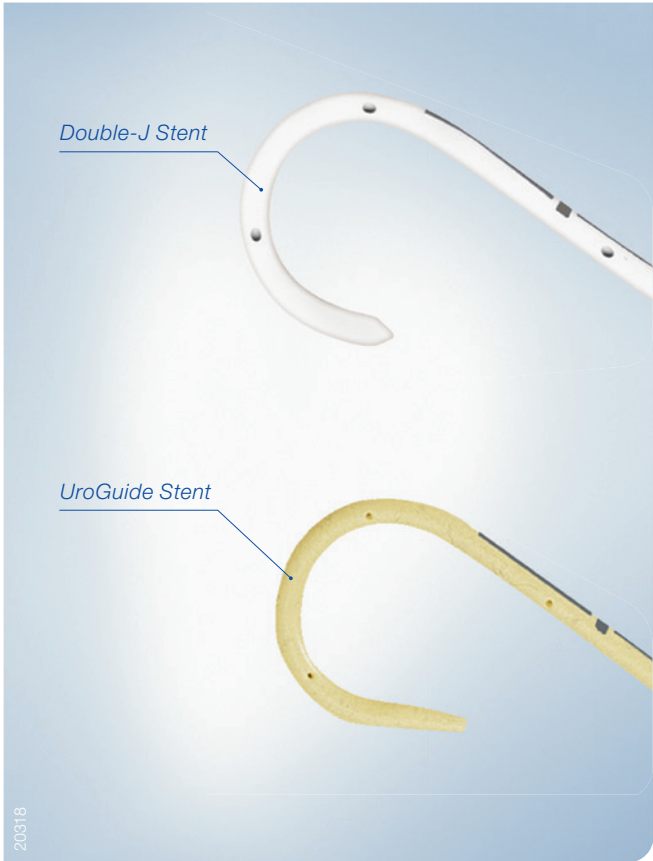
DRAINAGE



We offer a broad selection of premium-quality stents from specialty to everyday usage. Our Single-J and Double-J as well as UroGuide stent minimize encrustation thanks to being made of silicone. Silicone is used in various medical applications because of its softness which allows easy insertion and removal of the stent.

Olympus understands your procedural needs and has pioneered advanced drainage technology without compromise. As an indication of the quality of the material, all TecoFlex stents are approved for 365 days of indwelling time.

Silicone Stents



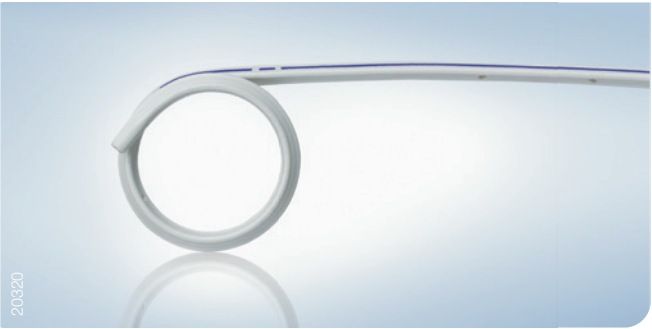
Single-J Stent
Single-J stent with 90 cm length for superior drainage.

Double-J Stent
Silicone stent with closed tips for reliable drainage after stone treatment.

UroGuide Stent
Silicone stent for easy insertion and high incrustation resistance with open ends.

TecoFlex Stents

LithoStent
TecoFlex stent with triangular shape to resist sidewall collapse and ensure optimized drainage.



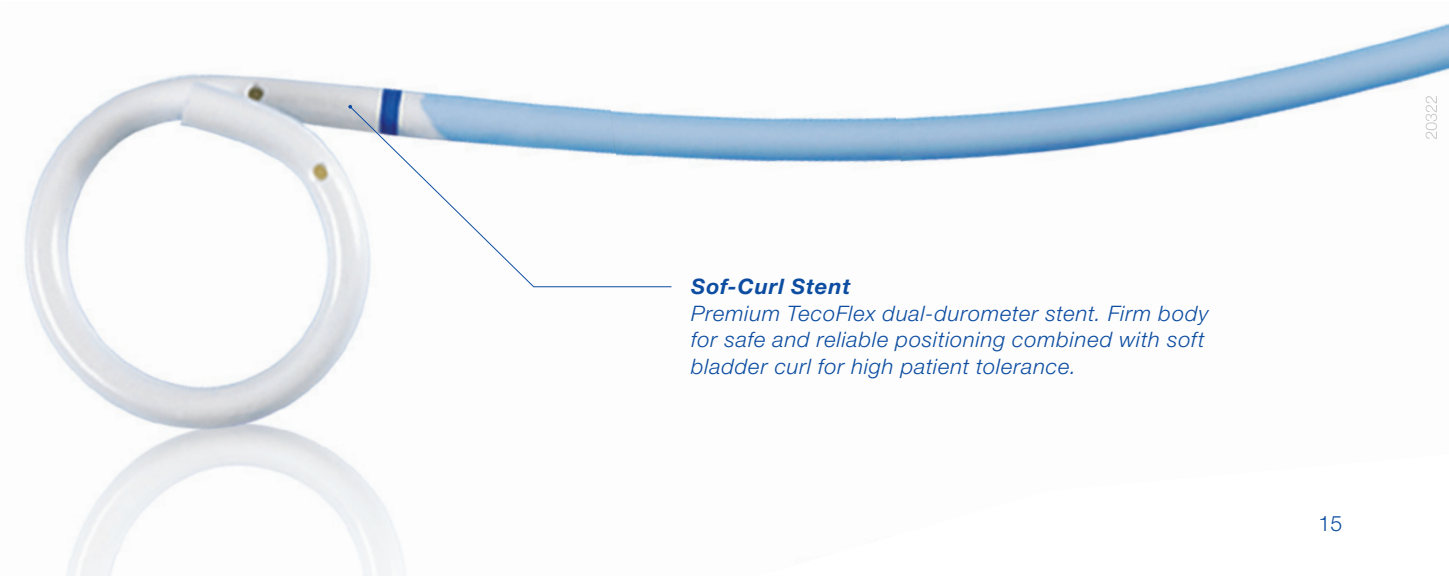
Quadra-Coil Stent
Soft TecoFlex stent with specially designed bladder curl. The multilength concept allows for patient adjusted placement from 22–28 cm.



Classic Double Pigtail Stent
Soft TecoFlex stent for high patient comfort due to the softness of the material.



Lubri-Flex
Firm TecoFlex stent for safe and reliable placement.



Sof-Curl Stent
Premium TecoFlex dual-durometer stent. Firm body for safe and reliable positioning combined with soft bladder curl for high patient tolerance.



www.olympus.eu



As medical knowledge is constantly growing, technical modifications or changes of the product design, product specifications, accessories and service offerings may be required.

OLYMPUS

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Wendenstrasse 14-18, 20097 Hamburg, Germany
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www.olympus-europa.com

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

Registration No.: HD 60123878 0001

Report No.: 12018179 022

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 and additional sites included)

Replaces Approval, Registration No.: HD 60078827 0001

Expiry Date: 2022-11-02

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: 2017-11-03

Date: 2017-10-12



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 D197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev.0

**Attachment to
Certificate**

Registration No.: HD 60123878 0001

Report No.: 12018179 022

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
Disinfecting Units
Capsule Endoscopes and Systems
Ultrasound Diagnostic Imaging Systems



Notified Body

M. Aihara

M.Sc. M. Aihara

Date: 2017-10-12

Traducere din limba engleza



APROBARE
Directiva CE 93/42/CEE Anexa II, excluzând Secțiunea 4
Sistem complet de asigurare a calității
Echipamente medicale

Nr. Înregistrare: HD 60123878 0001
Nr. Raport: 12018179 022

Producător: Olympus Medical Systems Corp.
2951 Ishikawa-cho
HACHIOJI-SHI, TOKIO 192-8507
JAPONIA

Produse: Proiectare și dezvoltare, producție de sisteme de endoscopie medicală, produse de diagnostic, operație și tratament.
(a se vedea atasamentele pentru produse și locații suplimentare incluse)
Înlocuiește Aprobarea cu nr. de înregistrare: HD 60078827 0001

Data expirării: 02.11.2022

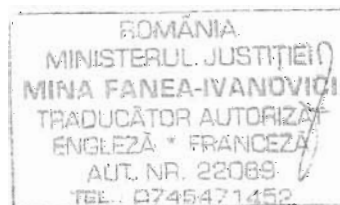
Organismul Notificat declară prin prezenta că au fost îndeplinite cerințele Anexei II, excluzând secțiunea 4 a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menționat a stabilit și aplică un sistem de asigurare a calității, care este supus unei supravegheri periodice, definită în Anexa II, secțiunea 5 a directivei menționate anterior. Pentru comercializarea echipamentelor din clasa III acoperite de acest certificat, este necesar un certificat CE de examinare proiectare în conformitate cu Anexa II, secțiunea 4.

Data intrării în vigoare: 03-11-2017

Data: 12.10.2017

Organism notificat
Ștampilă:
TUV Rheinland LGA Products GmbH
Zertifizierungsstelle
M.Sc. M. Aihara
(semnătură indescifrabilă)

TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nürnberg
TÜV Rheinland LGA Products GmbH este un Organism Notificat în conformitate cu Directiva
93/42/CEE cu privire la echipamentele medicale, cu numărul de identificare 0197



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Atasament la
Certificat

Nr. de înregistrare: HD 60123878 0001
Nr. raport: 12018179 022

Producător: Olympus Medical Systems Corp.
2951 Ishikawa-cho
HACHIOJI-SHI, TOKIO 192-8507
JAPONIA

Produse incluse:

- Sisteme medicale de endoscopie:
 - Endoscoape
 - Echipamente endoterapie
 - Procesoare de imagine
 - Pompe pentru endoscopie
 - Surse de lumină
 - Unități de detectare poziție
 - Unități de cauterizare electrotermică
 - Sisteme endochirurgicale integrate
 - Unitati de control/reglare endoscopice
- Echipamente electrochirurgicale
- Sonde și traductoare pentru litotriptoare cu ultrasunete
- Insuflatoare laparoscopice
- Echipamente chirurgicale cu ultrasunete
- Unitati de sterilizare
- Sisteme și endoscoape capsulă
- Sisteme de imagistica pentru diagnostic cu ultrasunete

Data: 12.10.2012

Organism notificat
Șampilă:
TUV Rheinland LGA Products GmbH
Zertifizierungsstelle
M.Sc. M. Aihara
(semnătură indescifrabilă)



EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60123877 0001

Report No.: 12018179 022

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

Products: Sterile Endotherapy Devices used in conjunction with
Endoscopes, Sterile Non Active Instruments used in
conjunction with Endoscopes and Sterile Non Active
Instruments used in conjunction with Medical Ultrasound
Diagnostic Imaging Systems
Replaces Approval, Registration No.: DD 60116725 0001

Expiry Date: 2022-11-02

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2017-11-03

Date: 2017-10-12



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.

Traducere din limba engleza



CERTIFICAT CE
Directiva CE 93/42/CEE Anexa V
Asigurarea calității producției
Echipamente medicale

Nr. Înregistrare: DD 60123877 0001

Nr. Raport: 12018179 022

Producător: Olympus Medical Systems Corp.
2951 Ishikawa-cho
HACHIOJI-SHI, TOKIO 192-8507
JAPONIA

Produse: Echipamentelor sterile pentru endoterapie, utilizate împreună cu endoscoape, instrumente sterile non-active utilizate împreună cu endoscoape și instrumente sterile non-active utilizate împreună cu sisteme medicale de imagistică diagnostic cu ultrasunete.
Înlocuiește Aprobarea. nr. înregistrare: DD 60116725 0001

Data expirării: 02.11.2022

Organismul Notificat declară prin prezenta că au fost îndeplinite cerințele Anexei V a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menționat a stabilit și aplică un sistem de asigurare a calității, care este supus unei supravegheri periodice, definită în Anexa V, secțiunea 4 a directivei menționate anterior. Pentru comercializarea echipamentelor din clasa IIb și clasa III acoperite de acest certificat, este necesar un certificat CE de examinare tip în conformitate cu Anexa III.

Data intrării în vigoare: 03-11-2017

Data: 12.10.2017

Organism notificat

Ștampilă:

TÜV Rheinland LGA Products GmbH

Zertifizierungsstelle

M.Sc. M. Aihara

(semnătură indescifrabilă)

TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nürnberg
TÜV Rheinland LGA Products GmbH este un Organism Notificat în conformitate cu Directiva 93/42/CEE cu privire la echipamentele medicale, cu numărul de identificare 0197



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

has established and applies a quality management system for medical devices
for the following scope:

**Marketing, sales and servicing of optical, opto-digital,
electronic and mechanical systems as well as associated
accessories and consumables in the field of
endoscopy and microscopy**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

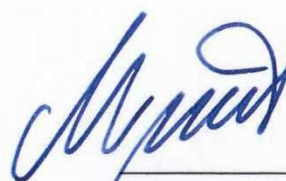
are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-06-21
Certificate Registration No.: SX 60148788 0001
An audit was performed. Report No.: 60319405 001
This Certificate is valid until: 2023-06-20

Certification Body



Date 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope: Subsidiary:

Olympus Europa SE & Co. KG
Albert-Schweitzer-Ring 24-26
22045 Hamburg
Germany

Scope:
Servicing of optical, opto-digital, electronic and
mechanical systems as well as associated accessories
in the field of endoscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope: Subsidiary:

Olympus Deutschland GmbH
Albert-Schweitzer-Ring 35
22045 Hamburg
Germany

Scope:

Servicing of optical, opto-digital, electronic and
mechanical systems as well as associated accessories
in the field of endoscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope: Subsidiary:

Olympus Deutschland GmbH
Amsinckstr. 63
20097 Hamburg
Germany

Scope:
Marketing, sales and servicing of optical, opto-digital,
electronic and mechanical systems as well as associated
accessories and consumables in the field of endoscopy
and microscopy

Certification Body



Date: 2020-04-29



TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope: Subsidiary:

Olympus France S.A.S.
65 Rue de Monthléry
94533 Rungis
France

Scope:
Servicing of optical, opto-digital, electronic and
mechanical systems as well as associated accessories in
the field of endoscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 5/13, Rev.0

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

OLYMPUS IBERIA S.A.U.
PL. Europa 29-31
08908 L'Hospitalet de Llobregat
Barcelona
Spain

Scope:

Marketing, sales and servicing of optical, opto-digital,
electronic and mechanical systems as well as associated
accessories and consumables in the field of endoscopy
microscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus France S.A.S.
19 rue d'Arcueil
94150 Rungis
France

Scope:

Marketing, sales and servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories and consumables in the field of endoscopy and microscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope: Subsidiary:

Olympus Czech Group, s.r.o.
Evropská ul. 176/16
160 41 Praha 6
Czech Republic

Scope:
Marketing, sales and servicing of optical, opto-digital,
electronic and mechanical systems as well as associated
accessories and consumables in the field of endoscopy
and microscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Czech Group, s. r.o.
clen koncernu
Telickova 457/29
751 24 Prerov-Predmosti
Czech Republic

Scope:

Servicing of optical, opto-digital, electronic and
mechanical systems as well as associated accessories
in the field of endoscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Service Facility Portugal
Tecnologias Opticas e Digitais, Lda.
Rua de Alcorredores 43 A
3020-923 Torre de Vilela (Coimbra)
Portugal

Scope:

In-house servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories in the field of endoscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 10/13, Rev.0

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Austria GmbH
Shuttleworthstr. 25
1210 Vienna
Austria

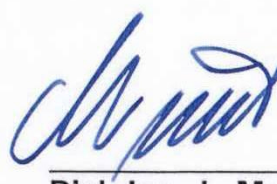
Scope:

Marketing, sales and servicing of optical, opto-digital,
electronic and mechanical systems as well as associated
accessories and consumables in the field of endoscopy
and microscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Nederland B.V.
Simon Smitweg 18
2353 GA Leiderdorp
Netherlands

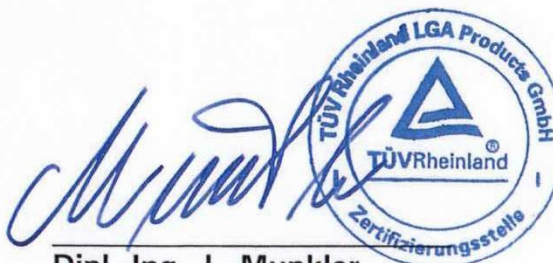
Scope:

Marketing, sales and servicing of optical, opto-digital,
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and microscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope: Subsidiary:

Olympus Schweiz AG
Chriesbaumstr. 6
8604 Volketswil
Switzerland

Scope:

Servicing of optical, opto-digital, electronic and
mechanical systems as well as associated accessories
in the field of endoscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Schweiz AG
Richtiring 30
8304 Wallisellen
Switzerland

Scope:

Marketing, sales and servicing of optical, opto-digital,
electronic and mechanical systems as well as associated
accessories and consumables in the field of endoscopy
and microscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler



Certificat

Organismul de certificare al TÜV Rheinland LGA Products GmbH

certifică prin prezenta faptul că organizația

OLYMPUS EUROPA SE & Co. KG

**Amsinckstr. 63
20097 Hamburg
Germania**

a implementat și aplică un sistem de management al calității pentru dispozitive medicale pentru următoarele domenii:

Marketing, distribuție și service pentru sisteme optice, opto-digitale, electronice și mecanice, precum și pentru accesoriile corespunzătoare și consumabilele din domeniul endoscopiei și microscopiei

S-a furnizat dovada faptului că au fost îndeplinite cerințele specificate în

EN ISO 13485:2016

Sistemul de management al calității este supus unei supravegheri anuale.

Data intrării în vigoare: 21.06.2020

Nr. înregistrare certificat: SX 60148788 0001

A fost efectuat auditul, raport nr. 60319405 001

Acest certificat este valabil până la 20.06.2023.



Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl. Ing. I. Munkler

TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nürnberg

Tel: +49 221 806-1371 Fax: +49 221 806-3935 email: cert-validity@de.tuv.com <http://www.tuv.com/safety>



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate: Filială

Olympus Europa SE & Co. KG
Albert-Schweitzer-Ring 24-26
22045 Hamburg
Germania

Domeniul de aplicabilitate:

**Service pentru sisteme optice, opto-digitale, electronice și mecanice,
precum și pentru accesoriile corespunzătoare și consumabilele din
domeniul endoscopiei**



Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate: Filială

Olympus Deutschland GmbH
Albert-Schweitzer-Ring 35
22045 Hamburg
Germania

Domeniul de aplicabilitate:

**Service pentru sisteme optice, opto-digitale, electronice și mecanice,
precum și pentru accesoriile corespunzătoare și consumabilele din
domeniul endoscopiei**



Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germany**

Domeniu de aplicabilitate: Filială

Olympus Deutschland GmbH
Amsinckstr. 63
20097 Hamburg
Germany

Domeniul de aplicabilitate:

**Marketing, distribuție și service pentru sisteme optice, opto-digitale,
electronice și mecanice, precum și pentru accesoriile corespunzătoare și
consumabilele din domeniul endoscopiei și microscopiei**



Data, 29.04.2020

Organism de certificare
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Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler





TÜVRheinland®

Doc. 4/13 Rev. 0

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Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate:

Filială

Olympus France S.A.S.
65 Rue de Monthléry
94533 Rungis
Franța

Domeniul de aplicabilitate:

**Service pentru sisteme optice, opto-digitale, electronice și mecanice,
precum și pentru accesoriile corespunzătoare și consumabilele din
domeniul endoscopiei**



DAKkS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și șampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate: Filială

Olympus Iberia S.A.U.
PL. Europa, 29-31
08908 L'Hospitalet de Llobregat
Barcelona
Spania

Domeniul de aplicabilitate:

Marketing, distribuție și service pentru sisteme optice, opto-digitale, electronice și mecanice, precum și pentru accesoriile corespunzătoare și consumabilele din domeniul endoscopiei și microscopiei



Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate: Filială

Olympus France S.A.S.
19 rue d'Arcueil
94150 Rungis
Franța

Domeniul de aplicabilitate:

Marketing, distribuție și service pentru sisteme optice, opto-digitale, electronice și mecanice, precum și pentru accesoriile corespunzătoare și consumabilele din domeniul endoscopiei și microscopiei



Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler





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**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate:

Filială

Olympus Czech Group, s.r.o.
Evropská ul. 176/16
160 41, Praga 6
Republica Cehă

Domeniul de aplicabilitate:

**Marketing, distribuție și service pentru sisteme optice, opto-digitale,
electronice și mecanice, precum și pentru accesoriile corespunzătoare și
consumabilele din domeniul endoscopiei și microscopiei**



DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
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Dipl.-Ing. I. Munkler





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**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate:

Filială

Olympus Czech Group, s.r.o.
clen koncernu
Telickova 457/29
751 24 Prerov-Predmosti
Republica Cehă

Domeniul de aplicabilitate:

**Service pentru sisteme optice, opto-digitale, electronice și mecanice,
precum și pentru accesoriile corespunzătoare și consumabilele din
domeniul endoscopiei**



DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Data, 29.04.2020

Organism de certificare
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Doc. 9/13 Rev. 0

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate: Filială

Olympus Service Facility Portugal
Tecnologias Optica e Digitais, Lda.
Rua de Alcorredores, 43 A
3020-923 Torre de Vilela (Coimbra)
Portugalia

Domeniul de aplicabilitate:

**Service intern pentru sisteme optice, opto-digitale, electronice și mecanice
precum și accesorii corespunzătoare din domeniul endoscopiei.**



DAKkS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate: Filială

Olympus Austria GmbH
Shuttleworthstr. 25
1210 Viena
Austria

Domeniul de aplicabilitate:

Marketing, distribuție și service pentru sisteme optice, opto-digitale, electronice și mecanice, precum și pentru accesoriile corespunzătoare și consumabilele din domeniul endoscopiei și microscopiei



Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate: Filială

Olympus Nederland B.V.
Simon Smitweg 18
2353 GA Leiderdorp
Țările de Jos

Domeniul de aplicabilitate:

**Marketing, distribuție și service pentru sisteme optice, opto-digitale,
electronice și mecanice, precum și pentru accesoriile corespunzătoare și
consumabilele din domeniul endoscopiei și microscopiei**



Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate: Filială

Olympus Schweiz AG
Chriesbaumstr. 6
8604 Volketswil
Elveția

Domeniul de aplicabilitate:

**Service pentru sisteme optice, opto-digitale, electronice și mecanice,
precum și pentru accesoriile corespunzătoare și consumabilele din
domeniul endoscopiei**



Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

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Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate: Filială

Olympus Schweiz AG
Richtiring 30
8304 Wallisellen
Elveția

Domeniul de aplicabilitate:

Marketing, distribuție și service pentru sisteme optice, opto-digitale, electronice și mecanice, precum și pentru accesoriile corespunzătoare și consumabilele din domeniul endoscopiei și microscopiei



Data, 29.04.2020

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