



Olympus Surgical Technologies Europe

Specific Requirements and Challenges for the Miniaturization of Minimal-Invasive Medical Devices

Olympus | Dr. Harald Hanke | Lübeck | 2023-02-22

- 01 Corporate Philosophy
- 02 Global Facts & Figures
- 03 Olympus Surgical Technologies Europe
- 04 Specific Requirements and Challenges for our Products



01

Corporate Philosophy

“

We will continue to make people's lives healthier, safer, and more fulfilling.

”



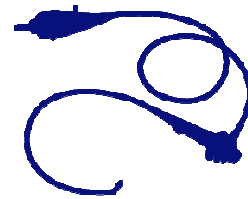
02 Global Facts & Figures

Olympus: Preventing, Detecting and Treating Cancer



1.9 million

New Incidents of Colon Cancer*



50 million

Colonoscopies Performed Worldwide**

*Source: GLOBOCAN 2020

**Numbers for the US, Canada, Germany, France, Italy, Spain, the UK, Japan, China, South Korea, Australia and India. As of 2018 or 2019 depending on the region.

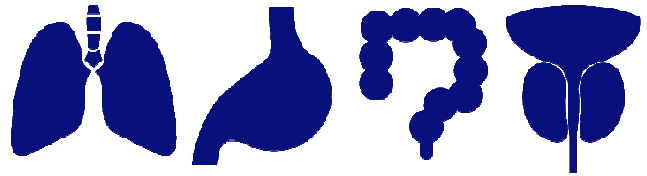
Olympus: Preventing, Detecting and Treating Cancer



100

Diseases or Conditions Treated

At Olympus we have versatile medical devices with the ability to treat approximately 100* diseases or conditions



TOP 4

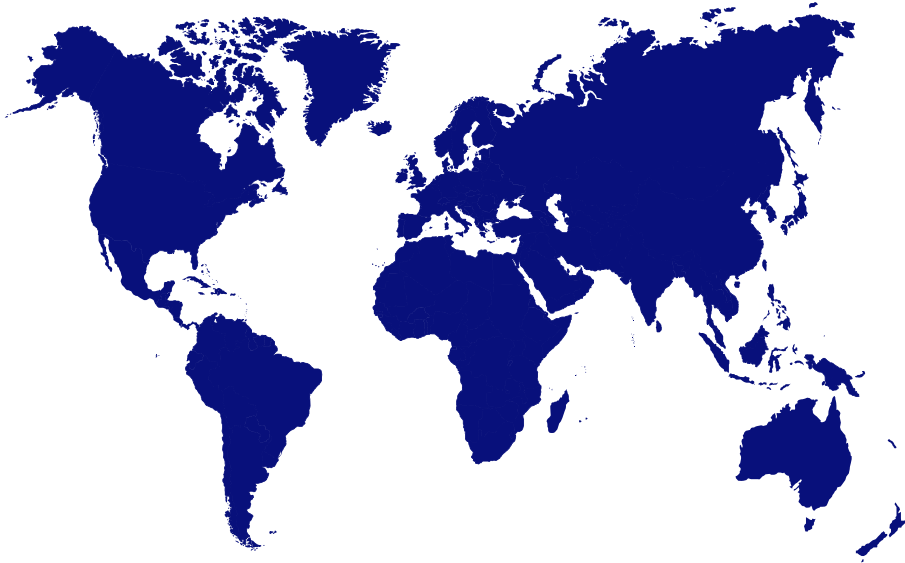
Cancers Treated

Olympus provides products/solutions for lung, stomach, colon and prostate cancers - the top 4** highest incidence of cancers

*As of March 2021

**Top 4 highest incidence of cancers excluding breast cancer, as of March 2021. Source: GLOBOCAN 2020

Making people's lives healthier, safer and more fulfilling



31,557

Employees Worldwide

39

Countries or Regions

Facts and figures as of fiscal year ending March 2022

03 Olympus Surgical Technologies Europe

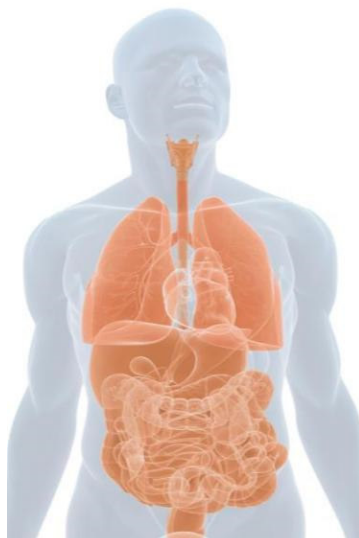
Medical Disciplines



UROLOGY



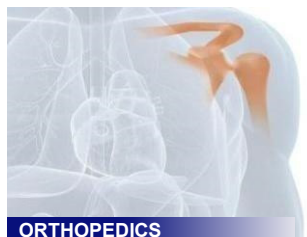
GYNECOLOGY



**GASTROINTESTINAL
GENERAL SURGERY**



EAR NOSE THROAT

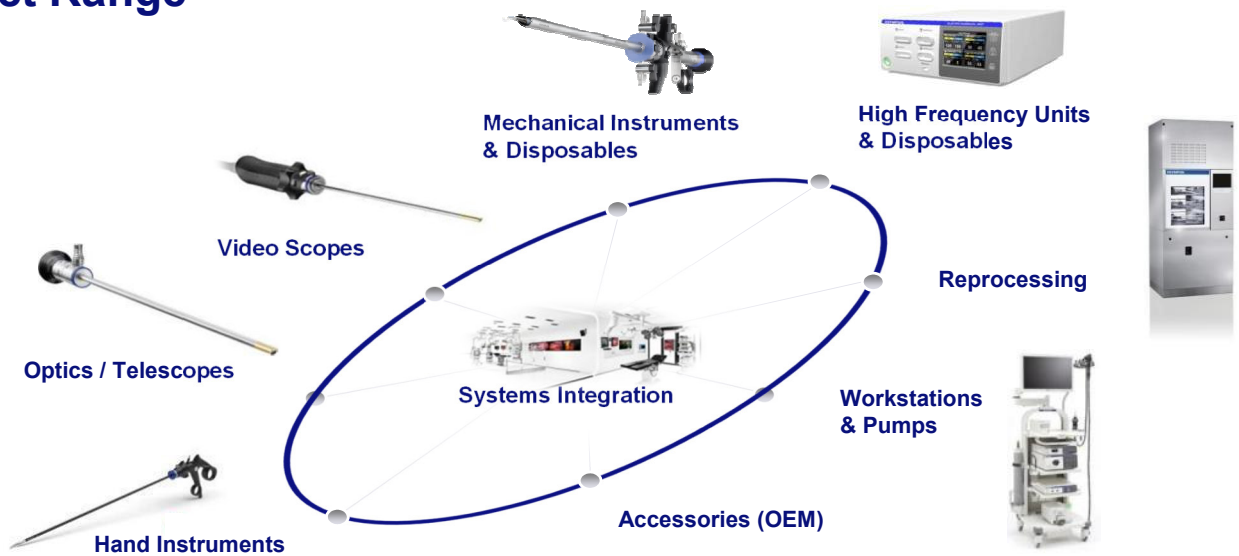


ORTHOPEDICS



PHLEBOLOGY

Product Range



OLYMPUS

04 Specific Requirements and Challenges for our Products

Specific Requirements and Challenges for the Miniaturization of Minimal-Invasive Medical Devices

Miniaturization of Manufacturing Technology

IHU (Innen-Hochdruck-Umformen) Hydroforming
Transfer from "Metal-Industry"
to Medical Device Industry

Miniaturization of Actuators

Realization of sharp endoscopic image
with high resolution

Reprocessing of Reusable Minimal-Invasive Medical Devices

Patient safety within minimal footprint



Tube-Forming as Core Technology for Endoscope Manufacturing

Basic requirement

Provide a long tube with small diameter and thin wall thickness
having multiple different profiles

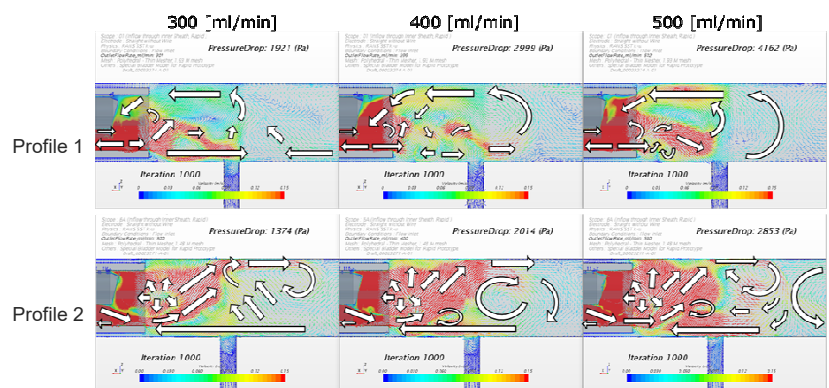
Specific Requirements

- Precise dimensions and tolerances
- Straightness
- Complex profile changes to fulfil flow requirements
- Medical steel grade

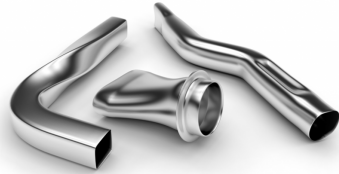
Challenges

- Size of our tubes, very long but very thin walled
- Forming of reprocessing resistant and biocompatible materials
- Required quantities $100 < > 10.000$

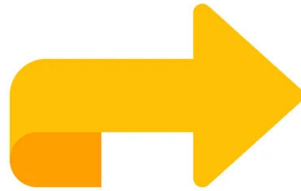
Simulation for Flow Optimization



Miniaturization of Manufacturing technology

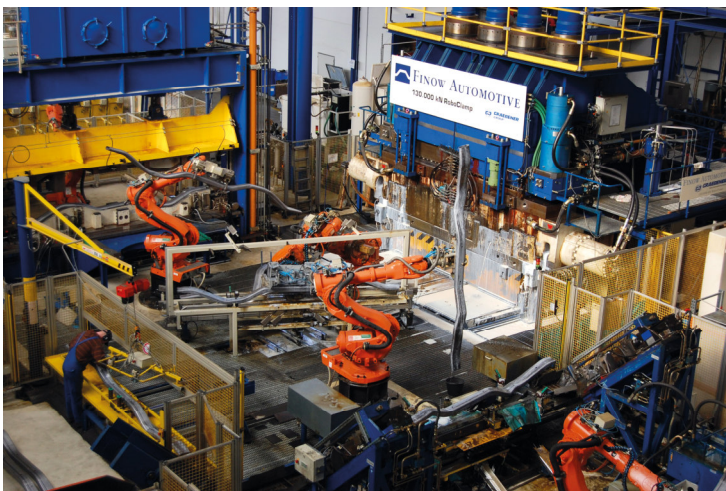


Source: <https://macrodynepress.com/>

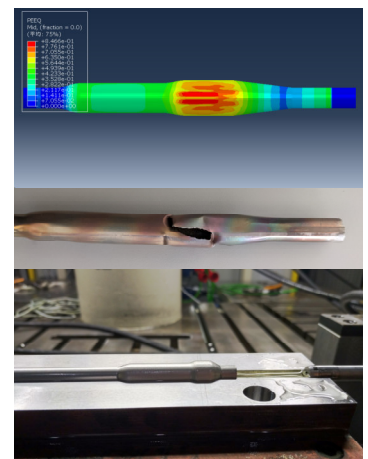


Hydroforming Transfer from “Metal-Industry” to Medical Device-Industry

Miniaturization of Manufacturing technology



Source: Gräbener Maschinentechnik GmbH & Co. KG
Robo-Clamp with closing force 13.000 t (130.000 kN) – 240.000 p.a.



Development of miniaturized Hydroforming-equipment and process parameters together with the equipment manufacturer

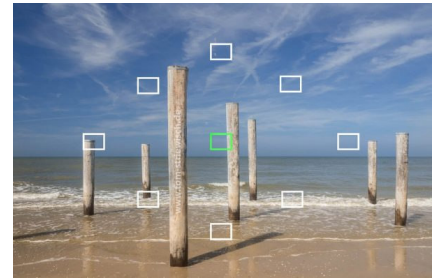
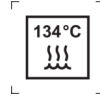
Miniaturization of Actuators for autoclavable Video-Endoscopes

Basic requirement

Provide a sharp image for all working distances the surgeon needs.

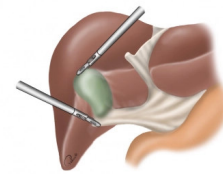
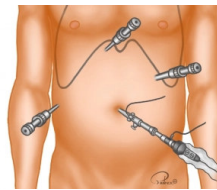
Specific Requirements

- Stable position of the lenses
- Short axial moving distance, e.g. <math><0,5\text{mm}</math>
- Lowest possible radial space for the drive mechanism
- Compatible with autoclave reprocessing

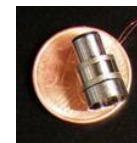
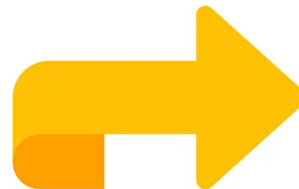
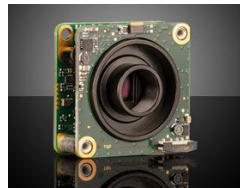


Challenges

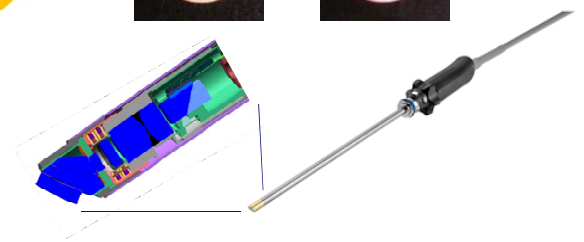
- No direct transfer of technology from consumer products, like smartphones or digital cameras
- Required radial space for drive mechanism will decrease "space for image quality"



Miniaturization of Actuators for autoclavable Video-Endoscopes

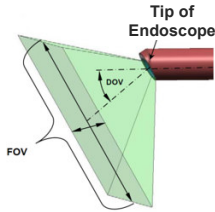
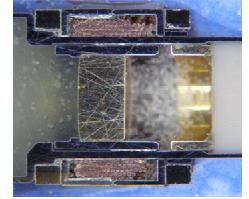
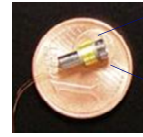
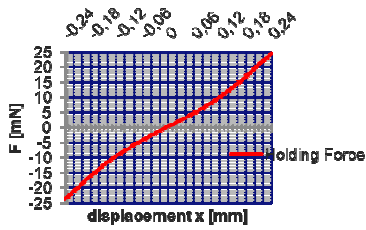
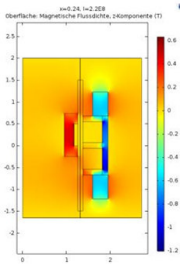


- Voice Coil Motor (VCM)
- MEMS
- Liquid lenses
- Piezo
- Shape Memory
- ...



**Only a few technical actuator principles fit to Endoscopes
Specific restrictions especially given by limited radial space and steam sterilization**

Miniaturization of Actuators for autoclavable Video-Endoscopes

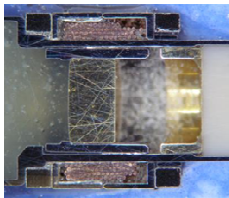


The surgeons need to control the image quality permanently which is given by manual change of the focus (bi-stable) instead of dynamic autofocus

Miniaturization of Actuators for autoclavable Video-Endoscopes

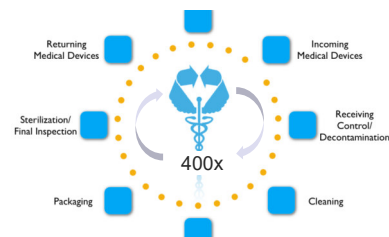
Autoclave (Steam Sterilization) challenge
Many different material in compact arrangement

- Steel
- Copper
- Glass
- Brass
- Glue
- Magnetic Mat.



Hermetic housing required

- Vacuum Technology
- Hermetic passage



Different thermal expansion leads to mechanical stress which must not compromise the image quality over the lifetime of the medical device

Reprocessing of Reusable Minimal-Invasive Medical Devices

Basic requirement

Provide a sterile medical device for the treatment of the patient prior to each procedure

Specific Requirements

- Consider worst case parameters
- Proof of evidence by certified laboratories
- Typical lifetime of 400 cycles

Challenges

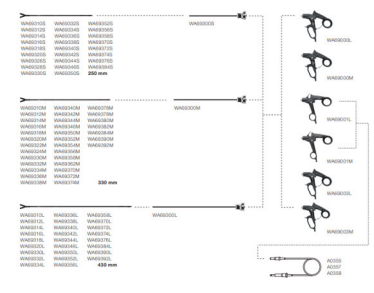
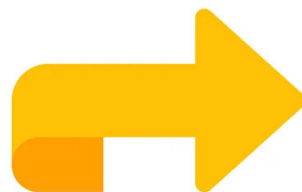
- Functional integration vs cleanability
- Limited availability of compatible materials
- Usability of reprocessing instructions easy to understand but accurate enough



Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
Guidance for Industry and Food and Drug Administration Staff

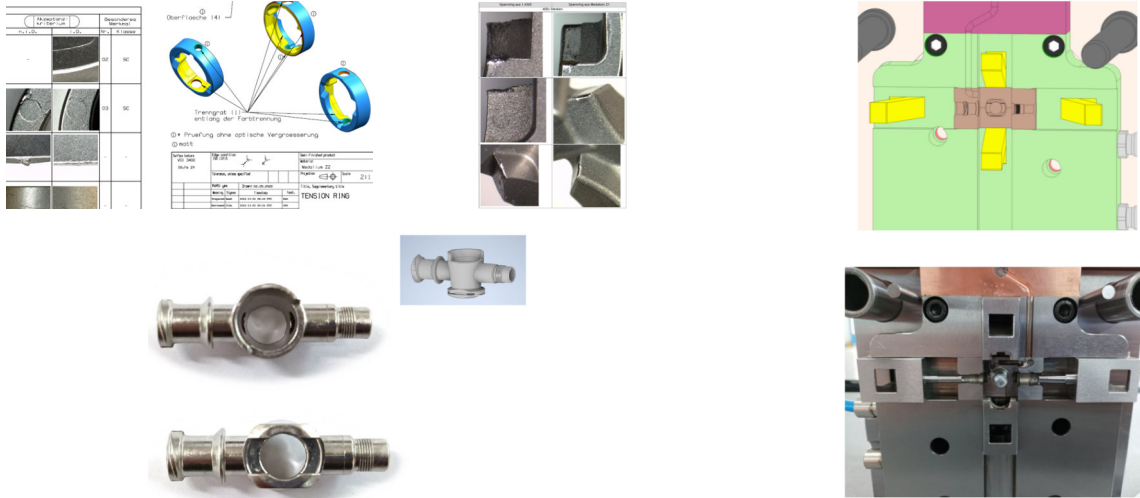


Reprocessing of Reusable Minimal-Invasive Medical Devices



Single-use device with high functionality
reusable device with several interfaces to allow proper reprocessing

Reprocessing of Reusable Minimal-Invasive Medical Devices



New manufacturing technology for precise metal interface parts using amorphous metal (metallic glass)

Research & Development

It always starts with curiosity and the desire to offer added value for customers and patients. To turn this into product innovations is what drives Research and Development at the various locations of Olympus Surgical Technologies Europe day after day – interdisciplinarily in a European and global context.



Visions become reality: the medical technology of tomorrow starts today

Quality & Regulatory

Quality Management System

Alignment of Olympus' processes landscape to global regulatory requirements.

Regulatory Affairs

Registration of new products in global markets.

Product Quality Management

Implementing highest quality standards in design and manufacturing as well as with suppliers.

Market Quality

Preventing complaints and managing escalated cases in a professional manner.



Quality is achieved through design, processes and attitude. It is at the center of our activities within the entire life cycle of our products.