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

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

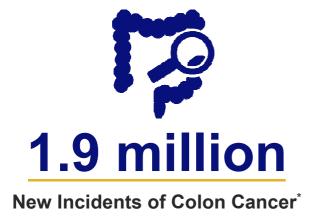


O 1 Corporate Philosophy



02 Global Facts & Figures

Olympus: Preventing, Detecting and Treating Cancer





Source: GLOBOCAN 2020

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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



Diseases or Conditions Treated

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



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

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Making people's lives healthier, safer and more fulfilling



31,557

Employees Worldwide

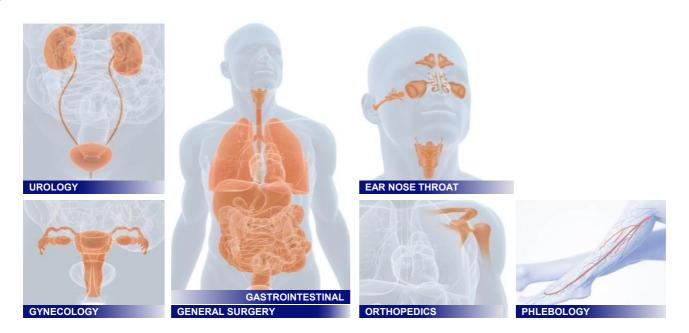
Countries or Regions

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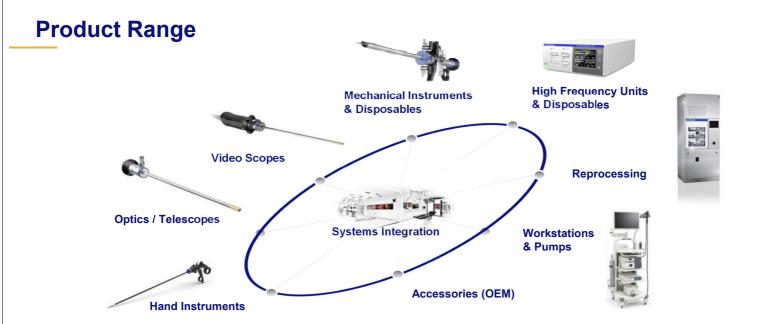
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Medical Disciplines

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O4 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



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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

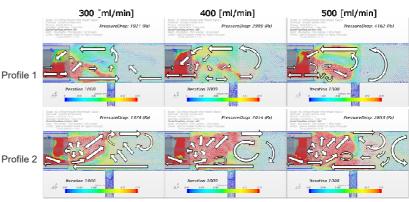
Specific Requirements

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

Challenges

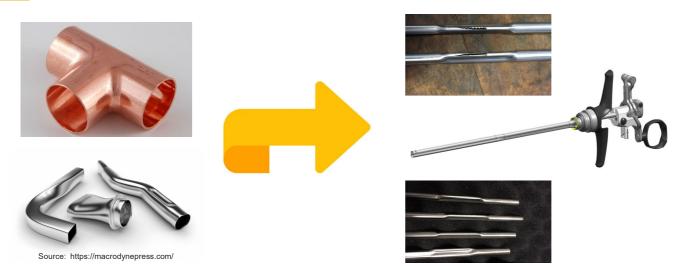
- Size of our tubes, very long but very thin walled
- Forming of reprocessing resistant and biocompatible materials
- Required quantities 100< >10.000

Simulation for Flow Optimization



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Miniaturization of Manufacturing technology



Hydroforming Transfer from "Metal-Industry" to Medical Device-Industry

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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

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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. <0,5mm
- 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"







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Miniaturization of Actuators for autoclavable Video-Endoscopes





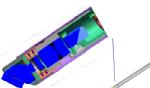














- Voice Coil Motor (VCM)

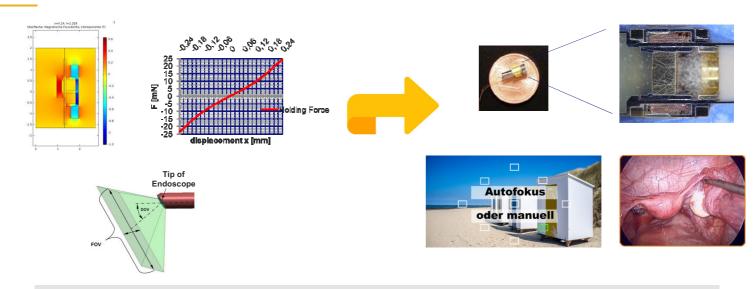
- MEMS
- Liquid lenses
- Piezo
- Shape Memory

- ..

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

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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

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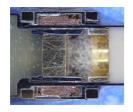
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Miniaturization of Actuators for autoclavable Video-Endoscopes

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

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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



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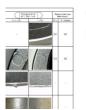
Reprocessing of Reusable Minimal-Invasive Medical Devices



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

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Reprocessing of **Reusable Minimal-Invasive Medical Devices**



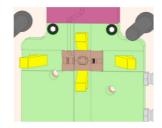














New manufacturing technology for <u>precise</u> metal interface parts using amorphous metal (metallic glass)

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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

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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 <u>and</u> attitude. It is at the center of our activities within the entire life cycle of our products.

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