

OLYMPUS Investor Day 2018  
Enhancement of Infection Prevention Activities

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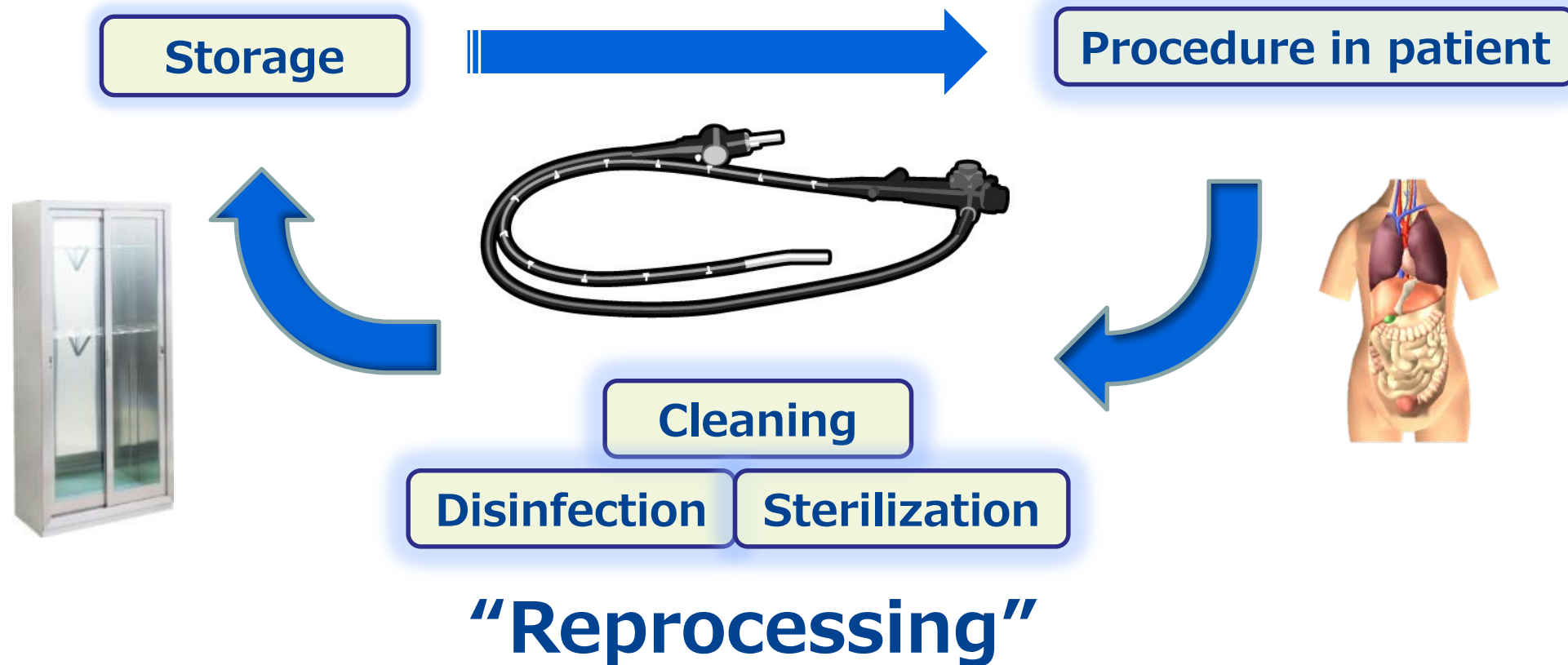
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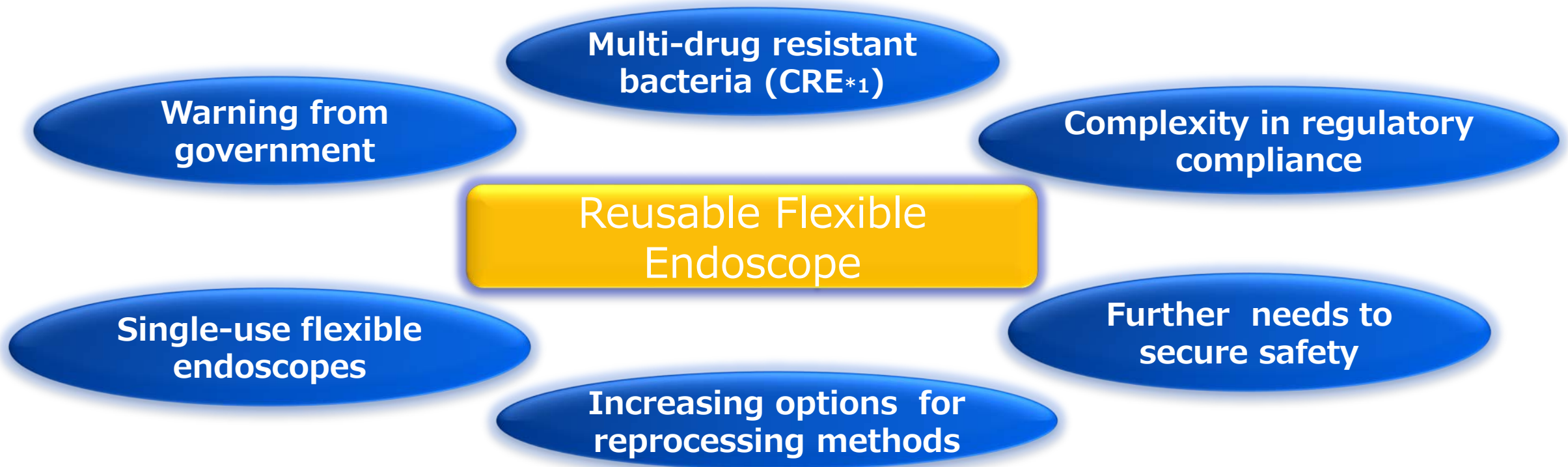
# Medical Device “Reprocessing”

## Reprocessing

Complete processes for cleaning, disinfection and/or sterilization in order to utilize a medical device again



# Environmental Changes at Endoscope Industries



Will show our intensive activities to adjust environmental changes

\*1 CRE, which stands for carbapenem-resistant Enterobacteriaceae, are a family of germs that are difficult to treat because they have high levels of resistance to antibiotics. Healthy people usually do not get CRE infections – they usually happen to patients in hospitals, nursing homes, and other healthcare settings. Patients whose care requires devices like ventilators (breathing machines), urinary (bladder) catheters, or intravenous (vein) catheters, and patients who are taking long courses of certain antibiotics are most at risk for CRE infections. (CDC, <https://www.cdc.gov/hai/organisms/cre/index.html>)

# Waning from Regulatory Authorities regarding

## Infection risks with Duodenoscope

- ✓ The FDA has issued safety communications about the risk of multidrug-resistant bacteria transmission via endoscopes.
- ✓ In Japan, the Ministry of Health, Labor and Welfare has issued a notice based on the cases in the USA.

### USA

▸ FDA, February 19, 2015

Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning : FDA safety communication ]

### JAPAN

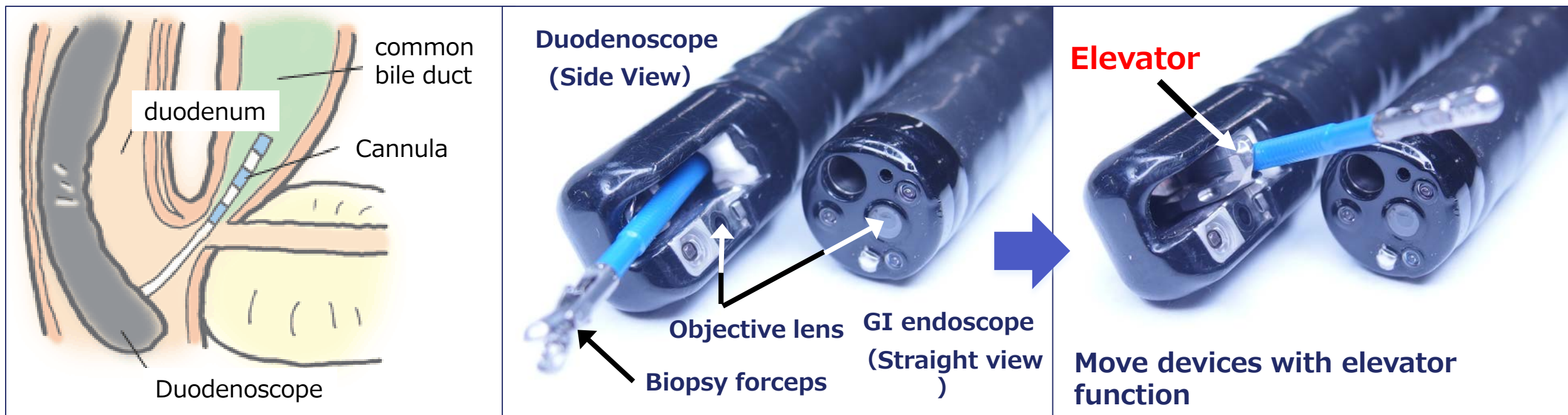
▸ MHLW, March 6, 2015

Potential outbreak of multi-drug resistant  
Hospitals need to comply guidelines from the medical societies and instruction manuals

# Duodenoscope

## Pay attention on reprocessing process for the endoscope with elevator function

- Duodenoscope was developed for conducting ERCP procedure efficiently.
- Duodenoscope has a side viewing which is different from regular GI endoscope
- Elevator function lift elevator with endotherapy devices such as biopsy forceps





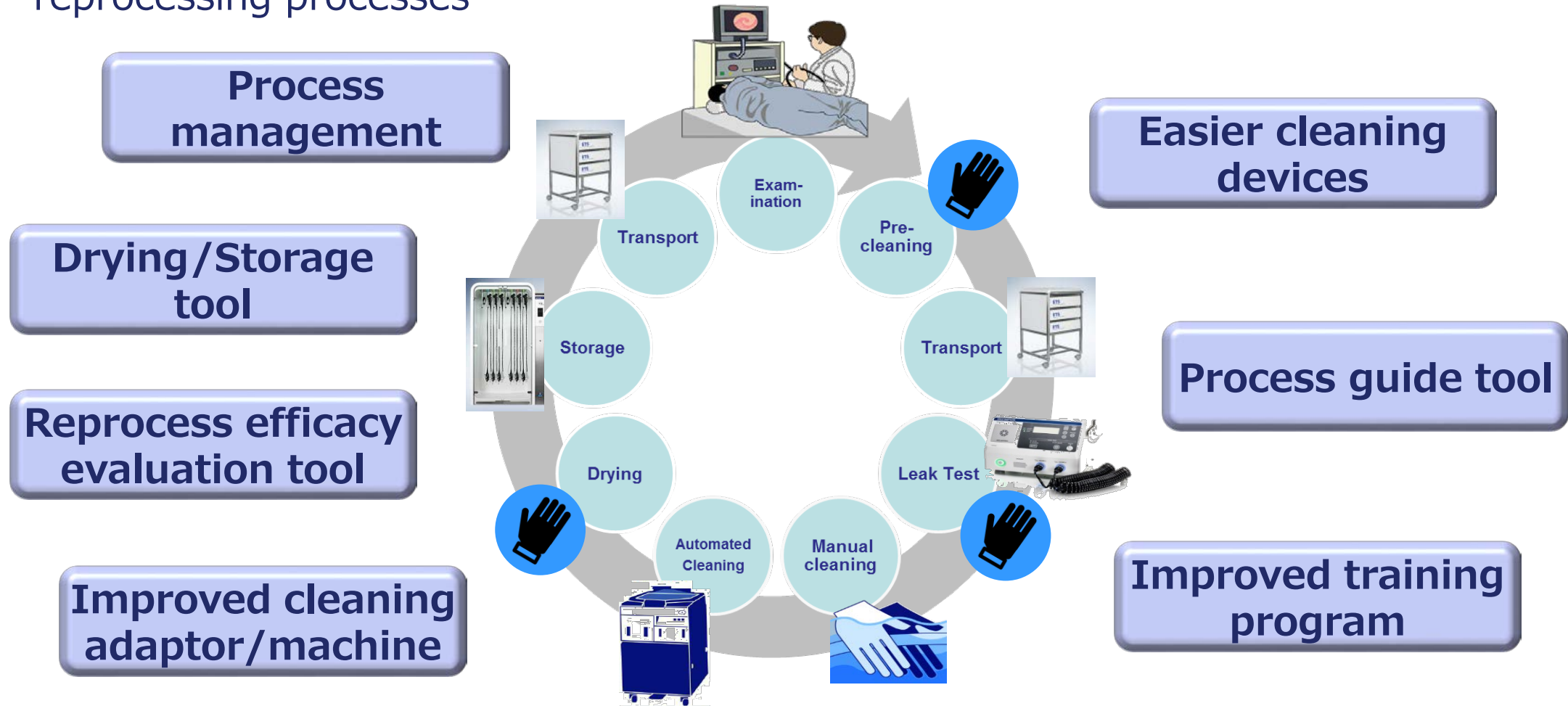
# Our Approaches to Improve Safety

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- 1. Provide *comprehensive solution* covering all reprocessing processes**
  - ✓ Develop/procure more effective/efficient endoscopy and reprocessing products
  - ✓ Develop/improve reprocessing methods to make a process easier to reduce mistakes
- 2. Enhancement of *training program* for the HCPs and *guide tools***
  - ✓ Reinforce external/internal thorough training for cleaning and disinfection technicians
  - ✓ Strict adherence to cleaning procedures and methods as dictated by tablets
  - ✓ Revise Reprocessing Manual for better understanding
- 3. Establish *testing capabilities* to validate reprocessing efficacy, efficiency and workability**
  - ✓ Reprocessing efficacy with a validation test using organic microorganisms or artificial soils
  - ✓ Compatibility/durability of the medical devices with chemicals or reprocessing machines
- 4. Enhance *proactive communication* with appropriate stakeholders**
  - ✓ Expand the audience for relevant new product and solution launches
  - ✓ Facilitate and participate in stakeholder discussions
  - ✓ Set a new organization taking a leadership to handle global reprocessing issues

# 1. Provide Comprehensive Solutions

- ✓ Secure safety for all patients or HCPs who might have a potential infection risks
- ✓ Plan to deliver multiple solutions that addressing issues comprehensively at all reprocessing processes





# Develop Easier Handling Endoscopes/Cleaning Adaptors



**Detachable Disposable Distal Cap**



**New Cleaning Adaptor**

- Provide devices, endoscope or cleaning adaptor, with easier handling/cleaning structures



Cleaning /Disinfection

**New additional functions on cleaning /disinfection machine**

- Provide more efficient automated endoscope preprocessor



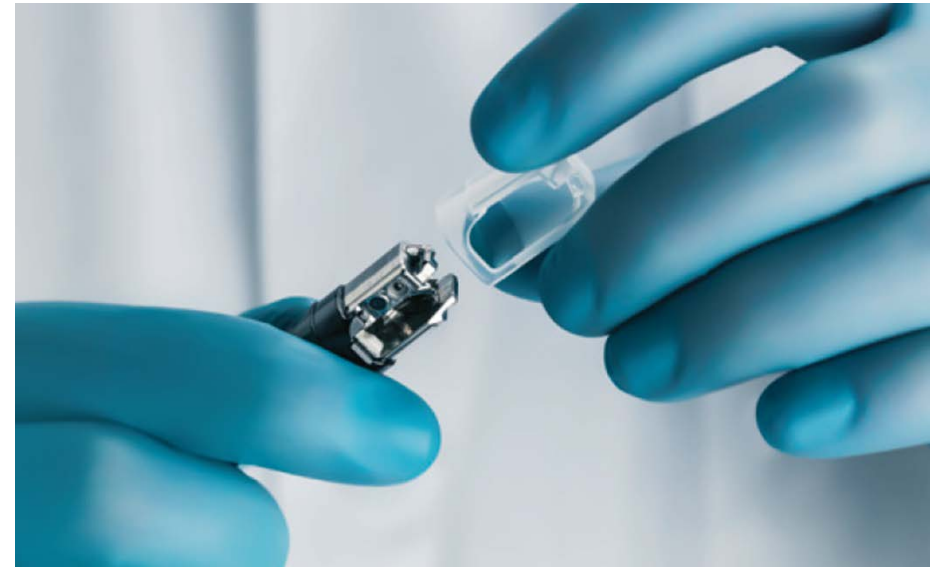
# Product Development for New Duodenoscope

## Features

- New duodenoscope is a side-viewing scope characterized by high-resolution imaging and narrow band imaging (NBI) capabilities.
- Post-procedure, reprocessing is performed by detaching the disposable distal cap and cleaning and disinfecting the tip of the scope.
- In addition, we have developed a new adaptor that can be attached to the tip of the duodenoscope to inject a cleaning solution, meant to improve cleaning efficiency.



**Tear open the cap along the cut**



**Detach the cap completely from the distal end of the endoscope**

# Items for Reprocessing Efficacy Evaluation and Drying/Storage

## Cleaning Efficacy Evaluation Device

- Provide a quick evaluation tool for cleaning efficacy



## Sampling & Culturing Kit

- Provide supporting tools to evaluate reprocessing efficacy



## Storage Cabinet with Drying Function

- Provide an item to keep the endoscope clean and dry until next procedure



Evaluation  
/Drying-Storage



# Reprocessing Process Management (Software base system)



←  
**Process management**

**Reprocessing Documentation, Workflow and Asset Management System**  
 With Unifia connecting and collecting data from reprocessing and storage devices has never been easier. Unifia's wireless scanner technology puts the ability to capture data from virtually all automated endoscope reprocessors, storage cabinets, leak testers and bio burden test kits in the palm of your hand. OER-Pro users can gain greater insight into their reprocessing times, scope serial numbers and HLD temperatures.

# 3. Supporting Tools and Training Program Enhancement

## Enhanced training programs



- Develop and continue reprocessing training program for HCPs to provide an opportunity to be trained.

## Tablet for guiding processes



- Provide guiding tools to make reprocessing process more visible/ intuitive and improve efficiency
- Revise Reprocessing Manual for better understanding

# 3. Enhancement of Reprocessing Tests Capabilities

## 4.0 billion Japanese Yen was invested to enhance function

- Compatibility tests with detergent, disinfectant, reprocessing/sterilization machines
- Validation tests for reprocessing, cleaning, disinfection or sterilization, efficacy



Working on establishment of the testing capability to meet various regulatory requirements



## 4. Enhance Communication with Stakeholders

- **Patients/HCPs safety first**

Prioritize safety for patients or HCPs by reducing potential infection risks.

- **Collaborations with stakeholders**

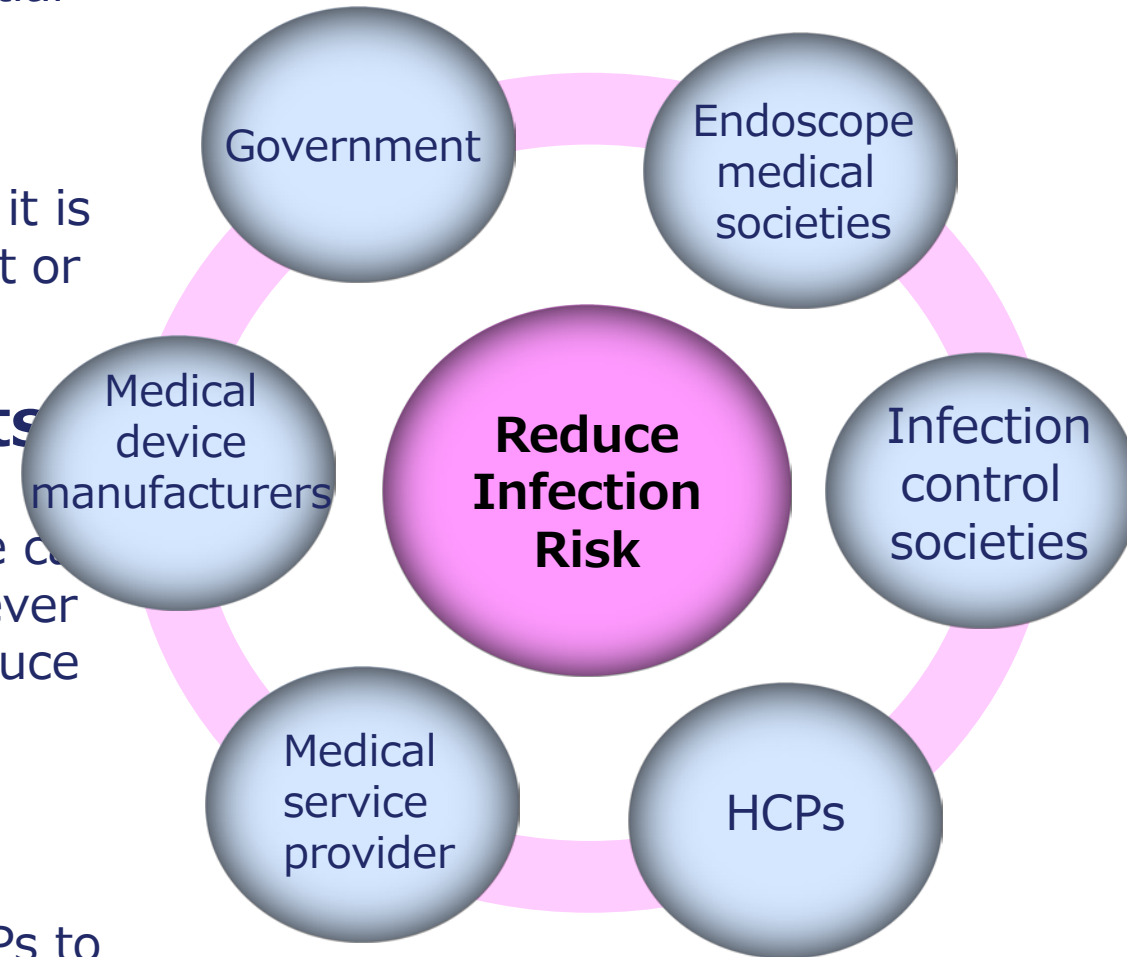
With the best efforts by Medical device manufacturers, it is important to collaborate closely with HCPs, government or medical societies.

- **Balancing between risks and benefits**

Risks of using medical devices can't be eliminated completely. HCPs may decide whether a medical device can be used by weighing potential risks and benefits. However manufacturers need to continue their best effort to reduce or mitigate risks.

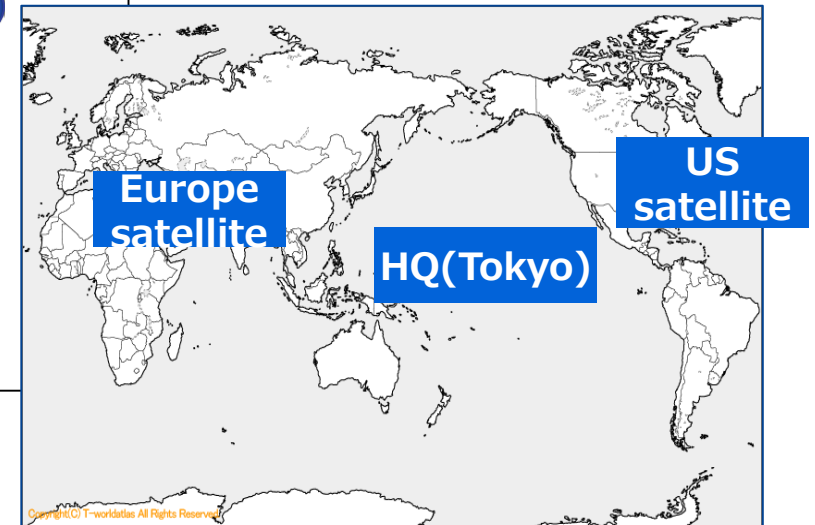
- **Risk management**

Evaluate potential risks by hazard analysis method and implement risk mitigation actions. Collaborate with HCPs to address potential risks and take actions for risk mitigation.



# Enhancement of Organization

## Enhancement of internal collaborative structure



**Executive Officer, Medical Reprocessing Strategy:  
Yoshio Tashiro**

**Enhancement of  
global team structure**

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# Summary

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- When developing, manufacturing or distributing medical devices, our first priority must be safety for patients and HCPs.
- The medical use of endoscopy is well established and continues to expand to better diagnose and treat patients. Drug-resistant bacteria are an emerging threat to patients. We are analyzing all reprocessing processes to address this issue.
- Need to review all processes including storage, transportation and others beyond “cleaning” or “disinfection” until a device is delivered to the next patient. All potential risk factors need to be reviewed and comprehensive solution must be considered.
- In order to secure safety of medical device, medical device manufactures will make a best effort to provide HCPs with safe and dependable devices. And then, they will collaborate with stakeholders like HCPs, government or medical societies together in order to enhance infection control programs.

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