

Clinical Survey on DEC™ Duodenoscope

**Attachment and removal of
disposable elevator cap and
distal end brush cleaning**

Objective of the Study

The objective of this survey study was to establish user confidence in the use of the attachment and the removal of the OE-A63 (DEC™) and distal end brush cleaning of the ED34-i10T2 (DEC™ Duodenoscope). In 2017, PENTAX Medical commissioned this clinical study to evaluate clinical perceptions of the new endoscope as they relate to patient safety, infection control, and user satisfaction.

Survey Methodology

Surveys were developed in collaboration with PENTAX Medical Global Clinical Affairs, Global and Regional Marketing, and Global Research and Development personnel, and were randomly administered to participants attending three major scientific conferences in three different continents (USA, Europe, and Australia) to provide a global sample population for the study. The survey respondent population was interprofessional by design and consisted of various healthcare professionals with the following job titles:

- Nursing Director
- Nurse Endoscopist
- Department Manager
- Endoscopy Technician/Reprocessing Technician
- Staff Nurse
- Clinical Nurse Specialist
- Research Nurse Coordinator

Because of the true diversity in the types of healthcare disciplines involved with handling, using, reprocessing, transporting, and using an endoscope, it was necessary to survey a wide variety of healthcare professionals that are directly involved in the reprocessing process. The innovative OE-A63 and ED34-i10T2 were specifically engineered to help clinicians achieve the Institute for Healthcare Improvement Triple Aim concept by improving overall population health, improving the patient experience, and

reducing healthcare delivery costs (see Figure 1). The Institute for Healthcare Improvement (IHI) Triple Aim is a framework that describes a unique approach to optimizing healthcare system performance, costs, and overall quality of care. IHI healthcare experts have demonstrated that innovative approaches to healthcare must take place simultaneously to most directly improve overall healthcare. These approaches include¹:

1. Improving the patient experience of care, which includes healthcare quality and patient satisfaction.
2. Improving the overall health of the population served.
3. Reducing the per capita cost of healthcare.

Figure 1:
Institute for Healthcare Improvement Triple Aim

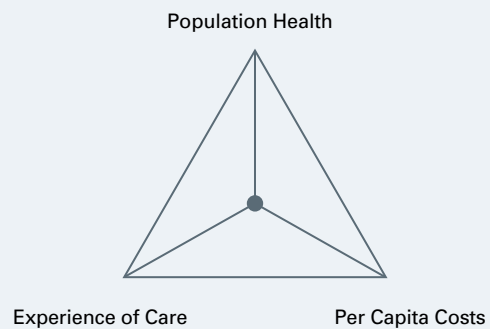
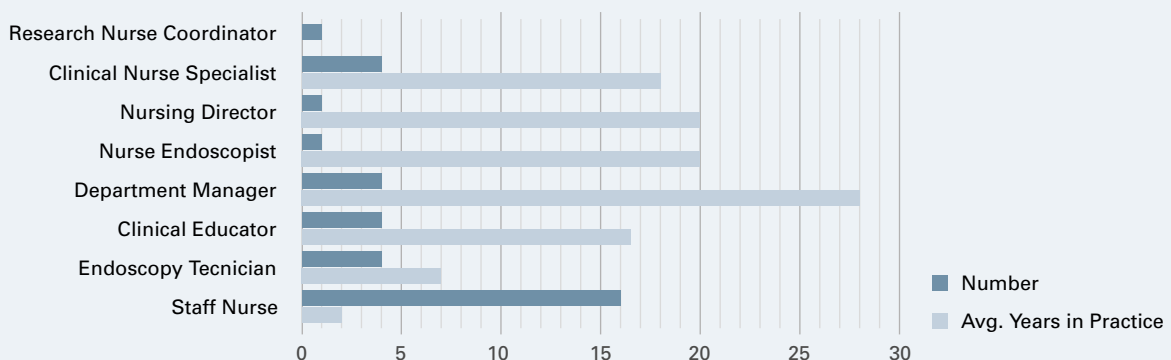
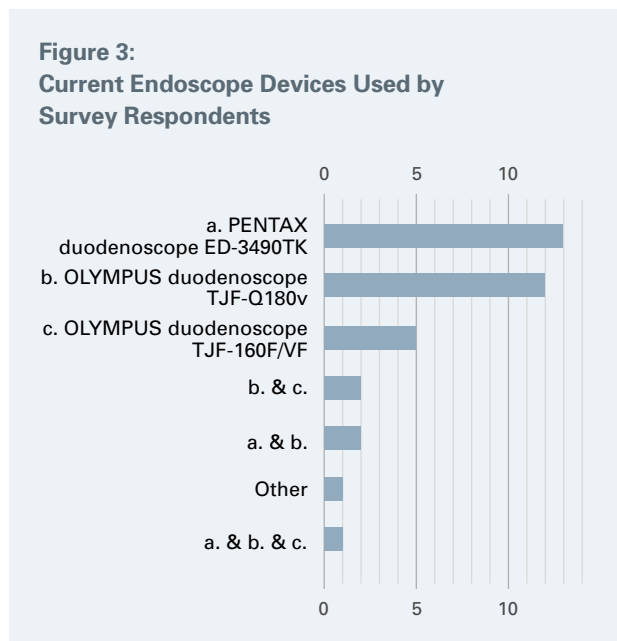


Figure 2: Demographics of Survey Respondents



¹Triple Aim for Populations, electronically accessed November 13, 2017 from Institute for Healthcare Improvement, www.ihl.org/tripleaim.

Survey respondents were asked to provide detail on the types of endoscopes that they currently used in their clinical practice within their institution. Figure 3 summarizes the type of endoscopes that were reported to be used in the survey by the respondents. Respondents came from the regions of the United States, Europe, and Australia to account for potential regional differences related to the clinical application of the device.



Additionally, the respondents practiced in a variety of healthcare delivery settings including Academic Medical Centers (23), Community Healthcare Settings (2), Government Facilities (7), and Outpatient/Ambulatory Facilities (3) representing a total of thirty-five (35) facilities.



The survey consisted of several direct questions, which included the following:

Please rate the “attachment” performance of the OE-A63. Do you find this better or worse than your current practice? Why?

- o Excellent Performance (26)
- o Good Performance (8)
- o Acceptable Performance (1)
- o Poor Performance (0)
- o Bad/Not acceptable Performance (0)

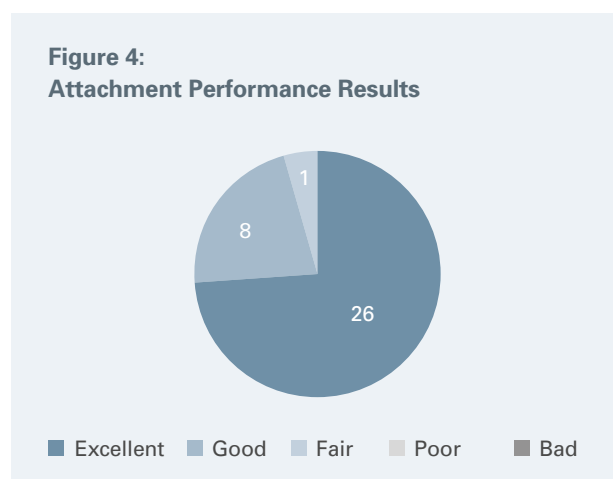
Please rate the “removal” performance of OE-A63. Do you find this better or worse than your current practice? Why?

- o Excellent Performance (28)
- o Good Performance (7)
- o Acceptable Performance (0)
- o Poor Performance (0)
- o Bad/Not acceptable Performance (0)

Please rate the brush cleaning of the distal end of the ED34-110T2. Do you find this better or worse than your current practice? Why?

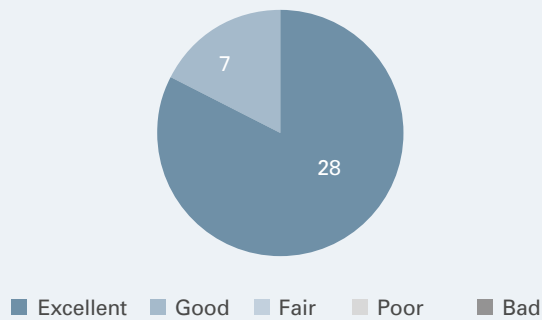
- o Easier than current practice (24)
- o Better than current practice (23)
- o Shorter (time) than current practice (10)

Results



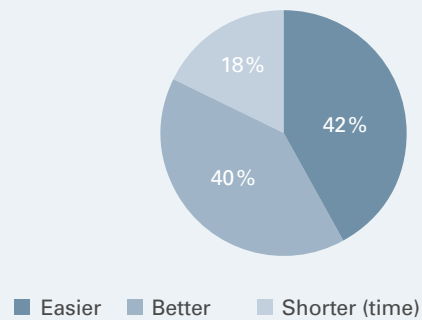
The majority of respondents (74%) found the attachment performance to be excellent compared to their currently utilized device. Additionally, 23% of respondents found the attachment performance to be good compared to their currently utilized device. A total of 97% of all survey respondents found the study device to be preferred for clinical use.

**Figure 5:
Removal Performance Results**



Most of the respondents (80%) found the removal performance to be excellent compared to their currently utilized device. Additionally, 20% of respondents found the attachment performance to be good compared to their currently utilized device. 100% of all survey respondents found the study device to be preferred for clinical use.

**Figure 6:
Brush Cleaning Results**



100% of all survey respondents rated brush cleaning of the distal end superior to their current practice. 42% felt the brush cleaning was easier, 40% assessed the brush cleaning to be better than their current practice and 18% felt the study brush required shorter time than their current practice.

Conclusions

Overall survey results from the interprofessional respondents were extremely positive, indicated a superior performance of the disposable distal end cap with integrated elevator, and improved cleaning abilities compared to current marketed technologies. This innovative technology allows for improved cleaning capabilities and compliance with established evidence-based practices for reprocessing and endoscope cleaning. This translates to critical reprocessing savings due to improved high reliability in the process, improved patient safety efforts, and associated reductions in potential cross-contamination of the distal cap by nature of the technology being single-patient use and disposable.

Additional References

- DEC™ Survey Results for SGNA, BSG, and AGW Meetings
- IHI Triple Aim www.ihio.org