

## Disposable tips decrease but do not eliminate duodenoscope contamination from high and low/moderate-concern organisms

### INTRODUCTION:

- The FDA advised endoscopy units to adopt duodenoscopes with disposable components to minimize the risk of duodenoscope-associated infections
- We hypothesized that disposable tips will not eliminate high-risk bacterial contamination, which could be clinically significant

### STUDY DESIGN:

- Prospective Observational Study of 46 Pentax duodenoscopes with disposable tips (Oct 2021-Mar 2022)

### METHODS:

- 2 time points for culture on each duodenoscope: after one manual wash (MW) and high-level disinfection (HLD), as well as after 2 MW and 2 HLD
- Samples were collected from 4 sites on the duodenoscope tip at each time point (Figure 1)
- Samples were plated on routine medias for enteric pathogens including *Clostridium difficile* and *Enterococcus spp.*; antibiotic resistance assessed via PCR for Vancomycin-resistant *Enterococcus* (VRE)
- Observed percentages and estimated 95% Confidence intervals (CI) are reported for bacterial growth type (high, low concern) between sample time points

### RESULTS:

- 46 Duodenoscopes were sampled at 4 sites resulting in 184 sample events at each of 2 time points (a total of 368 sample events)
- After one MW-HLD cycle, 8 of 184 site samples (8 unique duodenoscopes) remained contaminated with >100 CFU low/moderate-concern organisms, 2 of which also grew VSE
- 11 of 184 sites (8 unique duodenoscopes) were contaminated with *Enterococcus spp.* (5 +VRE and 6 +VSE sites) after one MW-HLD cycle
- After the second MW+HLD cycle, 5 sites (5 unique duodenoscopes) remained contaminated with >100 CFU low/moderate-concern organisms
- 2 sites (1 unique duodenoscope) remained contaminated with *Enterococcus spp.* (2 +VSE sites)

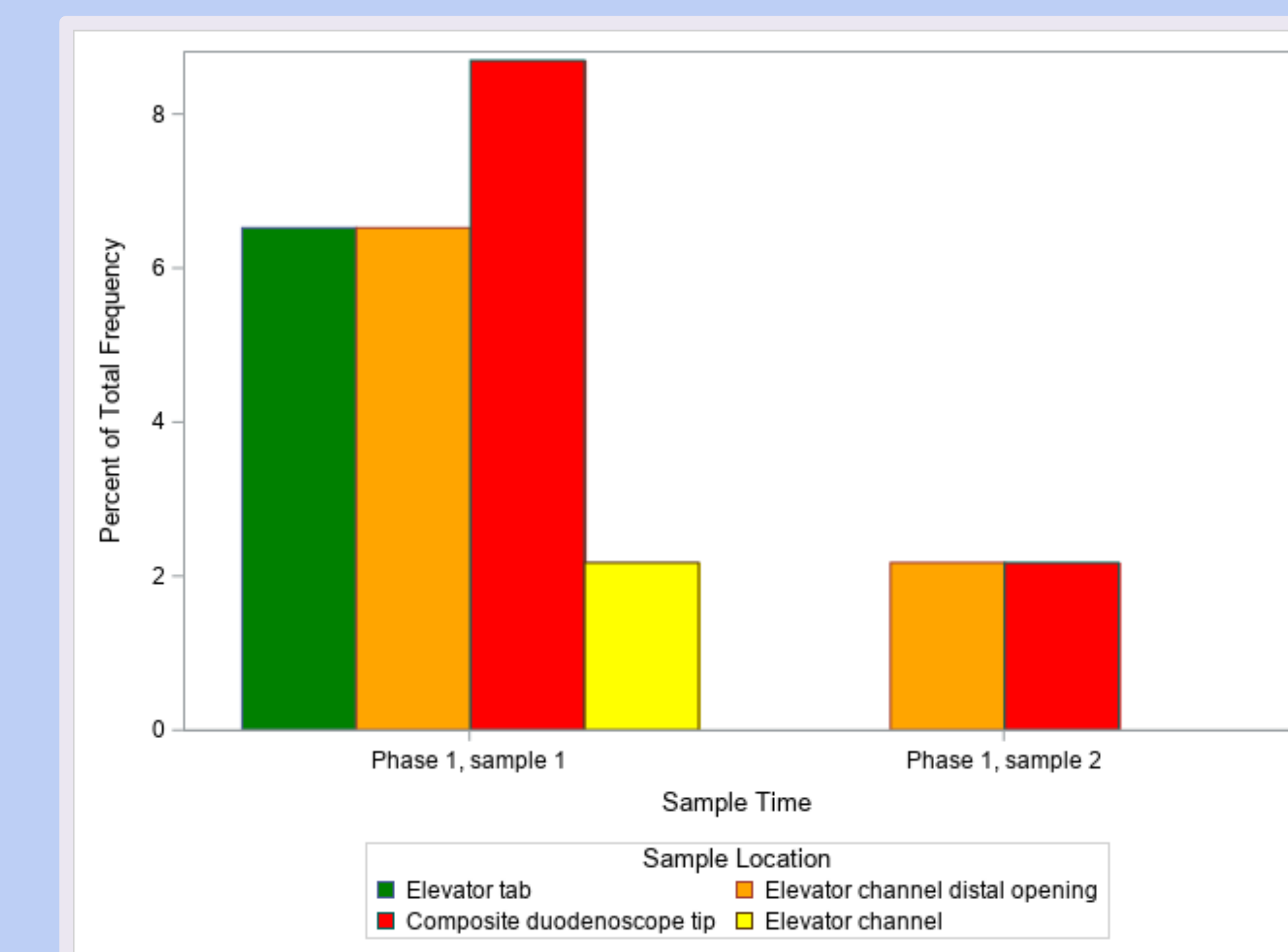
**Table 1:** Comparison of observed rates at each time point compared to FDA surveillance data of Pentax duodenoscopes

Outcome	Contamination Rate after 1 MW + HLD (95% CI) (N=184)	Contamination Rate after 2 MW + HLD (95% CI) (N=184)	Historical Rate <sup>1</sup>
Total <b>low/moderate-concern</b> organism >100 CFU presence	8 (4.3%) (1.9%, 8.4%)	5 (2.7%) (0.9%, 6.2%)	8.2%
Total <b>high-concern</b> organism ( <i>Enterococcus</i> & <i>C difficile</i> ) >1 CFU presence	11 (6.0%) (3.0%, 10.4%)	2 (1.1%) (0.1%, 3.9%)	6.0%



**Figure 1.** Sample locations:  
 1) The elevator tab  
 2) instrument channel distal opening  
 3) composite duodenoscope tip  
 4) the instrument channel

**Graph 1:** Percentage of samples with >1 CFU VSE/VRE by site and sample time



### CONCLUSION:

- After complete reprocessing, low/moderate and high concern bacteria remained on the duodenoscope despite the disposable tip
- Bacteria remained on the distal opening of the instrument channel and duodenoscope tip, but not on the elevator tab or in the instrument channel
- Compared to historical FDA data from reusable duodenoscopes, bacterial contamination of duodenoscopes with disposable tips was lower, and the confidence intervals excluded historical rates

<sup>1</sup> Bacterial pathogenicity is classified by the FDA<sup>1</sup> as high-concern (any CFU) and low/moderate-concern organisms (>100 CFU)