Endoscope Case Study

"In early 2014, following a superbug outbreak at a hospital in Illinois, the FDA asked Fujifilm Holdings Corp, Olympus Corp and Pentax, which make the [endoscope] devices, to submit their test results for review…. In some cases the tests were poorly carried out. In others, they were properly conducted but the cleaning and disinfecting protocol failed,"
Dr. Stephen Ostroff, FDA chief scientist[1]

There have been several recent outbreaks of multidrug resistant bacteria (superbug) infections from contaminated duodenoscopes, which are cleaned/disinfected then reused on patients. A few cases have resulted in death of the patients. Prior to the 2014 FDA request, manufacturers were not required to submit the data from their validation testing of the cleaning protocols for their duodenoscopes during the 510k process.

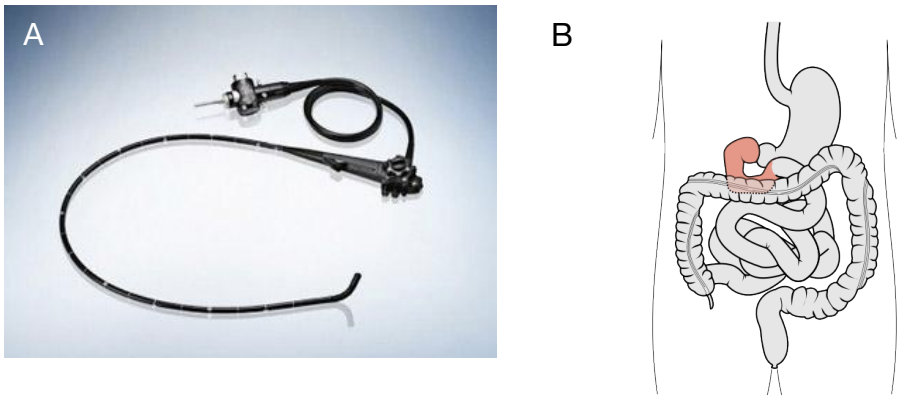

Figure 1: (A) Olympus TJF-Q180V duodenoscope [2] (B) Schematic of the gastrointestinal tract with duodenum highlighted [3]

March 4, 2015 Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning: FDA Safety Communication:

"The FDA wants to raise awareness among health care professionals, including those working in reprocessing units in health care facilities, that the complex design of ERCP endoscopes (also called duodenoscopes) may impede effective reprocessing. Reprocessing is a detailed, multistep process to clean and disinfect or sterilize reusable devices. Recent medical publications and adverse event reports associate multidrug-resistant bacterial infections in patients who have undergone ERCP with reprocessed duodenoscopes, even when manufacturer reprocessing instructions are followed correctly. Meticulously cleaning duodenoscopes prior to high-level disinfection should reduce the risk of transmitting infection, but may not entirely eliminate it."

1 http://www.reuters.com/article/2015/03/02/usa-superbug-fda-idUSL1N0W40PY20150302
2 http://medical.olympusamerica.com/products/duodenoscope/evis-exera-ii-tjf-q180v
3 "Tractus intestinalis duodenum" by Olek Remesz

Summary of Problem and Scope:

More than 500,000 ERCP procedures using duodenoscopes are performed in the United States annually. The procedure is the least invasive way of draining fluids from pancreatic and biliary ducts blocked by cancerous tumors, gallstones, or other conditions. Duodenoscopes are flexible, lighted tubes that are threaded through the mouth, throat, stomach, and into the top of the small intestine (the duodenum). They contain a hollow channel that allows the injection of contrast dye or the insertion of other instruments to obtain tissue samples for biopsy or treat certain abnormalities. Unlike most other endoscopes, duodenoscopes also have a movable "elevator" mechanism at the tip. The elevator mechanism changes the angle of the accessory exiting the accessory channel, which allows the instrument to access the ducts to treat problems with fluid drainage.

Although the complex design of duodenoscopes improves the efficiency and effectiveness of ERCP, it causes challenges for cleaning and high-level disinfection. Some parts of the scopes may be extremely difficult to access and effective cleaning of all areas of the duodenoscope may not be possible."

Figure 2: Close-up view of an ERCP endoscope tip[4]

Fun Fact: The Olympus device in Figure 1A has been on the market since 2010 but was not cleared by the FDA until January 2016. The device was not initially recalled for fear of a shortage of devices.[5]

Sterilization vs disinfection[6]:

Sterilization: A process to eliminate "100%" of all microbial organisms. Examples: high heat or steam pressure treatment; Ethylene oxide gas treatment – EtO is a known carcinogen and toxic by inhalation, and is also highly flammable and explosive!

Disinfection: A process to eliminate most or all pathogenic microorganisms, except bacterial spores. Example: ortho-phthalaldehyde is high level disinfectant used for medical devices that come in contact with mucous membranes

4 FDA Safety Communication, March 4, 2015
5 http://www.cnn.com/2015/03/04/us/superbug-endoscope-no-permission/index.html
6 http://www.cdc.gov/hicpac/Disinfection_Sterilization/1_sumIntroMethTerms.html

Questions:

1. What steps, if any, should the FDA make to mitigate further outbreaks of multidrug resistant microbes?

2. From an engineering design perspective, how can we mitigate the risk of infection from microorganisms?