

Endoscopes and Infection

Bioengineering 100

Fall 2016

Chicago Tribune

Superbug found at suburban hospital

Lutheran General, health officials taking steps to prevent spread of CRE

January 10, 2014 | By Robert McCoppin and Cynthia Dizikes, Tribune reporters

- 38 patients tested positive out of 114 tested; 243 had endoscope procedure over 9 months

Los Angeles Times

Superbug linked to 2 deaths at UCLA hospital; 179 potentially exposed

- February 2015

The Seattle Times

More ‘superbug’ cases linked at Virginia Mason

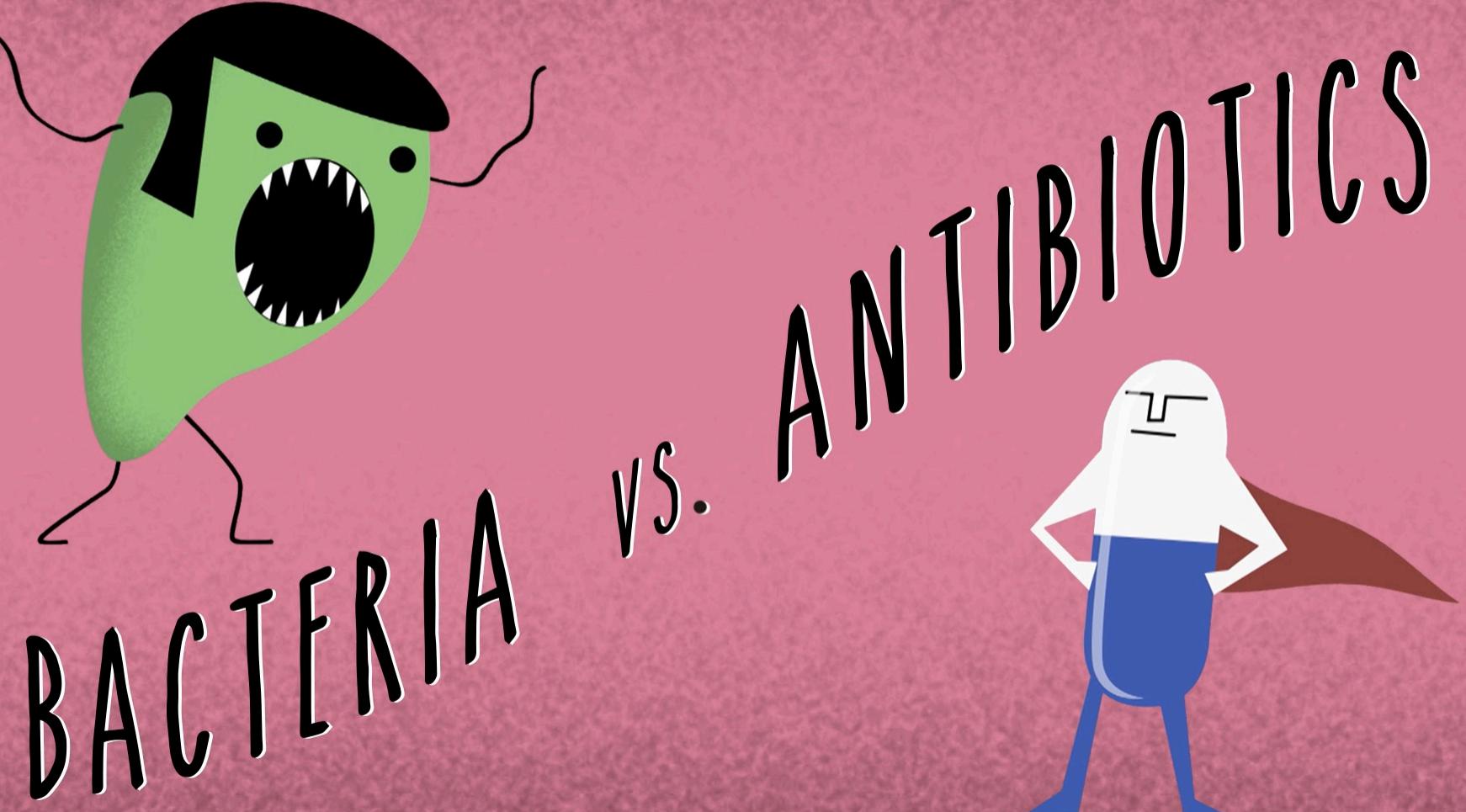
Originally published April 28, 2015 at 9:20 pm | Updated April 30, 2015 at 8:36 am

At least 39 people are included in an outbreak of multidrug-resistant infections spread by contaminated medical scopes at Virginia Mason. But health officials say the hospital has successfully halted the outbreak.

What is an infection?

‘Superbug’ infections are a serious
problem.

Agree or Disagree?

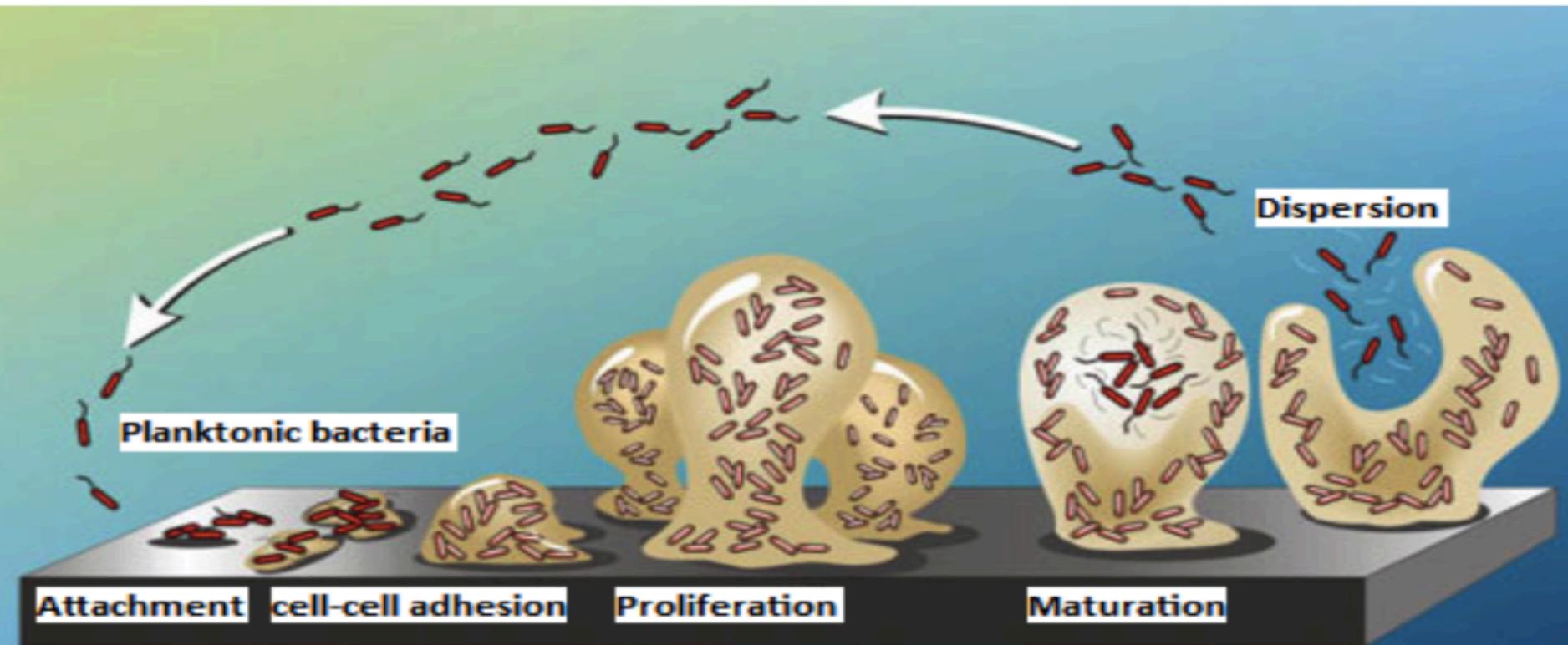


Hospital Acquired Infections

1 in 25 patients has at least one hospital acquired infection.

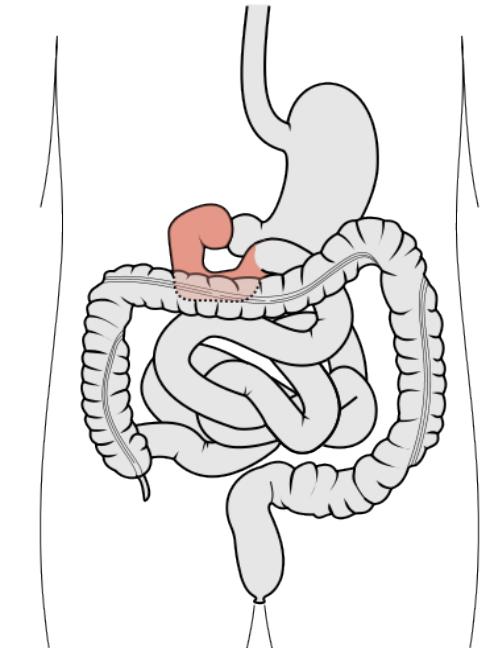
HAI Estimates Occurring in US Acute Care Hospitals, 2011	
Major Site of Infection	Estimated No.
Pneumonia	157,500
Gastrointestinal Illness	123,100
Urinary Tract Infections	93,300
Primary Bloodstream Infections	71,900
Surgical site infections from any inpatient surgery	157,500
Other types of infections	118,500
Estimated total number of infections in hospitals	721,800

What about microbe & material interactions? Biofilm considerations

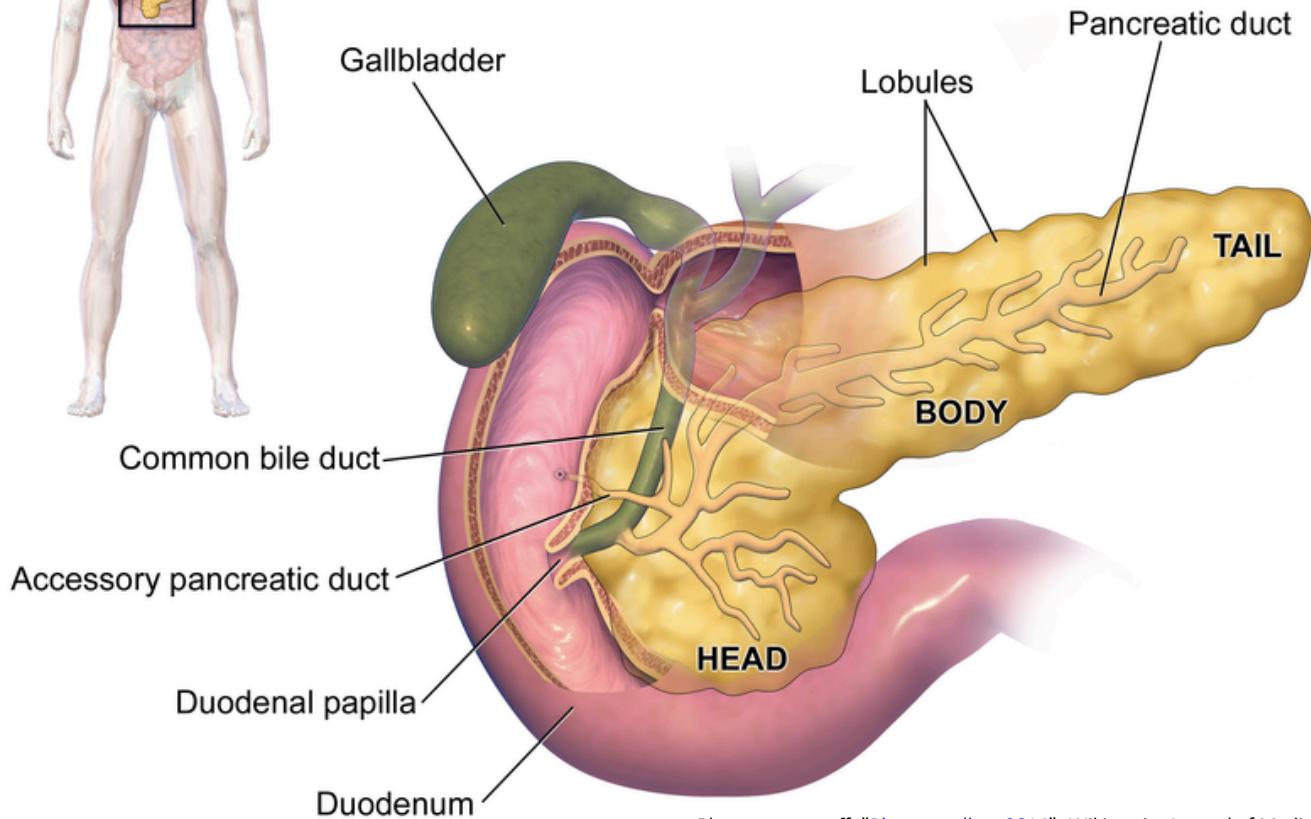
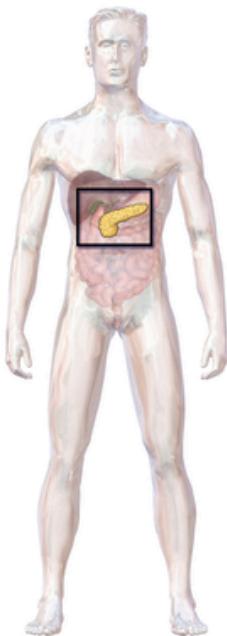


Endoscopic Retrograde Cholangiopancreatography (ERCP) endoscopes/ Duodenoscopes

- 500,000 procedures/year
- Treats pancreas/bile duct problems
 - Stretch out narrow segments
 - Remove/crush gallstones
 - Diagnose conditions
 - Take tissue samples of pancreas, bile ducts, gall bladder
 - Drain blocked areas



More outbreaks linked to contaminated endoscopes than any other device

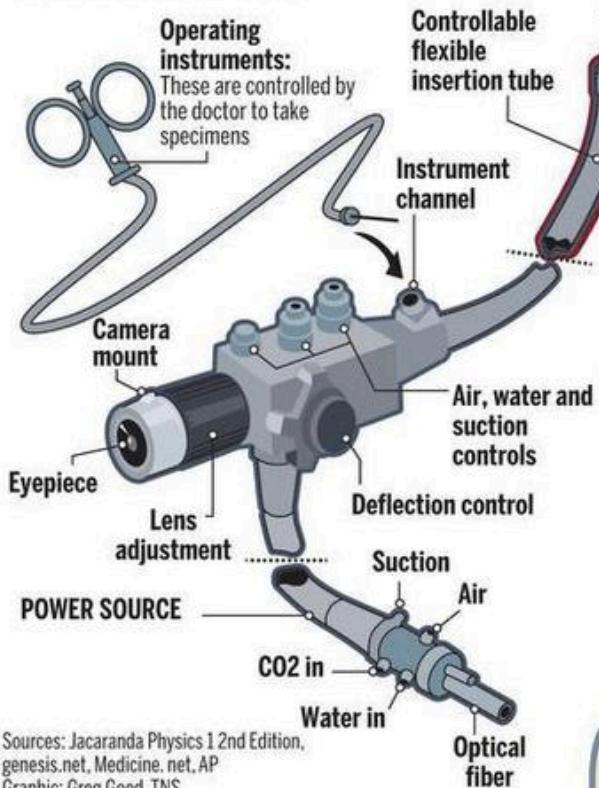




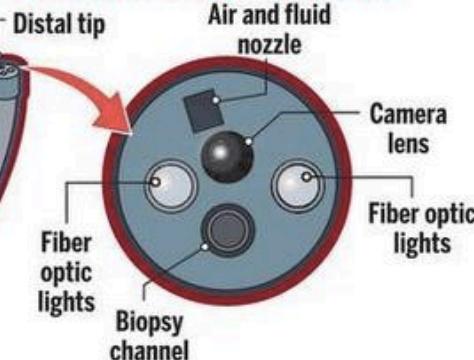
Superbug source

At least seven people, two of whom died, have been infected with a potentially lethal, antibiotic-resistant strain of bacteria known as carbapenem-resistant Enterobacteriaceae, or CRE, after undergoing procedures using an endoscope. The infections may have been transmitted through contaminated endoscopes even though they had been cleaned and sterilized.

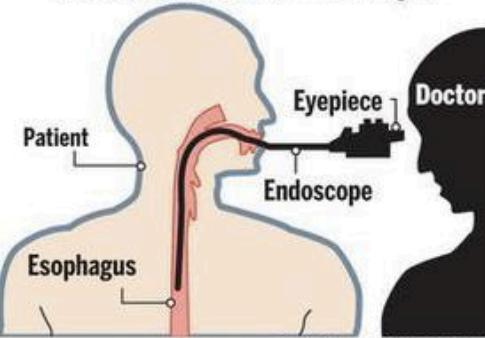
PARTS OF AN ENDOSCOPE



POSSIBLE SOURCE OF INFECTIONS



An endoscope is a thin, flexible fiber optic tube that is inserted down the throat to enable a doctor to examine an organ.



Sources: Jacaranda Physics 1 2nd Edition, genesis.net, Medicine.net, AP
Graphic: Greg Good, TNS

TRIBUNE NEWS SERVICE

Sterilization vs High-level Disinfection

- 100% free of ALL microorganisms
- Common Methods:
 - steam under high pressure
 - Dry heat
 - Ethylene Oxide gas
 - Hydrogen peroxide gas plasma
 - Liquid chemicals
- Eliminate many microorganisms except bacterial spores
- Common Methods:
 - Liquid chemicals
 - Wet pasteurization

Figure 1. Decreasing order of resistance of microorganisms to disinfection and sterilization and the level of disinfection or sterilization.

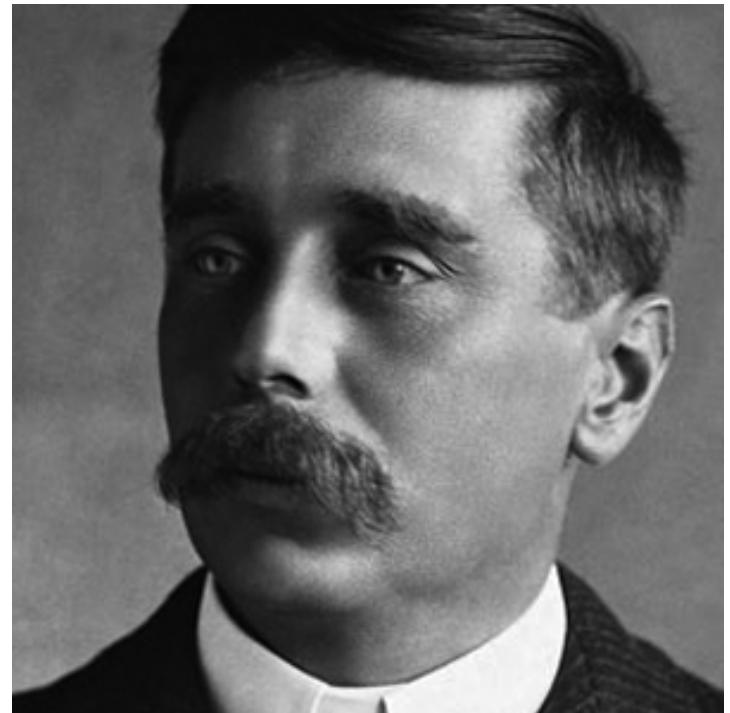
Resistant	Level
Prions (Creutzfeldt-Jakob Disease)	Prion reprocessing
Bacterial spores (<i>Bacillus atrophaeus</i>)	Sterilization
Coccidia (<i>Cryptosporidium</i>)	
Mycobacteria (<i>M. tuberculosis</i> , <i>M. terrae</i>)	High
Nonlipid or small viruses (polio, coxsackie)	Intermediate
Fungi (<i>Aspergillus</i> , <i>Candida</i>)	
Vegetative bacteria (<i>S. aureus</i> , <i>P. aeruginosa</i>)	Low
↓ Lipid or medium-sized viruses (HIV, herpes, hepatitis B)	

Susceptible

Modified from Russell and Favero^{13, 344}.

A rational approach: Spaulding Classification

Classification	Contact	Requirements
Critical	Sterile body cavity	Sterilization
Semi-critical	Mucous membranes	High level disinfection
Non-critical	Intact skin	Low level disinfection



Endoscope Disinfection Protocol:

- 1. **Clean**: mechanical clean internal/external surfaces
- 2. **Disinfect**: immerse endoscope in high level disinfectant and perfuse into all accessible channels
- 3. **Rinse**: rinse all channels with sterile/filtered water
- 4. **Dry**: rinse all channels with alcohol and dry with forced air
- 5. **Store**: store endoscope in a way that prevents recontamination and promotes drying

Factors to consider:

- Number/location of micororganisms
- Innate resistance of microorganisms to germicides/ sterilization processes
- Concentration/potency of disinfectants
- Physical/Chemical factors (temperature, pH, humidity, water hardness)
- Organic/inorganic matter
- Duration of exposure
- Biofilms

Automated Endoscope Reprocessors (AER) (ie. The most expensive dishwasher you've ever seen)

- Automate/standardize important reprocessing steps
- Reduce likelihood steps will be skipped
- Reduces personnel exposure to disinfectants



>2% Glutaraldehyde

- High level disinfectant/chemical sterilant
- Mode of action: alkylation of sulphhydryl, hydroxyl, carboxyl, and amino groups of microorganisms, which alters RNA, DNA, and protein synthesis
- Noncorrosive to metal
- Does not damage lenses, plastics, rubber
- Colitis from residuals
- Dermatitis, mucous membrane irritation, pulmonary symptoms

Ethylene Oxide

- Good for heat sensitive/
moisture sensitive
devices
- 2.5 hour sterilization
cycle plus 8-12 hour
aeration time
- Known carcinogen
- Toxic by inhalation
- Highly flammable
- Explosive

*Shown to have failed in inactivating spores in endoscope channels;
average 62ppm residual EtO after standard degassing time*

Olympus TJF-Q180V

On market since 2010; 510k filed October 2014



Elevator

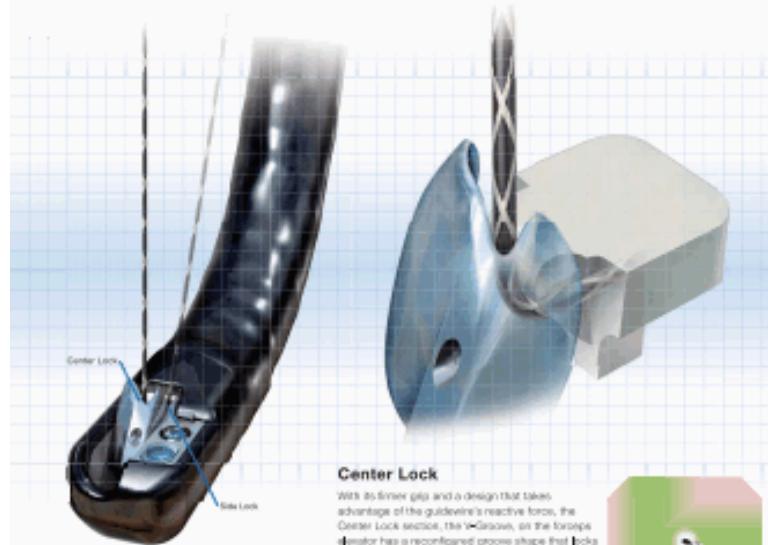
Lowered/
closed



Raised/
open



Setting a New Standard for Ease of Use, Security, and Flexibility, the Unique Dual Locking Mechanism Supports Enhanced ERCP Efficiency



Center Lock

With its firmer grip and a design that takes advantage of the guidewire's reactive force, the Center Lock section, the **Valvoleo**, on the forceps elevator has a reconfigured groove shape that locks the guidewire more securely than ever.

When the papilla is in the green area as shown in the figure on the right, the Center Lock will be used.

Dual Locking Mechanism Securely Locks 0.025" and 0.035" Guidewires

Completely redesigned to ensure greater reliability and flexibility, the TJF-Q180V's dual locking mechanism is optimized to equal the reactive force of the guidewire. The forceps elevator has been modified to broaden the range of scope positions in which the

guidewire can be securely locked. Thanks to the firmer grip of the new dual locking mechanism, a 0.035-inch guidewire can now be locked in addition to a 0.025-inch guidewire in either a Center or Side Lock orientation.



Side Lock

A new Side Lock section has been added to the side of the forceps elevator to increase guidewire locking flexibility. It physically fixes the guidewire even when it is positioned to the side of the forceps elevator.

When the papilla is in the blue area as shown in the figure on the right, the Side Lock will be used.

■ indicates area to grasp. ■ The non-grasp area is not secured by these locks.

Excellent Image Quality

The TJF-Q180V incorporates a high-resolution CCD that delivers the sharp, clear images Olympus is known for, displaying them in a large screen size for easy viewing. Advanced Narrow Band Imaging™ capability is also supported with this scope.



Easier Cleaning (Unique Fixed Distal End Design)

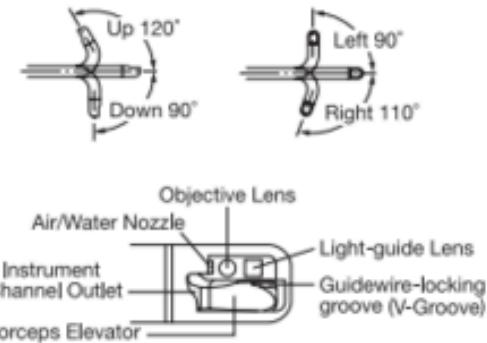
In addition to the clinical performance benefits of the TJF-Q180V's locking mechanism, the elevator wire channel port is now sealed so separate cleaning is no longer necessary. The result is faster, easier cleaning that makes scope reprocessing more efficient.



Olympus Q180V Specs (2010)

Specifications

Optical System	Field of view	100°
	Direction of view	Backward side viewing 5°
	Depth of field	5 to 60 mm
Distal End	Outer diameter	13.7 mm
Insertion Tube	Outer diameter	11.3 mm
Bending Section	Range of distal end bending	Up 120°, Down 90°, Right 110°, Left 90°
Working Length		1,240 mm
Total Length		1,550 mm
Instrument Channel	Inner diameter	4.2 mm
	Minimum visible distance	10 mm
	Endotherapy accessory entrance/exit position in field of view	



The endoscopes implicated in the
'superbug' outbreaks should not be
recalled because it would result in a
device shortage.

Agree or disagree?

Stakeholder Discussion

- FDA: Groups 1, 5, 9
- CDC: Groups 2, 6, 10
- Hospitals: Groups 3, 7, J
- Manufacturer: Groups 4, 8, Q

Apply the 4 A's:

*what are the possible actions your
stakeholder could take?*

Mixed Group Discussion

- As a team, develop some potential short and long term goals

What is your short term (within 30 days) plan?

What is your long term (6 months+) plan?

The endoscopes implicated in the
'superbug' outbreaks should not be
recalled because it would result in a
device shortage.

Agree or disagree?

FDA clears Olympus TJF-Q180V duodenoscope with design modifications intended to reduce infection risk

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For Immediate
Release

January 15, 2016

- On market since 2010
- 510k filed October 2014

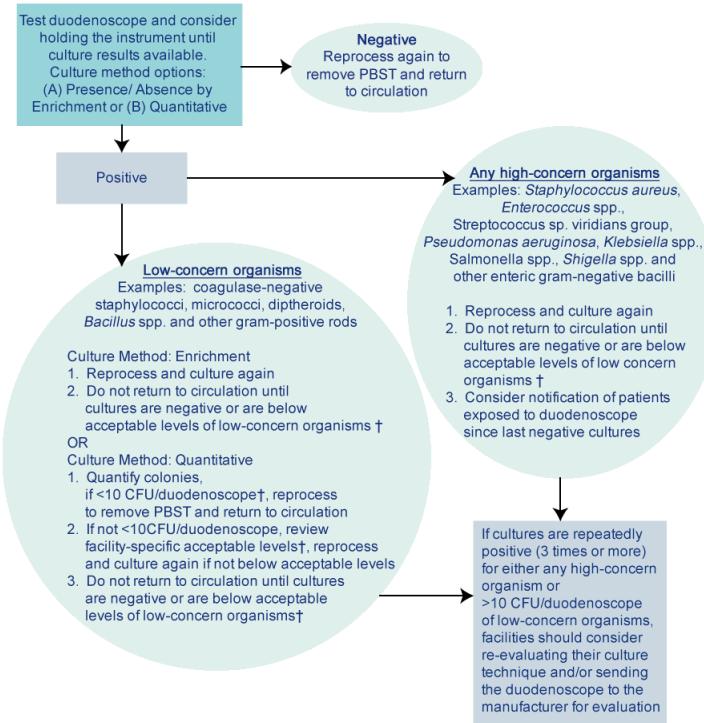


Olympus TJF-Q180V

- February 2016: began replacing elevator mechanism on existing models
- “The forceps elevator replacement will result in minor changes to the dimensional tolerance of the forceps elevator mechanism and O-ring. These changes will not be apparent through visual inspection.”
- New reprocessing protocol



CDC Interim Duodenoscope Surveillance Protocol



† The levels of low-concern organisms on a duodenoscope may vary depending on the reprocessing, handling, and culturing practices in a facility. Therefore, the acceptable level of these organisms can vary. Facilities can monitor the levels of low-concern organisms during the first month of surveillance testing to develop an appropriate baseline for those organisms. Typically, fewer than 10 CFU of these microbes does not require intervention; interpretation of culture results with ≥ 10 CFU of non-pathogenic microbes should be considered in the context of expected culture results at the facility

Definitions

Negative – A liquid enriched culture is not turbid

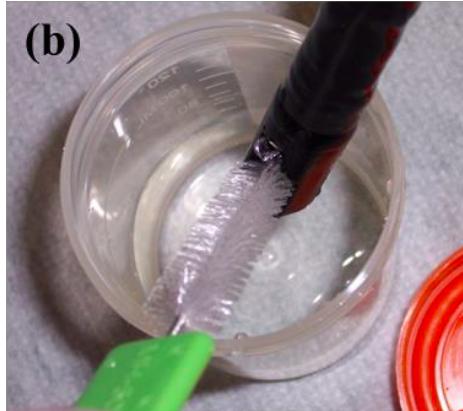
Positive – A liquid enriched culture is turbid

CFU – colony forming units

PBST – Phosphate buffered saline with Tween®-80 solution

Sampling Method

- Elevator/Channel:
 - Brush distal end
- Channel:
 - Flush with sterile water



Culture Method



Blood agar: hemolytic activity

