Medical Xpress

FDA approves redesign of endoscope tied to infections

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(HealthDay)—A redesigned Olympus TJF-Q180V duodenoscope (a type of endoscope) that has a reduced chance of spreading infection has been approved by the U.S. Food and Drug Administration.

According to an FDA news release, Olympus is voluntarily recalling the older version of the duodenoscope, an instrument used to drain fluid from blocked pancreatic and biliary ducts without the need for more invasive surgery. These ducts could be blocked by cancerous tumors, gallstones or other gastrointestinal conditions, the agency said.

Duodenoscopes are used in more than a half-million procedures each year. The Olympus device was redesigned because "there is evidence that some have been associated with the transmission of infectious agents, including antibiotic-resistant infections," the FDA said.

The device's "elevator channel sealing mechanism" was modified to "create a tighter seal and reduce the potential for leakage of patient fluids and tissue" into the device, the agency said.

Olympus is recalling the original TJF-Q180V to replace the elevator channel sealing mechanism at the top of the scope, a 4-day process Olympus says should be done throughout the United States by August 2016. Until each scope is modified, health care facilities may continue to use the scope, but should carefully follow the maker's instructions, the FDA said.

Olympus also will perform an annual inspection on each scope to identify any erosion of the elevator channel and replace potentially contaminated parts, the agency said.

More information: The FDA has more about this action.

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