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FDA lays out extra steps to clean scopes linked to outbreaks (Update)

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Federal health officials laid out extra safety measures that hospitals can take to clean specialized medical scopes that have been linked to sometimes deadly bacterial outbreaks across the U.S.

However, Food and Drug Administration officials acknowledged on Tuesday that not all hospitals have the staff, expertise and resources to take the steps, including sterilizing scopes with toxic gas to kill bacteria. Even with such steps "the risk of infection transmission cannot be completely eliminated," the FDA said in an online statement

Despite the risks of infection, the FDA says the devices should remain available because they benefit "appropriately selected patients."

Known as duodenoscopes, the scopes consist of a flexible tube and specialized tip that surgeons guide into the digestive tract to diagnose and treat blockages of the bile and pancreatic ducts. They are used in an estimated half-million procedures per year.

The FDA came under heavy criticism earlier this year for its oversight of the hard-to-clean devices after two Los Angeles hospitals reported patients infected with antibiotic-resistant bacteria, or "superbugs," despite following manufacturers' cleaning instructions. According to government figures, there have been eight outbreaks of antibiotic-resistant bacteria linked to the devices at U.S. hospitals since 2013.

Duodenoscopes' complex design—intended to help physicians drain

fluids from the body—also makes the instruments extremely difficult to clean. Bodily fluids and other particles can stay in the device's crevices even after cleaning and disinfection.

In May, the agency assembled a panel of outside experts to make recommendations for improving the cleaning and design of the instruments. Tuesday's recommendations reflect the suggestions of those experts and internal FDA staff.

Currently most scopes are cleaned manually by hospital staff or automated machines designed to disinfect the instruments. In addition to these steps, the FDA says hospitals should consider:

— performing bacterial testing on scopes that have been cleaned to make sure they are bacteria-free

— sterilizing scopes with ethylene oxide gas to kill all bacteria

— using additional sterilizing chemicals to kill bacteria

— cleaning scopes multiple times using standard manual or machine-assisted techniques

All of these steps come with additional costs and potential drawbacks. For instance, testing scopes for bacteria requires hospitals to purchase additional scopes that can be cycled in and out of use. One duodenoscope can cost about $40,000.

The agency also notes that ethylene oxide gas can be dangerous for hospital staff and patients, if residue of the toxic gas stays on the scopes after sterilization.

FDA critics, including several members of Congress, have suggested that

the instruments should be redesigned to reduce risks of infection. The agency has previously said it cannot require manufacturers to redesign their products. But in its release Tuesday, the agency laid out several design changes that could reduce risks of contamination, including using disposable components for hard-to-clean areas.

"The FDA is currently working with manufacturers as they explore design innovations incorporating these features," the agency said.