

Product Bulletin

For Distribution To:

- International Distributors
- International Management
- U.S. Field Sales & Clinical Specialists
- U.S. Technical & Field Service

Date: February 20, 2015

RE: CRE-ERCP Statement

This bulletin has been written in response to the information recently released by the FDA and certain endoscope manufacturers pertaining to the potential transmission of CRE through endoscopes fitted with exposed elevator wire channels and bridge mechanisms (duodenoscopes, specialist gastroscopes and certain ultrasound endoscopes).

MEDIVATORS family of high-level disinfectants is completely effective against CRE, VRE, MRSA and other antibiotic-resistant organisms. Antibiotic-resistance does not mean disinfectant resistant. However, more complicated cleaning requirements for these types of endoscopes prior to disinfection can lead to higher risk of disease transmission if instructions are not meticulously followed.

The duodenoscope fitted with an exposed elevator wire channel and associated with ERCP is the combination of the worst challenges of reprocessing, and crosses almost all of the boundaries referenced by the Spaulding classification. Flexible GI endoscopes (including duodenoscopes) are classified as semi-critical devices that require high-level disinfection as the standard of decontamination. The exposed elevator wire channel presents one of the most challenging aspects of reprocessing this type of endoscope, as it cannot be dismantled; brushed or accessed in any way to visually ensure that it has been meticulously cleaned. The only method of cleaning is by flushing with a syringe.

ERCP by its very nature typically crosses the critical device boundary by producing a wound associated with the insertion of stents and/or the use of sphincterotomes or some other therapeutic intervention.

The termination of the elevator wire channel at the distal end of the endoscope is in very close proximity to the open end of the biopsy channel, with the result that debris from an improperly cleaned elevator wire channel, which is loosened by the action of the elevator lever can fall into the path of an accessory exiting the biopsy channel. This contamination is then introduced directly into the common bile duct.

It is imperative that the elevator wire channel is meticulously cleaned and staff associated with reprocessing these types of endoscopes should receive additional training with respect to this channel. CRE in itself is no more of a challenge than any other organism found in GI endoscopy, which is ironic as this infection control issue and ERCP³ related infection has been around since elevator wire channels were first introduced.

It is vitally important that facilities understand the history of their duodenoscopes as poor manual cleaning in the past can certainly influence successful high-level disinfection outcomes today. ETO or other methods of sterilization of these endoscopes can give a false sense of security as the same manual cleaning challenges apply equally to high-level disinfection as well as sterilization^{1,2}.

If you have questions related to this topic, please do not hesitate to contact MEDIVATORS Technical Support at 1-800-444-4729.

References

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

- 1 William A. Rutala, Ph.D., M.P.H.
Hospital Epidemiology
University of North Carolina Health Care System
Chapel Hill, NC 27514
- 2 David J. Weber, M.D., M.P.H.
Division of Infectious Diseases
University of North Carolina School of Medicine
Chapel Hill, NC 27599-7030
- 3 Banerjee S, Shen B, Baron TH, et al. Antibiotic prophylaxis for GI endoscopy.
Gastrointest Endosc. May 2008;67(6):791-8.

MEDIVATORS® is a registered trademark of Medivators Inc.



Medivators Inc.
14605 28th Avenue North
Minneapolis, MN
55447-4822 USA
Tel: +1.800.444.4729
Fax: +763.553.3387

Medivators BV
Sourethweg 11
6422PC Heerlen
The Netherlands
Tel: +31.45.5.471.471
Fax: +31.45.5.429.595

Cantel Medical Asia/Pacific Pte. Ltd.
1 A International Business Park
#05-01 Singapore 609933
Tel: +65.6227.9698
Fax: +65.6225.6848

Medivators Inc. Beijing Representative Office
Room 1801, Floor 18th, Tower A,
Beijing Marriott Hotel, Office Building
No. 7, Jianguomen South Avenue,
Dongcheng District, Beijing 100005 China
Tel: +86 10 65204039

www.medivators.com