

Nuevos Retos en el Reprocesamiento de Endoscopios

Carlos Lozano-Clinical Specialist

Jornada COIB 2017

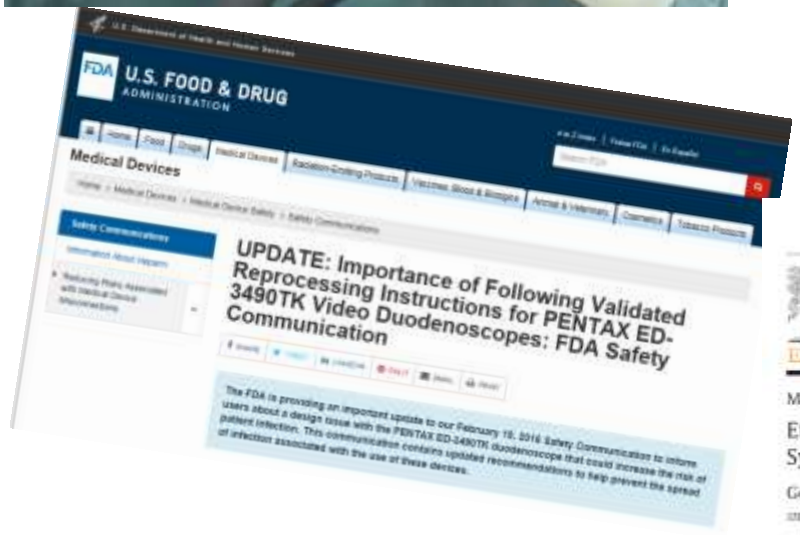
Las IRAS en la endoscopia flexible

4. Inadecuate Reprocessing of Endoscope and Surgical Instruments.

1. Inadecuate Cleaning of Flexible Endoscopes before Disinfection Can Spread Deadly Pathogens.

2. Inadecuate Cleaning of Complex Reusable Instruments Can Lead to Infections.

Contexto actual de las IRAS



FDA Orders Duodenoscope Manufacturers to Conduct Postmarket Surveillance Studies... Página 1 de 2

FDA Orders Duodenoscope Manufacturers to Conduct Postmarket Surveillance Studies in Facilities

The Food and Drug Administration (FDA) today ordered the three manufacturers of duodenoscopes marketed in the U.S. to conduct postmarket surveillance studies to better understand how the devices are reprocessed in real-world settings.

"This is a significant step in the effort to combat infections spread through duodenoscopes. The FDA has undertaken an in-depth investigation into the factors that may play a role in infection transmission associated with duodenoscopes, and is now requiring manufacturers to study the devices in the clinical setting where they are being used," says William Maisel, MD, MPH, deputy director for science and chief scientist at the FDA's Center for Devices and Radiological Health. "These studies will provide critical information about the effectiveness of current reprocessing instructions and practices that may provide additional information to inform the FDA's actions to protect the public health and help reduce the risk of infections."

The three manufacturers – Olympus America, Inc., Fujifilm Medical Systems, U.S.A., Inc., and Hoya Corp. (Pentax Life Care Division) – that market duodenoscopes sold in the U.S will have 30 days to submit surveillance plans to the FDA. These proposals must detail their plans to conduct studies to

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Major article

Effectiveness of the SYSTEM 1E Liquid Chemical Sterilant Processing System for reprocessing duodenoscopes

Gerald McDonnell PhD, Michele Ehrman BS *, Sara Kiess BS

STERIS Corporation, Mentor, OH

STERIS

Enterobacterias productoras de carbapenemasas

ICT | INFECTION CONTROL TODAY

> At least two strategies have been proposed to mitigate the risk of transmission of CRE and other
>
> routine sterilization
>
> HLD of endoscopes between patients:
>
> culturing endoscopes for CRE
>
> to ensure safety prior to use.

Contexto actual de las IRAS

AAMI
Celebrating Fifty Years of Building Tomorrows

Study Shows Endoscope Processing Practices Often Insufficient

Posted March 22, 2017

Strong Evidence for Sterilization of Endoscopes Presented at Stakeholder Meeting

Posted September 13, 2017

An Approach to Improving the Quality and Consistency of Flexible GI Endoscope Reprocessing

Grace Thornhill, Technical Service Specialist
Larry Talapa, Technical Service Specialist
Craig Wallace, Senior Technical Specialist

3M Infection Prevention Divisi
3M Center, Building 0275-04-E-(
St. Paul, MN 551(

ICT INFECTION CONTROL TODAY

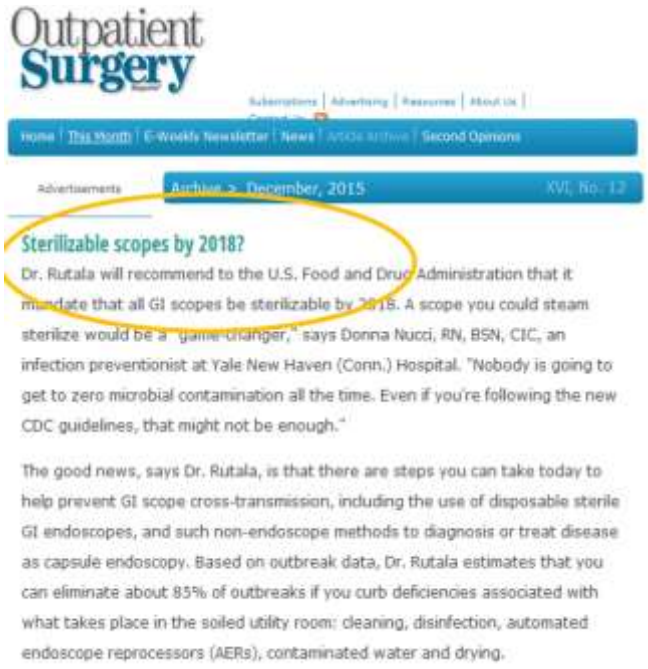
Futuro del reprocesamiento en endoscopia flexible

Ohio APIC Conference, October 2017…Duodenoscopes and Endoscope Reprocessing: A Need to Shift from Disinfection to Sterilization

OCTOBER 24, 2017 by AMY POWELL

"I don't believe we are ever going to eliminate the microbial contamination of an endoscope in the absence of sterilization."

– William Rutala, PhD, MS, MPH, CIC



Outpatient Surgery

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Sterilizable scopes by 2018?

Dr. Rutala will recommend to the U.S. Food and Drug Administration that it mandate that all GI scopes be sterilizable by 2018. A scope you could steam sterilize would be a "game-changer," says Donna Nucci, RN, BSN, CIC, an infection preventionist at Yale New Haven (Conn.) Hospital. "Nobody is going to get to zero microbial contamination all the time. Even if you're following the new CDC guidelines, that might not be enough."

The good news, says Dr. Rutala, is that there are steps you can take today to help prevent GI scope cross-transmission, including the use of disposable sterile GI endoscopes, and such non-endoscope methods to diagnosis or treat disease as capsule endoscopy. Based on outbreak data, Dr. Rutala estimates that you can eliminate about 85% of outbreaks if you curb deficiencies associated with what takes place in the soiled utility room: cleaning, disinfection, automated endoscope reprocessors (AERs), contaminated water and drying.

La endoscopia en la actualidad

ACTUAL SITUACIÓN DEMOGRÁFICA

MAYOR POBLACIÓN

POBLACIÓN MÁS ENVEJECIDA

MAYOR NÚMERO DE INTERVENCIONES.

DESARROLLO DE LA TECNOLOGÍA

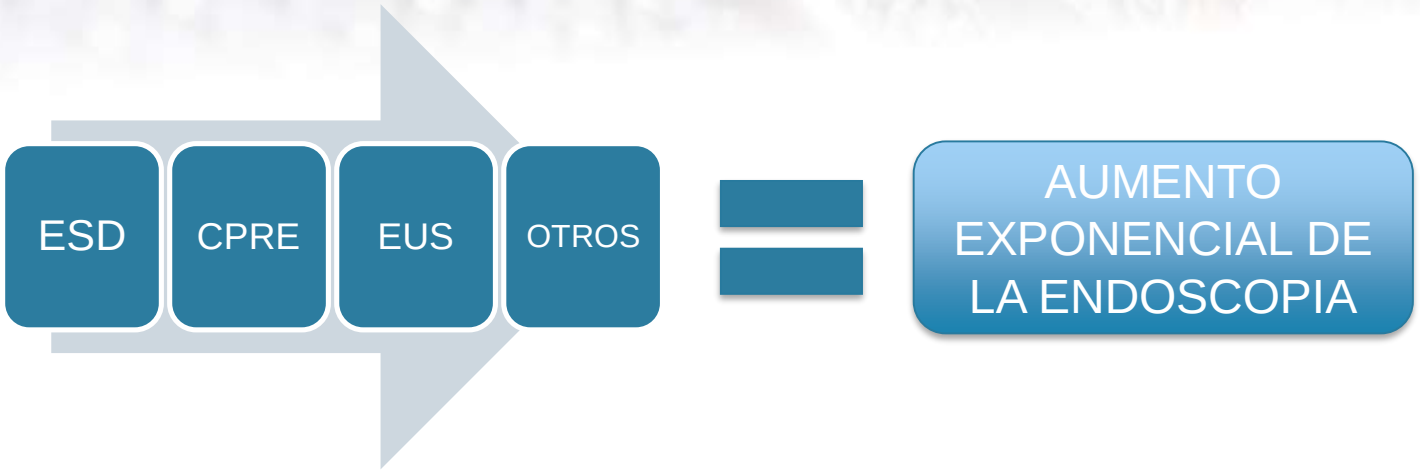
TÉCNICAS MENOS INVASIVAS:

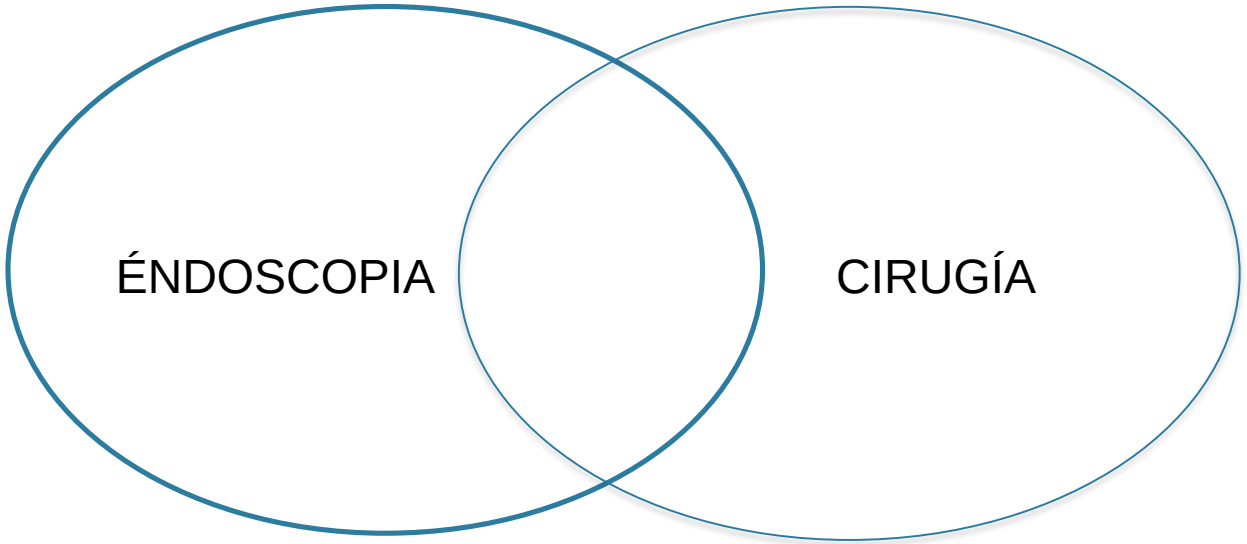
CIRUGÍA MíNIMAMENTE INVASIVA.

ENDOSCOPIA TERAPÉUTICA

NUEVOS DISPOSITIVOS

La endoscopia terapéutica en la actualidad





Reinterpretando los usos de dispositivos según la clasificación de Spaulding

NIVEL	TIPO DE EQUIPO	EJEMPLO	MINIMO NIVEL REQUERIDO
NO CRITICO	Objeto en contacto con piel intacta.	Manguito de presión sanguínea, Otoscopio, etc.	Desinfección de Mediano y Bajo nivel
SEMI-CRITICO	Objeto en contacto con mucosa intacta.	Endoscopios flexibles, tubos endotraqueal, laringoscopios, etc.	Desinfección de Alto nivel (D.A.N.)
CRITICO	Instrumento inducido directamente en el torrente sanguíneo o en zonas estériles del cuerpo.	Instrumentales quirúrgicos, cateterismos cardíacos; Catéteres IV, etc.	Esterilización.

Reinterpretando los usos de dispositivos según la clasificación de Spaulding

SERVICIO	DISPOSITIVO	PRUEBA	
GI		CPRE	-Retirada de piedras. -Dilatación/corte papila. -Drenaje del conducto biliar.
Neumología		Broncoscopia terapéutica	-Biopsia transbronquial -Punción aspirativa transbronquial -Lavado broncoalveolar
Urología		Cistoscopia	-Toma de biopsias. -Extracción de cálculos.

Reinterpretando los usos de dispositivos según la clasificación de Spaulding

Classification	Definition	Level of Processing/Reprocessing	Examples
Critical Device	Device that enters sterile tissues, including the vascular system	Cleaning followed by Sterilization	▪ Surgical instruments ▪ Biopsy instruments ▪ Foot care equipment ▪ Cystoscopes*
Semi-critical Device	Device that comes in contact with non-intact skin or mucous membranes but do not penetrate them	Cleaning followed by High-Level Disinfection (as a minimum) Sterilization is preferred	▪ Respiratory therapy equipment ▪ Anaesthesia equipment ▪ Tonometer ▪ Cystoscopes*
Noncritical Device	Device that touches only intact skin and not mucous membranes, or does not directly touch the client/patient/resident	Cleaning followed by Low-Level Disinfection (in some cases, cleaning alone is acceptable)	▪ ECG machines ▪ Oximeters ▪ Bedpans, urinals, commodes

*Cystoscopes – 2012 appear in Critical and Semi-critical classification section. The preferred level of reprocessing is sterilization.

Best Practice Guidelines for Cleaning, Disinfection and Sterilization in Health Authorities - October 2011 British Columbia Ministry of Health

Endoscopios, alta tecnología y material termosensible

Las características de los endoscopios en cuanto a su diseño complejo y materiales los convierten en equipos muy delicados que requieren de nuevas técnicas de desinfección y esterilización
Los métodos clásicos de alta temperatura no cubren las necesidades de estos dispositivos por ser material termosensible. No son, por tanto susceptibles de ser esterilizados en autoclave.

Opciones baja temperatura
Los oxidantes

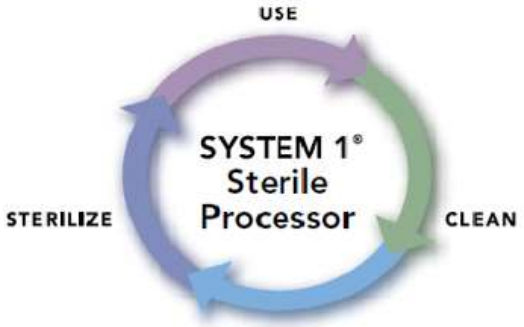
- **Óxido de Etileno (EO)**
- **Ácido Peracético**
- **Peróxido de Hidrógeno**
  - **Plasma**
  - **Vaporizado VHP**

Esterilización por inmersión en Ácido Peracético en cámara cerrada

ISO 14937

- Proceso completo en **18 min**.
- ***Just in Time***
- Para dispositivos críticos y semicríticos previamente lavados.
- Miles de dispositivos validados.
- Proceso seguro para el paciente, usuario, los dispositivos y el medio ambiente.
- 30 años de experiencia en esterilización química líquida.

SYSTEM 1® EXPRESS



Esterilización por inmersión en Ácido Peracético en cámara cerrada

Ventajas

- Rotación de alta velocidad.
- Minimiza necesidades de inventario.
- Máxima eficacia contra biofilms.
- Facilita la programación de la agenda
- Sin almacenaje-transporte y presentación aséptica de los dispositivos.

SYSTEM 1® EXPRESS

Esterilización por Peróxido de Hidrógeno Vaporizado en cámara cerrada

ISO 14937

- Proceso en seco a baja temperatura para dispositivos críticos y semicríticos delicado con los instrumentos.
- Ciclo flexible para endoscopios flexibles quirúrgicos.
- Proceso completo en menos de 40 minutos.
- Esterilización efectiva, inactivación de priones.
- Sin residuos tóxicos al final del ciclo; sólo agua y oxígeno.
- Proceso seguro para el paciente, el personal y los dispositivos.

BE V-PRO active

Esterilización por Peróxido de Hidrógeno Vaporizado en cámara cerrada

BE V-PRO active

Ventajas

- Elevada tolerancia a la humedad.
- Proceso delicado con los intrumentos libre de plasma.
- Matriz On line, garantía de compatibilidad.
- Minimiza necesidades de inventario.
- No requiere preinstalación ni ventilación o bancadas de aire.

Muchas gracias!!

Carlos Lozano-Especialista Clínico
Carlos_lozano@steris.com