

Ambu



REPROCESSING UROLOGICAL ENDOSCOPES

ARE YOU AWARE OF THE IMPACT?

REPROCESSING IN THE ENDOSCOPY SUITE PRESENTS MANY CHALLENGES TO STAFF, PATIENTS AND THE ENVIRONMENT

Urological endoscopes, including cystoscopes and ureteroscopes are classed as semi-critical devices due to contact with intact mucous membranes and therefore require high-level disinfection during reprocessing¹. However, high-level disinfectants (HLDs) are categorised as hazardous and pose an inherent risk to both reprocessing personnel and patients exposed to the chemicals. High quantities of personal protective equipment (PPE), reprocessing cleaning materials and harmful chemicals bear a heavy environmental burden, where toxic chemicals released in the environment also have long-lasting effects on the aquatic environment. With zero reprocessing, single-use endoscopy solutions at Ambu eradicate such concerning challenges to ensure patient and staff safety are not compromised while forging the way with environmental sustainability.

04 Occupational health hazards associated with reprocessing chemicals

06 Patient hypersensitivity induced with Ortho-Phthalaldehyde

08 Environmental risks associated with endoscope reprocessing

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14 Ambu's commitment to sustainability



OCCUPATIONAL HEALTH HAZARDS ASSOCIATED WITH REPROCESSING CHEMICALS

Healthcare workers reprocessing Urological endoscopes are often having to handle and come into contact with high-level disinfectants, in order to minimise cross-contamination¹. In doing so, staff are continually exposed to toxic HLDs day after day, increasing their risk to occupational asthma (OA).

Glutaraldehyde (Glut), a well-known asthmagen, was withdrawn from UK market, with the aim to eliminate OA³. However, alternative reprocessing chemicals used in NHS endoscopy units, including ortho-phthalaldehyde (OPA) is also capable of causing OA³. In addition, Peracetic Acid (PA) is associated with further occupational hazards.⁴



“17,000

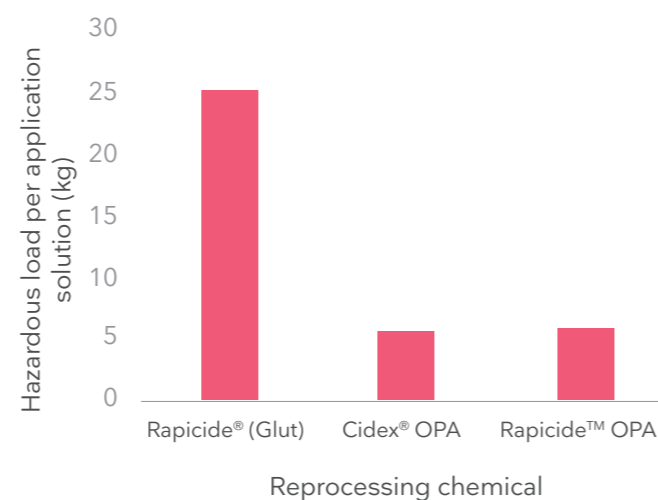
Estimated new UK cases of self-reported ‘breathing or lung problems’ caused or made worse by work...substantial proportion may be work-related asthma”²

174

Estimated new UK cases of OA in 2019²



Sensitising hazard of reprocessing chemicals capable of causing occupational asthma⁴



HEALTH HAZARD EVALUATIONS

1 LOCATION: Kaleida Health-Buffalo General Hospital, New York HIGH-LEVEL DISINFECTANT: PA

Health problems identified were **headache, shortness of breath, eye irritation, and diminished sense of smell**. Concentrations of PA were thought to be low (less than 0.2 ppm). Two workers reported prior **chemical burns** from contact with Steris 40™ Sterilant Concentrate.⁵

2 LOCATION: Marseille University Hospital, France HIGH-LEVEL DISINFECTANT: PA

Subject No.1: Soon after beginning employment, a 48-year-old anaesthetist nurse reprocessing endoscopes in an endoscopy unit suffered from **rhinorrhoea, conjunctivitis and dry cough**.

Subject No.2: A 47-yr-old auxiliary nurse in an endoscopy unit, performing decontamination procedures 3 times daily developed **chest tightness, rhinorrhoea, and conjunctivitis**. A positive result of the specific inhalation challenge test to PA confirmed the diagnosis of **occupational asthma**.⁶

3 LOCATION: University Institute of Cardiology and Respiriology of Quebec, Canada HIGH-LEVEL DISINFECTANT: OPA

A 55-year-old reprocessing personnel whom regularly handled Cidex® OPA for the HLD of endoscopes attended an emergency department with **dyspnoea, wheezing, conjunctival redness and low peak expiratory flow**.⁷



PUTTING STAFF SAFETY FIRST

The single-use Ambu® aScope™ 4 Cysto minimises the risk of cross-contamination by ensuring sterility straight from the pack. In addition, our single-use scopes eliminate reprocessing and the associated exposure to hazardous HLDs, thereby ensuring staff safety.

HLD OCCUPATIONAL HAZARDS SUMMARY³⁻⁷

Peracetic Acid



Severe skin burns



Severe eye damage



Respiratory irritation



Drowsiness and dizziness

Ortho-phthalaldehyde



Skin irritation



Gastro intestinal tract irritation



The health and safety of endoscopy staff should not be compromised.

PATIENT HYPERSENSITIVITY INDUCED WITH REPROCESSING CHEMICAL ORTHO-PHTHALALDEHYDE

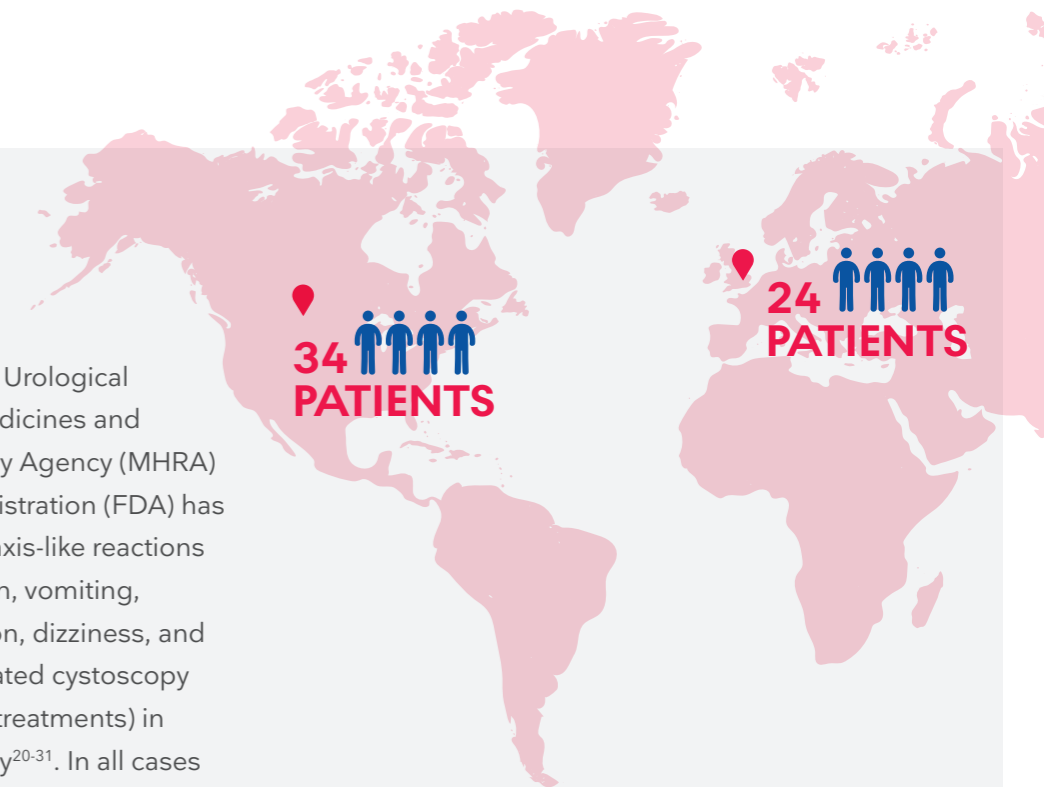
When considering patient safety concerns regarding reprocessing chemicals, the most important factor is biocidal efficacy. However, the inherent risk of toxic reprocessing chemicals on patients post-cystoscopy must also be considered.



During reprocessing, the final rinse stage is designed to eliminate any remaining traces of high-level disinfectant, however, traces can and do remain. The use of ortho-phthalaldehyde is contraindicated for reprocessing Urological endoscopes in



patients with a history of bladder cancer.¹³⁻¹⁹



Out of approximately 1 million Urological procedures worldwide, the Medicines and Healthcare products Regulatory Agency (MHRA) and US Food and Drug Administration (FDA) has increasingly reported anaphylaxis-like reactions (including nausea, hypotension, vomiting, breathing difficulty, eye irritation, dizziness, and anaphylactic shock) after repeated cystoscopy procedures (typically after 4-9 treatments) in 24 and 34 patients, respectively²⁰⁻³¹. In all cases the manufacturer has indicated that the instruments had been manually re-processed.

PUTTING PATIENT SAFETY FIRST

The Ambu® aScope™ 4 Cysto offers guaranteed sterility with no reprocessing, eliminating the use of toxic high-level disinfectants including OPA and the inherent risk of anaphylaxis-like reactions in patients with bladder cancer. Patient safety always comes first with our single-use solution, where the flexible cystoscopy procedure is performed with a single-use sterile cystoscope opened straight from the package just for them.



ENVIRONMENTAL RISKS ASSOCIATED WITH ENDOSCOPE REPROCESSING

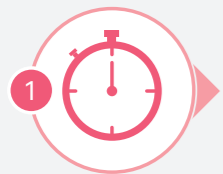
The Department of Health Technical Memorandum for Decontamination of flexible endoscopes highlight seven critical stages that need to be performed during each reprocessing cycle, increasing the time to clean reusable endoscopes, PPE used, and environmental impact.^{1,10}

The incineration of clinical waste generated from reprocessing one endoscope has high primary energy consumption and CO² emissions,

adversely impacting our environment.¹¹



10



PRECLEANING

Fresh PPE must be worn. Wipe the outside of the endoscope with disinfectant wipes, flush channels



MANUAL LEAK TEST

Fresh PPE must be worn. Detect internal/external damage



MANUAL CLEAN

Fresh PPE must be worn. Change PPE and wash hands after manual cleaning



VISUAL INSPECTION

If cleaning verification test fails, change PPE and re-clean endoscope immediately



AUTOMATED CLEANING & HIGH-LEVEL DISINFECTION

For patients with definite/probable vCJD, single-use disinfectant should be used

Gloves should be changed between loading and unloading an endoscope into and from an AER



DRYING & STORAGE

Dry external surfaces, flush channels with alcohol, purge with HEPA filtered air



INSPECTION, VALIDATION, TRACK & TRACE & SURVEILLANCE



REPEAT PER PROCEDURE^{1,10}

FREQUENT PPE CHANGES ARE RECOMMENDED DURING MOST REPROCESSING STEPS

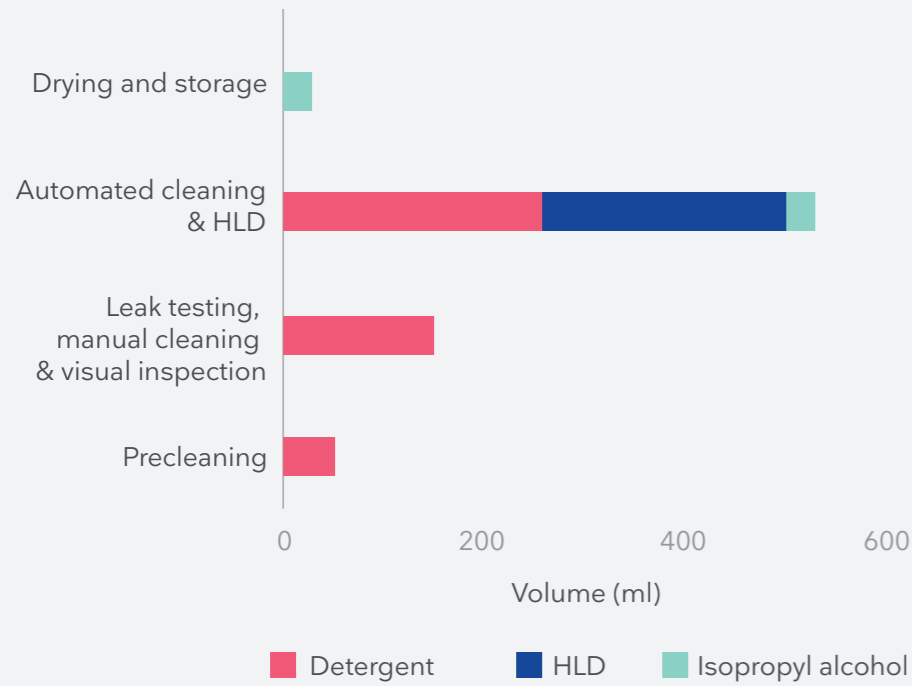
The use of PPE during reprocessing is crucial for eliminating infectious endoscope contaminants. However, continued use of contaminated gloves increases the risk of cross-transmission of healthcare-associated pathogens among healthcare staff and the clinical environment⁸. Due to this, frequent changes of PPE are recommended during reprocessing to prevent cross-contamination.^{1,9,10}

PPE & CLEANING MATERIALS REQUIRED DURING ONE REPROCESSING CYCLE ¹⁰	QUANTITY
Hair cover	2
Pop-up face shield	2
Gloves (pair)	4
Extended-cuff gloves	1
Impermeable gown or apron	2
Shoe covers	2
Cloth (lint free)	6
Container	2
Disinfectant wipes	10
Transport container	2
Transport container liner	1
Syringe	4
Single-use port/valve brush	1
Single-use channel brush	1
ATP water effluent test (cleaning verification)	1
MEC test strips (for AER)	1
Mesh bag	1
Towels to line counter	2
Label	1

How much PPE and cleaning materials are used during the reprocessing cycle of one reusable endoscope?

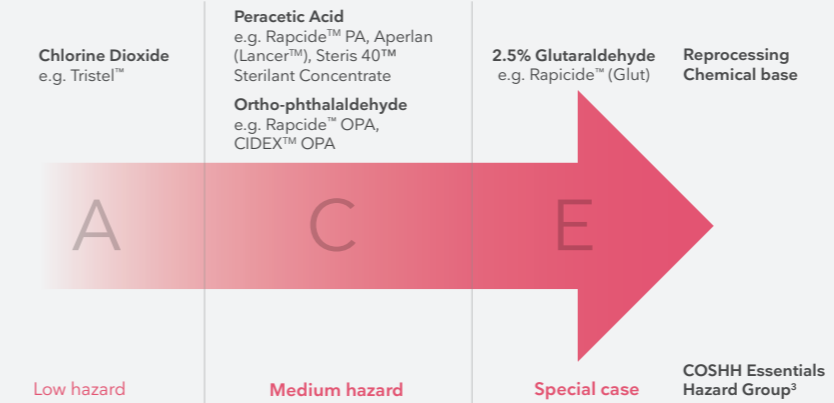
Reprocessing guidelines state that personnel should wear full PPE when reprocessing endoscopes¹. Furthermore, personnel should don fresh PPE during different steps of the reprocessing cycle.¹⁰

LARGE VOLUMES OF HAZARDOUS CHEMICALS ARE USED THROUGHOUT THE REPROCESSING CYCLE OF A REUSABLE ENDOSCOPE¹²

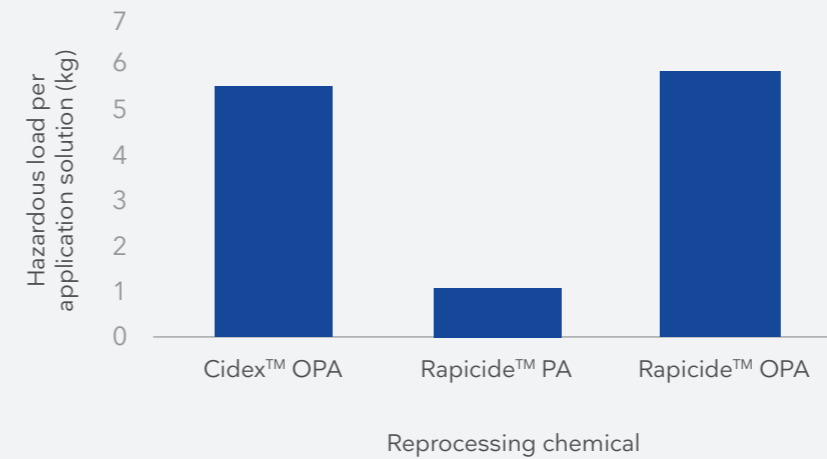


The aScope™ 4 Cysto removes the reprocessing encumbrance, thereby eliminating all reprocessing waste, including decontamination consumables and chemicals.

HIGH TOXICITY OF REPROCESSING CHEMICALS TO AQUATIC ENVIRONMENT



Aquatic Hazard: Toxicity of reprocessing chemicals towards water organisms with lasting effects⁴



Reprocessing chemicals used in NHS endoscopy suites are classified by the Health and Safety Executive as medium-special case COSHH Essentials Hazard Group³. Disinfectants entering into wastewater have adverse environmental effects on aquatic systems due to high toxicity, bioaccumulation and/or low biodegradability.⁴



With zero reprocessing, single-use endoscopy solutions eradicates the release of toxic chemicals to the environment thus protecting aquatic wildlife, microbial ecology and crucial waste water treatment processes.



SINGLE-USE ENDOSCOPY SOLUTIONS

Ambu believes that single-use endoscopy solutions for Urology procedures, such as the Ambu® aScope™ 4 Cysto, should perform like conventional ones, only with the added advantages of increased availability and improved patient safety.

With single-use, there is no need for reprocessing or repair, which eliminates these costs and frees up resources, allowing staff to relocate their time to assist on more procedures. In addition, single-use endoscopy eradicates the handling and disposing of toxic, hazardous reprocessing chemicals and associated waste, thereby protecting HCP and our environment.

Find out more about our single-use endoscopy solutions:



“ Ambu was founded over 80 years ago with a mission to make a difference in patients’ lives and to change the world for the better. We carry this legacy with us and feel a responsibility towards future generations to seek sustainable paths for our business. We strive to set the standard for sustainability in the area of single-use medical devices. Juan José Gonzalez, CEO

TAKING A STAND ON THE ENVIRONMENT

Ambu continuously seeks new ways to promote the circular economy and to grow sustainably.

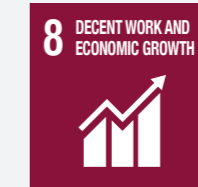
We are committed to supporting all of the UN Global Compact’s 17 Sustainable Development Goals (SDGs) and have a special focus on the below 4 SDGs, where we believe we will be able to have the biggest impact.



GOOD HEALTH AND WELL-BEING
Ambu takes actions that help reduce contamination of the air, water and soil.



AFFORDABLE AND CLEAN ENERGY
Ambu sources operational electricity, in part, from renewable sources.



DECENT WORK AND ECONOMIC GROWTH
Ambu takes actions to contribute to improving resource efficiency in production and consumption, and strives to decouple economic growth from environmental degradation.



RESPONSIBLE CONSUMPTION AND PRODUCTION
Ambu takes actions to achieve sound environmental management of all waste and chemicals throughout their life cycle, and to significantly reduce their release to air, water and soil.
Ambu also contributes by reducing waste generation through reduction, recycling and reuse.


Our sustainability targets are

 100% **phthalate-free** products by 2020


COMPLETED

 95% of new products released after 2025 to be **PVC-free**

ON TRACK

 100% **recyclable, reusable or compostable** packaging applied by 2025*
*if solutions and/or technology exists

ON TRACK

 Work towards reducing our **carbon emissions** by 50% by 2025 compared to 2019 baseline

ON TRACK

INNOVATIVE SUSTAINABILITY PARTNERSHIPS

As we work toward future possibilities for safe processing and recycling of endoscopes, we seek other ways to contribute to the circular economy.

A plastic-neutral partnership between Ambu and Plastic Bank®

Plastic Bank® is an organisation that builds ethical recycling ecosystems and reprocesses the materials for reintroduction into the global manufacturing supply chain. Ambu will prevent over 100 tons of plastic from entering the ocean in partnership with Plastic Bank®.

Facts:

- Collectors in coastal communities in the Philippines and Indonesia gather plastic waste that otherwise would have ended up in the ocean in exchange for a premium.
- The quantity of plastic collected will correspond to the amount of plastic used in all of the Ambu single-use aScope products in EMEA and Latin America throughout the year.
- Plastic Bank's blockchain platform, Alchemy™, ensures that the amount of plastic collected is transparent and traceable.



Operation Clean Sweep® (OCS)

An international program designed to prevent and help keep plastic litter materials out of the marine environment. Signing with OSC commits Ambu to handle plastic pellets, flakes and powders that pass through manufacturing facilities with the care they deserve, so they do not end up in a body of water.

Facts:

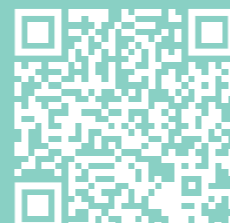
- Pellet spills can occur at all stages along the plastics value chain.
- Stages where spills can occur include production, handling, transportation, conversion and recycling.



“Imagine if, through our product design efforts, we could provide sustainable solutions that make a positive impact on the environment around us.”

Nicklas Funk,
Sustainability Engineer

Find out more about our environmental standpoint:



Abbreviations

COSHH; control of substances hazardous to health, EWD; endoscope washer disinfectant, HLD; high-level disinfectant, HSE; health and safety executive, MEC; minimum effective concentration, OPA; ortho-phthalaldehyde, PA; peracetic acid, PPE; personal protective equipment, SDG; sustainable development goals, vCJD; variant Creutzfeldt-Jakob disease

References

1. Public Health England. Health Technical Memorandum 01-06: Decontamination of flexible endoscopes Part A: Policy and management. Department of Health; 2016. [Internet]. Available at: https://www.england.nhs.uk/wp-content/uploads/2021/05/HTM0106_PartA.pdf [Accessed 07.12.21].
2. Health & Safety Executive. Work-related asthma statistics in Great Britain, 2020. [Internet]. Available at: <https://www.hse.gov.uk/statistics/overall/hssh1920.pdf> [Accessed 03.06.21].
3. Karen Niven. Health and Safety Executive 2007. An evaluation of chemical disinfecting agents used in endoscopy suites in the NHS. [Internet]. <https://www.hse.gov.uk/research/rrhtm/rr445.htm>. [Accessed 09.05.21].
4. HCWH Europe. Promoting safer disinfectants in the healthcare sector. SAICM 2.0 Report. [Internet]. Available at: <https://noharm-europe.org/documents/promoting-safer-disinfectants-in-the-healthcare-sector>. [Accessed 09.05.21]
5. Sylvain, D. & Gibbins, J. (2009) Evaluation of worker exposures to peracetic acid-based sterilant during endoscope reprocessing. Health Hazard Evaluation Report [Internet]. Available at: <https://www.cdc.gov/niosh/hhe/reports/pdfs/2006-0298-3090.pdf>. [Accessed 01.06.21]
6. Cristofari-Marquand E, Kacel M, Milhe F, Magnan A, Lehucher-Michel MP. Asthma caused by peracetic acid-hydrogen peroxide mixture. J Occup Health. 2007;49(2):155-8. doi: 10.1539/joh.49.155
7. Robitaille C, Boulet LP. Occupational asthma after exposure to ortho-phthalaldehyde (OPA). Occup Environ Med. 2015;72(5):381. doi: 10.1136/oemed-2015-102847
8. American Society for Microbiology. Contaminated gloves increase risks of cross-transmission of pathogens. Infection Control Today. 2016 [Internet]. Available at: <https://www.infectioncontrolday.com/view/contaminated-gloves-increase-risks-cross-transmission-pathogens>. [Accessed 10.05.21].
9. ECRI. 2019 Top 10 Health Technology Hazards: Executive Brief.
10. Ofstead CL, Quick MR, Eiland JE, Adams SJ. A glimpse at the true cost of reprocessing endoscopes: Results of a pilot project [Internet]. Available from: <https://www.bostonscientific.com/content/dam/bostonscientific/uro-wh/portfolio-group/LithoVue/pdfs/Sterilization-Resource-Handout.pdf>. [Accessed 01.06.21]
11. Birgitte Lilholt Sørensen, Henrik Grüttner, Comparative Study on Environmental Impacts of Reusable and Single-Use Bronchoscopes, American Journal of Environmental Protection. Vol. 7, No. 4, 2018, pp. 55-62. doi: 10.11648/j.ajep.20180704.11
12. Ambu internal communications 2021, data on file.
13. Cabral Duarte F, Spinola Santos A, Carvalho A, Pereira Barbosa M. Immediate allergic reaction after a cystoscopy: A case report. Allergy: European Journal of Allergy and Clinical Immunology. 2010;65:251.
14. Cooper DE, White AA, Werkema AN, Auge BK. Case report: Anaphylaxis following cystoscopy with equipment sterilized with Cidex® OPA (Ortho-phthalaldehyde): A review of two cases. Journal of Endourology. 2008;22(9):2181-4. doi: 10.1089/end.2007.0358.
15. Draikiwicz S, Monteleone C. Anaphylactic reaction to repeated exposures of cidex-opa (ortho-phthalaldehyde) during cystoscopy for bladder cancer. Journal of Clinical Urology. 2014;7(1):61-2.
16. Hedberg CL, Demers LN, Pilgrim FJ, Wilson MR. Recurrent anaphylaxis after cystoscopy in a gentleman with bladder and prostate cancer. Annals of Allergy, Asthma and Immunology. 2012;109:A66.
17. Passeri LA, Psaltikidis EM, Leichsenring ML, Nakamura MHY, Burstoff JM. Alternative high level disinfectants to processing flexible endoscopes. Value in Health. 2013;16(7):A712.
18. Sokol WN. Nine episodes of anaphylaxis following cystoscopy caused by Cidex OPA (ortho-phthalaldehyde) high-level disinfectant in 4 patients after cytoscopy. Journal of Allergy and Clinical Immunology. 2004;114(2):392-7. doi: 10.1016/j.jaci.2004.04.031.
19. Sompornrattanaphan M, Kanistanon D, Srinoulprasert Y, Udnaen S, Jongjarearnprasert K, Wongsu C, et al. Ortho-phthalaldehyde-induced anaphylaxis after cystoscopy: Confirmation by the basophil activation test. Journal of Investigational Allergology and Clinical Immunology. 2020;30(5):365-7. doi: 10.18176/jiaci.0505.
20. Medical and Healthcare Products Regulatory Agency (MHRA), Medical Device Alert. Cidex OPA ortho-phthalaldehyde high level disinfectant solution. 2004, MDA/2004/022. [Internet]. Available at: <https://www.gov.uk/drug-device-alerts/medical-device-alerts-archived-in-may-2015>
21. U.S Food and Drug Administration. MAUDE. Report number 2084725-2021-00299. [Internet]. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=12425316&pc=MED. [Accessed 18/11/21].
22. U.S Food and Drug Administration. MAUDE. Report number 2084725-2021-00300. [Internet]. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=12425322&pc=MED. [Accessed 18/11/21].
23. U.S Food and Drug Administration. MAUDE. Report number 2084725-2020-00050. [Internet]. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=10350456&pc=MED. [Accessed 18/11/21].
24. U.S Food and Drug Administration. MAUDE. Report number 2084725-2020-00051. [Internet]. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi_id=10350484&pc=MED. [Accessed 18/11/21].
25. U.S Food and Drug Administration. MAUDE. Report Number: 2084725-2016-00760. [Internet]. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi_id=6160079&pc=MED. [Accessed 18/11/21].
26. U.S Food and Drug Administration. MAUDE. Report Number: 2084725-2016-00212. [Internet]. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi_id=5579398&pc=MED. [Accessed 18/11/21].
27. U.S Food and Drug Administration. MAUDE. Report Number: 2084725-2016-00214. [Internet]. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi_id=5579706&pc=MED. [Accessed 18/11/21].
28. U.S Food and Drug Administration. MAUDE. Report Number: 2084725-2016-00213. [Internet]. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi_id=5579962&pc=MED. [Accessed 18/11/21].
29. U.S Food and Drug Administration. MAUDE. Report Number: 2084725-2013-00545. [Internet]. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=3517582&pc=MED. [Accessed 18/11/21].
30. U.S Food and Drug Administration. MAUDE. Report Number: 2084725-2011-00055. [Internet]. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=2179426&pc=MED. [Accessed 18/11/21].
31. U.S Food and Drug Administration. MAUDE. Report Number: 2084725-2011-00012. [Internet]. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=1979590&pc=MED. [Accessed 18/11/21].



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