Firson ㈜퍼슨

ETC

High-level disinfectant

OPIDEX OPA

0.55% ortho-phthalaldehyde

OPIDEX OPA Solution with **CE & ISO certification** is the most frequently used High Level Disinfectant in KOREA

Features

OPIDEX was **certified CE & ISO** and **exported abroad !**

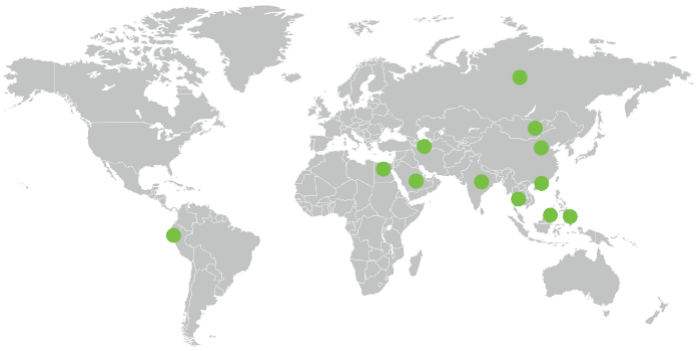
Certified by CE & ISO and exported to 20 countries including Europe.

Certification

CE

ISO

Exportation



OPIDEX OPA Solution was manufactured by GMP facilities.[1]

(Products which was not produced at GMP facilities will not be distributed from March 2022 by KFDA.)

OPIDEX OPA Solution provided High Level Disinfection when immersed devices for 5 minutes at room temperature.

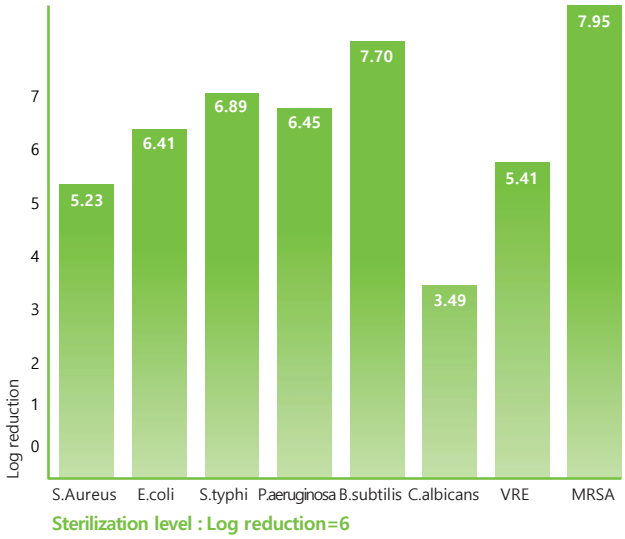
- Bacteria with spores took 10 minutes (Experimental data on efficacy equivalence of tuberculosis specialized institutions in August 2012)

No corrosion with neutral pH and convenient to use.

Effectiveness

OPIDEX sterilized 99.99% strains in 1minute[2].

Sterilization Effect



Sterilization level : Log reduction=6

Experimental data on the efficacy equivalence of tuberculosis specialized institutions (Aug, 2012)

Name of germs	1 minute		
	CFU/Control Plate (Colony Count)	CFU/Test Plate (Colony Count)	세균감소율(%)
S.Aureus	1.7*10^5	0	100%
E.coli	2.6*10^6	0	100%
S.typhi	7.7*10^6	0	100%
P.aeruginosa	2.8*10^6	0	100%
B.subtilis	5*10^7	0	100%
C.albicans	3.1*10^3	0	100%
VRE	2.6*10^5	0	100%
MRSA	9.0*10^7	0	100%

99.99% reduction in tuberculosis bacteria within 1 minute, complete sterilization within 10 minutes.

Experimental data on the efficacy equivalence of tuberculosis specialized institutions (Aug, 2012)

Name of germs	2 minutes			5 minutes			10 minutes		
	Control Group	Experimental Group	(CFU/Plate) Bacterial reduction rate(%)	Control Group	Experimental Group	(CFU/Plate) Bacterial reduction rate(%)	Control Group	Experimental Group	(CFU/Plate) Bacterial reduction rate(%)
Mycobacterium tuberculosis(Rv)	3.1*10^9	7.6*10^4	99.998%	3.1*10^9	7.7*10^4	99.998%	3.1*10^9	4.5*10^4	99.999%
Mycobacterium tuberculosis(Ra)	3.4*10^8	9.4*10^3	99.997%	3.4*10^8	8.7*10^3	99.998%	3.4*10^8	3.1*10^3	99.999%
Mycobacterium avium	5.2*10^10	2.2*10^3	99.999%	5.2*10^10	3*10	99.999%	5.2*10^10	-	100%
Mycobacterium intracellular	1.2*10^9	1.0*10^3	99.999%	1.2*10^9	-	100%	1.2*10^9	-	100%
Mycobacterium kansasii	3.1*10^7	-	100%	3.1*10^7	-	100%	3.1*10^7	-	100%
MDR (Clinical isolate)	2.2*10^7	2.0*10^2	99.999%	2.2*10^7	1.7*10^2	99.999%	2.2*10^7	1.1*10^2	99.999%
XDR (Clinical isolate)	3.1*10^7	2.8*10^2	99.999%	3.1*10^7	2.6*10^2	99.999%	3.1*10^7	2.2*10^2	99.999%

Average number of cycles

OPIDEX maintained an effective concentration to 60 Cycles or more [3]

At 65Cycle, the incidence below MEC was 30%.

Number of Cycles	Number of samples	Average con centration	Rate of occurre nce below MEC	Highest concentration	Lowest concentration
Less than 30times	8	0.42%	-	0.46%	0.39%
30~39 times	25	0.37%	-	0.50%	0.32%
40~44 times	28†	0.35%	25%	0.47%	0.19%
45~49 times	55	0.34%	24%	0.51%	0.25%
50~54 times	63	0.36%	14%	0.48%	0.23%
55~59 times	27	0.33%	37%	0.45%	0.22%
60~64 times	56	0.32%	30%	0.44%	0.19%
65 times	36	0.31%	36%	0.38%	0.24%
70 times	37	0.30%	51%	0.37%	0.22%
75 times	32	0.28%	72%	0.37%	0.21%
78 times	1	0.30%	-	0.30%	0.30%
93 times	1	0.27%	100%	0.27%	0.27%

* Period: March 2017 ~ July 2018 (17 months), Number of hospital : 15 locations, Number of HPCL progresses : 27 times

† Minimum concentration source : 40 times of colonoscopy

The above data are reference materials.
Be sure to verify the MEC of OPIDEX OPA Solution using the Test strip !

Notice

OPIDEX OPA Solution must be disposed and replaced whenever the MEC fails or the reuse life expires.

MEC, Minimum Effective Concentration

OPIDEX OPA Solution **may be reused for up to maximum of 75 days after its opened** [4]

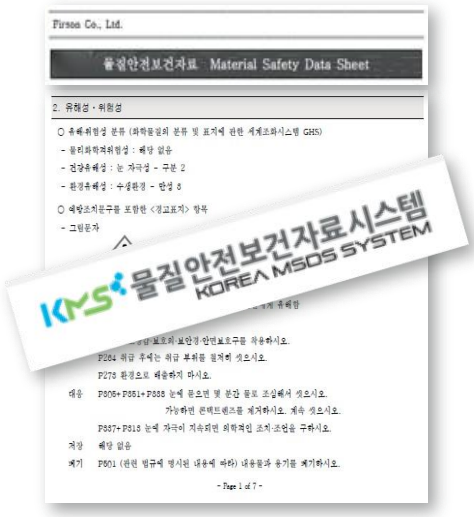
As a result of the chemical test, stability was achieved **in all test items up to 75 days** after opening.

Test item	Test standard	Manufacturing	75days after opened
Appearance	Light blue transparent liquid	Light blue transparent liquid	Maintenance
pH	7.2~7.8	7.39	7.36
Confirmation test	Persistent dark red	Dark red	Maintenance
	Peak retention time equal to standard solution	Same RT	Same RT
Purity test	Composition A Under 0.2%	0.08%	0.0 %
	Composition B ~7.0%	%	6%
	Un .2%	0.12%	0.14%
Content test	82.0%~	100.3%	98.2%
Mass deviation Average	More than amount	101.3%	-
Mass deviation Individual	More than amount	101.3%	-
Density	No signs of seepage into the test reagent	N/A	-

PASSED

Firson data, Results of a chemical test

It can be used it safely through **MSDS.**



1. PRODUCT AND COMPANY INFOR MATION
2. HAZARDS IDENTIFICATION
3. COMPOSITION/INFORMATION ON INGREDIENTS
4. FIRST AID MEASURES
5. FIRE-FIGHTING MEASURES
6. ACCIDENTAL RELEASE MEASUR ES
7. HANDLING AND STORAGE
8. EXPOSURE CONTROL /PERSONAL PROTECTION
9. PHYSICAL AND CHEMICAL PROPERTIES
10. STABILITY AND REACTIVITY
11. TOXICOLOGICAL INFORMATION
12. ECOLOGICAL INFORMATION
13. DISPOSAL CONSIDERATIONS
14. TRANSPORT INFORMATION
15. REGULATORY INFORMATION
16. OTHER INFORMATION

Endoscope reprocessing 5

Preparation of Endoscope reprocessing

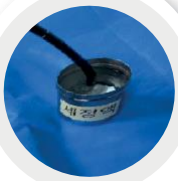
Basically, it should be implemented based on the principle of standardism.

Protective gear (waterproof gowns, goggles, masks, gloves, blocked-and-waterproof shoes, etc.) is important **not only for the safety of workers** but also for the prevention of **discoloration** due to the definite action of OPA agents

1. Pre-cleaning

As the first step of Endoscope reprocessing, the process of removing contaminants as soon as possible immediately after endoscopy

Immediately after endoscopy, foreign substances on the surface of the endoscope are removed with a disposable cloth or gauze coated with cleaning liquid or sterile distilled water.



The end of the endoscope is put in a cleaning agent, inhaled the cleaning liquid, and repeatedly blew in air to remove any contaminants remaining in the endoscope channel.

Finally, the endoscope is removed from the body after suctioning the air.

In order to reduce the possibility of infection due to contaminated endoscopy, the endoscope is placed in a dedicated container and moved to a cleaning room separated from the examination room.

Importance of Pre-cleaning

Biofilm attached to the inner tube of the endoscope lowers the disinfection effect, and if this process is not performed immediately after the test, contaminants such as body fluids and blood solidify in a narrow channel and cannot be completely removed by the subsequent disinfection process.

2. Cleaning

As the most basic stage of disinfection and sterilization, water, mechanical friction, and enzyme cleanser are used together to remove mucus, blood, and secretions from the digestive system and increase the efficiency of disinfection

* In the case of endoscopic disinfection using an automatic washer, hand washing should be performed until this process.

After removing all removable parts through the endoscope, perform a **leak test** before cleaning

Make sure that it does not leak, soak the endoscope in a cleaning solution, and wipe the outside of the endoscope with a clean cloth or sponge.

Using a brush that fits the endoscope channel, completely remove contaminants inside the **channel and the forceps.**

* This process is very important because it reduces 99.9-99.999% of pathogens in the endoscope, and if contaminants remain in the channel, it will reduce the sterilization effect of the disinfectant

After brushing, **use clean water** to wash the remaining cleaning solution completely in all areas.

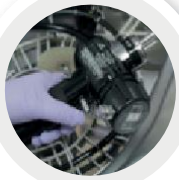
* **To prevent dilution of the disinfectant** due to remaining water, wipe the surface of the endoscope with a dry cloth, and blow the compressed air in to all channels to remove the water.

3. Disinfection

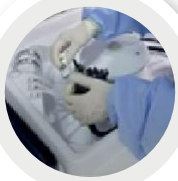
The **process of killing bacterias** that have not been removed in the process of charter pre-cleaning and cleaning

Excellent disinfection effects can be expected if **high-level disinfectants** are used to comply with the manufacturer's recommended policy.

After hand washing, open the lid of the automatic washing and disinfecting machine and place the endoscope so that it does not get twisted.



Fit the waterproof cap to the endoscope.



Connect the disinfectant cable and the endoscopic channel..

Start after checking the manual setting time.

* Set the time according to how to use the automatic cleaning and disinfectant and operate the device.

4. Rinsing

Wash the endoscope and forceps sufficiently using drinking clean water.

: The remaining disinfectant can damage the skin and mucous membrane, so wash the endoscope, forceps, and the inside of the channel with clean water enough to drink.

5. Drying

The process of drying the interior channels and the exterior of the instrument

: After thoroughly rinsing the endoscope, **remove all the valves and cap of the channel** and dry them.

* Even if sufficiently clean water is used during the rinsing process**, alcohol must be perfused.** Water evaporates quickly into the air when combined with alcohol, so that the inside of the channel can be dried more effectively. **If used below the recommended concentration, there may be no drying effect.**

Dry the outer surface of the endoscope by wiping it with a clean, soft cloth.

Pass 70-90% ethyl alcohol or isopropyl alcohol through all channel passages of the endoscope until visible at the tip of the endoscope.

Use compressed air to dry.

* Compressed air used during drying is useful for fast drying, but too high pressure may damage the inside of the channel of the flexible endoscope, so caution is required.

6. Storage

To prevent the disinfected endoscope from being re-contaminated, it is stored in a storage room located in a separate clean and dust-free space.

Drug Information

Ingredient	In 100mL Ortho-Phthalaldehyde---------- 0.55g Coloring agnet(Tar)---------- Green Dye #201 (KPTaCS)
Appearance	Light blue transparent liquid
Indication	**Chemical sterilization or sterilization of medical devices** - Chemical sterilization and disinfection of highly contaminated instruments or subcutaneous tissue or instruments directly applied to mucous membranes by microorganisms or organic substances - Disinfection of devices that are expected to be contaminated with hepatitis B virus **Target instrument** - Surgical instruments such as endoscopes, lens mounting instruments, anesthesia equipment, ventilators, artificial dialysis equipment, scalpel and catheter, obstetric and comparative instruments, dental instruments or auxiliary instruments, injection tubes, thermometers, or non-heat-sterilizable rubber and plastic instruments, etc
Dosage	**1. It is used as an undiluted solution** **2. Usage method** 1) Immerse the disinfectant completely in the liquid. Be careful to make sufficient contact with the liquid for instruments with pores. 2) Put it in the sterilization of the instrument for at least 5 minutes. 3) After deposition, the removed instruments are removed and sufficiently cleaned with a large amount of sterile distilled water. Depending on the purpose of use, rinse the tap water with alcohol and dry it with pressurized air. Also, wash equipment with fine workmanship carefully.
Storage	Airtight container, 15~30°C
Packing	4L X 4
Expiration date	24 months (Can be stored for 75 days after opening and 14 days after use)

High-level disinfectant

OPIDEX OPA

0.55% ortho-phthalaldehyde

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