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SCOTELIN[®]

Reference Manual



 **Huons Medicare**

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I. INTRODUCTION

With the increase of medical coverage, numerous 2nd infections in hospital become a social problem and each country prescribed some regulations about hygienic disinfection and disinfectants for the hygienic control of medical institutions. In early 1960, Spauling (USA) classified medical devices into critical, semi-critical and non-critical according to risk of infection and indicated disinfectants and disinfection methods for each category, and the classification is still being used nowadays. US Food & Drug Administration (FDA) just regulated aldehyde and peracetic acid (PAA) disinfectants as high level disinfectants for they can kill all of the germs including spores, and FDA also restricted application area of each disinfectant in order to not only reduce the infection in the hospital, but also minimize the efficacy and a side effect of disinfectants.

Specially, rapidly increasing of endoscope inspection and operation is used in the various endoscopes and not simple inspection but extend to range of medical treatment and if possible, decrease surgical permanent lesion and extend the area of operation in order to return soon in society. In late 1980, *Helicobacter pylori* (*H. pylori*) which persist in gastric acid was founded and that presented dangerousness of 2nd infection caused by imperfect cleaning & disinfecting on endoscopes as well as some risk cases were published in inside and outside of the countries.¹⁾ Now, many counties in the world prepared 『guideline for cleaning & disinfecting endoscope』 depend on their circumstance and required to observe it. In 1995 KSGE (Korean Society of Gastrointestinal Endoscope) in Korea also prepared 'Method for cleaning & disinfecting endoscope and had emphasized the importance of prevention against infection accidents.

The most popular disinfectant used in medical facilities like endoscopes and medical instruments in the world is glutaraldehyde disinfectant, it is substitute for formaldehyde and is developed in Johnson & Johnson, and it has been using till nowadays.

But a glutaraldehyde disinfectant (vapor as well as solution) have problems like toxicity in mucosa of the respiratory organs, on skin and eyes and in case of exposed patients and user(nurse), there is occasion such as headache, irritation of breath, allergy, bronchial trouble, stinging of eyes. Because the density of glutaraldehyde vapor weighs higher than air, UK Health and Safety Executive (HSE) considered the toxicity impact on user and patients, so, they prescribed strict standard of disinfectant on using environment but it was removed from the marketplace by the EPA, FDA and Federal Trade Commission in 1991.^{2) 3)} Also in Italy, they regulated concentration of glutaraldehyde in waste water from hospital in order to decrease effect of glutaraldehyde to environment pollution.⁴⁾

Also in case of ethylene oxide gas that is used for sterilization of medical instruments was operated by large general hospitals or medical institutions, but recently it is reported that exhausted ethylene oxide has an effect on environment pollution. So the usage of ethylene oxide in medical and treatment facilities was reported by annual and they control it by operating thorough supervision system in Tokyo Metropolitan government in Japan.^{5) 6)}

Above all, medium hospital conducted sterilization method through chemical disinfectant because need time for aeration after of ethylene oxide treatment and the administration of a high-priced facilities and persons.

Peracetic acid, an environmentally friendly disinfectant, was considered as oncoming disinfectant for its overcoming the environmental pollution and it is becoming the substitution for chemical disinfectants in some medical developed countries. But peracetic acid products have difficulty of manufacturing, storing, circulating and handling because of its rapid decrease of concentration caused by high reactivity of peracetic acid and hydrogen peroxide. So it needs a lot of time and technique to circulate as disinfectant and just several developed countries have the techniques. Especially strong acid-disinfectants were still being mainly used because medical disinfectants with low concentration were required long period of time for practical use.

They are just applied to disinfection of hemodialysis machine, water purifier and water supply systems and drain system as well as dialyzer reprocessing sterilizing in the medical facilities of hemodialysis. Peracetic acid disinfectant not only has shorter sterilization time than other disinfectants about killing all of the germs including spores, but also has cleaning effect which is

different from other disinfectants. So peracetic acid disinfectant can effectively remove and prevent biofilm in inside of medical devices and it was approved as high-level disinfectant. Especially with consumers' improvement of environmental pollution cognizance and strengthening of medical waste water regulation, aldehyde disinfectant (including formalin, glutaraldehyde etc,) and chloride disinfectant (including sodium hypochlorite) were limited to use, therefore the necessity of development on peracetic acid with low concentration and multi-purpose become a prominent figure. So we reduced the strong acetic acid smell for users, minimized the corrosiveness by peroxides, developed as liquid for convenience and maximized user's safety that is the new peracetic acid disinfectant-**SCOTELIN®**.

II. Product Information

1. GENERAL INFORMATION OF SCOTELIN®

(1) Composition of SCOTELIN®

SCOTELIN® is 2-pack type, working solution is prepared by mix additives (90 mL) with base solution (4 L).

- Active ingredients (the base solution 4 L with additives 90 mL) :

Peracetic acid (PAA) 0.13%

- Sub ingredients (the base solution 4 L with additives 90 mL) :

Corrosion inhibitors etc. A proper quantity

- Solvent:

Purified water

A proper quantity

(2) Physical properties of SCOTELIN®

- Colorless liquid with alcohol odor

- Non-flammability

- Simply rinse after using, mixed with water in any proportion

- pH

Base: 2.7~4.7

Additive: 2.4~4.4

- Density : approx. 1.0 g/cm³

2. EFFICACY of SCOTELIN®

Peracetic acid displays short-term disinfectant efficacy and hydrogen peroxide produces long-lasting disinfectant efficacy as well as removes organics.

Peracetic acid and hydrogen peroxide are peroxide (-O-O-). They make oxygen (nascent oxygen: O₂) when they contact with organics. Occurred nascent oxygen oxidized all kinds of protein components of microbial cell.

(1) Efficacy of SCOTELIN® in pathogens

Efficacy test of SCOTELIN® is operated by Seoul National University Hospital about bactericidal, tuberculocidal and fungicidal which are main factors bacterial of pathogenic inspection. Bactericidal was tested by EN 1040, fungicidal was tested by EN 1275 according to valuation measures of disinfection effect in EU.

H.pylori which becoming a problem in endoscopes disinfection was tested in Research Center for Gastroenterology in Dan Kook University.

Table 1. Sterilization effect of SCOTELIN® in pathogens (*in-vitro test*)

Test Institute	Test microorganisms		Result
Seoul National University Hospital medical device evaluation center	Bactericidal		
	<i>Staphylococcus aureus</i> ATCC 6538 1×10 ⁷ CFU/ml	saline	1 Min.
		1% yeast extract	5 Min.
	<i>Pseudomonas aeruginosa</i> ATCC 15442 1×10 ⁷ CFU/ ml	saline	1 Min.
		1% yeast extract	1 Min.
	MRSA 021016166 1×10 ⁷ CFU/ ml	saline	1 Min.
		1% yeast extract	1 Min.
	VRE 020903043 1×10 ⁷ CFU/ ml	saline	1 Min.
		1% yeast extract	1 Min.
	Cefotaxime-resistant <i>Enterobacter cloacae</i> 021014337 1×10 ⁷ CFU/ ml	saline	1 Min.
		1% yeast extract	1 Min.
	Imipenem-resistant <i>P. aeruginosa</i> 021017153 1 × 10 ⁷ CFU/ ml	saline	1 Min.
		1% yeast extract	1 Min.
	Tuberculocidal		
	<i>Mycobacterium bovis</i> BCG 1×10 ⁷ CFU/ ml	saline	1 Min.
		1% yeast extract	5 Min.
	Fungicidal		
	<i>Candida albicans</i> ATCC 10231 1×10 ⁶ CFU/ ml	saline	5 Min.
		1% yeast extract	5 Min.
	<i>Aspergillus niger</i> ATCC 16404 1×10 ⁶ CFU/ ml	saline	5 Min.
		1% yeast extract	10 Min.
Research center of Gastroenterology in Dan Kook Univ.	<i>Helicobacter pylori</i> ATCC 43504 1×10 ⁸ CFU/ ml	-	15 Sec.
Institute of Animal Medicine GYEONGSANG National Univ.	Sporicidal		
	<i>Bacillus subtilis</i> ATCC 6633	-	5 Min.
ATS Labs - Antimicrobial testing lab in USA	Virucidal		
	Adenovirus type2 ATCC VR-846, ≥5.75log	1% FBS	5 Min.
	Herpes simplex type1 ATCC VR-733. ≥4.75log	1% FBS	5 Min.
	Influenza A virus ATCC VR-544, ≥5.75log	1% FBS	5 Min.
	Polio virus ATCC VR-1562, ≥3.75log	1% FBS	10 Min./ 30℃

(2) Efficacy of SCOTELIN® in clinic

Clinical study A.

In vivo test is operated in Gury Hospital of Hanyang University, Korea. The follows comments are summarized result for contribution comments in The Korea Society of Gastrointestinal Endoscopy.

Three endoscopes (A: 2003, B: 2000, C: 1997) and two automatic washers (a: 2003, b: 2000) that differed in purchasing year were used and we classified them into 4 groups (Aa: 35, Ab: 17, Cb: 8). For 3 months, a total of 86 gastrointestinal inspections with the use of endoscopes were included in the study. And then the endoscopes were cleaned and disinfected with SCOTELIN® for 10 minutes according to disinfection guideline of The Korea Society of Gastrointestinal Endoscopy. Sampling method is as bellow.⁹⁾

S1: Slowly poured with 30ml of sterilized saline through S1 and collected dropping liquids from tip insertion in sterilized test tube

S2: Swabbed surface with sterilized swab

S3: Swabbed surface with sterilized swab

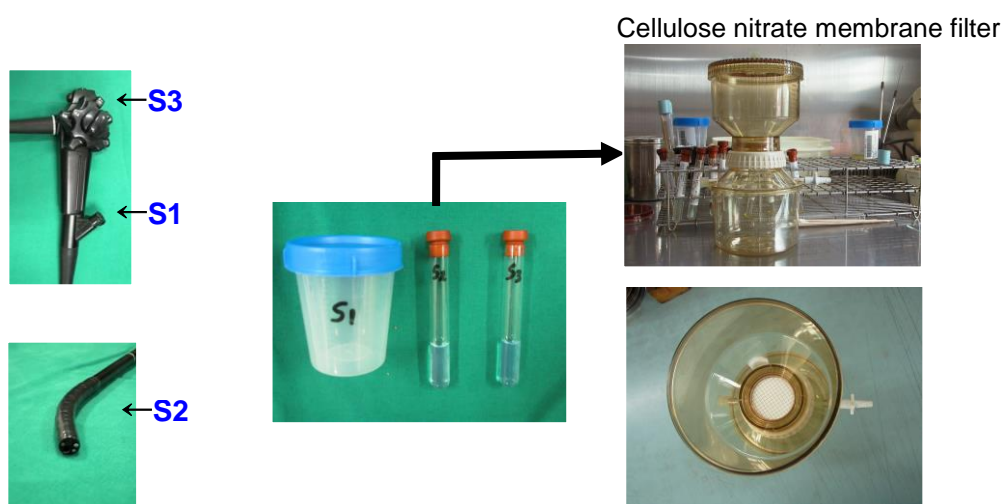


Figure 1. Swabbed position and method of samples in endoscopes in efficacy evaluation

Each collected sample was observed after tip of insertion tube incubate for 48 hours at 35 °C and 5% CO₂ using blood agar. Test result is as below table, and we compared the result with the result of using glutaraldehyde endoscope disinfectant which was published in *The Korea Journal of Gastrointestinal Endoscopy*^{10), 11)}

Table 2. Efficacy test result of SCOTELIN® in clinic (*in-vivo* test)

	Detection rate of microorganism			
	SCOTELIN® ¹⁰⁾			Glutaraldehyde disinfectant ¹¹⁾
		(disinfection time:10 minutes)		(disinfection time: 20 minutes)
S1	All cases	36.0 %	(31/86)	20.0 % (6/30)
	Aa case	11.4 %	(4/35)	
S2	All cases	5.8 %	(5/86)	0.0 % (0/30)
	Aa case	0 %	(0/35)	
S3	All cases	3.5 %	(3/86)	20.0 % (6/30)
	Aa case	0 %	(0/35)	

The older endoscopes and automated endoscopes reprocessors (AER) were, significantly the more culture positive rates were showed. This is because biofilm which formed in biopsy forceps channel of old machines was effectively removed by **SCOTELIN®** which is a peracetic acid disinfectant.

On the assumption that Aa group's (using the new endoscopes and AER) culture rate (36 cases) is a basis, it indicated low culture-positive rate of microorganism as S1 11.4%, S2 0%, S3 0%.¹⁰⁾ This shows lower culture-positive rate than that of glutaraldehyde disinfectant.¹¹⁾

19 among 86 samples which exposed positive reaction to *H.pylori*, exposed negative in *H.pylori* culture test and just 1 sample was positive in DNA PCR (polymerase chain reaction) test. These results proved excellent disinfection efficacy of **SCOTELIN®** in short time.

Clinical study B:

This is operated in KANTO Medical center NTT EC, JAPAN. Clinical in-used 18 gastroscopes and 18 colonoscopes were cleaned and disinfected in manual system and Olympus Automated Endoscopes Reprocessor (AER) system. These are cultured at S1 point for evaluation of **SCOTELIN®** efficacy. (Refer to Figure 1)

After clinical procedures, all endoscopes were cleaned following guidelines the Society of Gastroenterology, Japan. Those results showed disinfection efficacy of Scotelin®. Almost of detected bacteria were environmental bacteria, which were considerable as contaminated evidence in sampling procedure. Potency of Scotelin® (PAA concentration) is stable after 3 weeks as 0.3% PAA.









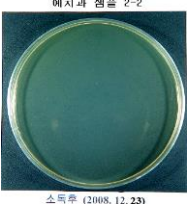
Table 3. Efficacy test result of **SCOTELIN®** in KANOT Medical center NTT EC (Clinical study)

Methods	Exposure time	Target	position	Detection rate of
Manual system	5 minutes	Gastrosopes	S1	2/18 cases (11.1%)
		Colonoscopes	S1	3/18 cases (16.6%)
AER	10 minutes	both	S1	2/30 cases (6.6%)

Clinical study C:

This is operated in Ye dental clinic, Seoul, Korea. Disinfection targets are 4 duplicating models of dental impression. All samples are swabbed before and after disinfection. They were sprayed on samples to fully immerse and rinsed out with tap water.

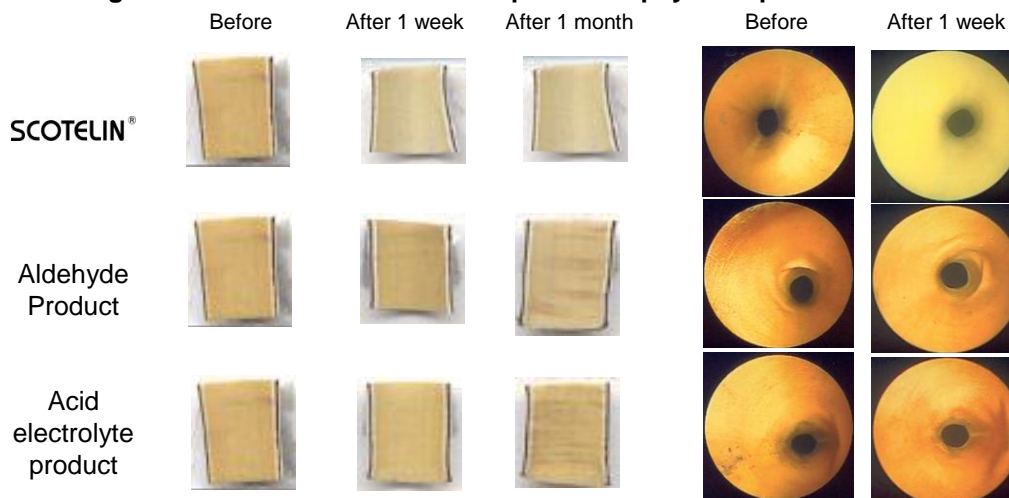
Table 4. Efficacy test result of **SCOTELIN®** in Ye dental clinic (Clinical study)

Test method	Tap water (passing automatic washer)	Sample 1 (upper piece)		Sample 1 (lower piece)	
		1-1 Before disinfection	1-1 After disinfection	1-2 Before disinfection	1-2 After disinfection
Total bacteria	0 CFU/ml  원수 (2008. 12. 23)	N.C. CFU/5ml  예지과 샘플 1-1 소독전 (2008. 12. 23)	0 CFU/5ml  예지과 샘플 1-1 소독후 (2008. 12. 23)	N.C. CFU/5ml  예지과 샘플 1-2 소독전 (2008. 12. 23)	0 CFU/5ml  예지과 샘플 1-2 소독후 (2008. 12. 23)
Test method		Sample 2 (upper piece)		Sample 2 (lower piece)	
		2-1 Before disinfection	2-1 After disinfection	2-2 Before disinfection	2-2 After disinfection
Total bacteria		N.C. CFU/5ml  예지과 샘플 2-1 소독전 (2008. 12. 23)	0 CFU/5ml  예지과 샘플 2-1 소독후 (2008. 12. 23)	N.C. CFU/5ml  예지과 샘플 2-2 소독전 (2008. 12. 23)	0 CFU/5ml  예지과 샘플 2-2 소독후 (2008. 12. 23)

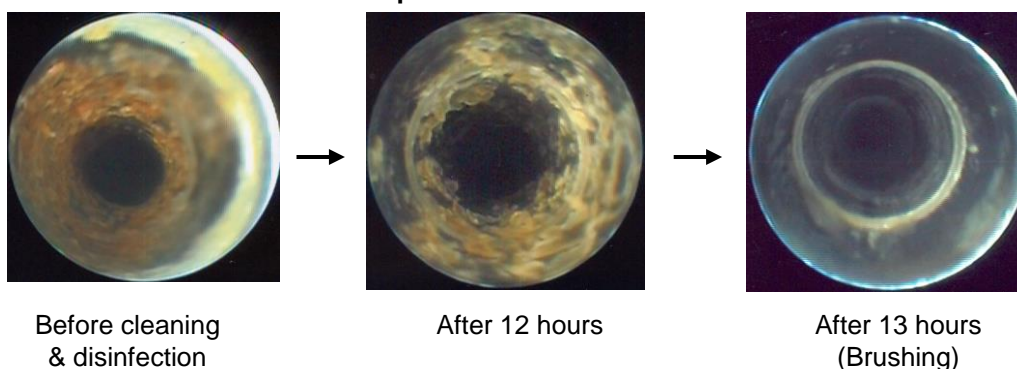
N.C. means “uncountable many bacteria detected”.

(3) CLEANING EFFECT OF SCOTELIN®

■ Cleaning effect test on tubes and inner part of biopsy forceps channel



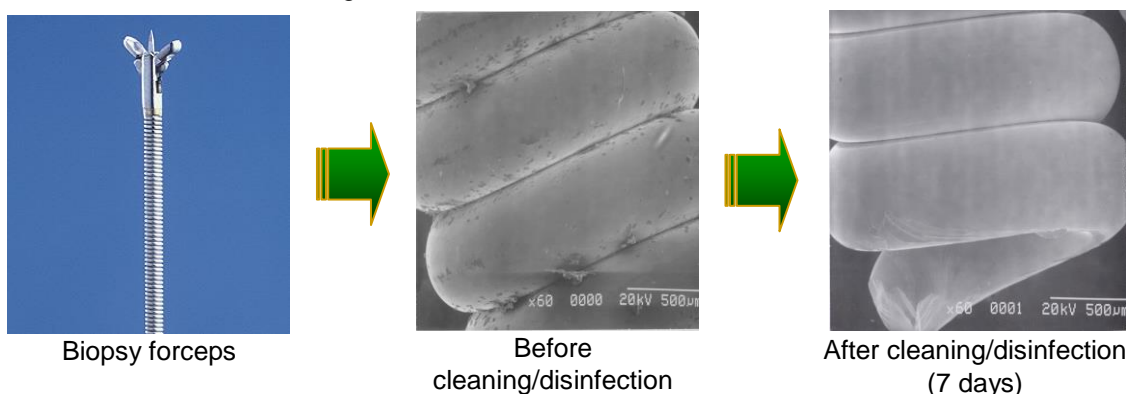
■ In vivo test on a bronchoscope



We can observe from the test result that **SCOTELIN®** showed better cleaning effects than pre-used disinfectant. Though **SCOTELIN®** can not remove big amounts of contamination pollutants just at one time but we predict that **SCOTELIN®** can remove all contaminations with continuously using for long period.

■ In vivo cleaning test on biopsy forceps

Biopsy forceps is one of the easiest parts to be contaminated because its dense structure and the using purpose (sampling a living creature organs). The first picture (left) is about general biopsy forceps. We observed the surface of biopsy forceps by Scan Electrical Microscopy (SEM). We could observe that the biopsy forceps were perfectly cleaned and disinfected after contacting with **SCOTELIN®**.



3. SAFETY OF SCOTELIN®

(1) Non-irritant and safe for users

Toxicity test of **SCOTELIN®** was tested in Nelson Lab, Institute in USA and KIT (Korea Institute of Toxicology) in Korea. The tests were about skin, ocular, inhalation toxicities of a dose. Peracetic acid 0.4% solution doesn't affect to human skin according to the documents of HSDB(Hazardous Substances Data Bank.¹²⁾ But chloride was prescribed to toxic chemical substance in OSHA(Occupational Safety and Health Administration.¹³⁾

Table 5. Toxicity result of **SCOTELIN®**

Test	Laboratory animal	Toxicity
Primary skin	Rabbit	No irritation
Skin sensitization	Guinea pig	No sensitization
Ocular irritation	Rabbit	Mild irritant
28 days repeat dose dermal toxicity	Rabbit	Mild dermal irritant & non toxic
Acute dermal irritation	Rabbit	Non-toxic
Acute oral toxicity	Rat	LD ₅₀ * > 2000mg/kg

*LD₅₀ : Lethal dose 50

(2) Compatibility of endoscope accessories and Auto Endoscope Reprocessor

The corrosiveness was observed by using parts of endoscope installation and physical synthetic resins for testing stability of **SCOTELIN®**. (Table 6)

We put the sample in **SCOTELIN®** that is undiluted solution for 5 days at 25℃ and checked results as weight method. Also O-ring of inside endoscope, some channels and biopsy forceps were tested as same method.

Table 6. Corrosiveness of **SCOTELIN®** in each parts of endoscope (Unit: g)

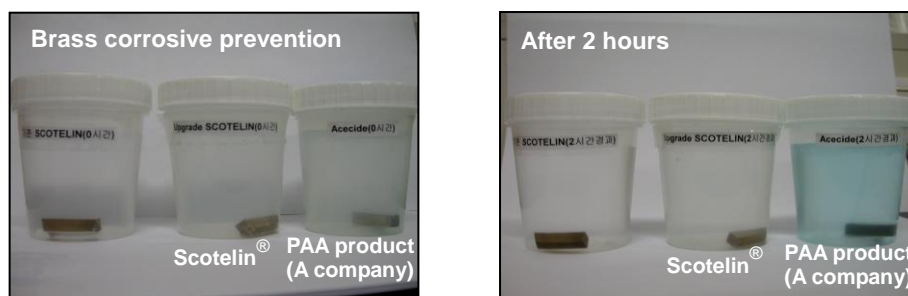
Part name	Before elution (g)	After elution (g)	Variation (g)
Bending rubber	1.24	1.24	0.00
O-ring	0.15	0.15	0.00
Biopsy channel	0.20	0.20	0.00
Suction channel	0.32	0.32	0.00
Air/water channel	0.23	0.23	0.00
Biopsy forceps	0.57	0.57	0.00

Table 7. Annual corrosion rate in each metal (Unit: mm/y)

Product name	Naval brass	Al alloy	Cr plating	SUS
SCOTELIN®	0.06	-	-	-
PAA product(KRD)	0.241~0.273	0.140~0.245	0.084~0.163	0.002~0.003
PAA product(A company)	0.252~0.330	0.199~0.245	0.181~0.244	0.005~0.009
Acid electrolyte product	0.464~0.509	0.028~0.080	0.008~0.024	0.011~0.013

*Institute of Industrial Science and Technology Pukyung National University, 2002.12

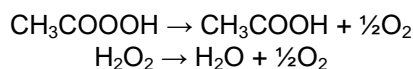
*** [Warning] There is little corrosion in case of Cu, Zn and kinds of their alloy, don't soak in SCOTELIN® for more 10 minutes(sterilization within 5 minutes)**



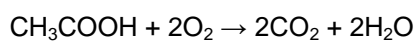
SCOTELIN® is developed by improving corrosiveness which is weak point of general PAA product, and is proved more excellent than other disinfectant in circulation in domestic.

(3) Environmental friendliness for disposal

SCOTELIN® oxidizes microorganisms, bloodstains and the viscous liquid by using nascent oxygen. The remained nascent oxygen becomes stable oxygen. During the reaction, peracetic acid is decomposed into acetic acid and hydrogen peroxide. In the mean time, hydrogen peroxide is decomposed into water and oxygen.



After acetic acid formatted from peracetic acid dissolves and removes calcium carbonate. Oxidized by nascent oxygen of hydrogen peroxide and peracetic acid, lastly decomposed into water and carbon dioxide.



We measured biodegradability of **SCOTELIN®** according to OECD 302C method (Inherent biodegradability). Put sample and 500ml of basal culture medium (mineral substrate) and 10 ml of inoculums ($10^4 \sim 10^7$ CFU/ml) into an airtight test container and keep airtight. Build an airtight test container in microbial measuring instrument of inhaling rate and keep at 25℃ and pour oxygen. After 28days, calculate BOD by measuring spent BOD by **SCOTELIN®**. Biodegradability was calculated as rate of BOD in Theoretical Oxygen Demand. As a result biodegradability is 84%; it indicated high level of natural disintegration rate

4. STABILITY OF SCOTELIN®

(1) Stability of mixed solution in high temperature

When store **SCOTELIN®** that mix additives with undiluted solution at high temperature (54°C), examined the change of PAA, HP, pH, stability. When stored for 14 days at high temperature (54°C), there was about 90% over initial concentration. This can consider that stability is indicated by 90% stability after 1 year when convert into normal temperature (20°C).

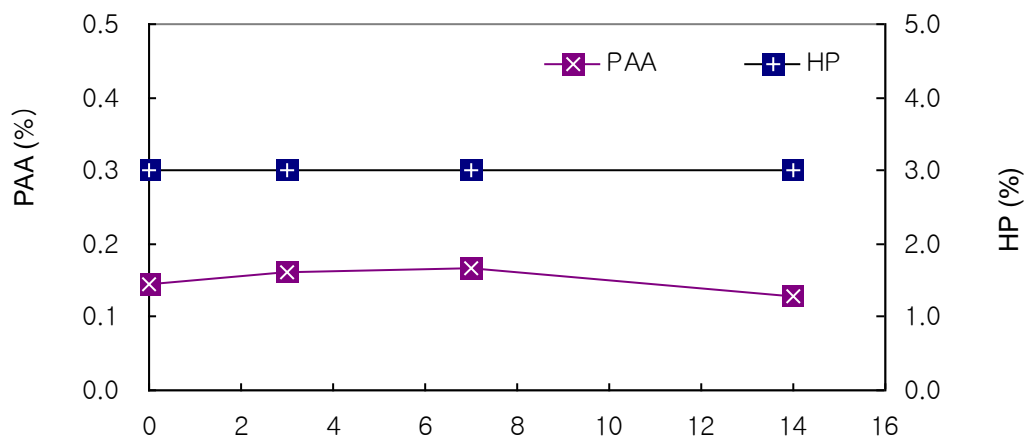


Figure 2. Stability of main ingredients of mixed solution (storage for 14 days at 54°C)

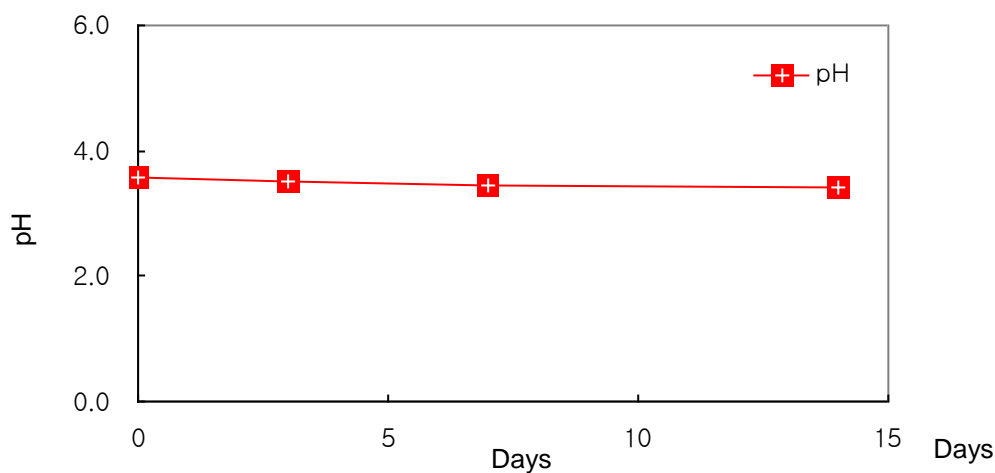


Figure 3. Stability of pH of mixed solution (storage for 14 days at 54°C)

(2) Stability of mixed solution in normal temperature

The mixed solution, when it was stored in room temperature, concentration was gradually increased to 110~130%. Originally when you open the peracetic acid product in established PAA product, peracetic acid slowly and naturally decomposed. But **SCOTELIN®** is developed by improving weak point of established PAA products, **SCOTELIN®** can slowly be made extra peracetic acid with the passage of time. It indicates that when use **SCOTELIN®**, stability is increased.

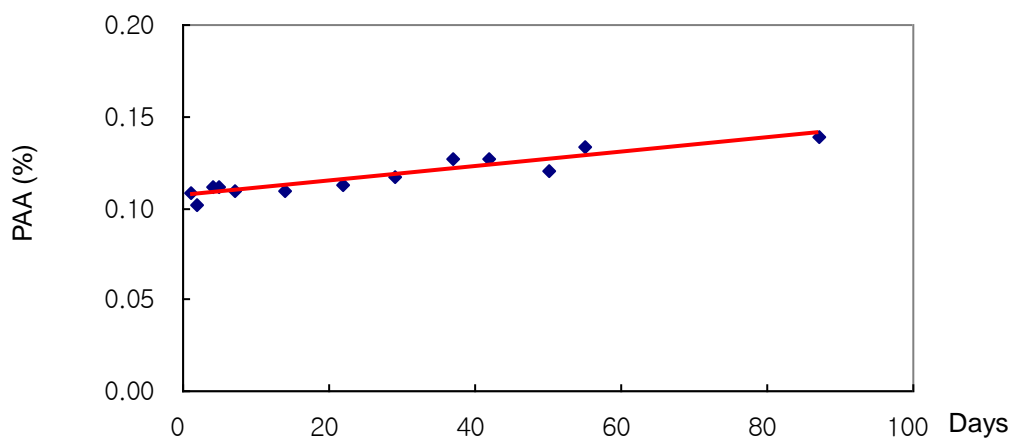


Figure 4. Stability of mixture solution in high temperature

(3) Stability and efficacy test of peracetic acid concentration in reusing

We checked the change of peracetic acid concentration and disinfection efficacy in reusing. When we use **SCOTELIN®** for 20 times per week, the change of peracetic acid concentration was indicated by graph, when we tested sterilizing power, we checked germs which were not detected. (Figure 5 and table 8)

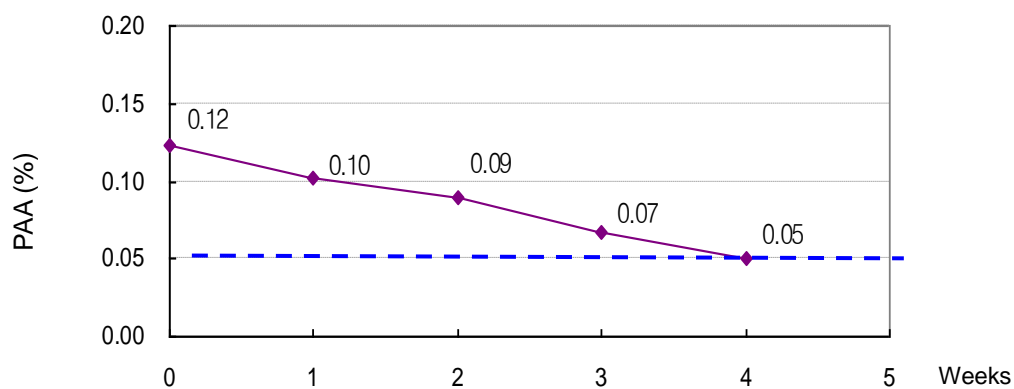
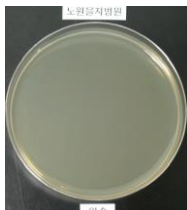
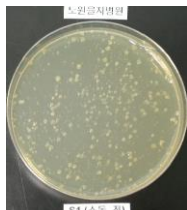
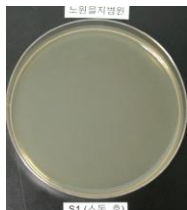
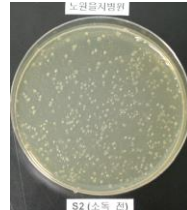
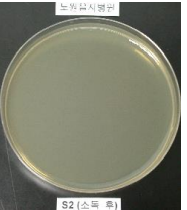


Figure 5. Change of peracetic acid concentration by reusing









Table 8. Field test result in E hospital (Sep. 22, 2005, PAA concentration 0.1%)

Test method	Tap water (passing automatic washer)	Suction channel(S1)		Tip of insertion tube(S2)	
		Before disinfection	After disinfection	Before disinfection)	After disinfection
Total bacteria	0 CFU/ml	7.0×10^4 CFU/20ml	0 CFU/20ml	1.9×10^4 CFU/swab	0 CFU/swab
					



5. DIRECTIONS FOR USE

- ♦ Applications:
Disinfecting and sterilization for the flexible endoscopes, performed manually or by AER
Disinfecting and sterilization for medical devices and surgical instruments
- ♦ Mix base solution (4 L) with additives (90 mL) and use.
- ♦ Users can decide the using time of **SCOTELIN®** according to types of endoscopes, pollution state, and infectious bacteria of patients.
- ♦ Before treat with **SCOTELIN®**, do wash the after-use endoscopes with normal cleaner first.
- ♦ Do rinse with alcohol or sterile water after treat with **SCOTELIN®**
- ♦ Cleaning and disinfection sequence is as follows, do take the leakage test before disinfection, if there is leakage, users must stop disinfection immediately.





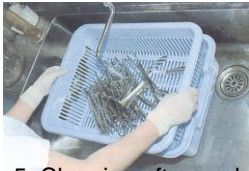



(1) Cleaning and disinfection of endoscopes by manual operation

- | | | | |
|---|---|--|---|
|  |  |  |  |
| 1. Advance preparations (clothes, hand washing) | 2. Recovery of instrument and arrangement | 3. Pre cleaning (detergent) | 4. Checking the water-leakage and inspection |
|  |  |  |  |
| 5. Disinfection & sterilization
Don't soak more than 10 min | 6. Cleaning after soaking | 7. Checking oddity | 8. Dry and arrangement (alcohol), |

(2) Cleaning and disinfection of endoscopes by using AER

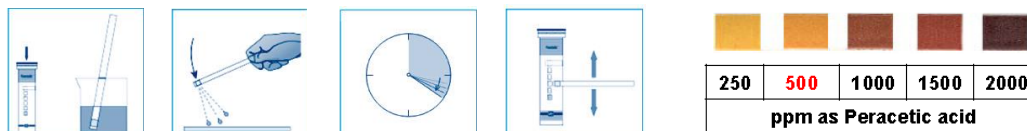
- | | | | |
|--|---|--|--|
|  |  |  |  |
| 1. Advance preparations (clothes, hand washing) | 2. Pre cleaning (Regular detergent) | 3. Setting in cleaning machine | 4. Checking the water leakage and inspection |
|  |  |  | |
| 5. Automatic disinfection & Sterilization, rinse,
Available for 4 weeks or 80 times | 6. Dry and arrangement (alcohol) | 7. Storage | |

(3) Cleaning and disinfections of accessories (biopsy forceps)

- | | | | |
|---|---|--|---|
|  |  |  |  |
| 1. Advance preparations (Clothes, cleaning) | 2. Arrangement and preparation after use | 3. Pre cleaning (detergent) | 4. Disinfection, sterilization
Don't soak over 10 mins |
|  |  |  |  |
| 5. Cleaning after soak and rinse thoroughly | 6. Dry | 7. Arrangement | 8. Separation of product after sterilization and sealing |

(4) Potency test of SCOTELIN®

You can check the minimum effective concentration of **SCOTELIN®** by using peracetic acid test strip on the market. To exist over 500 ppm of peracetic acid is to indicate that is enough to disinfect.



(IBT Peracid Test 기준)

- ① Dip test strip into using **SCOTELIN®** solution for 2 sec.
- ② After 2 sec, immediately pull out and powerfully shake off solution on the test strip.
- ③ After assigned time(15~30 sec.), compare the strip color with color table and judge the result by reading the figures.
- ④ If peracetic acid concentration is over 500 ppm, you can check that disinfection is effectively well away by **SCOTELIN®**.

■ Available strip

- ☐ HEMOCHECK Peracetic acid 2000 (MACHEREY NAGEL, Germany)
- ☐ PERACID TEST(IBT, US)
- ☐ Peracetic acid Merquoquant strip(MERCK, Germany, #110001)

(5) Residual test of SCOTELIN®

You can check residue of **SCOTELIN®** as hydrogen peroxide.

- ① After disinfection by **SCOTELIN®** and test.
- ② Dip residual test strip into this solution that finally rinse endoscopes and equipments for 1 sec and shake solution off.
- ③ After assigned time, compare strip with color table. If test result is judged as positive rinse again and then re-test. If the test result is below 0.5 ppm, you judge to be suit.

■ Available strip

- ☐ HEMOCHECK Peracetic acid 2000(Germany)
- ☐ Renal check® PX (IBT, USA.)
- ☐ Peroxide Merquoquant strip (MERCK, Germany, 110011)

6. STORAGE AND PRECAUTION

(1) Warning

Do not apply **SCOTELIN®** to human body.

First aid

- In case of contacting in eyes and skin, it may cause a damage or skin stimulus. So, you should notice that you reach out of skin, clothes when you use **SCOTELIN®**, after using, you thoroughly wash. In case of contacting to eyes and skin, rinse immediately with plenty of water.
- When use **SCOTELIN®**, users need to wear gloves, eye protection and right protective equipment or clothes.
- If you swallow **SCOTELIN®**, drink plenty of water for dilute and then don't try to vomit, contact doctor and take measures. And you don't gastric irrigation because there is damage of mucosa.

(2) Generally precautions

- Don't use **SCOTELIN®** by mixing with other disinfectants.
- Do not use this medicine for other purpose except for original purposes.
- When disinfect, wear protective equipment such as rubber gloves, gown, mask, protective glasses for stopping sticking or inhalation of disinfection and infectious substances.

(3) Directions in application

- Check the concentration of peracetic acid by peracetic acid test strip then use (concentration should be over 500 ppm).
- Check the hydrogen peroxide residue by using peracetic acid test strip (starch paper of potassium iodide or hydrogen peroxide test strip), if there still remains hydrogen peroxide residue, increase rinse time to remove the residue.
- Do store the mixture disinfectant in the container with cap, and user have to close the cap when using.
- Instruments of copperware must not be dipped in disinfectant for a long time (less than 10 minutes).
- Do check the structure material of medical instrument and if equipment was consisted of natural rubber, it would cause degeneration, raw rubber by repeat using would decrease disinfection effect.
- If the equipment was cracked or got rust, don't use because it would decrease the disinfection effect.
- Do check whether the water leaks or not when use in the endoscopes. If there is water leaks, don't use for protection of instruments
- Dip equipments into preparation disinfectant after cleaning and removing moisture because remaining moisture on equipment is possible to affect to efficacy of disinfectant and stability
- If want to extinct of spores, user have to disinfect for 10 min.

(4) Storage & handling

- Keep out of children.
- Do not store in direct rays of sun and high temperature.
- To put in other container, it should be factor of accident and undesirable in quality management, so store in original container.
- Do not pour back the used solution in any circumstances.

(5) Package/ Storage condition/ Shelf life

- Package : (Base 4 L + Additive 90 mL) X 2 / Box
 - Storage condition: room temperature (1~30℃)
 - Shelf life : 18 months (in original, sealed package)
- If expire dates of base and additive are different, it is limited by closer date of them.

III. CONCLUSION

Many research institutes in the world have reported environmental contamination and toxicity problems of aldehyde and chlorine group disinfectants. Especially, Aldehyde group disinfectant has strong toxicities to operators and need long contact time for sterilizing. It may also produce carcinogens when exposed to chlorine.²⁸⁾

All tests proved **SCOTELIN**®'s excellent efficacy. **SCOTELIN**® has shown a broad sterilizing power and sterilized microorganism including spores at low temperature and in low concentration. **SCOTELIN**® shows superior restraint power and removal power of biofilm which adhered on the inside and outside of endoscope channel. Furthermore **SCOTELIN**® was proved to be environmental friendliness product because **SCOTELIN**® can be perfectly decomposed into water and carbon dioxide and cause no 2nd environmental pollution.

IV. Reference

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