



Specializing in endoscope cleaning systems

PSK Connectors Pty. Ltd.

ABN 17 669 562 782

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Company Profile and Mission Statement

Company Profile

PSK Connectors is a privately owned Australian Company. Over the last ten years PSK Connectors has developed strong expertise in endoscopy cleaning devices and has established an excellent reputation in the Australian market as a company offering the latest technological improvements in endoscopic accessories as well as nurse and patient care. In 1994 the PSK Endoscope Cleaning System was presented for the first time at the medical trade show. Since then our Endo-Suction Cleaning System has been regularly presented to medical audiences during various trade shows in Europe, America and Japan. Research materials have also been presented by the Endo-Suction Cleaning System inventor at numerous conferences around the world.

PSK Connectors Pty Ltd is associated with the Society of Gastroenterology Nurses and Associates INC. (SGNA), Society of International Gastroenterology Nurses and Endoscopy Associates Society (SIGNEA), Gastroenterological Nurses College of Australia (GENCA) and the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA).

Mission Statement

PSK Connectors is in the business of designing, developing, commercializing and distributing new products that improve the efficiency of cleaning and maintaining all types of endoscopes.

Our sustainable competitive advantage comes from our ability to offer revolutionary products based on new patented methods that ensure increased efficiency and effectiveness in the medical industry.

We see huge growth opportunities in every direction. We understand the need for effective and efficient methods of cleaning endoscopes. We foresee strong growth in the number of procedures performed worldwide. Our intention is to expand efforts in exporting and distributing to capture the world market and facilitate business relationships.

ENDOSCOPE CLEANING - A PAIN IN NECK

Endoscope cleaning does not have to be a chore !

PSK Connectors Pty Ltd introduces the Endo-Suction Cleaning System. This unique, patented product is based on the concept of cleaning endoscopes through suction as opposed to pushing syringes.



The Endo-Suction Cleaning System is available for all Pentax,

VALUES:

- Better patient care through less risk of post-procedural infections.
- Less risk of costly litigation due to cross-contaminations.
- Less work related staff insurance claims.
- Less delayed or cancelled endoscopy procedures.
- Cost of the Endo-Suction Cleaning System will be saved in labour costs alone within

COMPLETE SYSTEM

Get started today. Order your introductory kit.

Each kit is a complete system. It comes with Endo-Suction Cleaning System, a suction and rinsing units and is tailor made to suit your individual needs. By using the Endo-Suction Cleaning System your hospital or clinic will enjoy all the benefits and in

To order or obtain more information visit our



PSK Connectors Pty.
Ltd.

P.O. Box 928 Mt. Waverley, VIC 3149,
AUSTRALIA

BENEFITS:

- No more pushing syringes.
- Eliminates blockages.
- Much quicker than syringe method.
- Increases certainty of an endoscope being available for next procedure on time.
- Simple to use.
- Less repetitive physical action.
- Invented by a nurse for nurses.

A comparison of using the Endo-Suction Cleaning System (ESCS) versus syringe method

Endo-Suction Kit System

1. Cleaning



An endoscope is connected to a suction via ESCS and immersed in cleaning solution. Fluid flows simultaneously through all channels.

Time spent: 15 to 30 seconds.

2. Draining the cleaning solution



Take endoscope out of the solution. All channels are drained simultaneously.

Time spent: 3 to 5 seconds.

3. Rinsing from the cleaning solution



Immerse endoscope into drinking water for rinsing the cleaning solution using suction.

Time spent: 5 to 10 seconds.

4. Draining, then disinfecting or placing into an automatic washer



Take endoscope out of the water. All channels are drained simultaneously.

Time spent: 3 to 5 seconds.

5. Rinsing the residual from the disinfectant



Immerse into drinking water. All channels are rinsed simultaneously. No assistance is required.

Time spent: 60 to 120 seconds.

6. Drying



All channels of the endoscope are drained simultaneously. No assistance is required.

Time spent: 3 to 5 seconds.

Manual syringe method

Requires pushing 20ml syringe to individual channels.
Total: minimum 12 times.
You have to remember to count.

Time spend: minimum 315 seconds.



Requires pushing 20ml syringe to individual channels.
Total: minimum 3 times.
You have to remember to count.

Time spent: minimum 40 seconds.



Requires pushing 20ml syringe to individual channels.
Total: minimum 12 times.
You have to remember to count.

Time spent: minimum 210 seconds.



Requires pushing 20ml syringe to individual channels.
Total minimum 12 times.
You have to remember to count

Time spent: minimum 40 seconds.



Requires pushing 20ml syringe to individual channels. Total minimum 24 times.
You have to remember to count & assistance is required.

Time spent: minimum 440 seconds.



Requires pushing 20ml syringe to individual channels. Total minimum 3 times. You have to remember to count & assistance is required.

Time spent minimum 40 seconds.



**Total syringe pushing
Total time**

**0
89 - 175 seconds**

**Minimum 66 times
Minimum 1085 seconds**

Testimonial



11/2002 MON 11:42 ID:

TEL:

P: 01



PENINSULA
ENDOSCOPY
CENTRE

17 Yuille Street Frankston 3199
Tel: 9783 1847
Fax: 9781 1250
E-Mail: jdennison@endoscopy.com.au
Web Site: www.endoscopy.com.au

To whom it may concern,

We would like to inform that since Barbara Puszko developed and implemented in 1993 her PSK Endoscope Cleaning System also known as Endo-Suction Cleaning System it has been used for cleaning of all endoscopes in our clinic.

It is our policy to regularly send samples for microbiology testing. The results from the last 9 years showed no signs of any bacteria growth.

If you would like to get details about the procedure and testing protocols please contact the PSK Connectors Pty Ltd directly.

Please find attached the latest microbiology results related to endoscopes cleaned by the Endo-Suction Cleaning System.

Signed: _____
Mr P Gray
Director

Signed: _____
Mrs J Dennison
Director of Nursing

Microbiology Testing Protocols & Procedures



CONNECTORS

About microbiological testing of endoscopes

The process of medical trials of PSK Endoscope Cleaning Systems for Pentax endoscopes utilized at Peninsula Endoscopy Centre, Melbourne, Australia took place between 20th February 1991 and 10th January 1994. All pathology tests were performed at Dr. Neil Trezise Pathology or Gribbles Pathology, Collingwood for infection control.

As an example we include a copy of the results from the test from 10th January 1994.

Here we include fragments from Infection and Endoscopy (3rd edition) prepared by Gastroenterological Society of Australia and Gastroenterological Nurses Society of Australia which were used during all the tests.

MICROBIOLOGY TESTING OF ENDOSCOPES

Whether or not bacteriological screening of standard endoscopes and colonoscopes needs to be performed and if so how frequently remains controversial. On the other hand MICROBIOLOGICAL MONITORING OF DUODENOSCOPES IS ESSENTIAL. Numerous studies document the transmission of infection by contaminated duodenoscopes during E.R.C.P. In many of these outbreaks the endoscopes units involved were unaware of the instruments contamination and the serious clinical infections being caused. The outbreaks were frequently overlooked for prolonged periods and only came to light as a result of hospital infection control measures.

1. RECOMMENDATIONS

1. If major changes are made to the cleaning regimen, unit personnel or if there is a clinical of cross infection related to endoscopy, then microbiology screening should be undertaken in conjunction with consultation by a clinical microbiologist
2. Duodenoscopes should have regular bacteriological monitoring, preferably monthly.
3. Bacteriological monitoring of endoscopes and colonoscopes together with the endoscopy unit work environment is considered to be useful but not mandatory. Where performed, a four to six monthly interval is usually adequate.
 1. Disinfecting machines must have regular bacteriological monitoring. Endoscopes processed by these machines must also have regular bacteriological monitoring.

1. MICROBIOLOGICAL TESTING PROTOCOLS

Method of Sampling

1. 10mls of sterile water (or Ringer's solution) is withdrawn from a freshly opened bottle using a sterile needle and syringe and put into a sterile universal container.
2. A sterile endoscope brush is passed down the biopsy channel, withdrawn and swirled in the universal container containing the sterile water (or Ringer's solution). The brush will need to be handled using sterile gloves. The endoscope brush should be sterilised by autoclaving or gas sterilization.
3. A further 10mls of sterile water (or Ringer's solution) is flushed through all the channels (air-water, suction) by using a sterile syringe. The rinse fluid (20mls to 30mls) is collected in another sterile universal container.

Microbiology Testing Protocols & Procedures



CONTROLLED COPY

Name: Endoscope washings
No. mi-w-75 Version: 21/08/2000
Authorised: S Lloyd Jones Page 1 of 3

ENDOSCOPE WASHINGS

(This includes gastroscopes, duodenoscopes, endoscopes, colonoscopes and bronchoscopes)

1 Sample and Sample Preparation:

Washings or brushings collected by hospital/clinic staff according to guidelines from Gastroenterology Society of Australia.

2 Reagents, Materials & Preparation:

Culture Media – refer to Work Instruction 4.2.

3 Instrumentation and Apparatus:

35°C incubator, 30°C incubator, sterile centrifuge tubes.

4 Work Instruction:

- 4.1 Classify the sample as clear or cloudy and record on endoscope worksheet (mi-f-59)
- 4.2 Using Labsystem labels label processing material as follows
 - 1 × yellow cap sterile centrifuge tubes
 - 1 × HBA plates
 - 2 × mycobacteria (Brown and Buckle) slopes, one labelled for incubation at 30°C and the other for incubation at 35°C.
- 4.3 Centrifuge 10ml of sample (2500rpm for 10 minutes).
- 4.4 Decant off 9.0 ml.
- 4.5 Using a 100µl pipette, inoculate HBA plate and streak out with a wire loop.
- 4.6 Using a 100µl pipette, inoculate the 2 mycobacteria slopes.
- 4.7 Place inoculated HBA plates in CO₂ incubator at 35-37°C for 24-48 hours.
- 4.8 Place mycobacteria slopes in TB lab. in the appropriate incubators
- 4.9 Examine HBA plates at 24 and 48 hours for bacterial growth.
- 4.10 Quantify bacterial growth. (scanty, light, moderate or heavy).
- 4.11 Pure cultures should be identified as per identification manual.
- 4.12 Low numbers (less than 10 colonies) of environmental organisms may be isolated. These organisms are more likely to represent collection contamination rather than a significant problem with disinfection or cleaning.

Microbiology Testing Protocols & Procedures



CONTROLLED COPY

Name: Endoscope washings	Version: 21/06/2000
No: mi-w-75	Page 2 of 3
Authorised: S Lloyd Jones	

4.13 Use the following codes for reporting results where appropriate.

If no growth,

NGAO: No growth aerobically after two days incubation.

If no growth or growth of an occasional spore-forming organism only, add comment
ADEQ: Cleaning/ disinfection of the endoscope is likely to be adequate but the presence of bacteria in very low numbers cannot be excluded.

If less than 10 colonies of other organisms isolated add the comment
COLCON: This is likely to represent collection contamination rather than a significant problem with disinfection or cleaning.

If a significant growth is isolated then add the comment
INAD: Number of organisms recovered suggests inadequate cleaning/disinfection.

4.13 Refer cultures with significant growths to Medical Microbiologist for interpretation.

4.14 Mycobacteria Cultures: Refer to Examination of Mycobacteria Cultures.
(Controlled documents no. mi-w-62).

5 Calculations

Not applicable.

6 Quality Control:

Not applicable

7 References:

Microbiological Testing of Endoscopes and Automatic Endoscope Disinfectors –
Gastroenterological Society of Australia.

8 Notes:

ATTACHMENTS:

Endoscope worksheet (mi-f-59)

Microbiological Testing of Endoscopes and Automatic Endoscope Disinfectors
Gastroenterological Society of Australia.

Microbiology Testing Protocols & Procedures

CONTROLLED COPY

Name: Endoscope washings
No: mi-w-75 Version: 21/06/2000
Authorised: S Lloyd Jones Page 3 of 3

ENDOSCOPE WORKSHEET

Document Name: Endoscope Washings

Document Number: mi-w-75

Original Author: Máire Lyddy

Directory: maire/manuals/environmental specimens

File Name: Endoscope washings

Backup Information: master disc 19

Date:	Reviewed by:	Edits:	Version
21/06/00	Máire Lyddy S. Lloyd Jones	Revised and rewritten in ISO format.	21/06/2000

Microbiology Testing Protocols & Procedures



5 15 TUE 12:57 FAX

CONTROLLED COPY

ENDOSCOPE WORKSHEET

Name: EndoscopeWorksheet	Version: 26/06/00
No: mi-f-59	Page 1 of 2
Authorised: S.Lloyd Jones	

SCOPE	TEST No.9901	Signature
Type of scope	Serial No.	
Site of Specimen		Set up []
Appearance		
CULTURE		Culture []
Free form		
		I []
COMMENT		C []
		Verified
		I []
		C []
CULTURE	24HRS []	48 HRS []

Microbiology Testing Protocols & Procedures

Appendix 2

Infection control and microbiology testing

Microbiology tests were performed at the Peninsula Endoscopy Centre 24 hours after cleaning each endoscope. Individual endoscopy channels were flushed with Ringer solution. The specimens were sent to the Pathology Department. From more than 100 tests performed, only one showed candida growth. This was due to the endoscope not being completely dried, and left wet overnight.

All microbiology tests were performed according to GENSA and GE Society Guidelines in Australia.

Summary results of microbiological study 1994-1997
Peninsula Endoscopy Centre, Melbourne, Australia

Year	No of tests	Results
1994	24	no growth
1995	24	23 times no growth, 1 time Candida
1996	25	no growth
1997	24	no growth

All microbiology tests performed according to GENSA and GE Society Guidelines.

Summary of results from the microbiological study. As can be seen, from 100 tests only one showed candida growth.

To further investigate any post endoscopy problems, the following form was designed.

Microbiology Testing Protocols & Procedures



NURSING PROGRESS SUMMARY

- | | | |
|--|---|---|
| <input type="checkbox"/> Awake and alert | <input type="checkbox"/> S/B Endoscopist | <input type="checkbox"/> Report Given |
| <input type="checkbox"/> Tolerating fluids <input type="checkbox"/> Diet | <input type="checkbox"/> Discharge medication | <input type="checkbox"/> Discharge Instructions Given |
| <input type="checkbox"/> Ambulating unassisted | <input type="checkbox"/> IV Cannula Removed | <input type="checkbox"/> Appointment Made |
| | | <input type="checkbox"/> Further Investigations |

Transport By:

Time: Pulse Resp. BP/.....

Comments:

Discharge time: hrs

Discharge authority:

DISCHARGE TELEPHONE FOLLOW UP

1. Have you had any problems since discharge?

☐ No ☐ Yes

If so, please comment

2. Did you and/or your family understand the discharge information you received?

☐ No ☐ Yes

If so, please comment

Nurses Name:

Date:

Figure 23 Nursing progress summary form used during the study to investigate any post endoscopy problems

This form has been used to call each patient within 24 hours after an examination. Since the introduction of the Endo-Suction Cleaning System in 1994, no post-endoscopy infections were reported.

The Pre-Cleaning System for Endoscopes was used 2,570 times for pre-cleaning before using Steris System 1 machine and from all the procedures, the 'Chemical Monitoring Strip' for Steris Process Product (No S3010) has shown the endoscope to be 100% clean every time.

During regular everyday usage of the Pre-Cleaning System in two endoscopy clinics (where more than 10,000 procedures were performed), the probability of a blockage occurring was $P < 0.0001$. Later it was found that this incident occurred due to the fact that a new nurse did not use the system.

Year	No of blockages	Results
1994	No blockages	No repair of air/ water nozzle.
1995	No blockages	No repair of air/ water nozzle.
1996	No blockages	No repair of air/ water nozzle.
1996	No blockages	No repair of air/ water nozzle.

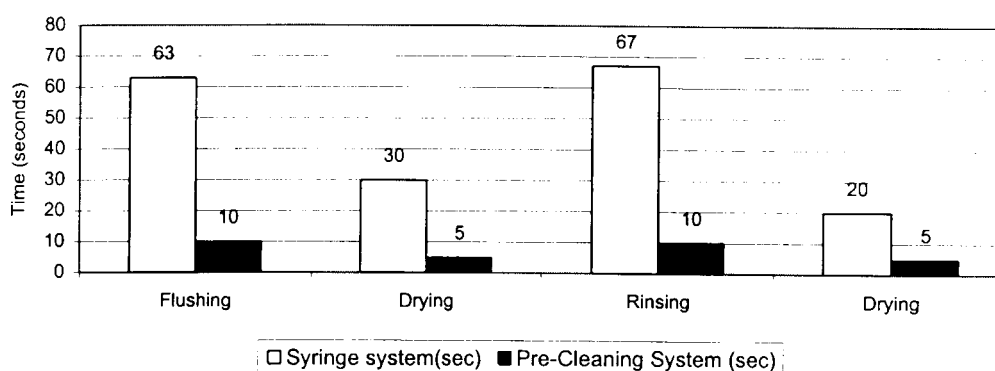
Savings in Pre-Cleaning Time

Pre-cleaning time

Comparison of average pre-cleaning time associated with syringe method and the Pre-Cleaning System for Pentax colonoscopes & gastroscopes

	Syringe system(sec)	Pre-Cleaning System (sec)
Flushing	63	10
Drying	30	5
Rinsing	67	10
Drying	20	5

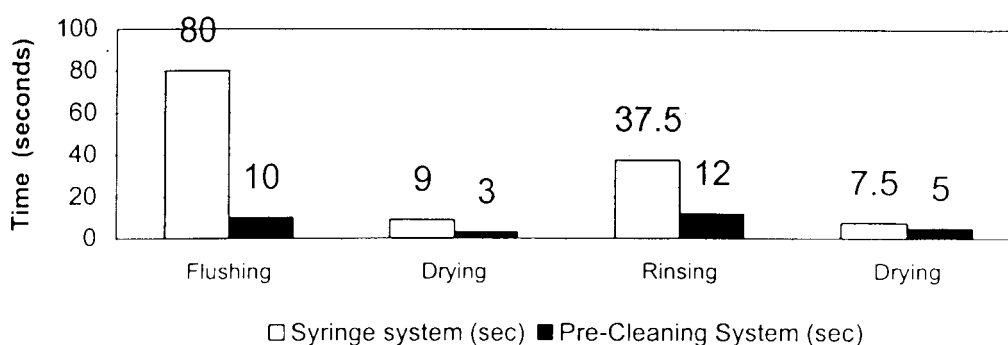
Average cleaning time of Pentax colonoscopes & gastroscopes with 3 channels



Comparison of average pre-cleaning time associated with syringe method and the Pre-Cleaning System for Olympus flexible gastrointestinal (GI) endoscopes with 4 channels

	Syringe system (sec)	Pre-Cleaning System (sec)
Flushing	80	10
Drying	9	3
Rinsing	37.5	12
Drying	7.5	5

Average cleaning time of Olympus Olympus flexible gastrointestinal (GI) endoscopes with 4 channels



Savings in Pre-Cleanig Time for Pentax duodenoscopes



Average pre-cleaning time of Pentax duodenoscopes

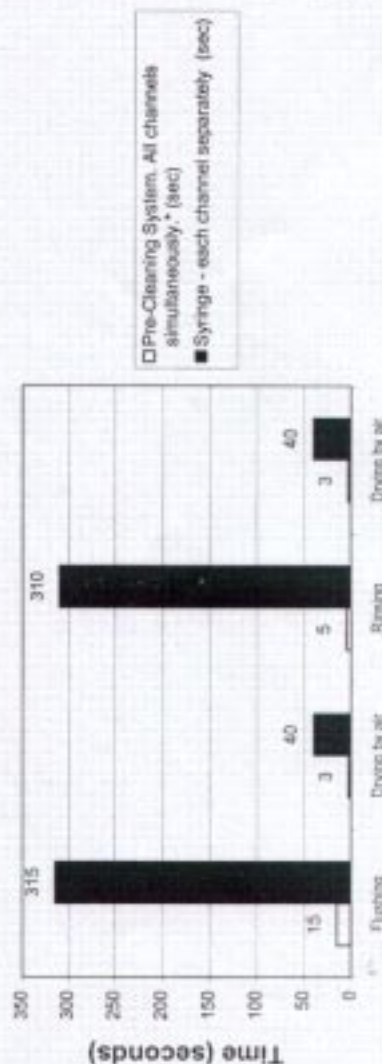
180ml as required by Gastroenterological Nurses Society of Australia and Gastroenterological Society of Australia guidelines



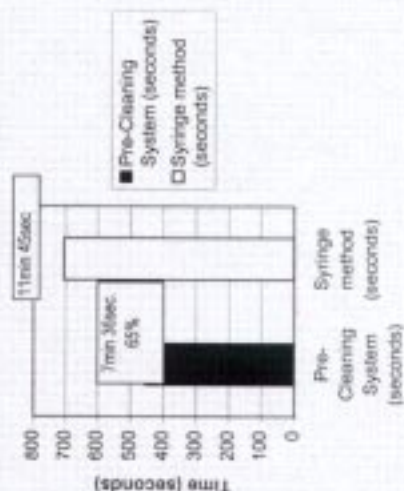
	Pre-Cleaning System				Syringe method				Elevator channel (sec)	Total Time
	Pre-Cleaning System, All channels simultaneously* (sec)	Biopsy channel only (sec)	Suction channel only (sec)	Air/water channel only (sec)	Elevator channel only (sec)	Syringe - each channel separately (sec)	Biopsy channel (sec)	Suction channel (sec)	Air/Water channel (sec)	
Flushing	15	5	6	90	210	315	25	20	30	456
Drying by air	3	3	3	5	5	40	10	10	10	705
Rinsing	5	5	6	90	210	310	25	20	25	
Drying by air	3	3	3	5	5	40	10	10	10	

* with elevator channel closed

Comparison of the Pre-Cleaning System for Pentax duodenoscopes vs syringe method



Comparison of total time of pre-cleaning Pentax duodenoscope



Savings in Pre-Cleanig Time for Olympus duodenoscopes

Average pre-cleaning time of Olympus duodenoscopes

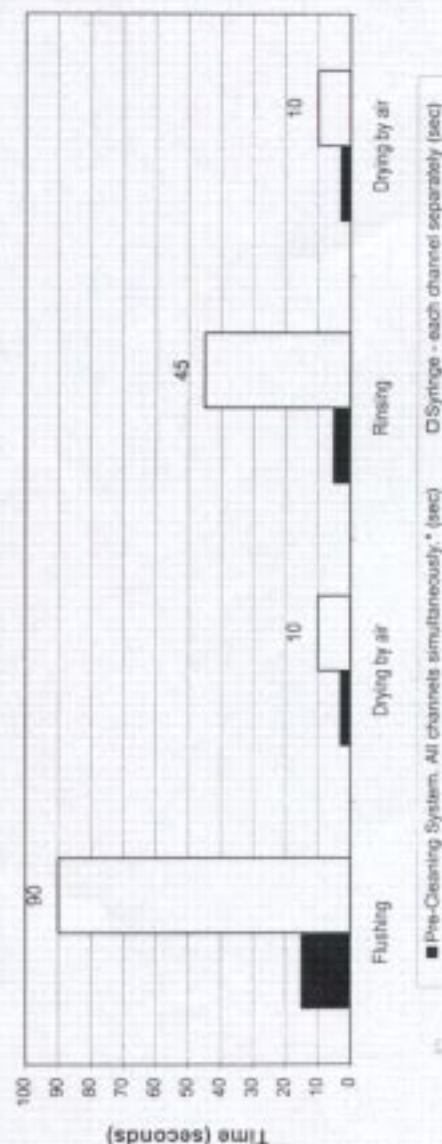
180ml as required by Gastroenterological Nurses Society of Australia and Gastroenterological Society of Australia guidelines



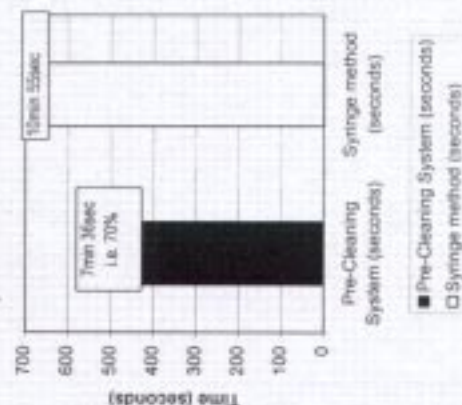
	Pre-Cleaning System					Syringe method			Pre-Cleaning System (seconds)	Syringe method (seconds)	Total Time
	Pre-Cleaning System. All channels simultaneously.* (sec)	Biopsy channel only (sec)	Suction channel only (sec)	Air/Water channel only (sec)	Elevation channel only (sec)	Syringe - each channel separately (sec)	Elevation channel only (sec)				
Flushing	15	5	6	90	210	90	20ml		456		655
Drying by air	3	3	3	5	5	10					
Rinsing	5	5	6	90	210	45					
Drying by air	3	3	3	5	5	10					

* with elevator channel closed

Comparison of the Pre-Cleaning System for Olympus duodenoscopes vs syringe method



Comparison of total time of pre-cleaning Olympus duodenoscopes



Therapeutic Goods Administration, Australia (TGA) Regulations Exempt



Therapeutic
Goods
Administration

PO Box 100 Woden ACT 2606 Australia

☐ Woden Telephone: (06) 289 1555 Fax: (06) 289 8709 ⁸⁷
☒ Symonston Telephone: (06) 239 8444 Fax: (06) 239 8605



COMMONWEALTH
DEPARTMENT OF
HUMAN SERVICES
AND HEALTH

Contact Officer: Helen Kosmas

Ms Barbara Puszko
PSK Connectors Pty Ltd
5 Dart Crt
MT WAVERLEY VIC 3149

Dear Barbara

Further to your letter of the 20 December 1995 and following our telephone conversation on 5 January 1996, regarding the PSK Endoscope Cleaner and whether it requires listing in the Australian Register of Therapeutic Goods (ARTG). The PSK Endoscope Cleaner as presented in the documents provided is not considered to be a therapeutic good under Section 3 of the Therapeutic Goods Act 1989.

Under Section 3 these goods are not considered to be for therapeutic use. Therapeutic use is defined for the purposes of the Act as:

- (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or
- (b) influencing, inhibiting or modifying a physiological process in persons or animals; or
- (c) testing the susceptibility of persons or animals to a disease or ailment;

and includes use in, or in connection with, contraception with, contraception or testing for pregnancy

As such, this product is not subject to the controls of the Therapeutic Goods Act and Regulations

Yours faithfully

HELEN KOSMAS
SENIOR TECHNICAL REVIEWER
THERAPEUTIC DEVICES BRANCH
8 January 1996

FDA (Food and Drug Administration) U.S.A. Approval



08:00 12:40 FAX 3389923586

THE SCOPE EXCHANGE, INC

002-003



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2000

PSK Connectors Pty. Ltd.
c/o Mr. Brian Newton
President
The Scope Exchange
311 South Main Street
Kernersville, NC 27284

Re: K000216
Pre-Cleaning System for Endoscopes
Dated: April 14, 2000
Received: April 17, 2000
Regulatory Class: II
21 CFR §876.1500/Procode: 78 KOG
Regulatory Class: I
21 CFR §876.1500/Procode: 78 FEB

Dear Mr. Newton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

FDA (Food and Drug Administration) U.S.A. Approval



08:00 12:41 FAX 3368923588

THE SCOPE EXCHANGE, INC

003:003

K000216 Page 1 of 1

INDICATIONS FOR USE STATEMENT

510(k) Number: K000216/

Device Name: Pre-Cleaning System for Endoscopes

Indications For Use: Pre-Cleaning System is used for flushing flexible gastrointestinal (GI) endoscopes prior to higher level disinfection/sterilization.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒

OR

Over-The-Counter Use

(Per 21 CFR §801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number

K000216

Presentation to the 39th Gastroenterological Endoscopy Conference
29 Nov 1997 Tokyo International Forum

Topic: A comparison of cleaning and sterilising endoscopes by hand by suction cleaning versus by injection method.

*By doctors and nursing staff at the Endoscopy Centre at
Teikyo University Hospital*

When washing and sterilising endoscopes it is important to regard all patients as sources of infection, and it is most desirable to have the endoscopes soak in 2% *Gurutaruarudehido** for ten minutes after they have been thoroughly cleaned.

However, due to the fact that there are limited number of endoscopes and few sterilising machines, and many examinations to get through in a specific length of time, the reality is that washing and sterilising by hand is inevitable.

Compared to washing and sterilising by machine, washing and sterilising by hand can be done relatively quickly and this is an advantage. However, the disadvantage is that it takes significant effort to do it by hand. Until now we have managed with in the endoscopy cleaning section by using an injection type apparatus to repeatedly inject and suck the cleaning fluids through and rinse the scopes.

We then had an opportunity to use the PSK cleaner, an apparatus using a water pump and cleaning tubes which can clean and sterilise the endoscopes. We compared the effectiveness of the cleaning process, of the level of effort required by staff, the time it took and the overall process using the PSK cleaner, and the method we had used up until now.

Page 2

Slide 1

The PSK cleaner

Diagram

Comment:

This is the PSK cleaner

- (1) Suction pump: when this is negative, it becomes (30PSI: 2 points of atmospheric pressure)
- (2) The red section is connected to the forceps end of the endoscope and the suction route opening clasp and the end of the forceps is attached with tubing
- (3) The blue part is connected to the water pump opening and the air/water pump tubing
- (4) The air/water pump channel has a metal cap

* You can suck and wash, rinse and dry the forceps end/tip of the endoscope

Slide 2

Cleaning with the injection method (apparatus to clean the entire tube, used until now)

Diagram

Comment: This is the method used until now, this apparatus does the same thing as the PSK cleaner, namely, washing, rinsing and drying.

2.

Slide 3

Cleaning-Sterilisation specifications

1. After use: soaking in disinfectant (*Insulnet* 120 strength)
2. Washing the outside of the endoscope (neutral disinfectant)
3. Suction and brushing the biopsy channel (once)*
4. Soaking in *Insulnet* (five minutes at 350)*
5. Soaking in over 2% of *Gurutaruarudehido* for ten minutes)*
6. Rinsing (washing machines 2 – 4 minutes)

(*A comparison of both cleaning methods)

Comment: After use the endoscopes were sucked through with *Insulnet*, were washed on the outside, were soaked in *Insulnet* and disinfected with *Gurutaruarudehido*

Slide 4

Items surveyed

1. Effectiveness of cleaning
 - a. after brushing
 - b. after soaking
2. Length of time for tasks
 - a. attaching the apparatus and injecting the disinfectant and oxygen
 - b. washing with water
 - c. disinfecting
3. Level of effort for tasks
 - a. Attachment of the apparatus
 - b. Injecting with the disinfectant and oxygen
4. Safety aspects
 - The level of contaminated residue from the patient

Comment: The items surveyed were; Effectiveness of cleaning, length of time for tasks, level of effort involved in the tasks, and the safety (hygiene) aspects.

Slide 5

Effectiveness of cleaning results

1. Level of contamination of the endoscope
Endoscopes with over five biopsies where the endoscope is in contact with blood
2. Sampling
 - a. Place the tip of the endoscope in a test tube to a depth of 20ml
 - b. From the forceps end inject and flush out 5 ml of saline solution (10 times)
 - c. Brushing (3 times)
 - d. Injecting and flushing out (10 times)

3. Reaction to residual blood contamination (Hermastics; + reaction is positive)

Comment: The results of the cleaning were determined by the reaction to the residual blood

Slide 9 Result 4

Effort required to perform tasks

PSK Cleaner	Set up took time Suction tube easy to connect		
Other method	Attachment/setup <i>Insulnet</i> flush	Flush 200ml	<i>Gurutaruarutehido</i> * Flush
	10 times	+10 times	+10 times = 30 times (per each endoscope)
	Easy to set up but takes substantial effort to use		

Comment: In terms of ease of use, the PSK cleaner took some time to attach, but once attached, it was easy to use. On the other hand, the Other, or conventional method, was easy to attach but required substantial effort to use.

Slide 10 Result 5

Safety aspects of use

PSK Cleaner	In normal use, there was no splashing (spattering) of liquids
Other method	When flushing, there was some splashing, or spattering of liquids
Comment:	In terms of safety of use, splashing of liquids occurred when using the "Other" or conventional methods, but did not occur when using the PSK Cleaner.

Slide 11

Final Summary

	<u>PSK Cleaner</u>	<u>Other method</u>
1. Cleaning effect:	Same effect if twice the volume of fluids used to flush	Good
2. Setting up	Good	Takes time
3. Effort required	Good	Substantial effort required
4. Safety	Good	Danger of contamination

Comment: From the above results we determined that the "other" or conventional method was effective as a cleaning method. However, it is a time consuming method, takes substantial physical effort and some danger of contamination exists.

On the other hand, the PSK cleaner had the same cleaning effectiveness if used for the same amount of time as the "other" or conventional method. In addition, there was hardly any effort required and its safety was of a high standard.

Notes:

Gurutaruarutehido = presumably a chemical solution for disinfection. English equivalent unknown to me
Insulnet = presumably a chemical solution for disinfection. English equivalent unknown to me

"Other method" refers to the conventional methods the Centre has been using

Slide 6

Effectiveness: 1 Effectiveness of washing

Comparison of the Endoscope Cleaner and the other (conventional) methods of cleaning

A. *Insulnet* 200ml, brushing once + 200ml of flushing

<u>Apparatus:</u>	<u>Reaction to residual blood</u>					<u>Degree of positiveness</u>
	-	±	+	2+	3+	
Endoscope cleaner	7	3	0	0	0	3/10
Other method	9	1	0	0	0	1/10

Comment: After use the endoscopes were sucked with 200ml of *Insulnet*, brushed once and rinsed with 200ml of water. The PSK Cleaner rated 3/10 of and the Other methods rated 1/10.

Slide 7

Results 2

An overall comparison of the PSK Cleaner Other methods

B: (A) + soaking in *Insulnet* at 35 5minutes+ 200ml of flushing

<u>Apparatus:</u>	<u>Reaction to residual blood</u>					<u>Degree of positiveness</u>
	-	±	+	2+	3+	
PSK Cleaner	8	1	1	0	0	2/10
Other method	10	0	0	0	0	0/10
PSK Cleaner (400ml flush)	10	0	0	0	0	0/10 (*+ is also positive)

Comment: With the second comparison, after the soaking in *Insulnet*, the instruments were then rinsed and all showed negative, but the PSK Cleaner showed a positive of 2/10. However, when the PSK Cleaner was flushed with 400ml, it showed negative on all counts.

Slide 8

Result 3

<u>Apparatus</u>	<u>Attachment/setup Insulnet flush</u>	<u>Flush 200ml</u>	<u>Gurutaruarutehido* Flush</u>
PSK Cleaner	39 seconds	22 seconds	24 seconds
Other method	39 seconds	48 seconds (118%increase)	29 seconds (21% increase)

*(n = 3)

Comment: The time taken to set up the apparatus with *Insulnet* was basically the same. However, in the other two tasks, the traditional method clearly took 21 % and 118 per cent longer than the PSK Cleaner.

Manual Cleaning of Endoscopes: A Comparison Study of Syringe Versus Suction Methods Using the Endo-Suction Cleaning System

G. Barbara Puszko, BHSc, ND, RN

The manual syringe method of cleaning endoscopes involves numerous problems, including cross-infection, contamination, wasted time, and employee safety issues. This article describes the development of an alternative system by a nurse entrepreneur for endoscopic cleaning using a suction method. Scientific findings gathered over four years are presented supporting the efficacy and usefulness of this system, the Endo-Suction Cleaning System, also known as the PSK System.

There are many problems associated with the manual syringe method of cleaning endoscopes, including cross-infection, contamination, and inefficiency (ASGE, 1997, May 13; Babb & Bradley, 1995; Blanc, Parret, Janin, Rasselli, & Francioli, 1997; Bronowicki et al., 1997; Fujita, 1997; Merighi et al., 1996; Tooth, 1996). The manual syringe cleaning of endoscopes is a time-consuming method that has a tendency to neglect blockages within the smaller channels of endoscopes (Babb & Bradley; Puszko, 1998). In addition, an endoscope that is not pre-cleaned effectively before being placed into an automatic washer or disinfectant may contaminate the machine and endoscope (Axon, 1991; Merighi et al.; ASGE, 1997 May 14). Breaches in protocol may lead to post-procedural infections and possible litigation due to inadequate rinsing of endoscope channels after disinfection (Fujita; GESA & GENSA, 1995; Babb & Bradley; Milson, 1998).

Manual cleaning of endoscopes with syringes is also a complicated procedure. Employees pressed for time may be tempted to take short cuts in the cleaning process. Manual

cleaning may also cause procedure delays because an endoscope is not always available for the next procedure in a timely manner. In addition, nursing staff using the syringe method are exposed to high levels of contact with harsh disinfectants, which may result in allergic reactions and high-risk accidents leading to possible work cover compensations being filed (Puszko, 1998; Worksafe Australia, 1995; Stenton, Beach, Dennis, Keaney, & Hendrick, 1994). The syringe method also requires repetitive physical effort leading to sore hands and the possibility of employee injury or disability (Shelley & Dennis, 2000).

The author, who has 30 years of personal experience working in hospitals in Poland, Germany, and Australia, has gathered information about the typical problems associated with the syringe method from a variety of sources including an extensive review of healthcare literature; discussions at various forums organized by the Gastroenterological Nurses Society of Australia (GENSA); participation at international gastroenterological conferences in Australia, Austria, Japan, and the United States; and annual participation at various medical trade shows. As a result of these experiences, the author has developed an alternative system for endoscopic cleaning using a suction method. This alternative system, the Endo-Suction Cleaning System (ESCS) (also known as the PSK System) underwent a four-year study. The author hypothesized that most problems relating to the manual method of cleaning endoscopes with syringes could be min-

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GASTROENTEROLOGY NURSING

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imized or eliminated by the use of the ESCS. The study took place at the Peninsula Endoscopy Centre, Frankston (where the ESCS was developed) and the Whitehorse Day Surgery, Box Hill, both in Victoria, Australia.

Procedure

The author reviewed results from 10,310 endoscopy procedures performed at the Peninsula Endoscopy Centre and 6,450 endoscopies performed at the Whitehorse Day Surgery. Of the 16,760 procedures analyzed, the author personally cleaned 7,314 endoscopes using the new cleaning system. The other endoscopes were cleaned by state enrolled (e.g., nursing assistant) and state registered (e.g., licensed) nurses. The approximate distribution of endoscopes among the different endoscopy manufacturers was as follows: Pentax 55%, Olympus 45%, and Fujinon 5%. The cleaning system was also tested for four years as a pre-cleaning device before endoscopes were placed into the Steris System 1 endoscopic cleaning device. All manufacturers' (i.e., Pentax, Olympus, Fujinon, and Steris) recommendations were strictly followed.

The researcher collected descriptive data on infection control microbiology testing as specified by GENSA and GESA (GESA & GENSA, 1995; SGNA, 1997; Moore, 1998) including cleaning times, volume of water required for cleaning endoscopes, and costs involved in using the ESCS. In addition, Pentax, Olympus, and Fujinon guidelines for cleaning, rinsing, and disinfecting endoscopes were systematically followed.

During the study, the applied suction pressure for aspiration of cleaning solution, air, and water through an endoscope was set at or below 24 PSI (165kPa) as recommended by Pentax. A manometer was attached to the suction unit allowing the user to verify and assure use of the appropriate suction pressure. Tap water was used for cleaning gastroscopes and colonoscopes and sterile water was used for cleaning duodenoscopes. Additional steps of the cleaning procedure are described in the following section.

Description of the Endo-Suction Cleaning System

The ESCS is a dual-use device. It may be used as a manual cleaning system for use with any Pentax, Olympus, or Fujinon fiber-optic or video endoscope where there is access to a water faucet or an external suction unit. The system can also be used for pre-cleaning endoscopes before using automatic washers and disinfectors. The focus point of the ESCS lies in its ability to use a single source of suction to clear all channels simultaneously or individually. This is due to its ability to isolate channels as required during the cleaning process.

The ESCS is made from medical-grade silicon and connected with medical-grade, autoclavable plastic connectors. The inventor chose medical-grade plastic to reduce the effect of chemical reactions between the acidic disinfectant and any metal parts. The ESCS is simple to connect, requiring the attachment of clearly marked silicone tubing to air/water, suction, and biopsy channels (Figure 1). The ESCS is then connected to a suction unit necessary to create pressure to move the cleaning solution, disinfectant, water, and air through all individual channels of the endoscope. Initially, a portable electric suction unit was used in the study. Later, the Nalgene® Vacuum Pump-Ventura system was connected to a standard

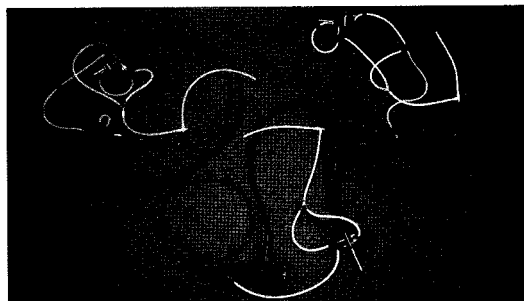


FIGURE 1 • Endo-Suction Cleaning System adapted for various endoscope models.

water tap. The reason for the change was that hospitals did not regularly use a portable electric suction unit. In addition to the Nalgene® Vacuum Pump, a small manometer was attached to measure applied pressure.

Attachment of the ESCS to the Endoscope

An example of connecting the ESC System to a Pentax endoscope is shown in Figure 2. Connections to Fujinon and Olympus endoscopes are similar. The tubing is color-coded with the blue tubing connecting to the air-water channel, the red tubing connecting to both the suction and biopsy channels, and the white tubing connecting to the suction unit. The green tubing connects to the elevator channel on duodenoscopes.

Stages of Cleaning Using the ESCS

The suction unit is connected to the endoscope via the ESCS during the cleaning process. The endoscope is moved from the cleaning solution to air and then submersed in water. Throughout all cleaning steps, fluid and air flows from the distal end of the endoscope, which is smaller in diameter, to the larger diameter channels, taking debris out from the endoscope.

Findings

Cleaning Times

A comparison of cleaning times between the traditional syringe method and the ESCS was conducted using a 3-channel Pentax endoscope. A minimum of 715 seconds (11.92 minutes) was required for the traditional cleaning method versus 75–175 seconds (1.25–2.92 minutes) for the ESCS method. The ESCS was 75–90% faster than the syringe method. The average cleaning times for Olympus endoscopes with four channels using the traditional syringe method was a minimum of 337 seconds (5.62 minutes). Using the ESCS, the cleaning time was between 75–175 seconds (1.25–2.92 minutes), resulting in a 48–80% time savings compared to the syringe method. Due to the reduction in time taken to clean endoscopes using the ESCS between June 1993 to November 1997, there was a significant increase in the number of procedures performed (Figure 3).

The ESCS produced benefits when used with all endoscopes. The most significant difference between the ESCS and syringe system occurred, however, during duodenoscopy

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Description of Pre-Cleaning System for Endoscopes

OVERVIEW

The Pre-Cleaning System for Endoscopes is based on the patented concept and method (USA patent # 925894387) to circulate fluids and/or air within endoscope channels using negative and positive pressure. From a single source of suction it can flush all channels simultaneously or each channel may be isolated and flushed independently.

Users may utilise any type of suction unit available upon its compliance with endoscope manufacturer recommendations and local hospital/clinic policy. Maximum effective level is suggested around 24PSI (165kPa).

Pre-Cleaning System for Endoscopes completely eliminates the need to manually push a syringe as the current method prior to higher level disinfection/sterilization.

As a result users may achieve: reduction of pre-cleaning time, reduction of cross contamination, reduction of running costs and reduction of liabilities. See [Appendix 2](#).

Attachment and connections to a GI flexible Pentax endoscope are shown in [Appendix 3](#). *Instructions for use*, as supplied with the purchase of the Pre-Cleaning System for Endoscopes.

There are only minor differences in model design between the Pre-Cleaning System for GI flexible endoscopes from Pentax, Olympus and Fujinon.. Otherwise, the principle and usage between the three different models is identical. The range of models of the Pre-Cleaning System for Endoscopes is shown in [Appendix 4](#). Please note, models for Olympus and Fujinon are also available.

Typical flow through internal channels of a GI flexible Pentax endoscope with 4 channels is shown in [Appendix 5](#).

INTENDED USE

Pre-Cleaning System for Endoscopes has been designed for flushing GI flexible Pentax, Olympus and Fujinon endoscopes prior to higher level disinfection/sterilization. Thus any type of Pentax, Olympus and Fujinon flexible fiberoptic and video endoscope that is fully immersible in liquid i.e. colonoscope, gastroscope, duodenoscope and sigmoidoscope may be flushed using the Pre-Cleaning System.

It is not intended to be used as the terminal process, also it does not belong to generic type of *“those washer/Disinfectors which are electromechanical and may be microprocessor controlled”* Guidance on Premarket Notifications [510(k)] for Endoscope Washers/Disinfectors, and Disinfectors Used in Health Care Facilities.

Design Standards

DESIGN, CONSTRUCTION, COMPONENTS & ACCESSORIES

Materials

The main components of Pre-Cleaning System for Endoscopes are made from a medical grade of silicone tubing. They can withstand not only typical enzymatic cleaning solutions but also the very harsh glutaraldehyde. Other components, for example connectors are delivered by companies specializing in manufacturing medical accessories mainly from USA. Details are supplied in enclosed [Appendix 6](#).

Installation requirements

No special installation process is required.

Input requirements

There are no special input requirements i.e. water quality, water pressure, pressure required to move fluids or air are as used with a traditional manual syringe method. Water - means clean, potable water or potable water that has been filtered by passage through a 0.2µm filter or otherwise treated by a method documented to improve the microbiological quality of water

PROCESS MONITORS

Users may monitor the flow through each channel by observing the flow through each clear tubing. Further each channel may be isolated to identify the blocked channel and measure the outgoing fluid if needed,

PROCESS PARAMETERS

Time for flushing endoscope depends on any blockages but as a rule of thumb it varies between 3 and 5 seconds per channel.

Temperature, hardness of water and any other preprocessing conditions are identical as with a manual syringe method.

There are no post-processing conditions. Again, the process is similar to the manual syringe method.

POTENTIAL HAZARDS

Are there any qualitative potential hazards?

No. According to supplier's data of main components - Wacker-Chemie GmbH - critical hazards to man and environment are not applicable. See attached Safety Data Sheets (91/1 55/EEC) in [Appendix 7](#).

If a new, much stronger detergent, and disinfectant are used they may shorten the life of the product or lead to leaks during the flushing process.

Design Standards

During normal use, there occurs a change of colour and deterioration of the silicone tubing. The most popular disinfectants: glutaraldehyde and peracetic acid, effect the tubing by changing the colour first to light yellow and than darkening it to light brown. Factors which contribute to the discolouration and deterioration are:

- Type of disinfectant
- Concentration of disinfectant
- Duration of immersion in disinfectant
- Frequency of insertion in disinfectant.

There is a strong correlation between the above factors and the density of discolouration. The factor with the highest impact is the time of immersion of the Pre-Cleaning System for Endoscopes in disinfectant. The change of colour does not indicate any reduction of the quality of product but only its aesthetic appearance.

Are there any quantitative potential hazards?

No.

Various tests indicate that the Pre-Cleaning System for Endoscopes can be safely used in a typical endoscope clinic for 1 to 2 month but there are numerous examples of clinics successfully using it for more than 12 months. It is impossible to quantify the exact number of times the device can be used. The following factors may significantly reduce the life of the product:

- Number of daily procedures
- Type of detergent and disinfectant used in a clinic
- Internal protocols
- Chemical concentration of detergent and disinfectant
- Duration of the life of the disinfectant, which is usually meticulously specified in each clinic's internal protocol
- Storage environment
- Handling methods

Does the device come into contact with the patient?

No.

The Pre-Cleaning System for Endoscopes has no direct contact with patients as the device is used to pre-clean the endoscope before continuing the cleaning process in automated endoscope reprocessor (AER).

Does the device come into contact with drugs?

No. Not applicable

Design Standards

Is the device subject to environment influences? No.

Temperature: Minimum and Maximum.

The Pre-Cleaning System for Endoscopes should be used at average room temperatures but can withstand continuous temperatures ranging from -40°C to 100°C in a dry environment. In the case of temperatures higher than the maximum or lower than the minimum, the silicon glue may lose adhering properties and some leaks on joints may occur.

Pressure: Minimum and Maximum (effect on channels)

The atmospheric pressure occurring on the earth will not effect the quality of the Pre-Cleaning System for Endoscopes. Any abnormal pressure may create some leaks on joints but the manufacturer does not take responsibility for this.

Humidity: Minimum and Maximum

The humidity occurring on all continents will not effect the quality of Pre-Cleaning System for Endoscopes. Any abnormal humidity may create some leaks on joints but the manufacturer does not take responsibility for this.

Are any of the materials of the device toxic?

No.

According to present experiences, silicone tubing made from 60006603 Elastosil R 401/60 S are physically compatible and to present experience, the material is neither mutagenic, cancerogenic nor teratogenic.

Elastosil E43 transparent glue after cross-linking and removal of volatile substance products, is neither mutagenic, cancerogenic nor teratogenic, and is not hazardous to humans or any ecology. See Appendix 6.

Do any accessories to the device carry any potential hazards?

No.

Is routine cleaning or calibrating of the device necessary?

Yes, Pre-Cleaning System for Endoscopes should be routinely cleaned in automated endoscope reprocessor (AER) together with an endoscope, or separately by gas sterilization.

The Pre-Cleaning System for Endoscopes is not intended to replace adapters provided by manufacturer of the reprocessor.

No calibration is required.

Does the shelf life carry any potential hazards?

If stored and handled in accordance with standard industrial practices, no hazardous reactions are known.