

DIRECTIONS FOR USE

To achieve a log reduction of > log8 the following programme should be followed:

1. Rinse the instrument/device with clean water and brush off surface debris as necessary.
2. Thoroughly brush with F10SCXD Disinfectant/Cleanser at a 1:100 dilution (or F10CLXD Disinfectant/Cleanser at a 1:20 dilution) and leave fully submerged for 10 minutes.
3. Rinse thoroughly with clean water.
4. Fully submerge in F10 STERILANT for 10 minutes (ensure all surfaces are exposed to the solution and lumens are filled), no need to rinse.
5. Remove wearing sterile gloves, dry and store in sterile container.
6. Replace solution daily.

STABILITY

The product has a 2 year shelf life providing it has not been contaminated and the cap replaced after each use.

REPLACE CAP AFTER USE**TOXICOLOGY**

Studies were carried out by a GLP laboratory in accordance with OECD and EPA guidelines.

- Acute Oral Toxicity – Non toxic
- Acute Dermal Toxicity – Non toxic
- Inhalation Toxicity – Non toxic
- Acute eye irritation – Non irritating
- Acute dermal irritation – Non irritating
- Skin Sensitisation – Causes no skin sensitisation

CORROSION

Tests were carried out on fully submerged carbon steel scalpel blades. After 10 days there was still no evidence of corrosion on the blades.

FREE RINSING

All F10 Disinfectants are free rinsing at recommended dilutions (complies with SABS test 1593.11).

WATER INSOLUBLE MATTER CONTENT

The water insoluble matter content of F10 STERILANT is < 0.3g/litre (complies with SABS 15936.12).

PRECAUTIONS

Ingestion: Do not induce vomiting. Give milk or water to drink.

Eye contact: Rinse eyes with water, seek medical advice if necessary.

WARNINGS

- Do not mix with soap or other chemicals. Avoid contact with eyes. Keep out of reach of children, uninformed persons and pets.
- **Not to be used on aluminium.**

PRESENTATION

A clear pouring liquid in a 5 litre HPE bottle.

STORAGE INSTRUCTIONS

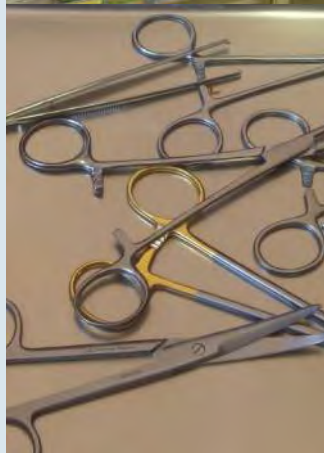
Store below 30° C in dry conditions, out of direct sunlight.

REGISTRATION HOLDER

Health and Hygiene (Pty) Ltd. Cnr Leader & Hoefsmid Roads, Stormill, Roodepoort. PO Box 906, Florida Hills, 1716.

MANUFACTURED BY

Health and Hygiene (Pty) Ltd in accordance with GMP (Good Manufacturing Practice) license reference M-4586 issued by APVMA and SABS 636 Permit 6656/9863.



F10[®] Sterilant

With Rust Inhibitor



F10 STERILANT

(Liquid, ready to use (RTU) in 5L)
GNR529/29990/040/150,



REGISTRATION AUTHORITIES

DTI, Act 29/1993 (SA)

COMPOSITION

LEVEL OF ACTIVES	OTHER	PH
QAC and biguanide 0.058%	<ul style="list-style-type: none"> Ampholytic surfactants and sequesterants Rust inhibitor Water to balance 	±7.5

INDICATIONS

A broad spectrum biocide effective against bacteria, fungi, viruses and bacterial and fungal spores as indicated below:

BACTERIA GRAM POSITIVE SPP	BACTERIA GRAM NEGATIVE SPP	FUNGI/YEASTS/ MOULDS SPP	VIRUSES	BACTERIAL SPORES
Actinobacteria	Acinetobacter	Aspergillus	Adenovirus	Bacillus
Bacillus	Bordetella	Candida	Avian Influenza	
Clostridium	Campylobacter	Microsporium	Canine Parvovirus	
Corynebacterium	Chlamydia	Trichophyton	Circovirus	
Enterococcus	Citrobacter	Penicillium	Feline Herpesvirus	
Listeria	Escherichia		Hepatitis B	
Mycobacterium	Enterobacter		HIV	
Staphylococcus	Klebsiella		Infectious Bursal Disease Virus	
Streptococcus	Legionella		Newcastle Disease Virus	
	Leptospira		Rabies	
	Mycoplasma			
	Ornithobacterium			
	Pasteurella			
	Proteus			
	Salmonella			
	Vibrio			

APPLICATIONS

The F10 STERILANT is a high performance, surface acting, biocidal compound derived from the F10 core actives common to the F10 disinfectant product range, for use in the rapid sterilization of heat sensitive devices and surgical instruments. The product can be used for the cold sterilization of stainless steel instruments, flexible and rigid endoscopes, urinary catheters, endotracheal tubes, suture needles, latex drains, clipper blades and sensitive dental, orthopedic and ophthalmology instruments.

ANTIMICROBIAL ACTION

The antimicrobial action of the preparation is based upon the proprietary branded F10 compound. The mechanism of action of F10 is derived from those of each component taken separately, in addition to those due to the additive synergistic action of all components combined. At the concentrations in the product F10 has been assessed as giving a > log³ reduction in microbial counts against gram positive and gram negative bacteria, fungi, yeasts and moulds, enveloped and non-enveloped viruses, bacterial and fungal spores.

SPORICIDAL ACTIVITY

The indicator micro-organism used in challenge tests for a cold sterilant is *Bacillus subtilis*. Tests carried out at the SABS Microbiological Laboratories, Pretoria, South Africa showed the following:

REPORT NO.	TEST STANDARD	CONTACT TIME	RESULT
1733791/04-5/X18434	Simulated cleaning and disinfection cycles for endoscope sterilization utilizing an electronic bath	5 minute cycles	99.999% kill
1733791/04-6307/W18008/9a	Simulated cleaning and disinfection cycles for endoscope sterilization utilizing a mechanical shaker	15 minute cycles	99.999% kill
1733791/04-3294/X38022-3	EN13704-2002 - Log 4 reduction pass criteria	5 minutes	99.99% kill



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