stella™

Automated disinfection made simple


stella™
stella
Stella

CONTENTS

1. STELLA / BENEFITS

Stella is an automated system designed specifically for the disinfection of heat-sensitive small and medium-sized, rigid and flexible, non-lumened and single-lumened endoscopes used in Urology, Gynaecology, IVF, Cardiology, ENT, Anesthesiology and Respiratory.

Stella combines the simplicity of manual soaking with the sophistication of a fully automated washer disinfector.

INCREASES PATIENT THROUGHPUT

Stella's high-level disinfection cycle time is five minutes. When cleaning is included, the cycle time is ten minutes.

CUTS CAPITAL EXPENDITURE

Stella requires minimal capital investment when compared to a fully automated washer disinfector. The short cycle time improves the productivity of instruments enabling you to operate with fewer of them.

SAFE FOR INSTRUMENTS

When Stella irrigates the lumen it monitors the back pressure of the Tristel liquid passing through it and adjusts the pressure to protect it. The solution also pulses through the lumen, rather than moving at an even flow, dislodging soil and bio burden in the process.

SMALL FOOTPRINT

Stella measures 70cm x 48cm x 18cm and weighs 5.5kg when empty. The base and lid can be stacked and easily transported due to their portable size and weight.

GIVES YOU PEACE OF MIND

Prior to the start of each cycle, Stella confirms that Tristel solutions for Stella are used. It also checks that there is no channel blockage.

At the end of each cycle, Stella irrigates the channel and provides the user with a unique traceability code.

APPROVED BY MANUFACTURERS

Tristel Fuse for Stella was tested and confirmed to be compatible with medical devices from major manufacturers including*:

- BK Ultrasound
- Canon (Toshiba)
- Carestream
- Esaote
- Fujifilm (Fujinon)
- Gaeltec
- GE Healthcare
- Hitachi
- Karl Storz
- Philips
- Siemens
- Sonosite
- Unisensor
- Xion

IMPROVES HEALTH & SAFETY

Fuse for Stella utilises Tristel's proprietary chlorine dioxide chemistry, a well-documented and highly effective biocide. The Health and Safety profile of chlorine dioxide is superior to that of sodium hypochlorite, peracetic acid and glutaraldehyde.

** Material compatibility relates to specific instruments/models.*

stella™ System

PRODUCT CODE: STELLA A

The **Stella System** provides a five minute turnaround of instruments. It records electronic validation information which can be downloaded to software for traceability.

INTENDED USE

For the high-level disinfection of non-lumened medical devices, such as transoesophageal echocardiographic probes, transvaginal probes, transrectal probes, manometry catheters and laryngoscope blades.

stella™ with Pulse System

PRODUCT CODE: STELLA B

The **Stella with Pulse System** provides all the benefits of the Stella System whilst additionally confirming instrument connection and determining blocked instruments, protecting them from over-pressure.

INTENDED USE

For the high-level disinfection of non-lumened (see Stella System) and single-lumened medical devices, such as hysteroscopes, cystoscopes, nasendoscopes, intubation endoscopes and bronchoscopes.

stella™ with Pulse & Cleaning System

PRODUCT CODE: STELLA C

The **Stella with Pulse & Cleaning System** provides all the benefits of the Stella with Pulse System, plus a cleaning cycle. It has a ten minute turn around of instruments; five minutes for automated cleaning and five minutes for automated high-level disinfection.

INTENDED USE

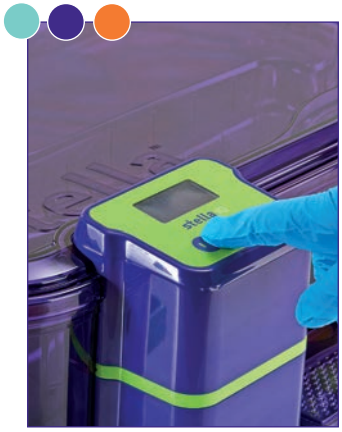
For the cleaning and high-level disinfection of single-lumened and non-lumened medical devices, such as those listed above.

**All Stella systems exclude consumables, which are ordered separately.*

Order codes: Tristel Fuse for Stella - (Citrus) TSL010601 & (Unfragranced) TSL010701 - Tristel Clean for Stella - TSL041001

3. STELLA / HOW TO USE

KEY
- Stella System
- Stella with Pulse System
- Stella with Pulse & Cleaning System

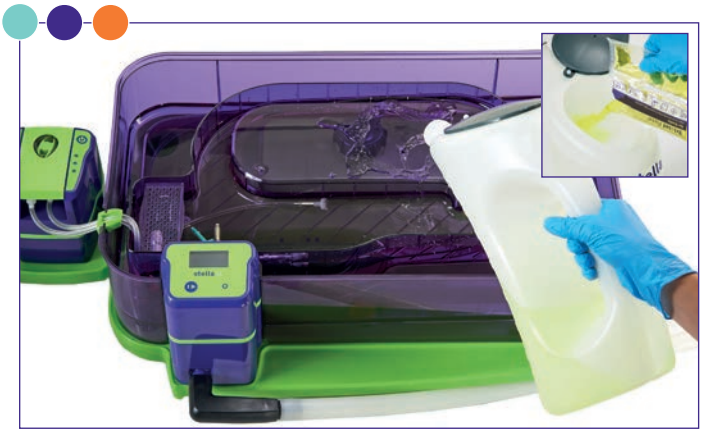


1. Turn on Stella IQ.

2. Turn on Stella Pulse.

3. Add the pre-cleaned instrument – connecting lumened instruments to Stella Pulse.

4. If using Stella for instrument cleaning prior to high-level disinfection, prepare five litres of Tristel Clean for Stella and add to the inner compartment of the base.



5. For the high-level disinfection cycle, add one sachet of Tristel Fuse for Stella to five litres of water and add to the inner compartment of the base.

6. Close the lid and Stella will do the rest. The high-level disinfection cycle time is five minutes. When cleaning is included, the cycle time is ten minutes. Stella drains automatically.

7. At the end of the cycle, Stella will issue a validation code to confirm it has completed successfully. This should be recorded in the Stella Quality Audit Trail Record Book or downloaded to the Stella Suite.

Refer to the Stella Help Guides, Quick Guides and Instructions for Use for full instructions.

PULSE AND TUBE SET

Stella Pulse is the lumen irrigation device used for the disinfection of single-lumened endoscopic devices.

IQ

Stella Pulse works in conjunction with Stella IQ. The units are connected via Bluetooth. The IQ controls the operation of Pulse. At the start of the cycle, Pulse will irrigate the lumen and ensure that it is filled with disinfectant. At the end of the disinfection cycle, Pulse removes the disinfectant from the lumen.

TOOLBOX

SMALL PARTS TRAY

LUBE POT

DRAINAGE OUTLET CAP

GROMMETS

DRAINAGE HOSE

** Stella also includes full user instructions, installation software, a traceability book, chargers and a USB cable to connect Stella IQ to your PC for full traceability reports.*

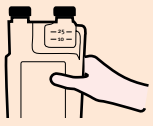
TRISTEL CLEAN FOR STELLA IS A NON-ENZYMATIC DETERGENT DESIGNED SPECIFICALLY FOR EFFECTIVE INSTRUMENT CLEANING IN STELLA.

A disinfection cycle is only effective when the medical device has undergone thorough cleaning. Tristel Clean for Stella decomposes organic substances and proteins quickly and effectively.

Tristel Clean for Stella has an integrated 25ml dosing cap, meaning the correct dosage is easy to achieve for each application.

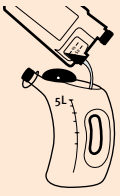
- Decomposes organic substances and proteins quickly and effectively
- Novel corrosion inhibitors extend the lifecycle of the instrument
- No intermediate rinsing is required if Tristel Fuse for Stella is used for high-level disinfection
- Safe to use
- Class I Medical Device
- Two-year shelf life

HOW TO USE TRISTEL CLEAN FOR STELLA



STEP 1

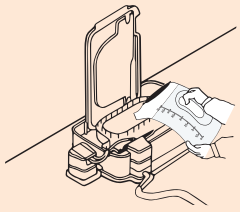
Prepare 25ml of Tristel Clean for Stella concentrate by squeezing the bottle until the marking on the cap is reached.



STEP 2

Pour the 25ml concentrate into a sink (for manual pre-cleaning) or jug containing 5L of ambient water.

Note: *Do not use hot water.*



STEP 3

Pour diluted Tristel Clean for Stella into the inner compartment of the base when prompted by Stella IQ and follow further instructions on the screen.

STEP 4

The cleaning cycle time is five minutes. Upon completion of the cycle, Stella will drain automatically.

Tristel™ Clean
for Stella

Tristel Clean for Stella is CE marked as a Class I Medical Device in accordance with the European Medical Devices Directive 93/42/EEC and the 2007/47/EC amendments thereto.

TRISTEL FUSE FOR STELLA IS A SINGLE-USE DISINFECTANT SOLUTION DESIGNED SPECIFICALLY FOR THE HIGH-LEVEL DISINFECTION OF SEMI-CRITICAL MEDICAL DEVICES IN STELLA.

Tristel Fuse for Stella incorporates two separate compartments that contain 50ml Tristel Base solution (citric acid) and 50ml Tristel Activator solution (sodium chlorite). When mixed upon bursting the sachet, Tristel's proprietary chlorine dioxide chemistry is generated for dilution into five litres of water.

Tristel Fuse for Stella is sporicidal, mycobactericidal, virucidal, fungicidal and bactericidal in five minutes.

Chlorine dioxide has been tested in accredited laboratories worldwide and is proven effective against microorganisms of concern such as:

- *Bacillus subtilis*
- *Clostridium sporogenes*
- *Mycobacterium terrae* (TB)
- Adenovirus
- Poliovirus
- *Klebsiella pneumoniae*
- Herpes Simplex Virus T1
- Murine norovirus
- Vancomycin-resistant *Enterococcus faecium*
- *Pseudomonas aeruginosa*

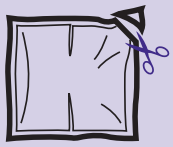
For a full efficacy overview please consult the micro summary available at: http://www.tristel.com/tristel-products/tristel-fuse-stella

Tristel Fuse for Stella is available in boxes of 40 sachets (citrus or unfragranced).

HOW TO USE TRISTEL FUSE FOR STELLA

STEP 1

Fold the sachet in half and squeeze one side to burst contents through the centre seal. Contents will start to turn yellow. Allow a 30 seconds mixing time.



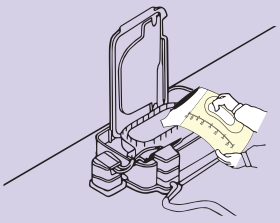
STEP 2

Tear or cut the corner of the sachet.

STEP 3

Pour contents into five litres of ambient water.

Note: *Do not use hot water.*



STEP 4

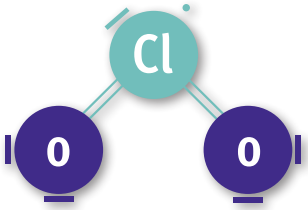
Add the prepared Tristel Fuse for Stella solution to the inner compartment of the base when prompted by Stella IQ and follow further instructions on the screen.

STEP 5

The high-level disinfection cycle time is five minutes. Upon completion of the cycle, Stella will drain automatically.

Tristel Fuse™ for Stella

Tristel Fuse for Stella is CE marked as a Class IIb Medical Device in accordance with the European Medical Devices Directive 93/42/EEC and the 2007/47/EC amendments thereto.



TRISTEL'S PROPRIETARY CHLORINE DIOXIDE CHEMISTRY

Tristel Fuse for Stella utilises Tristel's proprietary chlorine dioxide chemistry (ClO_2), a well-documented and highly effective biocide. ClO_2 is a strong oxidant whose germicidal characteristics are well known. It can oxidise lipids and proteins present in bacterial and fungal cell membranes, leading to a loss in membrane integrity and ultimately cell death. ClO_2 can also penetrate cells and degrade nucleic acids via an oxidative pathway. Similar mechanisms are responsible for the ability of ClO_2 to inactivate viral particles.

NO NEED TO RINSE

Scientific and clinically derived data demonstrates that Tristel's chlorine dioxide solution does not require rinsing from instruments post-disinfection. Documented evidence demonstrates that the most likely source of contamination post-disinfection, infection or injury post-endoscopic procedure is more likely to occur as a result of contaminated rinse water than of ineffective disinfection or residual disinfectant.*

Tristel's chlorine dioxide chemistry has been included in numerous guidelines for the reprocessing of semi-critical medical devices, including:

BRITISH SOCIETY OF GASTROENTEROLOGY GUIDELINES FOR DECONTAMINATION OF EQUIPMENT FOR GASTROINTESTINAL ENDOSCOPY.

ESGE-ESGENA GUIDELINE: CLEANING AND DISINFECTION IN GASTROINTESTINAL ENDOSCOPY UPDATE.

DISINFECTION OF INTRACAVITY ULTRASOUND TRANSDUCERS. ASA GUIDELINES (AUSTRALIAN SONOGRAPHERS ASSOCIATION).

GUIDELINES FOR TRANSOESOPHAGEAL ECHOCARDIOGRAPHY PROBE CLEANING AND DISINFECTION FROM THE BRITISH SOCIETY FOR ECHOCARDIOGRAPHY.

GUIDELINES FOR REPROCESSING NON LUMENED HEAT SENSITIVE ENT ENDOSCOPES. OFFICIAL JOURNAL OF THE ITALIAN SOCIETY OF OTORHINOLARYNGOLOGY - HEAD AND NECK SURGERY.

NATIONAL PATIENT SAFETY AGENCY. NATIONAL REPORTING AND LEARNING SERVICE. THE REVISED HEALTHCARE CLEANING MANUAL.

GUIDANCE ON THE DECONTAMINATION AND STERILIZATION OF RIGID AND FLEXIBLE ENDOSCOPES. ENT UK TRADING AS BRITISH ACADEMIC CONFERENCE IN OTOLARYNGOLOGY (BACO) AND BRITISH ASSOCIATION OF OTORHINOLARYNGOLOGY - HEAD AND NECK SURGERY.

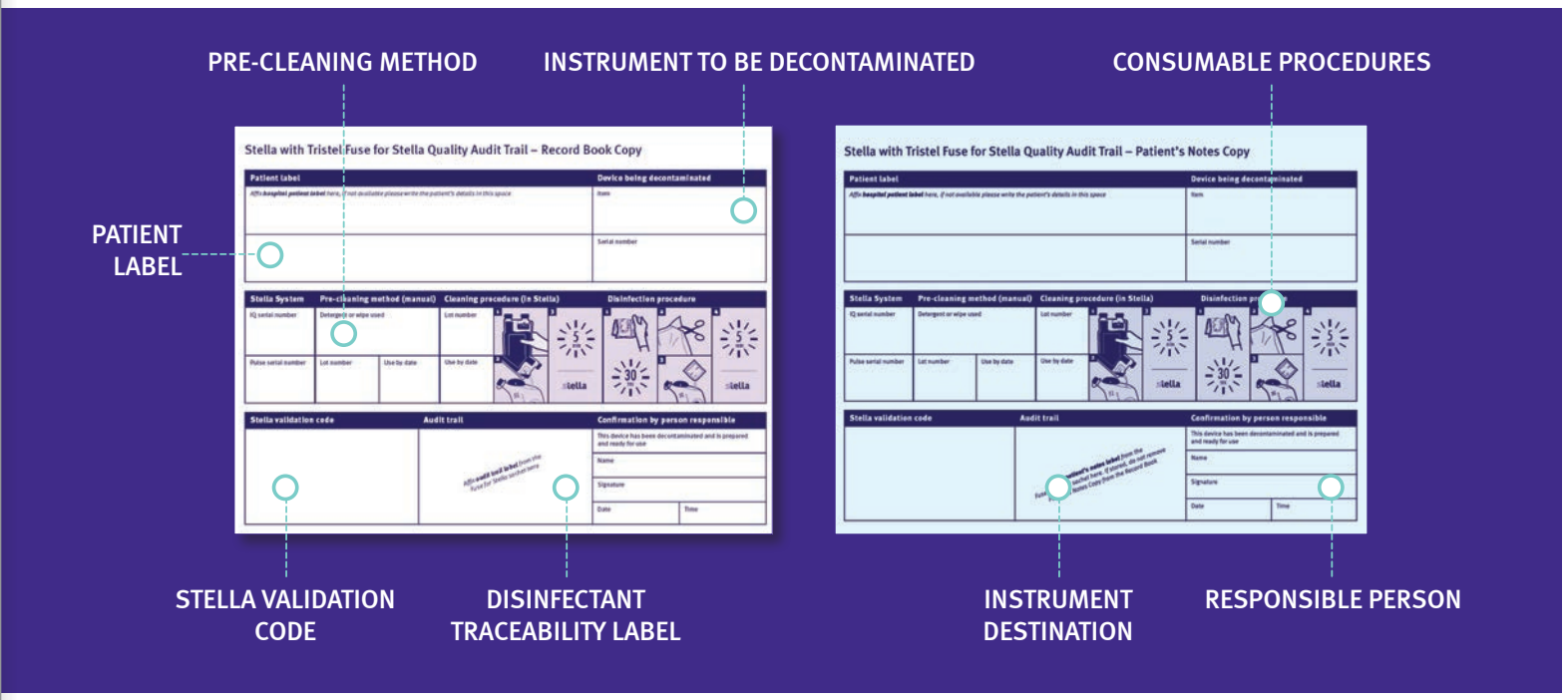
** White Paper: Why there is no requirement to rinse instruments following disinfection with Tristel chlorine dioxide solutions. Lucy R Welch. November 2011.*

6. STELLA / TRACEABILITY

Stella provides electronic validation when a successful cycle has been completed. The validation code is stored in the Stella IQ memory against a date and time stamp. This can be downloaded by software to electronic records and provide proof for manual records.

STELLA QUALITY AUDIT TRAIL RECORD BOOK

The Stella Quality Audit Trail Record book records the decontamination process:



STELLA SUITE ELECTRONIC RECORDS

Stella Suite electronic records can be downloaded to a PC when Stella Suite software is installed. This enables the user to view the data that Stella IQ records, including time and date-stamped validation codes. Filters within the Stella Suite Software allow the user to choose the data required to appear in the Stella Suite report.

STELLA WITH PULSE & CLEANING SYSTEM

If a user is running a paperless system with a 2D scanner, a barcode validation option can be switched on. When the Stella cycle has successfully completed, an alpha validation code and barcode appear on the Stella IQ screen. By holding the 2D scanner to the IQ screen, the validation code will be logged into the paperless system. Tristel Fuse for Stella chemistry audit labels can also be scanned, capturing the chemistry Lot and use by dates.

Stella reduces capital spend and reprocessing times.
Xuan Wu Hospital. January 2016.

"Stella has had an incredible impact on our capital expenditure, because we are no longer facing the need to invest in more instruments in order to rotate with those that are being disinfected."

Stella enables Shanghai Pulmonary Hospital to high-level disinfect bronchoscopes nine times faster.
Shanghai Pulmonary Hospital. January 2016.

"Stella gives us the reassurance and the speed we need in order to keep patient throughput high. Stella has enabled us to high-level disinfect our bronchoscopes nine times faster."

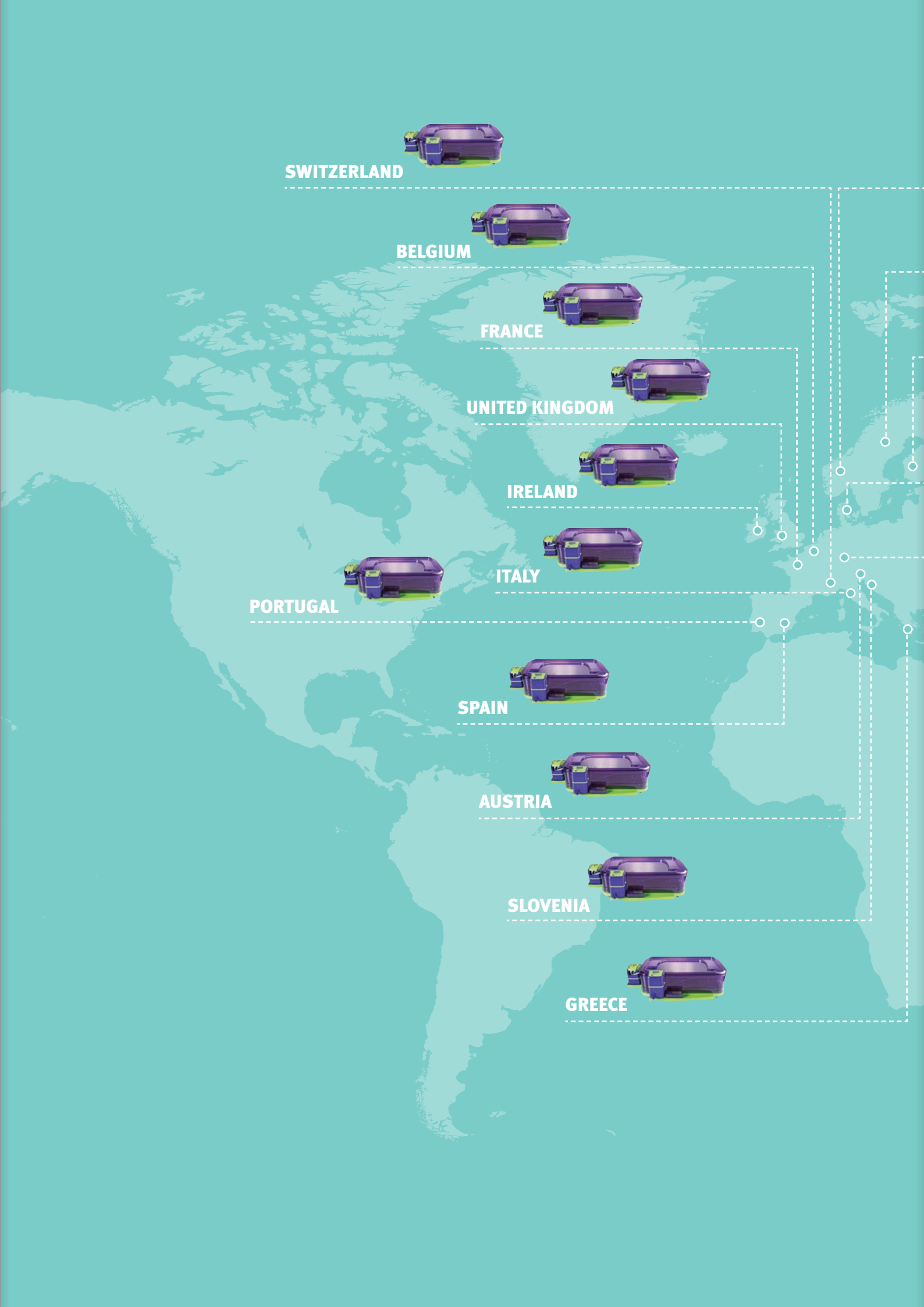
A randomised single-blind comparison of the effectiveness of the high-level disinfectants Tristel Fuse (chlorine dioxide) and Cidex OPA (ortho-phthalaldehyde) for use with flexible cystoscopes. Peter J Gilling, Michael Addidle, Rana Reuther, Michelle Lockhart, Christopher Frampton and Mark R Fraundorfer.

Stella for simple cystoscope reprocessing.
Time for a change at the Reading Urology Partnership. April 2012.

Stella for simple GI manometry disinfection.
Rising to the challenge at Castle Hill. May 2012.

Also available on the website are Instructions for Use, wall charts, Safety Data Sheets and microbiological efficacy summaries.

STELLA USERS WORLDWIDE


SWITZERLAND
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stella™

NORWAY

SWEDEN

FINLAND

RUSSIA

DENMARK

GERMANY

ROMANIA

CHINA

HONG KONG

UAE

THAILAND

SAUDI ARABIA

MALAYSIA

ISRAEL

AUSTRALIA

TURKEY

NEW ZEALAND

AND GROWING...

9. STELLA / REGULATORY

Stella is classified as a Class IIb Medical Device and meets the provisions of the European Council Medical Device Directive 93/42/EEC and amendment thereto 2007/47/EC.

To indicate product classification and approval, Stella carries a CE Mark and product compliance is demonstrated through:

A DESIGN FILE AND FULL QUALITY ASSURANCE SYSTEM

COMPLIANCE WITH THE ESSENTIAL REQUIREMENTS

QUALITY ASSURANCE PROCEDURES IN ACCORDANCE WITH BS EN ISO13485:2003

THE IMPLEMENTATION OF A SYSTEMATIC PROCEDURE FOR POST-MARKET SURVEILLANCE

By placing the CE marking on Stella, Tristel declares sole responsibility for the conformity with all of the legal requirements to achieve CE marking, compliance with EU legislation, and meeting EU safety, health and environmental requirements. Thus ensuring validity for Stella to be sold throughout Europe.

External assessment and auditing is a key requirement in designating that a medical device conforms to the EU Medical Devices Directive (MDD).

The British Standards Institute (BSI) is Tristel's Notified Body for Stella. A Notified Body, in the EU, is an organisation that has been accredited by a Member State to assess whether a product meets certain preordained standards. The Assessment from the BSI includes at least two audits of our facility each year, inspection and examination of products, and their design and manufacture.

Stella is sold across the EEA in the United Kingdom, France, Ireland, Italy, Portugal, Spain, Belgium, Scandinavia, Slovenia, Switzerland, Greece, Romania and Germany.

Countries outside the European Union have their own regulatory frameworks. Stella has received a license from the Health Department of the People's Republic of China and approval from Russian Ministry of Health for import and sales in Russian Federation. Other approvals include Hong Kong, Israel, Turkey, Saudi Arabia and Singapore.

In Australia and New Zealand Stella is regulated as a Therapeutic Good by the Therapeutic Goods Administration (TGA).

Stella meets TGA requirements and has been approved as a Class IIb medical device since 26 May 2015 (ARTG Identifier is 239073).

STELLA AND ISO 15883

In order for the Stella's classification as a medical device to be verified, its conformity with the Essential Requirements, Annex I of the MDD is examined externally by Tristel's Notified Body, the BSI.

The MDD stipulates 'it is desirable to use harmonized European standards to protect against the risks associated with the design, manufacture and packaging of medical devices'. ISO15883 series is a set of European standards that has been prepared as a means of conforming to the Essential Requirements of the MDD for automated washer disinfectors.

The relationship between the Essential Requirements of the MDD and ISO15883 are listed clause by clause in the text of Annex ZA of ISO15883.

Whilst Stella is not classed as a fully automated washer disinfector, and does not fall into the definition 'Washer Disinfector WD' from ISO15883-1, it is recognised that it performs the function of automated disinfecting with a manual pre-clean and rinse function. As a result Tristel have implemented ISO15883 in its guidance for the intended use of the product.

Where deviations from the ISO15883 are warranted, these aspects are addressed in Tristel's comprehensive User Instructions, factsheets and brochures.

STELLA IS USED IN CONJUNCTION WITH FUSE FOR STELLA, A SPORICIDAL HIGH-LEVEL DISINFECTANT SOLUTION THAT ACHIEVES EFFICACY IN FIVE MINUTES. EFFICACY HAS BEEN TESTED IN ACCORDANCE WITH RELEVANT EUROPEAN STANDARDS.

Section 4 of ISO15883-1, Performance requirements dictates that any item which has been processed in a WD conforming to the ISO 15883 series shall have been cleaned, disinfected, rinsed and, when appropriate, dried.

Stella conforms to this standard using manual pre-clean and rinse procedures and meets the requirements of section 4.3.2 on chemical disinfection.

In accordance with ISO15883-1 (4.6 and 5.1), the safety of Stella conforms to BS EN 60601-1. The chemicals are delivered with all necessary documents for safe handling.

The mechanical and process requirements set out in ISO15883-1 section 5 have been addressed during design development, where Tristel have achieved EC certification through accreditation to ISO13485, Quality Management Systems, for the 'Design and Manufacture of Disinfectant systems for use with invasive and non-invasive medical devices.' The design specification of Stella allows for disinfection of the Stella unit itself to be carried out by autoclaving.

THE UNIQUE DESIGN OF STELLA USED WITH FUSE FOR STELLA NEGATES THE NEED FOR TEMPERATURE MONITORING, AS THE SYSTEM IS EFFECTIVE AT AMBIENT TEMPERATURE.

Stella with Fuse has been tested in accordance with EN 15883-4 and HTM2030 using a surrogate single-lumened device and meets the criterion set in sub clause 4.1.3, which states the endoscope used within the washer disinfector must be free from vegetative bacteria after the disinfection process. The gram-negative bacteria *Pseudomonas aeruginosa* and *Escherichia coli* have been tested, alongside gram-positive bacterium *Staphylococcus aureus* and the yeast *Candida albicans*

Tristel™

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For Tristel patent information please visit: http://www.our-patents.info/tristel

Mkt-Bro-086-7
October 2018


Tristel
WE HAVE CHEMISTRY.