Navigating an effective, compliant path through Infection Control

In a Covid-affected world infection control has become something of a murky quagmire. Between the numerous product offerings now available, conflicting legislation, increased imports vs local products, personnel reactions, pricing wars, time constraints and patient awareness of such products it has become increasingly difficult to conduct successful infection control using appropriate products.

So how does a healthcare professional find their way through all of this? The answer is actually quite simple, when you split the rationale into four parts:

1. Be aware of what type of products are essential to successful infection control.
2. Be aware of the regulatory requirements for essential product types.
3. Make a conscious, informed choice when purchasing infection control products.
4. Make sure that staff conducting infection control practices are trained & competent to do so.

1. What product types are essential to successful infection control?

Infection Control products are categorised dependant on their intended use:

a) Human hygiene - products which are applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp:
   i. Soap products – intended to clean and disinfect human skin or scalp
   ii. Sanitiser products – intended to disinfect human skin or scalp only
b) Disinfectants – products which are not intended for direct application to humans or animals. In a healthcare context these are products used for the disinfection of surfaces, materials, instruments, equipment, furniture, air and waste.
   i. Detergent-disinfectants – intended to clean and disinfect surfaces, materials, instruments, equipment, furniture and waste.
   ii. Disinfectants – intended to disinfect pre-cleaned surfaces, materials, instruments, equipment, furniture, air and waste.
   iii. Chemical Sterilants – intended to sterilise pre-cleaned, non-autoclavable instruments.

The success of disinfection is always limited by the degree of diligence of the cleaning procedure that has preceded it.

When one applies the above principle to that list of product types an infection control essentials 'shopping list' can be seen to host a bare minimum of 6 products:

a) Soap product – it is not necessary for this to be a disinfecting soap product provided that a sanitiser product follows it.
b) Sanitiser product

c) Cleaning product for surfaces – it is not necessary that this product be a detergent-disinfectant provided that a disinfectant product follows it.
c) Disinfectant product for surfaces, materials, equipment, furniture, air and waste.
d) Cleaning product for instruments – it is not necessary that this product be a detergent-disinfectant provided that a disinfectant product follows it.
e) Sterilant product for instruments.

2. What are the regulatory requirements for essential product types?

In South Africa regulatory pathways have recently been updated and redefined leading to scenarios whereby end users are unsure of which products are being regulated by which authorities.

- Human hygiene products for use in healthcare areas are regulated by the South African Health Products Regulatory Authority (SAHPRA), previously known as the Medicines' Control Council (MCC), under the auspices of the Medicines and Related Substances Act (Act 101 of 1965), as amended.
- Disinfectant products for use on surfaces and equipment in healthcare areas are regulated by the National Regulator for Compulsory Specifications (NRCS) under the auspices of VC8054 (2017).
- Disinfectant products intended by the manufacturer for use on medical devices are themselves deemed medical devices and are regulated by both the NRCS under the auspices of VC8054 (2017) and SAHPRA under the auspices of the Medicines and Related Substances Act (Act 101 of 1965), as amended.

For products manufactured in other territories and imported into South Africa, the above two regulatory pathways are still mandatory, and therefore the issue should be clear. However the Covid environment has fostered the appearance of many new market entrants making advertising claims that they do not fully understand or realise are inappropriate. Therefore it is important to make the following distinctions:

a) The United States Environmental Protection Agency (US EPA) regulates disinfectants and sterilants used on environmental surfaces, and not those used on critical or semi-critical medical devices; the latter are regulated by the United States Food and Drug Agency (US FDA). (Refer the Food Quality Protection Act (FQPA) of 1996 which confirms that regulation of liquid chemical sterilants used on critical and semi-critical medical devices rests solely with FDA). Stand-alone EPA registration is therefore not appropriate for medical device disinfectants and or sterilants.
b) Antiseptics (soap and sanitising products used in healthcare environments) are considered antimicrobial drugs used on living tissue and thus are regulated by the US FDA under the Food, Drug and Cosmetic Act. EPA registration is therefore also not appropriate for healthcare soap & sanitising products.

c) CE Marking is achieved based on regulatory compliance to the claims made by the manufacturer. A disinfectant compliant for domestic, industrial and institutional use will carry the same CE Mark as a disinfectant compliant for healthcare use. The onus is on the user to determine whether the labelling, advertising and supporting information match their intended use.

As professionals we use regulatory compliance as an indicator of both quality and efficacy, as we should. However, it is also important to understand the requirements for regulatory compliance such that we are able to cut through marketing claims and determine whether or not that regulatory compliance is appropriate for our own intended usage.

SAHPRA Registration of human hygiene products under Act 101 of 1965, is dependant on the verification that the essential principles of safety and efficacy have been met. A registration number of the format X/XX.X.X/XXXXXX indicates, amongst other requirements, that the product is both safe and fit for purpose according to the manufacturer's claims. Whilst the exact proof of efficacy requirements for soap and sanitiser products are flexible, it is likely that the following methods would be amongst those considered by SAHPRA to provide the necessary efficacy reports:

SANS 490:2020	Alcohol-based hand rubs and sanitisers
SANS 5499 (EN 1499)	Chemical disinfectants and antiseptics - Hygienic handwash - Test method and requirements (phase 2, step 2).
SANS 5500 (EN 1500)	Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2, step 2).
SANS 52791 (EN 12791)	Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirements (phase 2, step 2).

NRCS Registration under VC8054.2017 is modelled upon the requirements of SANS 54885 (EN 14885) - Application of European standards for chemical disinfectants and antiseptics. A registration number of the format NRCS/8054/XXXXXX/XXXX indicates, amongst other requirements, that the following proof of efficacy reports have been provided to the Regulator dependant on the claims made by the product:

	Food, Domestic, Industrial & Institutional Use Products	**Healthcare Use Products**
Bactericidal	SANS 51276 (EN 1276) - Chemical disinfectants - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants used in food, industrial, domestic, and institutional areas - Test method and requirements (phase 2, step 1).	SANS 53727 (EN 13727) - Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants used in the medical area - Test method and requirements (phase 2, step 1).

Fungicidal / Yeasticidal	SANS 51650 (EN 1650) - Chemical disinfectants - Quantitative suspension test for the evaluation of fungicidal and yeasticidal activity of chemical disinfectants used in food, industrial, domestic, and institutional areas - Test method and requirements (phase 2, step 1).	SANS 53624 (EN 13624) - Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants used in the medical area - Test method and requirements (phase 2, step 1).
Virucidal	SANS 53610 (EN 13610) - Chemical disinfectants. Quantitative suspension test for the evaluation of virucidal activity against bacteriophages of chemical disinfectants used in food and industrial areas. Test method and requirements (phase 2, step 1).	SANS 54476 (EN 14476) - Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants used in the medical area - Test method and requirements (phase 2, step 1).
Sporicidal	SANS 53704 (EN 13704) - Chemical disinfectants - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic, and institutional areas - Test method and requirements (phase 2, step 1).	Not Applicable

The Regulator may also accept proof of efficacy reports that can be proven to be substantially equivalent to the above methods. These methods may be as follows, dependant on the substantive performance of the test product:

- EN (Europe & UK) – EN 13697 (SANS 53697), EN 14348 (SANS 54348), EN 14347, EN 14561, EN 14562, EN 14563 & EN 16777.
- FDA (USA) – ASTM Methods: E1153, E2111, E2197, E1052, E1053
- EPA (USA) - AOAC Methods: 6.3.05:2013 Official Method 966.04, AOAC 6.3.06:2012 Official Method 965.12, AOAC 6.3.02:2006 Official Method 955.17, AOAC 6.2.01:2013 Official Method 955.14, AOAC 6.2.04:2013 Official Method 955.15, AOAC 6.2.06:2013 Official Method 964.02.
- AFNOR (France) - NFT 72-150 Suspension Test & or NFT 72-190 Carrier Test
- DGHM (Germany) – GER Suspension & Carrier Tests
- TGA (Australia) – Antimicrobial Suspension & Carrier Tests

SAHPRA Registration of medical device disinfectants under Act 101 of 1965, is dependant on the verification that the essential principles of safety and efficacy have been met. A registration number of unknown format will indicate, amongst other requirements, that the product is both safe and fit for purpose according to the manufacturer's claims. This registration programme has not yet been rolled out by SAHPRA, and so there are no products as yet registered to this requirement. In the interim SAHPRA have called up all

manufacturers, importers, distributors and wholesalers of such devices to be licensed as Medical Device Manufacturers or Distributors or Wholesalers. As this deadline has already passed any entity from whom a dental practice purchases disinfectants fit for healthcare use should already be in possession of an MCC or SAHPRA license number of the format XXXXXXXXMD. Once registration call-up occurs, it is anticipated that the above-mentioned methods would be amongst those considered by SAHPRA to provide the necessary proof of efficacy. It is anticipated that proof of safety could be provided by a combination of appropriate SANS, OECD and ISO methods appropriate for the claims of the product.

3. *Make a conscious, informed choice when purchasing infection control products.*

From the above, your product choice checklist should be taking shape.

a. NRCS registration number present on product label.
b. MCC / SAHPRA Manufacturer's or Distributor's license number available.
c. MCC / SAHPRA Wholesaler's license number available.
d. SAHPRA Registration number on label where appropriate, and once available (anticipated in 2022).

From our infection control training we know that in healthcare we are required to choose between different levels of disinfection, dependant on the surface or piece of equipment on which disinfection is required. But what do they actually mean?

Disinfection level	**Definition**	**Qualification**	**Appropriate usage**
Low-level disinfection *(Equivalent to some food, domestic, industrial & institutional use registered products)*	A lethal process utilizing an agent that kills vegetative forms of bacteria, some fungi, and or lipid viruses.	Demonstrate a ≥5-log reduction of gram positive and negative bacteria. Demonstrate a ≥4-log reduction of fungi and yeasts. Demonstrate a ≥3-log reduction of an appropriate species of lipid virus.	Not strictly appropriate for healthcare facility use. Only indicated for non-patient contact areas such as kitchens or canteens.
Intermediate-level disinfection *(Equivalent to some healthcare use registered products)*	A lethal process utilizing an agent that kills viruses, mycobacteria, fungi and vegetative bacteria, but not bacterial spores.	Demonstrate a ≥5-log reduction of gram positive and negative bacteria. Demonstrate a ≥4-log reduction of fungi and yeasts. Demonstrate a ≥4-log reduction of	Indicated for patient-contact areas, but not necessarily all medical devices within those patient contact areas.

		appropriate species of virus. Demonstrate a ≥3-log reduction of an appropriate species of Mycobacterium.	
High-level disinfection *(Equivalent to some healthcare use registered products & eventually all medical device registered products)*	A lethal process utilizing a sterilant under less than sterilizing conditions. The process kills all forms of microbial life except for large numbers of bacterial spores.	Demonstrate a ≥6-log reduction of gram positive and negative bacteria. Demonstrate a ≥4-log reduction of fungi and yeasts. Demonstrate a ≥4-log reduction of appropriate species of virus. Demonstrate a ≥5-log reduction of an appropriate species of Mycobacterium.	Indicated for patient contact surfaces, semi-critical and or non-autoclavable critical medical devices.

But what about the information provided on labels by chemical manufacturers? All disinfectant products in South Africa have just undergone or are undergoing the re-registration process to VC8054.2017. This has seen manufacturers making often wholesale changes to the information contained on the labels, but not necessarily the overall appearance of the label. When was the last time your staff checked the label of the product that they have been using for years? Are the usage instructions still the same? Have extra warnings been added? Have disposal instructions changed? These are some of the questions that a practice should always be sure they check with every new chemical purchase.

On 29 March 2021 the Regulations for Hazardous Chemical Agents were added to the Occupational Health and Safety Act (Act No. 85 of 1993). These regulations require all chemical products to be classified according to the Globally Harmonised System of classification and labelling of chemicals (GHS). This system includes, amongst other things the inclusion of standardised warning systems on chemical product labels, packaging & safety data sheets, with products available on the South African market having 18 months to comply.

These warning symbols should appear, as appropriate on the label of chemical disinfectants and detergents when classified according to the weight of evidence on their properties, or the properties of their components. The pictogram should always appear alongside the details of the hazard.

	Hazard:	Details:
	Skull & Crossbones	Signal Word: Danger / Warning / None, as appropriate. Hazard Statement/s: Product Specific but using common terminology.
	Health Hazard	
	Irritation	
	Corrosion	
	Flammability	
	Environment	
	Oxidising Solid	
	Unstable Explosive	
	Chemicals or Gases under pressure	

It should be noted that even minor hazards will result in classification and must carry the appropriate warnings. Will your staff be trained to be aware of these hazards? Will they be trained to know that by December 2022 any chemical product without appropriate labelling should no longer be used? Lastly, will they be trained to adjust their usage protocol to mitigate the hazards they may face in use?

Therefore your product choice checklist should now have expanded to:

a. NRCS registration number present on product label.
b. MCC / SAHPRA Manufacturer's or Distributor's license number available.
c. MCC / SAHPRA Wholesaler's license number available.

d. SAHPRA Registration number on label where appropriate, and once available (anticipated in 2022).
e. Efficacy claims of product suitable for intended usage.
f. Warnings on labels understood in advance, and able to be taught, and mitigated through PPE and appropriate usage protocols in our facility.

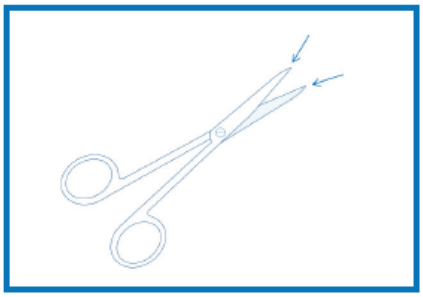
4. Make sure that staff conducting infection control practices are trained & competent to do so.

All 3 sections of knowledge above are irrelevant if the correct, compliant products are purchased, but used incorrectly. This breakdown occurs when that knowledge is not conveyed to the actual users of the infection control products or is not translated into use instructions that are clear and understandable for your staff.

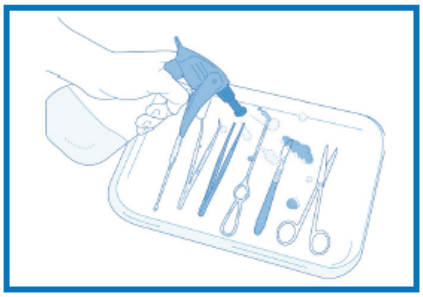
Apart from virtual, or in-person training, your staff should have access to simple use instructions or protocols for their critical infection control processes. These protocols should be as simple as possible to follow, and easy to understand. They should also ideally be non-product specific, or easily adaptable by yourself or the manufacturer to incorporate the information from the specific brands and types of products that you purchase and use. They should also be updated whenever the information on the product label changes, which requires that someone in your practice have the responsibility of reading the product labels on each new purchase to ensure that the instructions provided by the manufacturer have not been updated in any way.

Examples of such broad and easily adaptable protocols are as follows:

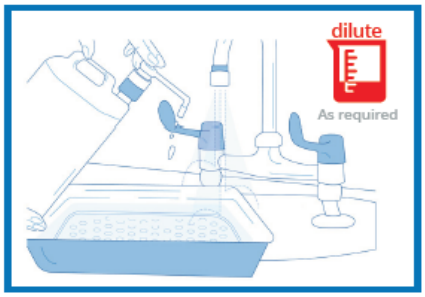
a. Chemical Instrument Reprocessing:



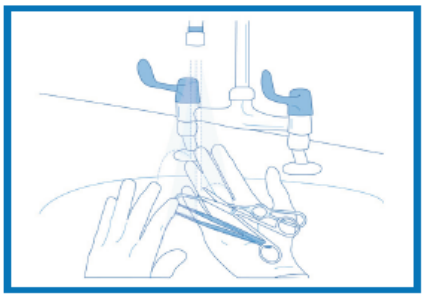
1. Immediately after use, disassemble instruments as appropriate & open all joints and hinges.



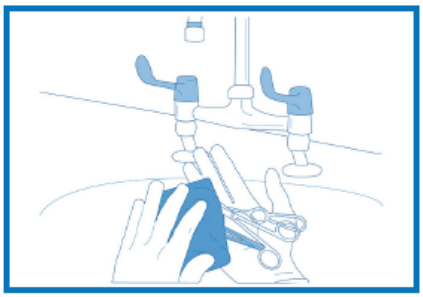
2. Place on a waterproof surface and spray with an enzymatic foam spray to prevent bioburden fixation.



3. Prepare a cleaning solution and thoroughly immerse the disassembled instruments. Ensure that no airpockets exist in complex instrumentation. Manual soak or ultrasonic cycle until visibly clean.

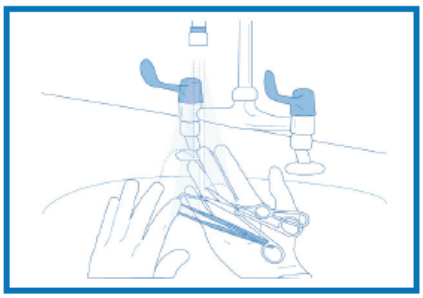


4. Wearing gloves, remove the instruments from the solution & rinse thoroughly under running water.

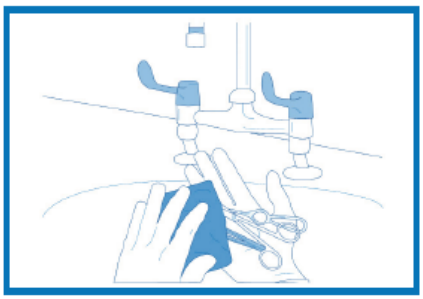


5. Wearing gloves, gently pat the rinsed instruments dry using paper towel or a clean, dry single-use towel.

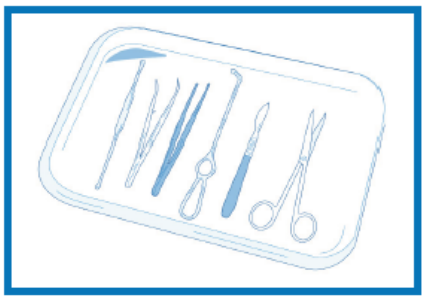
6. Place clean, rinsed, dry instruments in a clean, dry sterilisation tray and immerse in chemical sterilant ensuring that the required contact time is observed.



7. After chemical sterilisation, wearing gloves, remove instruments from sterilant & rinse thoroughly under sterile running water.

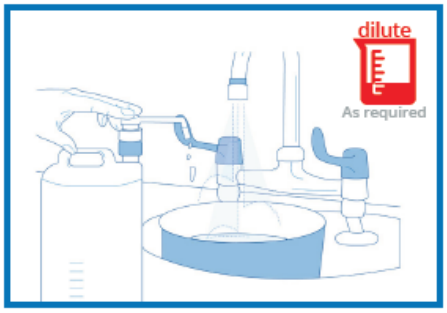


8. Wearing gloves, gently pat the rinsed instruments dry using paper towel or a clean, dry single-use towel. Then apply lubricant to points of friction.

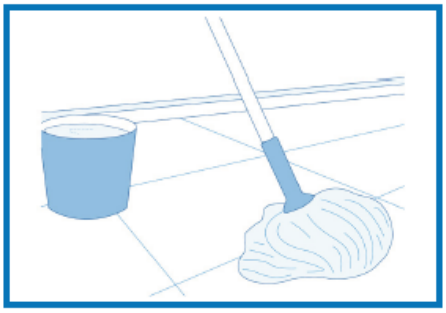


9. Place rinsed, dry, sterile instruments on a clean, dry, sterile tray and cover appropriately until use.

b. Surface Disinfection:

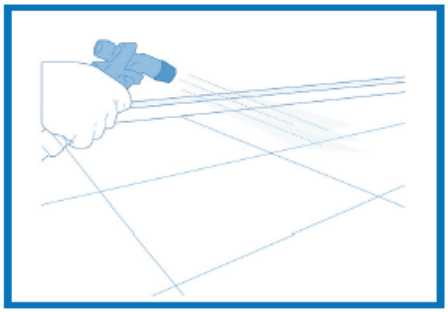


1. Dilute a detergent-disinfectant into a bucket as per the manufacturer's instructions.



2. Using the diluted solution, thoroughly mop all floors, ensuring that obvious soiling is completely removed.

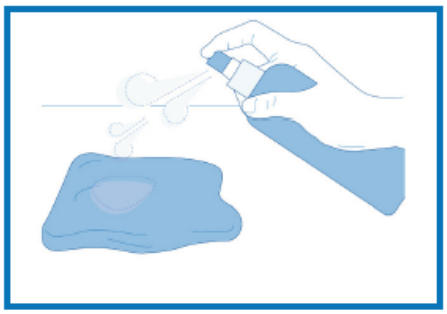
3. Using a cloth damped with the detergent-disinfectant solution, clean all high touch surfaces.



4. Rinse surfaces thoroughly (either by hosing them down where possible, or wiping them down with a cloth or mop dampened with water).

5. Using a dry cloth, dry any very wet surfaces to prevent unintended dilution of the subsequently applied disinfectants.

6. Thoroughly spray all high touch surfaces with a disinfectant, from a distance of about 30cm away, and leave to dry naturally.

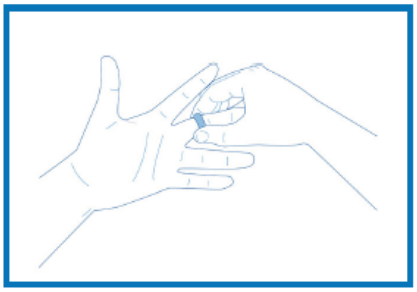


7. Where items require disinfection but should not be exposed directly to a liquid spray. Dampen a clean cloth with a disinfectant spray.

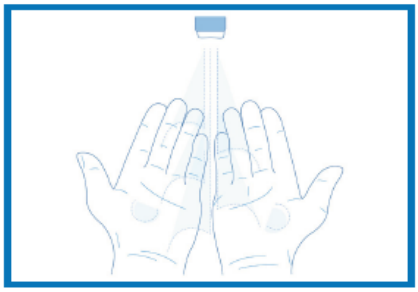
8. Using the dampened cloth or a disinfecting wipe, wipe down high touch electric equipment, and leave to dry naturally.

9. Using the dampened cloth or a disinfecting wipe, wipe down all touch screens, keyboards and monitors, and leave to dry naturally.

c. Hand Hygiene:



1. Remove all jewellery, including your watch.



2. Wet your hands thoroughly under running water.

3. Immediately dispense soap onto your dripping wet hands.

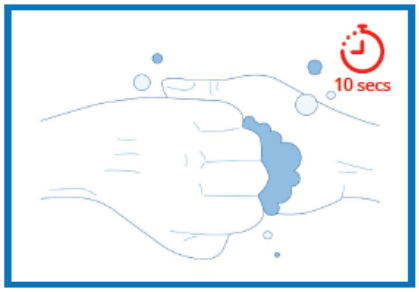
4. Rub your hands vigourously to create a lather or foam, and spread the lather or foam as follows:

5. Palm to palm, with fingers interlaced;

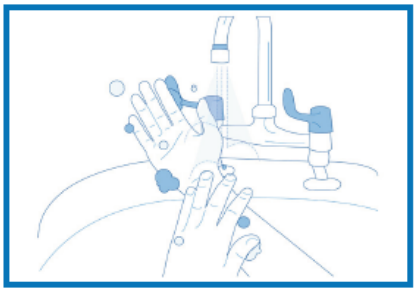
6. Rotate clasped fingertips in opposite palm in a circular motion;

7. Right palm over left dorsum, fingers interlaced. Repeat with left palm over right dorsum;

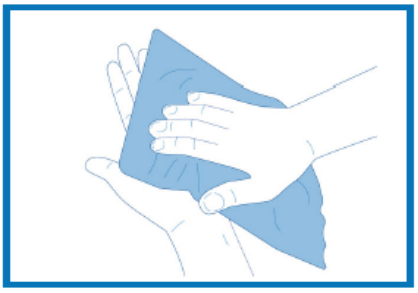
8. Rotational rubbing of left thumb clasped in right palm. Repeat with right thumb in left palm;



9. Back of fingers to opposing palms, with fingers interlocked.



10. Thoroughly rinse the lather or foam off of your hands and wrists under running water.



11. Dry your hands thoroughly using a disposable paper towel or a clean single-use towel.

12. Dispense hand sanitiser onto your hands and rub over all areas of your hands and wrists.

In closing, and despite the pandemic, infection control remains as simple as it ever was. We now know Covid-19 to spread predominantly by airborne transmission, from one person to the next. We know that surfaces do play a role, but no greater a role than in the transmission of any other virus which the dental industry have been combatting for years. We know that hand hygiene, as with the transmission of all viruses, and quite frankly most pathogens, is critical. And lastly we know that it is through our behaviour that we can control it.

If we take this same principle and apply it to Infection Control as a whole the paradigm does not shift. It is through our knowledge, our choices and our training that our infection control regimes are successful. Make today the day on which you take charge of your infection control.

References:

1. Medicines and Related Substances Act (Act 101 of 1965), as amended.
2. Minimum Compulsory Specification for disinfectants and detergent-disinfectants (VC8054.2017).
3. Occupational Health and Safety Act (Act No. 85 of 1993).
4. Regulatory Framework for Disinfectants and Sterilants. Guidance on the BPR: Volume II Parts B+C, Version 3.0. April 2018
5. Guideline for Disinfection and Sterilization in Healthcare Facilities, CDC, September 18, 2016.
6. Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019, (COVID-19) Public Health Emergency Guidance for Industry and Food and Drug Administration Staff. March 2020