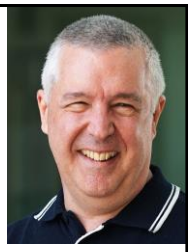
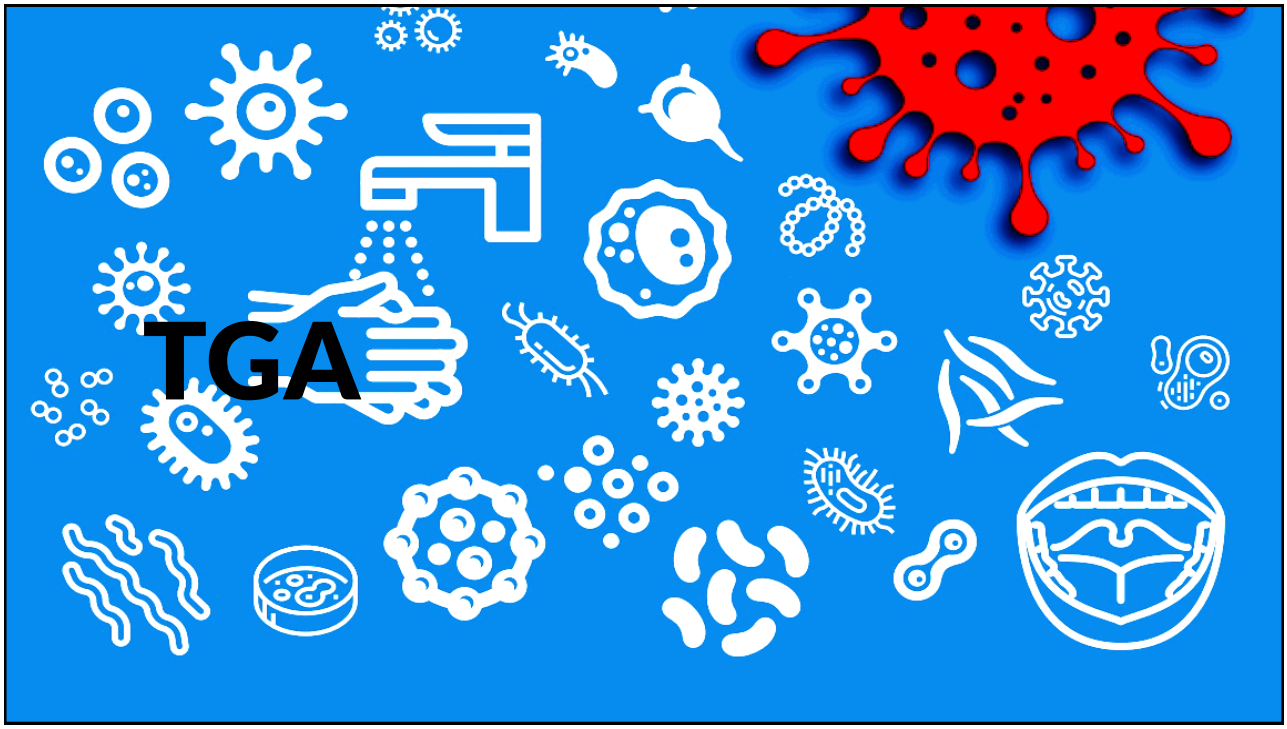
Contemporary Infection Control

2022



Emeritus Professor Laurence J. Walsh AO

BDSc(Hons), PhD, DDSc, GCEd, FRACDS, FFOP(RCPA), FFDT RCS Edin



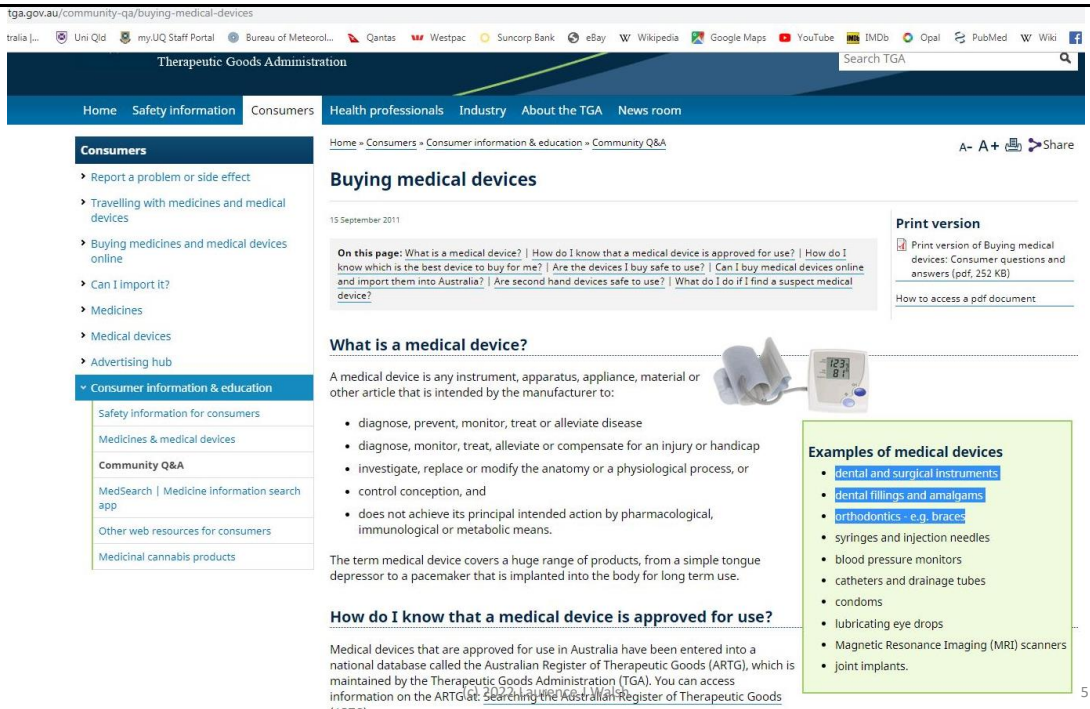
TGA Health Safety Regulation

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Use of non-TGA approved materials and equipment (2018 change to TGA regulations)

TGA and medical devices

- A medical device is any instrument, apparatus, appliance, material or other article that is intended by the manufacturer to:
  - diagnose, prevent, monitor, treat or alleviate disease
  - diagnose, monitor, treat, alleviate or compensate for an injury or handicap
  - investigate, replace or modify the anatomy or a physiological process,
  - and does not achieve its principal intended action by pharmacological, immunological or metabolic means.
- ARTG
- The Australian Register of Therapeutic Goods contains information on *medical devices and therapeutic goods* that can be supplied in Australia.
- This search engine is updated overnight https://www.tga.gov.au/australian-register-therapeutic-goods



Australian Government

Department of Health

Therapeutic Goods Administration

Canberra dental practice fined $266,400 for alleged unlawful supply of dental implants and bone grafts

30 July 2021

The Therapeutic Goods Administration (TGA), part of the Department of Health, has issued twenty infringement notices totalling $266,400 to a Canberra-based dental practice. The alleged breaches of the *Therapeutic Goods Act 1989* (//www.tga.gov.au/legislation-legislative-instruments) (the Act) include the importation and supply of dental implants (medical devices) and bone grafts (biologicals) that were not approved for use in Australia.

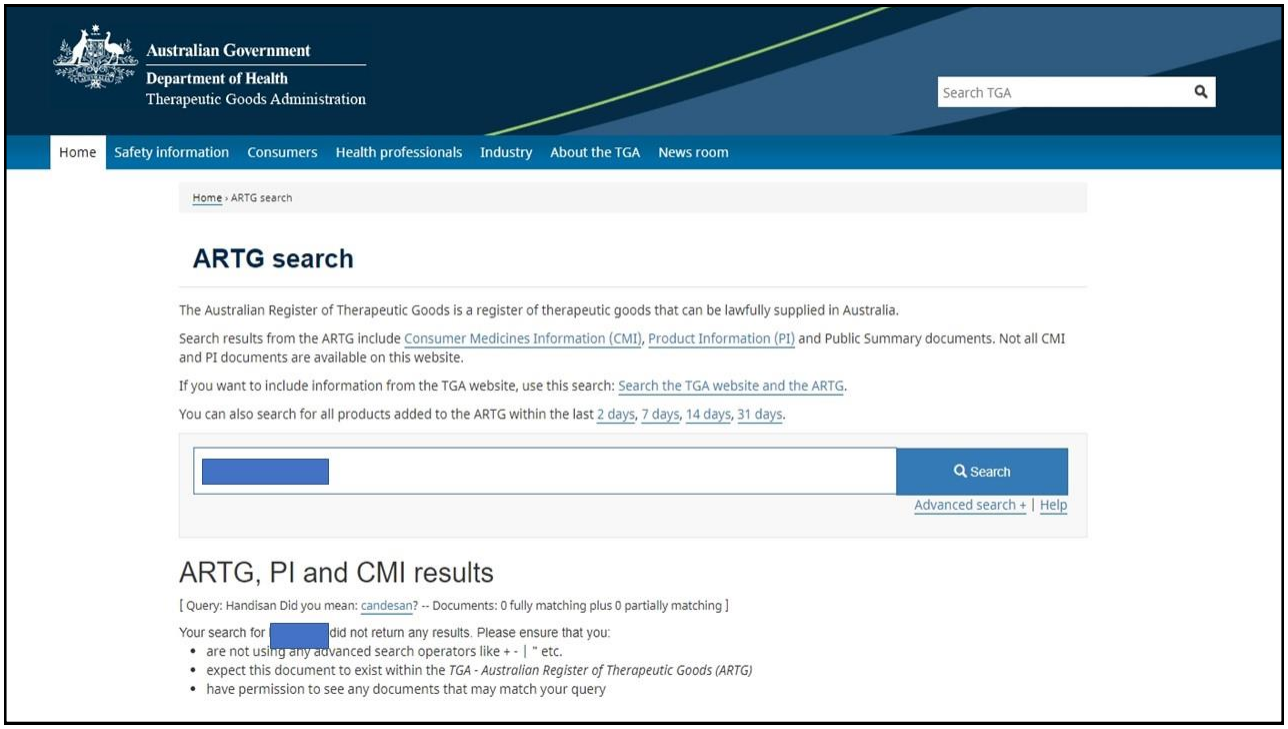
OTHER Risks of buying devices/medicines online and importing them

- may not meet TGA requirements for safety, quality and performance
- may not be manufactured under the required manufacturing controls
- may not be manufactured using the appropriate or quality materials
- may not be covered by warranty, it could be missing instructions and there may not be any after sales servicing available
- may not be correctly calibrated and could provide false readings or results
- may not be compatible with the Australian electrical standards (for electrically powered devices)
- may have been stored incorrectly or could be outside its expiry date
- may have been recalled due to a defect or safety issue
- may have been subjected to a corrective action due to a manufacturing problem
- may be a copy of a recognised brand name device
- may be second hand (used)
- may be over labelled or repackaged with a different brand name, product name, batch or serial number or a revised expiry date.

TGA – Essential principles

- *If an item can be sterilized*
- *What is disposed of*
- ***What barriers are used***
- *What surface treatment is needed*

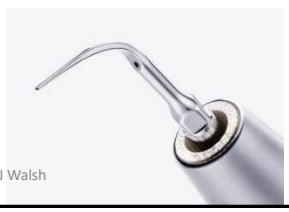
- **Do not "*make it up yourself*";** reprocessing must follow MFR instructions and reprocessing standards



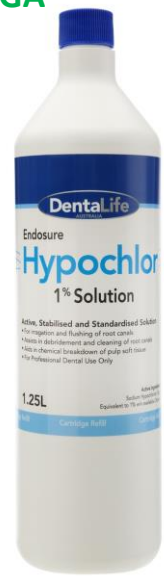
Ultrasonic Scalers

- What type of device?
  - Magnetostrictive (Cavitron)
  - Piezoelectric (EMS, Acteon, etc)
- Separate the tip
  - Tip is in the mandrel – to prevent sharps injury when in hanger and during steri
  - Are the tips critical items or not?

- Can the whole powered scaler **handpiece** be steam sterilized? See MFR instructions and TGA essential principles
- EMS scalers and handpieces can go through a DAC **green lid** cycle (cleaning only, no lube)



APPROVED by TGA



Not approved by TGA as an endodontic irrigant

Milton Anti-bacterial Solution for endodontic irrigation? Not recommended

It would appear that some dentists are using Milton Anti-bacterial Solution (2% sodium hypochlorite) as the sodium hypochlorite irrigant of choice when performing endodontic therapy. This material has not been approved by the Therapeutic Goods Association (TGA) for such a purpose and therefore its use is not recommended. Irrigants that have been approved by the TGA for use in endodontic procedures are the safest and the preferred choice. The status of an irrigant product can be checked with the supplier. Labels also disclose registration on the Australian Register for Therapeutic Goods (ARTG). This register lists specific solutions of sodium hypochlorite at concentrations of 1% and 4% for use in endodontics, as Class IIA Medical Devices. These solutions are registered with the intended function of assisting debridement, cleaning and chemical breakdown of pulpal soft tissues of the root canal.

Dissolution of porcine incisor pulps in sodium hypochlorite solutions of carrying compositions and concentrations by Clarkson *et al* remains a good source of information on this subject. This study demonstrated Milton Solution to be far inferior in dissolving tissue compared to the Endosure Hypochlor 4% forte and 1% solutions. Endosure sodium hypochlorite products have been approved by the TGA for use as dental irrigants. These products are available in multiple strengths and compared to Milton Solution, also contain a surfactant which has been proven to enhance the ability of sodium hypochlorite solutions in removing organic matter.

Remember as a registered dentist, should you become the subject of a complaint, the endodontic treatment you provided will be reviewed against what is considered acceptable by your peers. Using a product 'off label' (i.e. not approved for that use by the TGA) is allowable but only in certain circumstances and with the full knowledge of the patient.

For safety, always remember to ensure precautionary actions are taken when using sodium hypochlorite including soft tissue isolation with placement of a rubber dam, avoidance of forceful application of the needle or irrigant in the root canal, which may result in apical extrusion of solution as well as providing protection of operator, staff and patient eyes, skin and clothing.

Aust Dent J. 2006;51(3):245-251 https://onlinelibrary.wiley.com/doi/epdf/10.1111/j.1834-7819.2006.tb00437.x 03/01/2019.

Optimizing Antimicrobial Agents in Endodontics

Patricia P. Wright and Laurence J. Walsh

http://dx.doi.org/10.5772/67711

Key chemical aspects of sodium hypochlorite (NaOCl) versus Hypochlorous acid (HOCl)

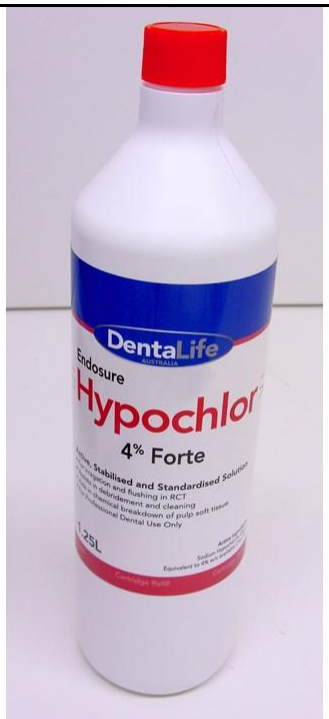
materials

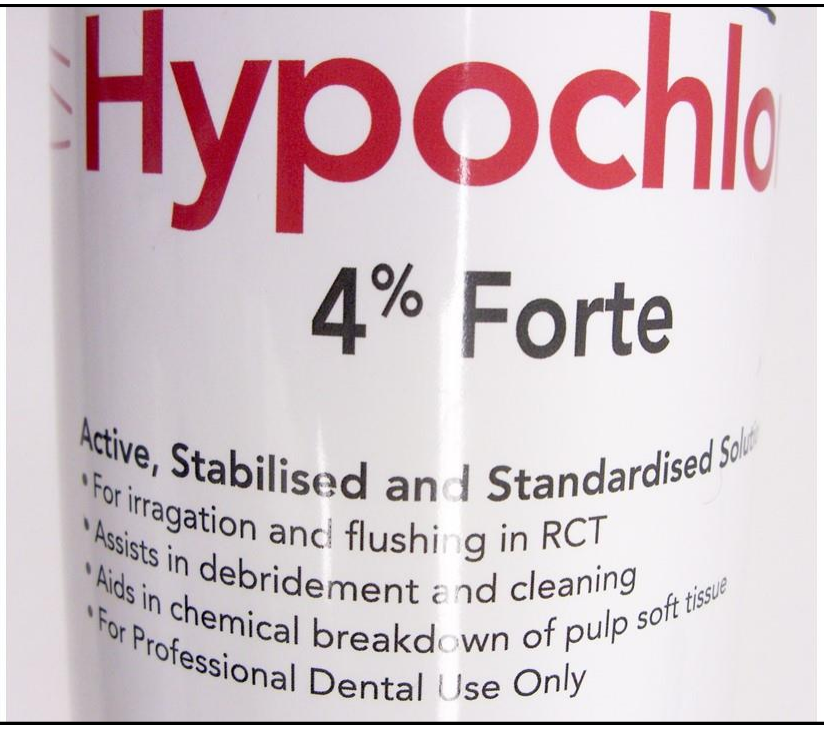
Review

Alkaline Sodium Hypochlorite Irrigant and Its Chemical Interactions

Patricia P. Wright *, Bill Kahler and Laurence J. Walsh

Materials **2017**, *10*, 1147; doi:10.3390/ma10101147





Barriers, IFU/MFR advice and chair brands

Barriers – decision making 1

- The need for any one dental practitioner to determine whether or not a barrier is needed, or whether the item can be cleaned, disinfected or sterilized should be very small, since **all TGA-approved specialised devices** used in clinical practice are required to come with **instructions from the manufacturer** on how to ensure appropriate control of cross-infection.
- If the manufacturer states that a barrier is required, then use a barrier (typically the manufacturer would also supply or specify what the barrier should be).

Barriers – decision making 2

- If the manufacturer states that the item is to be sterilized, then sterilize the item – **do not simply cover it with a barrier**.
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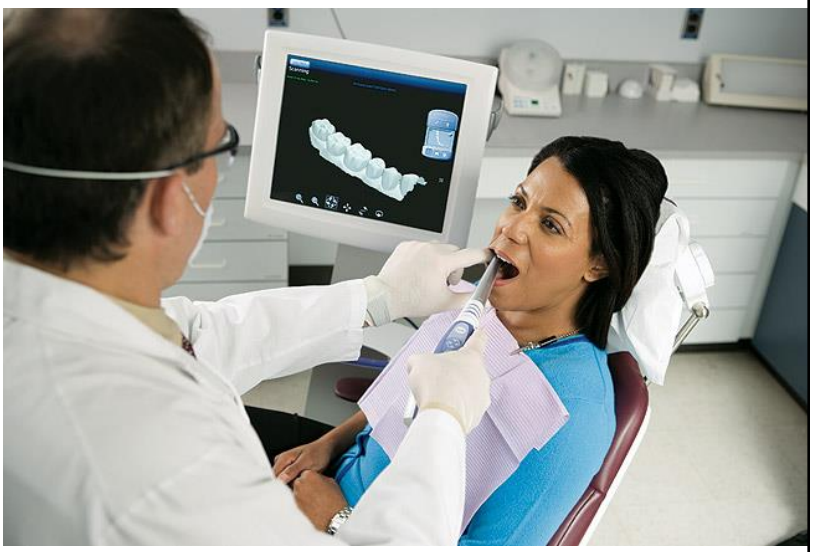
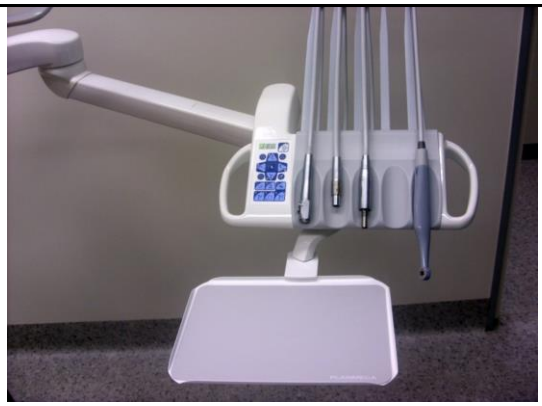
- An important example is **piezoelectric ultrasonic scalers**, many of which are designed to be sterilized.

Use the specified custom barriers or sheathes as per the manufacturer's instructions for specialized electronic and optical devices



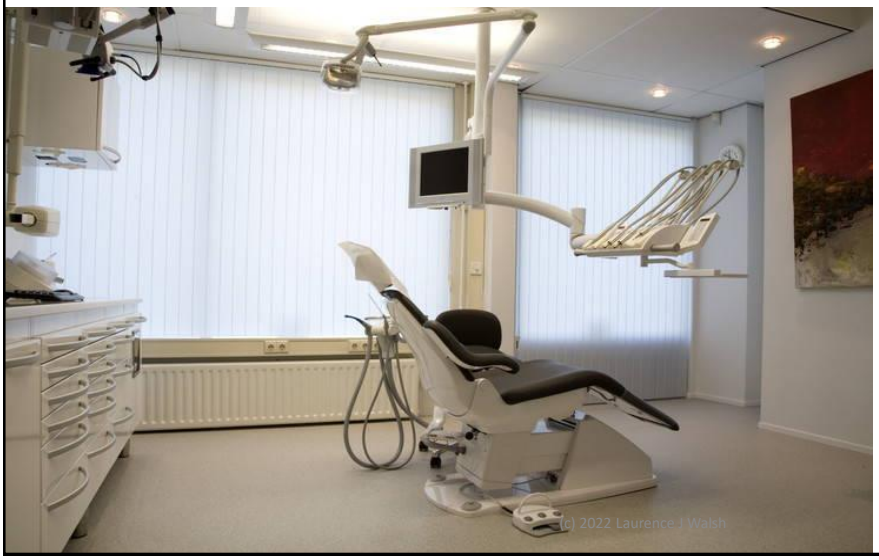


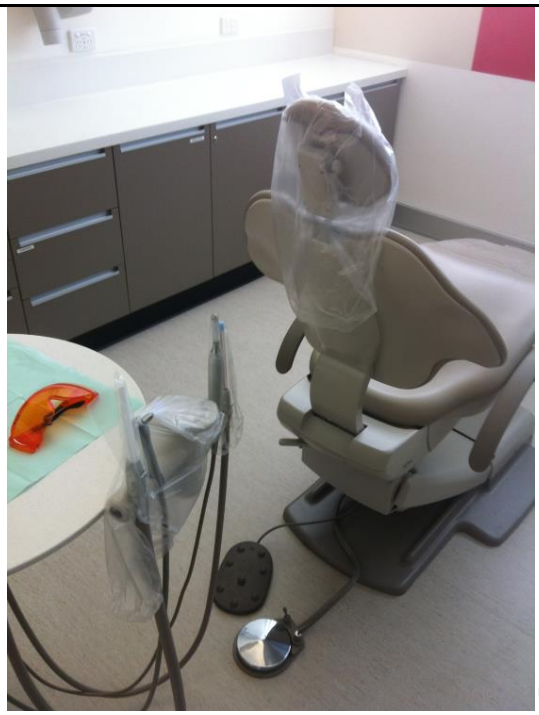
Handpiece tubing lines, instrument trays, and touch pad controls in modern dental chairs are designed to be smooth so that they can be readily cleaned using a wipe down method. This affects the need for plastic barriers to be applied to these surfaces (if at all).

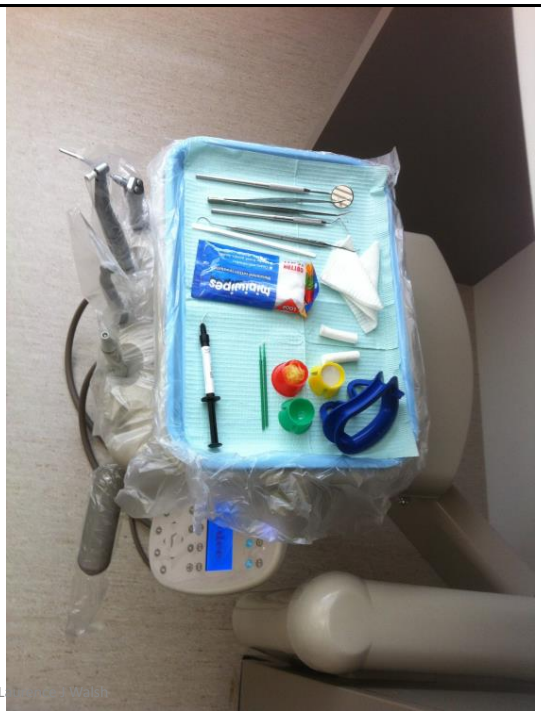
See MFR instructions!

Barriers

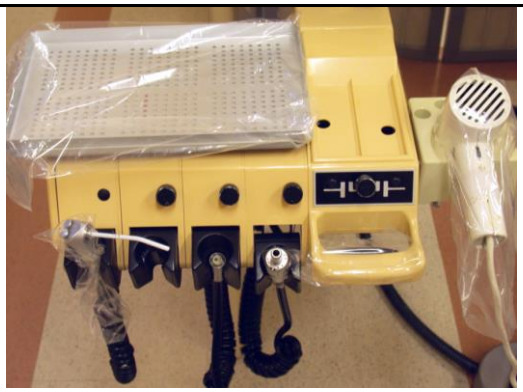
- Importance of IFU

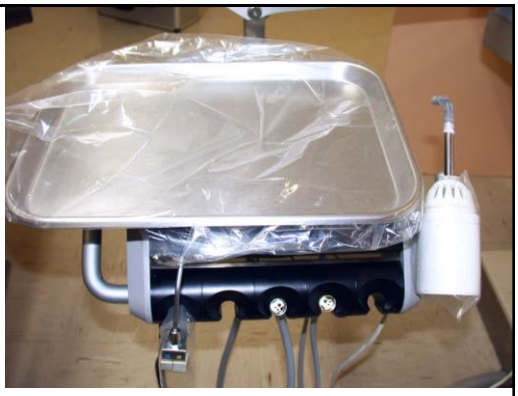




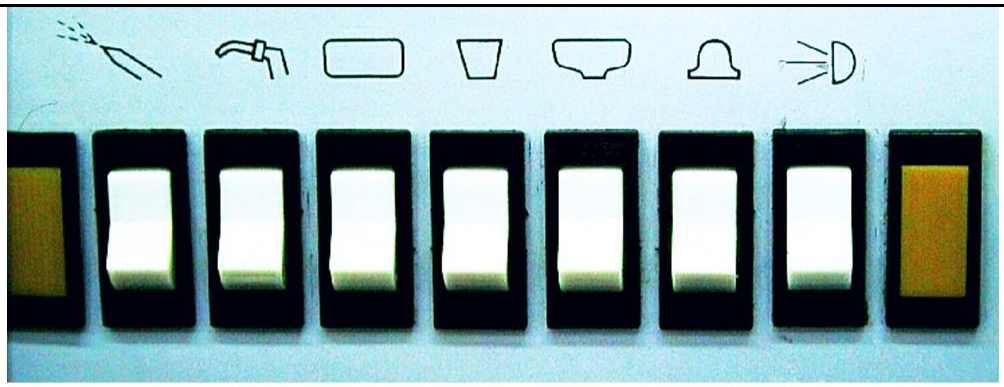


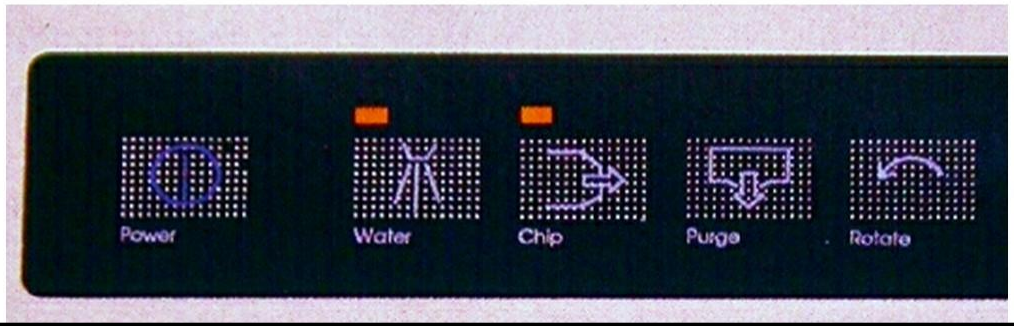
Barriers





Where older dental the equipment is being used, and where it has been decided that are necessary, the placement of these barriers must be reviewed carefully so that additional hazards are not introduced, e.g. By covering over the thermal exhaust ports of a halogen curing light.

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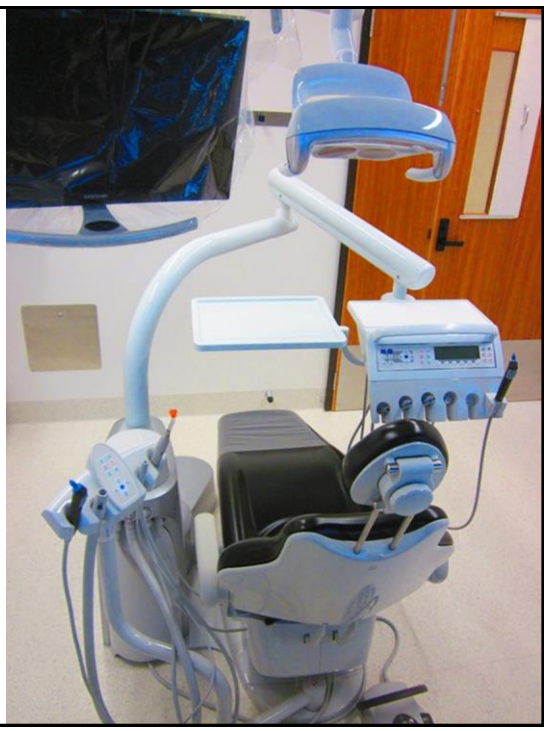

Barriers on equipment - *clarification*

- **For equipment**
  - For items that cannot be readily decontaminated such as X-ray films or sensors
  - When the use of a barrier has been **stipulated** by the manufacturer of the piece of equipment.
- Manufacturer instructions must be followed in terms of how items are managed, **both from a regulatory perspective and to ensure that the item is not damaged by incorrect processing.**
- Any surface barriers should be disposed of at the end of the appointment, and then replaced with a new barrier. Consideration should be given to ensuring how consistent and reliable management of surfaces will be achieved across different operatories by multiple staff members.

Touch panels

- Follow the manufacturer's instructions for how to manage equipment with touch panels.
- Many modern dental chairs have membrane switches that are designed to be cleaned by wiping over using specified products – in which case, use the specified products for cleaning the area, and do not use a barrier.
- Some lasers and surgical motor controllers have touch panels for operation, for which there are adhesive stick-on covers to cover the panel fully so that no wiping is required afterwards, as these simply pull-off and are discarded.
- There are other situations where wiping would not be appropriate, and a disposable barrier is employed.


UQ Oral Health Centre