

DentalOrganiser Ltd



BurButler LaminateButler, EndoButler, VisionButler BlockButler



VisionButler IFU 30/08/2023

Revision 30/08/2023

Intended use

Intended purpose

To provide access to the oral cavity of the patient with lip and cheek retraction.

To provide improve field of view and contrastor effect for dental photography

Use

For dental use only.

Description

VisionButler is an auxiliary aid for clinical use which allows the working field to be accessed with ease and comfort.

It provides retraction of lips and cheeks during dental treatment, offers the clinician increased visibility and accessibility and facilitates saliva and moisture control in the oral cavity.

The device, which features three dimensional flexibility and elasticity, ensures patient comfort and assists in keeping the patient's mouth open and teeth together or open. VisionButler is available in sizes Medium and Large. (see sizes later)

Indications: Short term retraction (>30min) of the lips and cheeks during diagnostic, preventive and therapeutic dental procedures as well as orthodontic procedures: e.g. diagnostics, professional teeth cleaning, fissure sealing, tooth whitening, periodontal treatment, restorative procedures, cavity preparation, impression taking physically or digitally, and cementation of restorations and orthodontic retention elements, oral surgical and implantology procedures .

Contraindications The use of VisionButler is contraindicated if the patient is known to be allergic to any of the components of VisionButler.

VisionButler is not sterile on delivery and should be autoclaved before use.

Side effects There are no known side effects to date.

Composition . PR 410/60 Silicone Rubber High Consistency Silicone Rubber (HCR)

VisionButler is latex-free.

Instructions for Use Flexible aid for full mouth access

Anatomy of the VisionButler. A. Labial Flange. B. Flat edge at bottom. C. Buccal flange (outer).
D. Buccal flange inner. E. Labial groove. F. Sulcus flange Upper. G. Sulcus flange.



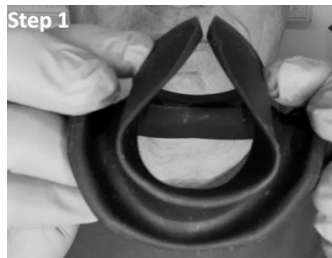
Front View



Tangential View

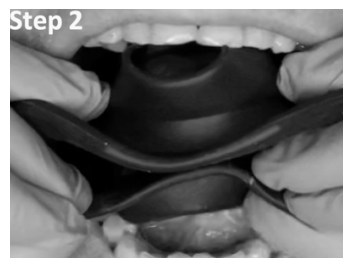


Rear View



Step 1

4. Hold labial Flanges (A)
5. Keep flat border (B) at lower edge
6. 3 Fold the buccal flanges (C) to meet.



Step 2

1. Hold labial Flanges (A)
2. Keep flat border (B) at lower edge
3. 3 Fold the buccal flanges (C) to meet.



Step 3

9. Insert folded buccal flange (C) behind upper and lower teeth and let teeth sit in labial groove



Step 4

7. Flip folded buccal flange (C) first over upper then lower teeth.
8. Or first over lower teeth then upper



Step 5

10. Flip folded buccal flange (C) first over upper then lower teeth.
11. Or first over lower teeth then upper



Applications: Examinations. Photography. Orthodontics. Restorative procedures. Composites. Bonding. Veneer placement. Whitening. Digital Imaging. Hygiene. Periodontal procedures.

Choosing the best size of VisionButler

We currently have Medium (and Large expected in November 2023) sizes of VisionButler.

As the VisionButler is reusable the correct size can be judged by the dentist.

The selection of the appropriate size should be guided by the distance between the corners of the mouth when the mouth is in a relaxed smile position (i.e. with the lips closed or slightly open) and corners of the mouth in a smile position..

The following guidelines apply: –

Medium VisionButler mouth corner distance ≈ 50 - 60mm

Large VisionButler corner distance ≈ 60 - 70mm

The size (M is for Medium L is for Large) is indicated on the packaging as well as on the side buccal flanges of the VisionButler.

In order to ensure optimum function, we recommend inserting the largest possible size that fits the patient's mouth comfortably.

VisionButler may be inserted from both the 12 o'clock position with the patient lying down, or from the 8 o'clock position with the patient sitting upright (or, the 4 o'clock position, if the clinician is left-handed).

The securely positioned VisionButler improves the overall view and accessibility of the working field. Lateral movements of the mandible and opening of the mouth or pulling of the margins of the VisionButler to various degrees may provide additional space and access to the treatment area or for photography.

Below are the sizes with the mouth open and VisionButler at rest, and the teeth closed (with the VisionButler compressed vertically the distance increases

Medium VisionButler: Internal measurements .

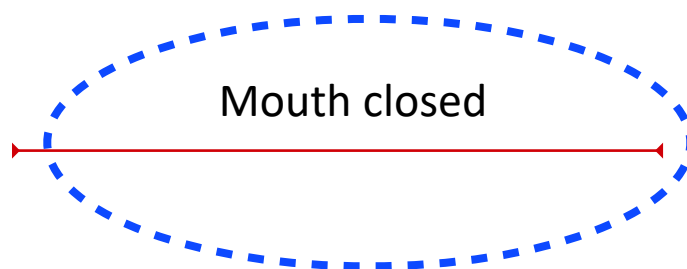
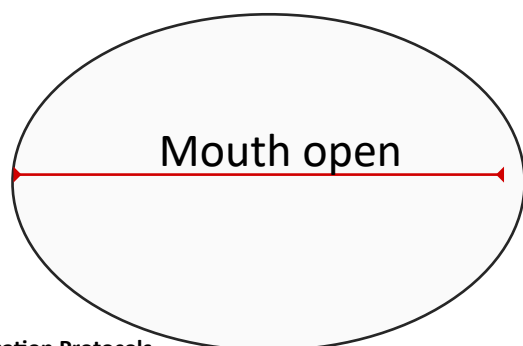
At rest:, mouth open : Width 55mm Height 43mm from lip corner to lip corner, side to side at rest (Black outline)

Teeth closed : Width 60mm Height 30mm from lip corner to lip corner, side to side

Large VisionButler.

At rest:, mouth open : Width 66mm Height 52mm from lip corner to lip corner, side to side at rest (Black outline)

Teeth closed : Width 60mm Height 30mm from lip corner to lip corner, side to side.



Sterilisation Protocols

Pre-cleansing: After each use the VisionButler should be washed in warm water to remove any debris and thoroughly dried prior to packaging for sterilisation. Rinse Retractors with distilled or demineralised water if possible. Inspect device for visual damage, wear and tear or deterioration. Discard broken, defective or worn-out products.

Ultrasonic cleaning: The VisionButler can be processed in an ultrasonic bath with appropriate ultrasonic cleaning agent (subject to the manufacturers instructions for silicon products) Any chemical disinfectant must be washed off and the retractor dried prior to packaging for sterilisation. Retractors damaged due to chemical residue are not covered under warranty.

Washer disinfectant: The VisionButler can be processed in a washer disinfectant.

Autoclave: The VisionButler can be placed in an autoclave pouch (eg Tvek) and autoclaved according to your local directives and autoclave instructions and parameters.– eg Steam sterilise only for 20 minutes at 245°F / 118°C. (134 degrees – 135 degrees) Follow your autoclave manufacturer's instructions regarding drying time/cycle.

Recommended drying time of 15-30 minutes depending on the type of steriliser being used: <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/tables/table7.html> Always follow your autoclave manufacturer instructions and adhere to AAMI ST79 standards for safe practices. After sterilization, cheek retractors are to remain in their sealed package and opened only at point of use.

Product	VisionButler
Reference	VisionButler
Company	Dental organiser Ltd (previously Gate Dental Services Ltd) Garrynagry Rosscahill Galway Ireland H91V8C5
Contact information and emergency phone number	sales@dentalorganiser.com +35391550944
Classification	Class 1 Medical Device directive 93/42/CEE
Product Description	Cheek retractor and Photoconstraster
COMPOSITION/INFORMATION ON INGREDIENTS	Medical grade silicon
FIRST AID MEASURES	
If inhaled:	No further relevant information available
In case of skin contact:	No further relevant information available
In case of eye contact:	No further relevant information available

If swallowed:	No further relevant information available
Symptoms caused by exposure:-	No further relevant information available
Medical attention and special treatment:-	The material is contra-indicated if a person is known to be allergic to any of the ingredients of the product.
FIRE FIGHTING MEASURES	
Suitable extinguishing equipment: -	Carbon dioxide, extinguishing powder, water fog, foam and dry chemicals. Not combustible under normal conditions. Adapt extinguishing measures to suit the environment.
Suitable extinguishing media:	CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam
Unsuitable extinguishing media:	Waterjet.
Specific hazards arising from the substance/ mixture/product:-	
Special protective equipment and precautions for fire fighters:-	
Special personal protective equipment:	When extinguishing fires, use breathing apparatus with an independent source of air. Firefighters should wear full protective clothing including self-contained breathing apparatus
Precautions:	No further relevant information available.
	Information on physical/chemical properties:- a) Appearance/Form: Flexible solid b) Colour: Black c) Odour: Odourless d) Odour threshold: Not determined. e) pH-value (10 g/l) at 20 °C: Not determined. f) Melting point/melting range: 1013 hPa g) Boiling point/boiling range: Not determined. h) Flash point: Not determined. i) Ignition temperature: Not determined. j) Self-igniting: Product is not self-igniting. k) Danger of explosion: Product does not present an explosion hazard. l) Upper/lower flammability or explosive limits: Lower Not determined. Upper Not determined. m) Vapour pressure 20oC: Not determined. n) Density at 20oC: Not determined o) Relative density: Not determined. p) Vapour density: Not determined. q) Evaporation rate: Not determined. r) Solubility in / Miscibility with water: Not Soluble s) Partition coefficient: n- octanol/water: Not determined. t) Viscosity: Dynamic Not applicable. Kinematic Not applicable. u) Solids content: Not determined.
TOXICOLOGICAL INFORMATION	Information on toxicological effects:- Acute toxicity / Values relevant for classification:
	Skin corrosion/irritation: No further relevant information available. Serious eye damage/eye irritation: No further relevant information available. Respiratory or skin sensitization: No further relevant information available. Germ cell mutagenicity: No further relevant information available. Carcinogenicity: No further relevant information available. Reproductive toxicity: No further relevant information available. Specific target organ toxicity - single exposure: No further relevant information available. Specific target organ toxicity - repeated exposure: No further relevant information available. Aspiration hazard: No further relevant information available.
Information on possible routes of exposure:-	Short Term (Acute) Exposure: No further relevant information available. Swallowed: No further relevant information available. Eyes: No further relevant information available. Skin: No further relevant information available. Inhaled: No further relevant information available. Long Term (Chronic) Exposure: No further relevant information available. Swallowed: No further relevant information available. Eyes: No further relevant information available. Skin: No further relevant information available. Inhaled: No further relevant information available.
ECOLOGICAL INFORMATION	
Ecotoxicity:-	No further relevant information available
Persistence/degradability:-	No further relevant information available
Bioaccumulative potential:	No further relevant information available
Mobility in soil:-	No further relevant information available

Other adverse effects:-	No further relevant information available
Additional ecological information / General notes:-	Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
Other adverse effects:-	No further relevant information available
DISPOSALCONSIDERATIONS	
Disposal methods:-	Concentrate: Avoid contamination of ground water or waterways. The product must not enter effluent, ground water, surface water or the soil. Clean up with liquid binding material (sand, dolomite, acid binders, universal binders and sawdust). Complete the disposal in compliance with all applicable Local, State and Federal government regulations.
Contaminated packaging	Contaminated packaging must be emptied of all residues and, following appropriate cleaning, may be sent to a recycling plant. Un-cleaned packaging must be disposed of in the same manner as the medium. Responsibility for proper waste disposal rests with the generator of the waste. Dispose of any waste material (including containers) in accordance with all applicable Local, State and Federal government regulations regarding waste management methods.
TRANSPORT INFORMATION	UN number ADR / IMDG / IATA:- Void UN proper shipping name or technical name:- ADR: Void IMDG, IATA: Void Transport hazard class(es): Void Label: Void Packaging group: Void Environmental hazards: Void Special precautions for user: Void Danger code: Void EMS Number: Void Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Void Transport/Additional information: Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). UN "Model Regulation":
Specifications	100 x 65 x 350 mm
Packaging	One item per bag
Shelf life	10 years
Intended use	Cheek retractor for holding soft tissue of lips and cheeks out of field of view and for short term (>30min) operative procedures. Photocontraster for photography Autoclavable to 134 - 135 degrees C (see https://www.cdc.gov/infectioncontrol/guidelines/disinfection/tables/table7.html)
Security	The VisionButler is supplied unsterile and should be autoclaved before use at 134-135degrees C. (see https://www.cdc.gov/infectioncontrol/guidelines/disinfection/tables/table7.html)
Transportation and Storage	The VisionButler can be stored in a temperature range of 10 - 50 degrees centigrade

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