INSTRUCTIONS FOR USE

Cervico Essential Mold

Benchtop mold for chairside customization of stock temporary abutments into anatomical healing abutments, using the implant system's stock lab analogs.

REF 5213006651779
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Device identification

Trade name	Cervico by VPI · Cervico Essential Mold
REF	5213006651779
Description	Benchtop mold for chairside customization of stock temporary abutments into anatomical healing abutments, using the implant system's stock lab analogs.

CERVICO ESSENTIAL MOLD · REF 5213006651779

COMPONENT	QTY	MATERIAL
Mold base (ring) with laser-marked well codes	1	Aluminium alloy 6082, anodized
Silicone insert: 24 anatomical wells (a, p, m1, m2 × S, M, L × centered, off-centered)	1	Medical silicone

- Each well is coded shape–size–symmetry, e.g. m1Lc = lower molar, large, centered; m1Lo = the same shape off-centered.
- Each well has a tear-shaped protrusion on its front face: the buccal reference.
- The bottom hole of each well accepts the stock lab analog of any implant system; no proprietary insert is required.
- The well to use is the one whose code matches the Cervico Guide tab selected in the mouth (Guide supplied in the Essential Kit or separately). Without the Guide, choose the tooth group from the tooth being replaced and the size from the cervical width of the future crown against the adjacent teeth.

Intended purpose, indications, contraindications

CERVICO ESSENTIAL MOLD

Intended purpose. The Cervico Essential Mold is intended for the customization of stock temporary abutments so that they acquire a shape resembling the cervical zone of the intended implant prosthesis.

Indications. Chairside or laboratory fabrication of custom anatomical healing abutments for partially edentulous implant cases, with any implant system that provides stock lab analogs. The emergence profile is then recorded by intra-oral scan or by a conventional impression; the Essential Mold does not produce custom impression posts.

Contraindications.

- None absolute. Do not use for patients in whom implant therapy is contraindicated.

INTENDED USERS

Licensed dental professionals (dentists, oral surgeons, prosthodontists) and, for the mold devices, trained dental assistants and dental technicians working under their direction. Users must be trained in implant dentistry and have read this document.

PATIENT POPULATION

Patients with partial edentulism undergoing implant therapy, with completed craniofacial growth (in general 20 years and above, no upper age limit). Use in pregnant or nursing women is not recommended.

USE ENVIRONMENT

Dental clinic or dental laboratory. Place the device on a flat, clean, dry, non-slip surface with good lighting.

CLINICAL BENEFIT

Selection of an anatomically correct cervical profile and its chairside transfer to a custom healing abutment supports peri-implant soft-tissue conditioning around the correct contour from placement onward, and the accurate recording of that contour for the definitive prosthesis. Expected performance: complete, correctly oriented abutment shaped to the well within approximately 4 minutes.

RESIDUAL RISKS AND UNDESIRABLE SIDE EFFECTS

- Aspiration or ingestion of a small part used intra-orally (Guide). Controlled by securing parts with floss or suture.

- Cross-contamination from inadequate reprocessing. Controlled by the validated reprocessing instructions.
- Malpositioned or mis-oriented healing abutment from a wrong well, orientation or depth. Controlled by the coding system, tear mark or VPI insert, and by clinical and radiographic verification at placement.
- Tissue irritation from incompletely cured or unpolished composite. Controlled by curing and polishing instructions and the composite manufacturer's IFU.
- Hypersensitivity to aluminium or stainless steel in patients with known metal allergy.

Warnings and precautions

Read this document before use
Keep it available at the point of use. The latest revision is published at vpicervico.com/instructions-of-use. Use of the device for any purpose other than the intended purpose is not permitted.

Supplied non-sterile
Clean and sterilize before the first use and before every use, following the reprocessing section. Inadequate reprocessing can transmit infection between patients.

Temperature limit 145 °C
Do not expose any part to more than 145 °C. Do not use dry heat, chemical, radiation or plasma sterilization.

Inspect before use
Do not use parts that are corroded, cracked, deformed, or silicone inserts that are torn or hardened. Damaged parts can produce a wrongly shaped abutment or shed fragments.

Prosthetic components and composite are not supplied
Temporary abutments, impression posts, lab analogs and screws must be the certified components of the implant manufacturer, used per their IFU. The customization material must be a composite intended for provisional intraoral use (a flowable nano-hybrid composite is recommended) and must be handled and cured per its manufacturer. Bis-acryl provisional materials are not recommended: they are brittle and polish poorly.

The fabricated abutment is a patient-contacting part
Polish the composite surface smooth, remove all debris, then disinfect or sterilize the customized abutment in the same way as any implant abutment before it enters the mouth. Verify seating clinically and radiographically, check occlusal clearance and torque the screw as the implant manufacturer specifies.

Allergies
Materials are biocompatible aluminium alloy 6082, stainless steel AISI 304 and medical silicone. Do not use parts intra-orally on patients with known hypersensitivity to these metals.

Storage
Keep out of direct sunlight. Store in the original box when not in use.

Serious incidents
Any serious incident related to the device must be reported to the manufacturer and to the competent authority of the country where the user or patient is established (contact details in section "Reporting").

Not for use on the patient
The mold is a benchtop tool. No part of it is intended to enter the mouth. Only the customized abutment made in it is placed in the patient.

Orientation is the user's responsibility
A healing abutment fabricated with the wrong rotational orientation or insertion depth will sit incorrectly in the mouth. Align the prosthetic connection reference to the tear mark (Essential Mold) or fit the correct VPI Prosthetic Connection Insert in the socket group matching the placement depth (Premium Mold) before filling.

Light curing
Cure fully. Fill large wells in two increments. As a general rule cure 60 seconds in the well and a further 60 seconds after removal, or longer if the composite manufacturer specifies. Uncured composite is a chemical and mechanical hazard for the tissue.

Symbols on the label

Manufacturer ISO 15223-1 5.1.1
Name and address of the legal manufacturer.

Catalogue number ISO 15223-1 5.1.6
REF: the product code shown on the label and in this document.

Batch code ISO 15223-1 5.1.5
LOT: traceability code of the production batch; it encodes the assembly date.

Unique device identifier ISO 15223-1 5.7.10
Typographic symbol next to the UDI carrier (GS1 barcode) on the label.

Medical device ISO 15223-1 5.7.7
The product is a medical device.

Non-sterile ISO 15223-1 5.2.7
Supplied non-sterile. Clean and sterilize before use.

Do not use if package is damaged ISO 15223-1 5.2.8
Inspect the package on receipt; do not use if it is damaged, and contact the manufacturer or distributor.

Keep away from sunlight ISO 15223-1 5.3.2
Store out of direct sunlight.

Temperature limit ISO 15223-1 5.3.7
Storage, transport and reprocessing between 5 °C and 145 °C. Never exceed 145 °C.

Caution ISO 15223-1 5.4.4
Important safety information in this document must be read before use.

Consult instructions for use ISO 15223-1 5.4.3
e-IFU: read this document before use. The QR code on the label and vpicervico.com/instructions-of-use give the latest version.

CE marking ISO 15223-1 —
Conforms to Regulation (EU) 2017/745. Class I, no notified body number.

Prescription only (USA) ISO 15223-1 21 CFR 801.109
Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed dentist or physician.

> Symbols reproduced from the product label artwork (ISO 15223-1:2021). UDI and Rx only are typographic symbols.

Devices and materials used with this device

The following are not supplied by VP Innovato Holdings and must carry their own conformity marking. Use them according to their manufacturer's instructions.

ITEM	NOTE
Temporary abutment	One- or two-piece, titanium or PEEK, from the implant manufacturer. Core of the custom healing abutment.
Stock impression post	Closed- or open-tray, from the implant manufacturer. Used for the conventional impression.
Lab analog (Essential Mold)	Stock analog of the implant system. Carries the abutment in the well.

ITEM	NOTE
Flowable nano-hybrid composite	Light-curing composite intended for intraoral provisional use, with the manufacturer's IFU.
Dental curing light	Output and time per the composite manufacturer.
Polishing mops, brushes and composite polishing paste	To finish the composite surface.
Sterile PTFE (Teflon) tape	To seal the screw access channel before composite.

Before first use

- Check the package and contents against the components list. Do not use a device with a damaged package or missing or damaged parts; contact the manufacturer or distributor.
- Remove all packaging material. Note the LOT number in your instrument records.
- Clean and sterilize every part as described in "Reprocessing". The device is supplied non-sterile.
- Read the procedures below and watch the video guides at vpicervico.com/instructions-of-use.

Instructions for use: Cervico Essential Mold

Custom healing abutment fabrication

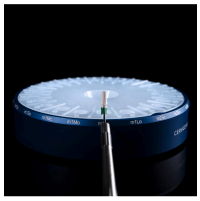
After consultation or at surgery; about 4 minutes

01 Choose the well

Use the well whose code matches the Cervico Guide tab chosen in the mouth (e.g. m1Lc). Centered (c) when the implant sits under the middle of the future crown, off-centered (o) when it does not. Without the Guide, choose by tooth group and the cervical width of the future crown.

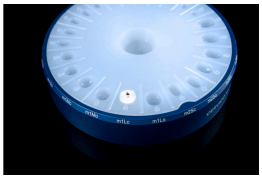
02 Connect the abutment to its analog and seat it in the well

Connect the temporary abutment to the lab analog of the implant system. Push or screw the analog into the bottom hole of the well until the shoulder of the abutment is level with the floor of the well. This is the final vertical position.



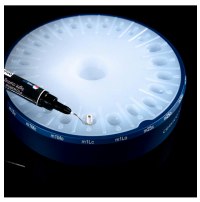
03 Rotate to the tear mark

Turn the assembly until the reference mark of the prosthetic connection on the abutment (e.g. flat seat of the hex) is aligned with the tear-shaped protrusion on the front of the well. If the implant was placed with its connection not facing buccal, see "Non-buccal connection orientation" below.



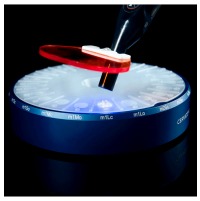
04 Fill with composite

Fill the open space of the well with flowable nano-hybrid composite. Fill large wells in two increments so each cures fully.



05 Light cure

Cure per the composite manufacturer. General rule: 60 seconds in the well, then 60 seconds more after removal from the mold.

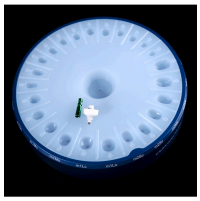


06 Remove from the mold

Hold the abutment pillar with tweezers and twist the assembly out, or engage the retention screw with the driver, rotate clockwise and pull.

07 Polish, separate and disinfect

Polish the composite with mops and polishing paste to an even, smooth surface. Disconnect the lab analog. Disinfect or sterilize the abutment as for any implant abutment before intraoral use.

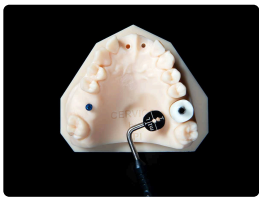


Placement of the custom healing abutment

At implant placement (one-stage) or at uncovering

01 Seat and verify

Screw the abutment to the implant with the retention screw of the temporary abutment, torqued per the implant manufacturer. Confirm complete seating clinically and radiographically.



02 **Seal the screw access**
Place a first layer of sterile PTFE tape, then fill the remaining channel with composite and cure.

03 **Check occlusion**
Verify occlusal clearance and reduce the abutment height if needed. Allow the implant to integrate, or if the abutment was placed at uncovering allow the tissue to mature for 4 to 6 weeks.

Impression — After tissue maturation

01 **Remove the healing abutment**
Remove the composite and PTFE from the screw access, unscrew and remove the abutment.

02 **Record the profile**
Scan the emergence profile with an intra-oral scanner, or take a conventional impression with a plain stock impression post. Work one implant at a time and reseat the healing abutment promptly so the tissue does not collapse.

03 **Laboratory**
The recorded emergence profile is the template for the submerged part of the prosthesis, preferably in titanium or zirconia.

Non-buccal connection orientation — When the implant's connection does not face buccal

01 **Mark buccal in the mouth**
Seat the temporary abutment on the implant and mark its buccal surface with a marker or a scored line.

02 **Align the mark to the tear**
In the mold, align that mark, not the connection feature, with the tear-shaped protrusion of the well, then fabricate as normal.

Reprocessing: cleaning, disinfection, sterilization

All Cervico instruments are supplied NON-STERILE and must be cleaned and sterilized before the first use and before every subsequent use. Thorough cleaning is a precondition for effective sterilization. The user is responsible for using validated equipment and for complying with local regulations and the hygiene policy of the facility.

POINT OF USE

- Immediately after use, wipe composite residue out of the silicone wells with a cotton tip soaked in alcohol. Do not let composite cure inside a well.
- Disassemble fully: silicone insert out of the mold base, VPI Prosthetic Connection Inserts out of their sockets, Guide tabs and pins off the handle and out of the case.
- Keep the parts moist until cleaning; do not allow soil to dry on.

AUTOMATED CLEANING (PREFERRED)

- Prefer a validated washer-disinfector (EN ISO 15883) with a program suitable for dental instruments and adequate rinsing cycles.
- Use a mildly alkaline or enzymatic detergent approved for dental instruments and compatible with aluminium and silicone.
- Final rinse with purified or deionized water (max. 10 CFU/ml, 0.25 EU/ml). Dry with filtered air.
- Service, inspect and calibrate the washer-disinfector according to its manufacturer.

MANUAL CLEANING

- Ultrasonic bath, 10 minutes at 50 °C, in an aldehyde-, phenol- and chlorine-free cleaning concentrate for dental instruments, all parts fully immersed.
- Rinse thoroughly with purified or deionized water. Manual cleaning is less effective than automated cleaning; always inspect.
- Dry completely before packaging.

DO NOT USE

- ✖ Strong alkalines (pH above 9) or strong acids (pH below 4)
- ✖ Phenols, iodophors, halogenated hydrocarbons
- ✖ Strong oxidizers, peroxides, organic solvents
- ✖ Metal brushes or steel wool on any part
- ✖ Dry heat, radiation, formaldehyde, ethylene oxide or plasma sterilization
- ✖ Immediate-use (flash) sterilization as the routine method

INSPECTION AND MAINTENANCE

After cleaning, inspect every part for residue, corrosion, cracks, deformation, torn or hardened silicone and wear of the tear-shaped orientation marks. Re-clean if soiled. Do not use damaged parts: replace the silicone insert or the part, or contact the manufacturer.

PACKAGING

Package dry parts in sterilization pouches or a cassette conforming to local standards and rated to at least 141 °C with adequate steam penetration. Size the pouch so it seals without strain.

STEAM STERILIZATION, MINIMUM PARAMETERS

ITEM	GRAVITY DISPLACEMENT	DYNAMIC AIR REMOVAL (PRE-VACUUM)	DRYING
Cervico Guide (case, tabs, pins, handle)	30 min at 121 °C (250 °F)	4 min at 132–134 °C (270–273 °F)	30 min minimum
Cervico Premium Mold (base, silicone insert, VPI inserts, screwdriver)	30 min at 121 °C (250 °F)	4 min at 132–134 °C (270–273 °F)	30 min minimum
Cervico Essential Mold (base, silicone insert)	30 min at 121 °C (250 °F)	4 min at 132–134 °C (270–273 °F)	30 min minimum

- Steam sterilization only: fractionated pre-vacuum (dynamic air removal) or gravity displacement, in a sterilizer conforming to EN 13060 / EN 285 or ANSI/AAMI ST55 / ST8, validated to EN ISO 17665-1 or ANSI/AAMI ST79.
- Never exceed 145 °C. The magnetic retention handle of the Guide must not be exposed to more than 145 °C.
- Allow parts to dry and cool completely before handling. Sterilizers with an automatic drying program are recommended.
- Use only purified or deionized feed water and maintain the sterilizer per its manufacturer.

STORAGE AFTER STERILIZATION

Store sterilized, wrapped parts dry, dust-free and out of direct sunlight in the clean zone, with sterilization status marked, separated from non-sterile instruments. Unsterilized devices are stored in the original box at normal office conditions.

REUSE AND SERVICE LIFE

The devices are reusable without a fixed limit of cycles. Service life depends on frequency of use, care and correct reprocessing. Silicone inserts are wear parts: replace when wells are torn, deformed, hardened or no longer release the abutment cleanly. Inspect before every use; the user is responsible for not using damaged or soiled parts.

Troubleshooting

OBSERVATION	LIKELY CAUSE	ACTION
Abutment sits rotated in the mouth	Orientation reference not aligned to the tear mark, or the implant connection was placed off the T-line direction	Re-fabricate using the buccal mark method: mark buccal on the abutment in the mouth and align that mark to the tear.
Composite tears or leaves residue in the well	Undercured composite, or separating medium in an anatomical well	Cure in increments, 60 seconds in the well. Never coat anatomical wells. Clean the well with a cotton tip soaked in alcohol.
Silicone well torn, deformed or hardened	Wear	Replace the silicone insert. Do not keep using a damaged well.

OBSERVATION	LIKELY CAUSE	ACTION
Abutment too tall or too short	Lab analog not fully seated in the well	Push the analog in until the shoulder of the abutment is level with the floor of the well. Trim the height intra-orally if it is only slightly tall.
Abutment and analog will not come out of the well	Composite locked around the analog	Grip the remaining abutment pillar with tweezers and twist the assembly out. Alternatively engage the retention screw with the driver and rotate clockwise while pulling.

Manufacturer, regulatory information and reporting

Manufacturer	VP INNOVATO HOLDINGS LTD Poseidonos 4A, Aradippou 7101, Larnaca, Cyprus +357 99 883 898 · info@vpicervico.com https://innovatoholdings.com
SRN	CY-MF-000036072
Basic UDI-DI	521300665VPICW
REF	Cervico Essential Mold: 5213006651779
Classification (EU)	Class I, Rule 1 (non-invasive devices), Annex VIII, Regulation (EU) 2017/745. Conformity assessment per Annex II and III; CE marked under the manufacturer's sole responsibility. EU Declaration of Conformity available on request.
Nomenclature	EMDN Q010603 (non-active, non-implantable dental instrument)
Quality system	ISO 13485:2016, HEALTH CERT P.C. certificate 0252024MDM0054, valid to 25/06/2027
USA	FDA establishment registration 3014837662, owner/operator 10058387, device listing D329255, product code NDP (accessories, implant, dental, endosseous). Rx only. Caution: Federal law restricts this device to sale by or on the order of a licensed dentist or physician.
Reporting (EU)	Report any serious incident to the manufacturer (above) and to your national competent authority. Cyprus: Cyprus Medical Devices Competent Authority, Medical and Public Health Services, Ministry of Health, Corner of Prodromou 1 & Chilonos 17, 1449 Nicosia, Cyprus, +357 22 605 572, cymda@mphs.moh.gov.cy.
Reporting (USA)	Report adverse events to the manufacturer and through FDA MedWatch (www.fda.gov/medwatch).
Disposal	Clean and sterilize before disposal. Aluminium, steel and silicone parts are recyclable; dispose of them according to local regulations for contaminated instruments. No special hazards.
Warranty and service	Contact the manufacturer or your distributor. Do not attempt repairs; no user-serviceable parts other than the replaceable silicone insert.

Document control

Document	VPI-IFU-EM
Revision	2.0, issued 2026-09-09, supersedes v1.0 (01/01/2023)
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Latest version	https://vpicervico.com/instructions-of-use/