INSTRUCTIONS FOR USE

Cervico Guide

Reusable intraoral and extraoral evaluation instrument for selecting the cervical profile of a custom healing abutment and for centering the implant osteotomy.

REF 5213006650017
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Device identification

Trade name	Cervico by VPI · Cervico Guide
REF	5213006650017
Description	Reusable intraoral and extraoral evaluation instrument for selecting the cervical profile of a custom healing abutment and for centering the implant osteotomy.

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COMPONENT	QTY	MATERIAL
Autoclavable silicone case (tray)	1	Medical silicone
Anatomical tabs: anteriors (a), premolars (p), square molars (m1), elongated molars (m2), each in S, M, L	12	Aluminium alloy 6082 with stainless steel AISI 304 insert
Cylindrical tabs 5–12 mm with 2.5 mm central bore	8	Aluminium alloy 6082 with stainless steel insert
Guide pins in four diameters matching the drill sequence	4	Aluminium alloy 6082
Magnetic retention handle	1	Aluminium / stainless steel, magnet

- Every anatomical tab carries a laser-marked code (e.g. pS) identical to the code of the matching well in the Cervico Molds.
- The T-line on the top of each anatomical tab shows the direction the implant's prosthetic connection reference (e.g. flat seat of the hex) should face.
- Each anatomical tab has two bores so it can be seated on a guide pin centered or off-centered.
- Each cylindrical tab has a central line to align with the occlusal line of the adjacent teeth and a lateral bore for floss.

Intended purpose, indications, contraindications

CERVICO GUIDE

Intended purpose. The Cervico Guide is intended (1) to identify the optimum anatomical healing abutment in shape and size for a given edentulous site with the Cervico Guide tabs, so that the operator can then customize a stock temporary abutment and/or impression post chairside in a Cervico Mold, and (2) to guide the initiation of the osteotomy substantially centered in the mesio-distal dimension of single-implant edentulous sites.

Indications. Partially edentulous sites to be treated with endosseous dental implants, for selection of the cervical profile and for marking and monitoring the osteotomy position and inclination.

Contraindications.

- Complete edentulism (relative): the cylindrical tabs cannot reference adjacent teeth for osteotomy positioning.
- Known hypersensitivity to aluminium or stainless steel (intraoral parts).
- Patients for 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; the Guide additionally assists centering of the osteotomy within the prosthetic space. 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").

Aspiration and ingestion risk
Before any intraoral use, secure every tab and pin with dental floss or suture passed through the dedicated bore on the part and tied. A loose part can be swallowed or inhaled. If a part is lost in the mouth and cannot be retrieved, refer the patient immediately to a medical facility for evaluation, including a chest radiograph, as for any lost dental instrument.

Relative contraindication: complete edentulism
Without adjacent teeth the cylindrical tabs cannot reference the osteotomy position. Use the Guide for profile selection only, or use other means for osteotomy positioning.

Drill compatibility
Pass only a pilot drill with a tip diameter below 2.1 mm through the central bore of a cylindrical tab (bore 2.5 mm). Use the implant manufacturer's surgical kit and drilling protocol; the Guide does not replace it.

Short intraoral contact only
The tabs and pins are intended for evaluation and marking, in contact with tissue for seconds. They are not implants and must not be left in the mouth.

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.
Dental floss or suture (Guide)	To secure tabs and pins intra-orally.
Pilot drill below 2.1 mm and implant surgical kit (Guide)	From the implant manufacturer.

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 Guide

> Secure every tab and pin with floss or suture through its bore before it enters the mouth.

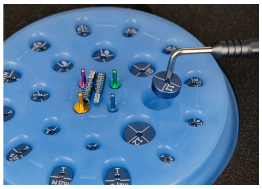
Cervical profile evaluation — Consultation or surgery

01 **Identify the tooth group**

Determine which tooth is being replaced: anterior, premolar, square (lower) molar or elongated (upper) molar.

02 **Mount the medium tab**

Push the tip of the retention handle into the side bore of the medium tab of that group; it holds by magnet and friction. Pass floss through the bore and tie it.



03 **Evaluate in the site**

Place the tab in the edentulous space, intra- or extra-orally on a model, and judge whether its outline is the cervical profile to be generated. Repeat with the small or large tab until the best fit is found. Thick biotype: width equal to the future crown at the cervix. Thin biotype: one size smaller.

04 **Chart the code**

Write the tab code (e.g. pS) in the patient chart. It names the mold well the assistant will use.

05 **Chart the orientation**

Note the direction the T-line faces. The engaging feature of the implant's prosthetic connection should face the T-line at placement (see the Prosthetic Connection Orientation Guide for your implant brand).

Osteotomy positioning and control

Surgery

01 **Choose the cylindrical tab**

Select the largest cylindrical tab that fits the space in light contact with both neighbours, or, with several teeth missing, the one matching the mesio-distal width of the tooth to be replaced. Tie floss through its lateral bore and mount it on the handle.

02 **Mark the entry point**

Align the central line on the tab with the occlusal line of the adjacent teeth. Pass a pilot drill (tip below 2.1 mm) through the central bore and mark the osteotomy entrance on the ridge. This is easiest before flap elevation; a flapless approach is also possible.

03 **Drill and check with a pin**

After each drill, insert the pin of matching diameter into the osteotomy, secured with floss through its bore. Seat the charted anatomical tab on the pin, centered or off-centered, and check the position and inclination of the osteotomy against the profile to be generated. Correct at the next drill.

04 **Note centered or off-centered**

The pin bore that gives the best tab position tells you which mold well family to use: centered (c) or off-centered (o).

05 **Place the implant**

Orient the prosthetic connection so its reference feature faces the T-line direction of the tab.

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
Tab or pin comes loose in the mouth	The part was not secured before intraoral use	Always pass floss or suture through the bore on the part and tie it before the part enters the mouth. If a part is lost and cannot be retrieved, refer the patient immediately for evaluation including a chest radiograph.
Pilot drill will not pass through the cylindrical tab	Drill tip wider than the 2.5 mm central bore	Use a pilot drill with a tip under 2.1 mm. Do not force a wider drill through the tab.
No cylindrical tab fits the space	Adjacent teeth closer than the smallest tab, or the site is fully edentulous	Choose the tab nearest the mesio-distal width of the tooth being replaced. With no adjacent teeth the cylindrical tabs cannot reference the site; position the osteotomy by other means.

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 Guide: 5213006650017

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-G
Revision	2.0, issued 2026-09-09, supersedes v1.0 (01/01/2023)
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