1.【Product Name】

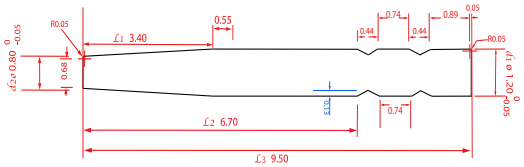
Stainless Steel Root Canal Post

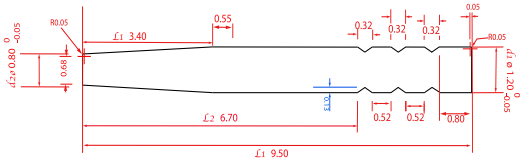
2.【Figure】



3.【Specifications and Models】

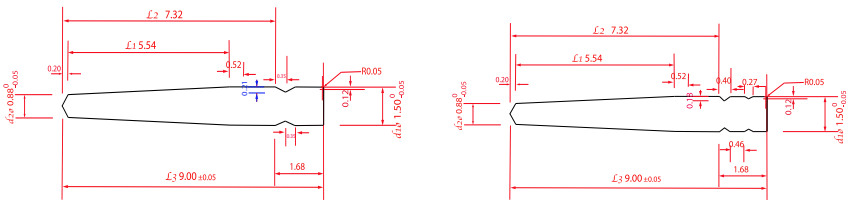
a) Cylindro-conical Models





Brand		Length 1 (mm)	Length 2 (mm)	Length 3 (mm)	Diameter 1 (mm)	Diameter 2 (mm)	Color Code
Click Up Model	Connectic Model	$L1$	$L2$	$L3$	$d1$	$d2$	
ISP-D120	FSB-D120i	3.40	6.70	9.50	1.20	0.80	white
ISP-D120L	FSB-D20Li	3.40	8.60	11.40	1.20	0.80	white
ISP-D130	FSB-D130i	3.90	6.70	9.50	1.30	0.88	yellow
ISP-D130L	FSB-D130Li	3.90	8.60	11.40	1.30	0.88	yellow
ISP-D140	FSB-D140i	4.75	8.70	11.50	1.40	0.88	red
ISP-D140L	FSB-D140Li	4.75	10.60	13.40	1.40	0.88	red
ISP-D150	FSB-D150i	4.75	10.40	13.50	1.50	0.99	blue
ISP-D160	FSB-D160i	6.00	11.78	15.50	1.60	1.08	green
ISP-D170	FSB-D170i	6.00	13.76	17.50	1.70	1.08	black

b) Conical Models



Brand	Length 1	Length 2	Length 3	Diameter 1	Diameter 2	Color Code

Click Up Model	Connectic Model	(mm) $L1$	(mm) $L2$	(mm) $L3$	(mm) $d1$	(mm) $d2$	
ISP-L9C	FSB-L9Ci	5.54	7.32	9.00	1.50	0.88	yellow
ISP-L11C	FSB-L11Ci	7.42	9.27	11.00	1.70	0.88	orange
ISP-L12C	FSB-L12Ci	7.27	10.05	12.00	1.80	0.99	green
ISP-L13C	FSB-L13Ci	9.37	11.05	13.00	1.80	0.88	red
ISP-L14C	FSB-L14Ci	10.78	11.74	14.00	1.90	0.99	blue
ISP-L16C	FSB-L16Ci	12.50	13.75	16.00	2.20	0.99	purple

4.【Structure and Composition】

Each root canal post is manufactured from a single piece of 316L stainless steel

5.【Intended Purpose】

The Stainless Steel Root Canal Post is intended to be temporarily inserted into a prepared root canal of an endodontically treated tooth to:

1. **Facilitate conventional impression taking** for the fabrication of a custom-made inlay-core restoration.
2. **Provide short-term mechanical support** for a provisional dental restoration, such as a temporary crown. When used to support a provisional restoration, the device is intended for temporary intra-radicular placement for a maximum duration of **7 days**.

The device is intended for use by qualified dental professionals.

6.【Indications and Contraindications】

6.1 Indications

The Stainless Steel Root Canal Post is indicated for temporary intra-radicular use in endodontically treated teeth for conventional impression taking for the fabrication of a custom-made inlay-core restoration and/or for temporary mechanical support of a provisional dental restoration, such as a temporary crown.

The device is intended for use exclusively by qualified dental professionals in dental clinics or hospitals.

6.2 Contraindications

The Stainless Steel Root Canal Post should not be used in the following situations:

1. Teeth that have not undergone root canal treatment or in which adequate root canal obturation has not been achieved.
2. Root canals in which an adequate apical seal cannot be maintained, including cases where preservation of at least 5 mm of apical gutta-percha is not possible.

3. Teeth with vertical root fractures, root perforations, severe internal or external root resorption, or other structural defects that compromise root integrity.
4. Teeth with insufficient remaining root dentin thickness or root structure to permit safe post-space preparation or temporary post placement.
5. Patients with known hypersensitivity or allergy to stainless steel or its constituent metals, including nickel and chromium.

The suitability of temporary Stainless Steel Root Canal Post placement shall be determined by the treating dental professional based on clinical and radiographic evaluation of the treated tooth, including consideration of root anatomy, remaining dentin thickness, post-space dimensions, and integrity of the apical seal.

7.【Directions for use】

Root Canal Preparation

Prior to insertion of the Stainless Steel Root Canal Post, the root canal must be endodontically obturated and sealed with gutta-percha.

Select a suitable Root Canal Enlarger based on clinical and radiographic evaluation. Prepare the coronal portion of the root canal using the selected Root Canal Enlarger, ensuring that at least 5 mm of apical gutta-percha remains intact and that sufficient residual root dentin thickness is preserved.

Post Selection and Clinical Procedure

1. Select two Stainless Steel Root Canal Posts of the same appropriate size, corresponding to the Root Canal Enlarger previously selected based on the clinical and radiographic evaluation of the root canal and used for canal preparation.
2. Remove the colour-coded markings from the heads of both Stainless Steel Root Canal Posts before processing.
3. Clean, disinfect and sterilise both posts in accordance with the validated **Step-by-Step Instructions** provided in Section 10.
4. **Conventional impression taking**: Insert one processed post into the prepared root canal and take a conventional impression. Ensure that the post is retained within the impression when it is removed from the mouth. Send the impression containing the post to the dental laboratory for fabrication of the custom-made inlay-core restoration.
5. **Temporary crown support**: Insert the second processed post of the same size into the prepared root canal to provide temporary mechanical support for a provisional crown. The maximum intended duration of intra-radicular placement is 7 days.

8.【Warning】

1) The Stainless Steel Root Canal Post is supplied non-sterile and must be cleaned, disinfected and steam-sterilised before clinical use in accordance with the manufacturer's validated instructions.
2) The device is intended for single use only. Reuse may result in cross-contamination, infection or compromised device performance.
3) The device is intended exclusively for temporary intra-radicular use and must not be used for permanent post-and-core reconstruction or definitive prosthetic support.
4) When used to support a provisional restoration, such as a temporary crown, the device must be removed within a maximum of **7 days**. Prolonged placement may compromise the coronal seal and increase the risk of bacterial penetration.

9.【Precautions】

1) The device must be used only by qualified dental professionals who have received appropriate training in post-endodontic restorative procedures.
2) Select the appropriate post length and diameter according to the prepared root canal dimensions, the Root Canal Enlarger used and the clinical situation.
3) Follow the manufacturer's validated cleaning, disinfection and steam sterilisation instructions before clinical use.
4) Use a dental dam during the procedure to maintain isolation of the treatment area and reduce the risk of accidental ingestion or aspiration.
5) Appropriate personal protective equipment, including gloves, protective clothing, eye protection and a mask, should be worn during clinical procedures.
6) During root canal preparation and post insertion, preserve an apical seal of at least **5 mm of gutta-percha** and ensure sufficient residual root dentin thickness to minimise the risk of root perforation or fracture.
7) Avoid excessive insertion force or inappropriate post placement to minimise the risk of root damage, perforation or fracture.
8) Avoid exposing the device to strong acids, alkalis or other corrosive substances that may damage the stainless steel surface.
9) Inspect the device before use for signs of corrosion, discoloration, deformation, fracture, surface damage or other visible defects. Do not use damaged devices.
10) After impression taking, remove the device in accordance with the clinical procedure.
11) Following removal of a post used for provisional restoration support, evaluate the integrity of the root canal seal and perform resealing, re-obturation or other restorative treatment as clinically appropriate.
12) Dispose of used devices in accordance with applicable regulations for potentially infectious medical waste.

10.【Cleaning, Disinfection and Sterilization】

Step-by-Step Instructions

Operation		Activities	Warning and remarks
1	Automated Cleaning with	- Place the devices in a kit, support, or container (made from stainless steel	- Discard any devices with large obvious defects (broken, bent, ...). - Avoid any contact between instruments when

	washer/disinfector	or titanium) to avoid any contact between devices. - Place the devices in the washer/disinfector and execute the defined cycle: • Step 1. Precleaning with cold tap water for 1 min; • Cleaning: 0.5% cleaner neodisher® Mediclean Forte at 55 °C for 5 min with demineralized water; • Step 3. rinsing with demineralized water for 1 min； • Step 4. Thermodisinfection with demineralized water at 93 °C for at least 5 min - Use a detergent solution with cleaning properties (we recommend Neodisher Mediclean Forte at 0.5%).	placing in the washer/disinfector, use kits, supports or containers. - Follow instructions and concentrations given by the manufacturer of the detergent. - Follow the instructions of the washer/disinfector and verify the success criteria after each cycle have been met as stated by the manufacturer. - The final rinse step should be with demineralized water. For other steps follow the water quality defined by the manufacturer. - Use only approved washer/disinfector according to EN ISO 15883, maintained and validated regularly. - It is recommended to use an alkaline detergent with tensides, which has grease removal, disinfection (against bacteria/ fungi) and corrosion inhibition properties. The detergent should be approved for its efficacy (VAH/DGHM-listing, CE marking, FDA approval) and used in accordance with its IFUs. The detergent should be aldehyde free and without di- or triethanolamines as corrosion inhibitor.
2	Inspection	- Inspect the devices functionality. - Inspect devices and sort out those with defects.	- Dirty devices must be cleaned again. - Discard devices, which show any defect as described in Precautions above (point 9).
3	Packaging	- Place the devices in a kit, support or container to avoid any contact between instruments and pack the devices in “Sterilisation pouches”.	- Device must be double-packaged using paper-plastic pouches for steam sterilization prior sterilization. Ensure that the pouches are suitable for steam sterilization and were validated and manufactured as per ISO 11607 and EN 868-5. - Use an appropriate packaging, moist-heat resistant (141°C, 286°F) and compliant with ISO 11607. - Avoid any contact between instruments or during sterilization. Use kits, supports or containers. - Seal the pouches according to the recommendation of the pouch manufacturer. If a thermo-sealer is used, the process must be validated and thermosealer must be calibrated and qualified. - Check the validity period of the pouch given by the pouch manufacturer to determine the shelf life.
4	Sterilization	- Use a validated fractionated pre-vacuum steam sterilization procedure in accordance	- The instruments must be sterilized according to the packaging labelling. - When sterilizing multiple instruments in one autoclave cycle ensure that the sterilizer’s

		with ISO 17665:2024, at 134°C for 18 minutes, followed by a minimum drying time of 16 minutes.	maximum load is not exceeded. - Place the pouches in the steam steriliser according to the recommendation given by the steriliser manufacturer. - Use only steam steriliser that are matching the requirements of EN 13060 (class B, small steriliser), EN 285 (full size steriliser). - Respecting the maintenance procedure of the sterilizer is under the responsibility of the the owner and should be performed following the requirements for medical devices sterilization (examples: planning of maintenance, qualification, acceptance criteria of condensate and water as per EN 285). - Control the efficiency and acceptance criteria of the sterilisation procedure (packaging integrity, no humidity, no colour change of packaging, positive physico-chemical indicators, conformity of actual cycle parameters, to reference cycle parameters). A special attention should be paid to the packaging integrity if the sterilization cycle 134°C (273.2°F), 18 min was used. - Store traceability records and define shelf-life according to packaging manufacturer guidelines.
5	Storage	- Keep devices in sterilization packaging in a clean environment, away from sources of moisture and direct sunlight. Store at ambient temperature (typically 15 - 25°C / 59 - 77°F).	- After sterilization, the product should be manipulated with care in order to keep the integrity of the packaging (sterile barrier). - Sterility cannot be guaranteed if packaging is open, damaged or wet. - Check the packaging and the medical devices before using them (packaging integrity, no humidity and use by date). In case of damage, a complete rework should be performed.

The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for use. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

11. 【Signs and Symbols】

	Catalogue number		Batch code		Date et pays de fabrication
	Manufacturer		Authorised representative in the European Union		Caution

	Keep dry	CE 0197	CE marking of conformity, and Notified Body Code		Consult instructions for use
	Keep away from sunlight		Do not re-use		Non-sterile
	MR Unsafe	MD	Medical device		Steam sterilization at 134 °C for 18 minutes
UDI					

12. 【Packaging】

- 20 Stainless Steel Root Canal Posts per plastic jar (5 mL).
- 1 jar per polyethylene (PE) bag.
- 243 bags per transport carton (L 350 mm x W 190 mm x H 230 mm).
- Instructions for Use are available electronically (eIFU).

13. 【Single use】

The device is intended for single use only. Do not re-use.

14. 【Storage】

The device shall be stored in its original packaging at room temperature, in a clean and dry environment, protected from dust, moisture, direct sunlight, and corrosive gases until use.

15. 【Date of Manufacture and Shelf Life】

Shelf life: 5 years from the date of manufacture.

16. 【Manufacturer】



Hangzhou Yinuowei Technology Co., Ltd.

Add: Floor 3, Building 5, No. 112, Datang Road, Jinnan Street, Linan District, Hangzhou, P.R.C

Tel /fax：+86 571 636 277 91

E-mail: hzinnovation@hotmail.com

17. 【European Representative】

EC REP **SGM INNOVATION**

Add: 95 boulevard Saint Michel, 75005 Paris, France

Tel: +33 752 413 711

E-mail: sgminnovation@gmail.com

18. 【Contact information】

Hangzhou Yinuowei Technology Co., Ltd.

ADD: Floor 3, Building 5, No. 112, Datang Road, Jinnan Street, Linan District, Hangzhou, 311300 Zhejiang Province, P.R. China

Tel/fax：+86 571 636 277 91

E-mail: hzinnovation@hotmail.com

Basic UDI-DI: 697515621SS1801J3

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation (EU) 2017/745 on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website: https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

For additional information, contact your Hangzhou Yinuowei Sales Representative or Hangzhou Yinuowei Customer Service.