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For dental use only

GB

DIRECTION FOR USE – Radix® fiber post C0613 – C0614

0) Composition

Zirconium enriched Glass Fiber 60 % volume
Epoxy resin 40% volume

1) Indications for use

These instruments have to be used only in a clinical or hospital environment, by qualified users.
Application field:
In case of insufficient residual tooth substance (< 4 mm), the Radix fiber is needed to support the coronal restoration.

2) Contraindications

Insufficient residual dentin: at least 2 mm of tooth structure is required around the preparation.

3) Warnings

None known.

4) Precautions

- The Post is a Single Use device.
- Re-use of Radix Fiber Post can increase the risk of cross contamination, poor cementing and breakage
- The post must be sterilized before insertion in the canal.
- Avoid touching the posts with your fingers after cleaning.
- Shortening the post should be done outside of the mouth.
- Dentsply Maillefer recommends the use of a rubber dam.

5) Adverse Reactions

In the present technical state, no adverse reaction has been reported so far.

6) Step-by-step Instructions

1. Root canal preparation. Ensure that sufficient space exists to place the post. Remove residual gutta percha out of the root canal.
2. Select correct Radix fiber size, according to anatomical situation of tooth using the radiograph and the information provided below. Select the Largo® Peeso Reamer and Radix fiber Precision Drill corresponding to the selected Radix fiber size.

Radix fiber	**Nr. 1**	**Nr. 2**	**Nr. 3**	**Nr. 4**	**Nr. 5**	**Nr. 6**
A) Tip diameter [mm]	0.8	0.8	1.0	1.0	1.3	1.3
B) Head diameter [mm]	1.35	1.47	1.67	1.83	2.04	2.22
C) Largo® Peeso Reamer	Nr. 1	Nr. 1	Nr. 2	Nr. 2	Nr. 3	Nr.3
D) Radix fiber Precision Drill	Nr. 1	Nr. 2	Nr. 3	Nr. 4	Nr. 5	Nr. 6

3. Determine the length of the coronal build-up which will account for 1/3 of the final post length. Remove the root canal obturation with the selected Largo® Peeso Reamer (rotation speed 800 – 1200 rpm) as deep as necessary for the post to be inserted at 2/3 of its length. At least 4 mm of root canal filling should remain in the apical region.
   In case of curved canals, the length has to be reduced.
4. Drill the canal with the selected Radix fiber Precision Drill (rotation speed 1000 – 1200 rpm).
5. Check that the post is properly seated in the canal.
6. Shorten the post to its final length with a diamond disc outside of the mouth. Never use a crimping instrument, such as wire cutters, as the pressure can destroy the structure of the post.
7. Clean the post with alcohol.
8. Apply etchant in the canal and to the exposed dentin for 15 seconds. (e.g. Dentsply DeTrey® Conditioner 36%; *).
   Rinse for 10 sec. Dry gently with paper points but leave surface moist.
   Do not put the etchant in contact with the gingival.
   If it is not possible, prefer the solution of a self-etching primer.
9. Mix the primer and its self-cure activator (e.g. Dentsply Prime&Bond® NT™ Dual Cure; *). Apply 2 coats of the preparation with a brush (e.g. Dentsply DeTrey® Applicator Tips) in the root canal and leave for 20 seconds. Remove excess using paper points and gently air dry all surfaces. Enamel and dentin surfaces should have a uniform, glossy appearance, if not, repeat the application.
10. Apply a single coat of primer to the post. Gently air dry for 5 seconds and light-cure the post for 10 to 20 seconds outside the mouth.
11. Mix the cement(e.g. Dentsply Calibra™; *) and apply it in the canal and optionally to the post using a Lentulo spiral filler (e.g. Dentsply Maillefer, REF A 0022) or a syringe tip. Seat the post immediately. Remove excess with appropriate instruments. Light-cure for 40 to 60 seconds, applying gentle pressure on the post with the tip of the curing light optic.
12. Apply 2 coats of bonding agent (e.g. Dentsply Prime&Bond® NT™ Dual Cure; *) to the exposed post, cement and coronal areas and leave for 20 seconds. Remove excess with a jet of air. Light-cure for 30 seconds.
13. Directly model the build-up using a composite core build-up material (e.g. Dentsply Core X™)

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7) DISINFECTION, CLEANING AND STERILIZATION:

Procedure for Posts and accessories

Foreword

For hygiene and sanitary safety purposes, all instruments not marked “sterile” must be cleaned, disinfected and sterilized before usage to prevent any contamination.

Area of application

Disinfection and sterilisation before usage concerning:

Implantable devices:

Dentinal and radicular posts made of steel, titanium and glass fibers. Supports, kits and organiser systems for posts.

General recommendation

1 - Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, FDA approval) and in accordance with the DFU of the disinfecting solution manufacturer. For all metal instruments, it is recommended to use anticorrosion disinfecting and cleaning agents
2 - For your own safety, please wear personal protective equipment (gloves, glasses, mask).
3 - The user is responsible for the sterility of the product as well as for the usage of damaged or dirty instruments where applicable after sterility.
4 - Single use marked instruments are not approved for re-use.
5 - The water quality has to be convenient to the local regulations especially for the last rinsing step or with a washer-disinfector.
6 - Plastic supports, are degraded by Hydrogen Peroxide (H_2O_2) solution.
7 – Supports made of aluminium are degraded in presence of caustic soda solutions with mercury salt. Do not use acid (pH < 6) or alkaline (pH > 8) solutions.
8 - The washer-disinfector is not recommended for support made of aluminium

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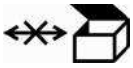
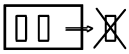
Step-by-step procedure

	Operation	*Operating mode*	*Warning*
1a.	Automated Cleaning with washer-disinfector	- Place the devices in a kit, support or container to avoid any contact between devices. - Put them in the washer-disinfector (Ao value > 3000 or, at least 5 min at 90 °C).	- Discard any posts with large obvious defects (broken, bent). - Avoid any contact between devices when placing in the washer-disinfector use kits, supports or container. - Follow instructions and observe concentrations given by the manufacturer (see also general recommendations). - Use only approved washer-disinfector according to EN ISO 15883, maintain and calibrate it regularly.
OR			
1b	Manual Cleaning or assisted by an ultrasonic device	- Place the devices in a kit, support or container to avoid any contact between devices. - Immerse in the disinfecting solution with cleaning properties, assisted by an ultrasonic device if suitable.	- No visible impurities should be observed on the Posts. - Discard any Posts with large obvious defects (broken, bent, and twisted). - Follow instructions and observe concentrations and time given by the manufacturer (see also general recommendations). - The disinfecting solution should be aldehyde free and without di- or triethanolamines as corrosion inhibitor.
5.	Rinsing	- Abundant rinsing (at least 1 min)	- Use quality water in accordance with local regulations. - If a disinfecting solution contains a corrosion inhibitor, it is recommended to rinse the posts just before the autoclaving. - Dry on a single use non-weaved cloth, or with a drying machine or filtered compressed air.
6.	Inspection	- Inspect devices and sort out those with defects. - Assemble the devices (stops)	- Dirty posts must be cleaned and disinfected again. - Discard Posts which show any deformations (bent, twisted), damages (broken, corroded) or defects (loss of colour coding or marking) affecting the resistance, the safety or the performance of the posts.
7.	Packaging	- Place the devices in a kit, support or container to avoid any contact between devices and pack the devices in “Sterilisation pouches”.	- Avoid any contact between devices during sterilization. Use kits, supports or containers. - Check the validity period of the pouch given by the manufacturer to determine the shelf life. - Use packaging which are resistant up to a temperature of 141°C (286°F) and in accordance with EN ISO 11607.
8.	Sterilization	- Steam sterilisation at: 134 °C / 273°F during 18 min.	- The posts and the plastic supports must be sterilized according to the packaging labelling. - Use only autoclaves that are matching the requirements of EN 13060, EN 285. - Respect the maintenance procedure of the autoclave device given by the manufacturer. - Use only this recommended sterilization procedure, validated according to ISO 17665-1 standard. - Control the efficiency (packaging integrity, no humidity, colour change of sterilisation indicators, physico-chemical integrators, digital records of cycles parameters). - Ensure Traceability of procedure records
9.	Storage	- Keep devices in sterilization packaging in a dry and clean environment	- 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 validity period).

	Symbols
	Expiry date
	Manufacture date
	Manufacturer
	Caution : See directions for use
	Recording on an input medium
	Can be sterilized at the specified temperature
	One use only
	Recommended rotation speed
	Opened packages are not replaced
	Batch number
	Reference number
	Can not be sold separately
	Fiberglass
	Stainless steel
	Keep away from sunlight and heat

➔ **Visit our website: www.dentsplymaillefer.com**

CE 0459

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