Revision History

Item	Rev	Description	Release date
1	A0	New Issue	2023-05-23

Instructions For Use

Microscope Paste Carriers

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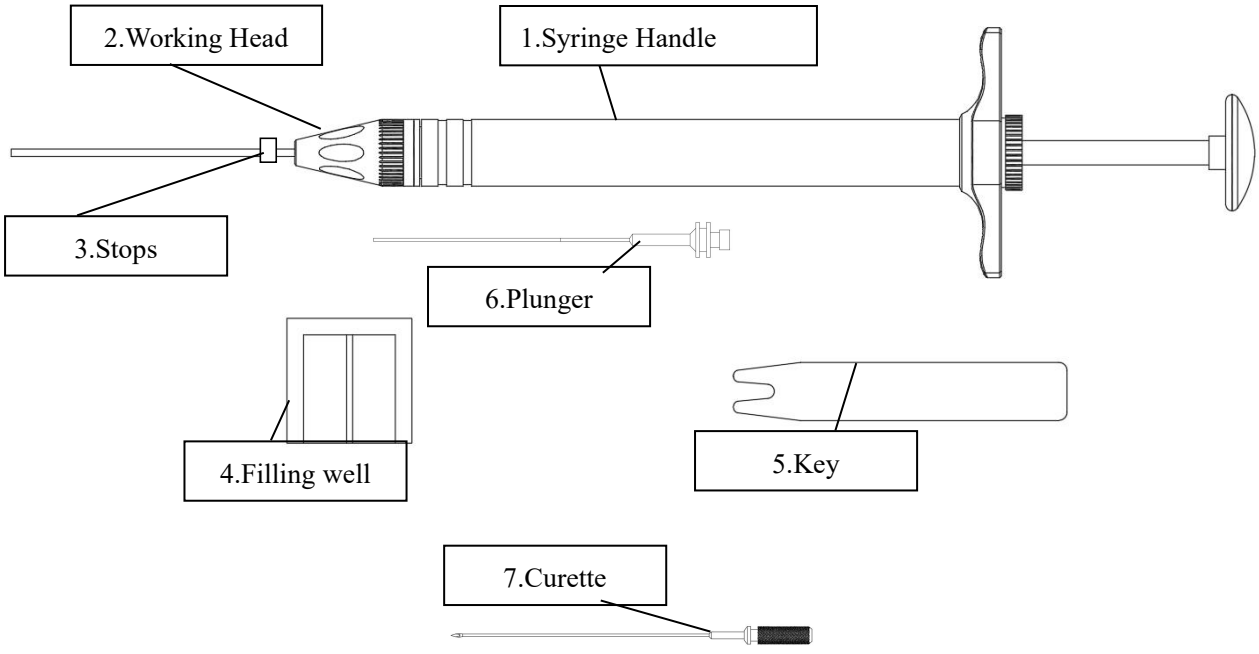
Before using the products, please see the instruction manual as indicated below.

1. Brief of the product

Microscope Paste Carriers is designed for used under microscope manually placing PDTM MTA White endodontic repair material.
It is reusable and non-sterile instruments.
For Dental Use Only.

2. Product Structure and materials

2.1. Microscope Paste Carriers is composed of 1.Syringe Handle 2.Working Head 3.Stops 4.Filling Well 5.Key 6.Plunger 7.Curette.
The main Materials:
1) Syringe Handle: Stainless steel
2) Working Head: Stainless steel + NiTi
3) Stops: Silicon Rubber
4) Filling well：Stainless steel
5) Key：Stainless steel
6) Plunger：Plastic or NiTi
7) Curette: NiTi + Aluminium alloy



3. Safety Notes

<Warnings>

- Strictly follow this Instruction for Use and the General Processing Instructions For Endodontic Products (see section 8) to minimize following risks to the device, the patient

and/or the user:

○ Breakage of instrument.

○ Cross-contamination.

○ Heat generation due to insufficient lubrication and irrigation.

○ Swallowing of working part of the instrument.

○ Toxic or allergic reactions caused by processing residues.

<Contraindications and prohibitions>

None Known

<Adverse Reactions>

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

4. Re-Processing

4.1 The DENCO Manual Root Canal Files are reusable instruments, the maximum number of processing cycles of the DENCO Manual Root Canal Files is 8 (number of processing cycles validated without affecting the functionality and safety of the products).

Pls follow the processing instructions for the disinfection, cleaning and sterilization steps before each reuse as Item 7 of this IFU.

4.2 Do not re-use silicone stoppers. Remove and discard silicone stoppers after each use.

4.3 LIMITATION ON RE-USE

• The products shall not be processed more than the number of maximum cycles indicated in the table in section 4) STEP-BY-STEP INSTRUCTIONS. It is the responsibility of the user to monitor the number of processing cycles. Meanwhile re-use is permitted only when the product is defect free and following a visual inspection (see item below). Since certain applications may cause the instruments to prematurely reach the end of their useful life the “Max number of processing cycles” will not always be reached (e.g. when shaping an extremely curved root canal with a file).

• In any case inspect the products before re-use, and discard them in case of defects. These include but not limited to the following:

- Plastic deformation (bent, unwound, distorsion, sign of twisting, elongation, uneven flutes);
- Breakage;
- Loss of colour coding or marking;
- Bent instrument;
- Untwisted threads;
- Damaged cutting surfaces and edges;
- Dull cutting blades;
- Missing size marking;
- Corrosion (e.g. dull spots);
- Wear.

• For shaping extremely curved canals it is safer to use the file only to shape one canal in order to reduce the risk of breakage. Pay attention to the following good practices:

- Use a new file and discard it after the canal was treated (single canal use).
- Use manual instead of Manual Root Canal Files.

- Use small size, flexible files (this will help avoid canal transportation).
- Visually inspect the active part for all the defects listed in the former paragraph during use (i.e after each wave).
- Avoid the standard reaming continual rotational motion and instead use small angle motions (filing motion, watch winding oscillation motion, or balanced force technique) in order to limit the rotational bending fatigue on the instruments and improve their expected life.

5. Specifications and Method of Use

5.1. The Specification of Carrier Part as the below table :

Type	Specification
NiTi Needle Carrier Part	0.9mm/1.1mm/1.3mm/1.5mm
Stainless Steel Needle Carrier Part	0.9mm/1.1mm/1.3mm/1.5mm
Hooked Needle Carrier Part	0.9mm/1.1mm/1.3mm/1.5mm
Serpentine Needle Carrier Part	0.9mm-L/1.1mm-L/0.9mm-R/1.1mm-R
Hooked&Serpentine Needle Carrier Part	0.9mm-L/1.1mm-L/0.9mm-R/1.1mm-R

5.2. According to its intended use, the dentists can choose the most appropriative type for each case and follow the general method.

6. Precautions for use

- Use a rubber dam system during the endodontic procedure.
- For your own safety, wear personal protective equipment (gloves, glasses, mask).
- Inspect the packaging before use and do not use the instruments if the packaging is damaged.
- Do not use the instruments after expiration date.
- Check the instrument before each use for signs of defects such as deformations (bent, unwound) breakage, corrosion, damaged cutting edges, loss of color coding or marking.
  With these indications the devices are not able to fulfil the intended use with the required safety level, instruments should be discarded.
- Check instrument and clean working part frequently during instrumentation, inspecting for signs of distortion, elongation or wear, such as uneven flutes, dull spots. With these indications that the devices are not able to fulfil the intended use with the required safety level, instruments should be discarded.
- Instruments should not be fully immersed in a sodium hypochlorite solution (NaOCl). Only the working part of the instrument, which is in contact with the patient should be immersed in a NaOCl solution concentrate at NOT more than 5%.
- Exercise caution in the apical area and in canals that divide, and/or exhibit abrupt curvatures or recurvatures.
- Irrigate abundantly and frequently the canal throughout the procedure and after each instrument used (according to good dental practices).
- Always use minimal apical pressure. Never force the files down the canal.

- When instrument does not easily progress, clean and inspect the cutting flutes, then irrigate, recapitulate with a manual file and reirrigate.
- For shaping extremely curved canals it is safer to use the file only to shape one canal in order to reduce the risk of breakage. Pay attention to the following good practices:
  ○ Use a new file and discard it after the canal was treated (single canal use).
  ○ Use small size, flexible files (this will help avoid canal transportation).
  ○ Visually inspect the working part for all the defects listed in the former paragraph during use (i.e after each wave).
  ○ Avoid the standard reaming continual rotational motion and instead use small angle motions (filing motion, watch winding oscillation motion, or balanced force technique) in order to limit the rotational bending fatigue on the instruments and improve their expected

7. Precautions for use:

7.1. To prevent infection, pls clean and disinfect the product (pls see item 7) and make sure sterilization is completed before using.
7.2. Choose the most appropriative type for each case and follow the general method.
7.3. Wear rubber dam etc. to avoid accidental ingestion and falling.
7.4. Do not use this instrument for any purposes except for applications above (Item 1).
7.5. Only for use by dentists.
7.6. This product should be treated as medical waste when disposed.
7.7. Dispose the product if damaged or contaminated.
7.8. For your own safety, please wear personal protective equipment (gloves, glasses).
7.9. This product has possibility that be corrosive if sunk into NaOC1, EDTA and etc. for a long time.
7.10. Plastic and NiTi parts are degraded by Hydrogen Peroxide (H2O2) solution

8. Cleaning Disinfection and Sterilization

8.1. General Recommendation

8.1.1. Please use cleaning agents suitable for cleaning surgical instruments, rubber, medical plastics, instruments and other medical instruments, such as multi-enzyme cleaning agents. When using, please strictly abide by the manufacturer's regulations on the concentration, temperature, action time and shelf life of the solution used. For your own safety, please wear personal protective equipment (gloves, glasses, masks).
8.1.2. The user should be responsible for the sterilization or disinfection of the product in the first cycle and each subsequent use, as well as the use of damaged or dirty equipment after sterilization.
8.1.3. In the final rinsing step, deionized water must be used regardless of whether an automatic washer sterilizer or manual cleaning method is used. Tap water can also be used for other rinsing steps.
8.1.4. Before or during disinfection or cleaning, avoid equipment drying out. Dry biological materials may be difficult to remove.
8.1.5. Only use the appropriate support of the device for post-processing.

8.1.6. Only use washer-disinfectors approved in accordance with EN ISO 15883 and regularly maintained and verified.

8.1.7. After using, wash it with medical cleaning agent and brush, then wash away foreign substances like adherent body fluids and body tissues.

8.2. Limitations and restrictions on reprocessing

8.2.1. The device is validated for 50 reprocessing cycles.
The appearance of defects such as cracks, deformations (bent, twisted), corrosion, loss of color coding or marking, are indications that the device is not able to fulfill the intended use with the required safety level.

8.2.2. The water quality has to comply with the local regulations especially for the last rinsing step or with a washer disinfector.

8.2.3. Do not use disinfecting solutions containing Phenol or any products which are not compatible with the instruments.

8.2.4. The detergent should not contain di-or triethanolamines as corrosion inhibitor

8.2.5. NiTi Instruments are degraded if immerged more than 5 minutes in a solution of NaOCl at more than 5%.

8.2.6. Plastic and NiTi parts are degraded by Hydrogen Peroxide (H2O2) solution.

8.2.7. Do not use acid (pH< 6) or alkaline (pH> 8) solutions.

8.3. Operation Steps

8.3.1. **Disassembling**:

1)Remove the stopper from the instrument and dispose of it.
2)Disassemble the device immediately after the ejection of the Paste.
3)Separate the plastic plunger from the needle

8.3.2. **Clean and Disinfection:**

8.3.2.1. **Initial Clean**

1)Clean inside the head within 15 minutes. Can use a stiff threader dental floss like EMOFORM Triofloss or ProxySoft 3 in1 Floss. The dental floss needs to enter the needle (from the back).
2)Flushing: Perform a large amount of flushing (at least 1 minute) under flowing deionized. If visible impurities are observed on instruments, brush the surface using a soft-bristled brush for minimum 20 seconds.

8.3.2.2. **Manual Cleaning assisted by an ultrasonic device:**

8.3.2.2.1. Manual cleaning with ultrasonic equipment

8.3.2.2.2. Place the instrument in a kit, stand or container (made of stainless steel, polypropylene or titanium).

8.3.2.2.3. Immerse in a detergent solution(for example, Metrex EmPowder concentration 1:128) with cleaning properties, if appropriate, soak for at least 15 minutes with the aid of ultrasonic equipment.

8.3.2.2.4. Flushing: Perform a large amount of flushing (at least 1 minute) under flowing

deionized water temperature 20°C ~ 40°C.

8.3.2.2.5. Drying: Dry with a disposable non-woven fabric or hot air dryer not exceeding 110°C.

8.3.2.3. **Automated Cleaning using a cleaning and disinfecting device**

8.3.2.3.1. Place the instrument in a kit, stand or container (made of stainless steel or titanium).

8.3.2.3.2. Perform the defined cycle with detergent solution (for example, Metrex EmPowder concentration 1:128 ~ 1:512) for at least 5 minutes in the washer-disinfector with temperature 20°C ~ 40°C.

8.3.2.4. **Disinfection using a washer-disinfector device**

8.3.2.4.1. Place the instrument in a kit, stand or container (made of stainless steel or titanium).

8.3.2.4.2. Perform the defined cycle with mild neutral enzyme cleaning agent solution (for example, Metrex EmPowder concentration 1:128) for at least 5 minutes in the washer-disinfector with temperature >90°C, A_0 >3000.

Note:

1) Discard any instruments with obvious defects (broken, bent, etc.).

2) When the instruments are placed in the cleaning kit, support or container, avoid any contact with each other.

3) Follow the instructions and concentration provided by the detergent solution manufacturer (see also general recommendations).

4) Follow the instructions of the washer-disinfector and verify the success criteria after each cycle is reached according to the manufacturer's instructions.

5) The final rinse step should use deionized water. For other steps, follow the water quality defined by the manufacturer. Place the devices in a kit, support, or container (made from stainless steel or titanium) to avoid any contact between devices or posts.

6) In case of needle obturation due to dry paste: the NiTi curette can be used to dredge the pipe; then follow the reprocessing procedure as usual.

8.3.3. **Rinsing:** Abundant rinsing (at least 1 min) under running water (ambient temperature).

1) Use deionized water for rinsing.
2) If the previously used cleaning solution contains a corrosion inhibitor, it is recommended to do the rinsing step just before starting the autoclaving.

8.3.4. **Drying:** Devices should be thoroughly dried before inspection and packaging.

1) Dry on a single use non-woven cloth, or with a hot air drier at not more than 110°C.
2) Devices should be dried until visual traces of moisture are eliminated.
3) Particular attention has to be paid to effectively dry joints or cavities within a device.

8.3.5. **Inspection:**

8.3.5.1. Inspect the devices functionality.

8.3.5.2. Inspect devices and sort out those with defects.

1) Dirty devices must be cleaned again.

2) Do not re-use silicon stoppers.
3) Discard devices, which show any defect

8.3.6. **Packing:** Place the devices in a kit, support or container to avoid any contact between instruments or posts and pack the devices in “Sterilization pouches”.

1) Avoid any contact between instruments or posts during sterilization. Use kits, supports or containers.
2) For sharp devices that are not contained within a box, silicon tubes should be placed around the devices to prevent packaging piercing.
3) Seal the pouches according to the recommendation of the pouch manufacturer. If a thermo-sealer is used, the process must be validated.
4) Check the validity period of the pouch given by the pouch manufacturer to determine the shelf life.

8.3.7. Sterilization:

8.3.7.1. Steam sterilization at 132°C / 273°F during 4 min is recommended for these devices, for the purpose of de- activating potential prions.
8.3.7.2. The instruments and posts must be sterilized according to the packaging labelling.
8.3.7.3. Place the pouches in the steam sterilizer according to the recommendation given by the sterilizer manufacturer.
8.3.7.4. Use only steam sterilizer that are matching the requirements of EN 13060 (class B, small sterilizer), EN 285 (full size sterilizer).
8.3.7.5. Use a validated sterilization procedure according to ISO 17665 with a minimum drying time of 20 min
8.3.7.6. Respect the maintenance procedure of the sterilizer given by the sterilizer manufacturer.
8.3.7.7. Control the efficiency and acceptance criteria of the sterilization procedure (packaging integrity, no humidity, no colour change of packaging, positive physico-chemical indicators, conformity of actual cycle parameters, to reference cycle parameters).
8.3.7.8. Store traceability records and define shelf-life according to packaging manufacturer guidelines.
8.3.7.9. Shorter sterilization cycles according to local regulations are possible but are not guaranteed to de-activate prions.

8.3.8. Storage

Keep devices in sterilization packaging in a clean environment, away from sources of moisture and direct sunlight. Store at ambient temperature.

1) Sterility cannot be guaranteed if packaging is open, damaged or wet.
2) Check the packaging and the medical devices before using them (packaging integrity, no humidity and use by date).

8. Transportation

8.1 To prevent damage to the medical device during transit, use a specific racks, trays or rigid containers may be recommended.

8.2 Packaged products can be transported using standard transportation methods or as specified in the specified in the contract. It strictly prohibited to mix with harmful, inflammable and explosive material.Avoid heavy pressure, exposure to sunlight, and direct contact with rain and snow during transportantion.

8.3 When the package was broken, then it is non-sterilize, must be cleaned, disinfected and sterilized before using.

9. Storages and duration of use

9.1 Keep products in a dry and clean environment, away from sources of moisture and direct sunlight.

9.2 The shelf time of root canal files are 5 years.

9. Disposal

For proper disposal, always observe national laws and recommendations of the authorities.

10. Packaging

Needle Type	Quantity
Syringe Handle	1
NiTi Needle Working Head	1
Stainless Steel Needle Working Head	1
Hooked Needle Working Head	0 or 1
Serpentine Needle Working Head	0 or 1
Hooked&Serpentine Needle Working Head	0 or 1
Plunger	8 or 16
Filling weel	1
Key	1
Stops	100
Curette	1

11. Explanation of related symbols

Symbols	Explanation
	Medical device

CE 0197	CE notify body code
For Dental Use Only	For Dental Use Only
	Do not reuse
LOT	Batch code
NON STERILE	Non-Sterile
REF	Catalogue Number
	Expired Date
	Consult instructions for use
EC REP	Authorized representative in the European Community
	Manufacturer
132°C	Can be sterilized at the specified temperature

Legal manufacturer>

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