ZPlugger

DIRECTIONS FOR USE

1) PRODUCT STRUCTURE AND PROPERTY
The Endodontic Hand Instruments are composed of an operating part, shanks and limit block. The operating part is made of nickel-titanium alloy and stainless steel wire, and shanks adopt the TPX material.

2) INTENDED USE
The Endodontic Hand Instruments are used to explore, shape, clean and fill root canal systems.

3) TYPE OF ENDODONTIC HAND INSTRUMENTS
Standard instrument
- Type 1: standard instrument (taper=02).

Non-standard instrument
- Type 2: taper instrument (taper other than 02).
- Type 4: non-uniform taper instrument (more than one taper).

4) CONTRAINDICATIONS
People allergic to stainless steel and nickel-titanium alloy are prohibited from using this product.

5) WARNINGS
This product is non-sterile packaging and needs to be sterilized before use.

6) PRECAUTIONS
1) Before using this product, please be sure to read the instructions for use carefully, or contact us to receive relevant skills training, so as to better understand the operation process of this product.
2) This product is for professional dentists only.
3) To prevent infection, please sterilize this product by high pressure steam before use, and use it after confirming sterilization. The user shall bear the responsibility for the failure to operate in accordance with the instructions for use or sterilize using unverified methods.

4) Determine the working length by X-ray or root apex locator, select the appropriate model, and apply it correctly.
5) Before using this product on patients, please confirm whether there is any crimping, defect, crack, etc. on it. Once found, it should be discarded immediately and treated as medical device waste.
6) Select hand file up to #15 for preliminary preparation according to general usage.
7) For models with thin, long and large heads, please avoid using them with excessive force or at an unreasonable angle, which may cause breakage or bending to them.
8) When enlarging the file, the tip of file should not exceed the apical foramen.
9) If the enlargement of the root canal is incorrect, the rotation angle exceeds 180°, the preparation of the root canal is not carried out in accordance with the number sequence, thus forming steps, the root canal is not smooth, and there is resistance or excessive force, it is difficult to achieve the best application effect of this product.
10) Do not apply excessive force in the direction of the root apex.
11) It is suggested that the user takes personal protective measures during operation, such as wearing protective glasses and dust masks.
12) It is suggested to use rubber dam in pulp operation to effectively prevent instrument drop, accidental swallowing and transmission of pathogenic factors.
13) To prevent the surface corrosion of this product, it should not be immersed in sodium hypochlorite solution.
14) During root canal plasty, the root canal should be thoroughly and frequently irrigated, and debris attached to the file needle should be removed on a regular basis.
15) Clean immediately with a medical lotion and brush after use to completely remove the attached fluids, biological tissues and other foreign bodies.
16) To avoid damage to the edge when cleaning with ultrasonic instrument, please put it into a fixed box for cleaning.
17) This product has a sharp tip, so the user should be careful not to stab his/her fingers.
18) This product can be reused for no more than 5 times. Do not overuse it, as it may lead to broken needles. After the operation, this product should be immediately put into the disinfection box to clean. Before reuse, sterilize it effectively according to the recommended sterilization method.

7) CLEANING, DISINFECTION AND STERILIZATION PROCESSING

1	**Device**	The device is supplied non-sterile but is intended to be used in a clean, disinfected and sterile state and therefore will require processing prior to use.The devices are reusable. The devices must be reprocessed after clinical use. Re-use what is not reprocessed after clinical use may result in infection, patient injury or death.
2	**Advise**	The devices have to be cleaned, disinfected and sterilized prior to the use. The devices are reusable. The devices must be reprocessed after clinical use. Re-use what is not reprocessed after clinical use may result in infection, patient injury or death.

Processing Instructions		
3	**Preparation prior to processing**	The product is supplied in clean, but non-sterile state. Remove the packaging material of the products and put the products onto a cleaning tray for cleaning and disinfection.
4	**Pre-Cleaning**	Usually, no manual pre-cleaning is required for such devices. In case of heavy contamination, submerge the instruments in a cleaning solution and clean the surfaces with a soft bristle brush.
5	**Cleaning**	Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated processing methods. Preference is to be given to automated processing methods, especially due to the better standardizing potential and industrial safety. Automated Cleaning: Use a washer-disinfector meeting the requirements of the ISO 15883 series. Put the instrument into the washer/disinfector on a tray and start the program: • 4 minutes pre-washing with cold water (<40°C). • Emptying. • 5 minutes washing with a mild alkaline cleaner at 55°C. • Emptying. • 3 minutes neutralising with warm water (>40°C). • Emptying. • 5 minutes intermediate rinsing with warm water (>40°C). • Emptying. The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert). **Note** Acc. to EN ISO 17664 no manual processing methods are required for these devices. If a manual processing method has to be used, please validate it prior to use.
6	**Disinfection**	Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN 15883). A disinfection cycle of 5 min disinfection at 90°C has been validated for the device to achieve an A0 value of > 3000. Here we suggest a disinfection cycle of 5 min disinfection time at 93 °C.

7	**Drying**	Automated Drying: Drying the instrument through drying cycle of washer/ disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.
8	**Functional Testing, Maintenance**	Visual inspection for cleanliness of the instruments. After cleaning and disinfection, a thorough inspection and maintenance ensures that the products are fit for use. • Check that the product has no dents, cracks, deformations, scratches or corrosion. • Check all markings on the product for clear visibility. Defective device should be immediately discarded. The defects include: material deformation and corrosion for Endodontic Hand Instruments.
9	**Packaging**	Pack the instruments in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607.
10	**Sterilization**	Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements. **Minimum requirements:** 5 minutes at 134° C **Maximum sterilization temperature:** 137° C **Drying time:** For steam sterilization, we recommend a drying time of 15 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave's instructions for use. **After sterilization:** a) Remove the product from the autoclave. b) Let the product cool down at room temperature for at least 30 minutes. Do not use additional cooling. c) Check that the sterilization wraps or pouches are not damaged. Flash sterilization is not allowed on lumen instruments!
11	**Storage**	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.
12	**Processing validation study information:**	The above-mentioned processing (cleaning, disinfection, sterilization) has been successfully validated. Refer to test reports: • United Dental_Cleaning Disinfection Validation Report, Report No.: RDS-RECD-210730-0084, Revision No.: 00 • United Dental_Sterilization Validation Report, Report No.: RDS-RES-210730-0085, Revision No.: 00

12	**Processing validation study information:**	• United Dental Evaluation Report of Processing acc.to EN ISO 17664 incl. Cleaning, Disinfection, Sterilization for Medical Devices Processed Prior to Use, Report No.: RDS-REV-210730-0087, Revision No.: 00

Additional Instructions: None

It is the duty of the user to ensure that the processing including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.

8) INSTRUCTIONS FOR USE

Please complete the preliminary works such as opening the pulp cavity, sterilizing the root canal and pulling out the pulp first before using this product. This product should be sterilized before use.

1) Finger-feeling and X-ray root canal measurement are recommended to measure the length of root canal.
2) Use this product in number sequence from thin to thick. Do not pass any number, and replace with another one only when each file reaches the root apex.
3) In the process of operation, the file should be rotated clockwise against the wall of the root canal, and the rotation angle should not exceed 180°. Do not rotate when there is resistance, and then pull it up with tension force.
4) The main function of the H File is filing cutting in a pulling way, that of the Reamer File is rotary cutting, and that of the K File and C File is rotary cutting and cutting in a pulling way.
5) It should be filed and irrigated at the same time, and the instrument should enter the root canal slowly and gently.

9) PACKING SPECIFICATIONS

3 pcs/plate, 4 pcs/plate, 6 pcs/plate.

10) SHELF LIFE

5 years.

11) STORAGE

The Endodontic Hand Instruments should be stored in a room with no more than 80% relative humidity, no corrosive gases and good ventilation.

12) EXPLANATION OF SYMBOLS

Symbols	Identification
	Expiry date
	Batch number
	Date of manufacture
	Manufacturer
	Catalogue number
	Medical device
	Caution
	Consult instructions for use
	Non-sterile
	Sterilizable in a steam sterilizer (autoclave) at 134°C
	CE marking of conformity
	Authorized representative in the EU
	Nickel Titanium
	Stainless Steel
	Model number
	Humidity limitation

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