HDAToolR
Hader Dental Attachments Tool
Reusable

English

Instructions for Use

HL Technology S.A., rue Jardinière 153
CH 2300 La Chaux-de-Fonds
Tel: +41 (0)32 925 90 50
www.hl-technology.ch

Table of contents

1 System Description

Hader Dental Attachments Tools are the devices completing the Hader Dental Attachments, which are 3 families' clip-on attachment systems. The devices are used to hold a partial or complete removable denture in the mouth of the patient.

Additional tools are required to prepare and mount these elements in the patient's mouth. These class I tools are explained in this technical file.

The Hader Dental Attachment Tools (HDATools) are reusable elements and have to respect cleaning and re-sterilization methods. It is used in the chairside for the preparation of the canal root. However, there is one exception for the screwdriver, which is used in the dentist's office and the laboratory.

1.1 Intended Use

Hader Dental Attachments Tools are intended to prepare the installation of overdentures partial dentures in the mandible or maxilla to restore masticatory function.

1.2 Intended user

The use of the components with the prosthesis must be performed by a properly trained professional.

1.3 Indications for use and patient population

1.3.1 Indication for Use

- To be used with natural tooth / tooth root abutments or via welding to dental implant-retained metal. structures allowing retention of the prosthesis using an axial ball and a clip.
- To be used with a suitable handpiece.
- For fully or partially edentulous jaws.
- To retain overdentures and removable partial dentures to be removed and replaced by the patient.
- When a resilient attachment is required to reduce stress transfer to the abutment.

1.3.2 Intended patient population

- Adolescents – Age > 16 years
- Adults
- Seniors

1.4 Contra-indications

It is recommended that these elements not be used with attachment systems other than HADER components. Other items may not be compatible.

These elements must not be mounted/drilled in milk teeth.

As with all attachment systems the following general contraindications also apply;

- Sick and senile patients (prosthesis with attachments must be inserted along one precise path of insertion, thus the patient must possess an average degree of manual skill to be able to attach/ remove the prothesis),
- Patients with severe periodontosis.
- Patients with abnormally high caries rates.
- Patients where there is inadequate space to employ them (teeth that are very narrow facio-lingually).
- Patients with poor neuromuscular coordination and in neuromuscular disorders.

1.5 Warnings/ Precautions

- In case of poor oral hygiene, irrespectively of the kind of attachment the clinician chooses, the gums will be inflamed and swollen, which sometimes makes it impossible for the overdenture to be retained.
- Common systemic disturbances can have a significant effect on the treatment of the patient, as well as the overall success of the treatment and include the following:
    - Diabetes – uncontrolled diabetes is characterized by xerostomia, macroglossia, and rapid periodontal breakdown; patients bruise easily and heal slowly.
    - Arthritis – if arthritic changes occur in the temporomandibular joint, recording jaw relation can be difficult and changes in the occlusion may occur.
    - Anemia – anemic patients have pale mucosa, sore tongue, xerostomia, and gingival bleeding.
    - Epilepsy – any seizure may result in fracture and aspiration of the prosthesis, and possibly the loss of additional teeth. Consultation with the patient's physician is essential before treatment is initiated. The construction of removable partial dentures is usually contraindicated if the patient has a frequent, severe seizure with little or no warning.
    - Cardiovascular disease - patients with the following symptoms require medical approval before any dental procedures:
        - Acute or recent myocardial infarction
        - Unstable or recent onset of angina pectoris
        - Congestive heart failure
        - Uncontrolled arrhythmia
        - Uncontrolled hypertension
    - Cancer – oral complications are also common side effects of radiation and chemotherapy for malignancies in areas other than the head and neck (oral malignancy). The most common oral complications are mucosal irritations, xerostomia, and bacterial and fungal infections.
- Some of the frequently prescribed drugs that can affect prosthodontic treatment include:

- Anticoagulants – postsurgical bleeding could be a problem for patients receiving anticoagulants who undergo extractions or soft tissue or osseous surgery.
- Antihypertensive agents – treatment for hypertension usually includes the prescription of a diuretic agent, which can contribute to a decrease in saliva and an associated dry mouth.
- Endocrine therapy - patients receiving endocrine therapy may develop an extremely sore mouth. If the patient is wearing a prosthesis, it could incorrectly be blamed for causing the discomfort.

- Poor bone quality – systemic factors like diabetes and osteoporosis increase the rate of resorption of the bone; the efficacy and success of the procedure and system could be compromised.

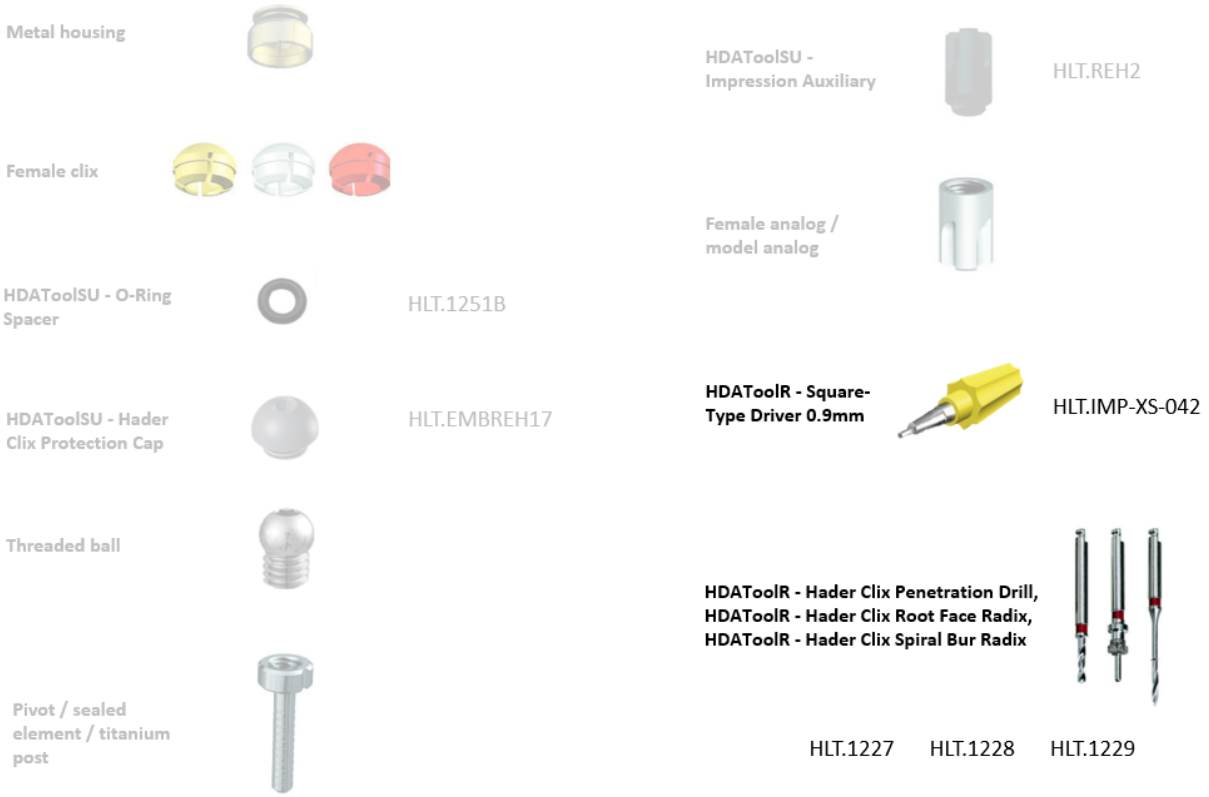
Secondary factors like smoking, pan chewing, chronic alcoholism may modify the systemic status and evoke concerns regarding the hygiene, maintenance, and wear of the denture.

2 Components

The components presented below are necessary for the preparation and installation of the prosthesis. These tools are from class I. Non-medical devices such as the composite adhesive and the tin spacer are not mentioned in this document.

The picture below shows the devices from the Hader Dental Attachments Tools and the Hader Dental Attachments (Hader Clix). The elements in transparency show the parts of the Hader Clix family and single-use parts.

Concerned elements for this IFU: HLT.IMP-XS-042, HLT.1227, HLT.1228, HLT.1229.



3 Packaging / Storage

The parts come in a vacuum-sealed plastic bag. If the pouch is no longer sealed or under vacuum upon receipt of the parts, they must be returned to the distributor.

The parts should be kept in a clean, dry place and protected from direct sunlight. The temperature of the storage conditions must remain at room temperature.

All components are delivered non-sterile in a PE/PET bag and are vacuum-packed, as shown in the pictures below. The components can be packed per single piece or as a set. The picture shows the labeling for a reusable component.

Reusable tool packaging

4 Treatment

Before the first use, all elements need to be treated because they are delivered non-sterile. In the case of reusable elements, they are prepared for the first time and retreated after each use following the next sections.

4.1 Cleaning

Before the first use and after each use, the elements must be passed underwater and brushed with a soft bristle brush to remove all residue.

4.2 Disinfection

In a bath containing a disinfectant product (HelveMed Disinfection Instrument Forte+) diluted to 1.5% in room temperature water. Let the elements soak for 5 minutes in an ultrasonic bath. Rinse the parts in distilled water. This step does not concern the set of drills because they can blunt due to the ultrasonic bath. Only the cleaning, rinsing, inspection, and sterilization steps are allowed.

Visually inspect if parts are residue-free.

4.3 Sterilization

The medical device must undergo steam sterilization, 1 cycle.

Recommended cycle: 3 (4 for the US market) pre-vacuums, 18 minutes at 134°C / 273°F at 2 bars and drying for 20 minutes.

We recommend the use of devices fitted with vacuum pumps (type B) to reduce the risk of air pockets forming. This recommendation is particularly important for hollow tools and to guarantee perfect drying. The hot air sterilizer is not recommended as it can accelerate the aging of the plastics materials.

5 Recommendations for use

5.1 Specific precautions

All components which are altered or damaged (corrosion, breakage, …) have to be immediately thrown away and not used.

Reusable components such as drills have to be carefully manipulated. The user should be aware of the cleaning and use of the three drill bits (HLT.1227, HLT.1228, HLT.1229). The drills are not cleaned in an ultrasonic bath cause of potential damage like blunt. During the tooth's drilling, the drills are manipulated in a way to avoid a fracture due to a high-pressure application, slanted insertion, and exerted lever arm effect. Besides, an efficient lubrification system (water coolant) is required to decrease the drilling's temperature. The physical phenomenon could provoke, at a certain temperature range, tooth ankylosis and bone resorption (Gokturk et al., 2015, Eur J Dent.).[1] The supplier recommends 800 revolutions per minute (rpm) for the drills' use.

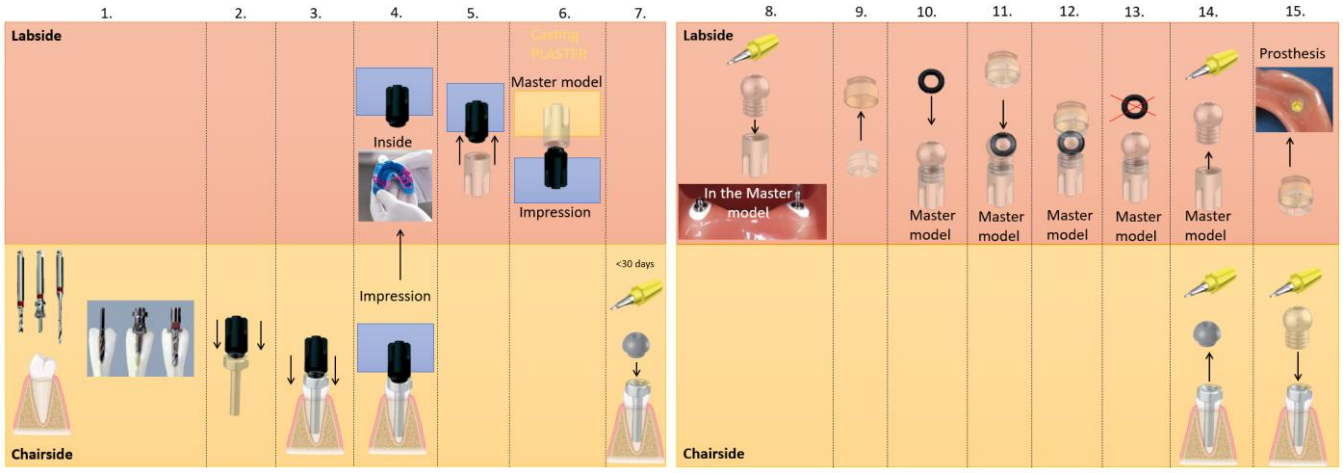
These precautions are signaled by the presence of the "caution logo" on the label and by this IFU document.

5.2 Use case scenario

The use case scenario varies in function of the procedure, it is presented for information purposes. The section below describes a possible procedure to create a new prosthesis with the Hader Clix, and a second method explains the adaptation of an existent prosthesis where the attachment system is changed for a Hader Clix system. The difference between these two procedures is highlighted because the Hader Dental Attachments Tools are used differently.

The following text describes the general scenario, and the bold text specifies more exactly the action related to a reusable component.

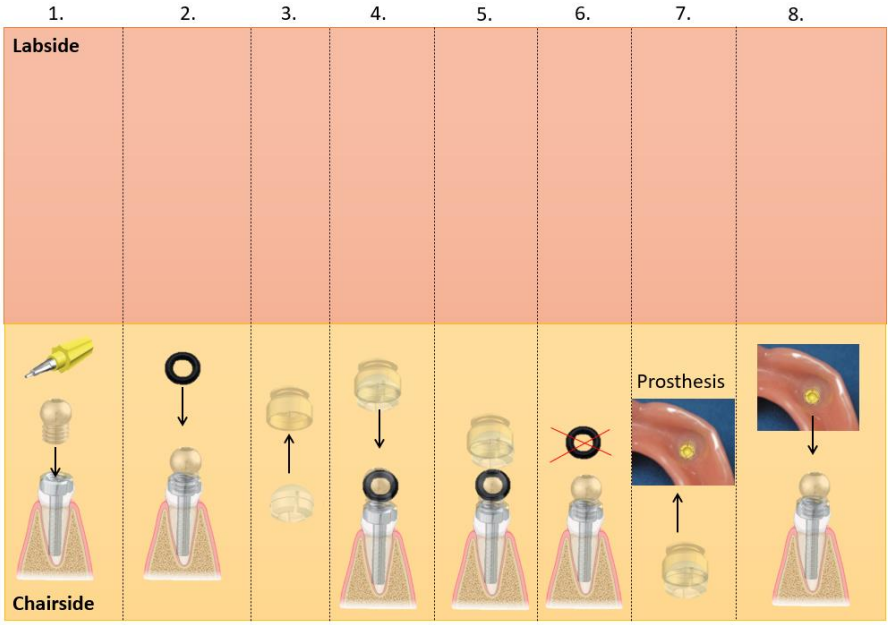
5.2.1 Fabrication of a new prosthesis



1. After an endodontics treatment, **the tooth is drilled with three different drills to create a canal.**
2. The black tool is screwed in the titanium post (implant class IIa). The black tool will protect the threading of the post from cementation.
3. The post and the black tool are inserted in the canal root.
4. The impression of the patient's mouth is taken. The impression auxiliary is stuck in the impression and the post is removed. The impression paste and the black tool are sent to the laboratory for the creation of a future prosthesis.
5. Afterwards, the female analog is threaded on the impression auxiliary to set the exact future position of the attachment.
6. When both components are attached, the master model is cast on the impression. Then, the female analog is fixed in the master model. The impression auxiliary is unscrewed and thrown away because it is a single-use component.
7. **In the meantime, in the patient's mouth, a protection cap is screwed in the post** to protect the threading until the prosthesis is ready. This component is considered a short-term device (less than 30 days in the mouth).
8. In the labside, the female analog is fixed in the master model. **The threaded ball (implant class IIa) is screwed in the female analog** to prepare the position of the future attachments.
9. In between, the Hader Clix system is mounted, it consists of the assembly of the female Clix inserted into the metal housing.
10. Back to the master model, the O-Ring spacer is placed on the threaded ball.
11. Then, the female parts are snapped on the O-Ring and the threaded ball.
12. With any flat instrument, the position of the female parts is set to coincide with the future denture.
13. When the position is taken, the assembly is disassembled and the O-ring spacer is thrown away because it is a single-use component.
14. **The treaded ball is removed and discarded or sent to the dentist's office. On the chairside, the protection cap is removed** and discarded as well because it is also a single-use component.
15. The metal housing with the female Clix is inserted and polymerized in the prosthesis. **On the chairside, the transferred or a new threaded ball is screwed in the post.**

Finally, the prosthesis is attached to the Hader Dental Attachment in the patient's mouth.

5.2.2 Adaptation of prosthesis' attachments



1. **The treaded ball is screwed on the titanium pivot in the patient's mouth.**
2. The O-Ring is placed on the treaded ball. This spacer is uniquely used in the mouth. Otherwise, it stays in the laboratory.
3. On the other side, the female Clix is snaped in the metal housing.
4. The Harder Clix system and the implant are mounted together.
5. The position and titling are set.
6. The O-Ring is discarded after taking the position.
7. The Harder Clix system is fixed and polymerized in the prosthesis.
8. The prosthesis is fixed on the prepared attachment.

As the patient's tooth is already drilled and the position is known, the steps in the laboratory with the impression/master model are useless. The major difference is about the use of the O-Ring Spacer and the number of suppressed steps because the procedure takes place on the chairside. In fact, the spacer is basically used in the laboratory. In this case, it enters in direct contact with the patient.

6 Disposal

Disposal must be done following the regulations applied in the country of use.

7 References

1. Gokturk H, Ozkocak I, Taskan MM, Aytac F, Karaarslan ES. In vitro evaluation of temperature rise during different post space preparations. *European Journal of Dentistry*. 2015;9(4):535-541. doi:10.4103/1305-7456.172630