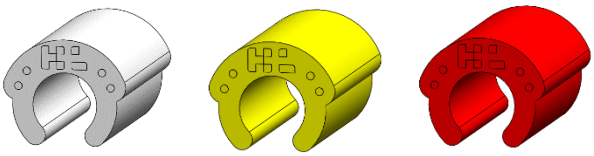
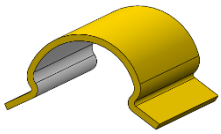
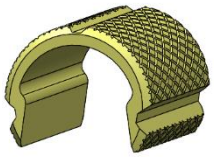
Hader Rider







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

CE 1250

Table of contents

1 System Description

Hader Rider is a clip-on attachment system. This system is for use with a partial or complete removable prosthesis which can be either mandibular or maxillary. The assembly of the elements with the prosthesis must be carried out by a professional who has received adequate training. The patient must be trained by the person who will install the prosthesis on the use of the clip system as well as the recommendations for keeping the elements in good condition.

All components are delivered NON-STERILE. They must therefore be sterilized before being used in the mouth.

1.1 Intended Use

Hader Rider is intended to be used with a bar spanning an edentulous area to attach overdentures and removable partial dentures in the mandible or maxilla in order to restore masticatory function.

1.2 Intended user

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

The prosthesis and male components must be installed by a professional trained in the field of prosthetics. This person is responsible for instructing the patient on the proper use of the medical device.

1.3 Indications for use and patient population

- To be used with a bar spanning an edentulous area, which joins natural tooth / tooth root abutments or dental implants, allowing retention of the prosthesis by means of a bar and clip
- For fully or partially edentulous jaws
- To retain overdentures and removable partial dentures to be removed and replaced by the patient
- When resilient attachment is required to reduce stress transfer to the abutment

1.4 Contra-indications

It is necessary to avoid drinking soda and smoking. Abuse of these basics may impair the proper functioning of the clip system.

It is recommended never to use these elements with attachment systems other than HADER components. The components may not be compatible.

The parts are single use. Damage may occur when removing them from their housing. For this reason, do not reassemble the parts (clip-on elements) after disassembly for later use.

Do not engage labial soft tissue undercuts with the denture base flange, as this will alter the path of insertion and cause excessive wear and servicing requirements.
As with all attachment systems the following general contraindications also apply;

- Sick and the 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 rate
- 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 a 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 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

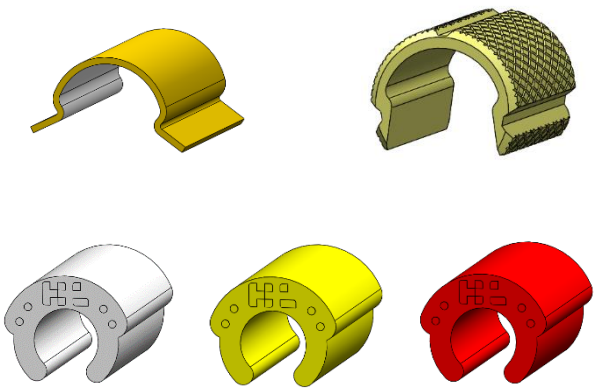
- Cancer – oral complications are also common side effects of radiation and chemotherapy for malignancies in areas other than the head and neck (oral malignancy). The most common oral complications are mucosal irritations, xerostomia, and bacterial and fungal infections.

- Some of the frequently prescribed drugs that can affect prosthodontic treatment including:
  - 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 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 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:

All the components described below can be found as a kit or sold separately. All male elements are compatible with female components.

2.1 Female Components



Retention is adjusted to improve user comfort

Use of Hader Rider

When placing the prosthesis, it is recommended to use normal retention.

The retention can then be adjusted to improve user comfort. Red for a better hold, white to facilitate the maintenance of the prosthesis (less force required to remove and replace the prosthesis).

2.2 Tools

The tools listed below are the only tools approved for setting up Hader Rider systems.

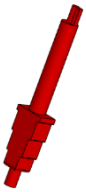
2.2.1 Instruments for use in the patients' mouth

Before use, the tools must follow the reprocessing cycle according to the recommendations of the IFU validated by the tool manufacturer.

Tool for fitting Hader Clix

- ➔ Horizontal insertion tool HLT.1705
- ➔ Vertical insertion tool HLT.1804

Horizontal Insertion Tool



Vertical Insertion Tool.

2.2.2 Instruments for use in the laboratory

2.2.3 Adjustment tools:

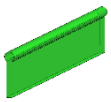
- ➔ Horizontal Rider Parallel Mandrel HLT.1708
- ➔ Frontal Rider Parallel Mandrel HLT.EMB1845

Vertical Parallel Mandrel

Horizontal Parallel Mandrel

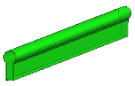
Burnout components:

- ➔ Plastic Bar green
- ➔ Plastic Bar green short

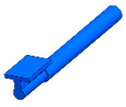


Burnout plastic bar green

Burnout plastic bar green short

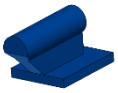


- ➔ Horizontal Plastic Bar HLT.1803



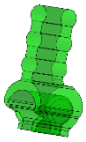
Burnout plastic bar with guide for Horizontal paralleling mandrel

- ➔ Vertical plastic bar with guide HLT.1813



Burnout plastic bar with guide for vertical parallelizer

- ➔ Vertical green castable housing HLT.1808



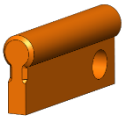
Matrice female to manufacture the overdenture for vertical rider use

- ➔ Horizontal green processing spacer HLT.1703

Matrix female to manufacture the overdenture for horizontal rider use

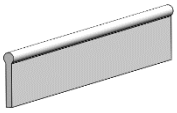
Analogue:

- ➔ Brass Analogue HLT.1819

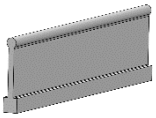


Brass Analogue used for the vertical positioning

- ➔ Plastic Analogue HLT.1707
- ➔ Aluminum Analogue HLT.19070P



Plastic and Aluminum Analogue used for the horizontal positioning



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.

The device should not be used more than 5 years after the manufacturing date. The limit is visible on the label. With the following symbol:

4 Treatment before insertion:

Before the Hader Rider system is placed in the patient's mouth, the components must be disinfected and sterilized. For cleaning the device, the recommendations of the denture manufacturer must be followed. However, the parameters and dosage defined below must be observed.

It is forbidden to re-sterilize the device. Re-sterilization as well as any other disinfection or sterilization methods of the device may lead to increased ageing of the plastics and may therefore cause a change in the retention force.

No automatic cleaning is permitted for cleaning this device. The use of such a system would influence the performance of the device.

4.1 Disinfection

Soak the elements for 5 minutes in an ultrasonic bath containing a disinfectant product (Helvemed Disinfection Instrument Forte +) diluted to 1.5% in water at room temperature. Rinse the elements with distilled water.

Visually check that all parts are free of residue.

4.2 Sterilization

The medical device must undergo steam sterilization.

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

We recommend the use of devices equipped with vacuum pumps (type B) to reduce the risk of air pockets forming.

5 Daily treatment

Patient should respect daily cleaning process recommended by the prothesis manufacturer. This includes: Remove by hand for the night, brush to remove dirt, soak it in water overnight and clean with disinfection solution on a regular basis (Amukina MED (Dakin solution), maximum 10 minutes per month).

6 Recommendations for use

- The plastic clip-on parts are parts which will wear. It is necessary to change them regularly (max every 5 years) in order to maintain sufficient retention force. This is in order to prevent the prosthesis from unclipping during chewing. For optimal comfort, it is advisable not to remove the prosthesis more than once a day.
- When changing a clipped element, all of the elements, as well as the maintenance of the sealed parts, must be checked.
- The parts are for single user only. It is possible that damage will occur when removing their accommodation.
- After having disassembled plastic part from the housing the parts (clipped elements), the plastic part need to be replaced When using the medical device, the patient must maintain adequate dental hygiene.
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- Patient should respect daily cleaning process recommended by the prothesis manufacturer. This includes: Remove by hand for the night, brush to remove dirt, soak it in water overnight and clean with disinfection solution on a regular basis.
- As the CrCo parts are visible, it is recommended brushing them on a daily basis with a toothpaste, in order to avoid the oxidation of these parts.

7 Disposal

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