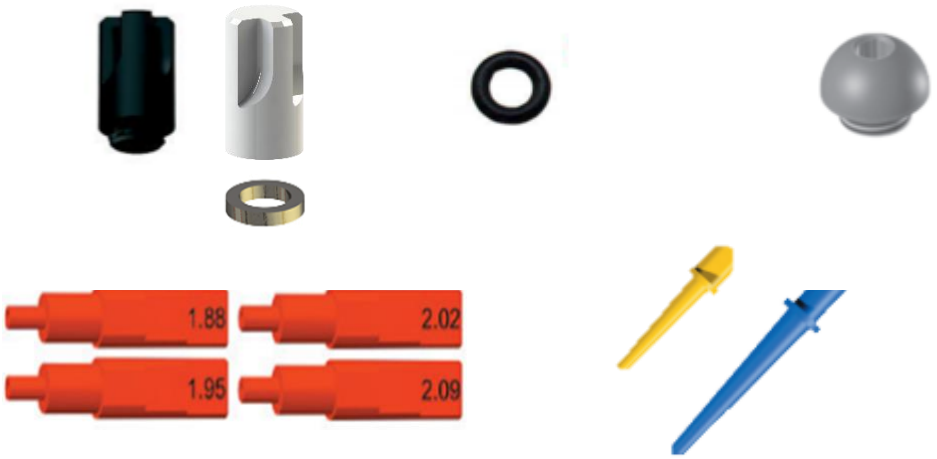
HDAToolSU

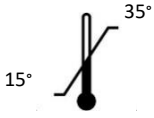
Hader Dental Attachments Tool

Single use



English

Instructions for Use



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1 System Description

The Hader Dental Attachments Tools are devices used complementary to the Hader Dental Attachments, (Hader CX, Hader VX, Hader SX and Hader RX) to prepare and mount these elements in the patient's mouth.

This IFU covers single-use elements that are used chairside in the process of preparation and processing of the prosthesis, including transferring to the laboratory.

All components are delivered NON-STERILE. They must therefore be cleaned and sterilized before being used in the mouth. The parts are single use only.

1.1 Intended Use

Hader Dental Attachments Tools are intended to aid in the preparation and processing of overdentures and partial dentures, in the mandible or maxilla in order to restore the function of masticatory.

1.2 Intended User

These components are to be used by trained dental and medical professionals only.

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 by means of an axial ball and a clip.
- 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 used in deciduous teeth.

As with all attachment systems the following general contra-indications also apply:

- Senile patients and/or patients with affected motricity (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 periodontitis.
- Patients with high caries rate.
- Cases with insufficient space to fit these elements.
- Patients with poor neuromuscular coordination and neuromuscular disorders.

- Unwillingness of the patient to correctly follow the aftercare/recall instructions.
- Patients with bruxism or further uncontrolled parafunctional habits.
- Unilateral dentures without transverse bracing; at the date of emission of these instructions for use no undesirable side effects have been reported.

1.5 Warnings/ Precautions

- A good oral hygiene must be maintained to ensure the correct function and fit of the attachments' elements. An unsatisfactory oral hygiene might cause gum swelling, which will obstruct the space necessary for the attachments' elements to retain the prosthesis. And ensure that the parts are cleaned regularly to avoid soft tissue inflammation.
- 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.

Allergies This product must not be used for patients known to be allergic to one or several of the elements contained in the attachment materials. With patients suspected of being allergic to one or several of the elements contained in any one of the attachment materials, this product can only be used after preliminary allergological testing and proof that no allergy exists.

During chairside / intraoral use, all products should generally be secured against aspiration!

2 Components

The components presented are single use tools, which are necessary for the preparation and installation of the prosthesis.

Non-medical devices as well as composite adhesive and the tin spacer are not mentioned in this document.

M2: 5011044

M3: 5051109

Protection caps for protecting the threading of the base rings. Only used less than 30 days (short term).

5011024

O-ring is an elastic ring to keep space between male and female during processing.

M2: 5011044

M3: 5051109

Male impression tool for base rings on post copings or bar constructions.

M2: 5011043

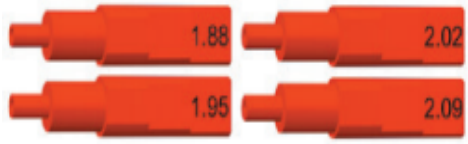
M3: 5051110

Female impression tool. It can be used in the laboratory as an analogue for 5011044 and 5051109, or to combine with a spring pin and a space maintainer and use as an impression tool for cases where the female is on the post coping or extracoronal.

M2: 5051077

M3: 5051076

Space maintainer to combine with spring pin and female impression tool, for impressions of cases where the female is on the post coping or extracoronal.



5051078 Spring Pin Indicator Set

To measure an existing Hader RX female base and chose the corresponding spring pin.

1051010

1051009

1052002

(Set with 50 pcs of each post)

Impression posts for chairside use, to transfer the internal shape of a root canal to the laboratory for production of a post coping.

The parts must not be heated.

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. Storage conditions must remain at room temperature.

All components are delivered non-sterile in a PE/PET vacuum-sealed bag. The components can be packed as a single piece or a set.

4 Treatment

All elements are delivered non-sterile and for single use. Before placing the medical device in the patient's mouth, the components must be cleaned and sterilized according to below instructions.

Single use tools must not be re-sterilized. Re-sterilization of elements could cause loss of mechanical, chemical and/or biological characteristics.

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

4.1 Cleaning

Soak the elements for 5 minutes in an ultrasonic bath containing a cleaning-disinfectant product (The validation has been realized with Helvemed Disinfection Instrument Forte +) diluted as recommended by the manufacturer of the cleaning solution. Rinse the elements with distilled water to remove all soap residues.

Visually check that all parts are free of residue.

Cleaning	
Step	**Description**
1	5 minutes ultrasonic bath with cleaning-disinfection solution (ex: HelveMED Disinfection Instrument Forte +).
2	Rinse with distilled water to remove all soap residues.
3	Verify visually that the parts are free of residues.

Normal cleaning cycle

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.

Sterilization		
Minimum Temperature	**Minimum exposure time**	**Minimum Drying**
134°C / 273°F	3 minutes	20 minutes
132°C / 270°F	4 minutes	20 minutes
134 °C / 273°F	18 minutes	20 minutes

Validated sterilization cycle

The choice of sterilization cycle should follow local or national regulations, whichever is more restrictive.

5 Maintenance

Dentists have the responsibility to keep the proper functionality and retention of the attachments assuring the safety of the patient by constant maintenance. In order to maintain the high-quality standard offered by the present products and to avoid the loss of performances, it is suggested to plan a maintenance and periodic care every year.

6 Recommendations for use

6.1 Specific precautions

All components which are altered or damaged (corrosion, breakage, cracks, …) must be immediately disposed and avoid use.

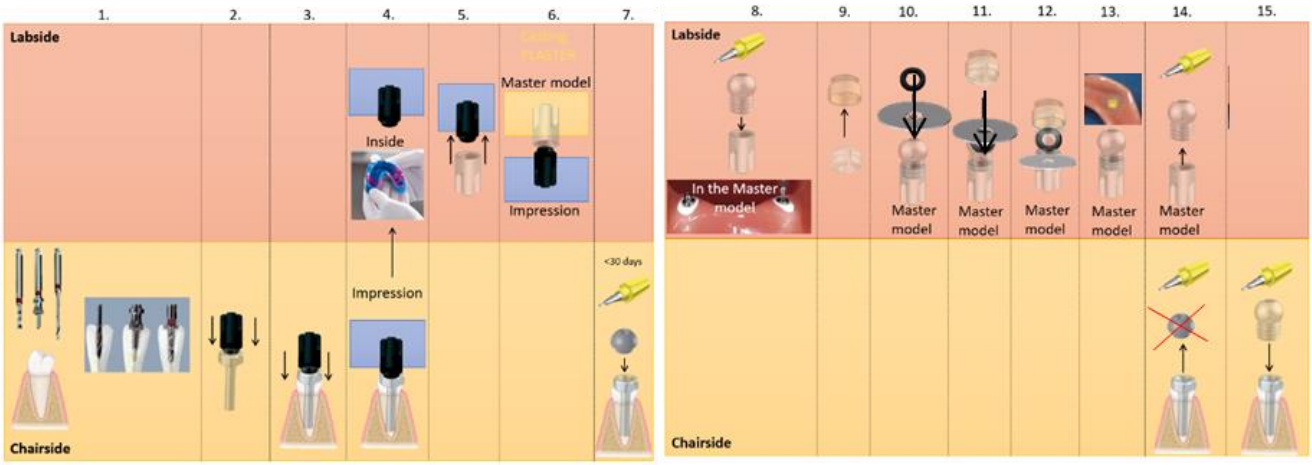
The impression auxiliary must be carefully manipulated. To avoid surface scratching, it is recommended to screw this component by hand and avoid using tweezers, which could lead to plating deterioration and releasing of metallic particles.

6.2 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 Hader CX, and a second method explains the adaptation of an existent prosthesis, where the attachment system is changed for a Hader CX system. The difference between these two procedures is highlighted because the Hader Dental Attachments Tool could be used differently.

The following text describes the general scenario, and the **bold text** specifies specifically the action related to a single-use component.

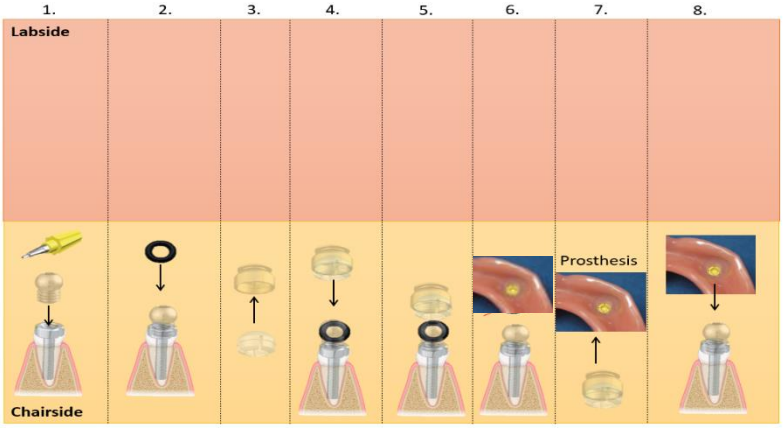
6.2.1 Fabrication of a new prosthesis (CX System)



1. After an endodontic treatment, the tooth canal is prepared with three different drills.
2. **The black impression tool is screwed in the titanium post. The black tool will protect the threading of the post from cementation, as well as helping with handling of the post.**
3. **The post and the black tool are inserted in the root canal and the post is cemented.**
4. The impression of the patient's mouth is taken. **The impression auxiliary will leave an index in the impression, after it is set, the tool can be unscrewed from the post and included in the impression to be sent to the laboratory for the processing of the future prosthesis.**
5. **Afterwards, the female impression analog is threaded on the black impression tool to set the exact future position of the attachment.**

6. **When both components are attached, the master model is set in the impression. Then, the female analog is fixed in the master model. The impression tool is unscrewed and discarded as 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 lab side, the female analog is fixed in the master model. The threaded ball is screwed in the female analog to prepare the position of the future attachments.
9. In between, the Hader CX system is mounted, it consists of the assembly of the female CX inserted into the metal housing.
10. **Back to the master model, the O-Ring spacer and Tin Spacer are placed on the threaded ball.**
11. **Then, the female parts are snapped on the threaded ball with the O-ring.**
12. With a paralleling mandrel or any flat instrument, the position of the female parts is set to the desired angled.
13. When the position is established, the prothesis is processed. The female assembly will be included in the resin of the denture. **The O-ring spacer and tin spacer can be disposed as they are single-use components.**
14. The treaded ball is removed and discarded or sent to the dentist's office along with the processed denture. **On the chairside, the protection cap is removed and discarded as well because it is also a single-use component.**
15. On the chairside, the threaded ball is screwed in the post. And finally, the prosthesis is installed in the patient's mouth.

6.2.2 Adaptation of prosthesis' attachments (CX System)

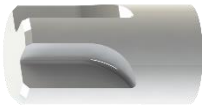


1. **The treaded ball is screwed on the titanium post in the patient's mouth.**
2. **The O-Ring is placed on the treaded ball. It is also recommended to place a thick rubber dam around the ball to create a space between the resin and the coping.**
3. On the other side, the female CX is snapped in the metal housing.
4. The Hader CX system and the male ball are mounted together.
5. The position and orientation are established.
6. The denture is processed by filling the space where the housing will with acrylic, and letting it set for 6 minutes or as per the acrylic manufacturer indications.

7. **After processing, the female assembly will be included in the resin of the denture. The O-ring spacer can be disposed as it is a single-use component.**
8. The prosthesis is installed in the patient's mouth.

6.2.3 Impression taking of female in extracoronal attachment and/or female in coping

In point 6.2.1 it is mentioned the use of the female impression tool, as an analogue in the laboratory. Here, it will be described the use of the same tool and the space maintainer, as an instrument for chairside impression taking.



M2: 5011043

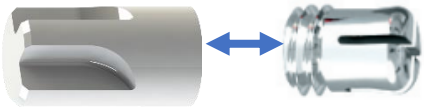
M3: 5051110

M2: 5051077

M3: 5051076

Chairside Steps

1- The dentist must identify the female size/dimension (M2 or M3).
2- Thread a corresponding M2 or M3 spring pin into the 5011043 or 5051110 impression tools.
3- Place space maintainer on top of spring pin.



4- Click the previous assembly into the female part (extracoronal or post coping).
5- Take impression.
6- Remove impression and unclick the assembled impression tool.
7- Send to the laboratory.

Laboratory Steps

1- Assemble the impression tool with the corresponding analogue (5051092 or 5051088).

2- Reposition the assembly into the impression with the analogue (5051092 or 5051088) facing up.
3- Pour out the plaster model. The female analogue will remain in the model.
4- Process the prothesis.

6.2.4 Spring Pin Indicator Use

In the case of a worn female of the Hader RX family, it is possible to use an oversized spring pin to compensate.

The oversized spring pins are 0.07mm, 0.14mm and 0.21mm larger in diameter. The right size of spring pin can be determined with the one of the indicators of set 5051078. A Set of 4 indicators with diameters of 1.88mm, 1.95mm, 2.02mm and 2.09mm.

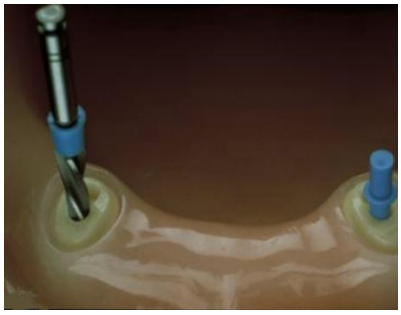
1. Select the smallest diameter of indicator and pressed into the female.
2. Continue with the immediate larger diameter until finding the one with the most friction that fit the female.

6.2.5 Impression Posts Use

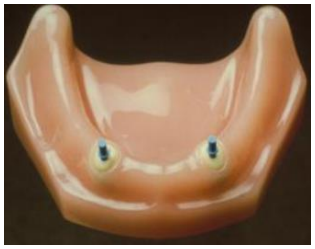
To aid on the impression taking, for the production of a post coping.

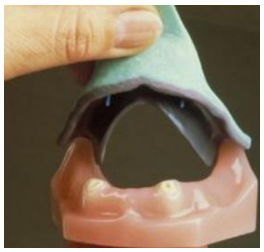
1. The root canal is prepared with a yellow or blue root canal reamer (a).

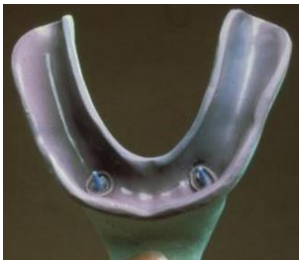
a.



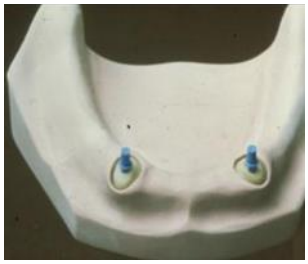
2. The yellow or blue opaque impression post is then introduced into the canal and an accurate impression is taken. These impression posts have been designed with contours that act as grips that allow them to be carried with the impression material after the impression tray has been lifted off (b – d).
   1051009 – Blue Posts
   1051010 – Yellow Posts
   1052002 – Set (50 yellow posts, 50 blue posts)

b. 

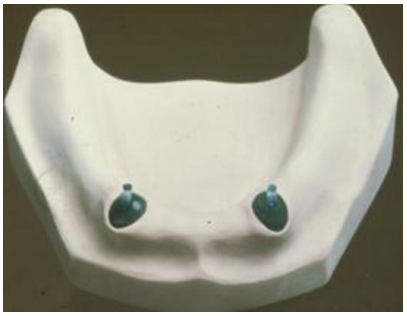
c. 

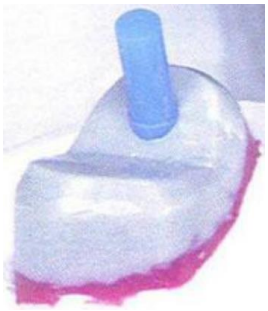
d. 

3. Dental stone is then poured over the impression and the mould for the master model is formed.

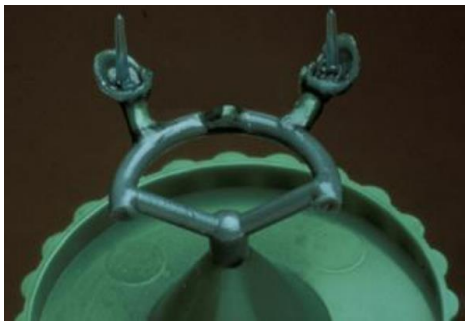
e. 

4. The impression post is then removed in the laboratory and replace with a transparent post for the burn out process. This post is then cut to the required length and the wax pattern is constructed directly on it (f – g).

f. 

g. 

5. Finally, the finished pattern is casted to form a metallic crown with a post coping that fits it exactly (h – i).

h. 

i. 

7 Disposal

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

8 Economic operator

8.1.1 Swiss authorized representative (CH-REP)

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8.1.2 UK Responsible Person (UK-REP)

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