# Instructions for use
# ARCUSevo

Always be on the safe side.

KaVo. Dental Excellence.

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CE

# Contents

# 1 User instructions

## 1.1 User guide

**Requirement**
Read these instructions before the initial startup to prevent misuse and damage.

### 1.1.1 Abbreviations

| Short form | Explanation |
|---|---|
| GA | Instructions for use |
| PA | Care instructions |
| MA | Assembly instructions |
| TA | Technician's instructions |
| STK | Safety check |
| IEC | International Electrotechnical Commission |
| RA | Repair instructions |
| EMC | Electromagnetic compatibility |

### 1.1.2 Symbols

| | |
|---|---|
|  | See the section Safety/Warning Symbols |
|  | Important information for users and technicians |
|  | CE mark (Communauté Européenne). A product with this mark meets the requirements of the corresponding European directive, i.e., the applicable European standard. |
| ▶ | Action required |

### 1.1.3 Target group

This document is for dentists and office personnel.

## 1.2 Service

Service hotline:
+49 7351 56-1600
Service.Zahntechnik@kavo.com
Please indicate the product serial number in all requests.
Additional information can be obtained at: www.kavo.com

## 1.3 Warranty provisions

The following warranty conditions apply to this KaVo medical device:

KaVo provides the end customer with a warranty of proper function and guarantees zero defects in respect of material and processing for a period of 12 months from data of invoice, subject to the following conditions:
In case of justified complaints, KaVo will honour its warranty with a repair or free replacement. Other claims of any nature whatsoever, in particular with respect to compensation, are excluded. In the event of default, gross negligence or intent, this shall only apply in the absence of mandatory legal regulations to the contrary.
KaVo cannot be held liable for defects and their consequences that are or may be due to natural wear, improper handling, cleaning or maintenance, non-compliance with operating or connection instructions, calcination or corrosion, contaminated air or water supplies or chemical or electrical factors deemed abnormal or impermissible in accordance with KaVo's instructions for use or other manufacturer specifications. The warranty does not usually cover lamps, light conductors made of glass and glass fibres, glassware, rubber parts and the colourfastness of plastic parts.
Defects or their consequences that can be attributed to interventions on or changes made to the product by the customer or a third party not authorised by KaVo are excluded from the warranty.
Service warranty claims will only be accepted if the product is submitted along with proof of purchase in the form of a copy of the invoice/delivery note. The dealer, purchase date, unit number or type and serial number must be clearly visible on this document.

## 1.4 Transportation and storage

### 1.4.1 Packaging ordinance of August 28,1998

**Note**
Only applicable for the Federal Republic of Germany.

KaVo transport packaging must be disposed of and recycled by local disposal service providers and recycling companies in accordance with Dual System requirements.
For more information about disposal and recycling, and an up-to-date list of local disposal service providers and recycling companies, please visit the following Internet sites:
http://www.umweltdatenbank.de
http://www.quality.de
KaVo will bring KaVo transport packaging returned by the customer at the customer's own cost to the appropriate recycling companies without reimbursement..

### 1.4.2 Transportation damage

### In Germany

If external damage to the packaging is visible upon delivery, follow the procedure below:
1. The recipient must record the loss or damage in the notice of delivery. The recipient and employee of the transportation firm must sign the notice of delivery.
2. Leave the product and packaging unchanged.
3. Do not use the product.
4. Report damage to the shipping company.
5. Report damage to KaVo.
6. A damaged product cannot be returned before talking with KaVo.
7. Send the signed notice of delivery to KaVo.

If the product is damaged and there is no discernable damage to the packaging upon delivery, proceed as follows:
1. Report damage immediately or at least 7 days after the delivery to the delivery company. .
2. Report damage to KaVo.
3. Leave the product and packaging unchanged.
4. Do not use a damaged product.

**Note**
If the recipient does not follow one of the above instructions, the damage will be held to have occurred after the delivery (according to ADSp. Art. 28)..

## Outside of Germany

**Note**
KaVo is not liable for damage arising from transportation.
Immediately inspect the delivery after receipt!

If external damage to the packaging is visible upon delivery, follow the procedure below:

1. The recipient must record the loss or damage in the notice of delivery. The recipient and employee of the transportation firm must sign the notice of delivery. The recipient can only assert damages against the transportation company based on these records.
2. Leave the product and packaging unchanged.
3. Do not use the product.

If the product is damaged and there is no discernable damage to the packaging upon delivery, proceed as follows:

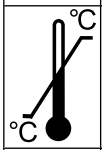
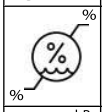
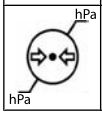
1. Report the damage immediately or at least 7 days after the delivery to the delivery company .
2. Leave the product and packaging unchanged.
3. Do not use a damaged product.

**Note**
If the recipient does not follow one of the above instructions, the damage will be held to have occurred after the delivery (according to . CMR law , section 5, Art. 30).

### 1.4.3 Storage

**Note**
Keep the packaging for returning the product for service or repairs .

The symbols printed on the outside are for transportation and storage, and have the following meaning:

| | |
|---|---|
|  | Transport upright with the arrows pointing upwards |
|  | Fragile - protect against knocks |
|  | Keep dry |
|   | Maximum permitted stacking load |
|   | Temperature range |
|   | Humidity |
|   | Air pressure |

# 2 Safety

## 2.1 Description of safety instructions

### 2.1.1 Warning symbol

| | |
|---|---|
|  | Warning symbol |

### 2.1.2 Structure


DANGER

**The introduction describes the type and source of the hazard.**
This section describes the potential consequences of non-observance.
- The optional step contains necessary measures for avoiding hazards.

### 2.1.3 Description of hazardous steps

Safety instructions with three hazard levels are used in this document for avoiding personal and property damage.


CAUTION

**CAUTION**
indicates a hazardous situation that can lead to property damage or minor to moderate injury.


WARNING

**WARNING**
indicates a hazardous situation that can lead to serious injury or death.


DANGER

**DANGER**
indicates a maximum hazardous situation that can directly cause serious injury or death.

## 2.2 Proper use

### 2.2.1 General information

The user must ensure that that the device works properly and is in a satisfactory condition before each use.

This KaVo product is intended only for use in the field of dentistry. It is impermissible to use the product for a purpose for which it was not intended.
"Proper use" includes following all the instructions for use and ensuring that all inspections and service tasks are performed.

Apply and meet the overarching guidelines and/or national laws, national regulations and the rules of technology for medical devices applicable for startup and use of the KaVo product for the intended purpose.

Responsibility is accepted for the safety, reliability and performance of the components supplied by KaVo provided:
- installation, upgrades, adjustments, changes or repairs are carried out by technicians trained by KaVo or third parties authorised by KaVo, or by the personnel of authorised distributors.
- The unit is operated in accordance with the instructions for use, care and installation.
- The IT components supplied by the operator meet the technical requirements in these instruction for use for hardware and software, and they are installed and set up according to the descriptions of these components.
- If it is repaired, the requirements of VDE 0751-1 "Repeat tests and tests before start-up of electrical items of medical equipment and systems - general regulations" must be met in full.

The user must observe the following:
- - only use properly operating equipment.
- protect himself or herself and third parties from danger.
- avoid contamination from the product.

During use, national legal regulations must be observed, in particular:
- the applicable health and safety regulations.
- the applicable accident prevention regulations.

Authorised to repair and service the KaVo product:
- The technicians of KaVo branches.
- Technicians of authorised dealers specially trained by KaVo.

In Germany, the operator, person responsible for the device and user must operate their devices in accordance with the provisions of the Medical Device Law.

These service tasks include all testing tasks that are stipulated in the Operator Ordinance (MPBetreiber V) § 6.

**Note**
The product must be cleaned and serviced according to instructions if it is not to be used for a long period.

**Note**
Only those accessories may be used that are approved for the device.

### Disposal

**Note**
The waste that arises must be recycled or disposed of in a manner safe for humans and the environment. Observe the applicable national regulations.
Please direct all questions regarding the proper disposal of KaVo products to the nearest KaVo branch.

## 2.2.2 Product-specific

The ARCUSevo facial bow records the position of the patient's maxilla. When creating a prosthesis, a working or tooth model can be correctly positioned in an articulator.
The facial bow is suitable for recording the Frankfurter horizontals and the Camper's plane.

## 2.3 Safety

### 2.3.1 General information

CAUTION

**Premature weary and malfunctions from improper servicing and care.**
Reduced production time.
- Perform regular proper care and maintenance.

WARNING

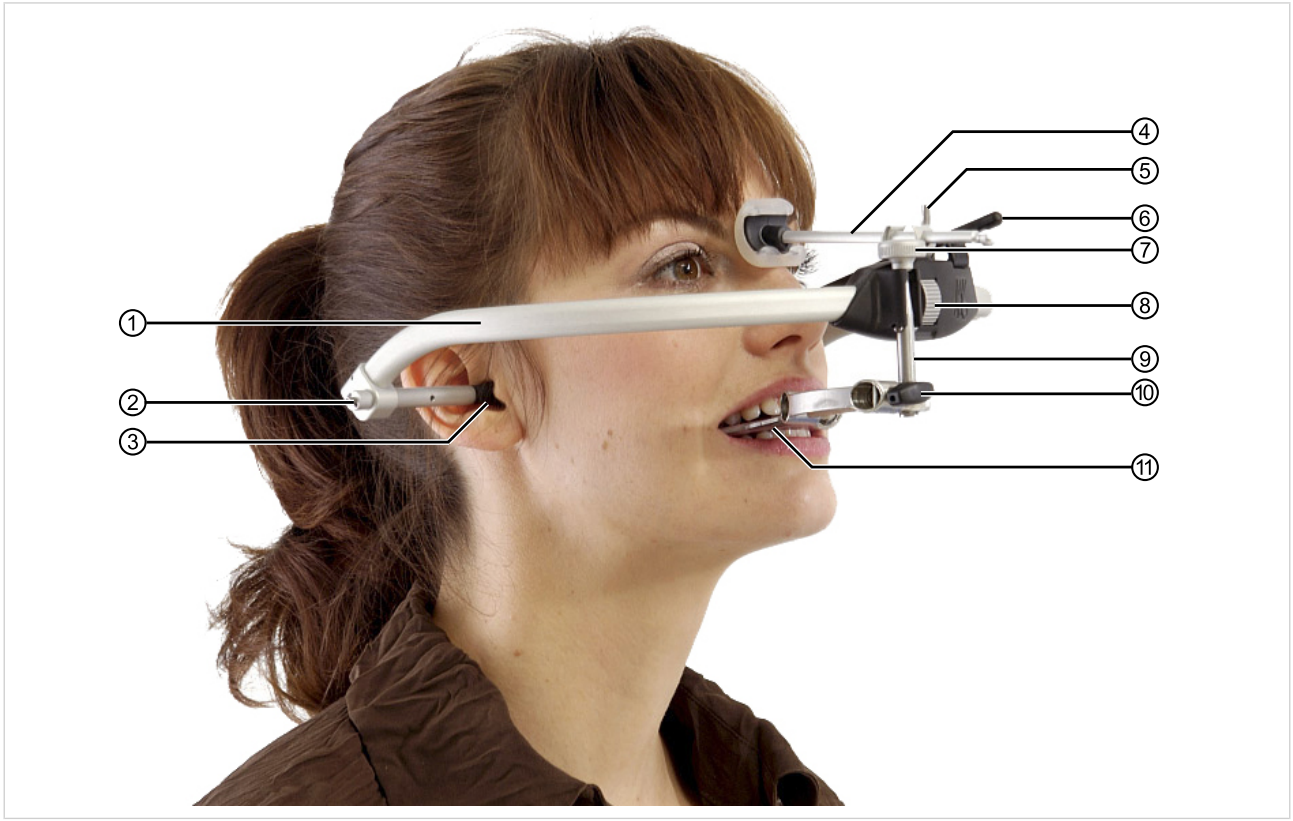
**Injury or damage from damaged functional parts.**
When functional parts are damaged, it can cause additional damage or personal injury.
- When operating parts are damaged: Stop working and eliminatethe damage, or notify a service technician.
- Check the electrode lines and accessories for damage to the insulation.

CAUTION

**The reference pointer can contact patients.**
Hitting/scaring the patient.
- Move the reference pointer carefully toward the patient.

# 3 Product description

## 3.1 ARCUSevo



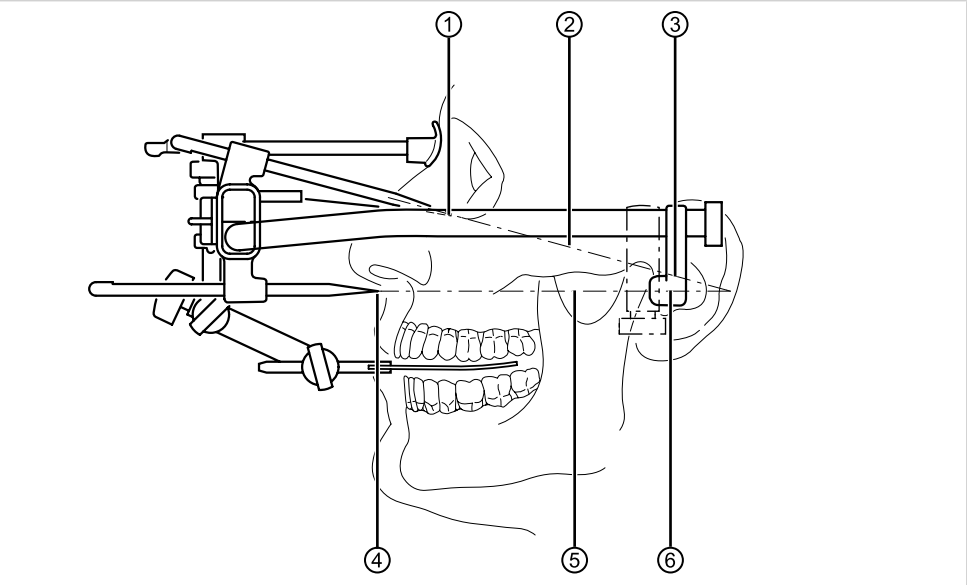

① Bow
② Fastening nut for the earbud
③ Earbud
④ Nose support
⑤ Lock lever for the nose support
⑥ Reference pointer for the Frankfurter horizontal and Camper's plane
⑦ Fastening nut of the bite fork support
⑧ Adjustment wheel for adjusting the facial width
⑨ Bite fork support
⑩ Knurled screw of the bite fork support
⑪ Bite fork

## 3.2 Technical data

### Dimensions and weight

| | |
|---|---|
| Max. width | 345 mm |
| Depth | 300 mm |
| Height | 100 mm |
| Weight | 250 g |
| Weight of bite fork/bite fork support | 100 g |

### Information on the planes and reference points




Frankfurter horizontal ② (FH):
Connection between the infraorbital point ① and porion ③

Camper's plane ⑤ (CP):
Connection between the subnasal point ④ and Targus medialis ⑥

The angle difference between the FH and CP is 15°.

## 3.3 Scope of delivery

| Figure | Designation |
|---|---|
|  | ARCUSevo facial bow incl.<br>Earbuds<br>Nose support<br>Reference pointer |
|  | Bite fork support |
|  | Bite fork |
| | Instructions for use |

# 4 Operation

## 4.1 Adapting the facial bow


- Turn the adjustment wheel ③.
  The earbuds ② move further apart. The bow ① can be placed on the patient.

## 4.2 Mount the facial bow

The facial bow is mounted with reference to the Frankfurter horizontal and the Camper's plane.

CAUTION

**Unapproved registration materials**
Endangerment of the patient
- Only use approved registration materials according to 93/42 EEC!

CAUTION

**The reference pointer can contact patients.**
Hitting/scaring the patient.
- Move the reference pointer carefully toward the patient.

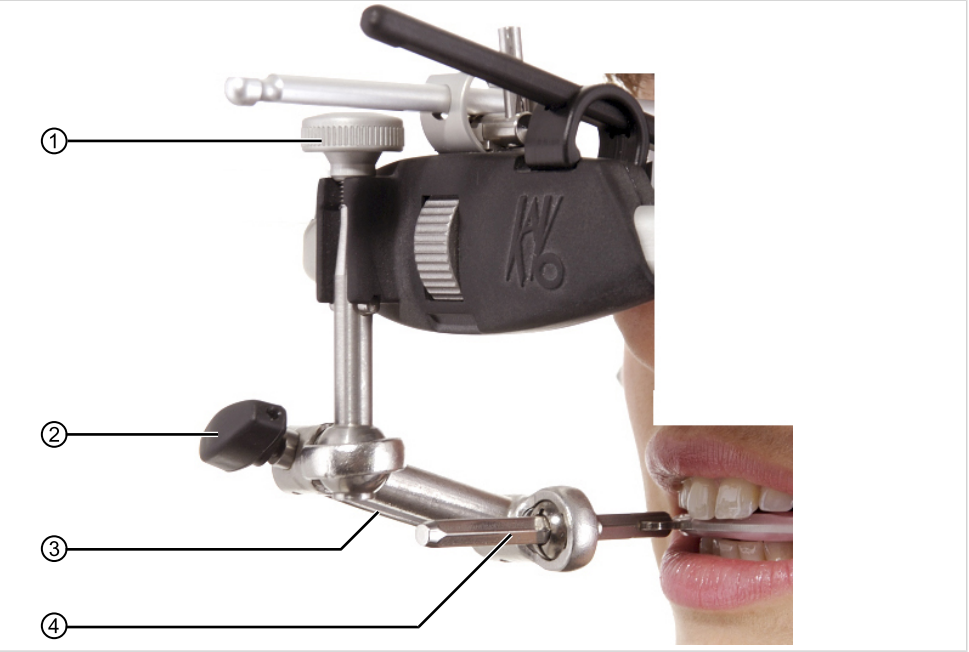
- Place the prepared bite fork in the patient's mouth.


- Adapt the bow ⑥ to the width of the patient's face.

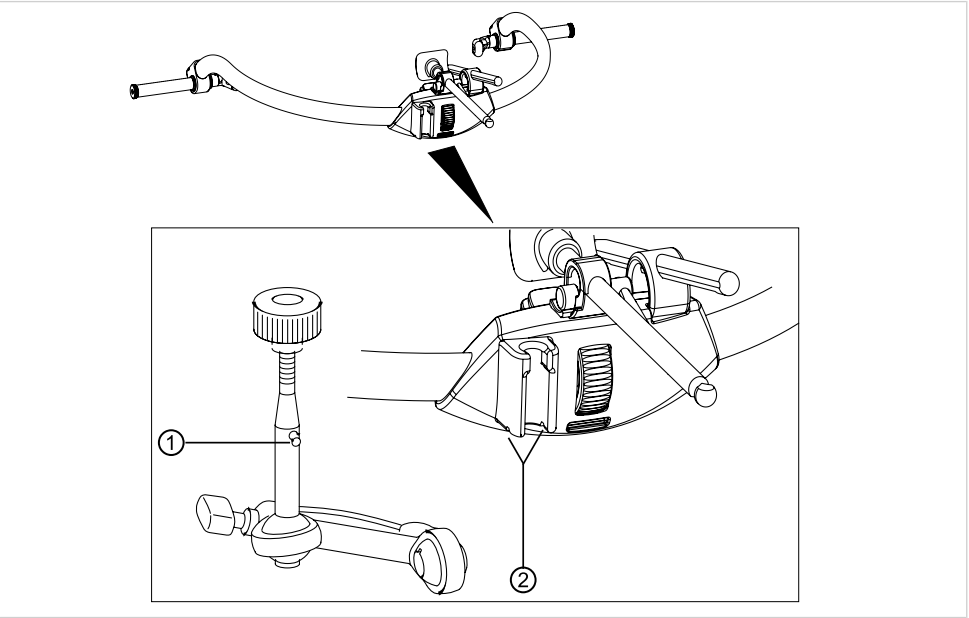
**See also:** 4.1 Adapting the facial bow, Page 15

- Insert the earbuds ⑦ into the outer auditory channel of the patient.
- Align the facial bow with the desired reference point (infraorbital point for the Frankfurter horizontal or the subnasal point for the Camper's plane).
- Affix the nose support ① with the the lock lever ②.

**Note**
If the Frankfurter horizontal is used, the reference pointer must be inserted with the pointer guide at position ④ as in the picture.
If the Camper plane is used, the reference pointer must be moved with the pointer guide below the adjustment wheel at position ⑤.

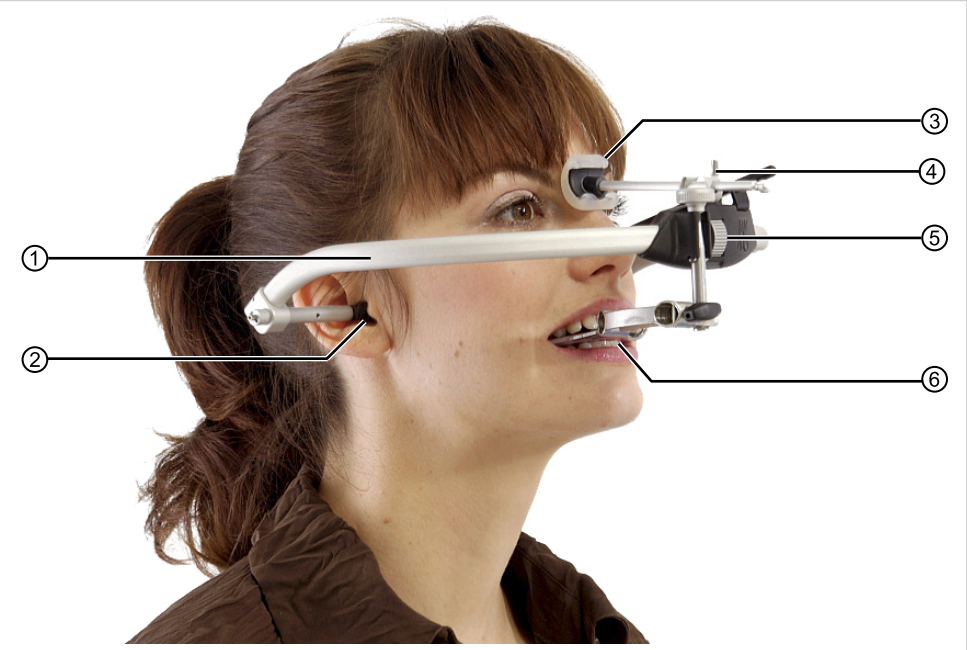



- Remove the knurled screw ②.
- Shove the bite fork support ③ onto the bite fork ④.
- Suspend the bite fork support ③ on the facial bow and tighten it with the fastening nut ①. Make sure that the guide pins of the bite fork support ③ engage in the guide groove of the facial bow.
  **See also:** following picture.
- Tighten the knurled screw ② to affix the bite fork ④.




① Guide pins of the bite fork support ② Guide groove of the facial bow

## 4.3 Removing the facial bow




- Open the lock lever ④ of the nose support ③, push back the nose support ③ and fix.
- Turn the setting wheel ⑤ to remove the earbuds ② of the facial bow ① from the ears.
- Completely remove the facial bow from the patient with bite fork ⑥ fixed in the correct position.

Transfer to the articulator:

**See also:** Instructions for use of the articulator

# 5 Preparation methods DIN EN ISO 17664

**Note**
All of the components that contact the patient's mucous membrane must be sterilized after use.

The following components must be sterilized:
- Normal bite fork (**Mat. no. 0.622.0911**)

## 5.1 Cleaning

### 5.1.1 Manual cleaning

- ▸ Before sterilization, clean the bite fork under flowing water (tap water quality, 30°C ± 5°C, flow rate: 2 litre/min) 30 seconds with a medium-hard toothbrush.
- ▸ Sterilise directly before cleaning.

### 5.1.2 Machine cleaning

Not applicable.

## 5.2 Disinfection

### 5.2.1 Manual disinfection

Allowed disinfectants
- Microcide liquid (Schülke & Mayr)

- ▸ Wipe-disinfect all components.

### 5.2.2 Automated disinfection

Not applicable.

## 5.3 Sterilisation

- Sterilise the bite fork in a fractionated initial vacuum at 134°C ± 1°C, 3.04 bar for 4 minutes (sterilisable up to max. 138°C).

# 6 Accessories

| Designation | Material number |
|---|---|
| 1 pair of adjustable axial pins | 1.004.7640 |

# 7 Spare parts sheet

Verk.-Nr. Gesichtsbogen
ARCUSevo

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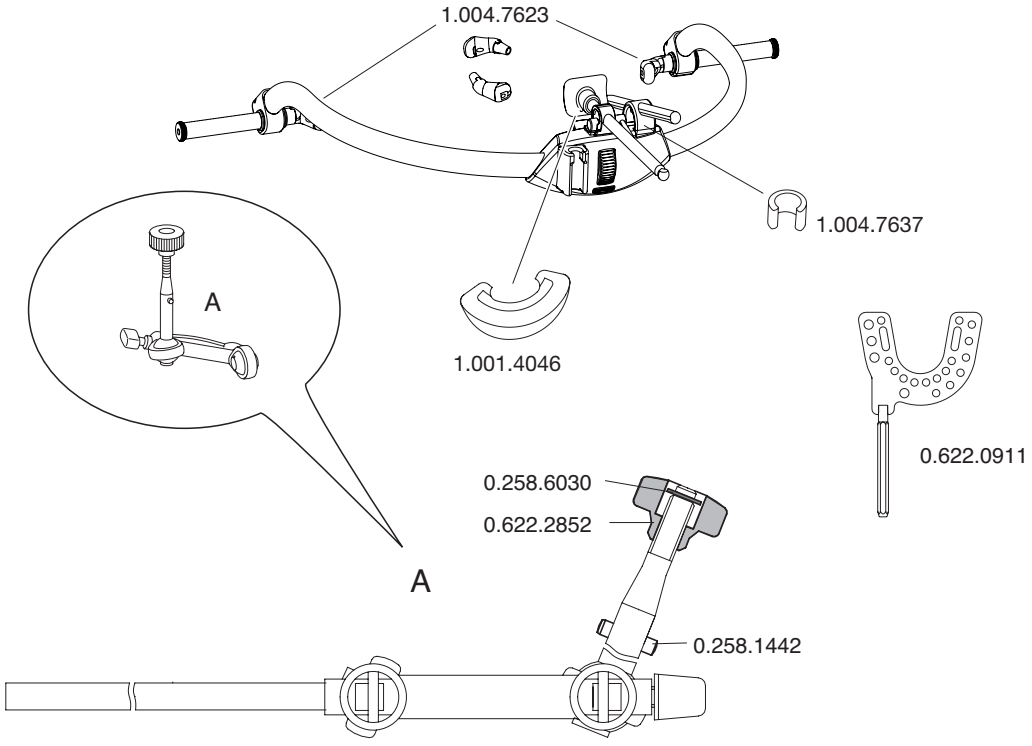
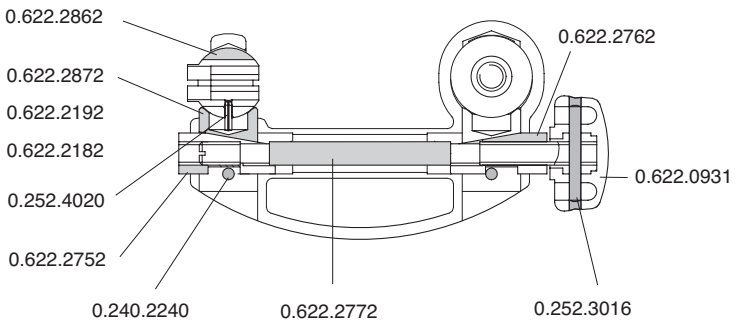
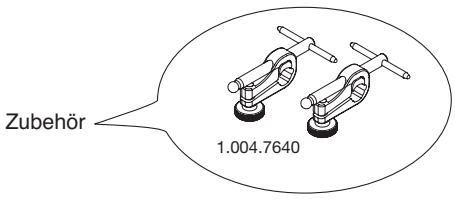
09.30




2/2

7 Spare parts sheet

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