



# Gerber Medical Diagnosis System

Important: Please read.

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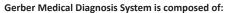
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Gerber Condylator GmbH Seeweg 162, CH-8804 Au ZH Switzerland www.condylator.com gerber@condylator.com

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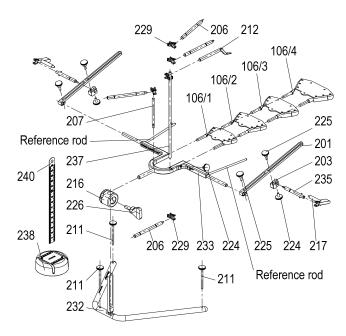


- Gerber Facebow DED®
- Gerber Facebow DED® Accessories
- Gerber Condylator®

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- Gerber Condylator® Accessories
- Gerber Registration Instruments<sup>®</sup>

# Gerber Facebow - DED® and Accessories and Assembly instructions for Gerber Facebow - DED®



# Article List Gerber Facebow - DED® and Accessories

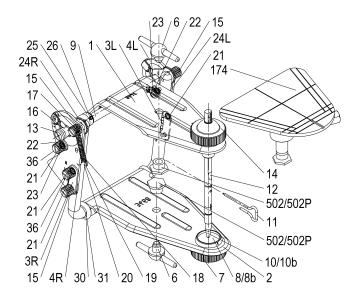
201	Arm
203	Clamp slider
206	Pointer
207	SNA rod
211	Base adjustment screw
212	Incisal indicator
216	Guide slider
217	Tragus pointer
224	Holding screw
225	Arm screw
226	Guide screw
229	Snapper
232	Stand assembly
233	
235	Pencil assembly
237	Esthetical indicator assembl
238	Ruler holder
240	Ruler
106/1	Transfer Registration Plate,
	Size 1
106/2	Transfer Registration Plate,
	Size 2
106/3	Transfer Registration Plate,

Size 3

Size 4

106/4 Transfer Registration Plate,

# Gerber Condylator® and Accessories

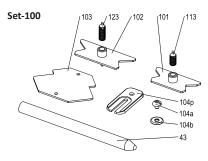


# Article list Gerber Condylator® and Accessories

- Upper arm
- 2 Lower arm
- 3R Vario R
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- Model-Mounting-Wing-Screw
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- Incisal table 15°;
- 5°, 10°, 20°, 40°
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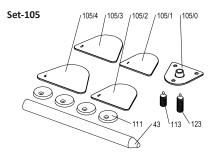


# Gerber Registration Instruments® (Sets)

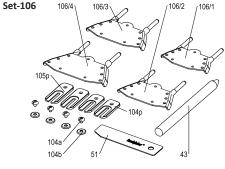


Registration-Plate-Upper small-101 (1) Registration-Plate-Upper big-102 (1) Registration-Stylus long-123 (1) Registration-Stylus short-113 (1) Registration-Plate-Lower-103 (1) Disposable-Plexiglas-Plate short-104p (1) Screw fixing Plexiglas-Plate-104a (1) Washer fixing Plexiglas-Plate-104b (1)

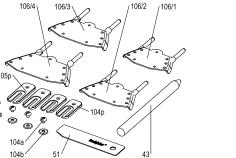
Registration-Dermo-Crayon blue-43 (1)

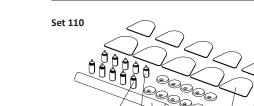


Registration-Plate-Upper-105/0 (1) Registration-Stylus short-113 (1) Registration-Stylus long-123 (1) Registration-Plate-Lower-105/1 (1) Registration-Plate-Lower-105/2 (1) Registration-Plate-Lower-105/3 (1) Registration-Plate-Lower-105/4 (1) Disposable-Plexiglas-Disc-111 (4) Registration-Dermo-Crayon blue-43 (1)



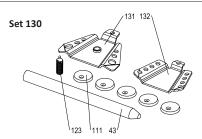
Transfer-Registration-Plate-106/1 (1) Transfer-Registration-Plate-106/2 (1) Transfer-Registration-Plate-106/3 (1) Transfer-Registration-Plate-106/4 (1) Disposable-Plexiglas-Plate short-104p (2) Disposable-Plexiglas-Plate long-105p (2) Screw Fixing Plexiglas-Plate-104a (4) Washer Fixing Plexiglas-Plate-104b (4) Registration-Dermo-Crayon blue-43 (1) Flat-Screwdriver-51 (1)





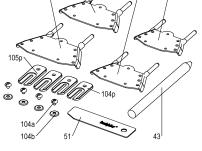
Registration-Stylus with sleeve short-112/113 (5) Registration-Stylus with sleeve long-122/123 (5) Registration-Plate small-115 (5) Registration-Plate big-125 (5) Disposable-Plexiglas-Disc-111 (10) Registration-Dermo-Crayon blue-43 (1)

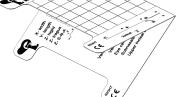
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Registration-Plate-Upper-131 (1) Registration-Stylus long-123 (1) Registration-Plate-Lower-132 (1) Disposable-Plexiglas-Disc-111 (5) Registration-Dermo-Cravon blue-43 (1)







Registration Card-244

**Registration Card** 







The Gerber Medical Diagnosis System provides a basis for reconstructing a damaged or missing dentition in an anatomo-physiological correct relation to the temporomandibular joint. The registration method can be used in the diagnosis of occlusal disharmonies associated with dentition and periodontal disease and/or temporomandibular joint disorders. The Gerber Medical Diagnosis System is composed of following parts: Gerber Facebow – DED® (Dynamic Esthetic Diagnostics), Gerber Facebow – DED® (Dynamic Esthetic Diagnostics) Accessories, Gerber Condylator®, Gerber Condylator® Accessories, Gerber Registration Instruments®.

The Gerber Facebow – DED® (Dynamic Esthetic Diagnostics) is a kinematic and dynamic Facebow, a sophisticated analogue instrument for axiography and/ or pantography, determining the individual values of different parameters established in patients mandible and head. The determined values provide information to program the Gerber Condylator®-articulator, including exact hinge axis, condyle eminence, sagittal condylar path inclination (indirectly Bennett angle and Immediate Side Shift). The Gerber Facebow – DED® (Dynamic Esthetic Diagnostics) together with the Gerber Condylator®, Gerber Registration instruments® and the Accessories are indispensable parts of the Diagnostic Instrumentation. The Gerber Condylator® is a device used to simulate the mandible movements and to assess the maxillo-mandibular relation, with the purpose of studying the occlusion and production of dental devices that will be used by the patient. The values registered with the Gerber Medical Diagnosis System are used to produce orthodontic appliances and prosthodontic appliances (crowns, bridges, occlusal splints, fixed and removable restorations of patients dentition).

All instruments of the Gerber Medical Diagnosis System are delivered unsterile. The Gerber Medical Diagnosis System is composed by single use and reusable parts.

Please check the labelling of individual parts for more information. Read the Reprocessing Instructions below that describe the cleaning and disinfection of the Gerber Medical Diagnosis System step by step. The plastic parts have to be disinfected prior contact with the patient and are single use and therefore need to be disposed correctly.

#### Intended use

The Gerber Medical Diagnosis System (the Gerber Facebow – DED® and the Gerber Condylator®) is used to replicate the kinematics of the mandible to design dental restorations with high precision.

# Indications

The Gerber Medical Diagnosis System (the Gerber Facebow – DED® and the Gerber Condylator®) is indicated in cases of pathologic function of TMJ's (Temporo-Mandibular-Joint) and in facial esthetic disharmony.

#### Contraindications

The Gerber Facebow – DED® and the Gerber Registration Instruments® are contraindicated in children under 8 years or patients with conditions that do not allow them to maintain a stable posture during registration procedure. The Gerber Condylator® can be used in all cases.

# Intended users and intended patients

The Gerber Medical Diagnosis System is made to be used by health care professionals such as dentists, prosthodontists, orthodontists, maxillofacial surgeons, dental technicians, professionals in aesthetic medicine or anthropologists.

The Gerber Medical Diagnosis System is used for patients with incorrect functioning of the masticatory system and problems with disturbed facial aesthetics.

The instrumentation is intended to be used to perform diagnosis on any patient group except children under 8 years and people with conditions that do not allow them to maintain a stable posture during registration procedure.

#### Cautions

Caution: Handle the pencil tips of the pencil assembly with care during Facebow application and registration.

Caution: It is strongly recommended that the Gerber Medical Diagnosis System: Gerber Facebow – DED® (Dynamic Esthetic Diagnostics), Gerber Facebow – DED®, Accessories, Gerber Condylator®, Gerber Condylator® Accessories and Gerber Registration Instruments® are used only together. Gerber Condylator GmbH does not guarantee the correct functioning of the system if other parts not belonging to the Gerber Medical Diagnosis System are used.

Caution: It is strongly recommended that clinicians and technicians always go through the offered training before undertaking a new treatment method. Gerber Condylator GmbH offers a wide range of courses. For more information, please visit www.condylator.com. Caution: All components, instruments and tooling from the Gerber Medical Diagnosis System must be maintained in good condition following these instructions for use and the Gerber Medical Diagnosis System reprocessing instructions.

#### Assembly Instructions

The Gerber Condylator® and the Gerber Facebow – DED® come assembled and ready for use. The Gerber Facebow – DED® must be disassembled for cleaning and reassembled as shown in the assembly instructions.









Warning: Use gloves during the entire procedure.

# 1a. Manual – Dynamic Registration with the Gerber Facebow – DED® Step 1.

- Mark on the skin the actual exact position of the right and left condyle lateral pole by palpating, using a dermal-pen.
- Define the proper vertical dimension. Place the Transfer-Registration-Plate (106/1, 106/2, 106/3, 106/4) exactly and symmetrical in the occlusal plane on the lower dentition or lower byte key using Silicone-O-Bite-material (Variotime Bite, O-Bite (Occlusia-Bite), Fa. Kulzer) or Acrylic/Composite plates (Silatray, Fa. Siladent).
- Place the Registration-Stylus (113, 123) on the upper Registration Plates (101, 102, 105/0, 131, or on individually made upper plates using: 112/113, 122/123), on the maxilla positioning with its tip in the middle of occlusal plane, which is where the middle line is crossing with the line between the distal wall of the right and left upper second premolars using Silicone-O-Bite.
- Adjust the possible minimal opening and check the distance and write it down.

# Step 2. - Figure ▶

Assemble the cleaned/disinfected Gerber Facebow – DED® in the way that the arms stand opposite the sliding direction, as shown in the picture on the right.

**Caution:** Be careful when placing at the face, avoid collision with eyes.

# Step 3.

Slide the Gerber Facebow – DED® on the Transfer-Registration-Plate (106/1, 106/2, 106/3, 106/4) which is fixed in the patients mouth all the way to the stop points and

fix it by tightening the Holding screw (224) securing the Transfer plate.

#### Step 4.

Adjust the R&L Arm (201) and place the open Pencil assembly (235) at each marked side pole of the condyle, firmly fixing the R&L Arm screw (225) for arm length (225) adjustment and R&L Arm screw (225) for arm width adjustment.

#### Step 5.

Place the Disposable Registration-Card (244) between the patient's face and the Pencil assembly (235) in the way that all the horizontal lines on the card are aligned with the Reference rod. Carefully activate the Pencil assembly. Caution: handle with care and activate the Pencil assembly slowly.

Warning: Carefully handle the Pencil assembly (235) (avoid causing pain or scratching the face).

## Step 6.

Conduct the axiography: Ask the patient to make the protrusive and retrusive mandible movements, always sliding the Registration-Stylus (113, 123) against the Transfer-Registration-Plate (106/1, 106/2, 106/3, 106/4). The Pencil assembly (235) will trace the sagittal condylar path on the Disposable Registration-Card (244).



Assess the angle of the condylar path inclination on the Registration Card using the Protractor and the calculation based on the Vertical Opening during the registration. The condylar path inclination is to be set on the Mechanical Condylator® Joints → see description 3. Manual − Mounting the models into the Gerber Condylator® on the base of the Dynamic Registration with the Gerber Facebow − DED®. Inside the Disposable Registration-Card there is the possibility of marking the position of width, length, height of the set Gerber Facebow − DED®, the position of SNA (206-207) and Tragus Pointers (217), and other settings during registration with the Gerber Facebow − DED®.

## Step 7.

Close the Pencil assembly on both sides.

Warning: Carefully handle the Pencil assembly (235)
(avoid causing pain or scratching the face).

Gerber Facebow – DED® on Stand positioning: Unscrew the Holding screw (224) securing the Transfer-Registration-Plate (106/1, 106/2, 106/3, 106/4). Slide the Gerber Facebow – DED® off the Transfer-Registration-Plate (106/1, 106/2, 106/3, 106/4). Slide the Gerber Facebow – DED® into the Guide slider (216) on its Stand assembly (232). Firmly tighten the Guide screw (226).

#### 1b. Manual - Intraoral Dynamic Registration

#### Step 1.

- Choose the Transfer-Registration-Plate (106/1, 106/2, 106/3, 106/4) or other lower Registration-Plate (103,105/1, 105/2, 105/3, 105/4, 115, 125, 132) according to the patient's intraoral anatomy and place it exactly and symmetrical in occlusal plane on the lower dentition or lower byte key using Silicone-O-Bite-material or acrylic/composite supporting plates (Silatray, Fa. Siladent).
- Place the Registration-Stylus (113, 123) on the

maxilla positioning its tip in the middle of occlusal plane, which is where the middle line is crossing with the line between the distal wall of the right and left upper second premolars using Silicone-O-Bite-material or acrylic plates.

Adjust the possible mouth opening.

# Step 2.

Cover the lower Registration-Plate (106/1, 106/2, 106/3, 106/4, 103,105/1, 105/2, 105/3, 105/4, 115, 125, 132) with the Registration-Dermo-Crayon blue (43) and place it back into the mouth.

# Step 3.

The patient is tracing the addiction movements, the protrusive and retrusive movements, the side movements to one side, the side movements to the other side.

#### Step 4.

- Mark the mandible Central Relation by placing a Disposable-Plexiglas-Disc (111) or Disposable-Plexiglas-Plate (104p, 105p) above the traced Central Relation point.
- Ask the patient to close his mouth placing the tip
  of the Registration-Stylus (113, 123) on the marked
  by the Disposable–Plexiglas-Disc (111) or Disposable-Plexiglas-Plate (104p, 105p) Central Relation.
  Place the silicon-O-Bite-material between the upper
  and lower arch making the occlusal keys.

# 2. Manual – Esthetical Registration

#### Step 1.

Proceed to the functional Dynamic Registration.

#### Step 2.

Proceed to the Intraoral Dynamic Registration using the Transfer Registration Plate (Set 106).



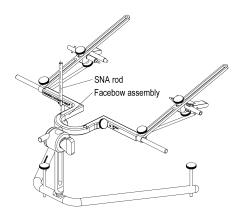


- The upper and lower registration plates joined by the occlusal keys have to be placed into the mouth and place the set Gerber Facebow – DED® onto the Transfer-Registration-Plate (106/1, 106/2, 106/3, 106/4)
- Check if the position of the right Arm and left Arm (201) and the Pencil assembly (235) are correct.

## Step 4.

Register the position of the patients Camper Plane.

- Step 4a. Figure ▼
- Mount the vertical SNA rod (207) into the Facebow Assembly (233) by screwing it in.



- Using the Snapper (229) place the Pointer (206) onto the vertical SNA rod (207) and position it pointing the level of Spina Nasalis Anterior or pointing the level of Ala-reference point. Caution: Apply the snapper with care for better patient comfort.
- Step 4b.
   Place the R & L Tragus pointer (217) onto the R & L
   Pencil assembly (235). Position the Tragus pointers (217) pointing the level of right and left Tragus.

#### Step 5.

Register the esthetical parameters.

• Step 5a.

Place the vertical Esthetical indicator assembly (237) into the Facebow Assembly (233).

- Step 5b.
- Record the distance between mouth corner and the eye pupil when looking into the distance using the Snappers (229) and Pointers (206).
- Place the Pointer (206) in Snapper (229) onto the Esthetical indicator assembly (237) and position it pointing the level of the eye pupil when looking into the distance.
- The distance between the tip Pointer (206) and the Facebow Assembly (233) is the registered distance between mouth corner and the internal the eye pupil when looking into the distance.
- Step 5c.
- Register the distance between the Me'-menton point and the Sn-subnasale point using Snappers (229) and Pointers (206).
- Place the Pointer (206) in Snapper (229) onto the Esthetical indicator assembly (237) and position it pointing the level of the point Me'-menton.
- Next place the Pointer (206) in Snapper (229) onto the Esthetical indicator assembly (237) and position it pointing the level of the point Sn-subnasale. The distance between tips of these two Pointers (206) is the registered distance between the Me'-menton point and the Sn-subnasale point.

#### Step 6.

- Record the incisal edge position of the central upper incisor using the Incisal indicator (212) in the Snapper (229).
- Place the Incisal indicator (212) in the Snapper (229) onto the Esthetical indicator assembly (237) and position it pointing the incisal edge position of the central upper incisor.

#### Step 7.

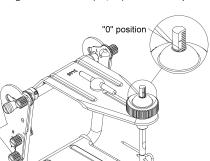
Gerber Facebow - DED® on Stand positioning:

- Unscrew the Holding screw (224) securing the Transfer-Registration-Plate (106/1, 106/2, 106/3, 106/4).
- Slight the Gerber Facebow DED® off the Transfer-Registration-Plate (106/1, 106/2, 106/3, 106/4).
- Slight the Gerber Facebow DED® into the Guide slider (216) on its Stand assembly (232).
- Tighten the Guide screw (226).

# 3. Manual – Mounting the models into the Gerber Condylator® on the base of the Dynamic Registration with the Gerber Facebow – DED®

# Step 1. - Figure ▼

- Set the Gerber Condylator into the "0" position as shown in the figure below.
- Tighten the Vertical-Incisal-Pin (12) in the 0 position with the Lock nut of vertical pin (14).
- The middle of the Incisal-Table (8) placed opposite the Vertical-Incisal-Pin (12)
- The Lock R and Lock L (24R, 24L) are blocking the movements – only the hinge movement is open.
- The right and left Vario (3R, 3L) is set on "0" position.



#### Step 2.

Align the mandible axis registered with the Gerber Facebow – DED® with the axis of the Gerber Condylator®

#### Step 3.

Fix the lower model to the Transfer-Registration-Plate (106/1, 106/2, 106/3, 106/4).

#### Step 4.

Slide in the Transfer-Registration-Plate (106/1, 106/2, 106/3, 106/4) with the lower model into the Gerber Facebow – DED®

# Step 5.

Place the mounting plaster (Siladent Plaster) onto the Lower arm (2), around the Model Anchor/Disposable Model Anchor (502, 502P) of the Gerber Condylator® and place the lower model over the plaster. Registered with the Gerber Facebow – DED® on the patient's face the mandible axis and the axis of the Gerber Condylator® are aligned and the middle line of the lower model is aligned with the middle line of the Gerber Condylator®.

# Step 6.

When the plaster is set/hardened take the Facebow away from the Gerber Condylator®.

# Step 7.

Fix the upper model with the lower mounted model using the occlusal keys made at the Intraoral Registration.

# Step 8.

- Place the mounting plaster onto the upper model and close the Upper arm (1), around the Model Anchor/Disposable Model Anchor (502, 502P) of the Gerber Condylator®.
- Make sure that the Vertical-Incisal-Pin (12) is resting in the middle of the Incisal table (8).











## Step 9.

Set the condylar path inclination on the Gerber Condylator® mechanical joints as described in 1a. Manual – Dynamic Registration with the Gerber Facebow – DED®, Step 6.

4. Manual – Mounting the models into the Gerber Condylator® on the base of the Esthetical Registration with the Gerber Facebow – DED®

# Step1.

Bring the tips of the right and left Tragus pointer (217) and the tip of the Pointer (206) of Spina Nasalis Anterior Ala-point (the Camper Plane) to the real horizontal position by adjusting the Base adjustment screws (211) of the Stand assembly (232), using the Ruler (240) on its Ruler Holder (238).

# Step 2.

- Set the Condylator into the "0" position (see above figure).
- Tighten the Vertical-Incisal-Pin (12) in the 0 position with the Lock nut of vertical pin (14).
- The middle of the Incisal-Table (8) placed opposite the Vertical-Incisal-Pin (12)
- The Lock R and Lock L (24R, 24L) are blocking the movements – only the hinge movement is open.
- The right and left Vario (3R, 3L) is set on "0" position.

#### Step 3.

Align the Camper Plane registered with the Gerber Facebow – DED® with the axis of the Gerber Condylator®.

### Step 4.

Fix together the upper and lower model according to occlusal keys made during intraoral registration using the Transfer Registration Plate (106).

# Step 5.

Slide-in the Transfer-Registration-Plate (106/1, 106/2, 106/3, 106/4) with the models into the Gerber Face-bow –  $DED^{\oplus}$ .

#### Step 6.

- Place the mounting plaster (Siladent Plaster) onto the model, around the Model Anchor/Disposable Model Anchor (502, 502P) and close the Upper arm (1), of the Gerber Condylator®.
- Make sure that the Vertical-Incisal-Pin (12) is resting in the middle of the Incisal table (8).

# Step 7.

When the plaster is set/hard take the Gerber Facebow – DED® away from the Gerber Condylator®.

# Step 8.

- Place the mounting plaster (Siladent Plaster) onto the Lower arm (2), around the Model Anchor/Disposable Model Anchor (502, 502P) of the Gerber Condylator® and the model and close the Gerber Condylator®.
- Make sure that the Vertical-Incisal-Pin (12) is resting in the middle of the Incisal table (8).
- Manual Mounting the models into the Gerber Condylator® on the base of the Model-Mounting-Table (174)

#### Step1.

Place the Model-Mounting-Table (174) on the Lower Arm (2) of the Gerber Condylator®.

# Step 2.

- Set the Condylator into the "0" position (see above figure).
- Tighten the Vertical-Incisal-Pin (12) in the 0 position

with the Lock nut of vertical pin (14).

- The middle of the Incisal-Table (8) placed opposite the Vertical-Incisal-Pin (12).
- The Lock R and Lock L (24R, 24L) are blocking the movements – only the hinge movement is open.
- The right and left Vario (3R, 3L) is set on "0" position.

#### Step 3.

Place the upper model with the adjusted wax rim on the Model-Mounting-Table (174).

#### Step 4.

- Place the mounting plaster (Siladent Plaster) onto the model, around the Model anchor/Disposable Model Anchor (502, 502P) and close the Upper arm (1) of the Gerber Condylator®.
- Make sure that the Vertical-Incisal-Pin (12) is resting in the middle of the Incisal table (8).

#### Step 5.

When the plaster is set/hard take the Model-Mounting-Table (174) away from the Gerber Condylator®.

#### Step 6.

Fix the opposite model with the mounted model using the occlusal keys made at the Intraoral Registration.

#### Step 7.

- Place the mounting plaster (Siladent Plaster) onto the Lower arm (2), around the Model anchor/Disposable Model Anchor (502, 502P) of the Gerber Condylator® and close the Gerber Condylator®.
- Make sure that the Vertical-Incisal-Pin (12) is resting in the middle of the Incisal table (8).







Warning: The use of devices which were not processed according to the Gerber Condylator GmbH Reprocessing Instruction may lead to infection of tissues or infectious diseases. Read the instructions carefully and do not deviate from the described reprocessing instructions.

**Caution**: Rinse the registration tools/transfer plates/ instruments each time after removal from the patient's mouth.

## **Automated Cleaning**

# (including Pre-Cleaning, disinfection and drying)

- Disassemble the Gerber Facebow DED® before cleaning.
- 2. Flush difficult to reach areas under running warm water, scrub with a soft brush.
- Put all the parts to be cleaned into the washer-disinfector.
- Carry out automatic cleaning and disinfection under consideration of national requirements following EN ISO 15883.

The manufacturer's Instructions must be strictly followed.

- 2 minutes pre-washing with cold water.
- 5 minutes washing with tap water at 55°C with a 0.5% solution of alkaline cleaning agent.
- 3 minutes rinsing with cold water.
- 5 minutes thermal disinfection with water at 93°C.
- Dry the devices according to the instructions provided by the manufacturers of the washer-disinfector.
- Reassemble the instruments according to the Assembly instructions.

**Caution**: The single-use parts are available as spareparts and must be disposed after each use.

# Maintenance and packaging

After cleaning, disinfection and drying, visually inspect the devices. Check all parts for corrosion and damage. All devices with signs of corrosion and/or damage must be disposed and replaced. Note: The Gerber Facebow – DED® and the accessories have been validated to withstand at least 50 cleaning cycles.

With the cleaning instructions described in the Reprocessing instructions of the Gerber Medical Diagnosis System, Gerber Condylator GmbH provides a validated procedure ensuring the use of clean and disinfected products. According to EN ISO 17664, it is the user's responsibility to ensure that the reprocessing as actually carried out using equipment, materials and personnel at the place of use and achieves the desired result.

# Point of use

Dispose single-use instruments after use. Control before each use all the articles for signs of corrosion and if necessary, dispose and replace any other worn-out reusable instruments.

**Warning**: Do not use device if the packaging has been damaged or previously opened.

#### End of Life

Control regularly and if necessary, dispose and replace any worn-out reusable instruments directly after use and dispose and replace all the parts if you find signs of corrosion or mechanical damage resulting from misuse. End of life for stainless steel or other material is determined by wear and damage (corrosion).

#### Materials

The Gerber Medical Diagnosis System contains stainless steel instruments (plates, screws: parts of Gerber Facebow – DED®, parts of Gerber Registration Instruments®, parts of Gerber Condylator®) and graphite (Refill) for multiple use, disposable plexiglas and plastic parts (discs, plates, model anchors, snappers, pointers).

# Disposal

Disposal of the single-use and reusable devices shall follow local regulations and environmental requirements, taking different contamination levels into account.

# Storage, handling and transportation

The device must be stored and transported carefully. Protect against moisture. Incorrect storage and transportation may influence device characteristics leading to failure. The package must be correctly disposed upon arrival of the device.











Manufacturer: Gerber Condylator GmbH

Seeweg 162

CH-8804 Au ZH Switzerland

Email: gerber@condylator.com



Manufaktura Dentystyczna Paulina Owoc ul. M. Szembekowej 14A

63-400 Ostrow Wielkopolski

Poland

E-mail: tdlowoc@gmail.com



Date of manufacture





Caution



Lot number



Article number



Non-sterile



Do not reuse



Reusable



Do not use if package is damaged



Consult instructions for use



Fragile, handle with care



Keep dry



Use by date

Made in Switzerland

IFU 241, 7640225281100: 21.04.2020

