



## Instructions for the preparation of Dentaurum wires and wire elements.

These instructions apply to all Dentaurum wires and wire elements that are approved for use on patients. These instructions comply with the requirements of EN ISO 17664 : 2018 and RKI (Robert Koch Institute) guidelines.

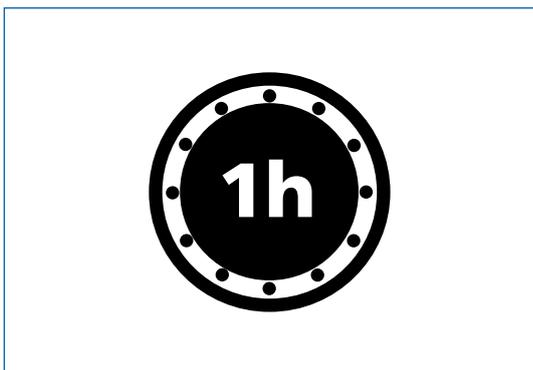
# General requirements

If necessary, all wires and wire elements should be cleaned, disinfected and sterilized. This also applies for initial use following delivery. As a general rule, wires and wire elements are delivered non-sterile. Thorough cleaning and disinfection are essential for an effective sterilization.

These instructions describe the initial preparation of wires and wire elements as well as their preparation after they have been tried on a patient, but not fixed.

**It is not permissible to process (recycle) wires and wire elements that have been fixed.**

## Manual preparation



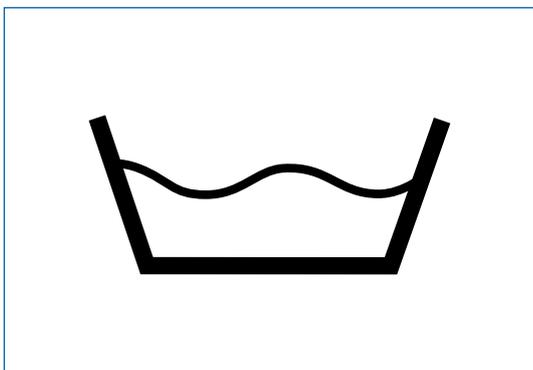
Surface contamination must be removed from wires and wire elements immediately after use, at the latest within one hour.

Rinse the wires and wire elements under running water and immerse in a disinfectant solution.

Use only a soft brush (nylon brush) or a clean soft cloth for manual removal of contamination.

Do not use metal brushes or steel wool.

Disinfectants should be aldehyde-free (otherwise possibility of fixation of blood residue), have a certified effectiveness (e.g. DGHM [German Society for Hygiene and Microbiology] or FDA approval or CE marking), be suitable for disinfecting wires and wire elements and be compatible with the wires and wire elements.



## Mechanical cleaning and disinfection

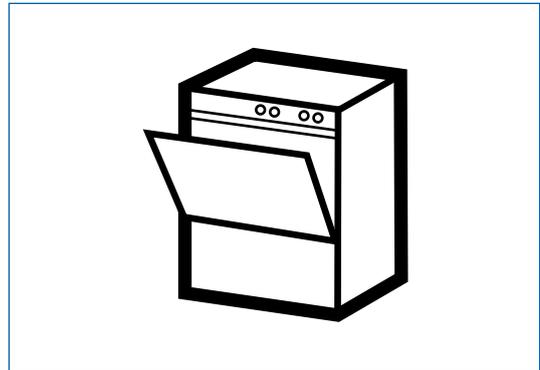
### When using a disinfectant, make sure:

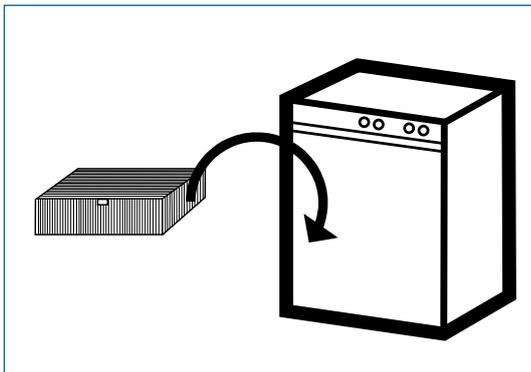
- the efficacy of the disinfectant has been certified (e.g. DGHM or FDA approved or CE marking according to DIN EN ISO 15883),
- a certified program for thermal disinfection (min. 5 mins at 90 °C / 194 °F or an  $A_0 > 3000$ ) is used (with chemical disinfection there is the risk of disinfectant residue on the wires and wire elements),
- for rinsing, it uses only water that is sterile or has a low bacteria count (max. 10 bacteria/ml) and is low in endotoxins (max. 0.25 endotoxin units/ml) (e.g. purified water/highly purified water), and
- the air used for drying is filtered.

### When choosing a cleaning agent system, make sure:

- it is suitable for cleaning metal wires and wire elements,
- an additional disinfectant with certified efficacy (e.g. DGHM or FDA approved or CE marking) is used – provided that thermal sterilization is not used – and that it is compatible with the cleaning agent used, and
- the chemicals used are compatible with the wires and wire elements (see chapter Material resistance).

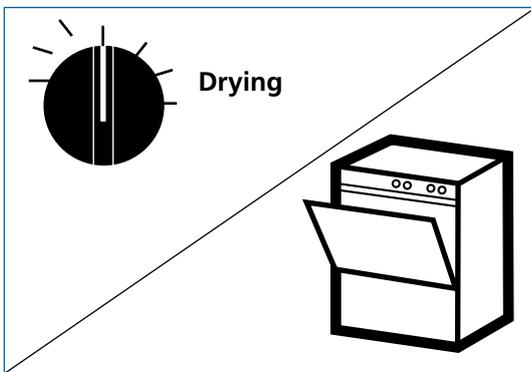
**Adhere to the concentrations given by the manufacturer of the cleaning agent and disinfectant.**





### Procedure

- 1 Place the wires and wire elements on a suitable tray (closable sieve) into the disinfectant.
- 2 Start the program.
- 3 Remove the wires and wire elements from the disinfectant at the end of the program.
- 4 Check and pack the wires and wire elements, immediately after removal if possible.
- 5 **If the disinfectant does not have an automatic drying program, leave the door of the unit slightly open to dry the wires and wire elements.**



Proof of basic suitability for effective automatic cleaning and disinfecting was provided by an independent, accredited test laboratory using a G 7836 CD disinfectant (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh, Germany) and the cleaning agent neodisher® Medizym (Dr. Weigert GmbH & Co. KG, Hamburg). The procedure described above was taken into account during the tests.

## Manual cleaning and disinfection.

### When choosing a cleaning agent and disinfectant, please take note of the following:

- the wires and wire elements must be suitable for cleaning and disinfecting.
- the cleaning agent must be suitable for ultrasonic cleaning.
- use only disinfectants with certified effectiveness (e.g. DGHM or FDA approval or CE marking). Disinfectants should be compatible with the cleaning agent used.

Do not use combined cleaning / disinfecting agents if possible. Combined cleaning/disinfecting agents can only be used if there is minimal contamination (no visible contamination).

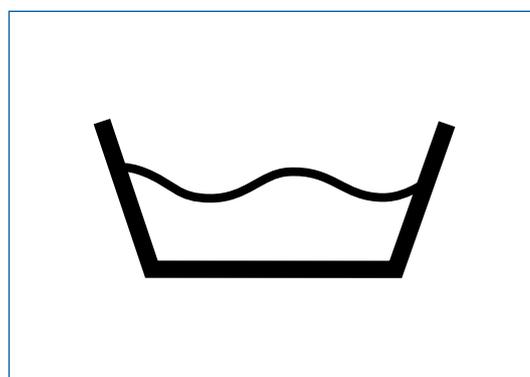
The concentrations and reaction times given by the cleaning agent and disinfectant manufacturer should be strictly adhered to. Use only freshly mixed solutions, only sterile or low-germ (max. 10 germs/ml) as well as low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) and only filtered air for drying.

### Cleaning procedure

- 1 Place wires and wire elements into the cleaning solution, on a tray if necessary, for the prescribed reaction time; ensure that they are adequately covered. If required use an ultrasonic cleaner or brush carefully with a soft brush.
- 2 Remove the wires and wire elements from the cleaning solution and rinse thoroughly with water.
- 3 **Check that the wires and wire elements have been properly cleaned.**

### Disinfection procedure

- 1 Place wires and wire elements into the cleaning solution, on a tray if necessary, for the prescribed reaction time; ensure that they are adequately covered.
- 2 Remove the wires and wire elements from the disinfectant solution and rinse thoroughly at least three times with water.
- 3 Do not pack the wires and wire elements until they are dry. Pack the dry wires and wire elements immediately.

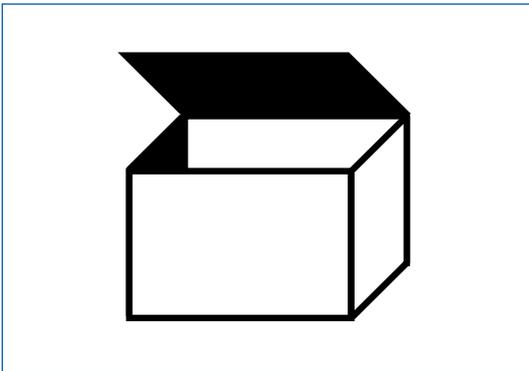


Proof of basic suitability for effective manual cleaning and disinfecting was provided by an independent, accredited test laboratory using Bodedex® forte cleaning agent and Korsolex® plus disinfectant (Bode Chemie, Hamburg, Germany). The procedure described above was taken into account during the tests.

## Check

Check all wires and wire elements after cleaning or cleaning/ disinfecting for corrosion, damage or contamination. Discard all damaged wires and wire elements. Wires and wire elements that are still contaminated must be cleaned and disinfected again.

## Packaging



**Wrap the wires and wire elements or sterilization trays in disposable sterilization packaging (single or double wrap) and / or pack in sterilization containers that meet the following requirements:**

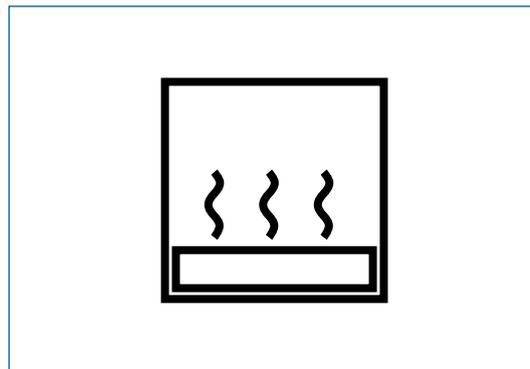
- DIN EN ISO/ANSI AAMI ISO 11607-1/2  
(formerly: DIN EN 868/ANSI AAMI ISO 11607)
- suitable for steam sterilization (temperature resistant to min. 134 °C / 273 °F, adequate steam permeability)
- adequate protection of wires and wire elements and sterilization packaging against mechanical damage
- regular servicing according to manufacturer's instructions (sterilization container)

## Sterilization

Only the following sterilization procedures should be used for sterilization. Other sterilization procedures are not suitable. Flash sterilization is not permitted. Do not use hot-air sterilization, X-ray sterilization, formaldehyde or ethylene oxide sterilization or plasma sterilization.

### Steam sterilization

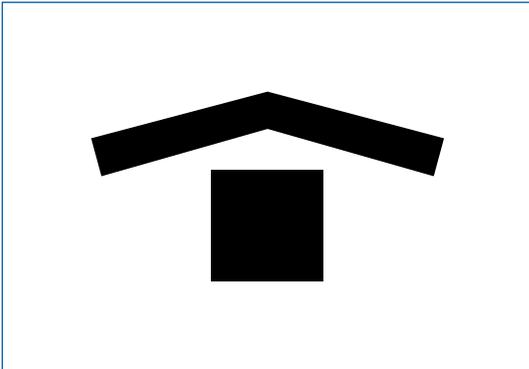
- fractionated vacuum process (with adequate product drying)
- steam sterilizer in accordance with DIN EN 13060 or DIN EN 285
- validated in accordance with DIN EN ISO/ANSI AAMI ISO 17665 (formerly: DIN EN 554/ANSI AAMI ISO 11134) (valid commissioning and product-specific performance evaluation)
- maximum sterilization temperature 134 °C/273 °F (plus tolerance in accordance with DIN EN ISO/ANSI AAMI ISO 17665 (formerly: DIN EN 554/ANSI AAMI ISO 11134))
- sterilization time (exposure time at the sterilization temperature) min. 5 minutes at 134 °C/273 °F



Proof of basic suitability for effective steam sterilization was provided by an independent, accredited test laboratory using a EuroSelectomat steam sterilizer (MMM Münchener Medizin Mechanik GmbH, Planegg, Germany) and the fractionated vacuum process as well as a Systec V-150 steam sterilizer (Systec GmbH Labor-Systemtechnik, Wettenberg, Germany) and the gravitation process. The procedure described above was taken into account during the tests.

\* Use of the less effective gravitation process is only permitted if a fractionated vacuum process is not available.

## Storage



Following sterilization, wires and wire elements should be stored dry and dust-free in the sterilization packaging.

## Material resistance

**When choosing the cleaning agent and disinfectant ensure that they do not contain the following components:**

- organic, mineral or oxidizing acids (maximum permitted pH 9.5, neutral/enzymatic cleaner recommended)
- strong alkali solutions
- organic solvents (e.g. alcohols, ethers, ketones, benzines)
- oxidation agents (e.g. hydrogen peroxides)
- halogens (chlorine, iodine, bromine)
- aromatic/halogenated hydrocarbons
- salts of heavy metals

Do not clean wires and wire elements with metal brushes or steel wool.

Do not expose wires and wire elements and sterilization trays to temperatures above 134 °C/273 °F!

## Processability

All wires and wire elements can be prepared up to five times if this is done with due care and the wires and wire elements are neither damaged nor contaminated. The operator bears responsibility for any further reuse or use of damaged and/or contaminated wires and wire elements.

**This is valid only for wires and wire elements that have been tried, but not fitted on a patient. It is not permissible to process (recycle) wires and wire elements that have been fixed.**

# Overview wires and wire elements

## Straight wires / Wires on coils

### Stainless steel (twisted and braided)



#### dentaflex® straight wire, round, 3-strand twisted

Strength category: super spring hard • 2500 – 2700 N/mm<sup>2</sup>  
Color coding on packaging: red

∅	Length	Diagonal measurement	REF	Quantity
0.38 mm / 15	each 380 mm		545-738-00	10 pieces
0.45 mm / 18	each 380 mm		545-745-00	10 pieces
0.50 mm / 20	each 380 mm		545-750-00	10 pieces

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#### dentaflex® straight wire, round, 6-strand co-axial

Strength category: hard plus • 1600 - 1800 N/mm<sup>2</sup>  
Color coding on packaging: red

∅	Length	Diagonal measurement	REF	Quantity
0.38 mm / 15	each 380 mm		545-638-00	10 pieces
0.45 mm / 18	each 380 mm		545-645-00	10 pieces

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### Stainless steel (twisted and braided)



#### dentaflex® wire on coils, round, 3-strand twisted

Strength category: super spring hard • 2500 – 2700 N/mm<sup>2</sup>

∅	Length	Diagonal measurement	REF	Quantity
0.38 mm / 15	4 m		545-738-01	1 piece
0.45 mm / 18	4 m		545-745-01	1 piece

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#### dentaflex® wire on coils, round, 6-strand co-axial

Strength category: super spring hard • 2500 – 2700 N/mm<sup>2</sup>

∅	Length	Diagonal measurement	REF	Quantity
0.38 mm / 15	4 m		545-638-01	1 piece
0.45 mm / 18	4 m		545-645-01	1 piece

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### Stainless steel (NiCr)



#### remanium® wire on coils, round

Strength category: extra spring hard • 2300 – 2500 N/mm<sup>2</sup>

∅	Length	Diagonal measurement	REF	Quantity
0.35 mm / 14	7.5 m		530-035-00	1 piece
0.40 mm / 16	7.5 m		530-040-00	1 piece
0.45 mm / 18	7.5 m		530-045-00	1 piece

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The overview contains all wires and wire elements approved for use on patients. The preparation instructions given should be adhered to, unless directed otherwise. Further information can be found at [www.dentaurum.com](http://www.dentaurum.com) or in the Orthodontics Catalog.

## Retainer wires / Retainer

### Stainless steel (NiCr)



#### rematain® flat retainer wire

For maxilla and mandible, 6-strand braided  
Easy to adapt and very flat, offering high patient comfort

□	Length	Diagonal measurement	REF	Quantity
0.25 x 0.73 mm / 10 x 29	150 mm	0.77 mm	530-000-00	10 pieces

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### Titanium



#### Titanium retainer wire, grade 1

For maxilla and mandible, 3-strand twisted  
Grade 1 has a very low oxygen content, is relatively soft and can be formed easily when cold.

∅	Length	Diagonal measurement	REF	Quantity
0.44 mm / 17	50 mm		528-001-01	10 pieces
0.50 mm / 20	50 mm		528-000-01	10 pieces

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#### Titanium retainer wire, grade 5

For maxilla and mandible, 3-strand twisted  
Grade 5 has a high mechanical strength.

∅	Length	Diagonal measurement	REF	Quantity
0.44 mm / 17	50 mm		528-001-00	10 pieces
0.50 mm / 20	50 mm		528-000-00	10 pieces

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#### Titanium retainer wire, grade 1

For maxilla and mandible, 3-strand twisted  
Grade 1 has a very low oxygen content, is relatively soft and can be formed easily when cold.

∅	Length	Diagonal measurement	REF	Quantity
0.50 mm / 20	2 m		528-000-02	1 piece

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### gold



#### Gold retainer

For maxilla and mandible, 3-strand twisted

∅	Length	Diagonal measurement	REF	Quantity
0.50 mm / 20	160 mm		529-000-00	1 piece

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# Overview wires and wire elements

## Retainer



### remanium® lingual retainer assortment

For lower cuspids 3-3, anatomically preformed.

**1 assortment = 20 pieces**

Material: Stainless steel

ø 0.80 mm / 32

<b>REF 728-500-00</b>	1 assortment
<b>CE</b> 0483	<b>Content:</b>
4 x Lingual retainer, 22 mm	REF 728-501-00
4 x Lingual retainer, 24 mm	REF 728-502-00
4 x Lingual retainer, 26 mm	REF 728-503-00
4 x Lingual retainer, 28 mm	REF 728-504-00
4 x Lingual retainer, 30 mm	REF 728-505-00



### remanium® lingual retainer

For lower cuspids 3-3, anatomically preformed.

The length given is the transverse distance between both lower cuspids.

Material: Stainless steel

ø	Length	REF	Quantity
0.80 mm / 32	22 mm	<b>728-501-00</b>	5 pieces
0.80 mm / 32	24 mm	<b>728-502-00</b>	5 pieces
0.80 mm / 32	26 mm	<b>728-503-00</b>	5 pieces
0.80 mm / 32	28 mm	<b>728-504-00</b>	5 pieces
0.80 mm / 32	30 mm	<b>728-505-00</b>	5 pieces

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### Titanium lingual retainer

acc. to Kimmich

For lower cuspids 3-3, anatomically preformed.

The length given is the transverse distance between both lower cuspids.

Material: Titanium

☑	Length	REF	Quantity
0.50 x 0.90 mm / 20 x 36	22 mm	<b>728-506-01</b>	1 piece
0.50 x 0.90 mm / 20 x 36	26 mm	<b>728-508-01</b>	1 piece
0.50 x 0.90 mm / 20 x 36	28 mm	<b>728-509-01</b>	1 piece
0.50 x 0.90 mm / 20 x 36	30 mm	<b>728-510-01</b>	1 piece

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### D.D retainer 3D maxilla

Unique fit using a three-dimensional construction design and with highest biocompatibility: milled retainer in Grade 5 titanium.

<b>REF 430-120-10</b>	1 piece
<b>CE</b> 0483	<b>NEW</b>



### D.D retainer 3D mandible

Unique fit using a three-dimensional construction design and with highest biocompatibility: milled retainer in Grade 5 titanium.

<b>REF 430-120-20</b>	1 piece
<b>CE</b> 0483	<b>NEW</b>

Similar to illustration

## Ligature wire / Ligatures



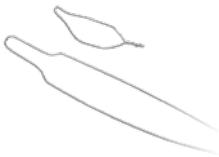
### remanium® ligature wire

Material: Stainless steel

Strength category: soft  $\leq 800$  N/mm<sup>2</sup>

ø	Length	REF	Quantity
0.25 mm / 10	80 m	<b>500-025-00</b>	1 piece
0.25 mm / 10	1.160 m	<b>501-025-00</b>	1 piece
0.30 mm / 12	60 m	<b>500-030-00</b>	1 piece
0.40 mm / 16	30 m	<b>500-040-00</b>	1 piece
0.50 mm / 20	50 m	<b>503-050-00</b>	1 piece
0.50 mm / 20	320 m	<b>501-050-00</b>	1 piece

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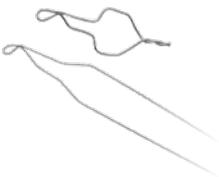
### remanium® preformed ligatures

Material: Stainless steel

Strength category: soft  $\leq 800$  N/mm<sup>2</sup>

Design	ø	REF	Quantity
short	0.25 mm / 10	<b>751-000-00</b>	1000 pieces
long	0.25 mm / 10	<b>751-001-00</b>	1000 pieces

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### remanium® Kobayashi ligatures

With hook for elastics.

Material: Stainless steel

Strength category: soft  $\leq 800$  N/mm<sup>2</sup>

Design	ø	REF	Quantity
short	0.30 mm / 12	<b>751-005-00</b>	100 pieces
short	0.35 mm / 14	<b>751-004-00</b>	100 pieces
long	0.30 mm / 12	<b>751-003-00</b>	100 pieces

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**NEW**

# Overview **wires and wire elements**

## Accessories / Bracket accessories



### Jaw fracture splint

With hook.  
Material: Stainless steel

REF 402-253-00	1 m
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### Titanium button with chain acc. to Watted

Bonding technique  
With laser-structured base and chain in titanium.  
For aligning retracted anteriors and cuspids.  
Length: 5 cm

REF 750-003-51	1 piece
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### Button

Bonding technique  
With laser-structured base, flat, square.  
For incisors.  
Dimensions (H x W): 3.5 x 3.5 mm

REF 750-002-51	10 pieces
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### Button

Bonding technique  
With laser-structured base, contoured, round.  
For cuspids and bicuspid.  
ø 3.0 mm

REF 750-001-51	10 pieces
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### Double hook

Bonding technique  
With net base for bonding, flat.  
For additional elastics or tension springs.  
Dimensions (H x W): 3.8 x 3.8 mm

REF 750-602-50	10 pieces
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### Gauze fine mesh

For making individual retention bases, periodontal splints etc., 10 x 10 cm.

REF 316-000-00	1 piece
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We have been writing dental history for the past 130 years.

**We are very proud of this!**

During this time, Dentaaurum has progressed from being a dental laboratory to a globally operating dental company. The secret to our success is our proximity to the market – the close contact with our customers and our willingness to encourage innovations. As an owner-managed family company, we are independent and flexible. We invest consistently in new technologies and are permanently optimizing our processes in order to conserve valuable resources and to achieve a sustainable future.

Our customers have always placed the highest demands on the quality of our products. This is why we develop and produce our products in Germany. The basis for our work lies in the regular exchange with our customers, active work on new developments and a professional quality management system. This establishes a secure basis for us to offer products and services that are in line with market requirements.



# Dentaurum

Germany | Benelux | España | France | Italia | Switzerland | Australia | Canada | USA  
and in more than 130 countries worldwide.



DENTAURUM  
QUALITY  
WORLDWIDE  
UNIQUE

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Date of information: 03/20  
Subject to modifications

