Champions® Condensers Instructions for Use

You can find the references in the current product catalog.

Please Note:

Please read these Instructions for Use carefully before using the Champions® implant system and the instruments. Please also follow the Champions® Condenser Protocol, explaining condensing sequences for the manual and mechanical use. Champions® Condensers may only be used by dental surgeons and doctors who are familiar with dental surgery, including diagnosis and preoperative management, considering its indication and general guidelines for dental/surgical applications as well as rules and regulations for safety at work and prevention of accidents.

Prior to each surgical treatment, check that all required parts, instruments, and auxiliary devices are complete, functioning correctly, and available in sufficient quantity.

These Instructions for Use alone are not sufficient to ensure a professional application for practitioners inexperienced in Implantology. Therefore, we recommend proper training by users with the necessary relevant experience and/or our implant courses and online courses.

1. Product description

Champions® Condensers are instruments allowing for bone condensing mainly in low density bone (D3 + D4). They serve as test instruments for determining the diameter of the implant that is to be placed. Follow the Champions® Condenser Protocol guidelines.

Mechanical Condensers are adjusted according to ISO 1797-1, which allows the Condenser to be connected to the manual torque wrench (by means of a torque wrench adapter). Manual Condensers are suitable for the use with the manual torque wrench. They are labeled, including the lot number and exact product data.

1.1. Material

The Condensers are manufactured with grade 5 titanium according to TiAl6V4 ELI, ASTM F 136, ISO 5832-3.

1.2. Accessories

3061, 3090

2. Delivery terms / sterilization / expiry date / returns

Attention: All supplied components are sterile and intended to be reusable.

Sterile products are labeled with the STERILE sign. The expiry date until the first use of the product is indicated on the label. The hourglass symbol refers to the expiry date.

The medical devices are sterile only in their closed original blister packaging.

Do not use the sterile products after the expiry date indicated on the packaging.

Before use, clean and sterilize the components. Follow the preparation instructions of the Champions® implant system.

Responsibility will be refused if the end-user has resterilized medical devices – regardless of the sterilization method.

Do not perform a treatment with these components if the package has been opened or damaged, otherwise sterility and/ or integrity of the products can be impaired.

These products are excluded from an exchange.

3. Indications / Purpose

Surgery: Condensers allow for bone condensing and to determine the diameter of the implant that is to be placed. They are used only in bone of average and low density (D3/D4). Champions® Condensers are intended only for the use with Champions® implants.

Note: Champions® Condensers can be used manually only in combination with the Torque Wrench.
Do not use Champions® Condensers in dense bone (D1/D2).

View of manually operated Condensers in colors and dimensions:

Silver	Light blue	Green	Yellow	Purple	Blue	Pink	Green
ø 2.4 mm	ø 2.8 mm	ø 3.0 mm	ø 3.3 mm	ø 3.8 mm	ø 4.3 mm	ø 4.8 mm	ø 5.3 mm

View of mechanically operated Condensers (with handpiece):

Silver	Light blue	Green	Yellow	Purple	Blue	Pink	Green
ø 2.4 mm	ø 2.8 mm	ø 3.0 mm	ø 3.3 mm	ø 3.8 mm	ø 4.3 mm	ø 4.8 mm	ø 5.3 mm

4. Contraindications / restrictions of use

Caution: Consider usual surgery procedures. Take great care not to injure nerves or blood vessels when drilling or condensing in the jawbone, appropriate to the jaw anatomy and X-rays.

Consider general contraindications of dental/surgical interventions in patients!

ATTENTION:

General Information:

It is strongly recommended that you should use the Condensers according to the Condenser Protocol. Failure to observe the maximum torque (40 Ncm) can result in damage to the Condenser and the handpiece.

Before surgery:

Care should be taken to ensure that the components, instruments, and devices that are used are in good condition. Carry out a visual inspection of them to check them for damage and wear and tear as well as visible markings.

During surgery:

Great care and maintenance of sterile instruments are needed to ensure a successful treatment.

Sterilization of instruments, allowing protection against infections, is decisive towards surgery results. Care should be taken to protect the patient against aspiration and ingestion of small components. Use specific auxiliary tools to prevent aspiration of loose parts (e.g. throat protection). In case of accidental swallowing of implants, abutments, Prep-Caps, or accessories, identify the destination of the object (e.g. X-rays), and undertake necessary medical action.

Intended users and groups of patients:
Condensers are to be used by dental professionals. Condensers are suitable for an implant treatment in patients. Treatment is recommended to patients only with a fully developed jawbone.

Performance requirements and limits:
For adequately performing, the Condensers are to be used only with the products described in these Instructions of Use in accordance with the intended purpose.
The Champions® Condensers are identified by color codes, dimensions and lengths, and/or corresponding direct identification on the products or product labels.

5. Clinical Benefits and Side Effects

Clinical Benefits:
Champions® Condensers are restoration components as part of the range of Champions® implant system products.
Patients benefit clinically from the replacement of missing teeth and/or the restoration with prosthetic superstructures.

Side Effects: With any surgical treatment, the following side effects may occur, including: temporary local swelling, edemas, hematomas, temporary limitation of sensibility, temporary limitation of chewing performance.

In rare cases bone fenestrations or fractures, perforations of adjacent structures, sinusitis, or sensorial/motor disorders can occur.
If iatrogenic injuries of special anatomic structures (incl. nerves, adjacent teeth, maxillary sinus) occur, a reversible or irreversible damage of these structures can occur.

NOTE:

Notes for use:

Manually operating the Condenser:
1. Adjust the torque wrench to a maximum torque of 20 Ncm.
2. Connect the Condenser to the Torque Wrench.
3. It is recommended that you should manually tighten it to achieve primary stability of 20–40 Ncm.

WARNING: do not exceed the maximum torque of 40 Ncm.

Mechanically operating the Condenser with handpiece connection:
1. Mechanical Condensers can be connected to the handpiece for mechanical instruments
2. It is recommended that you should mechanically insert it to achieve primary stability of 20–40 Ncm.

WARNING: the maximum torque for mechanical Condensers is fixed at 40 Ncm at a maximum rotation speed of 15 min^{-1}. Do not exceed the recommended torque. An excess of torque and/or excess rotation speed can result in the fracture of the Condenser and/or damage of the component or in bone overheating.

6. Surgical procedures and application

1. Prepare the implant site/pre-drill according to the Champions® Drilling Protocol for D3 and D4 bone:
   in case of immediate implantation or delayed implantation in low density D3/D4 bone, perform a pilot drilling with a yellow Conical Triangular Drill (and also eventually with the white Conical Triangular Drill) until you reach the required working length of the implant that is to be placed.

2. Condenser sequence:
   Then, perform bone condensing using Condensers of diameters in ascending order until you achieve stability at a minimum torque of 20 Ncm and at a maximum torque of 40 Ncm:
   Diameters: Ø 2.4 – 2.8 – 3.0 – 3.3 – 3.8 – 4.3 – 4.8 – 5.3 mm

   - If you achieve stability at 20 Ncm e.g. with the ø 3.8 mm-Condenser, place the ø 4.0 mm-implant
   - If you achieve stability at 20 Ncm e.g. with the ø 4.3 mm-Condenser, place the ø 4.5 mm-implant
   - If you achieve stability at 20 Ncm e.g. with the ø 4.8 mm-Condenser, place the ø 5.0 mm-implant
   - If you achieve stability at 20 Ncm e.g. with the ø 5.3 mm-Condenser, place the ø 5.5 mm-implant

NOTES:

1. For mechanical preparation, place the Condenser clockwise at a maximum of 15 min^{-1}.
2. For removing the Condenser from the bone cavity again, adjust the micromotor or the dental unity to "Reverse". Remove the Condenser COUNTERCLOCKWISE at 15 min^{-1}.

Maintenance notes:

All supplied mentioned instruments that constitute our product range are sterile. Disinfect, clean, and sterilize them after each use.

Mechanical cleaning and disinfection:

1. Place instruments in a suitable container in the thermal disinfector so that the spray jet can be directed at the products.
2. Place process chemicals in the device according to the recommendations indicated on the product label and the instructions of the thermal disinfector manufacturer.
3. Perform the Vario thermal disinfection program. Consider the A-value and the national standard (EN/ISO 15883).
4. After the program process, remove the products from the thermal disinfector and dry them (preferably with compressed air according to the recommendations of the Robert-Koch-Institut [RKI], a German organization that is responsible for disease control/prevention).
5. Carry out a visual inspection of the instruments for good condition and cleanliness. If you see visible residues on the instruments after the mechanical preparation, repeat cleaning and disinfecting until you do not see any residues anymore. This is not applicable for products that cannot be reprocessed.

Manual cleaning and disinfection (alternative):

1. Place instruments in the ultrasonic device or instrument bath filled with detergents and disinfectants (close the cover).
2. For chemical disinfection in the ultrasonic or instrument bath, observe manufacturer instructions concerning concentration and contact time. The contact time, which shall not fall below the minimum time, starts when the last instrument or system component has been placed in the bath.
3. After their contact time, rinse the instruments thoroughly with suitable water (to avoid residues, rinse with completely desalinated water [VE]).
4. Dry instruments (preferably with compressed air according to the recommendations of RKI).
5. Carry out the visual inspection of the instruments for good condition and cleanliness. If you see visible residues on the instruments, repeat cleaning and chemical disinfecting until you do not see any visible residues anymore. This is not applicable for articles that cannot be reprocessed. The Robert-Koch-Institut (RKI) recommends that cleaning and disinfecting should preferably be performed mechanically.

Sterilization in the autoclave:

All instruments can be sterilized. When sealing the sterilization film, take care that the film is not under tension. The components can be sterilized per steam in the vacuum procedure at 134°C in a device according to DIN EN 13060. For this procedure, meet the following requirements: steam sterilization in the vacuum procedure at 134°C in a device according to DIN EN 13060; validated processes.

- Fractional pre-vacuum (Type B)
- Sterilization temperature: 134°C
- Holding time: minimum of 5 minutes (full cycle)
- Drying time: minimum of 10 minutes

In order to avoid stains and corrosion, the steam must be substance-free. The limit values of feed water and steam condensate substances are defined according to DIN EN 13060. When sterilizing several instruments, do not overload the sterilizer by exceeding the maximum load. Follow the instructions of the device manufacturer. Do not use corroded system components anymore. Do not use damaged instruments anymore, otherwise there is a higher risk of fracture!

General remarks:

Observe the rules and regulations on medical device reprocessing that are valid in your country (e.g. www.rki.de). The manufacturer assures that the preparation methods mentioned above are suitable for preparing the concerned instruments for its reuse. The medical device operator is responsible for the preparation of the products with suitable equipment and material by qualified staff according to the valid RKI-recommendations. For this, routine check-ups of the validated mechanical processing procedures are necessary. In addition, the operator must carefully evaluate the effectiveness and possible disadvantageous consequences resulting from any deviation from the procedure described here.

Safety and liability

Worn or damaged instruments or system components are to be discarded immediately and to be replaced by new ones. Follow the above-mentioned Instructions for Use. The instruments or system components are intended to be used only for the aforementioned purpose. Failure to follow these safety instructions can result in injuries.

Liability

The user has sole responsibility for checking for suitability and applicability of the products for the intended purpose prior to use.

Contributory negligence by the user resulting in damage, particulary in case of non-observance of the Instructions for Use or warnings or inadvertent misuse by the user, can lead to the reduction or total exclusion of liability on the part of Champions-Implants GmbH.

7. Storage and Transport

Store and transport the products in their original packaging in a dry place at room temperature. Unsafe storage or transport can damage essential material characteristics and cause product failure.

8. Disposal

Dispose of contaminated or no longer usable medical devices safely as (clinical) health care waste in accordance with local health care directives as well as rules and regulations or directives from the state and the authorities. When separating, recycling, or disposing of packaging material, observe, where applicable, local rules and regulations from the state and authorities on packaging and packaging waste.

NOTES:

- All Champions® implants are intended to be used and restored only with the original Champions® instruments for this purpose such as Drills, Condensers, Insertion Tools, and Screwdrivers.
- The manufacturer reserves the right to modify the design of the product, components, or its packaging, to revise instructions for use as well as pricing and delivery terms. Liability is limited to the replacement of a defective product.
- Further claims of any kind are excluded.

Symbols glossary

You can find the following symbols on the product labels or on the accompanying product information.

CE 0297	CE Marking with notified body reference
	Manufacturer
REF	Article number
LOT	Batch code
	Date of manufacture
MD	Medical device
NON STERILE	Non-sterile
STERILE R	Sterilized using irradiation
	Use by date
	Do not resterilize
	Do no reuse
	Caution
	Consult Instructions for Use
	Do not use if package is damaged
	Temperature limit
	Keep away from sunlight
	Keep dry
SBS	Sterile packaging
SBS	Protective packaging with sterile barrier system inside
R_x only	Caution: U.S. law federal law restricts this device to sale by or on the order of a dental professional
QTY	Quantity
max.	Max. rotation speed
UDI	Unique Device Identifier

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