Instructions for Use Champions® Rotary Instruments

You can find article numbers in the current Product Catalog.

Please Note:

Please read these Instructions for Use before using the Champions® rotary instruments. Please also follow the Champions® Basic Rules & Drilling and Condenser Protocol as well as the product information about Drill Stop Sleeves and Mucosal Punches, explaining procedures for use.

The use of the Champions® rotary instruments is restricted to dentists 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 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. Use the Champions® rotary instruments only if they are in good condition. Care should be taken to protect the components used inside the patient's mouth against aspiration and ingestion. Therefore, we recommend that you should undergo proper training by users with the necessary relevant experience.

If in doubt regarding indication or application, refrain from usage until all items are clarified.

1. Product description

Champions® rotary instruments are part of the Champions® implant systems.

- Champions (R)Evolution® implant
- Champions® one-piece implants
    - Square "New Art"
    - Square "Classic"
    - Ball-Head

Champions® rotary instruments – Drills / Drill Stop Sleeves / Insertion Aids / Mucosal Punches and Condensers are one-piece instruments.

For the preparation of the implant bed, rotary instruments are manufactured in various diameters and lengths. Champions® rotary instruments are designed for use with standard handpieces.

For this purpose, they feature a handpiece shank in accordance with EN ISO 1797 for dental connections.

Champions® Drills are equipped with laser-etched colored depth markings, providing the user with visually secured and precise drilling.

Color-coded Drill Stop Sleeves further enhance safety during depth drilling.

Champions® Condensers are instruments primarily used in soft bone for bone compaction and serve as test instruments to determine the optimal implant diameter.

These are anodized in different colors according to the diameter.

Champions® Insertion Aids are intended for the placement of implants.

Champions® Mucosal Punches are suitable for preparing the gingiva.

1.1 Material

Designation	Material	Standard
Drills	Stainless steel 1.4197	EN ISO 7153-1
Insertion Aids/Mucosal Punches	Stainless steel 1.4197	EN ISO 7153-1
Condensers	Grade titanium 5	EN ISO 5832-3
Drill Stop Sleeves	TECAPEEK MT CLASSIX	–

1.2 Accessories

Champions® rotary instruments are designed for use with standard handpieces. For this purpose, they feature a handpiece shank in accordance with EN ISO 1797 for dental connections.

1.3 Intended purpose

Champions® rotary instruments are used to prepare and process the implant site and to insert Champions® implant systems.

1.4 Indication

Functional and aesthetic rehabilitation of the upper jaw and the lower jaw using implant systems.

1.5 Contraindications

Affected anatomical structures in the planned treatment site.

Allergies or hypersensitivity to chemical components of the material used.

In addition, observe all known contraindications for dental interventions.

1.6 Target patient group and intended user

Champions® rotary instruments are intended for use in patients with reduced or missing residual teeth. It is recommended that you should perform this treatment only in patients whose jawbone has reached maturity.

The use of Champions® rotary instruments is restricted to dental implantologists and dentists who are familiar with dental surgery, including diagnosis and preoperative management, considering its indication and general guidelines for dental/surgical applications.

Compliance with the Champions® – Basic Rules is a prerequisite for professional and safe use of the Champions® rotary instruments.

2. Delivery terms

Champions® rotary instruments are delivered sterile and bear the STERILE R symbol (gamma method).

The symbol LOT refers to the batch code.

3. Storage, use by date, packaging, and return

The product is to be stored in its original package and kept dry at room temperature and kept away from direct sunlight. Incorrect or unsafe storage can impair essential material characteristics and cause product failure.

The use by date for the first use of the product is indicated on the label.

The use by date is represented by the hourglass symbol. After the expiry of the use by date indicated on the packaging, the sterile products must be disinfected, cleaned, and sterilized before use.

Only medical devices in their original unopened blister or film packaging are sterile.

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

These products are excluded from an exchange.

4. Cleaning, disinfection and sterilization

Champions® rotary instruments are intended for reuse. They must be disinfected, cleaned, and sterilized after each use.

Frequent reprocessing has minimal impact on Champions® rotary instruments. Reuse has been validated for 220 applications/processing cycles.

If clear signs of wear and tear or damage become apparent on the Champions® rotary instruments due to heavy use before the completion of 220 cycles, the products must be discarded earlier.

Champions-Implants accepts no liability for clinical processing of originally sterile-delivered Champions® products by the end user. The validated procedures described below are recommended.

4.1 Initial treatment at the place of use

Without further preparatory treatment, the products should be processed within one hour.

Otherwise, fixed and dried surgical residues could impede cleaning or make it impossible.

If the specified time cannot be met due to the duration of use or organizational reasons, the users must define and validate measures, under their own responsibility, to prevent the complete drying of the soiling.

Immediately after use, it is recommended to remove heavy soiling from the instruments with a lint-free disposable cloth/paper.

4.2 Automated cleaning and disinfection

The use of a Washer-Disinfector (WD) complying with the ISO 15883 series of standards is recommended.

Validated process:

Step	Process	
1	**Pre-rinse**	
	Rinse agent:	Cold tap water
	Exposure time:	60 seconds
2	**Cleaning**	
	Rinse agent:	Tap water
	Rinse temperature:	55°C
	Detergent:	neodisher® MediClean forte / Manufacturer: Dr. WEIGERT
	Concentration:	0.50 %
	Exposure time:	Min. 300 seconds (RKI recommendation 600 seconds)
3	**Neutralizing (rinse)**	
	Rinse agent:	Tap water
	Rinse temperature:	40°C
	Neutralizing agent:	neodisher® Z / Manufacturer: Dr. WEIGERT
	Concentration:	0.10%
	Exposure time:	60 seconds
4	**Final rinse**	
	Rinse agent:	Tap water
	Rinse temperature:	40°C
	Exposure time:	60 seconds
5	**Thermal disinfection**	
	Disinfection temperature:	93°C
	Disinfection time:	300 seconds

Recommendations:

1. Place the instruments in a suitable container inside the thermo-disinfector so that the spray jet reaches the products directly.
2. When using alternative process chemicals, observe the manufacturer's instructions regarding dosage.
3. After completion of the program, remove the products from the thermo-disinfector and dry them (recommendations of the Robert-Koch-Institut (RKI [disease control/prevention]), preferably using compressed air).

4.3 Inspection and maintenance

After cleaning/disinfection, visually inspect the instruments to ensure they are macroscopically clean, i.e. they must be free from visible soiling and residues.

If soiling is detected, repeat the cleaning and disinfection process.

Check the instruments for damage:

- Cracks, broken parts, bent parts
- Sharp edges, notches, burrs, rough surface areas
- Damage that may damage surgical gloves
- Check for faded or incomplete markings on the instruments

Do not use damaged instruments. Discard damaged instruments immediately.

No further inspection or maintenance is required.

4.4 Packaging

For sterilization, the instruments must be sealed in hospital-grade packaging.

The packaging must meet the following criteria:

- Compliance with EN ISO 11607
- Suitability for steam sterilization (steam permeability), e.g., paper/film packages

Ensure that the film is not under tension when sealing in the sterilization film.

Sterilization accessories and sterilization packaging must be suitable for the size of the instruments as well as for the sterilization method used.

There are no additional requirements beyond those described.

4.5 Sterilization in the autoclave:

Champions® rotary instruments are sterilizable. For sterilization, sterilization using moist heat is recommended, employing a sterilizer compliant with EN 13060 or EN 285 and validated according to EN ISO 17665.

Validated procedure:

Pre-vacuum	3 times
Sterilization temperature	134°C
Sterilization time	3 minutes
Drying time	20 minutes

In order to prevent staining and corrosion, the steam must be free from constituents. Recommended limits for feedwater and steam condensate constituents are defined by EN 13060. Do not exceed the sterilizer's maximum load capacity when sterilizing multiple instruments. Follow the device manufacturer’s instructions. Do not use corroded system components anymore. Do not use damaged instruments anymore as they pose an increased risk of breakage!

4.6 General remarks

Observe the legal regulations concerning medical device reprocessing, valid in your country (e.g. www.rki.de). The manufacturer ensures that the processes mentioned above are appropriate for processing the concerned instruments for reuse. The medical device operator is responsible for the processing with suitable equipment and materials by qualified staff according to the valid RKI-recommendations.

For this, routine check-ups of the validated automated 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.

4.7 Safety and liability

Worn or damaged instruments or system components are immediately to be discarded and replaced by new ones. The above-mentioned instructions for use are absolutely to be followed. The instruments or system components shall be used only for the specified intended purpose. There will be a risk of injury if safety instructions are not followed.

Before using the products, users are obliged, on their own responsibility, to check the products for suitability and possibility of use for their intended purpose. Contributory user-caused damage will limit or entirely exclude the liability of Champions-Implants GmbH. This is especially applicable when the user has ignored Instructions for Use or safety instructions, or when he/she has accidentally misused the product.

5. Warnings

- For intra-oral use, Champions® products must be protected from aspiration. After accidental swallowing of products, the destination of the object is to be identified (e.g. X-rays), and necessary medical action must be undertaken.
- Champions® Basic Rules explain the use of the Champions® instruments, the drilling, Condenser, and insertion techniques, and the recommended insertion torque for transmucosal, minimally invasive treatment methods.
- When preparing the implant site, take care of special structures proximities (incl. nerves, maxillary sinus, adjacent teeth). Reversible or irreversible impairment (damage) of these structures can occur.
- It is crucial that you avoid overheating and overloading of the bone (bone necrosis).
- Ensure that the drill does not become misaligned or stuck during use (increased risk of breakage).

5.1 Notes

- Patients must be informed about the valid general precautions and behavioral guidelines to follow before the surgical procedure.
- To determine the exact position and depth of the drilling, it is recommended to perform computed tomography (CT) in addition to occlusal radiographs and orthopantomograms (panoramic X-rays).
- To avoid harming adjacent structures, the area surrounding the site where the instruments will be used must be carefully examined. Local anesthesia should be applied at the instrument's site of use.
- Surgical drills are subject to wear during use; timely replacement of drills is the user's responsibility. It is recommended to individually inspect the condition of each product before surgery and replace drills if necessary.
- The manufacturer reserves the right to change 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 the defective product. Further claims of any kind are excluded.
- Problems and incidents with Champions® products must be notified with details of the product (article number, batch code) to Champions-Implants GmbH, Flonheim. Serious incidents must be notified to the company Champions-Implants GmbH and to the competent statutory and regulation authorities.

6. Disposal

Safely dispose of contaminated or no longer usable medical devices 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.

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
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	Single sterile barrier system
SBS	Single sterile barrier system with protective packaging outside
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. rotation speed
UDI	Unique Device Identifier

Manufacturer in the EU:
Champions-Implants GmbH
Managing Director: Dr. med. dent. Armin Nedjat
Im Baumfeld 30 | Champions Platz 1
D-55237 Flonheim
Germany
Tel. (49) (0) 6734 - 91 40 80 | Fax (49) (0) 6734 - 10 53
info@champions-implants.com
champions-implants.com

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