Reprocessing Instructions for Use Champions® Instruments and Tools

You can find article numbers in the current Product Catalog.

Please Note:

The use of the Champions® 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® instruments and tools 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, you should be trained by a user experienced in this area. If in doubt regarding indication or application, refrain from usage until all items are clarified.

1. Product description

Champions® instruments and tools are part of the Champions® implant systems

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

Champions® instruments and tools are one-piece instruments, which are either used manually or connected to an active device.

You can find product-specific user guides in the Product Information at the website www.champions-implants.com (Media Library, Product Information).

1.1 Material

Material	Standard
Stainless steel	EN ISO 7153-1
Titanium alloy	EN ISO 5832-3
TECAPEEK	–

2. Delivery terms

Champions® instruments and tools are delivered in sterile packaging 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 protected from exposure to 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, disinfect, clean, and sterilize the sterile products before use.

Only medical devices in their closed original 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® instruments and tools are intended for reuse. They must be disinfected, cleaned, and sterilized after each use.

Frequent reprocessing has minimal impact on Champions® instruments and tools. Their reuse has been validated for 220 applications/processing cycles. If clear signs of wear and tear or damage are visible on the Champions® instruments and tools due to high stress 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	**Neutralization (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 macroscopic cleanliness, 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. Sort out damaged instruments immediately.

No further inspection or maintenance is required.

4.4 Packaging

For sterilization, the instruments and tools 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 and tools as well as for the sterilization method used.

There are no additional requirements beyond those described.

4.5 Sterilization in the autoclave:

Champions® instruments and tools are sterilizable. For sterilization, sterilization using moist heat is recommended, employing a sterilizer compliant with 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

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 its 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 to be sorted out immediately 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 users have ignored Instructions for Use or safety instructions, or when they have accidentally misused the product.

5. 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..

6. Conduct in case of serious incidents

Any incident related to the product must be reported to the manufacturer and the competent national authority.

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

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