Instructions for Use Champions® Instruments

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 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® instruments are part of the Champions® implant systems.

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

Champions® instruments are one-piece instruments.

Material

Designation	Material	Standard
Insertion Aids	Stainless steel 1.4197	EN ISO 7153-1
Rescue Tool	Stainless steel 1.4197	EN ISO 7153-1
Prosthetic Driver/Screwdriver	Stainless steel1.4197	EN ISO 7153-1
Shuttle-Extractor	Stainless steel 1.4197	EN ISO 7153-1
Condenser	Grade 5 titanium	EN ISO 5832-3
BBC Probe	Stainless steel 1.4310	EN ISO 7153-1
MIMI-Modulator	Ti6Al4V ELI	EN ISO 5832-3
	TECAPEEK MT blue (rod)	

2. Delivery terms

Champions® instruments are delivered in sterile packaging and bear the STERILE R symbol (gamma method).
The symbol LOT refers to the batch code.

3. Cleaning, disinfection and sterilization

Champions® instruments are reusable. They must be disinfected, cleaned, and sterilized after each use.

Frequent reprocessing has minimal impact on Champions® instruments.

Their reuse has been validated for 220 applications/processing cycles.

If, due to heavy usage, significant wear or damage is visible on the Champions® instruments 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. It is recommended to use the validated procedures outlined below.

3.1. Automated cleaning and disinfection:

1. Place the instruments in a suitable container inside the thermos-disinfector so that the spray jet directly sprays the products.
2. Add process chemicals to the device as indicated on the product label and the thermo-disinfector manufacturer's instructions.
3. Start the Vario thermos-disinfection program, including thermal disinfection.
   Thermal disinfection follows A-value considerations and complies with national regulations (EN / ISO 15883).
4. After the program finishes, remove the products from the thermo-disinfector and dry them (per recommendations of the Robert- Koch-Institut (RKI [disease control/prevention]), preferably using compressed air).
5. Visually inspect for intactness and cleanliness. If you see visible contamination after the automated preparation, repeat cleaning and disinfecting until you do not see any contamination.

Validated process:

Step	Process	
1	**Pre-rinse**	
	Pre-rinse:	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® N / **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

3.2. Manual cleaning and disinfection (alternative, non-validated):

1. Place the instruments in an ultrasonic device or instrument bath filled with detergents and disinfectants (lid remains closed).
2. Follow the manufacturer's instructions for concentration and exposure time for chemical disinfection in the ultrasonic device or instrument bath. The exposure time begins only after the last instrument or system component has been added to the bath and must never be shortened.
3. After the exposure time, thoroughly rinse the instruments with suitable water (preferably fully demineralized water [VE] to prevent residue).
4. Dry the instruments (preferably using compressed air, per RKI-recommendations).
5. Visually inspect the instruments for intactness and cleanliness. If visible contamination remains on the instruments, repeat the cleaning and chemical disinfection process until contamination is no longer visible. This does not apply to items that cannot be reprocessed. The Robert Koch-Institut (RKI) recommends automated cleaning and disinfection as the preferred method.

3.3. Sterilization in the autoclave:

Champions® instruments are sterilizable.

The components can be sterilized using steam in a vacuum process in a device compliant with EN 13060 at 134° C.

Validated procedure:

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

For sterilization, the products must be sealed in hospital-grade packaging (paper/ pouch packages compliant with EN ISO 11607-1 and EN 868-2). Ensure that the sterilization pouches are not under tension when sealing.

In order to prevent staining and corrosion, the steam must be free of components. Recommended limits for feedwater and steam condensate components 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!

3.4. General remarks

Observe the legal regulations concerning medical device reprocessing, valid in your country (e.g. www.rki.de).
The manufacturer ensures that the processing methods mentioned above are suitable 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.

3.5. Safety and liability

Worn or damaged instruments or system components are to be discarded immediately and replaced by new ones. The above-mentioned instructions for use are 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. 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.

4. 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, disinfect, clean, and sterilize the sterile products before use.

Only medical devices in their closed original blister 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.

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 relevant 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	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. rotation speed
UDI	Unique Device Identifier

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