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Instruction Manual for Specht®

CE

English

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1. Intended Use

The Specht® has been designed for:

- Femoral broaching in patients undergoing Total Hip Arthroplasty (THA).
- Implantation and removal of I/M nails.

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2. User Qualifications and Reporting

The use of the Specht® must be carried out by healthcare professionals trained and licensed in orthopedic or trauma surgery.
Users should report any serious incidents related to the device to the manufacturer and the competent authority of the member state where the user is established.
These instructions do not explain or discuss clinical procedures.

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3. Delivery Condition, Processing, and Storage

The Specht® was not sterilized before shipment.
Open the original package and ensure that the Specht® is intact.
Before the first use and immediately after each use, the Specht® must be cleaned, disinfected, and sterilized (see Chapter 8).

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4. Inspection of the Instrument

Before each use, check the Specht® for integrity at an air pressure of 7-8 bar (110-120 PSI).
Remove all watches and jewelry when operating the Specht®. The 70 Hz frequency can damage watches or jewelry.

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5. Maintenance

It is recommended that the Specht® be serviced regularly (**at least once per year**) at an authorized service center.

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6. Personal Protective Equipment

When using or processing the Specht® with the air hose, always wear appropriate personal protective equipment such as safety glasses, face masks, chemical-resistant gloves, and moisture-resistant clothing. Blood, tissue, and infectious materials pose an infection risk.

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7. Use

Use the Specht® only in combination with the installed handle or rasp.
Operating the Specht® without the installed adapter may damage the device.
Use nitrogen or clean, filtered compressed air to power the Specht®.
Effective operating pressure: 7-8 bar (110-120 PSI).

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8. Processing

Before the first use and immediately after each use, the Specht® must be cleaned, disinfected, and sterilized as described in this chapter. The Specht® must be protected from liquid intrusion during cleaning/disinfection.

8.1 General Basics

Particularly for the first use after delivery, the non-sterile Specht® must be cleaned, disinfected, and sterilized after the transport protective packaging has been removed.
Before each use, the Specht® must be cleaned, disinfected, and sterilized.
Effective cleaning and disinfection are indispensable prerequisites for effective sterilization.
As part of your responsibility for the sterility of the Specht® during use, please ensure that only validated device-specific and product-specific procedures are implemented. Used devices (disinfectors, sterilizers) should be regularly maintained and tested, and the validated parameters should be followed during each cycle.
Also, observe the legal provisions of your country and the hygiene regulations of the medical practice or hospital. This is especially important for the different guidelines on effective deactivation of prions.

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8.2 Cleaning and Disinfection

8.2.1 Basics

The Specht® is a non-sterile product and falls under the classification "critical A" without special requirements for reprocessing (see the classification of the Robert Koch Institute, Germany, and the WFHSS). Wherever possible, a machine process (disinfector) should be preferred. A manual process—even using an ultrasonic bath—should only be applied if a machine process is unavailable, as manual processes are significantly less effective. The use of a manual cleaning and disinfection procedure must be validated specifically for the product and process under the responsibility of the user. In both cases, pre-treatment is required.

8.2.2 Pre-treatment (Immediately After Use)

For cleaning the Specht® before its first use or after surgery, we recommend a neutral pH (or slightly alkaline) cleaning agent according to the manufacturer's recommendations. The disinfectant must be free from aldehydes (to prevent blood contamination fixation), have proven efficacy (e.g., DGHM approval, FDA approval, or CE marking), and be suitable for disinfecting instruments made from synthetic materials and metals. For manual removal of contamination, use only a soft brush or a clean soft cloth specifically for this purpose; never use metal brushes or steel wool. Please note that the disinfectant used during pre-treatment only protects the operator and cannot replace the disinfection step that follows cleaning. All instruments should be thoroughly rinsed and dried before steam sterilization.

8.2.3 Machine Cleaning/Disinfection

When selecting the **disinfector**, ensure that:

- The disinfector has proven efficacy (e.g., DGHM approval, FDA approval, or CE marking according to DIN EN ISO 15883).
- A validated program for thermal disinfection (at least 10 minutes at 93 °C or A0 value > 3000) is available.
- The program used is suitable for instruments and includes a sufficient number of rinse cycles.
- For the final rinse, only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g., aqua purificata) is used.
- The air used for drying is filtered.
- The disinfector is regularly maintained and tested.

When choosing a **detergent system**, ensure that:

- It is suitable for cleaning instruments made of synthetic materials and metals.
- If no thermal disinfection is performed, an additional suitable disinfectant with proven efficacy (e.g., DGHM approval, FDA approval, or CE marking) must be used.
- The disinfectant is compatible with the detergent used, and all materials used are compatible with the Specht® (see section 8.8 Resistance of Materials). The concentrations specified by the manufacturer of the detergent and disinfectant, if applicable, must be strictly followed.

Workflow:

1. Check whether the washing cup is mounted on the Specht®.
2. Place the Specht® in the disinfector. Make sure that the instruments touch each other as little as possible.
3. Start the program.
4. Remove the Specht® from the disinfector after the program has finished.

8.3 Inspection
Inspect the Specht® after cleaning or cleaning/disinfection for corrosion, damaged surfaces, chipping, and visible contamination. A still-contaminated Specht® must be cleaned and disinfected again.

8.4 Maintenance
Where possible, lubricants should not be used. If necessary, use only medical-grade instrument lubricants (white oil) that are suitable for steam sterilization at maximum sterilization temperatures and have proven biocompatibility.
Note that using unsuitable lubricants in conjunction with compressed air poses a risk of fire or explosion.

8.5 Packaging
Before sterilization, remove the washing cup from the Specht®.
We recommend sterilization in the sterilization tray or in disposable sterilization packaging (single or double packaging) according to the following requirements:

- DIN EN ISO 11607 / ANSI AAMI ISO 11607
- Suitable for steam sterilization (heat resistance of at least 141 °C, sufficient steam permeability).

8.6 Sterilization
Sterilization is carried out conventionally in an autoclave at 134°C. The washing cup must be removed before sterilization.
We recommend autoclaving according to standard hospital sterilization procedures and within the guidelines of the autoclave manufacturer to ensure a Sterility Assurance Level (SAL) of at least 10^{-6}.

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8.7 Storage
Store the Specht® between uses in the sterilization tray or sterile packaging.

8.8 Resistance of Materials
Never use metal brushes or steel wool for cleaning.

8.9 Reusability
The Specht® can be used as long as it functions properly and is undamaged.

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9. Specifications

- Nominal operating pressure: 7 bar
- Maximum operating pressure: 8 bar

WARNING: Operating at pressures above 8 bar (120 PSI) may result in personal injury or damage to the Specht®.

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