INSTRUCTION MANUAL

Valid for:
RISK CLASS I, IR AND IIA INSTRUMENTS
First digit of the item number: 2, 3, 7 (only trials), 8

GENERAL

Intended use Instruments in risk class I
The instruments are used during implantation or explantation of Hofer implants. The attending surgeon or user is responsible for the selection of the instruments, the operative use as well as the sufficient experience for the handling of the instruments. The use of the instruments with implants of other manufacturers has not been tested and can therefore not be recommended.

Intended use Instruments in risk class Ir
Reusable surgical instruments: Reusable surgical instruments are used for temporary use (< 60 minutes) during implantation or explantation of Hofer implants. The attending surgeon or user is responsible for the selection of the instruments, the surgical use as well as the sufficient experience for the handling of the instruments. The use of the instruments with implants of other manufacturers has not been tested and can therefore not be recommended. The instruments must not be used in combination with an active product. The instruments may be reused after cleaning, disinfection and sterilisation (according to Hofer's instructions) as long as the instruments are undamaged and free of contamination.

Intended use Instruments in risk class IIa
Drills: Drilling holes in bones

General Instruments: Surgical instruments are used during implantation or explantation of Hofer implants.

Instruments to determine size: Instruments to determine size are surgical instruments are for temporary use (<60 minutes). They are intended to assist the attending surgeon in choosing the appropriate implant size he use of the instruments with implants of other manufacturers has not been tested and can therefore not be recommended. The instruments must not be used in combination with an active product. The instruments may be reused after cleaning, disinfection and sterilisation (according to Hofer's instructions) as long as the instruments are undamaged and free of contamination.

Further intended use for instruments in general and instruments to determine size: The attending surgeon or user is responsible for the selection of the instruments, the surgical use as well as the sufficient experience for the handling of the instruments. The use of the instruments with implants of other manufacturers has not been tested and can therefore not be recommended. The instruments must not be used in combination with an active product. The instruments may be reused after cleaning, disinfection and sterilisation (according to Hofer's instructions) as long as the instruments are undamaged and free of contamination.

Indications
The surgical range of instruments from Hofer have no autonomous indication independent of the osteosynthesis implants. The indications of the instruments are based on the indications of the respective implants.

Contraindication
General: Patients deemed to be at risk for prion diseases (such as Creutzfeldt-Jakob Disease) and associated infections must be operated on using disposable instruments. Instruments used to operate on a patient with suspected CJD or proven disease must be discarded after surgery or currently valid national recommendations must be followed. The sterilization procedure specified in this manual is not suitable for the inactivation of prions.

Drill:
- Acute and chronic infections
- Muscle, nerve or vascular diseases that endanger the affected limb
- Localized bone tumors
- Systemic diseases and metabolic disorders

First use of the instruments
All surgical instruments are shipped "NON-STERILE" and must be cleaned, disinfected, and sterilized before use
Important note: Please consult the enclosed reprocessing instructions for reusable instruments for detailed reprocessing information. Where necessary, additional instrument-specific information regarding proper use of the instruments is available.
It is recommended to keep a second instrument in reserve ready to be used.

PREPARATION

Delivery
All products from Hofer Medical Solutions which are delivered NON STERILE must be cleaned, disinfected and sterilised before each use. This also applies to the first use after delivery. The delivery packaging of the implants is NOT suitable for sterilisation. It is only used for transport purposes and must be removed before cleaning, disinfection and sterilisation.

Reusability of products
A prerequisite for reuse is that the products are undamaged and uncontaminated. The reusable products must be reprocessed before each use. In case of disregard, the manufacturer excludes any liability.
Hofer Medical Solutions does not specify a maximum number for the use of reusable products. The life of the products depends on many factors, such as the manner and duration of each use, and/or handling, treatment between uses. Careful inspection and functional testing of the products before use are the best ways to determine the useful life of the product. The legibility of the labelling and, if available, the legibility of the UDI should also be checked during the inspection. In case of non-readability, the product should be replaced.

Restriction for reprocessing
Frequent proper reprocessing has little effect on these products. The service life is usually determined by wear and / or damage from use. The user is liable in case of application of damaged and / or contaminated medical products.

Assembly / disassembly
Assemblies that can be taken apart must always be cleaned dismantled. Joints and locks must always be kept open. More detailed information on the assembly / disassembly of instruments can be found in the instrument-specific brochures. Please note that instruments that do not have assembly/disassembly instructions must not be disassembled.

Materials used
Knowledge of the materials used and their properties is essential to ensure expert reprocessing and maintenance of the instruments.
- EN ISO 5832-1 Implant steel
- EN ISO 5832-2 Pure titanium grade 2
- EN ISO 5832-3 Titanium alloy grade 5
- EN ISO 7153-1 Instrument steel
- PEEK (polyetheretherketone)
- Anodised aluminium (storage systems, trays)

The materials used can be seen on the product label.

Basics of cleaning, disinfection and sterilisation
The basic principles described in this section must be observed in all reprocessing steps! Effective cleaning and disinfection is an indispensable prerequisite for effective sterilisation. To ensure hygienic safety, Hofer Medical Solutions products may only be reprocessed by means of mechanical cleaning and disinfection. **Manual cleaning and disinfection is excluded!**
As part of your responsibility for the cleaning, disinfection and sterility of the individual components, please always observe the following during use:

- Use only approved agents (RKI, DGHM/VHA, FDA, etc.), preferably (mildly) alkaline cleaners.
- Only use washer-disinfectors that comply with EN ISO 15883 Part 1 and Part 2.
- The validated and/or manufacturer-recommended parameters must be adhered to for each cycle.
- Use fully demineralised water and/or water quality according to DIN EN 285 or EN 13060.
- In addition, observe the legal/hygiene regulations applicable in your country.
- Products with cavities (lumens, cannulations) must also be completely rinsed on the inside. Suitable inserts with rinsing devices must be used for these products.

Warnings

- Reprocessing must be carried out as soon as possible after use. Soiling must not be allowed to cake on.
- Special attention must be paid to hard-to-reach areas such as hollow bodies, long and narrow cannulas, blind holes and joints. Clean cannulated products with tools such as cleaning wire, syringes and cannulas.
- Always disassemble instruments that can be disassembled before reprocessing.
- Always keep joints and locks in the open position.
- Do not clean instruments in the trays provided.
- Storage in metal containers (except stainless steel and aluminium containers) is not permitted.
- Always handle the instruments with the necessary care.
- Take measures to protect against damage during transport, cleaning and storage.

Tools for pre-cleaning
Never clean the products with metal brushes or steel wool. Noncompliance may damage the material.
Use clean, lint-free cloths and/or soft brushes as tools. For reprocessing cannulated products and / or products with cavities, you need cleaning pins, bottle brushes and / or disposable syringes with associated cannulas as an attachment.

Drying tools
Use lint-free disposable cloths or medical compressed air for drying.

Care products
Only use silicone-free care products that are suitable for the subsequent sterilisation process.

Information on preparation according to table A.1 of EN ISO 17664

<table>
<tr><td>Initial treatment at the point of use</td><td>Remove coarse soiling immediately after each application. Avoid caking on of tissue and blood, e.g. by wiping surfaces or rinsing cannulas, hollow bodies or blind holes with sterile or distilled water. Blood and tissue residues can lead to corrosion, for example. Take care to avoid fixation and adhesion of residues and germs (e.g.: aldehyde-free chemicals, cold water).
Do not return contaminated or used instruments to the screen basket or tray. Contaminated products must be reprocessed separately from the screen basket or tray. Contaminated instruments must not be transported or stored together with implants or other disposable products. Instruments can be damaged when being deposited, so care must be taken to ensure that instruments are deposited properly and that the instrument trays are not overfilled.</td></tr>
<tr><td>Preparation before cleaning</td><td>Clean the disassembled and opened instruments under running water. Tissue debris and other visible residues should be completely removed before machine cleaning. In the case of hollow bodies/cannulations, soft brushes or cannulas and disposable syringes should be used for this purpose. It is important that the brushes are of the correct diameter because cleaning will not be effective if the diameter is too small or too large.</td></tr>
<tr><td>Pre-treatment with ultrasound</td><td>If required. For pre-cleaning with ultrasound, prepare a fresh and clean cleaning solution. Observe the concentration/dilution, exposure time, temperature and water quality recommended by the manufacturer of the cleaning agent. Afterwards, the products must be thoroughly rinsed with fully demineralised water.</td></tr>
<tr><td>Cleaning & disinfection, drying</td><td>The manufacturer's instructions regarding exposure time, concentration and temperature of the detergent/disinfectant used must be observed.
To ensure hygienic safety, Hofer Medical Solutions products may only be reprocessed by means of mechanical cleaning and disinfection.
The following procedure has been validated by Hofer Medical Solutions:
<table>
<tr><td>Phase</td><td>Temperature</td><td>Duration</td><td>Medium</td></tr>
<tr><td>Rinsing</td><td>≤ 30°C</td><td>min. 1 min</td><td>Cold water</td></tr>
<tr><td>Cleaning</td><td>≥ 55°C</td><td>min. 10 min</td><td>0.5% neodisher Mediclean forte</td></tr>
<tr><td>Rinsing</td><td>10°C</td><td>min. 1 min</td><td>AD* or VE water</td></tr>
<tr><td>Thermal disinfection</td><td>≥ 93°C</td><td>5 min</td><td>AD* or VE water</td></tr>
<tr><td>Drying</td><td>110°C</td><td>20 min</td><td></td></tr>
</table>
* AD = Aqua Destillata / demineralised water</td></tr>
<tr><td>Inspection</td><td>Visually inspect the items to be rinsed, especially critical areas (e.g. blind holes, cannulations, joints, etc.), carefully for visible dirt residues and moisture residues. If necessary, repeat the process immediately.
Important: Avoid renewed contamination of the cleaned medical device. Sufficient cleanliness is a basic requirement for successful sterilisation!</td></tr>
<tr><td>Maintenance</td><td>Check instruments after reprocessing and before sterilisation for signs of end of product life, e.g. residues, damage, deformation, wear, corrosion and legibility of labelling. In case of damage, the instruments must be replaced!
After a successful visual inspection, instruments must be assembled in a cooled-down state. If not expressly indicated, do not assemble parts with force!
Check moving parts and articulated instruments for ease of movement, if necessary, use a small amount of validated, medically approved, silicone-free care products suitable for sterilisation.</td></tr>
<tr><td>Packaging</td><td>Before sterilisation, all products must be placed in the appropriate sieve.
For sterilisation, additionally use a suitable packaging system, such as a sterile barrier system according to ISO 11607-x (e.g.: sterilisation paper, sterilisation containers).
Protect the packaging and contents from mechanical damage.</td></tr>
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<table>
<tr><td>Sterilisation</td><td>All NON-STERILE products can be sterilised with steam in an autoclave. The autoclaves must comply with EN 285 or EN 13060 with regard to validation, maintenance and inspection. The specifications of the manufacturer concerning loading and operation of the sterilizer must be followed exactly
The following procedure has been validated by Hofer Medical Solutions:
<table>
<tr><td>Procedures</td><td>Fractionated pre-vacuum process</td></tr>
<tr><td>Temperature</td><td>134°C</td></tr>
<tr><td>Exposure duration</td><td>≥ 5 min</td></tr>
<tr><td>Drying time</td><td>≥ 20 min</td></tr>
</table>
If other procedures are used by the user, these must be validated by the user in accordance with EN ISO 17665-1. Ultimate responsibility for validation of sterilisation techniques and sterilisation equipment lies with the user.</td></tr>
<tr><td>Storage</td><td>Storage area with limited access that is climate-controlled, well ventilated, and dry and provides protection from dust, moisture, insects and parasites, as well as direct sun exposure. The maximum storage time depends on various factors such as packaging, storage methods, environmental conditions and handling. Users must define a maximum storage time for sterile products until use. Within this time, the products must be used or, if necessary, reprocessed (sterilised).</td></tr>
<tr><td>Transport</td><td>Implants should not be transported or stored together with contaminated instruments, materials and / or equipment. Always handle the products with the necessary care. Take measures to protect against damage during transport. Carefully handle packaging and sterilization containers and protect them from damage or negative influences, e.g., mechanical or climatic type of effects.</td></tr>
</table>

ADDITIONAL INFORMATION

Check and function test before every use

Prior to the function test, the products must be cooled to room temperature. The product must be checked after cleaning and disinfecting for cleanliness and function. Articulated joints must be lubricated with a small amount of appropriate, physiologically acceptable lubricant (validated and medically approved). Products that are bent or otherwise damaged must be discarded.

Handling

General: Always handle the instruments with the necessary care. Take measures to protect against damage during transport, cleaning, and storage. Do not allow products to come in contact with aggressive substances (acid, alkali, oxidizing or reducing substances, aggressive detergents, etc.).
Drill: The drills can be used at a maximum speed of 2000 rpm. Cool the hole with sterile saline.

Disposal

The respectively applicable disposal guidelines of each hospital must be observed.
Improper use renders the guarantee null and void.

For further questions, please contact the manufacturer.

RISKS AND NOTES

The dangers that can occur during use are minor. Nevertheless, in the event of incorrect operation or misuse, there is a risk of danger to:

- User
- Patients
- Instrument

All persons, who operate these tools, have to read and consider carefully the following notes carefully. It's about their safety.

Hazards for the operator

Warnings: The drill can be damaged irreparably if used in left hand (counterclockwise) rotation!! Drill only in clockwise rotation.

Warnings for cannulated drills: Only use guide wires and drills which show no surface damage and have a flawless, undeformed shaft.
Cleaning: Pass several times through the cannulation with an rotating nylon brush (steel wool or wire brushes must not be used) until the solvable residuals have been removed.

Attention:

The drills are delivered non-sterile. Before first use they have to be cleaned and sterilized. (see cleaning instructions). Only use perfect sharpened drills to avoid heating up, high feed forces and extreme stresses at the drive unit.

Hazards for the patient

Keep a constant feed force by drilling to get an optimal result and avoid thermal damage of bones and tissue (necrosis).
The medical gloves can be damaged by using a sharp-edged tool. This may lead to an increased contamination and infection risk. Therefore, be sure not to touch the cutting edge when changing tools or during use.

Risks for the instrument

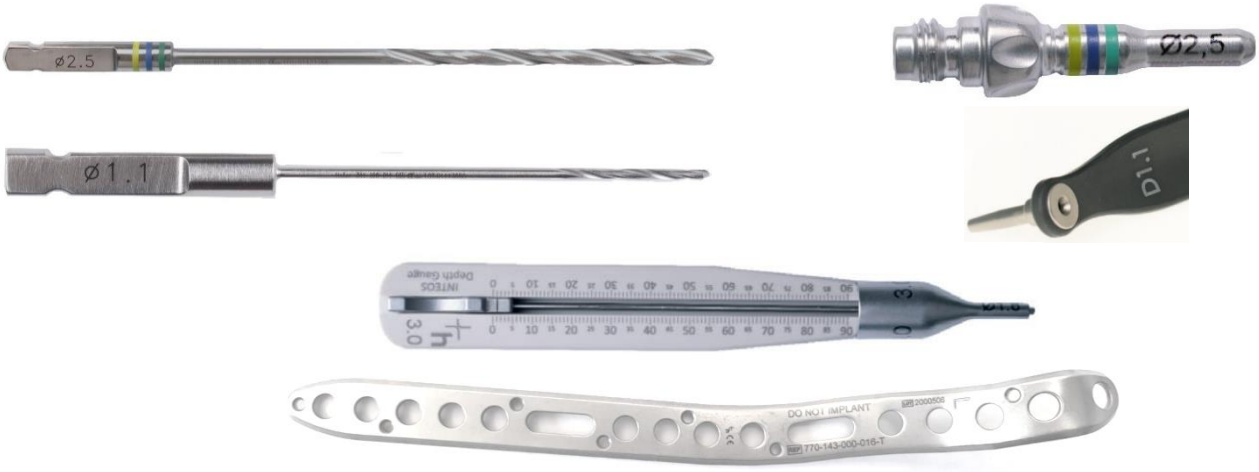
Only use drills without damaged edges or drill shafts to avoid risks and injuries.
Use drills only when the practiced function test is passed and no impairment has been detected. (see function test).

Functional test of instruments

- Before every use you must inspect the drive with the inserted drill. Watch out for damages at the drill shaft and the drill edges.
- Check if the drill is fixated tightly in the chuck. If the drill is locked secure it will be held in the handle.
- Check the compatibility of guide wire with the cannulated drill. Insert the guide wire into the drill, it has to go easily through the drill. Dispose guide wires with kinks and bendings to avoid abrasion during use.

COMBINATION OF PRODUCTS

The HOFER system components may not be used together with components of other manufacturers unless this is specifically mentioned. Always make sure that the color ring marking on the drill matches the color marking on the drill guide or that the specified drill diameter on the drill matches the specifications on the drill guide.
The system size is indicated on depth gauges. Trials are marked with the same item number as associated implants with an associated "-T".



Limited guarantee and exclusion of liability:
The products of Hofer Medical Solution are subject to a limited. Guarantee for material and manufacturing defects when delivered to the first purchaser. further explicit or implied guarantees, including those concerning marketability and suitability for a given purpose, are excluded hereby.

Serious incidents that have occurred in connection with a Hofer-medical product must be reported to the national competent authority for medical device surveillance and to the manufacturer.

Cross references to additional documents:
1) Article overviews for product specific details
2) Information on reprocessing reusable powered and non-powered surgical instruments

Description of Hofer-specific symbols used for labelling:

To be used only by appropriately trained clinical personnel.

non-clean / unprocessed implant - Clean before use.
Wash and disinfect before sterilizing as described in the current processing instructions.

Medical Device

Labelling for medical devices of risk class I (non-invasive instruments that are reusable)

Labelling for medical devices of risk class Ir and IIa (reusable surgical or surgically invasive powered and non-powered instruments)

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If more than two years have passed between the issue/revision date and the consultation date, please request the latest product information from Hofer Medical Solutions at +43 3382 53388.

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