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CE 0123

WS 2295-MULI-eIFU
R8/2019-11

ADD™ anterior distraction device

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SYSTEM:	**ADD™ anterior distraction device**
LANGUAGE:	**ENGLISH** **The only version applicable to users in the U.S. is the version intended especially for the United States.**
⚠	**BEFORE CLINICAL USE, TAKE NOTE OF THESE INSTRUCTIONS FOR USE AND THE SYSTEM-RELATED SURGICAL TECHNIQUE!**

GENERAL INFORMATION
Please ensure that you are using and observing the most current instructions for use and surgical technique of this system at all times. These can be downloaded any time free of charge at: www.ifu.ulrichmedical.com

INTENDED USE
The Anterior Distraction Device (ADD) is used for surgical reconstruction of substance defects of the anterior cervical and thoracic spine and as intervertebral interponat in the area of the thoracic and lumbar spine in humans.
Additional stabilizing instrumentation is necessary, for example, with a pedicle screw-rod-system.

INDICATIONS
Instabilities of different genesis, such as conditions after complete or incomplete corpectomy due to destruction of a vertebral body by tumor, fracture or conditions after removal of the disk for degeneration.

CONTRAINDICATIONS
- Patients with acute infection, whether superficial or deep
- Patients with fever or leukocytosis
- Patients with obesity
- Patients with a history of material allergy or who tend to react to foreign bodies
- The physician must consider carefully before treating patients who are in a generally unfavorable medical or psychological state and who could be made worse by the procedure
- Patients with inadequate bone quality or quantity (e.g. severe osteoporosis, osteopenia, osteomyelitis)
- Pregnancy

SPECIAL WARNING AND APPLICATION INSTRUCTIONS
- The ADD is used as an intervertebral interponat exclusively through the anterior approach. The ADD can be inserted in pairs here.
- The vertebral body is resected including the neighboring disks.
- The ADD is available in various external diameters and expansion ranges with a straight or angled support surface.
- The expandable implant is placed between the neighboring vertebral bodies, the defect is bridged by implant expansion and the spine is straightened.
- The ADD must be placed so that the implant end pieces are aligned parallel to the cover plates of the vertebral bodies.
- The height adjusted after the in-situ expansion is secured by means of a locking screw.
- The required height of the implant can be accurately set by turning the expansion ring on the ADD.
- Additional anterior or posterior instrumentation must be used to prevent dislocation of the ADD.
- The implant should be used in an anatomically correct position in compliance with currently valid standards for internal fixation.
- Implant failure is possible even after successful fusion.
- The implant cannot withstand physiological and biomechanical forces over the long term unless the bones fuse successfully.
- A prolonged healing phase, unsuccessful bone fusion or subsequent bone resorption or trauma can place undue stress on the implant, which, in turn, could lead to loosening, deformation, cracks or breakage of the implant.
- The inserted implant serves to reconstruct substance defects of the surgical site over a maximum two-year healing process. After the surgical site is fused, the implant is firmly anchored in the bone. The implant is therefore not intended to be removed unless there are complications, implant failure, or a delayed healing phase (no fusion within 2 years) that require implant removal. The decision to do so should only be made after a meticulous risk to benefit assessment by a medical specialist.

- After the surgery, it is recommended to wear a neck brace.

MATERIAL INFORMATION

The ADD implants are manufactured from a titanium alloy according to ISO 5832-3 and ASTM F136. The devices are biocompatible, corrosion resistant and non-toxic in the intended use as per EN ISO 10993-1.

MR conditional

MRI information

ulrich medical ADD implants are classified as "MR conditional" according to ASTM standard F2503.
The "MR conditional" components were tested according to the ASTM standards: F2052; F2182; F2213 and F2119. A patient with a ADD implant can undergo an MRI examination under the following conditions:

- Field strengths of 1.5 T and 3.0 T
- Highest field gradient of 30 T/m (3000 G/cm) or less
- Maximum specific absorption rate (SAR) of 2 W/kg for normal operating mode for a scan time of 30 minutes

Note: In the experimental test, heating of a maximum of 5.0°C was measured at:

- 1.5 T and 3.0 T
- a 15-minute scan time
- SAR 2 W/kg

Under these scan conditions, the risks to the patient during an examination are low. To minimize heating, the scan time should be as brief as possible and the SAR should be kept as low as possible.
Artefacts: MR imaging in the area of the implants can be impaired by artefacts. In the experimental test, there were artefacts up to 30 mm radially around the implant.
The scans were performed with the following parameters:
FFE sequence: TR 100 ms, TE 15 ms, flip angle 30°
SE sequence: TR 500 ms, TE 20 ms, flip angle 70°
The SE sequence demonstrates reduced artefacts (≤ 11 mm).

The attending physician should conduct a careful risk/benefit assessment.

Packaging and storage

The product is delivered non-sterile and must be sterilized before its first use. Before a system is used, all components should be meticulously checked for completeness, damages and defects. Damaged components must not be used. Corrosion may occur when instruments are stored under unfavorable conditions. In order to avoid this, they should be stored in a dry, dust-free area. Significant temperature fluctuations are to be avoided, so that no moisture (condensation) accumulates on the instruments. When directly exposed to metal, chemical substances may destroy this metal or release corrosive fumes. Therefore, instruments must not be stored together with chemical substances. The system-specific trays are to be used to store the instruments.

WARNINGS AND PRECAUTIONS

- Implantation should only be considered when all other treatment options have been carefully weighed and ruled out as a possible better option. A successful implant itself will also be inferior to the healthy moving element(s) of the spine. On the other hand, an implant may be beneficial for the patient by replacing one or more severely deformed or degenerated moving elements since this eliminates pain and a good load bearing capacity can be achieved.
- This product may only be used by a physician with experience in spinal surgery.
- The treating physician is responsible for making the proper selection for the patient, and for acquiring the training and experience required for implant selection and placement. This individual is also responsible for determining whether to leave the implant in following surgery or to remove it.
- The risks of the procedure and the use of the implant, including any revisions which may be necessary, should be explained to the patient in detail.
- The treating physician should meet with the patient for a detailed discussion of the results that may be anticipated from the surgery, particularly with regard to potential physical limitations of the implant. The degree of post-operative activity affects the life of the implant and the stability of the implant in the bone. As such, the patient must be informed of the limitations and risks inherent in daily activities and made aware of special guidelines for movement. The patient must absolutely follow the instructions given by the treating physician. Special attention should be given to post-operative consultation and the need for regular medical monitoring.

- Apply suitable diagnostic procedures both before, during and after surgery to ensure and monitor proper implant selection and placement. The use of a C-arm is strongly recommended.
- Errors in implant selection could result in premature clinical implant failure. The number of segments to be treated has to be determined accurately. The shape and composition of human bones limits the size and durability of the implant.
- After the implant has been used once, it must not be used again. Even if the implant appears undamaged, previous strain may have resulted in irregularities that could shorten the implant life. Only new, undamaged implants may be used. Used or potentially damaged implants must be discarded.
- The patient should be instructed to inform his or her treating physician immediately regarding any unusual changes in the area where the surgery was performed. The patient should be monitored if any change is detected in the implant area. The treating physician should assess the potential for clinical implant failure due to such changes and meet with the patient to discuss the necessary measures to promote continued healing.
- The product must be handled and stored carefully. Damages or scratches on the implant can have a significant negative impact on the product's stability and resistance to fatigue.

 Before use, carefully check the protective packaging for damage which could impair the sterility of the product.

POSSIBLE COMPLICATIONS

In many cases, potential complications are more likely caused by the application than by the implant:

- General risks and complications caused by the operation
- Wound healing disorder
- Infection
- Lung complications
- Cardiovascular complications, such as blood loss, thrombosis, embolism, coagulopathy
- Gastrointestinal complications, such as gastritis, ileus, ulcer
- Neurological complications, such as spinal or root lesions with temporary or permanent sensory and/or motor restrictions (bladder and colonic disorders, sexual dysfunctions)
- Risk of narcosis, blood transfusion risks, postural damage
- Intraoperative injury to blood vessels, massive hemorrhage, stroke, cerebral hemorrhage with potential life-threatening consequences
- Injury to organs adjacent to the spine, such as cervical viscera, thoracic and abdominal organs depending on the region operated on
- Failure of bone fusion and need for restabilization
- Implant removal or restabilization due to loosening, dislocation and/or failure of the implant
- Local or systemic reactions due to material intolerance
- Insufficient alleviation of complaint

These possible complications can require further operative interventions.

USE OF GENUINE PRODUCTS

Implants and instruments are developed and manufactured for common use. Unforeseeable risks and/or contamination of the materials may result from using the products of other manufacturers with those from ulrich medical, or implants and instruments may not fit together so that the patient, user or third party may be put at risk.

The combination of implants is only possible with implant components of this system unless otherwise stated in the application instructions. Only genuine instruments from the implant system which are exclusively designed for the purpose may be used for handling the implants. Please refer to the special handling instructions on the packaging insert of the respective instrument. Only genuine implants must be used.

CLEANING, DISINFECTION AND STERILIZATION

General information

For the cleaning, disinfection and sterilization of unsterilized implants and instruments, we refer to UH 1100 „Processing manual implants and instruments". For individual instruments which are correspondingly marked in the system-related surgical technique (⚠), we refer to the „Assembly and disassembly instructions with special cleaning instructions". You can download them any time free of charge at: www.ifu.ulrichmedical.com

Basic principles

Unsterilized implants must be thoroughly cleaned, disinfected and sterilized before use (clean and disinfect after removing the transport packaging and sterilize after packaging). Under no circumstances may implants which have already been in contact with a patient or have become contaminated be used again; these must be discarded.

Pretreatment

Clean/disinfect implants which you have touched, return them to the implant storage tray and sterilize the implant storage tray when it is fully loaded. Never use wire brushes or steel wool to clean any implants, implant storage trays or sterilization containers. Never apply oil and grease to implants. Please also follow the legal regulations which apply in your country as well as the hygiene regulations of the medical practice or hospital concerned.

Cleaning and disinfection

Use a mechanical method (disinfector) to clean and disinfect the implants where possible. Because a manual method is considerably less effective (even when using an ultrasound cleaning bath), it should only be used when a mechanical method is unavailable. To clean/disinfect, the implants must be taken out of the sterilization tray.

Manual cleaning/disinfection

Please note the following when selecting the cleaning and disinfecting agents to be used:

- The cleaning/disinfecting agents used must be fundamentally suitable for cleaning and/or disinfecting the implants.
- If applicable, the cleaning agent should be suitable for ultrasonic cleaning of the implants (no foam formation).
- Use a disinfecting agent that has been certified effective (e.g., VAH/DGHM-certified, FDA-approved or bearing the CE label). The disinfecting agent used must also be compatible with the cleaning agent used.
- The chemicals used must be compatible with the implants (see "Material stability" section).
- Where possible, avoid using the cleanser and disinfectant in combination.

Cleaning/disinfection using a machine

When choosing a disinfector, make sure that:

- The effectiveness of the disinfector has been thoroughly checked (e.g. VAH/DGHM or FDA approval or CE mark in compliance with DIN EN ISO 15883).
- A program for thermal disinfection which has been tested (A0 value > 3000 or for older devices at least 10 min. at 93 °C (199.4°F)) is used where possible (chemical disinfection involves the risk of disinfectant residues on the implants).
- The program used for the implants is suitable and contains a sufficient number of rinsing cycles.
- Only water which is sterile and free of germs (max. 10 germs/ml) and endotoxins (max. 0.25 endotoxin units/ml) is used for post-rinsing (e.g. Aqua purificata/Aqua purificata valde).
- The air used for drying is filtered.
- The disinfector is regularly checked and maintained.

When choosing the cleaning system to be used, make sure that:

- The cleaning system is generally suitable for cleaning implants.
- Providing no thermal disinfection is used, a suitable disinfectant is used which has been checked for its effectiveness (e.g.VAH/DGHM or FDA approval or CE mark) and that this is compatible with the cleaning agent used.
- The concentrations stipulated by the manufacturer of the cleaning agent and, if necessary, disinfectant are maintained.

Inspection

Inspect all implants for damage and contamination and discard damaged and contaminated implants.

Packaging

Use the implant storage tray provided or a suitable sterilization packaging (EN ISO 11607 / EN 868-2f).

Sterilization

- Flash sterilization is not permissible under any circumstances. Do not use hot-air sterilization or radiation sterilization procedures.
- All implants, implant storage trays or sterilization containers may only be exposed to temperatures less than 141°C (285.8°F).
- After sterilization, the implants must be stored in the sterilization packaging dry and free of dust.
- Only the following sterilization methods may be used for the sterilization.

Steam sterilization

- Validated according to DIN EN ISO/ANSI AAMI ISO 17665 (formerly: DIN EN 554/ ANSI AAMI ISO 11134) (valid commissioning (IQ/OQ) and product-specific performance assessment (PQ))
- Preferably fractionated vacuum procedure or gravitation procedure (with sufficient product drying)
- Steam sterilizer according to DIN EN 13060 or DIN EN 285
- Maximum sterilization temperature 138°C (280.4°F) plus tolerance as specified in DIN EN ISO/ ANSI AAMI ISO 17665 (formerly: DIN EN 554/ ANSI AAMI ISO 11134)
- Duration of sterilization of the fractionated vacuum procedure: (treatment time at the sterilization temperature) at least 4 min. at 132-134°C (269.6-273.2°F).
- Duration of sterilization of the gravitation procedure: Treatment time 4 min. at temperature 132°C (269.6°F).

Material stability

When choosing the cleaning agent and disinfectant, make sure that they do not contain the following components:

- Anticorrosives/corrosion inhibitors (triethanolamines are particularly problematic)

- Strong organic, mineral and oxidizing acids
- Stronger alkalis (pH > 12 is not permissible for implants, pH > 10.5 is not permissible for aluminum trays; neutral or weakly alkaline cleaning agents are recommended)
- Solvents (such as alcohols and acetone) and gasoline
- Oxidizing agents
- Ammonia
- Chlorine and iodine

Reusability

Implants are only permitted to come into contact with one patient once.

Identification and traceability

Implants are labeled with the catalogue number and batch code on the packaging label and, if technically feasible, these are marked on the implant itself. To ensure traceability, these data must be correspondingly documented in the hospital. For sterile-packaged instruments, appropriate stickers for documentation are included.

Disposal of used products

Follow country-specific regulations regarding disposal of hospital waste when disposing of used medical devices.