Fitbone™

Intramedullary Lengthening System

US

FITBONE™ TN AND FITBONE™ TLN

2

ORTHOFIX Srl
Via Delle Nazioni 9 - 37012 Bussolengo (Verona) - Italy
Tel. 0039 (0) 45 6719000 - Fax 0039 (0) 45 6719380

PQFBT B 02/25 (0433563)

US

Instructions For Use (IFU) are subject to change; the most current version of each IFU is always available online

Important information - please read prior to use
See also instruction leaflet PQFBP for Fitbone Control Set and Retraction Control Set
See also instruction leaflet PQFBR or PQRMD for Fitbone LOCKING SCREWS, STANDARD and REVISION LOCKING SCREWS and Fitbone reusable instruments.

Fitbone™ TN and Fitbone™ TLN

ORTHOFIX®
Orthofix Srl
Via delle Nazioni 9 - 37012 Bussolengo (VR) Italy
Tel. 0039 (0) 45 6719000 - Fax 0039 (0) 45 6719380

MEDICAL DEVICE INFORMATION

DESCRIPTION

The Fitbone Transport and Lengthening system consists of the implantable intramedullary transport and lengthening nail with a Receiver connected by a bipolar feed line. The external Fitbone Control Set consists of a control electronics station and a Transmitter. The power required for the distraction process is controlled by a hermetically enclosed motor which draws the telescope apart. The electro-magnetic field sent from the Transmitter to the Receiver is converted in the Receiver into DC-Voltage to supply the motor of the Fitbone Transport and Lengthening Nail with voltage, when actioned. There is no contact between the implanted intramedullary transport and lengthening nail or the implanted receiver with the surface of the body. The Fitbone Transport and Lengthening system can be implanted and removed using dedicated instruments.

The Fitbone Transport and Lengthening nails can be classified as follows:

- With the possibility of additional elongation up to 40mm maximum depending on overall nail length/size:
  - 20mm
  - 40mm
- Without the possibility of additional elongation.

Each "class" of nails is available with the following different variables:

- COMPARTMENT: Tibial nail (available only with Ø11) and Femoral nail (available in both Ø11 and Ø13 and with specific designs of distal screw holes for antegrade and retrograde approach).
- STROKE LENGTH: 40mm, 60mm or 80mm. The stroke length may be "recharged" by using Fitbone Retraction Control Set and thanks to the Recharging Screw.
- NAIL LENGTH: from 290mm to 490mm with 20mm increments.

The Fitbone Transport and Lengthening system must be fixed to the bone using Fitbone LOCKING SCREWS, available in diameter Ø4,5mm (with long and short thread) and STANDARD or REVISION Ø4.5mm LOCKING SCREWS.

Further information is available in section "Specific Information on the Device", below.

INDICATIONS FOR USE

The Fitbone Transport and Lengthening system is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, malunions, non-unions, or bone transport of the long bones.
The Fitbone Transport and Lengthening system is indicated for adult only.

CONTRAINDICATIONS

DO NOT USE the Fitbone Transport and Lengthening system if a surgical candidate exhibits or is predisposed to any of the following contraindications:

1. Patients with conditions that tend to retard healing such as blood supply limitations, peripheral vascular disease or evidence of inadequate vascularity
2. Patients with poor bone quality that would prevent adequate fixation of the device
3. Patients with compromised capacity for healing
4. Patients with metal allergies and sensitivities
5. Patients in which the implant would cross open, healthy epiphyseal growth plates
6. Insufficient intramedullary space which would lead to cortical weakening or vascular damage during an implantation
7. Patients with a body weight of > 100 kg
8. No free access for proximal insertion of the intramedullary transport and lengthening nail (e.g. coxa valga)
9. No reliable exclusion of bone infection
10. Expected non-compliance, mentally ill patient or patient with clouded consciousness
11. Pregnancy
12. Patients with pre-existing nerve palsies
13. Patients with bone defects larger than 120 mm
14. Patients with Gustilo open fracture Classification Grade IIIB or IIIC fractures

as it could result in a treatment failure in the intended population.

INTENDED PATIENTS

Proper patient selection and the patient's ability to comply with physician instructions and follow the prescribed treatment regimen will greatly affect the results. It is important to screen patients and select optimal therapy given physical and/or mental activity requirements and/or limitations.

Fitbone Transport and Lengthening system is indicated for adult only.

INTENDED USERS

The product is intended for use by Healthcare Professionals (HCP) only and such HCP must have full awareness of the appropriate orthopedic procedures and must be familiar with the devices, instruments and surgical procedures (including application and removal). One component of the system (Fitbone Control Set) is also intended to be used by the patient or caregiver. There are no specific requirements for the patient or caregiver. The HCP shall instruct the patient or caregiver on its correct use.

NOTES FOR USE

Retraction Function

In case of unintended over-distraction or if nail Rewind & Go is needed as per pre-operative plan, a Fitbone Retraction Control Set can be used to activate the nail retraction function. The Retraction Control Set is only available upon request from Orthofix or your distributor. The Retraction Control Set must not be handed over to the patient. Detailed instructions on safe use of the retraction function are available in the Fitbone Retraction Control Set Quick Guide.

Implant Removal

The Fitbone Transport and Lengthening system is not a permanent implant and must be removed. Removal of the implant is recommended when, according to the treating surgeon, the regenerated bone can support a sufficient load. In general, a period of 1 to 1 ½ years after implantation is recommended. If the explantation is delayed or not carried out, the Fitbone Transport and Lengthening Nail may break. Detailed instructions on implant removal are available in the dedicated FITBONE Operative Techniques: Fitbone Transport and Lengthening System Retrograde Femur Application, Fitbone Transport and Lengthening System Antegrade Femur Application and Fitbone Transport and Lengthening System Tibia Application.

DISCLAIMER

The HCP is fully responsible for the selection of the appropriate treatment and of the relevant device for the patient (including intraoperative procedure post-operative care).

MATERIAL

The implants are made from implant grade stainless steel, conforming to ASTM F138 and ISO-5832, and have also some parts, in contact with the body, made of other materials (NuSil MED-4870, NuSil MED-1511, NuSil MED-4750, NuSil MED2-4502). All these materials meet the biocompatibility requirements for implants.

WARNINGS

1. Never use a hammer to drive or remove the Fitbone nail into / from the medullary cavity since this could damage the implant.
2. If an eccentric cone has been used, do not rotate it while removing.
3. There is a risk of excessive cortical weakening and even perforation, leading to a fracture during treatment, particularly with the front cutting reamers.
4. Never use front cutting rigid reamers in the area of the final position of the tip of the Fitbone intramedullary nail.

PRECAUTIONS

1. Check the sterile packaging for integrity and expiration date before opening. Do not use if the sterile packaging is damaged.
2. Half-pins might be used to avoid unintentional axial and torsional deviations. These must be placed in such a way that they do not interfere with the insertion of the intramedullary nail into the medullary canal.
3. Do not directly hammer the cone because that will damage the cone end and tubes will not slide on the cone as required.
4. Monitor the entire reaming process with the image intensifier in two planes to detect any reaming errors in time.
5. Do not weaken the cortex as this could increase the risk of fracture during treatment.
6. After unpacking the intramedullary nail and the receiver, check them for integrity, especially the bipolar feedline.
7. Imprecisely set locking holes (oval, funnel-shaped, ragged) do not allow the implant to be fastened sufficiently. If the implant is insufficiently fastened, it may be helpful to use revision screws.
8. Make sure the white ring is in connection with the start of the coupling.
9. Do not hold the coupling or cable with surgical instruments and avoid bending the coupling or cable as this can lead to damage or unwanted disconnection.
10. Power transfer is optimal at approximately 5 mm distance from the Receiver. Avoid distances of more than 10 mm under the skin as such distances can negatively affect the function of the treatment system.
11. In doctor mode continuous operation, the Transmitter can reach a maximum temperature of 47.2 °C.
12. Excessive distraction can cause neuronal damage.
13. Please advise your patients not to remove the switch cover from the control set and not touch the switches.
14. The treating physician will decide about the risk and benefit of the following treatments.
    - Electrical therapy
        - Any form of electrical therapy in which current is passed through the patient´s body should be avoided on the affected limb as it could negatively affect the Fitbone intramedullary nail.
        - The leakage currents expected in the body of the patient when using defibrillators can negatively affect the Fitbone intramedullary nail.
    - Ultrasound therapy
        - Any form of therapeutic ultrasound should be avoided on the affected limb. Effects are not tested but could potentially result in unexpected harm and malfunction of the Fitbone intramedullary nail.
    - Electromagnetic therapy
        - Any form of magnetic and electromagnetic field application should be avoided on the affected limb as it could negatively affect the Fitbone intramedullary nail and cause unexpected harm..
    - High-energy ionizing radiation therapy
        - The manufacturer has no experience with how the Fitbone intramedullary nail responds to high-energy ionizing radiation. Such treatments must be avoided for the duration of the distraction phase, if possible.

If the above therapies cannot be avoided:

- The function of the Fitbone intramedullary nail must be carefully monitored to immediately identify any disruptions and also during distraction over the following 4 to 5 days.
- Never perform distraction while the above therapies are applied.

X-ray and ultrasound imaging is allowed on the affected limb. The manufacturer does not know of any events on reactions of the implantable Fitbone parts due to x-rays computer tomography. However, potential artefacts might be too high for proper imaging quality.

15. The distraction rate for adolescents should be appropriate to the accelerated rate of bone growth which could lead to a faster formation of new bone.
16. During energy transmission, monitor the retraction with the stethoscope and continuous X-ray monitoring. It is also important to consider that locking screws inserted in the bone transport segment should be placed at least 10mm away from any newly formed cancellous bone.
17. Fitbone must not be used for re-implantation.
18. The Fitbone implant is not suitable for applying compression forces.
19. If the Retraction Transmitter is positioned in an incorrect angle, an unintended distraction cannot be excluded.
20. During the distraction and consolidation phase, weight-bearing on the operated leg should be partial and limited to 20 kg (contact with the sole of the foot). Any exceeding load may cause the Fitbone intramedullary nail to break.
21. The patient must avoid unforeseen/unwanted excess weight-bearing as well as too early full weight-bearing. This may cause the Fitbone intramedullary nail to break. If excessive weight-bearing does occur, the patient must contact the treating physician.
22. The distraction phase should not be interrupted for more than 2 days at most because the risk of premature bone bridging is otherwise present.
23. Non-ionising radiation is used for energy and data transmission. Electromagnetic and magnetic pulses can cause malfunctions.
    - Note that radio equipment with transmission frequencies below 500 kHz may inadvertently lengthen the Fitbone intramedullary nail. Keep away from potential sources of such electromagnetic fields as, for example:
      a) Industrial equipment with wireless energy transmission, including production facilities and logistics centres. Please observe any posted warnings relating to increased electromagnetic radiation.
      b) Radio masts / radio towers used as time-signal transmitters.
    - Comply with the special safety precautions with regard to electromagnetic compatibility (EMC) according to the Fitbone Control Set Instructions for Use (PQFBP).
    - Only use the components (e.g. power supply units or cables) provided by the manufacturer.
24. Fitbone devices must not be stored with other electromagnetic, magnetic, ionizing, wireless or HF devices. Monitor/check the correct operation of the Fitbone System if the Fitbone Control Set is nevertheless stored in this way.
25. The drainage tube should slide without any resistance through the bony canal and the bipolar feedline should not enter and affect the adjacent joint. If not, check if the implant is deep enough inserted deeply enough (distance to notch 1cm).
26. Perform additional corrections or place blocking screws only with the dummy(trial) nail inside the bone, never while the Fitbone intramedullary nail is inserted.
27. Intraoperative functional test: check the functionality of the nail, by activating it via Fitbone Control Set. The operating noise of the nail (using the supplied stethoscope) and the flashing control light will confirm the functionality.
28. The cable must enter the bony tunnel as close as possible to the point it exits from the implant. If not, it may occur that a fibre of the patella tendon is captured, which might cause severe damage to the cable.
29. If the cable is not secured, patella tendon movement may result in damage to the cable.
30. If nail Rewind & Go is needed as per pre-operative plan, always replace the locking screw inserted in the bone transport segment with a new locking screw provided by the manufacturer.
31. If the 3mm guide wire used for opening the entry point is damaged or bent, a new guide wire must be used for insertion of the cannulated awl.
32. The patient shall be informed that the following symptoms indicate health risks:
    - Suddenly occurring severe pains
    - Sensory disturbances, numbness or other severe abnormal sensations
    - Pronounced cooling of the leg
    - Paleness or bluish colouring of the skin
    - Pronounced warming or reddening of the leg
    - Sudden fever not attributable to another cause

and that the patient in such cases shall urgently (i.e. at any time of the day or night) contact the hospital where the intramedullary nail was implanted.

33. If injections are necessary, it must be ensured that no implanted system components (e.g. Receiver) are damaged.
34. Please make sure to use the specific instrumentation according to the locking screw model as described in the Operative Technique.

Fitbone devices should be used together with their corresponding Fitbone implants, components, accessories and instrumentation following the Operative Technique recommended by the manufacturer. Orthofix does not guarantee the safety and effectiveness of the Fitbone when used in conjunction with other Orthofix devices if not specifically indicated in the Operative Technique.

Only for "STANDARD LOCKING SCREW" and "REVISION LOCKING SCREW" codes:

1. To ensure the correct proximal locking screw length, the tip of the trocar must go flat against the bone.
2. Choosing the appropriate length for the proximal locking screw is critical for the effective and safe stabilization of bone fragments. The length of the screw should be determined by using the dedicated instruments as described in the operative technique.
3. After proximal locking screw length measurements, make sure to hold the targeting handle in the same position: any movement of the targeting handle may result in a mismatch between the screw and the hole.
4. Overtightening of the screw should be avoided and the head of the screw should come just in contact with the cortex. Stop insertion when resistance is felt.

POSSIBLE ADVERSE EVENTS

A successful result is not achieved in every surgical case. Additional complications may develop at any time due to improper use, medical reasons or device failure that require surgical re-intervention to remove or replace the medical device. Preoperative and operative procedures including knowledge of surgical techniques and proper selection and placement of the device are important considerations in the successful utilization of the device by the HCP. Possible adverse events resulting from the usage of the Fitbone Transport and Lengthening system are:

- Superficial infection
- Deep infection
- Non-union, delayed union or malunion

- Premature bone callus consolidation during distraction
- Damage to bone or surrounding tissues resulting from surgery or treatment
- Damage to local vascularization resulting in bone or surrounding tissue necrosis
- Joint contracture, dislocation, instability or loss of range of motion
- Residual or new deformities, persistence or recurrence of the initial condition subject to treatment
- Bone fracture during or after treatment
- Pain, discomfort or abnormal sensations due to the presence of the device
- Compartment syndrome
- Complex regional pain syndrome
- Wound healing complications
- Injury to the healthy limbs, buttocks or head due to positioning during surgery
- Injury due to postural changes during post-operative treatment
- Loosening, bending, breakage or migration of implants
- Foreign body reactions due to implantable devices
- Reoperation to replace a component or entire nail configuration
- Events caused by intrinsic risks associated with anesthesia and surgery

MRI (Magnetic Resonance Imaging) SAFETY INFORMATION

Fitbone™ Transport and Lengthening nails are MR unsafe. Keep away from MRI examination room.
Instrumentation have not been evaluated for safety in the MR environment. They have not been tested for heating or unwanted movement in the MR environment. The safety of instrumentations in the MR environment is unknown. Performing an MR exam on a person who has these medical devices may result in injury or device malfunction.

Specific Information on the Device

Detailed information on the selection of suitable implants, accessories and related devices, including locking screws, is available in the dedicated FITBONE Operative Techniques: Fitbone Transport and Lengthening System Retrograde Femur Application, Fitbone Transport and Lengthening System Antegrade Femur Application and Fitbone Transport and Lengthening System Tibia Application.

RISKS DUE TO THE RE-USE OF "SINGLE USE" DEVICE

Implantable Device*

The "SINGLE USE" non implantable device of Orthofix is identified through symbol " ⊗ " reported on the product label. After the removal from the patient, the implantable device* has to be discarded. The re-use of implantable device cannot guarantee the original mechanical and functional performances, compromising the effectiveness of the products and introducing health risks for the patients.

(*) Implantable device: any device intended to be totally/partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is considered an implantable device.

Non Implantable Device

The "SINGLE USE" non implantable device of Orthofix is identified through symbol " ⊗ " reported on the label or are indicated in the "Instructions For Use" supplied with the products.The re-use of "SINGLE USE" non implantable device can not guarantee the original mechanical and functional performances, compromising the effectiveness of the products and introducing health risks for the patients.

STERILE & NON-STERILE PRODUCTS

Orthofix devices are provided as STERILE or NON-STERILE and they are labeled as such. In the case of STERILE products indicators on the sterile packaging serve as proof of sterilisation. Product integrity, sterility and performance are assured only if the packaging is undamaged. Do not use if packaging is compromised, unintentionally opened or if a component is believed to be faulty, suspect or damaged. The products supplied NON-STERILE require cleaning, disinfection and sterilization prior to use according to procedures reported in the following instructions.

CONTAINMENT, TRANSPORTATION AND DISPOSAL

Follow the hospital protocols for handling contaminated and bio-hazardous materials. Handling, collection, transportation and disposal of used devices must be strictly controlled to minimize any possible risks to patient, personnel and any area of the healthcare facility. Please note that the Fitbone Control Set must not be disposed but must be returned to Orthofix after completion of the treatment.

INSTRUCTIONS FOR PROCESSING AND REPROCESSING

For all Fitbone reusable instruments, Fitbone LOCKING SCREWS and STANDARD and REVISION LOCKING SCREWS follow the processing and reprocessing instructions described below and in the document PQRMD.

These reprocessing instructions have been written in accordance with ISO 17664 and have been validated by Orthofix in compliance with international standards. It is the responsibility of the health care facility to ensure that the reprocessing is performed in accordance with instructions provided.

Warnings

- Devices labeled "FOR SINGLE USE ONLY" can be reprocessed multiple times before their first clinical use but must not be reprocessed for re-use in a clinical setting.
- Single use devices MUST NOT BE REUSED, as they are not designed to perform as intended after the first usage. Changes in mechanical, physical or chemical characteristics introduced under conditions of repeated use, cleaning and re-sterilization may compromise the integrity of the design and/or material leading to diminished safety, performance and/or compliance with relevant specifications. Please refer to the device label to identify single or multiple use and/or cleaning and re-sterilization requirements.
- The personnel that works with contaminated medical devices must follow safety precautions as per the procedure of the healthcare facility.
- Cleaning and disinfection solutions with a pH 7-10.5 are recommended. Cleaning and disinfection solutions with a higher pH should be used according to the material compatibility requirements stated on the detergent technical data sheet.
- Detergents and disinfectants with fluoride, chloride, bromide, iodide or hydroxyl ions MUST NOT be used.

- Contact with saline solutions should be minimized.
- Complex devices such as those with hinges, lumens or mated surfaces must be thoroughly manually pre-cleaned before automated washing to remove soiling that accumulates in recesses. If a device needs particular care in pre-cleaning, a product specific IFU is available on the Orthofix website, which is accessible using the data matrix reported on the product labelling.
- DO NOT use metal brushes or steel wool.

Limitations on reprocessing
- Repeated reprocessing has minimal effect on devices for which reprocessing is allowed.
- End of life is normally determined by wear and damage due to use.
- Products labeled for Single Use only MUST NOT be reused regardless of any reprocessing in a clinical setting.

POINT OF USE

Reprocess the reusable medical devices as soon as is reasonably practicable to minimize the drying of soil and residuals. For optimal results, instruments should be cleaned within 30 minutes of use.
DO NOT use a fixating detergent or hot water because these can cause the fixation of residue.

CONTAINMENT AND TRANSPORTATION

Cover contaminated instruments during transportation to minimize the risk of cross contamination. All used surgical instruments must be regarded as contaminated.
Follow the hospital protocols for handling contaminated and bio-hazardous materials.
Handling, collection and transportation of used instruments must be strictly controlled to minimize any possible risks to patient, personnel and any area of the healthcare facility.

PREPARATION FOR CLEANING

This procedure can be omitted in case of direct subsequent manual cleaning and disinfection.
In the case of a highly contaminated reusable medical device, before starting an automatic cleaning process, a pre-cleaning and a manual cleaning (described below) are recommended.

Manual Pre-cleaning
1. Wear protective equipment in compliance with the safety precautions and procedures of the healthcare facility.
2. Ensure that the cleaning receptacle is clean and dry; no visible foreign material can be present.
3. Fill the receptacle with sufficient detergent solution. Orthofix recommends the use of a slightly alkaline enzymatic detergent solution based on a detergent containing <5% anionic surfactants and enzymes prepared using deionized water.
4. Carefully immerse the component in the solution to displace trapped air.
5. Scrub the device in the cleaning solution with a soft bristle nylon brush until all visible soiling is removed. Use a soft bristle nylon brush to remove residuals from lumens, with a twisting motion on rough or complex surfaces.
6. Rinse cannulations with cleaning solution using a syringe. Never use metal brushes or steel wool.
7. Remove the device from the cleaning solution.
8. Brush the single components in running tap water.
9. Clean the single components using an ultrasonic device in a degassed cleaning solution.
10. Rinse the components in purified sterile water until all traces of cleaning solution are removed. Use a syringe in case of lumens or cannulations.
11. Remove item from rinse water and drain.
12. Carefully hand-dry using absorbent not shedding cloth.

CLEANING

General considerations

Orthofix provides two methods of cleaning: a manual method and an automated method.
Wherever applicable, the cleaning phase should start immediately after the pre-cleaning phase to avoid soil drying.
The automated cleaning process is more reproducible and therefore more reliable, and the staff is less exposed to the contaminated devices and to the cleaning agents used.
Staff shall comply with the safety precautions and procedures of the healthcare facility regarding the use of protective equipment. In particular, staff should take note of the instructions provided by the cleaning agent manufacturer for correct handling and use of the product.
Observe all instructions provided by the detergent manufacturer regarding the immersion time of the device in the cleaning agent/disinfectant and its concentration.
The quality of the water used for diluting cleaning agents and for rinsing medical devices should be carefully considered.

Manual cleaning
1. Wear protective equipment in compliance with the safety precautions and procedures of the healthcare facility.
2. Ensure that the cleaning receptacle is clean and dry; no visible foreign material can be present.
3. Fill the receptacle with sufficient cleaning solution. Orthofix recommends the use of a slightly alkaline enzymatic cleaning solution.
4. Carefully immerse the component in the solution to displace trapped air; ensure that the cleaning solution reached all surfaces, including holes or cannulations.
5. Thoroughly scrub the device in the cleaning solution with a soft bristle nylon brush until all visible soiling is removed. Use a soft bristle nylon brush to remove residuals from lumens, with a twisting motion on rough or complex surfaces.
6. Rinse cannulations at least three times with cleaning solution using a syringe. Never use metal brushes or steel wool.
7. Remove the device from the cleaning solution.
8. Brush the single components in running tap water.
9. Put single components in an ultrasonic device with degassed cleaning solution at 2% for 10 minutes. Orthofix recommends the use of a detergent solution based on a detergent containing < 5 % anionic surfactants, non-ionic surfactants and enzymes, prepared using deionized water. Orthofix recommends using an ultrasound frequency of 35kHz, power = 300 Weff, time 15 minutes. The use of other solutions and parameters shall be validated by the user and the concentration shall be in compliance with the detergent manufacturer's technical datasheet.

10. Rinse the components in purified sterile water until all traces of cleaning solution are removed.
11. Rinse the cannulations, rough or complex surfaces at least three times with purified sterile water. When cannulations are present use a syringe to facilitate this step.
12. Remove item from rinse water and drain.
13. If, after completion of the cleaning steps, some encrusted soil remained on the device, the cleaning steps must be repeated as described above.
14. Carefully hand-dry using absorbent not shedding cloth.

Manual disinfection

1. Ensure that the cleaning receptacle is clean and dry; no visible foreign material can be present.
2. Fill the receptacle with sufficient disinfectant solution. Orthofix recommends the use of a 6% hydrogen peroxide solution for 30 minutes prepared using water for injection.
3. Carefully immerse the component in the solution to displace trapped air; ensure that the disinfectant solution reached all surfaces, including holes or cannulations.
4. Rinse cannulations, rough or complex surfaces at least three times with disinfectant solution. Use a syringe filled with disinfectant solution to rinse cannulations.
5. Remove the items from the solution and drain.
6. Soak in water for injection (WFI) to remove traces of disinfectant solution.
7. Rinse the cannulations at least three times with a syringe (filled with WFI).
8. Remove item from rinse water and drain.
9. Repeat the rinsing procedure as described above.
10. Carefully hand-dry using absorbent not shedding cloth.
11. Visually inspect and repeat manual cleaning and disinfection if necessary.

Automated cleaning and disinfection using washer-disinfector

1. Perform a pre-cleaning if necessary due to the contamination of the device. Take special care when the items to be cleaned contain or have:
    a) Cannulations
    b) Long blind holes
    c) Mating surfaces
    d) Threaded components
    e) Rough surfaces
2. Use a washer-disinfector in compliance with EN ISO 15883 that is properly installed, qualified and regularly subjected to maintenance and testing.
3. Ensure that the cleaning receptacle is clean and dry; no visible foreign material can be present.
4. Ensure that the washer-disinfector and all services are operational.
5. Load the medical devices into the washer-disinfector. Place heavier devices in the bottom of the baskets. Products must be disassembled before placing them in the baskets according to the specifi instructions provided by Orthofix. Wherever possible, all parts of disassembled devices should be kept together in one container.
6. Connect cannulations to the rinsing ports of the washer-disinfector. If no direct connection is possible, locate the cannulations directly on injector jets or in injector sleeves of the injector basket. Orient instruments into the automated washer's carriers as recommended by the washer manufacturer.
7. Avoid contact between devices because movement during washing could cause damage to devices and the washing action could be compromised.
8. Arrange medical devices to locate the cannulations in a vertical position and so blind holes incline downwards to promote the leakage of any material.
9. Use approved thermal disinfection program. When using alkaline solutions, a neutralizer must be added. Orthofix recommends that cycle steps are at least as follows:
    a) Pre-cleaning for 4 minutes;
    b) Cleaning with the appropriate solution. Orthofix recommends the use of a detergent solution based on a detergent containing <5% anionic surfactants, non-ionic surfactants and enzymes, prepared using deionized water for 10 minutes at 55°C;
    c) Neutralization with basic neutralizing agent solution. Orthofix recommends the use of a detergent solution based on citric acid, concentration 0.1% for 6 minutes;
    d) Final rinsing with deionized water for 3 minutes;
    e) Thermal disinfection at least 90°C or 194° F (max 95 °C or 203° F) for 5 minutes or until A0=3000 is reached. The water used for thermal disinfection must be purified.
    f) Drying at 110 °C for 40 minutes. When the instrument has a cannulation, an injector should be used to dry the internal part.
    g) The suitability of other solutions, concentration, time and temperature shall be checked and validated by the user following the detergent manufacturer's technical datasheet.
10. Select and start a cycle according to the recommendations of the washer manufacturer.
11. On completion of the cycle, ensure that all stages and parameters have been achieved.
12. Wearing protective equipment unload the washer disinfector when it completes the cycle.
13. If necessary, drain excessive water and dry by using absorbent not shedding cloth.
14. Visually inspect each device for remaining soil and dryness. If soil remains repeat the cleaning process as described above.

MAINTENANCE, INSPECTION AND FUNCTION TESTING

The following guidelines shall be applied to all Orthofix instruments that are labeled for multiple use.
All functional checks and inspections described below also cover the interfaces with other instruments or components.
The failure modes below may be caused by end of life of the product, improper use or improper maintenance.
Orthofix does not typically specify the maximum number of uses for re-usable medical devices. The useful life of these devices depends on many factors including the method and duration of each use, and the handling between uses. Careful inspection and functional testing of the device before use are the best methods of determining the end of the serviceable life for the medical device. For sterile devices the end of life has been defined, verified and specified with an expiration date.
The following general instructions apply to all Orthofix products:

- All instruments and product components must be visually inspected under good light for cleanliness. If some areas are not clearly visible, use a 3% hydrogen peroxide solution to detect the presence of organic residuals. If blood is present, bubbling will be observed. After the inspection, the device shall be rinsed and drained as per the instruction given above.
- If visual inspection evidences that the device was not properly cleaned, repeat the cleaning and disinfection steps or discard the device.
- All instruments and product components must be visually inspected for any signs of deterioration that may cause failure during use (such as cracks or damage to surfaces) and functions tested before being sterilized. If a component or instrument is believed to be faulty, damaged or suspect, it must NOT BE USED.

- Products that show excessive fading of marked product code, UDI and lot, thus preventing clear identification and traceability, must NOT BE USED.
- Cutting instruments must be checked for sharpness.
- When instruments form part of an assembly, check assembly with matching components.
- Lubricate hinges and moving parts with an oil that does not interfere with steam sterilization as per manufacturer's instructions before sterilization. Do not use silicone based lubricant or mineral oil. Orthofix recommends the use of a highly purified white oil composed by paraffinum liquidum of food and pharmaceutical grade.

As a general preventive action Orthofix recommends following the instructions in the operative technique to avoid damages related to incorrect use. Specific instructions may be available for some product codes. These instructions are linked to the product code and are available on a dedicated Orthofix website. Moreover, it is important to follow the cleaning procedure suggested by Orthofix to avoid damages related to incorrect handling.

PACKAGING

In order to prevent contamination after sterilization Orthofix recommends using one of the following packaging systems:

a) Wrap in compliance with EN ISO 11607, suitable for steam sterilization, and appropriate to protect the instruments or trays contained from mechanical damage. Orthofix recommends the use of a double wrap constituted of tri laminate non woven fabrics made of spunbond polypropylene and melt blown polypropylene (SMS). The wrap shall be resistant enough to contain devices up to 10kg. In the USA, a FDA cleared sterilization wrap must be used and compliance with ANSI/AAMI ST79 is mandatory In Europe, a sterilization wrap in compliance with EN 868-2 may be used. Fold the wrap to create a sterile barrier system according to a process validated as per ISO 11607-2.

b) Rigid sterilization containers (such as Aesculap JK series rigid sterilization containers). In Europe, a container in compliance with EN 868-8 may be used. Do not include additional systems or instruments in the same sterilization container.

Every other sterile barrier packaging not validated by Orthofix must be validated by the individual healthcare facility according to instructions from the manufacturer. When equipment and processes differ from those validated by Orthofix the healthcare facility should verify that sterility can be achieved using parameters validated by Orthofix. Do not include additional systems or instruments in the sterilization tray. Note that sterility cannot be guaranteed if the sterilization tray is overloaded. The total weight of a wrapped instrument tray should not exceed 10kg.

STERILIZATION

Steam sterilization according to EN ISO 17665 and ANSI/AMMI ST79 is recommended.
Gas plasma, dry heat and EtO sterilization MUST BE avoided as they are not validated for Orthofix products.
Use a validated, properly maintained and calibrated steam sterilizer.
The steam quality must be appropriate for the process to be effective.
Do not exceed 140°C (284°F).
Do not stack trays during sterilization.
Sterilize by steam autoclaving, utilizing a fractioned pre-vacuum cycle or gravity cycle according to the table below:

Steam sterilizer type	**Gravity**	**Pre-vacuum**	**Pre-vacuum**	**Pre-vacuum**
Notes	Not for use in EU	-	Not for use in US	WHO guidelines
Minimum exposure Temperature	132° C (270° F)	132° C (270° F)	134° C (273° F)	134° C (273° F)
Minimum exposure Time	15 minutes	4 minutes	3 minutes	18 minutes
Drying Time	30 minutes	30 minutes	30 minutes	30 minutes
Number of pulses	N/A	4	4	4

Orthofix recommends always using a pre-vacuum cycle for steam sterilization. The Gravity cycle was validated for wraps only, and it is suggested only when no other options are available. The Gravity cycle was not validated for sterilization in rigid containers.

STORAGE

Store the sterilized instrument in the sterilization packaging in a dry and clean environment at room temperature.

DISCLAIMER

The instructions provided above have been validated by Orthofix srl as being a true description for (1) processing a single-use device and a multiple use device for its first clinical use and (2) processing a multiple use device for its re-use. It remains the responsibility of the reprocessing officer to ensure that the reprocessing, as actually performed using equipment, materials and personnel in the reprocessing facility, achieves the desired result. This normally requires validation and routine monitoring of the process. The cleaning, disinfection and sterilization processes must be adequately recorded. Any deviation by the reprocessing officer from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences, and must also be appropriately recorded.

CLEANING AGENT INFORMATION

Orthofix used the following cleaning agents during validation of these processing recommendations.
These cleaning agents are not listed in preference to other available cleaning agents that may perform satisfactorily:

- For manual precleaning: Neodisher Medizym concentration 2%
- For manual cleaning: Neodisher Mediclean concentration 2%
- For automated cleaning: Neodisher Mediclean concentration 0.5%

ADDITIONAL INFORMATION

INFORMATION FOR THE PATIENT

The HCP shall inform the patient that the medical device does not replicate a normal healthy bone and counsel him/her about the correct behavior after implantation. The patient must pay attention to premature weight bearing, load carrying and excessive activity levels. The HCP shall inform the patient about any known or possible restrictions regarding the exposure to reasonably foreseeable external influences or environmental condition and in undergoing specific diagnostic investigations, evaluation or therapeutic treatment after implantation. The HCP shall inform the patient about the need for periodic medical follow-up and of the eventual removal of the medical device in the future. The HCP shall warn the patient about the surgical and residual risks and make him/her aware of possible adverse events. A successful result is not achieved in every surgical case. Additional complications may develop at any time due to improper use, medical reasons or device failure that require surgical re-intervention to remove or replace the medical device. The HCP shall instruct the patient to report any unusual changes to the operative site or in device performance to his/her physician. When handing over the Fitbone Control Set to the patient, the HCP shall hand over also the paper copy of the "Fitbone Control Set Instructions for Use" and verbally instruct the patient on how to use the Fitbone Control Set correctly for the distraction procedures at home. Before leaving the healthcare facility after implantation of Fitbone intramedullary nail, the patient must be supplied with the Intramedullary Nail implant card and the Subcutaneous Energy Receiver implant card. Both implant cards are supplied together with the implants. Before handing each implant card over to the patient, one of the labels available on the implant sterile packaging must be attached in the appropriate area on the implant card and the patient information must be filled-in by the HCP, following the instructions provided in the leaflet PQIPC.

NOTICE ABOUT SERIOUS INCIDENTS

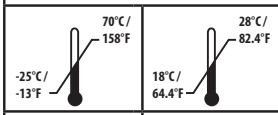
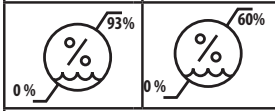
Report any serious incident involving a device to Orthofix Srl and the appropriate governing body in which the user and/or patient is established.

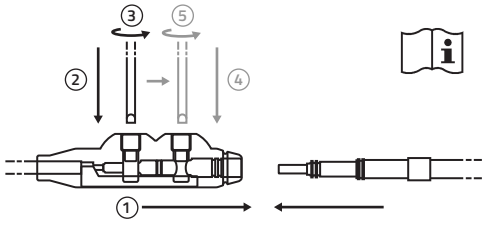
MANUFACTURER CONTACT

Please contact your local Orthofix sales representative for further details and ordering.

Symbols presented below may apply or not to a specific product: refer to its label for applicability. Please contact the manufacturer if the labels on the packaging are damaged or not legible.

Symbol	Description	
MD	Medical Device	
	Consult instructions for use or consult electronic Instructions for Use	CAUTION: Consult instructions for use for important cautionary information
	Single Use. Do not re-use	Orthofix note: discard appropriately after use (treatment) on patient
	Do not resterilize	
STERILE VH202	Sterilized using vaporized hydrogen peroxide	
	Non-sterile	
	Double sterile barrier system	
UDI	Unique Device Identifier	
REF LOT	Catalogue number	Batch code
	Use-by date (year-month-day)	
CE CE 0123	CE marking in conformity to applicable European Directives/Regulations	
	Date of manufacture	Manufacturer
	Do not use if package is damaged and consult instructions for use	
	The item is known to pose hazards in all MRI environments.	

Symbol	Description
SN	Serial number
Rx Only	CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician
	Electric voltage
	Follow instruction for use
	Non-ionizing electromagnetic radiation
	Disposal. In accordance with the WEEE 2012/19/UE Directive, the product and all its parts (cable, batteries, accessories, etc.) may not be treated as domestic waste. Please return the Fitbone Control Set to Orthofix after completion of the treatment.
	Patient name and surname
	Surgery date
	Doctor name and surname
	Patient information website
	Temperature limit
	Humidity limitation
For retraction only	For retraction only

Symbol	Description
	Please connect Intramedullary Lengthening Nail and Receiver via the bipolar plug connection. Please also note the instructions for connecting the connector and coupling in the Operative Technique.

ORTHOFIX Srl
Via Delle Nazioni 9 - 37012 Bussolengo (Verona) - Italy
Tel. 0039 (0) 45 6719000 - Fax 0039 (0) 45 6719380

PQFBT B 02/25 (0433563)