GEXFIX EXTERNAL FIXATION SYSTEM

Please read thoroughly before use

Class I devices (including ancillaries): CE Class IIb devices: CE 0459

English

INFORMATION FOR THE OPERATING SURGEON

INTENDED PURPOSE
The use of the variety of external fixation provides the surgeon with a means of bone fixation for the management of fractures and reconstructive surgery in different anatomical locations. External fixation devices are intended to hold bone surfaces in a position that aids and facilitates the normal healing process.

INTENDED PERFORMANCE
The Gexfix external fixation system is intended to provide fixation and stabilization of the bones to facilitate the natural healing in the frame of the surgical procedures listed in the INDICATIONS FOR USE section below.

DESCRIPTION
The invasive devices within the GEXFIX External Fixation System are manufactured from materials recognized and accepted for implantation into the body: either DIN 1.4441 stainless steel alloy compliant with ISO 5832-1 (ASTM F138) or DIN 3.7165 Grade 5 titanium alloy compliant with ISO 5832-3 (ASTM F1472).
The external elements and the ancillaries are Class I devices.
The invasive elements are Class IIb devices.

The devices are single use. However, when not yet used on a patient, they can be re-sterilized (see STERILIZATION below). Devices considered as used on a patient include components that have been attached to the patient, even if the components themselves have not been in direct contact with the patient.

Instruments and trays (ancillaries) are reusable.

The devices and ancillaries are non-sterile. They must be cleaned, disinfected and sterilized before use. Recommended procedures for cleaning, disinfection and sterilization are provided below.

INTENDED USER
Prior to performing surgery, the surgeon should be thoroughly familiar with the surgical procedure, in particular the instruments and devices characteristics as well as the mechanical and material aspects of the external fracture fixation.
The surgeon must be aware and the patient must be informed that these devices are intended only to assist healing, not to replace normal bone structures.

INDICATIONS FOR USE
1. Bone facture fixation
2. Osteotomy
3. Arthrodesis
4. Correction of deformity
5. Revision procedures where other treatments or devices have been unsuccessful
6. Bone reconstruction procedures

CONTRAINDICATIONS
GEXFIX SA relies on the experience and training of the surgeon to ensure that his choice and judgment with regard to the treatment and devices selected for each patient are the most appropriate to his/her medical condition.

It is important to note that the following conditions can result in an increased failure rate when using the devices:
1. Where there is an insufficient quantity of bone, or where the quality of such could prevent appropriate fixation of device.
2. In compromised vascular situations that inhibit adequate blood supply to the fracture or operative site.
3. Where there is previous history of infections.
4. Where there is any neuromuscular deficiency that could interfere with the patient's ability to limit load bearing.
5. Where there is any neuromuscular deficiency that could place and unusual heavy load on the device during the healing period.
6. In those situations where there is a malignancy in the fracture area.
7. Where mental, physical, addiction, or neurological conditions exists, which may impair the patient's ability to cooperate with the postoperative regimen.

WARNINGS
All devices and instruments should be thoroughly inspected before sterilization. Do not use apparently damaged devices and/or instruments, otherwise patient injury may result. Damaged devices and instruments should be forthwith replaced by new ones.
All devices and instruments must be cleaned and sterilized in accordance with these instructions before use, otherwise patient infection may result.
Do not use Gexfix devices in combination with devices from other manufacturers. Compatibility with other manufacturer's devices has not been tested, and is not guaranteed. Use with such devices may result in device failure or poor mechanical strength of the fixator construct and hence in an inefficient treatment or patient injury.
Do not persist in assembling and/or using a device and/or an instrument if it gets damaged during assembly and or use, otherwise this could lead to inadequate assembly and/or insufficient tightening of the fixator elements, resulting in a poor mechanical strength of the construct and hence inefficient treatment or patient injury.
The devices are designed and intended for single use only. Reuse of a device that has already been used on a patient may result in device reduced performance and/or failure and/or patient injury.
Re-use and/or re-sterilization may result the occurrence of ADVERSE EFFECTS as mentioned below, and therefore may put the patient's security at risk.

Refer to the MRI COMPATIBILITY section below for additional information regarding safety and compatibility in the MR environment.

When using these devices, the surgeon should take particular note of the following factors as they are extremely important to the eventual success of the surgical procedure being undertaken:

1 - Overweight or obesity, as well as a **patient's profession or activity** that might require the bearing of heavy loads, may produce excessive mechanical stress on the device, which, in some instances, may result in failure of the device.

2 - Where a patient suffers from **senility, mental illness, alcoholism and/or addiction**, the patient may ignore necessary limitations and precautions regarding the use of the device, which may lead to device failure or other complications.

3 - Where **sensitivity to a foreign body** (especially to the materials used in the invasive devices) is suspected, appropriate reaction screening tests should take place prior to device selection and implantation.

PREPARATION AND PRECAUTIONS
An external fixation cannot be expected to withstand activity levels to the same extent as a normal healthy bone. Indeed, the external fixation system will not have the same strength, reliability, and durability as a normal human bone and the longevity of the device will, to a certain extent, be dictated by load bearing and patient activity.
The assembly of the fixator must be undertaken by taking into account all the components. It is highly recommended that instruments provided by Gexfix SA be used to tighten the frame of the components, as compatibility with other manufacturer's equipment has not been tested and cannot be guaranteed. Use with such instruments may result in device failure or poor mechanical strength of the fixator construct and hence an inefficient treatment or patient injury.

Information for the patient:
It is important to ensure that the patient is properly instructed to immediately report any unusual changes of the operated site and/or any adverse or unanticipated effects to their physician. The surgeon should also ensure that the patient is monitored through a postoperative program in order to detect any change of the fracture site, thus evaluating the possibility or a subsequent clinical failure. Where necessary, the surgeon should also discuss with the patient the need of reducing activity levels, and/or revision surgery to help the fracture healing process.
The surgeon must explain to the patient all physical or psychological limitations inherent to the use of external fracture fixation appliances. In particular, the patient must be informed about premature load bearing, levels of activity, and the need for periodic medical follow-ups. Where necessary, the surgeon should inform the patient of the need to perform post-operative care of his surgical wound(s) and/or implant site(s). Where necessary, the surgeon should inform the patient to seek medical opinion before entering potentially adverse environments (such as MRI, extreme temperature, …) that can affect the performance of the implant.
The patient must be informed about the surgical risks resulting from the procedure as well as the potential adverse effects that may arise. It should be stressed to the patient that the device cannot and does not replicate a normal healthy bone and that, in certain situations, the device can break or become damaged as a result of strenuous activity or trauma.

POSTOPERATIVE CARE
The guidelines provided hereafter are to be understood as general considerations. Post-operative care remains under the responsibility of the medical professional.
1. Reduced and/or progressively increased activity and weight bearing, when appropriate, might be required and/or recommended according to practitioner's experience and desired treatment.
2. Pin and/or wire tract should be taken regular care of by cleaning and/or, where appropriate, disinfecting site with antiseptic. Persistent infection may necessitate systemic antibiotic treatment and/or wire or pin removal.
3. The fixation device integrity should be checked routinely for possible device bending, breakage, or loosening (including fixation of the pin in the bone).
4. Routine (every week or every other week) postoperative follow-ups and radiographs can be used for treatment monitoring. The frequency may be reduced during the final phase.
5. Subsequent to healing (which usually take place within 6 to 10 weeks, but remains under the evaluation of the practitioner), these devices do not serve any further functional purpose and should normally be removed (by simple reverse operation relative to implantation and assembly).
6. After fixation device removal, the pin and wire entry holes are usually dressed (with dressing replacement as required) until they close spontaneously.

Warning: explants and devices should be considered as contaminated after use, and disposed of with adequate precautions, with particular attention to the pins and wires sharp edges.

POSSIBLE ADVERSE EFFECTS
In certain instances, adverse results may be more related to the particular clinical situation or to way the devices are used than to related to the devices themselves, e.g.:
1. Certain situations, or clinical conditions (including some diabetes) and/or consequences of such (for example inhibited revascularization or poor bone formation) can result in an increase in loading and/or a delayed union or non-union of the fracture site. If this occurs, the appliance may eventually become loose, bend, crack, and/or finally break due to fatigue. There might also be a premature loss of fixation with the bone.
2. Improper alignment of the device can cause a mal-union and/or bending or failure of the device.
3. Early or late infection, either deep or superficial.
4. Deep venous trombosis.
5. Vascular necrosis.
6. Shortening of the affected bone/fracture site.
7. In some situations, subclinical nerve damage may occur as a result of the surgical trauma.
8. Refracture.
9. Osteoarthritis.
10. Compartment syndrome.
11. Invasive element migration.
12. Pain (including complex regional pain syndrome - CRPS)
13. Tissue (muscle), artery, or vein damage (with possible consequences such as woulnd healing issues, dehiscence).
14. Joint stiffness (related to immobilization).
15. Skin invagination

In case of loosening of the external frame or failure of any of the elements of the fixator (invasive or external), the patient should consult the treating surgeon for evaluation of possible mis-alignments and re-tighten or rebuild the frame.
In case of infection of the pin tracts, the patient must consult the treating surgeon prescription of the right antiseptic treatment.
In case of external elements and/or ancillary jamming, do not persist assembling or using such elements and replace with new ones.
In case of failure of an implant or ancillary inside the patient's body, the fragments may be located using X-Ray imaging.

Serious incidents related to the use of the devices should be reported to Gexfix and to the competent authority of your country.

CLEANING & DISINFECTION
The GEXFIX External Fixation devices and ancillaries are supplied visually clean. Before sterilization and use, already visually clean devices and ancillaries must be disinfected by thorough aspersion of a mixture of 70% medical grade alcohol and 30% distilled water (or water for injection), using a minimum of 10 ml of solution at

room temperature. After disinfection, the components must be well rinsed using a minimum of 20 ml of distilled water (or water for injection) at room temperature, and dried with a lint-free cloth until visually dry.
Individual devices can be disinfected in assembled form.

If the devices or ancillaries are not visually clean and/or suspected to be potentially soiled, please follow the cleaning instructions provided hereafter before performing the abovementioned disinfection:

Manual cleaning

1. Dismantle the dismantable ancillaries (take the trocar out of the trocar sleeve, and, where applicable unscrew the trocar sleeve from the handle).
2. Rinse the devices and dismantled ancillaries under warm (not hot, i.e. below 44°C) tap water to remove gross debris, and let them drain.
3. Immerse the devices and dismantled ancillaries in a sink or basin filled with warm (not hot, i.e. below 44°C) water or water containing enzymatic detergent and/or tensioactive agents ($7 \leq pH \leq 9$, and compatible with aluminum and stainless steel) to prevent drying of blood and to soften or remove blood from the devices and instruments. If necessary (when contamination is initially dry), let the devices and dismantled ancillaries rest in the sink or basin to allow for contamination rehydration (presoaking).
4. While immersed in the basin, scrub the soiled area of the devices and dismantled ancillaries with a clean brush until visually clean (the short trocar sleeve lumen can be checked if brilliant inside by looking at a light source through it).
5. Rinse with abundant distilled or de-ionized water (make sure to flush the trocar sleeve lumen).
6. Dry with a single-use non-fluffy fabric until visually dry.
7. Reassemble the ancillaries.

Automatic cleaning (multi-tank ultrasonic washer)

If the devices or ancillaries are heavily soiled, perform the manual cleaning up to step 5 then follow the procedure below starting from step 3.

1. Dismantle the dismantable ancillaries (take the trocar out of the trocar sleeve, and, where applicable unscrew the trocar sleeve from the handle).
2. Rinse the devices and dismantled ancillaries under warm (not hot, i.e. below 44°C) tap water to remove gross debris, and let them drain.
3. Wash the devices and dismantled ancillaries in the ultrasonic cleaning tank of the washer containing enzymatic detergent and/or tensioactive agents ($7 \leq pH \leq 9$, and compatible with aluminum and stainless steel) at 50°C ± 8°C for at least 3 minutes.
4. Rinse the devices and dismantled ancillaries in the first ultrasonic rinse tank of the washer in cold distilled or de-ionized water for at least 4 minutes.
5. Rinse the devices and dismantled ancillaries in the second (non-ultrasonic) rinse tank in cold distilled or de-ionized water for at least 4 minutes.
6. Dry the devices and dismantled ancillaries in the hot air tank of the washer for at least 45 minutes.
7. Verify that the devices and all parts of the dismantled ancillaries are visually clean (the short trocar sleeve lumen can be checked if brilliant inside by looking at a light source through it).
8. Reassemble the ancillaries.

If visually clean elements can not be obtained with these procedures repeat the whole procedure until visually clean. If repetition is unable to attain visually clean elements, discard elements according to procedures appropriate for potentially contaminated elements including potentially sharp edges, and use new ones.

STERILIZATION

All devices and ancillaries must be cleaned (see CLEANING & DISINFECTION section above) and thoroughly inspected before any sterilization. This includes any devices that are being re-sterilized as they have not yet been used on a patient.
Any damaged device or ancillary must be replaced with a new one.
The sterilization machine used, its installation, routine monitoring, calibration, and maintenance, as well as the related management and operation procedures (including for maintaining the process effectiveness and requalification requirements) shall comply with the relative clauses of the latest revision of the ISO 17665 standard.
The sterile barrier system realized prior sterlization must comply with the requirements of the latests revision of the ISO 11607 standard. The integrity of the sterile barrier system realized for sterilization must be inspected prior and after sterilization, including verification of absence of visible residual moisture. The sterilization process (as recommended below) shall not expose the product and its sterile barrier system beyond the limiting process, cycle parameter or contaminants.
The level of contamination of the steam used shall be controlled to avoid the steam to contaminated the devices being sterilized.
The following sterilization cycle has been validated for a Sterility Assurance Level (SAL) of 10^{-6}:

Method	Cycle type	Temperature(s)	Exposition time
Steam	Pre-vacuum $\Delta \geq 78$ kPa, for ≥ 1 minute	132 - 135 °C (270 - 275 °F)	Minimum 10 min.

Note: Individual devices can be sterilized in assembled form in the trays provided by GEXFIX SA. Unused devices can be re-sterilized up to 13 times.

MRI COMPATIBILITY

MRI unsafe: these devices have not been evaluated for safety and compatibility in the MR environment. Some parts can be made of, or may contain metals and may pose unacceptable risks to patients, medical staff or other persons in the MR environment, as well as to create image distortions and damage to the MR equipment.

EXPLANATION OF SYMBOLS

	Manufacturer. When used with a date nearby: manufactured in *date*		Caution: there are specific warnings or precautions associated with the device, which are not otherwise found on the package label. Synonym: "Attention, see instructions for use"
	Do not reuse. Synonyms are "Single use", or "Use only once	LOT	Lot number.
NON STERILE	Non-sterile	REF	Catalogue number
MR	MR unsafe. (Potentially: not evaluated)	SWISS MADE	Swiss made

UDI	Unique Device Identifier	MD	Medical Device
EC REP	Authorized representative in the European Community / European Union		Date of first product on the market in the EU: Aug. 2004 (lot: AS 00269)

The Summary of Safety and Clinical Performance can be found at the following internet address:
http://www.gexfix.ch/sites/default/files/documentation/fichier/sscp.pdf

GEXFIX S.A.
Ch. du Pavillon 2, 1218 Le Grand-Saconnex, Switzerland
Tel.: +41 22 308 16 70 Fax: +41 22 308 16 79 www.gexfix.ch

EC REP
Assut Europe S.P.A
Via Giuseppe Gregoraci 12
00173 Roma, ITALY

6010-2000 Rev. L - 2025-04