Device System Name
Konzept Fibula and Forearm Nailing System

Device Description
The AUXEIN MEDICAL'S Konzept Fibula and Forearm Nailing System consists of a variety of shapes and sizes of Nails, End Caps and Screws which can be rigidly locked into a variety configurations, with each construct being tailor-made for the individual case. The Konzept Fibula and Forearm Nailing System consists of Konzept Fibula and Forearm Nail, Konzept Fibula and Forearm Nail with compression which are used in part of the Fibula & Forearm Bone. Care should be taken so that the correct components are used in the Fibula and Forearm construct. Products included in the Fibula and Forearm Nailing System are following:

Konzept Fibula and Forearm Nailing system consist of:
- Konzept Fibula and Forearm Nail
- Konzept Fibula and Forearm Nail with compression
- End Cap, M4
- Compression End Cap, M4
- Cortical Screw, Self-Tapping (Hex Head)
- 2.7mm Cortical Screw, Self-Tapping (Hex Head)

To achieve best results, do not use any of the Konzept Fibula and Forearm Nailing System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another AUXEIN MEDICAL document. As with all orthopedic and implants, none of the Konzept Fibula and Forearm Nailing System components should ever be reused under any circumstances. Reuse may lead to infection and cross infection.

Purpose
The Konzept Fibula and Forearm Nailing System is intended to help provide Fibula and Forearm Nails to be treated for the fracture of Fibula and Forearm Bone.

Material
The Konzept Fibula and Forearm Nailing System is made from Titanium Alloy Ti-6Al-4V as per ISO 5832-3. This material is not compatible with other metal alloys. AUXEIN MEDICAL expressly warrants that these devices are fabricated from one of the preceding material specifications. No other warranties, expressed or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

Indications
Transverse, oblique and multifragmentary fractures of the shaft of ulna (2U2C, 2U2A2, 2U2A3), radius (2R2C, 2R2A2, 2R2A3) and fibula (4F2A & 4F2B), fractures of fibula in ankle joint area.

Contraindications
Contraindications maybe relative or absolute. The choice of particular device must be carefully weighed against Patient's overall condition. The conditions listed below may preclude or reduce the chance of a successful outcome:
The implant should not be used in a patient who has currently, or who has a history of:

- Local or Systemic acute or chronic inflammation.
- Local Active infection or inflammation.
- Suspected or documented metal allergy or intolerance.
- Symptomatic Arthritis.

Warning & Precaution

See package insert for warnings, precautions, adverse effects, information for patients and other essential product information.

Serious Post-operative complications may occur from the use of implant in a patient who-

- Lacks good general physical condition
- Has severe osteoporosis
- Demonstrates anatomical or physiological anomalies.
- The patient should be informed that the life expectancy of the device is unpredictable and once implanted, successful results cannot be guaranteed if adequate care and precautions are not taken.
- The reuse of implants after re-sterilization may not result in the same responses.
- The AUXEIN MEDICAL Fibula and Forearm Nails is not intended to support the body weight of the patient as it is too heavy.
- While rare, intraoperative fracture or breakage of the instrument can occur. Instruments which have been subjected to prolonged use or excessive force are more susceptible to fractures, depending on care taken during surgery, number of procedures performed and attention paid. Instruments should be examined for wear or damage before surgery.
- While inserting the screw, it is essential to set the screwdriver with the screw correctly. Following the instructions given allows for reduction of the risk of mechanical damage to the screw, screwdriver, or bony hole:
    - screw driver should be set in the screw axis.
    - apply proper axial pressure to ensure that the screwdriver goes as deep in the head of the bone screw as possible.
    - The final phase of tightening shall be performed carefully.
- Vascular disorders, including thrombophlebitis, pulmonary embolism, wound hematoma, avascular necrosis
- Delayed consolidation or nonunion that can lead to implant rupture
- Has immunological response, sensitization or hypersensitivity for foreign materials.
- Do Not Re-Use. Do not re-process. The device is not designed for re-processing. Reuse of the medical device intended for single use devices may lead to infection, degraded performance or a loss of functionality. The cleaning and disinfection / sterilization for re-processing of these single use devices has not been validated nor is any authentic information available. So re-process of the single-use device is not allowed.
- For Qualified surgeon use only.
- The important medical information given in this document should be conveyed to the patient.
- The selection of the proper shape and size of the implant appropriate for a specific patient is crucial to achieving success of the surgery. The surgeon handles this choice.

- Patients who are overweight, malnourished and/or abusing alcohol or drugs, with weak muscles and low quality bones and/or with nerve palsy are not the best candidates for the procedure of surgical stabilization. These patients are not able or not ready to observe the post-operative recommendations and limitations.
- The surgeon must warn the patient that the device cannot and does not restore the function and efficiency of a healthy bone.
- In the case of delayed union or non-union, the load or weight bearing may eventually cause the implant bending, loosening, disassembling or fatigue breakage.
- Implants should be stored in appropriate protective packages, in a clean, dry place with a moderate temperature and under conditions that provide protection from direct sunlight.

Precaution:

- Avoid notching, scratching, or striking the device.
- In the case of Nail contouring, poorly contoured Nails can lead to fracture displacement when the screws are fully tightened through the Nail. Avoid contouring of the implant in situ that may lead to implant malposition.
- Avoid sharp bends, repetitive and reverse bending as it increases the risk of implant breakage. Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin.
- Every implant must be discarded after use and should never be reused. Reuse may lead to infection and cross infection. It should be bent & then disposed of properly so that it becomes unfit for reuse.
- After healing occurs, these devices serve no functional purpose and therefore should be removed.
- Patients should be informed about the possible complications from not removing the device (corrosion with localized tissue reaction or pain, migration resulting in injury to soft tissue, visceral organs, or joints, risk of additional injury from postoperative trauma, breakage which could make removal impractical or difficult, pain, discomfort, or abnormal sensations which may occur due to the presence of the device, possible increased risk of infection, and bone loss due to stress shielding).
- Any decision to remove the device should consider the potential risk to the patient of a second surgical procedure and should be followed by adequate postoperative management to avoid re-fracture.
- Do not mix dissimilar metals and alloys that can accelerate corrosion and enhance fracture of implants. It is important that mechanical fit and metallurgical compatibility be considered in selecting mating implants.
- The patient should be informed that the life expectancy of the device is unpredictable and once implanted, successful results cannot be guaranteed if adequate care and precautions are not taken.
- If adverse effects happen, it may necessitate re-operation, revision or removal surgery.

Note: It is the responsibility of the surgeon to discuss, with the patient, the precautions, possible risks, warnings, consequences, complications and adverse reactions which may occur as a result of the surgical procedure and implantation of the device(s).

The patient should be informed that the life expectancy of the device is unpredictable and once implanted, successful results cannot be guaranteed if adequate care and precautions are not taken.

If adverse effects happen, it may necessitate re-operation, revision or removal surgery, arthrodesis or the involved joint and/or amputation of the limb.

Intended Patient Group

Only patients that meet the criteria described in the indications should be selected. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.

Surgeon Note

Although the surgeon is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.

Caution

To be used by Qualified and Trained Surgeons Only.

MRI Compatibility

The AUXEIN MEDICAL Konzept Fibula and Forearm Nails have not been evaluated for safety and compatibility in the MR environment. The AUXEIN MEDICAL Implants have not been tested for heating or migration in the MR environment. Patients should seek the opinion of medical experts before entering the MRI (Magnetic Resonance Imaging) environment.

Potential Adverse Events

All of the possible adverse events associated with Fibula and Forearm nail implantation without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:

- The adverse effects may necessitate re operation or revision. The surgeon should warn the patient about the possibility of adverse effects occurrence.
- The undermentioned list does not exhaust the topic of adverse events. There is a risk of occurrence of adverse events with unknown aetiology which may be caused by many unpredictable factors.
- Potential adverse events include but are not limited to:
    - Implant damage (fracture, deformation or detachment).
    - Early or late loosening, or displacement of the implant from the initial place of insertion.
    - Possibility of corrosion as a result of contact with other materials.

- Body reaction to implants as foreign bodies e.g. possibility of tumour metaplasia, autoimmune disease and/or scarring.
- Compression on the surrounding tissue or organs.
- Infection.
- Bone fractures or “stress shielding” phenomenon causing loss of bone above, below or at the operative site.

- Haemorrhage of blood vessels and /or hematomas.
- Pain.
- Metal sensitivity
- Inability to perform everyday activities.
- Mental condition changes.
- Death.
- Deep vein thrombosis, thrombophlebitis.

Note:

Additional surgery maybe necessary to correct some of these anticipated adverse events.

Other preoperative, intraoperative, and postoperative warnings are as follows

A successful result is not always achieved in every surgical case. This fact is especially true in Fibula and Forearm Nail surgery, where many extenuating circumstances may compromise the results.

Preoperative:

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure.

- It is essential to follow all of the physician's postoperative directions and warnings.
- It is essential to confirm the proper position of the implant by roentgenographic examination.
- In the postoperative period, in treatment, the correctness of implant positioning and immobilization of union should be confirmed by roentgenographic examination.
- Only patients that meet the criteria described in the indications should be selected. This system is intended to be used in skeletally mature patients.
- Before surgery, the surgeon must plan the operation to correct selection and sizing of the implant components and their positioning in the bone. The surgeon needs to ensure that: Instruments have been properly disassembled before cleaning and sterilization; Instruments have been properly assembled post-sterilization; Instruments have maintained design integrity; and, Proper size configurations are available.
- The implant bed is prepared using the appropriate Auxein Medical’s instruments for the specific replacement procedure being performed
- All informational material concerning the range of implants, instrumentation and surgical technique has been reviewed and is available and the surgeon and the surgical team are familiar with this information.
- The rules of medical skill, the state of the art, and the contents of scholarly publications by medical authors are known and observed.
- Re-use of any implant is prohibited as it includes risk of infection/disease.

Intra-operative:

- AUXEIN MEDICAL Konzept Fibula and Forearm Nailing System nails is available in various sizes to suit the patient’s fibula and forearm anatomy. Details of the implant size are explicitly marked on the packaging and/or on the implants themselves. In addition, the related product literature carries detailed information related to the selection of particular sizes.

- The correct use of these components should be clearly described in the relevant product literature corresponding with the Konzept Fibula and Forearm Nailing System being implanted.

Post-operative

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are crucial.

- Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required before firm bony union, the patient must be warned that bending, loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices.
- The surgeon must instruct the patient regarding appropriate and restricted activities during consolidation and maturation of the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and further clinical problems. The implant may break or become damaged as a result of strenuous activity or trauma, and may need to be replaced in the future.
- Failure to perform appropriate immobilization of bone when delayed or non-union occurs may lead to excessive fatigue stresses in the implant. Fatigue stresses may be a potential cause of implant becoming bent, loosened or fractured. If non-union of fracture or implant bending, loosening or fracture occurs, the patient should be immediately revised, and the implants should be removed before any serious injuries occur. The patient must be appropriately warned about these risks and closely monitored to ensure compliance during the treatment until the bone union is confirmed.
- The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone healing process. If a non-union develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s).
- The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed. The patient must be made to understand that artificial joint replacement implants are always inferior to the function of the natural joint, and only a relative improvement of the preoperative condition can be achieved. The patient must be explained that an artificial joint can loosen due to overloading, wear and tear, or infection. Implant loosening can necessitate a revision operation that, under some circumstances, offers no opportunity to restore joint function again.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the Fibula and Forearm Nails should ever be reused under any circumstances. Reuse may lead to infection & cross infection.

- Orthopedic surgeries do not generally involve major risks and complications. Orthopedic Surgeons are properly trained to avoid potential difficulties which might occur during an intervention, as well as to efficiently correct such problems if they appear. However, some of the risks and complications which may accompany an orthopedic surgical procedure are:

    - Postoperative infections: In order to avoid this complication, patients will be administered antibiotics before, during and after the surgery. If a patient has an ongoing infection (throat, urinary, dental etc.), it is highly recommended to treat it prior to the intervention, as it can reach your joint and a late infection could develop months or even years following orthopedic surgery.
    - Bleeding
    - Blood clots: They may occasionally appear after orthopedic surgery. Blood clots can be avoided with appropriate medication and physical exercise.
    - Blood vessel damage: This complication may appear if blood vessels located in proximity of the implant are affected during the procedure.
    - Allergic reactions: The patient might experience an allergic reaction to the metal components or cement used to fix the implant (titanium, stainless steel etc.)

Packaging

Packages for each of the components should be intact upon receipt. If a consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage before use. Damaged packages or products should not be used, and should be returned to AUXEIN MEDICAL PVT LTD.

Note:

Implants are supplied Sterile, no cleaning & decontamination is required for implants.

Decontamination By Steam Sterilization Method

In the case of implants, users don't require to do any of sterilization as the manufacturer has already provided the sterile implant.

All instruments that have been taken into a surgical field must first be sterilized by using steam autoclave process and reintroduction into a sterile surgical field.

The following method has been validated and recommended by the company*:*

Method:	Steam Sterilization (Autoclaving)
Temperature	Minimum 121 Degree Centigrade
Exposure Time:	20 Minutes
Pressure	15 Psi
Cycle Type	Vacuum Type

Note: FDA Approved wrap shall be used for steam sterilization.

Sterilization

AUXEIN MEDICAL'S Konzept Fibula and Forearm Nailing System is supplied Sterile. A sterility assurance level SAL 10^{-6} was achieved using gamma irradiation sterilization with minimum dose of 25kGy. Check the integrity of the packaging and labeling before opening the pack.

Storage

Store the implants at a dry place. Care should be taken in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments. The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.

Product Complaints

Customers or users of products, who have any complaints or who have experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the Manufacturer, AUXEIN MEDICAL or EU Representative. Further, if any of the implanted Fibula and Forearm Nails ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the Manufacturer or EU Representative should be notified immediately.

If any AUXEIN MEDICAL's product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

Further Information

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact your representative or distributor or contact the manufacturers directly.

Details of various Symbols used in Labeling

Symbol	Symbol Title	Description	Standard Title	Reference Number
	Date of Manufacture	Indicates the date when the medical device was manufactured.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.3
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 93/42/EEC.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.1.1

	Authorized representative in the European community	Indicates the Authorized Representative in the European Community.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.1.2
	Reorder Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.1.6
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.5
	Do Not Reuse	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.4.2
	Keep Dry	Indicates a medical device that needs to be protected from moisture.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.3.4
	Keep away from the sunlight	Indicates a medical device that needs protection from light sources	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.3.2
	Consult instructions for use	Consult instructions for use	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.2.3
	Do not use if package is damaged.	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.2.8

	Do not re-sterilize	Indicates a medical device that has not been subjected to a sterilization process.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.2.7
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.2.4
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.3.7
	Quantity	Indicates quantity of medical devices contained within the packaging.	N/A	N/A
	Material	Indicates the Material from which medical device is manufactured.	N/A	N/A
	Use by date	Indicates the date after which the medical device is not to be used.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.1.4
	Prescription only	The symbol for Prescription Device Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	N/A	N/A

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Revision Table

S. No.	Description of Change	Document No.	Status	Rev. No.	Effective Date	Prepared By	Approved By
1.	Instruction for use for Fibula and Forearm system	AMPL-IFU-KFFN/S-01	Initial Release	00	15-10-2022		