Device Description

The GIRO™ Growth Modulation System is a tether device used for guided growth and deformity correction. It is indicated for pediatric patients to aid in the correction of angular deformities of long bones and limb length discrepancy.

The implants are manufactured in medical grade stainless steel. The GIRO (coupling assembly) is offered in sizes ranging from 16 to 40 mm. Screws are offered in 4.5 mm and 6.0 mm diameters with lengths ranging from 20 to 35 mm. The Posts are offered in 4.5 mm and 6.0 mm diameter with assembly lengths ranging from 30 to 90 mm.

Intended Use

The GIRO™ Growth Modulation System is intended as a temporary implant to aid in the correction of the angle of growth of long bones by modulating growth of the physis in pediatric (child and adolescent) patients. It is indicated for the following conditions:

GIRO Screw configuration:

- Femur and tibia: varus, valgus, flexion, or extension deformities of the knee.
- Humerus: valgus or varus deformities of the elbow.
- Radius and ulna: flexion or extension deformities of the wrist.
- Ankle: varus, valgus or plantar flexion deformities of the ankle.

GIRO Post configuration:

- Limb length discrepancy of the femur and tibia.

This product is marketed for the specific indications described in the labeling. The use of this product for other than its intended purpose(s) is either contraindicated (see CONTRAINDICATIONS) or is without evidence to support the safety and effectiveness of such use. For the information of individuals and institutions contemplating the use of this product for other than labeled indication (i.e., off-label use), such use may be experimental and may be the subject of restrictions under applicable laws and regulations.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Contraindications

Do not use in any situation that is not described in the INDICATIONS section of this insert.

Devices should not be used:

- In patients without adequate tissues coverage at the implant site.
- In patients with a known metal sensitivity or intolerance.
- In a location where physical contact is possible between the GIRO, Posts, and Screws of this system and any implant made of different or incompatible metals.
- In anatomical location in which the device would interfere with other critical structures such as nerves, blood vessels, or other vital structures.
- In presence of documented infection, suspected latent infection, or marked local inflammation in and about the affected area.
- In presence of compromised vascularity inhibiting adequate blood supply to the operative site.
- In presence of severe muscular, neural, or vascular diseases.
- In the presence of severe osteopenia and/or osteoporosis, insufficient quality or quantity of bone/soft tissue, or in the presence of marked or rapid bone absorption, metabolic bone disease, sepsis, cancer, or any other tumor-like condition of the bone which may compromise fixation.
- In any medical or surgical situation that would preclude the benefit of surgery such as undiagnosed infection, end stage malignant disease, or other unexplained diseases.
- In patients with age-related, insufficient remaining growth of epiphyseal growth plates.
- In patients with closed epiphyseal growth plates due to skeletal maturity, trauma, or infection.
- In patients with a physiologic genu varum or valgum.

Surgeons should warn patients about these contraindications and limitations when appropriate.

Adverse Effects

The risks associated with this device are the same as with any metallic internal fixation device. These include, but are not limited to the following:

- Pain, discomfort or abnormal sensations due to the presence of the device.
- Irritation or inflammation of surrounding soft tissue or skin over implant is coverage is insufficient.
- Infection, both deep and superficial
- Metal sensibility and/or allergic reaction to a foreign body.
- Nerve damage resulting in temporary or permanent loss of neurological function.
- Possible neurovascular injury.
- Possible blood circulation or vessel damage, or necrosis of bone.
- Cessation of growth of the operated portion of bone.
- Bony formation around implant making removal difficult or impossible.
- Corrosion of implants.
- Additional injuries can occur as a result of postoperative trauma.
- Device bending, breakage, loosening, and/or migration as a result of improper insertion during implantation or as a result of the device not being removed at the appropriate follow up time.
- Overcorrection or under-correction of the angular deformity if the device is not removed at the appropriate time.
- Overcorrection or under-correction of the limb length discrepancy if the device is not removed at the appropriate time.
- Induction of unintended secondary deformity due to improper insertion of device during implantation.
- Postoperative bone fracture if implant size chosen is too big in relation to bone size.
- Unrecognized joint penetration.
- Inadequate healing.
- It may be necessary to perform additional surgery in order to correct adverse effects or reactions which may not be related to the actual system.

These adverse effects include adverse effects that are important considerations for metallic internal fixation devices. These risks and general surgical risks should be explained to the patient prior to surgery.

Warnings

- Pega Medical advises against the use of another manufacturer's component with any Pega Medical component. Any such use will negate the responsibility of Pega Medical for the performance of the resulting mix.
- Implants are single use items. Please note that single use devices (SUD) which come into contact with human blood or tissue should not be re-used and should be returned to the manufacturer or disposed of properly.
- Metal implants should never be re-implanted. Although appearing undamaged, the device may have small defects or internal stresses which may eventually lead to implant failure.
- Correct implant handling is extremely important in order to avoid notching or scratching of the surface of the device. It is also recommended that excessive contouring and bending of an implant be avoided. Contouring or bending of the device may reduce its fatigue strength causing failure under load. Discard all damaged or mishandled implants or return to manufacturer for proper disposal.
- Continuous screening with an image intensifier (fluoroscopy) during guide wire insertion and whenever cannulated instruments are advanced over a guide wire is recommended to prevent unintended guide wire advancement and penetration into the surrounding tissues.
- Failure to use largest possible components or improper positioning/ insertion of the device during implantation can increase the possibility of migration, loosening, bending, cracking, or fracture of the device or bone, or both.
- Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure.
- Improper insertion of the device during implantation can increase the possibility of breaking, loosening, or migration.
- Care should be taken not to cut through surgical gloves when handling any sharp-edged implants and instruments, and to take into account the risk of infection if a cut appears.

MRI Safety Information

The GIRO System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the GIRO System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Surgical Technique

Pre-operative procedures, knowledge of applicable surgical techniques, proper patient selection and correct placement of the implants are all equally important for the successful use of GIRO System. The surgical planning should involve measurement of the amount of correction needed, estimation of the remaining growth in the physis to be guided, and consider the rebound phenomena during surgery scheduling. The Surgical Technique manual details every step and should be carefully followed.

- Precise placement of the GIRO System to treat angular deformities is achieved by means of device-specific instrumentation that allows positioning of the screws above and below the growth plate. With the insertion points defined, predrilling of the screw holes can be done under image intensifier over Guide Wires with the appropriate Cannulated Drill. The Screws are then driven into the selected GIRO (coupling assembly).
- Precise placement of the GIRO System to treat limb length discrepancy is achieved by means of device-specific instrumentation that allows the perpendicular positioning of the Posts in relation to the growth plate. Once the insertion points are defined, the predrilling of the Post holes can be done under image intensifier over Guide Wires with the appropriate Cannulated Drills. The largest Posts in relation to the patient anatomy are then driven into the selected GIRO such that the Male Post is inserted into the Female Post.
- Avoid any damage of the periosteum during insertion and removal of the device. A physeal bar could be formed and generate further angular deformity or limb length discrepancy.
- It is recommended to perform a follow-up of patients every two months during the implantation period and an annual follow-up after removal until maturity to ensure maintenance of correction.
- The Male-Female Post overlap is intended to be sufficient for the entire growth potential during the implantation period. The engagement of the Posts should be monitored in order to reduce the risk of losing the engagement between both posts. If there is a need to increase the engagement between the Male and the Female Posts, the Female Post is to be replaced with a longer one, selected based on the total cortex-cortex distance of the bone. Refer to the Surgical Technique manual for Male and Female Post compatibility.
- Planned overcorrection might be necessary, especially in young patients, to compensate rebound deformity after removal.

Device Lifetime and Retrieval

Once the targeted deformation has been corrected, or over-corrected to account for rebounding after removal of the device, routine removal of internal fixation devices may reduce the occurrence of symptomatic complications of implant breakage, implant loosening and implant related pain.

It is recommended to follow-up with patients every two months during the implantation period, and annually after removal until bone maturity is reached. The final decision to recover the implant falls to the surgeon. It is based on careful follow-up of the patient's overall condition and the bone's healing. If removal is favorable, Pega Medical recommends the retrieval of implants to avoid bone reduction and weakening, particularly in young and active patients.

Although the final decision to retrieve the implants falls on the surgeon, a maximum Device Lifetime of 5 years for the implant has been defined to ensure material stability. The Surgical Technique manual details retrieval steps and should be carefully followed.

Cleaning and Re-Sterilization for Implant Components

All implants and instruments are provided NON-STERILE when shipped by Pega Medical.

All non-sterile components must be cleaned and sterilized before use. Implants are single use items; instruments may be reused after cleaning and sterilization. The instructions below should be followed for cleaning and sterilizing all devices supplied non-sterile. All metallic implants and instruments can be steam sterilized following the instructions and parameters listed below:

Note: For USA only: Sterilization wraps, pouches, indicators and sterilization trays should be FDA-cleared for the sterilization cycle parameters.

- Implants should be sterilized individually wrapped in two layers of polypropylene wrap using simultaneous envelope folding techniques
- Instruments should be sterilized wrapped in two layer of 1-ply polypropylene wrap using wrapping techniques.
- Devices should be dry before packaged for sterilization

Method	Steam
Sterilization type	Pre-vacuum
Minimal Temperature	270°F (132°C)
Minimal cycle time	4 minutes
Minimal drying time	60 minutes

Warning: Do not stack trays during sterilization.

Other sterilization methods and cycles may also be suitable. However, validation of any alternative method using appropriate laboratory techniques is advised.

Cleaning, Sterilization and Re-sterilization Instructions for Instruments

Please refer to document entitled: "Guidance for Instrument Care" for further information and instructions regarding cleaning, sterilization and re-sterilization of instruments.

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	Manufacturer	℞ ONLY	Caution: law prohibits dispensing without prescription
	See instruction for use	REF	Catalogue number
	Do not reuse	MD	Medical device
NON STERILE	Non sterile / No estéril / Non stérile	EC REP	Authorized representative
LOT	Batch number		Double sterile barrier system
	Do not use if damaged		

GIRO™

THE GIRO™

GROWTH MODULATION SYSTEM

Pega Medical™

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