Device Description

The Hinge Pediatric Plating System is an articulated plate used for guided hard tissue growth and deformity correction. It includes one plate and two screws. By fixing the plate by means of the screws at each side of the physeal plate, axial growth can be controlled and angular deformity corrected.
Plates and screws are manufactured in Medical grade Stainless Steel (316L as per ASTM F138).
The plate is provided in three different sizes with distances between the anchoring points of the screws of 12mm, 16mm and 20mm. The 4.5 mm diameter screws are provided in different lengths, 25mm, 30mm and 35mm.

Intended Use/Purpose

This implant system is indicated as a temporary implant to aid in the correction of the angle of growth of long bones by inhibiting longitudinal growth of the physis in pediatric patients.

Indications For Use

The system is indicated in the following locations and conditions:
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.

Intended Users

Note: The device is intended for professional use only

The intended users of the Hinge Pediatric Plating System are orthopedic surgeons.

Contraindications

Do not use in any situation that is not described in the Intended Use section of this insert.
Devices should not be used in patients with:

- Active or suspected latent infection or marked local inflammation in or about the affected area.
- 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, cancer, or any other tumor-like condition of the bone which may compromise fixation.
- Compromised vascularity inhibiting adequate blood supply to the operative site.
- Material sensitivity documented or suspected.
- Sepsis.
- Physeal bar – unresectable.
- Age-related, insufficient remaining growth of epiphyseal growth plates.
- Physiologic genu varum/valgum.
- Closed epiphyseal growth plates due to skeletal maturity, trauma, or infection.
- Patients with abnormal neurological or mental conditions that compromise their ability to follow a post-operative regimen.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

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

Disclosure of Residual Risks

While complications and adverse effects vary depending on the type of orthopedic surgery and while mitigations are implemented to reduce these risks as far as possible, some residual risks, associated with this system, can arise during and following surgery. These residual risks 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. The residual risks are listed in the sections below for Adverse Effects and Warnings.

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, stiffness or abnormal sensations due to the presence of the device.
- Postoperative bone fracture and pain.
- Unrecognized joint penetration.
- Metal sensibility and/or allergic reaction to a foreign body.
- Infection, both deep and superficial.
- Nerve damage due to the surgical trauma.
- Possible neurovascular injury.
- Inadequate healing.
- Irritation or inflammation of surrounding soft tissue or skin over implant if coverage is insufficient.
- Bony formation around implant making removal difficult or impossible.
- Necrosis of bone.
- Device breakage or damage due to increased loading associated with the treatment if the device is not 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.
- Possibility of loosening or migration of the implant due to improper insertion of the device during implantation.
- Bending, fracture or migration of the implant.
- 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.
- Corrosion of implants.
- Haematoma.

Warnings

- Device breakage or damage can occur when implant is subjected to increased loading associated with delayed union, non-union, or incomplete healing. Proper consolidation should be observed prior to full weight bearing.
- Contouring or bending of the device may reduce its fatigue strength causing failure under load.
- OrthoPediatrics Canada advises against the use of another manufacturer's component with any OrthoPediatrics Canada component. Any such use will negate the responsibility of OrthoPediatrics Canada for the performance of the resulting mix.
- Implants are single use items. Please note that Single Use Devices (SUDs) that come into contact with human blood or tissue should not be re-used, reprocessed, or re-sterilized and should be either returned to the manufacturer or disposed of properly. Reusing implants may lead to contamination and increase the risk of infection transmission.
- Implants should never be reimplanted. Even if they appear undamaged, the device may have small defects or internal stresses that could lead to implant failure or compromise its performance.
- Correct implant handling is extremely important. Avoid contouring of metallic implants. Discard all damaged or mishandled implants, or return them to the manufacturer for proper disposal.
- Avoid any damage of the periosteum during insertion of removal of the device. A physeal bar could be formed and generate further angular deformity.
- 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.
- Improper insertion of the device during implantation can increase the possibility of loosening or migration.
- The patient's mobility should be restricted at the region of the osteotomy or fracture to allow bony union. If a nonunion develops, the implants should be removed. If a solid fusion of bone does not occur, the site should be immobilized until solid bony fusion can be achieved. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses which are transmitted by the body to any temporary internal fixation device prior to healing of the fracture. Due to normal metal fatigue these stresses can cause eventual bending or breakage of the device.
- Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Implant removal should be followed by adequate postoperative management to avoid re-fracture or recurrent deformity.
- 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.
- The surgeon should be aware, and the patient informed of the following information and limitations:
  - o Compliance of the patient may affect the results of the fixation.
  - o Patients should be warned to avoid any sudden change in position, strenuous activity, or falls. To achieve a successful union, the patient should not be exposed to mechanical vibrations, whether intrinsic or extrinsic, that may lead to loosening of the device. The patient should be warned of this possibility and instructed to restrict physical activities especially those causing any type of mechanical stress on the area that is being secured by the system. The patient should avoid any type of sport activities or strenuous work during the postoperative or post implant removal healing period.
- Complications and/or failure are more likely to occur in:
  - o Physically active patients
  - o Debilitated patients or patients unable to follow instruction or use weight supporting devices.
  - o Patients that suddenly change position, fall, or are exposed to mechanical vibrations.

MRI Safety Information for the Hinge Pediatric Plating System

In non-clinical testing, the Hinge Pediatric Plating System implants were determined to be MR-Conditional. A patient with this device can be safely scanned immediately after device placement under the following conditions:

Static Magnetic Field Strength (B0)	1.5 T and 3 T
Maximum Spatial Field Gradient	20 T/m (2,000 gauss/cm) or less
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	No restriction on transmit-receive coils
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR	2.0 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Limits on Scan Duration	2 W/kg whole body average SAR for 60 minutes (one hour) of continuous RF (a sequence or back to back series/scan without breaks)
Image Artifact	The presence of this implant may produce an image artifact. Optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

- The presence of other implants or the health state of the patient may require a modification of the MR conditions.
- If information about a specific parameter is not included, there are no conditions associated with that parameter.

Safety Benefits and Performance Characteristics

The Hinge Pediatric Plating System reduces the incidence of implant breakage, particularly in high-stress clinical scenarios such as in obese patients or those with Blount's disease.
The Hinge Pediatric Plating System is designed to support deformity correction in pediatric patients with angular deformities. Accordingly, the performance characteristics of the implants have been determined to ensure that the devices fulfill their intended purpose after implantation.
Detailed information regarding the clinical benefits and performance characteristics of the device can also be found in the Surgical Technique and the Summary of Safety and Clinical Performance (SSCP) documents. Please refer to the SSCP for comprehensive details about the device's performance and expected clinical outcomes. The instruments associated with the system are primarily designed to assist with the correct alignment, sizing, implantation, and explantation of the implant.
For SSCP please visit our website for patients at www.pegamedical.com/en/for-patients and EUDAMED database.

Follow-up Information

Follow-up care is an important component of the treatment process following the implantation of the Hinge Pediatric Plating System. Regular monitoring is recommended to monitor the progress of deformity correction, confirm proper implant positioning, and detect any potential complications such as implant loosening, hardware failure, or overcorrection. The frequency and duration of follow-up visits should be determined by the treating surgeon, taking into account the patient's age, severity of the deformity, growth potential, and overall clinical condition.
During follow-up visits, healthcare professionals should monitor for potential complications. It is recommended a three months follow-up of patients during the implantation period and an annual follow-up after removal until maturity to assure maintenance of correction. Slight overcorrection might be necessary, especially in young patients, to compensate rebound deformity after removal.
The decision regarding the timing and extent of follow-up care is at the surgeon's discretion, based on clinical judgment and the specific needs of the patient.

Surgical Technique

Precise placement of the Hinge Pediatric Plating System is achieved by means of device-specific instrumentation that allows positioning of the implant plate and screws through guidance pins. Pre-operative procedures, knowledge of applicable surgical techniques, proper patient selection and correct placement and removal of the implants are all equally important for the successful use of this product. The Surgical Technique manual details every step and should be carefully followed.
Instrumentation is available to facilitate implantation and removal of the device. Therefore, this device can be used in combination with its surgical instrumentation for insertion and removal. The Surgical Technique manual is available on the OrthoPediatrics Canada ULC website with the required language translations, if applicable. For more details, visit https://www.pegamedical.com/en/for-users.

Device Lifetime and Retrieval

Removal or replacement of the implant is recommended subsequent to normal follow-up after the bone has consolidated, and the deformity correction has been achieved. Routine removal of internal fixation devices may reduce the occurrence of symptomatic complications of implant breakage, implant loosening and implant related pain. In addition, if removal is favorable, OrthoPediatrics Canada recommends the retrieval of implants in order to avoid bone reduction and weakening, particularly in young and active patients. Ensure that consolidation is complete prior to the removal of the device. 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.

General Care, Storage, Handling and Inspection

Store implants unopened in their respective protective packages until use. Protect the components from contact with objects, which may damage the surface finish. Avoid undue stress or strain when handling or cleaning. Tap water can contain many minerals that may discolor and stain the parts; therefore, it is recommended that deionized water be used for the final rinsing to prevent spotting.
Implant components can be reprocessed by the intended users according to the cleaning and sterilization instructions provided in this document. There is no specific limitation in the number of reprocessing cycles, however each reprocessed implant component must be visually inspected prior to use and dispose of implants that exhibit surface or configuration damage such as fractures, scratches, cracks, bending, warping, nicking, denting, chipping or evidence of corrosion or discoloration. In case the implant component is reprocessed, the device must be stored and transported in dry conditions.

Cleaning and Sterilization for Implant Components and Trays

Implants are provided clean, but are NON-STERILE when shipped from OrthoPediatrics Canada. The following instructions should be followed to sterilize non-sterile items or previously sterilized items that have not been used. Apply a standard cleaning protocol that is approved by the hospital before implant sterilization. All metallic implants and trays can be steam sterilized following the instructions and parameters listed below:

- Implant components of the Hinge Pediatric Plating System should be sterilized using sterilization pouches.
- Implant/instrument trays of the Hinge Pediatric Plating System should be sterilized wrapped in two layers of 1-ply polypropylene wrap using sequential wrapping techniques.
- Devices should be thoroughly dried before packaged for sterilization.

Method	Steam
Sterilization Type	Prevacuum
Preconditionning Pulse	3
Minimal Temperature	270°F (132°C)
Minimal Cycle time	4 minutes
Minimal Drying time	30 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

All reusable instruments must be cleaned and sterilized prior to every use. The instrument tray and instruments of the Hinge Pediatric Plating System should be sterilized wrapped in two layers of 1-ply polypropylene wrap using sequential wrapping techniques.
For further instructions on cleaning, sterilisation, and re-sterilisation of instruments, please refer to the document: "Guidance for Instrument Care" available on our website at https://www.pegamedical.com/en/for-users.

Disposal Information

After use, the device is a potential biohazard, since it may be contaminated with blood or other fluids, bone or tissue. Handle and dispose of product in accordance with accepted medical practice and with applicable local, state and national laws and regulations.

Reporting Problems:/ Notice to the User and/or Patient

Intended users and patients should report any suspected adverse medical device incidents related to the implanted device by informing the manufacturer at feedback@orthopediatrics.ca, the local OrthoPediatrics Canada ULC distributor, or delegated regulatory agency in the country where the suspected incident occurred as listed below:

Territory	For Intended Users (Healthcare Professionals)	For Patients
European Union	Refer to Vigilance contact points: https://health.ec.europa.eu/document/download/900ad9e7-fc79-4617-93be-f6712a3e3306_en?filename=md_vigilance_contact_points.pdf National Competent Authority of Specific EU countries: see https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en – Refer to Vigilance contact points	Refer to Vigilance contact points: https://health.ec.europa.eu/document/download/900ad9e7-fc79-4617-93be-f6712a3e3306_en?filename=md_vigilance_contact_points.pdf
Switzerland	Follow guidelines https://www.swissmedic.ch/dam/swissmedic below: MU680_20_008e_WL Incident report user (PDF, 474 kB, 18.02.2025) MU680_10_007e_WL Vigilance contact person for medical devices (PDF, 573 kB, 18.02.2025) Notify Swissmedic: materiovigilance@swissmedic.ch using the following form, which must be submitted electronically and in machine-readable format: MU680_20_015d_FO Anwendermeldung (PDF, 1 MB, 01.11.2023)	Report to: materiovigilance@swissmedic.ch
England Scotland and Wales	Use the Yellow Card scheme: https://yellowcard.mhra.gov.uk/ and report to Northern Ireland Adverse Incident Centre in https://www.health-ni.gov.uk/publications/niaic-adverse-incident-reporting-guidance-and-forms and to Health Facilities Scotland online incident reporting system in https://www.nss.nhs.scot/health-facilities/incidents-and-alerts/report-an-incident/, complete form and email to nss.iric@nhs.scot	Patients, parents, carers and their representatives should report adverse incidents involving medical devices directly to the MHRA using the Yellow Card scheme https://yellowcard.mhra.gov.uk/ or via the Yellow Card app https://yellowcard.mhra.gov.uk/report-guide select `Member of the public` option. Follow intuitive instructions to complete the reporting form.

The SSCP is available in the European database on medical devices (Eudamed), where it is linked to the Basic UDI-DI. (https://ec.europa.eu/tools/eudamed)

EU REP	**European Authorized Representative** MedEnvoy Global BV Prinses Margrietplantsoen 33, Suite 123, 2595 AM The Hague The Netherlands	CH REP	**Swiss Authorized Representative** MedEnvoy Switzerland Gotthardstrasse 28 6302 Zug Switzerland
UKRP	**European Authorized Representative** MedEnvoy UK Limited 85, Great Portland Street, First Floor, London, W1W 7LT, United Kingdom	**UK Importer**	MedEnvoy UK Limited 85, Great Portland Street, First Floor, London, W1W 7LT, United Kingdom

15223-1 Symbols and Descriptions

	Manufacturer	REF	Catalogue Number
	Consult instructions for use or consult electronic instructions for use	MD	Medical Device
	Do not re-use	EU REP	European Authorized Representative
NON STERILE	Non-Sterile	CH REP	Swiss Authorized Representative
LOT	Batch Code		Date Of Manufacture
UDI	Unique Device Identifier		Importer

Other Symbols:

℞ ONLY	*Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.*	UK CA	UK Conformity Assessed
MR	Magnetic Resonance (MR) Conditional	CE	CE Marking of Conformity

INSTRUCTIONS FOR USE

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