Peanut® Growth Control Plating System

An Innovative Approach To Hemi-Epiphysiodesis

- Provides controlled growth of healthy epiphysis, restoring proper anatomic alignment
- Advanced instrumentation enhances surgical efficiency and accommodates various surgical approaches including minimally invasive techniques
- Pre-contoured extra-periosteal plates for optimized fit and functionality
- Minimal post-operative rehabilitation and immediate weight bearing
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Introduction

The Peanut Growth Control Plating System is designed to restore proper anatomic alignment of long bone(s) in pediatric patients with an open physis.

Innovative design features of both the implants and instruments enhance efficiency and also accommodate various surgical approaches including minimally invasive techniques. Utilization of the Peanut Plate can void the need for an osteotomy, which effectively minimizes post-operative rehabilitation and allows immediate weight bearing.

Plate and Screw Material
Titanium Alloy (Ti-6AL-4V)

INDICATIONS
The Biomet® Peanut Growth Control Plating System is designed for redirecting the angle of growth of long bone(s) in pediatric patients (patients who have not had physeal closure/reached skeletal maturity). This is useful for gradually correcting angular deformities in pediatric patients with an open physis. Specific conditions/diseases for which the device will be indicated include valgus, varus or flexion extension deformities of the knee (femur and/or tibia); valgus, varus or plantar flexion deformities of the ankle, valgus or varus deformities of the elbow, as well as radial or ulnar deviation, flexion or extension deformities of the wrist (radius).

Patient selection factors to be considered include:
1. Need for alignment and stabilization of bone fractures,
2. Ability and willingness of the patient to follow postoperative care instructions until healing is complete, and
3. A good nutritional state of the patient.

CONTRAINDICATIONS
1. Physeal closure/skeletal maturity.
2. Active infection.
3. Patient conditions including blood supply limitations, and insufficient quantity or quality of bone.
4. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions or materials.
5. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.
**System Design Features**

- Plate Holding Forceps integrate a split K-Wire channel for a 1.6 mm guide wire. Offset design allows for easy passage of instruments into the plate and facilitates unobstructed fluoroscopic views.

- Plate design incorporates proximal and distal K-wire holes, providing the option of centering the plate without invading the physis.

- Non-locking, Fixed, and Variable 2.7 mm Drill Sleeves accommodate the Wire Sleeve Inserts for efficient stepwise screw insertion preparation and soft tissue protection.

- Variable Drill Sleeves limit extreme drilling trajectories which can cause poor screw seating.

- Working Cannula can be used to protect against soft tissue damage and can also serve as an inserter when used with locking drill sleeves.
• Plate Inserter/Extractor is cannulated to pass over a central guide wire

• Plate removal is simple. The Inserter/Extractor’s tip threads into the plate’s center hole to ensure captured removal as screws are disengaged

• 3.5 mm Cannulated Hex Driver with Ratcheting AO Handle

• Stepped tip securely holds hex slot to protect against screw loss

• In the event that a screw head becomes damaged during insertion or removal, the surgeon may utilize the 3.5 mm Hex Screw Extractor as a means of retrieval

• The Extractor tip is designed with cutting flutes that will engage any 3.5 mm hex

• Overwire Depth Gauge for accurate screw sizing
System Design Features (Continued)

- Low profile pre-contoured plate geometry conforms to patient anatomy for optimized fit and functionality. Two plate styles- Arched and Stepped - for enhanced plate-to-bone interface

- Built in washer and elevated plate design for reduced contact with growth plate and periosteum

- Color coded for easy discernment

- Threaded screw holes are designed to hold drill Sleeves securely within the plate during screw hole preparation

- Recessed screw holes allow for low profile seating of screws, increasing patient comfort

- Screw Material: Titanium alloy

  Tapered screw design effectively increases overall strength. Note the minor thread diameter tapering from the screw head towards the self-cutting tip

  - Reverse buttress threads to guard against pull out

- Both plates available in 16 mm and 12 mm sizes to accommodate varying patient anatomies
### Instrument Tray

**Instrument Tray**

**Catalog No.** | **Description** | **Qty**
--- | --- | ---
22880 | Ratcheting AO Handle | 1
24400 | Plate Holding Forcep | 1
24412 | 3.5 mm Cannulated Hex Driver | 2
24420 | Plate Inserter / Extractor | 1
24425 | Variable Drill Sleeve 2.7 mm | 2
24436 | Fixed Drill Sleeve 2.7 mm | 2
24440 | 2.7 mm Solid AO Drill | 2
24445 | 2.7 mm Cannulated AO Drill | 2
24470 | Working Cannula | 1
24472 | Non-Locking Drill Sleeve | 2
24474 | Wire Sleeve Insert | 3
24480 | Overwire Depth Gage | 1
24485 | 3.5 mm Hex Screw Extractor | 2
595402 | Instrument Tray | 1
**Implant Caddy**

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<td>456469</td>
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<tr>
<td>24415</td>
<td>8in Guide Wire, Threaded Tip</td>
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Surgical Technique

Patient Positioning

Position patient in the supine position on the appropriate sized fracture table. Abduct the leg for fluoroscopic unit access and drape in the customary fashion.

Step 1:

Fluoroscopically locate the growth plate and hold the Peanut® Plate in position using the Plate Holding Forceps (PN 24400). Mark a 2-3 cm incision on the skin.

Incise and carefully divide skin and fascia, avoiding disturbance of the periosteum.

For accurate positioning of the plate, insert a 1.6 mm K-Wire (PN 24415) into the growth plate as shown.

Select the appropriate sized plate to best match the patient’s anatomy (12 mm/16 mm plates available in both Arched and Stepped designs). The Stepped plates are designed primarily for usage on the proximal tibia, but either plate can be used according to surgeon preference.

Technique Note: If you elect to avoid wire placement in the growth plate, alternative K-Wire holes have been incorporated into the plate’s design to provide the option of placing wires proximally and distally to the physeal line.
Surgical Technique (Continued)

Step 2:

The appropriate drill sleeves are selected and threaded into the screw holes.

Wire Sleeve Inserts (PN 24474) are threaded into the drill sleeves. The surgeon has the option of using Fixed (PN 24436) or Variable (PN 24425) 2.7 mm Drill Sleeves.

Once the insertion apparatus is assembled, the plate is passed over the guide wire through the central hole of the plate, centering the plate over the physis. Confirm position with the fluoroscope.

Shown: 16 mm Stepped Plate (PN 24616) Top screw hole with Variable Drill Sleeve/Wire Sleeve Insert, bottom screw hole with Fixed Drill Sleeve/Wire Sleeve Insert
Technique Note: To allow for maximum screw angulation prior to becoming fixed, place wire/screws as parallel as possible.

With two or more K-Wires in place, two points of fixation are achieved allowing the Plate Holding Forceps and central guide wire to be removed.

Step 3

The epiphyseal guide wire is placed through the Wire Sleeve Insert followed by the metaphyseal guide wire. Once both wires are placed, the epiphyseal Wire Sleeve Insert is removed in preparation for drilling.

Step 4

After removing the Wire Sleeve Insert, the epiphyseal screw hole is prepared using the 2.7 mm Cannulated A/O Drill (P/N 24445). Bicortical drilling is not necessary.

Drill bits are calibrated to read off the top of the Drill Sleeves.
Step 5

An appropriate sized screw (16, 24, 32, or 40 mm) is selected and passed over the guide wire. Provisionally tighten the screw to allow for any later adjustments required when the second screw is introduced.
Step 6

Metaphyseal screw preparation ensues in the same fashion as the epiphyseal screw using the 2.7 mm Cannulated Drill.

Step 7

The metaphyseal screw can now be inserted over the guide wire.

Lastly, both screws are definitively tightened and fully seated into the plate.

Technique Note: Avoid over-tightening of screws. Doing so can create excessive pressure between the periosteum and plate.

Confirm fluoroscopically that screws are not violating the growth plate or joint space and close the wound in the customary fashion.
**Post-Operative Care**

Postoperatively, weight bearing can ensue immediately. Patients are typically discharged from the hospital the same or next day.

It is recommended that guided growth progress visits take place every 2-3 months to avoid over correction as well as to monitor implant condition.

**Removal**

Plate removal is imperative to avoid over correction and will usually occur within a window of 6 to 18 months following introduction. It is important to bear in mind that the time of removal is contingent upon the amount of correction needed to fully correct the deformity. Once the implant is removed, patients should also be monitored until skeletal maturity to protect against recurrent deformities.

Before disengaging the screws, the Plate Inserter/Extractor (PN 24420) is threaded into the central hole of the plate to ensure captured removal.
### Damaged Screw Removal

In the event that the hex head of the screw becomes damaged during insertion or removal, the surgeon may utilize the 3.5 mm Hex Screw Extractor (PN 24485) as a means of retrieval.

The Extractor tip is designed with cutting flutes that will engage any 3.5 mm hex slot.

### Sterilization

Unless supplied sterile, metallic internal fixation devices must be sterilized prior to surgical use. Product provided sterile is sterilized by exposure to a minimum dose of 2.5 Megarads (25kGy) gamma radiation. Where specified, do not use implants after expiration date. These guidelines also apply to devices provided sterile where the integrity of the packaging has been compromised and re-sterilization is required prior to initial use.

**Pre-Vacuum Steam Sterilization:**
- **Temperature:** 275°F/135°C
- **Time:** Eight (8) Minutes
- **Drying Time:** Eight (8) Minutes

Since Biomet is not familiar with individual hospital handling methods, cleaning methods, and bioburden, Biomet cannot assume responsibility for sterility even though the guideline is followed.
**Peanut® Growth Control Plating System Package Insert**

**DESCRIPTION**

The Biomet® Peanut Growth Control Plating System consists of contoured, low profile plates and screws comprised of Ti-6Al-4V.

**MATERIALS**

Titanium Alloy (Ti-6Al-4V)

**INDICATIONS**

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**CONTRAINDICATIONS**

1. Physeal closure/skeletal maturity.
2. Active infection.
3. Patient conditions including blood supply limitations, and insufficient quantity or quality of bone.
4. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions or materials.
5. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

**WARNINGS**

Internal fixation devices aid the surgeon in the alignment and stabilization of skeletal fractures and provide a means of fracture management in reconstructive surgical applications. While these devices are generally successful in attaining these goals, they cannot be expected to replace normal healthy bone or withstand the stress placed upon the device by full or partial weight bearing or load bearing, particularly in the presence of nonunion, delayed union, or incomplete healing. Metallic bone fixation devices are internal splints that align the fracture until normal healing occurs. The size and shape of bones and soft tissue place limitations on the size and strength of implants. If there is delayed union or nonunion of bone in the presence of weight bearing, or load bearing, the implant could eventually break. Therefore, it is important that immobilization (use of external support, walking aids, braces, etc.) of the fracture site be maintained until firm bony union (confirmed by clinical and radiographic examination) is established. Surgical implants are subject to repeated stresses in use, which can result in fatigue fracture. Factors such as the patient’s weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the service life of the implant. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but also must be aware of the mechanical and metallurgical aspects of the surgical implants.

1. Correct selection of the implant is extremely important. The potential for success in fracture fixation is increased by the selection of the proper type of implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal healthy bone. These devices are not designed to withstand the unsupported stress of full weight bearing, or load bearing. Patient selection factors to be considered include:

2. The devices can break when subjected to increased loading associated with nonunion or delayed union. Internal fixation devices are load-sharing devices that hold a fracture in alignment until healing occurs. If healing is delayed, or does not occur, the implant can be expected to break, bend or fail. Loads produced by weight bearing, and activity levels may dictate the longevity of the implant.

3. Implant materials are subject to corrosion. Implanting metals and alloys subjects them to constant changing environments of salts, acids, and alkalis that can cause corrosion. Putting dissimilar metals and alloys in contact with each other can accelerate the corrosion process that may enhance fracture of implants. Every effort should be made to use compatible metals and alloys when marrying them to a common goal, i.e., screws and plates.

4. Correct handling of implants is extremely important. Do not modify implants. Do not notch or bend implants. Notches or scratches put in the implant during the course of surgery may contribute to breakage. Intraoperative fracture of screws can occur if excessive force (torque) is applied while seating bone screws.

5. Remove after fracture has healed. Implants can loosen, fracture, corrode, migrate, or cause pain. If an implant remains implanted after complete healing, the implant may cause stress shielding, which may increase the risk of refracture in an active patient.
The surgeon should weigh the risks verses benefits when deciding whether to remove the implant. Adequate postoperative management to avoid refracture should follow implant removal.

6. Adequately instruct the patient. Postoperative care is important. The patient’s ability and willingness to follow instruction is one of the most important aspects of successful fracture management. Patients with senility, mental illness, alcoholism, and drug abuse may be at higher risk. These patients may ignore instructions and activity restrictions. The patient is to be instructed in the use of external supports, walking aids, and braces that are intended to immobilize the fracture site and limit weight bearing or load bearing. The patient is to be made fully aware and warned that the device does not replace normal healthy bone, and that the device can break, bend or be damaged as a result of stress, activity, load bearing, or weight bearing. The patient is to be made aware and warned of general surgical risks, possible adverse effects, and to follow the instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examination as long as the device remains implanted.

7. Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

**PRECAUTIONS**

Device is single use only.

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant.

Do not treat patients with implants that have been even momentarily placed in a different patient.

Instruments are available to aid in the accurate implantation of internal fixation devices. Intraoperative fracture or breaking of instruments has been reported.

Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

All trial, packaging, and instrument components must be removed prior to closing the surgical site. Do not implant.

**POSSIBLE ADVERSE EFFECTS**

1. Bending or fracture of the implant.
2. Loosening or migration of the implant.
3. Metal sensitivity, or reaction to a foreign body.
4. Decrease in bone density due to stress shielding.
5. Pain, discomfort, or abnormal sensation due to the presence of the device.
6. Nerve damage due to surgical trauma.
7. Necrosis of bone.
8. Postoperative bone fracture and pain.
9. Inadequate healing.
10. Early or late postoperative infection and/or allergic reaction.

**MAGNETIC RESONANCE (MR) STATEMENT**

The Peanut Growth Control Plating System has not been evaluated for safety and compatibility in the MR environment. The Peanut Growth Control Plating System has not been tested for heating or migration in the MR environment.

**STERILITY**

The Peanut Growth Control Plating System is provided in both sterile and non-sterile configurations.

1. The sterile system is provided sterile using a minimum dosage of 2.5 megaRad (25 kGy) of gamma radiation. Where specified, do not use implants after expiration date.

2. The non-sterile system must be sterilized prior to use. All packaging materials must be removed prior to sterilization. All components should be sterilized in a loosened state such that components may move freely.

3. Re-sterilization of sterile products which have been opened is permissible as long as the components have not been previously implanted, not been exposed to biological contamination, nor appear to have compromised mechanical integrity.

The following steam sterilization parameters are recommended:

**Pre-Vacuum Steam Sterilization:**

- **Temperature:** 270°F (132°C)
- **Time:** Eight (8) Minutes
- **Drying Time:** Twenty (20) Minutes

Individuals or hospitals not using the recommended method, temperature, and time are advised to validate any alternative methods or cycles using an approved method or standard.

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

#### Plates

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Further Information

This brochure is presented to demonstrate surgical techniques of Charles Price, M.D., Kenneth Noonan, M.D., and Jack Flynn, M.D. Biomet Trauma, as the manufacturer and distributor of this system, does not recommend this or any other surgical technique for use on a patient. The surgeon who performs any surgical procedure is responsible for determining and utilizing the appropriate techniques for implanting all products in each patient. Biomet is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.

For further information, please contact the Customer Service Department at:

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www.biomet.com
At Biomet, engineering excellence is our heritage and our passion. For over 25 years, through various divisions worldwide, we have applied the most advanced engineering and manufacturing technology to the development of highly durable systems for a wide variety of surgical applications.

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An Innovative Approach To Hemi-Epiphysiodesis

To learn more about this product, contact your local Biomet Sales Representative today.