



PROXIMAL HUMERUS

Instructions for Use



CAUTION: FEDERAL LAW RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Table of Contents

1. INTENDED USE	3
2. DEVICE DESCRIPTION	3
3. METHOD OF IMPLANTATION.....	3
4. CONTRAINDICATIONS.....	3
5. WARNINGS AND PRECAUTIONS	3
6. OPERATIVE PRECAUTIONS	5
7. PRODUCT COMPLAINTS.....	5
8. STORAGE INSTRUCTIONS	5
9. WARRANTY.....	5
10. FURTHER INFORMATION.....	5

1. **INTENDED USE**

The Conventus CAGE™ – Proximal Humerus is indicated for the fixation of proximal humerus fractures except when there are too many fracture fragments to repair the articular surface.

2. **DEVICE DESCRIPTION**

The Conventus CAGE™ – Proximal Humerus (PH CAGE) is an expandable implant which is deployed into the intramedullary canal of the proximal humerus and provides a Cage to which bone fragments can be attached using fragment screws. The PH CAGE is flexible during device placement, but once deployed creates a stable bone-implant construct at the completion of the surgical implantation procedure.

The PH CAGE is comprised of an Expandable Cage (Inner Cage, Outer Cage, Central Member), Proximal Screws, and Distal Screws. All components of the system are made of known biocompatible materials as listed in **Table 1**.

Table 1. Components and Materials of the PH CAGE

Component	Material and Standard
Expandable Cage	Cages: Nitinol (ASTM F2063) Central Member: Titanium alloy (ASTM F136)
Proximal Screws	Titanium alloy (ASTM F136)
Distal Screws	Titanium alloy (ASTM F136)

3. **METHOD OF IMPLANTATION**

Please see the PH CAGE Surgical Technique Manual for a more-detailed description of the implantation procedures. The surgical technique includes the following general steps:

- 3.1. Reduce and stabilize fracture.
- 3.2. Template and size implant location.
- 3.3. Insert guide pin at entry point.
- 3.4. Prepare site for PH CAGE.
- 3.5. Insert and lock Expandable Cage.
- 3.6. Secure bone fragments with Proximal Screws into Expandable Cage.
- 3.7. Close.

4. **CONTRAINDICATIONS**

The PH CAGE should not be implanted in patients with:

- any active or suspected latent infection, or marked local inflammation, in or about the affected area
- suspected or known sensitivity or allergies to Nickel or Titanium
- mental conditions that preclude cooperation with the rehabilitation regimen

5. **WARNINGS AND PRECAUTIONS**

Warnings:

- 5.1. Fracture fixation devices are neither intended to carry the full load of the patient, nor intended to carry a significant portion of the load for extended periods of time.
- 5.2. Do not use the PH CAGE with components from other manufacturers. Use only Conventus Orthopaedics devices.

Precautions:

- 5.3. Use care in handling and storage of implant components. Cutting, sharply bending or scratching the surface can significantly reduce the strength and fatigue resistance of the implant system. This, in turn, could induce cracks and/or stresses that could lead to fracture of the implants.
- 5.4. Additional surgical technique information is available upon request. The surgeon should be familiar with the devices, instruments and surgical technique before surgery.
- 5.5. Please refer to the surgical technique manual for proper implantation procedures.
- 5.6. If the implantation site is prepared with a fully expanded implantation site preparation instrument, a large implant device must be used.
- 5.7. Orthopedic implant removal is common in bone fracture patients. When using provided surgical techniques, the stem of the implant should be in contact with the cortical wall to facilitate optional removal access.
- 5.8. The surgeon should select patients carefully and preclude anyone with insufficient bone quality, an obliterated medullary canal or conditions which tend to retard healing, including but not limited to, blood supply limitations or previous infections.
- 5.9. Postoperative instructions to patients and appropriate nursing care are critical. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending or breaking the device. Early weight bearing should only be considered where there are stable fractures with good bone-to-bone contact. Patients who are obese and/or noncompliant, as well as patients who could be pre-disposed to delayed union or non-union, must have auxiliary support.
- 5.10. Even after full healing, the patient should be cautioned that refracture is more likely with the implant in place and soon after its removal, rather than later when voids in the bone left by implant removal have been filled in completely.
- 5.11. Patients should be cautioned against unassisted weight-bearing activity without physician direction or medical release.
- 5.12. Postoperative care and physical therapy should be structured to prevent loading of the humerus until stability is evident.
- 5.13. The Conventus Orthopaedics PH CAGE has not been evaluated for safety and compatibility in the MR environment and has not been tested for heating or migration in the MR environment.

Adverse Effects:

Potential adverse events may be related to surgery in general or the device. These may include, but are not limited to the following:

Potential adverse events related to any surgery: reactions to anesthesia, the anesthetic or other medications, bleeding, infection (both deep and superficial), ileus, blood vessel damage, nerve or soft tissue damage, atelectasis, pneumonia, hematoma, seroma, wound dehiscence or incisional hernia, urologic problems, embolism, anemia, colitis, thrombophlebitis, heart attack, stroke or death.

Potential adverse events related to the device: bending, cracking or fracture of the implant components, failure to achieve fracture healing, or loosening of the implant, limb shortening or loss of anatomic position with nonunion, malunion with rotation or angulation, irritational injury of soft tissues, including impingement syndrome, or tissue reactions which include macrophage and foreign body reactions adjacent to implants. Metal sensitivity or histological or allergic reaction resulting from implantation of a foreign material may occur. Additional surgery may be necessary for implant removal, repositioning or replacement.

The Expandable Cage and Delivery Tubeset of the PH CAGE are provided sterile. Each package should be inspected prior to use to ensure package integrity prior to use. Do not resterilize implants or single-use accessories if the package has been opened but the implant is not used.

Proximal Screws and Distal Screws are provided **NON-STERILE** in an autoclavable tray and must be sterilized prior to use according to the following cycle:

Cycle	Minimum Exposure Time	Minimum Temperature	Minimum Drying Time
Pre-vacuum Autoclave	4 Minutes	132°C	20 Minutes
Pre-vacuum Autoclave	3 Minutes	135°C	20 Minutes

All implants should be inspected prior to use for possible damage or defects. Any damaged or defective component should not be used and should be returned to the manufacturer. If an implant has been contaminated by blood or secretions, clean and steam sterilize the implant prior to returning it to the manufacturer.

The manufacturer is not responsible for any complications arising from incorrect diagnosis, incorrect choice of implant, incorrect operating techniques, the limitations of treatment methods or inadequate asepsis.

During the post operative phase, in addition to mobility and muscle training, it is of particular importance that the physician keeps the patient well informed about post-surgical activity requirements.

6. **OPERATIVE PRECAUTIONS**

The surgeon is to be thoroughly familiar with the PH CAGE, method of implantation, instruments and surgical technique.

Proper surgical procedures and techniques are the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience.

The implants are for single-implant use only. An explanted device must never be re-implanted.

7. **PRODUCT COMPLAINTS**

Any healthcare professional (e.g., a surgeon using the product) who has a complaint or who has experienced any dissatisfaction in the quality, identity, reliability, safety, efficacy, and/or performance of any Conventus product should notify Conventus Orthopaedics, or, where applicable, their distributor. In the event of serious incident, or risk of serious incident, having resulted in, or may potentially result in, the death or severe deterioration in the state of health of a patient or user, Conventus Orthopaedics or the distributor must be notified as soon as possible. When filing a complaint, please provide the component(s) reference number (model number), manufacturing lot number(s), your name and address, and the nature of the complaint in full detail, as well as notification of whether a written report is requested.

8. **STORAGE INSTRUCTIONS**

Store in a cool dry place and keep away from direct sunlight. Prior to use, inspect instruments and tray for signs of tampering.

9. **WARRANTY**

THE COMPANY REPRESENTS AND WARRANTS THAT THE PH CAGE WILL CONFORM TO THE COMPANY'S SPECIFICATIONS AND COMPLY WITH ALL APPLICABLE FDA STANDARDS, AS SUCH STANDARDS MAY BE AMENDED FROM TIME TO TIME. THE COMPANY MAKES NO OTHER EXPRESS OR IMPLIED WARRANTIES REGARDING THE PH CAGE.

10. **FURTHER INFORMATION**

For further Information, please contact:

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CONVENTUS

ORTHOPAEDICS

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



	Model /Part Number
	Lot Number
	Use Before Date
	Quantity
	Material
	Caution, consult accompanying documents
	Single Use Only
	Contents Sterile: Irradiation
	Contents are Non-Sterile
	Manufacturer