

Emergency Stabilization Instrument for Unstable
Injuries and Fractures of the Pelvic Ring

Pelvic C-Clamp II

Surgical Technique

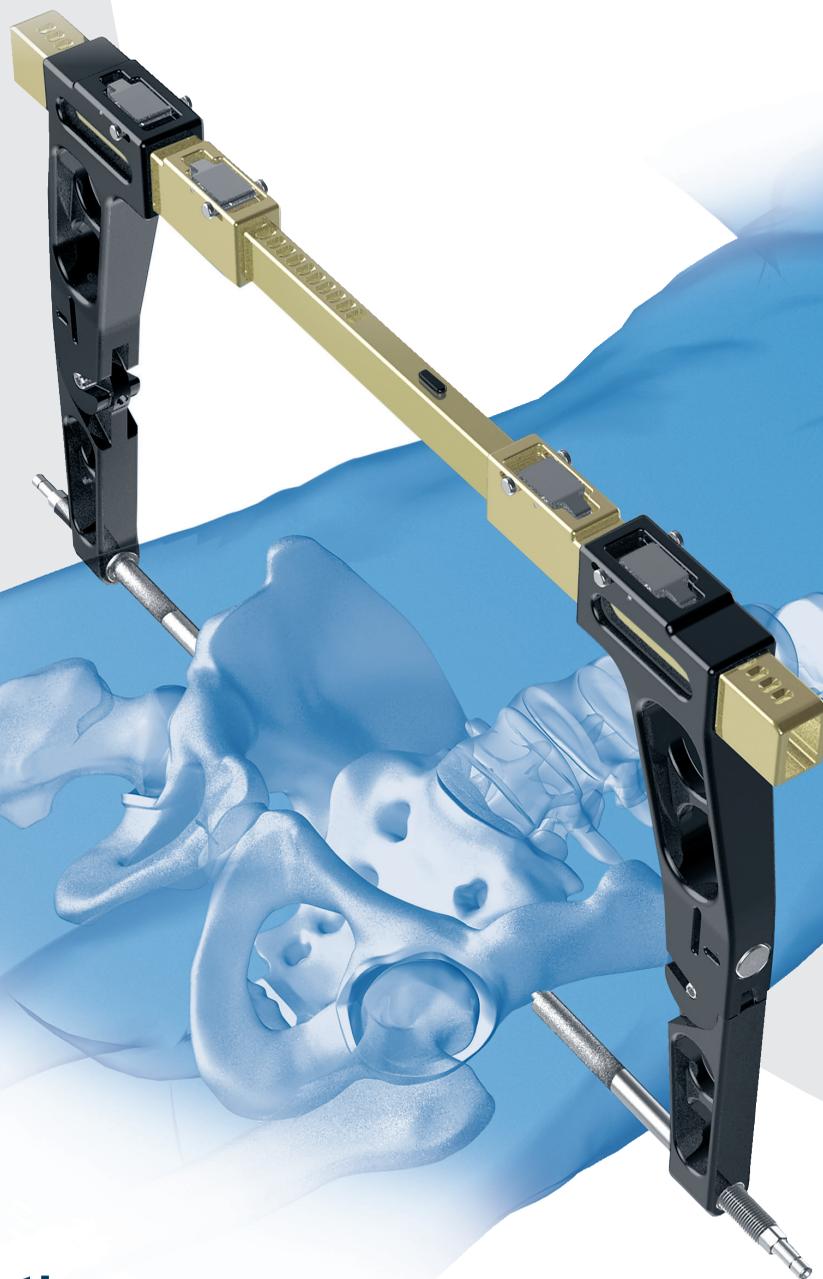


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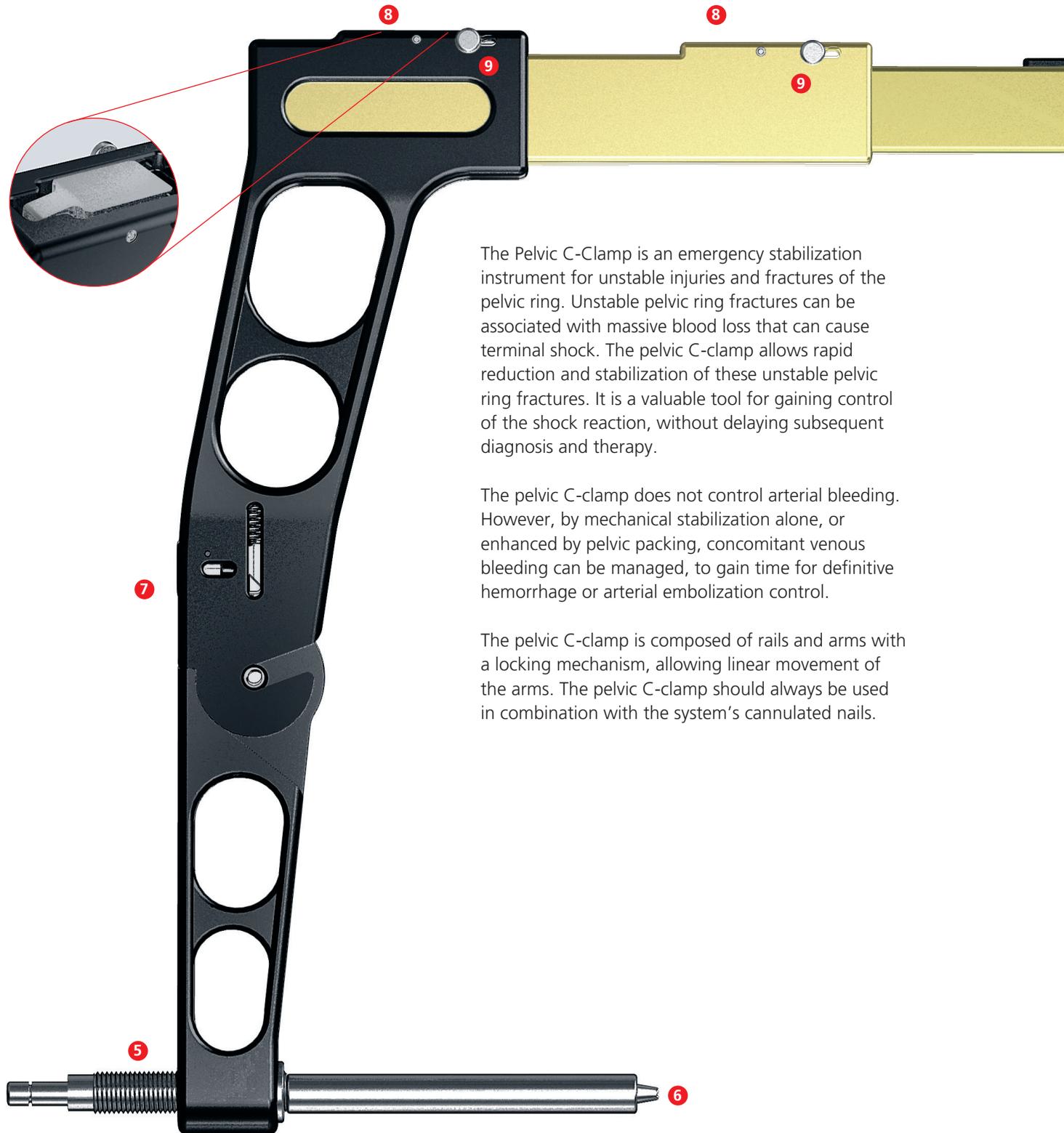
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MR Information

The Pelvic C-Clamp II 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 Pelvic C-Clamp II System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

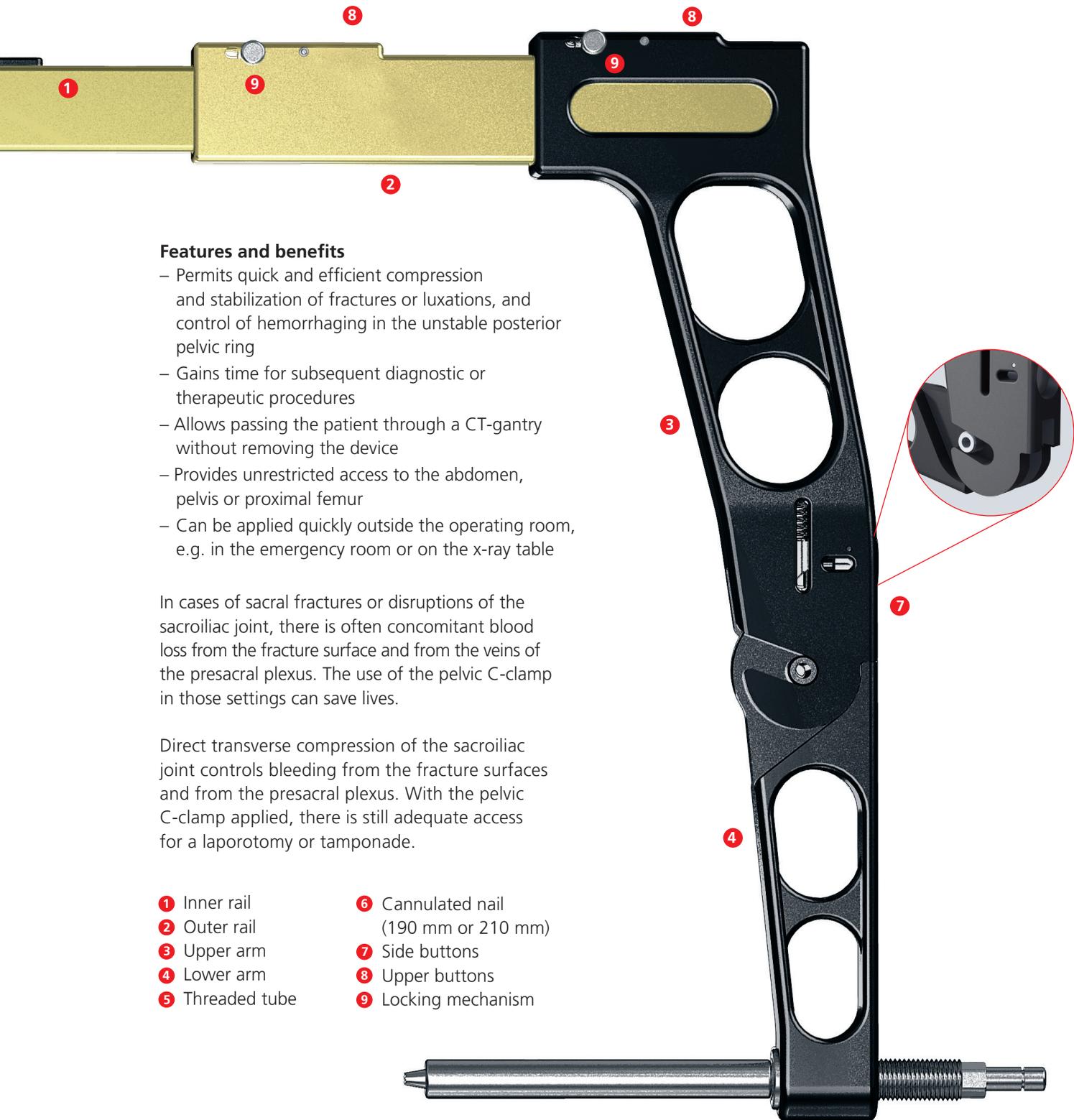
Pelvic C-Clamp II



The Pelvic C-Clamp is an emergency stabilization instrument for unstable injuries and fractures of the pelvic ring. Unstable pelvic ring fractures can be associated with massive blood loss that can cause terminal shock. The pelvic C-clamp allows rapid reduction and stabilization of these unstable pelvic ring fractures. It is a valuable tool for gaining control of the shock reaction, without delaying subsequent diagnosis and therapy.

The pelvic C-clamp does not control arterial bleeding. However, by mechanical stabilization alone, or enhanced by pelvic packing, concomitant venous bleeding can be managed, to gain time for definitive hemorrhage or arterial embolization control.

The pelvic C-clamp is composed of rails and arms with a locking mechanism, allowing linear movement of the arms. The pelvic C-clamp should always be used in combination with the system's cannulated nails.



Features and benefits

- Permits quick and efficient compression and stabilization of fractures or luxations, and control of hemorrhaging in the unstable posterior pelvic ring
- Gains time for subsequent diagnostic or therapeutic procedures
- Allows passing the patient through a CT-gantry without removing the device
- Provides unrestricted access to the abdomen, pelvis or proximal femur
- Can be applied quickly outside the operating room, e.g. in the emergency room or on the x-ray table

In cases of sacral fractures or disruptions of the sacroiliac joint, there is often concomitant blood loss from the fracture surface and from the veins of the presacral plexus. The use of the pelvic C-clamp in those settings can save lives.

Direct transverse compression of the sacroiliac joint controls bleeding from the fracture surfaces and from the presacral plexus. With the pelvic C-clamp applied, there is still adequate access for a laporotomy or tamponade.

- | | |
|-----------------|--------------------------------------|
| 1 Inner rail | 6 Cannulated nail (190 mm or 210 mm) |
| 2 Outer rail | 7 Side buttons |
| 3 Upper arm | 8 Upper buttons |
| 4 Lower arm | 9 Locking mechanism |
| 5 Threaded tube | |

Indications

The Pelvic C-Clamp II is intended for emergency stabilization of sacrum fractures or disruptions of the sacroiliac joint with associated circulatory instability.

Precautions: Avoid use where:

- Fractures of the ilium are present, as there is risk of pin perforation through the fracture line
- There are comminuted sacral fractures with the risk of compression of the sacral nerve plexus

Note: In life-threatening situations, hemorrhage control takes priority over the potential risk of nerve root compression.

Preoperative Preparation

1

Preoperative preparation

Required set

01.306.000 Pelvic C-Clamp II Set

The complete sterile pelvic C-clamp set should be kept ready for use in the resuscitation room. Depending on the type of injury, the orientation points in the pelvic region of the injured person may be unclear.

- Use an image intensifier during application of the pelvic C-clamp to verify anatomic references.
 - Anteroposterior (AP) plain pelvic radiograph if necessary, oblique views (inlet and outlet) or CT
 - Patient positioning must allow for intraoperative fluoroscopic controls in AP, inlet and outlet projections
 - Have an image intensifier available

Positioning

- Place the patient in a supine position
- To facilitate reduction, ensure free draping of the leg on the injured side and good coverage of the genital region
- To prepare the patient, disinfect the proximal femur and the buttocks and cover with sterile sheets

Preparation of the Pelvic C-Clamp

2

Preparation of the pelvic C-clamp

Instrument

03.306.010 Pelvic C-Clamp II

Open the lower side arms by depressing the buttons on the arms to prepare the pelvic C-clamp for use.

Note: Hold upper and lower arms with both hands and ensure that the lower arm is locked when fully extended.

Extend the upper bars by depressing the buttons on the upper rails while pulling on the side arms.

Note: Maximum extension of the pelvic C-clamp facilitates safe positioning.



With a light twist, place the cannulated nails of preferred length into the threaded tubes.

The buttons on the top of the pelvic C-clamp can be locked. Ensure the buttons are not locked when applying the pelvic C-clamp to the patient, or the side arms cannot be adjusted to apply compression.



1 Unlock, 2 Lock

Identify Insertion Point

3

Identify insertion point

Instrument

03.306.009 2.5 mm K-Wire Insertion Handle

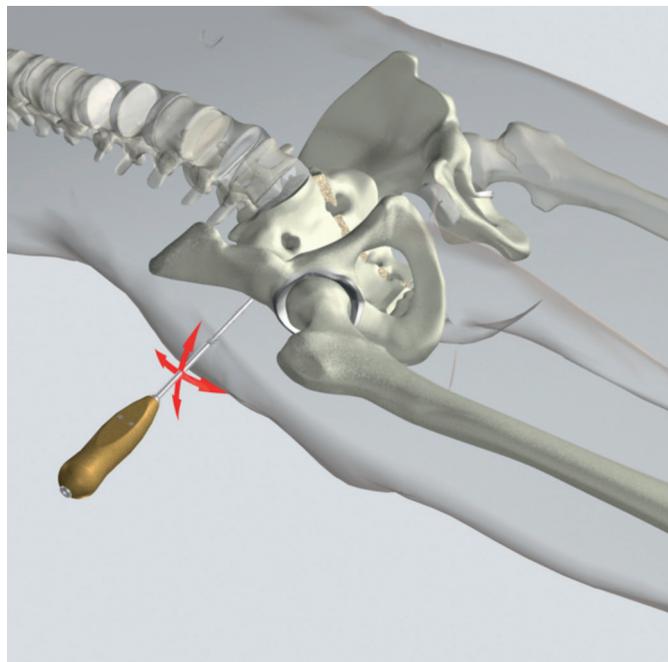
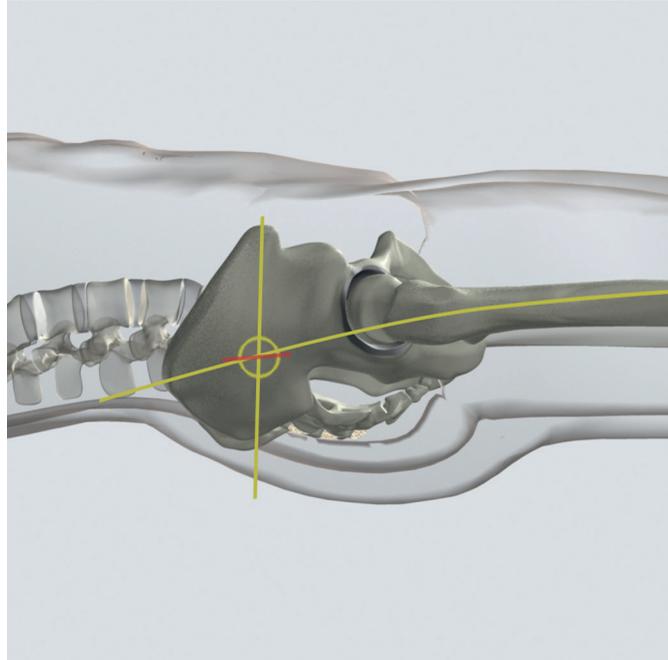
Make an incision at the intersection between the extension of the line of the femoral axis over the tip of the greater trochanter, and a vertical line from the anterior superior iliac spine in the dorsal direction.

- ⓘ If orientation is difficult, use an image intensifier.

The surface reference point of the outer side of the ilium changes at the level of the sacroiliac joints. In emergency situations, the resulting "fossa" can be used as a relatively secure point of reference aid. For secure anchoring, the pelvic C-clamp must be placed at the level of the sacroiliac joints. Palpation with a blunt instrument, such as the K-wire insertion handle, allows easy identification of this site, even with severe soft-tissue swelling.

Warnings:

- If the nails are placed too ventrally to the correct insertion point, there is a risk of perforation of the ilium, which can result in organ injury.
- Placement of the pins in an excessively dorsal position may result in injury to gluteal nerves and vessels.
- Inserting the nail too distally endangers the sciatic nerve and the gluteal vessels in the sciatic notch. Malpositioning of the nail in osteoporotic bone, combined with excessive compression, can result in unwanted nail penetration.



Place Kirschner Wire

4

Place Kirschner wire

Instruments

03.306.009	2.5 mm K-Wire Insertion Handle
292.26	2.5 mm K-Wire with Trocar Point, 285 mm
398.32	Socket Wrench with Hammer

Optional instrument

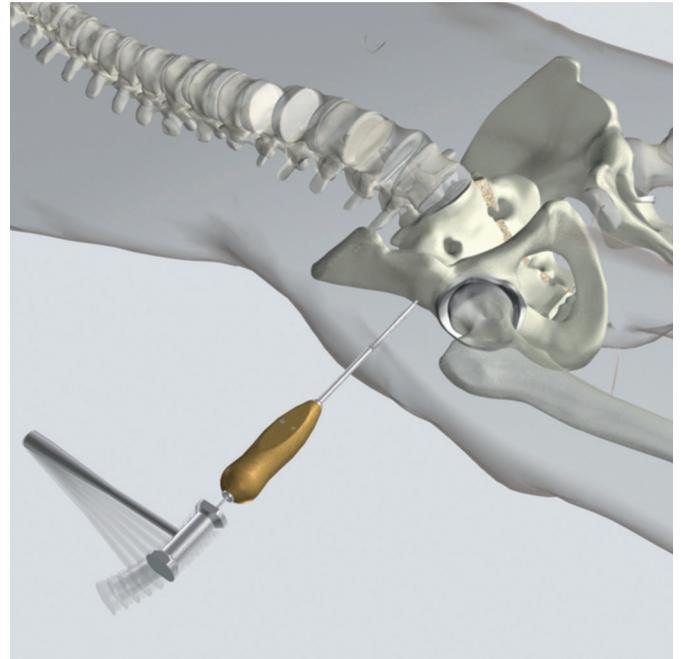
359.204*	Locking Pliers
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After identifying the insertion point, a Kirschner wire can be placed through the K-wire insertion handle (only on the uninjured side). Gently hammer the Kirschner wire into the bone with the socket wrench with hammer. This Kirschner wire will ensure exact placement of the cannulated nail and prevent the nail from slipping.

Note: Malpositioned Kirschner wires can be removed with the pliers.

Precautions:

- Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin.
- Handle devices with care and dispose of worn bone cutting instruments in an approved sharps container.
- Select the appropriate Schanz screw for the patient's bony anatomy.



*Also available.

Apply Pelvic C-Clamp

5

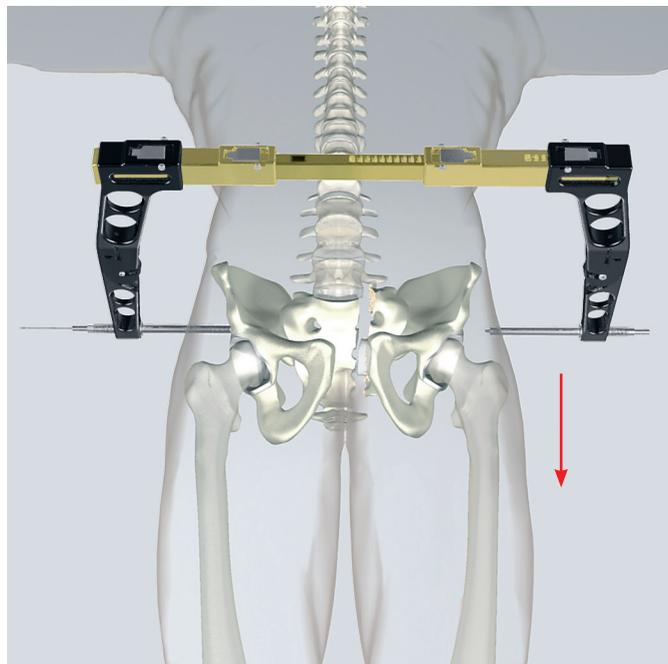
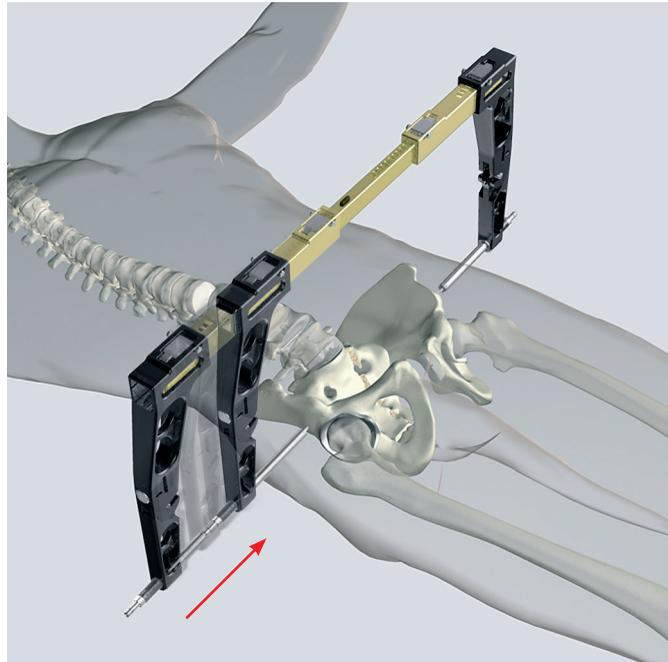
Apply pelvic C-clamp

Instruments

03.306.010	Pelvic C-Clamp II
03.306.011	8 mm Protective Cap
321.20	Ratchet Wrench, 11 mm width across flats
391.93	Wire Cutter, 220 mm

Be sure the fracture is correctly reduced before placement of the pelvic C-clamp. After inserting the Kirschner wire on the uninjured side, slide the clamp with cannulated nails over the wire and ensure that the tip of the nail grips the bone securely. Then place the second nail on the injured side (no Kirschner wire is necessary on this side).

Note: In cases of severe dislocations of the pelvis, pulling on the leg, internal rotation and even lateral compression may improve reduction and facilitate application of the pelvic C-clamp.



Alternative technique

Both nails can be placed at the same time by removing one side arm. After both nails have been seated properly the arm can be placed over the rail again and compression can be applied as described below.

When both nails are correctly seated, manually compress the upper side arms (figure A) and ensure final fixation by tightening the threaded tubes with the ratchet wrench (figure B).

The Kirschner wire must be cut off with the wire cutter. Place protective caps on each end of the two cannulated nails.

- After complete application of the pelvic C-clamp, verify fixation with an image intensifier or x-ray (pelvic AP view) and pad the nails.

Note: The locking mechanism locks the upper buttons, thus preventing unintended loss of compression during movement of the pelvic C-clamp.

Once mounted, the pelvic C-clamp can be swung caudally and cranially, e.g. for a laparotomy or an angiography.

Note: It is recommended to place a drape cloth or lap sponges as a cushion between the pelvic C-clamp and the patient.

Warning: Do not use the pelvic C-clamp to lift the patient.

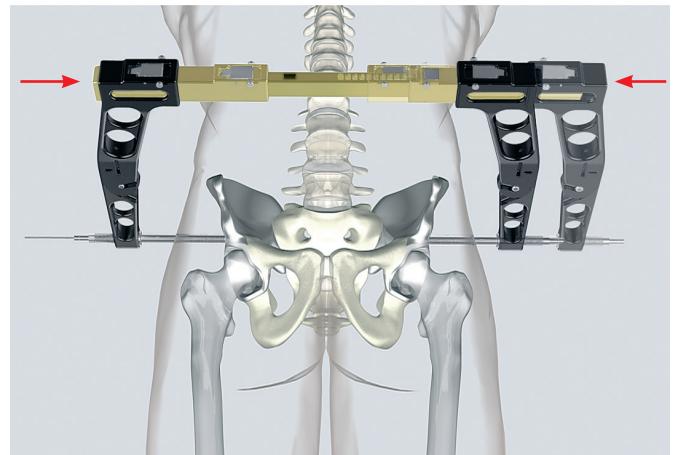


Figure A

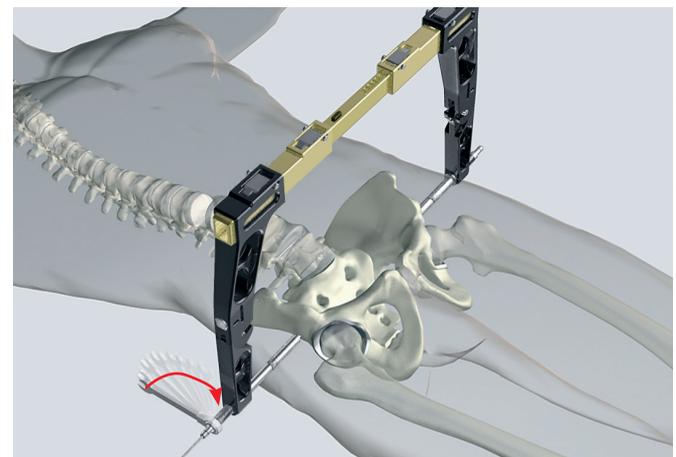
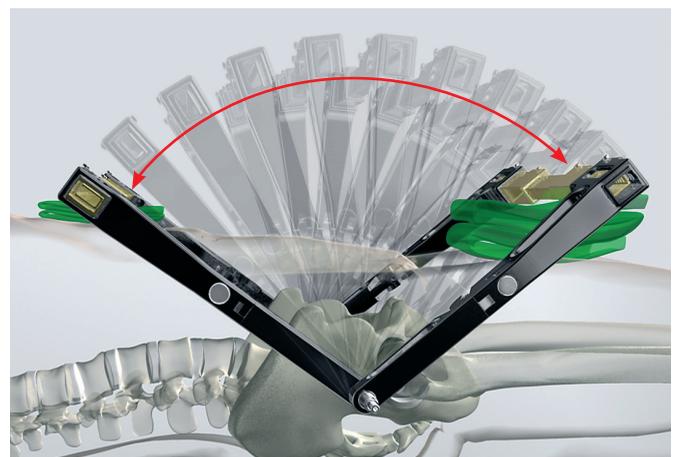


Figure B



Postoperative Management and Removal

6

Postoperative management

- AP plain radiograph, CT if required, rarely oblique view films after application of pelvic C-clamp and during follow-up
- Do not use the pelvic C-clamp to lift the patient.
- Wound closure; extended incisions may require a coapting skin suture
- Continuing injury management according to polytrauma protocols
- The nail insertion sites must be meticulously disinfected and dressed
- Should the patient need to be moved, he/she should on no account be placed on his/her side as this could cause one of the nails to penetrate the bone excessively

7

Removal

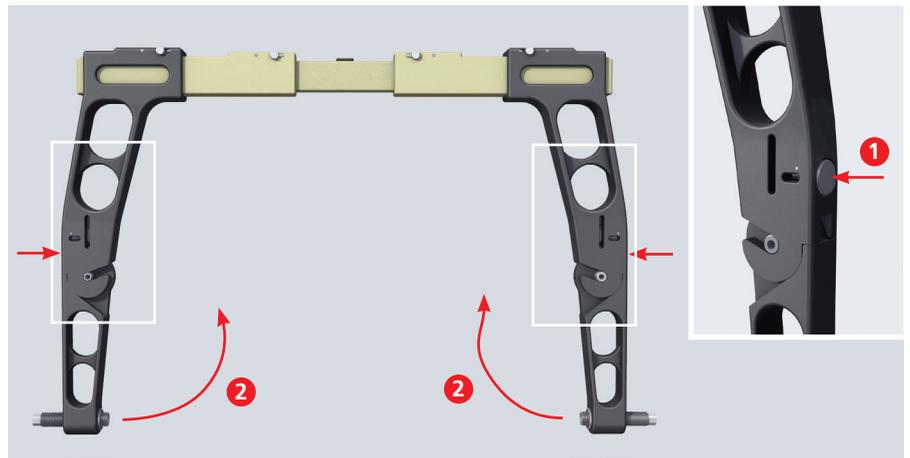
The pelvic C-clamp is removed before definitive treatment of the posterior pelvic ring injury. Be sure to remove the protective caps from the cannulated nails and Kirschner wire from the uninjured side.

Disassembly of the Pelvic C-Clamp

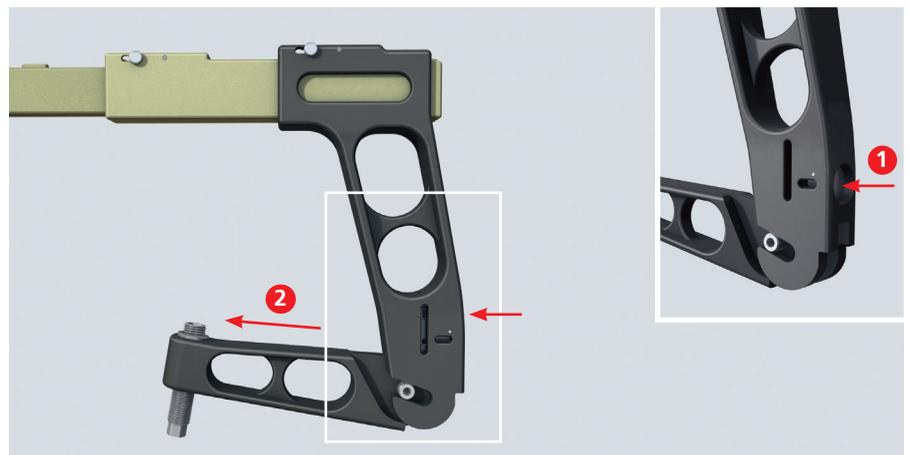
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Disassembly of the pelvic C-clamp

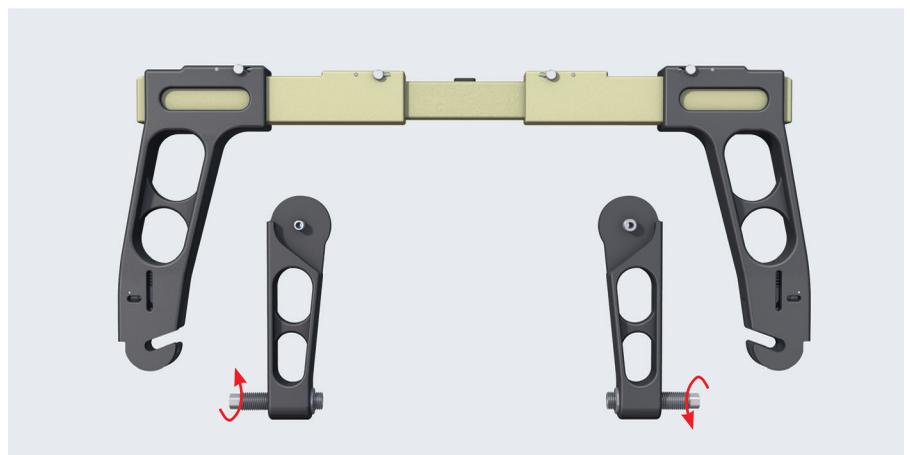
The lower arms can be raised by pressing the side buttons as depicted by the red arrows (1).



To remove the lower arms completely, keep the buttons depressed (1) and slide the arms out (2).

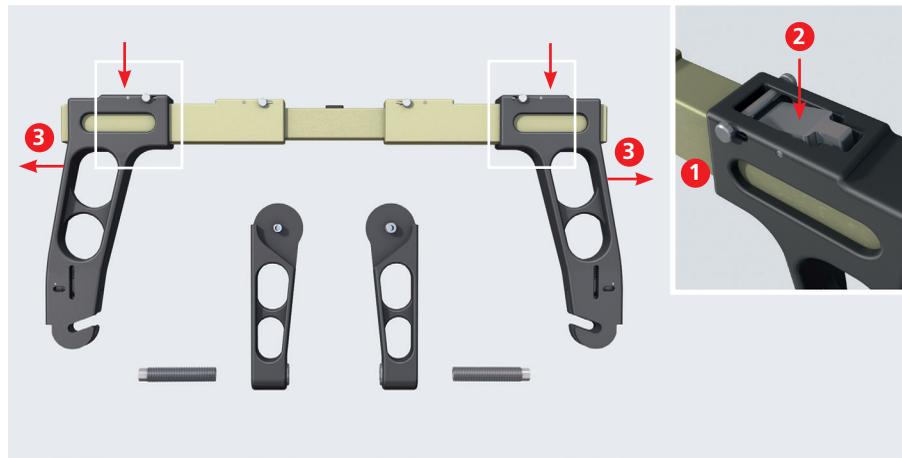


The threaded tubes can be unscrewed from the lower arms.

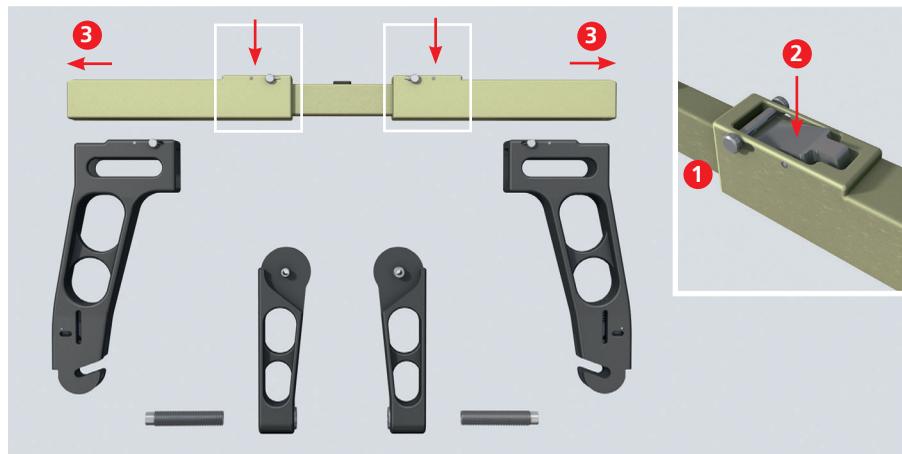


Disassembly of the Pelvic C-Clamp

Before removing the upper arms from the rails, make sure the locking mechanism is unlocked. The upper arms can be removed from the rails by pressing the top buttons (2) while pulling on the arms. Be sure to hold the rails during this procedure to prevent the rails from falling.



The outer rails can be separated from the inner rail by pressing the buttons on the outer rails (3) and pulling the two rails apart.



Care and Maintenance

9

Care and maintenance

Instrument

519.97* Special Autoclavable Oil

After disassembly, clean the rails, arms and threaded tubes manually, e.g. by using a brush. The springs in the upper arm at button (1) should be cleaned also. Broken or damaged parts should be replaced.

The cannulated nails are intended for single use only.

After cleaning, oil the thread of the threaded tube and the two holes located next to the side buttons and reassemble the device.

The pelvic C-clamp should be checked after every use/ cleaning/sterilization to confirm that all parts move freely as intended.

The complete, sterile pelvic C-clamp should be kept ready for use in the resuscitation room.

Because the pelvic C-clamp consists of stainless steel, aluminum and a few pieces of polymer, it should always be cleaned at temperatures below 284°F (140°C), using a detergent with a pH between 7 and 9.5.



*Also available.

Implants

02.306.006 Short Cannulated Nail for Pelvic C-Clamp II



02.306.007 Long Cannulated Nail for Pelvic C-Clamp II



292.26 2.5 mm Kirschner Wire, 285 mm, trocar point

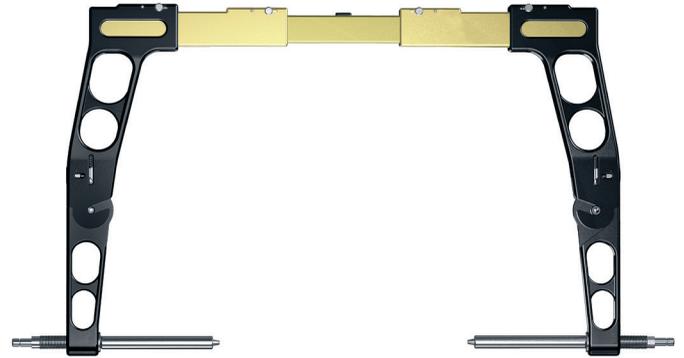


Instruments

03.306.009 2.5 mm K-Wire Insertion Handle



03.306.010 Pelvic C-Clamp II (shown with cannulated nails)



03.306.011 8 mm Protective Cap



321.20 Ratchet Wrench, 11 mm width across flats



391.93 Wire Cutter, 220 mm



398.32 Socket Wrench with Hammer



Pelvic C-Clamp II Set (01.306.000)

Graphic Case

- 68.306.000 Vario Case for Pelvic C-Clamp II
- 689.886 Bin for Vario Case, 64 mm x 29 mm x 53 mm

Contents

- 02.306.006 Short Cannulated Nail for Pelvic C-Clamp II, 2 ea.
- 02.306.007 Long Cannulated Nail for Pelvic C-Clamp II, 2 ea.
- 292.26 2.5 mm Kirschner Wire, 285 mm, trocar point, 1 pkg. of 10
- 03.306.009 2.5 mm K-Wire Insertion Handle
- 03.306.010 Pelvic C-Clamp II
- 03.306.011 8 mm Protective Cap, 4 pkgs. of 2
- 321.20 Ratchet Wrench, 11 mm width across flats, 2 ea.
- 391.93 Wire Cutter, 220 mm
- 398.32 Socket Wrench with Hammer

Also Available

- 359.204 Locking Pliers
- 519.97 Autoclavable Oil

Note: The Pelvic C-Clamp II (03.306.010) consists of:

- 03.306.000 Inner Rail for Pelvic C-Clamp II
 - 03.306.001 Outer Rail for Pelvic C-Clamp II, 2 ea.
 - 03.306.002 Upper Side Arm for Pelvic C-Clamp II, 2 ea.
 - 03.306.003 Lower Side Arm for Pelvic C-Clamp II, 2 ea.
 - 03.306.008 Threaded Tube for Pelvic C-Clamp II, 2 ea.
-

Note: For additional information, please refer to the package insert or www.e-ifu.com.

For detailed cleaning and sterilization instructions, please refer to www.depuy-synthes.com/hcp/cleaning-sterilization or sterilization instructions, if provided in the instructions for use.

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