

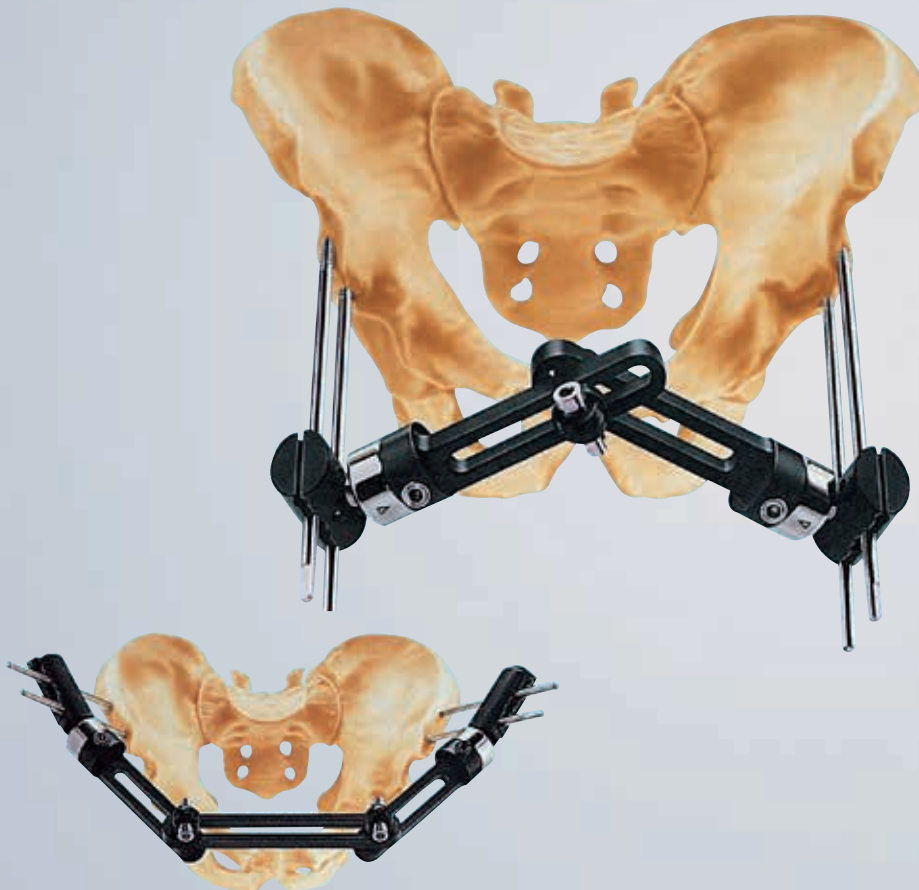
OPERATIVE TECHNIQUE

Pelvic

Fixator

PELVIC APPLICATIONS

FRACTURES AND DISRUPTIONS OF THE PELVIC RING
BY PROF. DR. D. PENNIG AND DR. L. RENZI-BRIVIO



Pelvic

Fixator

TABLE OF CONTENTS

1	CLASSIFICATION OF PELVIC RING INSTABILITIES	
3	EQUIPMENT REQUIRED	
5	PRE-OPERATIVE TECHNIQUE	
6	OPERATIVE TECHNIQUE	

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please kindly refer to the product IFU PQEFS, to the Orthofix implantable devices and related instrument IFU PQSCR, and to the reusable medical devices IFU PQRMD that contain instructions for use of the product.

Orthofix wishes to thank the following surgeons for his contribution to the development of the technique:
Prof. Dr. D. Pennig and Dr. L. Renzi-Brivio

CLASSIFICATION OF PELVIC RING INSTABILITIES

A retrospective analysis (Haeske-Seeberg, 1988) of 332 pelvic injuries in 755 multiple trauma victims was used to study the pattern of pelvic ring injuries and to develop a classification system (Pennig).

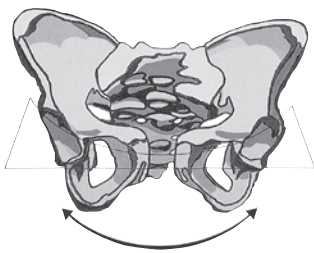
There are two main planes of instability: a horizontal plane and a vertical plane.



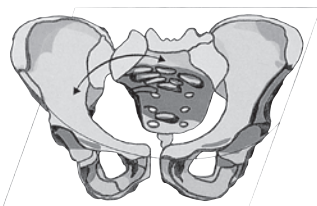
Pelvic ring instabilities are divided into three types.

Type I is defined as an **anterior horizontal instability** with a lesion of the anterior pelvic ring (symphysis pubis or pubic rami) and a stretching or rupture of the anterior portion of the sacroiliac ligaments without displacement of the posterior elements of the pelvic ring (SI joint, ilium or sacrum).

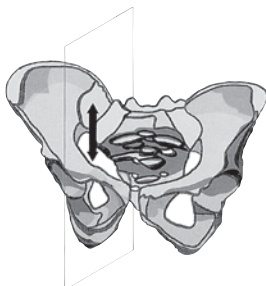
Type I Instability requires Anterior External Fixation



TYPE I. Anterior Horizontal Instability



TYPE IIA. Posterior Horizontal Instability



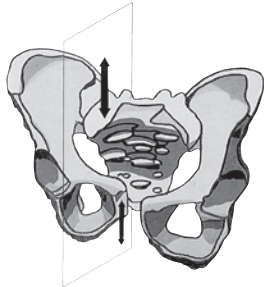
TYPE IIB. Posterior Vertical Instability

Type II is defined as a **posterior instability**, IIA being a posterior horizontal instability, IIB a posterior vertical instability. The lesion of the posterior ring consists of a fracture and/or disruption of the SI joint, ilium and/or sacrum. The anterior pelvic ring in these cases has to show no injury, or a non-significant injury without displacement.

Type II Instabilities require Posterior Internal Fixation



TYPE IIIA. Antero-Posterior Horizontal Instability



TYPE IIIB. Antero-Posterior Vertical Instability

Type III is an **antero-posterior instability**, IIIA being an antero-posterior horizontal instability, IIIB an antero-posterior vertical instability. The anterior pelvic ring in these cases shows a lesion with displacement of the symphysis pubis and/or the pubic rami. The posterior elements comprise a fracture and/or disruption of the SI joint, ilium and/or sacrum.

Type III Instabilities require:

Stage 1. Anterior External Fixation

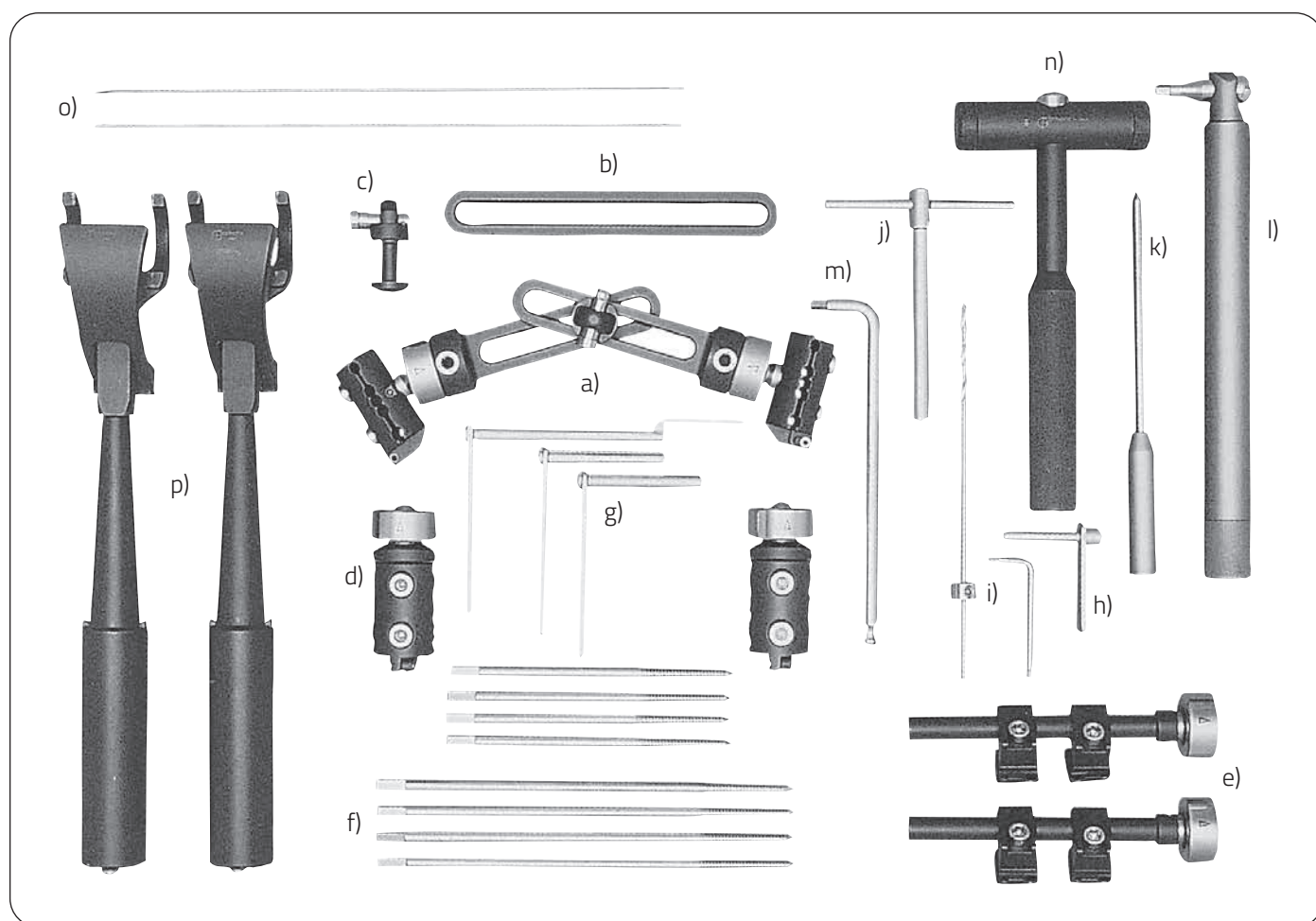
Stage 2. Posterior Internal Fixation

The classification is applied to each hemipelvis, with the POSTERIOR injury component being used to define the side of the injury.

SUMMARY OF MANAGEMENT STRATEGY

TYPE I	ANTERIOR EXTERNAL FIXATION
TYPE II	POSTERIOR INTERNAL FIXATION
TYPE III	ANTERIOR EXTERNAL FIXATION + POSTERIOR INTERNAL FIXATION

EQUIPMENT REQUIRED



a) One Pelvic Fixator for anterior application, complete with: two Primary Links (10087), one Connector Unit (10089), two Cams (10004), two Bushes (90005), two T-clamps (90007).

b) One Supplementary Link (10088), used when treating obese patients, or in patients who may need abdominal surgery and the iliac crest application has been used.

c) An additional Connector Unit (10089), for use in association with a Supplementary Link.

d) Two Straight Clamps (90006) for use in the iliac crest application.

e) Two Ball-Jointed Modules for Independent Screw Placement (10054) where the iliac crest application is used.

f) Four self-drilling screws with 6/5mm thread diameter. Where the patient is of average size 150/50 screws are recommended. In patients who are obese, or where the iliac crest application is employed, 220/50 screws should be used.

g) Two screw guides (11102 or 11103) or two special pelvic screw guides (11141)

h) One drill guide 3.2mm diameter (11106 or 11116)

i) One drill bit kit (drill bit 3.2mm diameter, stop unit and 3mm Allen Wrench) (13003)

j) T-Wrench (11000)

k) Tapered Trocar (11004)

l) Torque Wrench (10025)

m) 6mm Polyhedral Allen Wrench (10017)

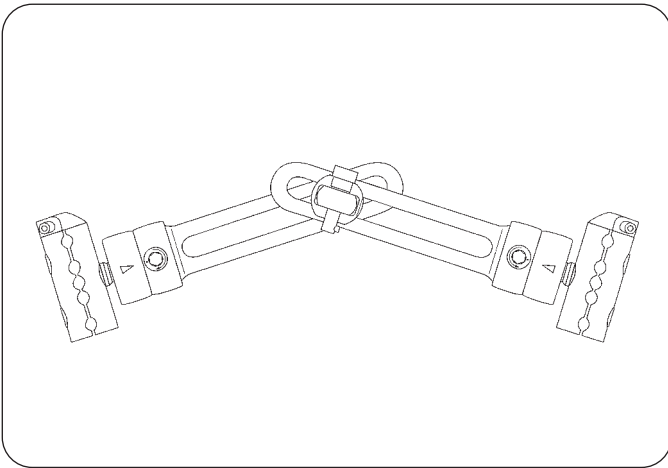
n) Hammer (11111)

o) Two Kirschner wires, 1.6mm diameter

p) Reduction Forceps (11201)

FIXATOR ASSEMBLY

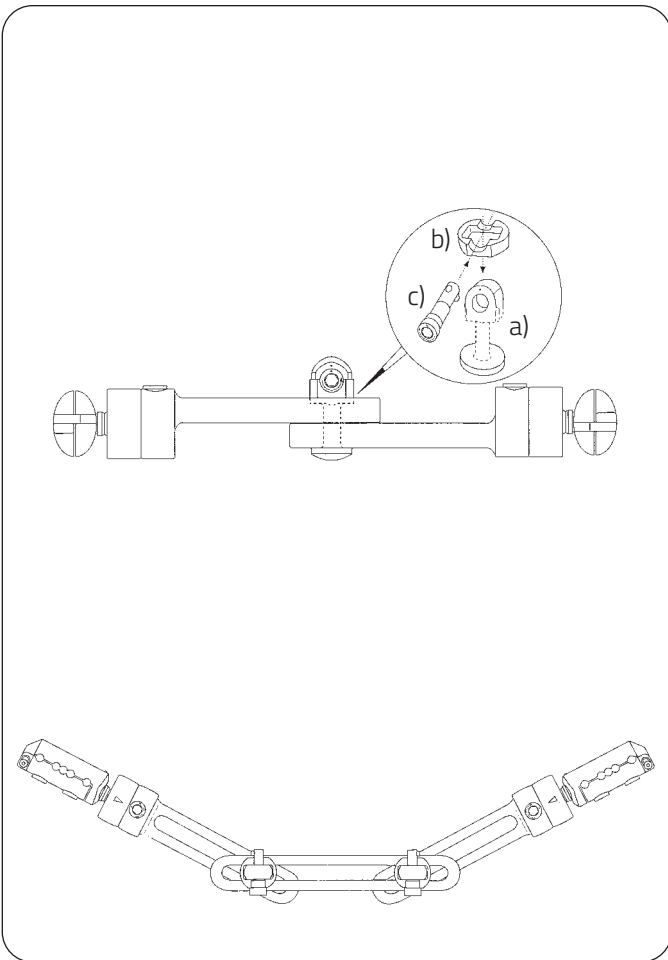
The fixator consists of two primary links with ball-joint attachment.



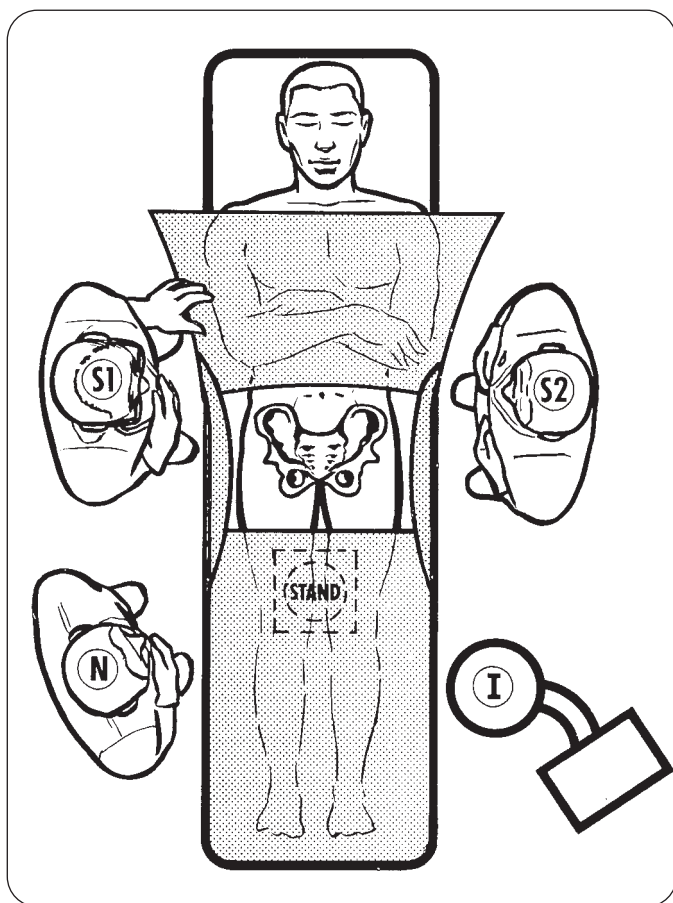
The primary links are joined via a connector unit which comprises:

- a) a connector post
- b) a grooved bush
- c) a self-retaining cam

To ensure that the clamps for the bone screws are correctly aligned when the fixator is assembled, the links must be presented to one another as shown above, one with the step beneath the collar facing upwards, and one with the step facing downwards. When assembling the fixator, insert the connector post into the two primary links and apply the grooved bush over it. Insert the self-retaining cam, with its pin facing downwards, from the side of the larger groove. If the pin at the extremity of the cam is not facing downwards, insertion of the cam is not possible. Slight rotational movements of the self-retaining cam may be needed to introduce it fully.



When a supplementary link is used the two primary links are attached to the same side of the supplementary link with the step beneath the collar of each primary link facing the same direction.



PRE-OPERATIVE TECHNIQUE

Please kindly refer to the product IFU PQEFS, to the Orthofix implantable devices and related instrument IFU PQSCR, and to the reusable medical devices IFU PQRMD that contain instructions for use of the product.

The Pelvic Fixator is compatible with Standard bone screws, Titanium bone screws, Standard coated bone screws, Self-drilling coated bone screws, Self-drilling bone screws, Transfixing Pins.

In positioning the patient, ready access of the Image Intensifier to allow AP imaging of the pelvis must be ensured pre-operatively, and the patient is moved on the operating table if necessary. The patient should be in the supine position and lower abdomen and proximal femora are shaved and disinfected. Draping is then carried out, leaving free access from the umbilicus to the pubic area. The Image Intensifier (I) is positioned opposite the surgeon (S1), who should begin with the uninjured side. One assistant (S2) is required and the scrub nurse (N) should work from the same side as the surgeon. The legs of the patient should be accessible to allow an unscrubbed assistant to help with the reduction.

OPERATIVE TECHNIQUE

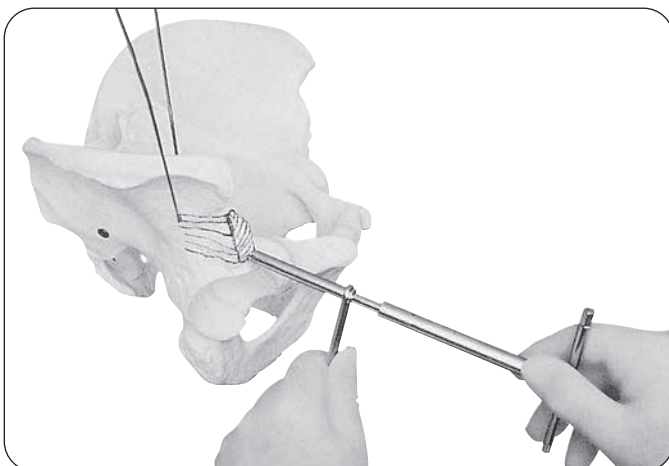
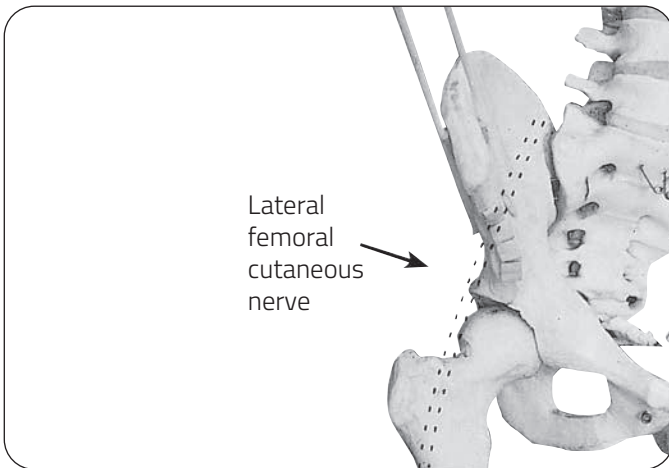
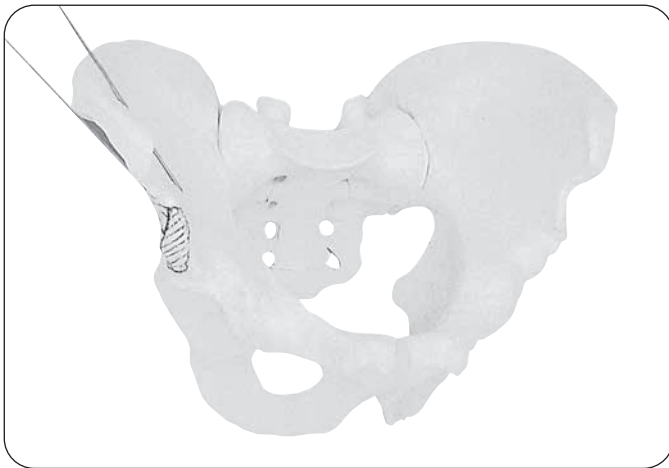
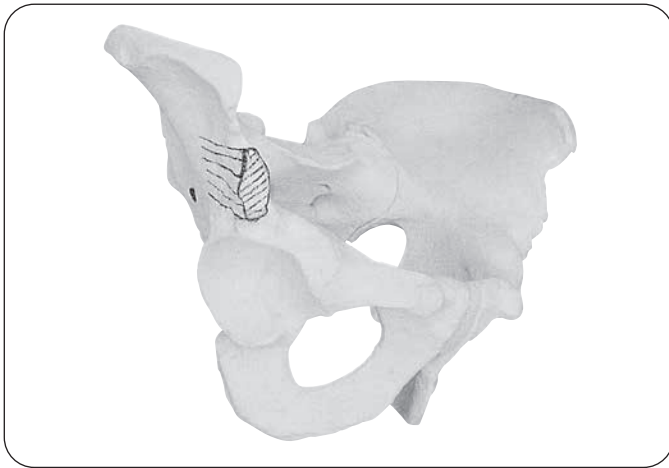
A. ANTERIOR APPLICATION

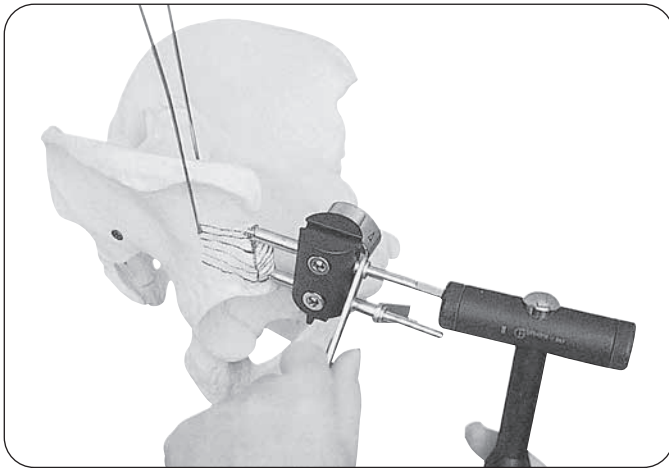
It is always advisable, where possible, to commence with the uninjured side, especially on the first few occasions that the external fixator is applied. The landmark for screw insertion is the anterior superior iliac spine which can be easily palpated. The screws should be inserted between the inferior and the superior iliac spines, starting with the screw at the level of the anterior inferior iliac spine. Screws should be angled slightly upwards to avoid penetration of the acetabulum and to allow the fixator body to be positioned in line with the anterior pelvic ring.

To establish the orientation of the hemipelvis, which may be significantly rotated externally (most likely) or internally, a pair of Kirschner wires (1.6mm) should be used. The first Kirschner wire is inserted from the iliac crest along the inner table of the ilium, while the second Kirschner wire is inserted along the outer table of the ilium.

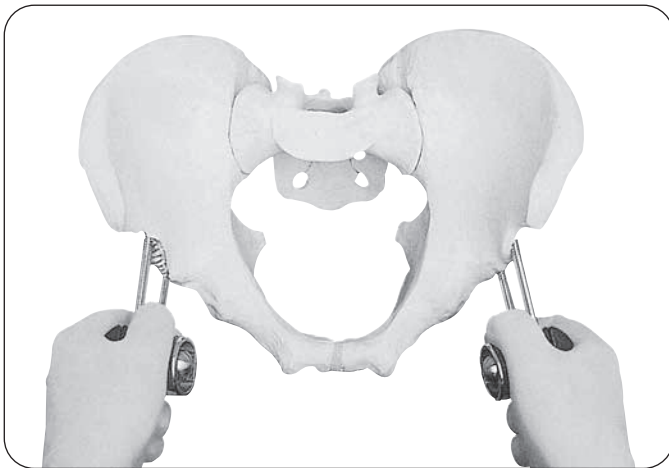
Once the position of the hemipelvis has been established, a short, 3cm incision should be made, starting just below the anterior superior iliac spine. The lateral femoral cutaneous nerve must be protected from injury, by means of Langenbeck retractors. The bone should be exposed, and the screw guide for the first bone screw inserted down to the bone, taking account of the orientation provided by the two Kirschner wires.

A self-drilling, self-tapping screw with its long axis in the SAGITTAL PLANE, should be hammered through the cortex with gentle taps and then screwed home with the T-wrench. It is of the utmost importance not to force the screw in any direction, but rather to let it find its way between the inner and outer tables of the ilium. The depth of insertion is 40-50mm, which is almost the entire thread length.

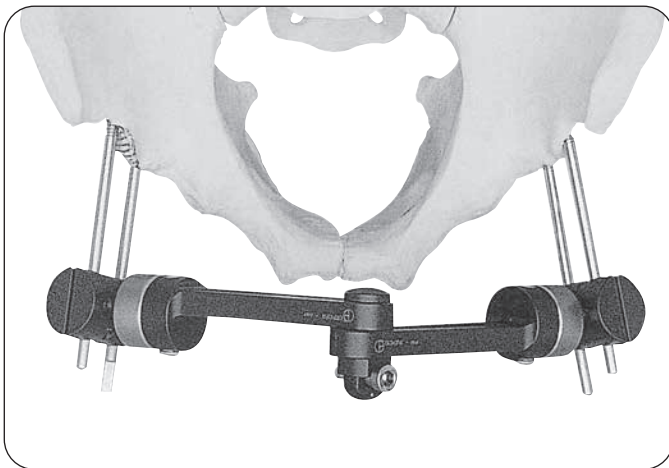




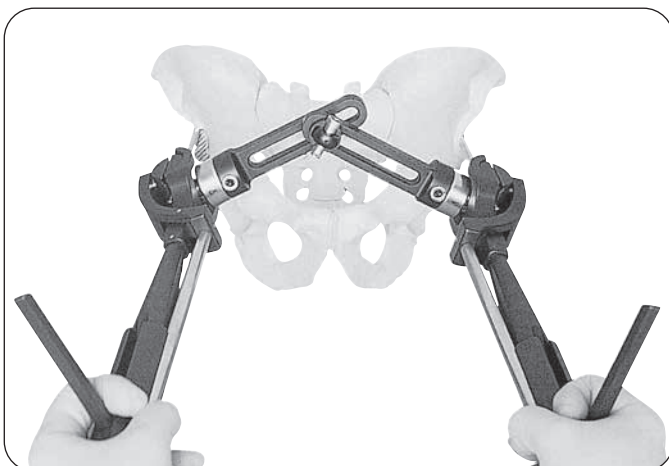
The first screw, in its screw guide, is now housed in the first seat of the T-clamp. The second screw should be placed about 2cm proximal to the first screw, which will correspond to the third or fourth clamp seat above it. It is important to make sure that the screw is not forced outside the pelvis. After a certain amount of practice, it may be preferable to insert the screws parallel to one another in both planes, free-hand. In case of hard cortex the use of a drill bit (3.2mm) to penetrate the cortex to a depth of 1cm, may be necessary. If a drill bit is used, this power instrument should be handled with extreme care, and a drill guide must be employed to protect the soft tissues.



When both screws have been inserted into the first hemipelvis, the procedure is repeated for the opposite hemipelvis. When choosing screw direction in the injured hemipelvis, its rotation must be taken into account. Once the second pair of screws has been inserted, both pairs should be grasped firmly to ensure that they will be able to withstand the loads exerted upon them by the fixator during the process of reduction. Should there be any doubt about the appropriateness of screw placement, an X-ray may be taken at this stage.



T-clamps should be mounted on each pair of screws at a similar distance from the skin. The fixator is now applied and reduction carried out. To ensure that the clamps for the bone screws are correctly aligned when the fixator is applied, the links must be presented to one another as shown, with the steps beneath the collars pointing in opposite directions.

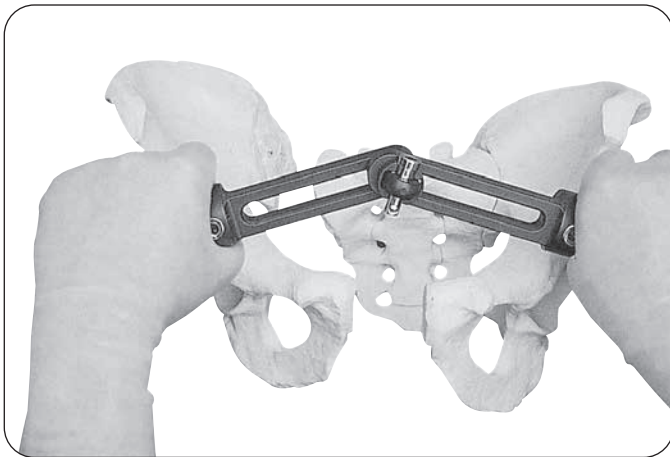


To assist reduction, which in most cases implies internal rotation of the injured side, the legs may be used to gain leverage. Reduction can be accomplished with the manipulation forceps, which distance the surgeon's hands from the X-ray beam.

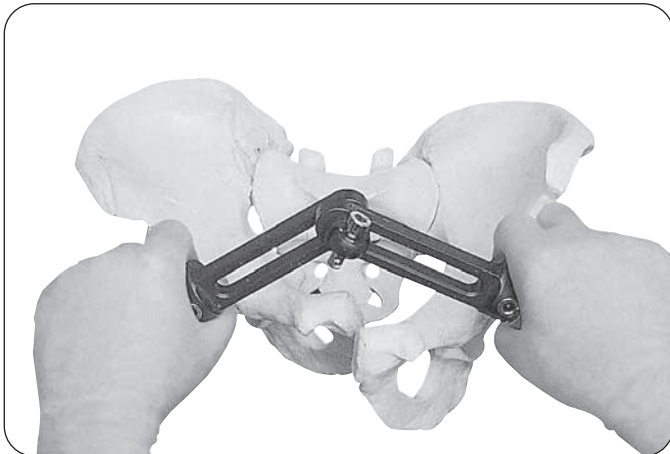


With the ball-joints and connector unit cam unlocked, reduction of the following types of pelvic displacement can be achieved under image intensification.

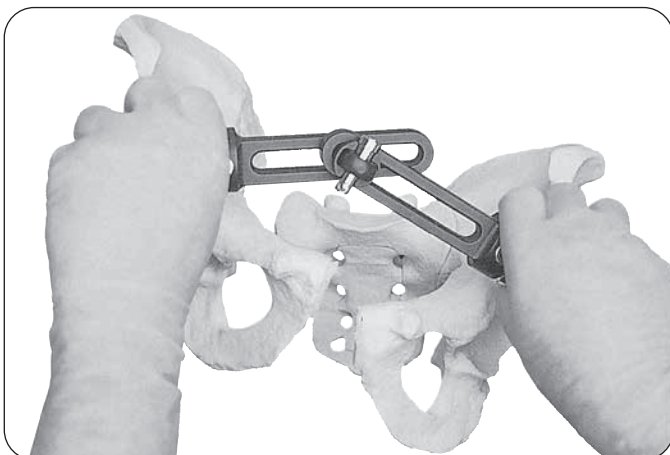
Type I injury [open book] (see also page 2).



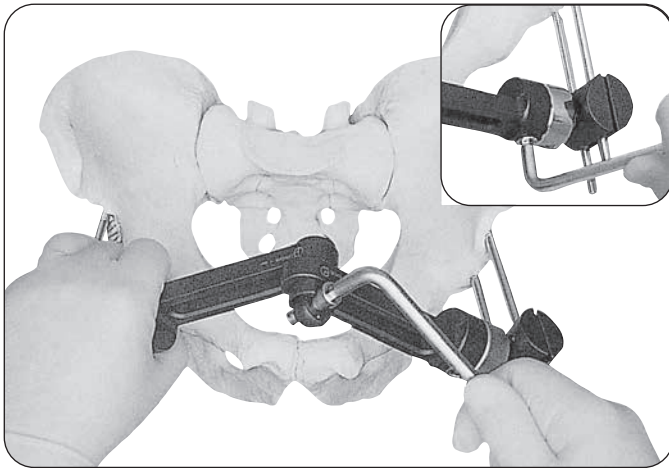
Type IIIA injury with external rotation of the hemipelvis [antero-posterior horizontal instability] (see also page 3).



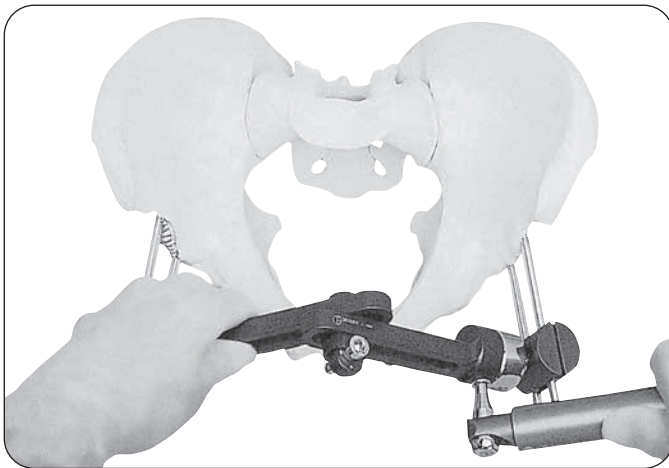
Type IIIA injury with internal rotation of the hemipelvis [antero-posterior horizontal instability].



Type IIIB injury [antero-posterior vertical instability] (see also page 3).



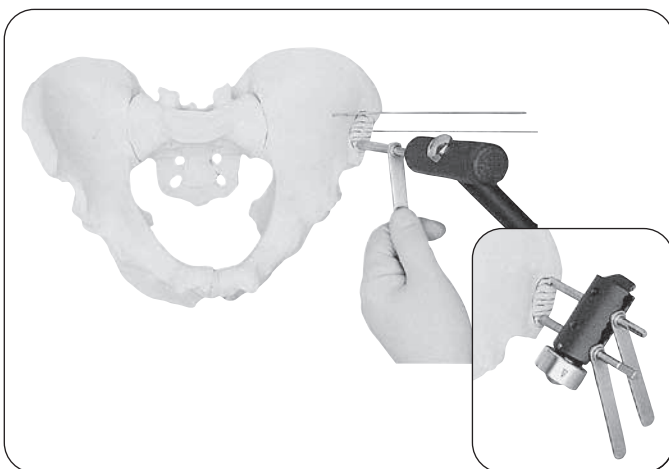
The nature of the fixator with its ball-joints and sliding links is such that it was possible to simulate all of the above examples of pelvic displacement starting from the neutral position shown opposite. After reduction has been achieved, the connector unit cam and the ball-joints are tightened with the Allen wrench.



It is important to make sure that the minimal distance between the fixator and the skin in all circumstances is more than 5cm, to allow for the bowel distention which commonly occurs during intensive care management of these patients. Should it be necessary, the fixator can be adjusted to take account of abdominal distention by loosening the clamp screws and moving it away from the pelvis, following which, the clamp screws are re-tightened. Final locking of the ball-joints is performed with the torque wrench.

B. ILIAC CREST APPLICATION

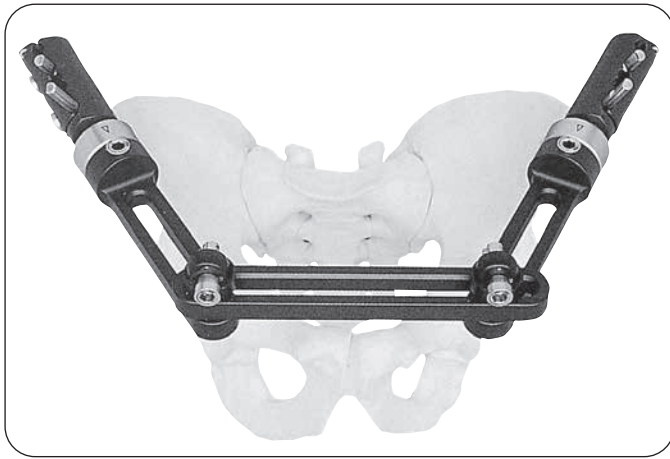
If it is desired to use this approach, there are certain technical aspects to be considered. Whereas the iliac crest itself has a diameter of 10-15mm, immediately below the iliac crest the diameter of the bone is often less than 5mm (distance between the two cortices). The likelihood of penetrating either the inner or the outer table is therefore considerable. In addition to the above, mention has already been made of the fact that reduction of pelvic displacement from the top rather than the front, is more cumbersome (compare closing a book from the top, or the front).



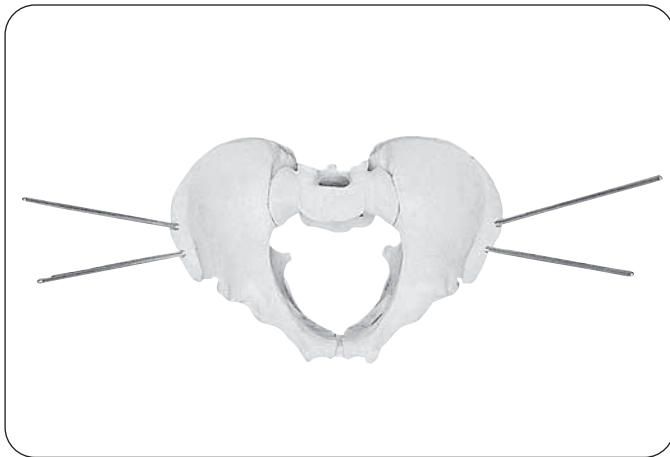
Application with Straight Clamps

Screws (220/50) should be inserted at an angle of 45° to the long axis of the body through a 3-4cm incision over the iliac crest. The first screw is inserted 1.5-2.0cm posterior to the anterior superior iliac spine through a screw guide.

The straight clamp is then mounted on the screw guide, and the second screw inserted about 2cm posterior to the first. Because of the hardness of the iliac crest, especially in patients with hard cortex, the path for the screws should be predrilled using a 3.2mm drill bit.

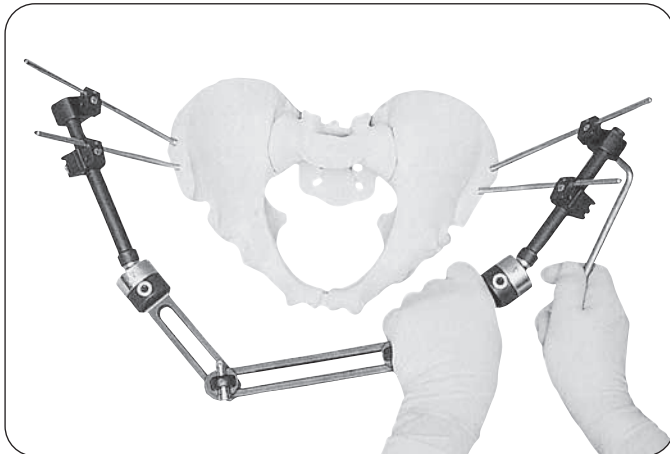


The procedure is then repeated on the opposite side. The fixator is applied and reduction carried out.

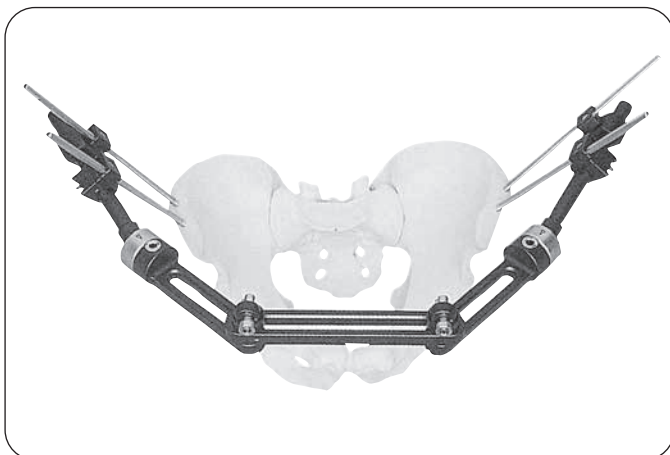


Application with Ball-Jointed Modules for Independent Screw Placement

Since the iliac crest is a curved structure, some surgeons may wish to have the option of placing screws other than parallel to one another in a straight line. Thus, they may choose to insert screws in the center of the crest where there is superior bone stock, and at angles which will allow them to find the ideal path between the inner and outer tables of the ilium. This may be achieved using Ball-Jointed Modules for Independent Screw Placement. Where these modules are used, screws are inserted freehand through a screw guide in the preferred positions.



They are then introduced into independent screw clamps (10055) which are locked both to the screws and to the bar of the Ball-Jointed Module on which they slide, by a single nut.



Reduction is then carried out in the usual manner (see pages 8-10).

Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, possible adverse events, MRI (Magnetic Resonance Imaging) safety information and sterilization.

Electronic Instructions for use available at the website <http://ifu.orthofix.it>

Electronic Instructions for use - Minimum requirements for consultation:

- Internet connection (56 Kbit/s)
- Device capable to visualize PDF (ISO/IEC 32000-1) files
- Disk space: 50 Mbytes

Free paper copy can be requested from customer service (delivery within 7 days):

tel +39 045 6719301, fax +39 045 6719370,

e-mail: customerservice@orthofix.it

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.



Manufactured by:
ORTHOFIX Srl
Via Delle Nazioni 9, 37012 Bussolengo
(Verona), Italy
Telephone +39 045 6719000,
Fax +39 045 6719380
www.orthofix.com

Rx Only

CE 0123

Distributed by:

