



Traumacentrum, KN Liberec, a.s. (Regional Hospital in Liberec)

The surgical technique was developed within the cooperation between the company MEDIN and Regional Hospital in Liberec. The method was invented by the Head Physician, MD Jaroslav Šrám and MD Stanislav Taller, Regional hospital in Liberec, with the co-author of the CT-defined projection of the pelvic entrance, Head Physician, MD Ladislav Endrych, RDG department at RH in Liberec.

Bibliography:

ŠRÁM J., TALLER S., LUKÁŠ R.: **Use of the Omega Plate for Stabilisation of Acetabular Fractures: First Experience.** Acta chirurgiae orthopaedicae et traumatologiae Čechoslovaca, 80, 2013, p. 118-124.

TALLER S., ŠRÁM J., LUKÁŠ R., KŘIVOHLÁVEK M.: **Surgical Treatment of Pelvic Ring and Acetabular Fractures Using the Stoppa Approach.** Acta chirurgiae orthopaedicae et traumatologiae Čechoslovaca, 77, 2010, 93-98.

Description of the medical device

It is an OMEGA pelvic plate, which allows stabilising most fractures of the acetabulum. By fixation to fixed sections of the pelvic ring, it temporarily replaces the unstable part of the circle in the area of the injured acetabulum. Through its quite large area and rigidity, it completes the repositioning and prevents further protrusion of fragments into the small pelvis area (Fig. 1 a, b).

Surgery kit consists of implants and surgery instrumentarium.

PLATES

There is a set of plates designed separately for the left and for the right side. There are 4 types of plates for each side in total. Each plate differs by the number of holes and by design. Plate design and customized mechanical properties of the material allow it's shaping. The plates are made of implant steel in accordance with ISO 5832-1; their thickness is circa 3 mm.

Between the holes, there are thinned sections (necks) to facilitate bending for shaping of the plate. To attach the plate to the bone, plates are provided with countersunk holes for the heads of the bone screws. The fixings are also provided with holes and allow for securing the plate in a second plane after shaping. The plates are available in BASIC, ILIAC, LONG and MAXI design. All these types are available in left and right design. The dorsal side of the plate features oval holes with a special finish for easy insertion of screws to tilt up to 45°.

OMEGA Pelvic Plates

a) OMEGA basic Pelvic Plate:

OMEGA basic Pelvic Plate, left 397 129 70 4160

OMEGA basic Pelvic Plate, right 397 129 70 4170

The plate is designed for most fractures of the anterior columns of the acetabulum, quadrilateral area, fractures above *linea arcuata*, as well as lateral fractures of the upper branch of the pubic bone.

Plate design is based on the shape of the direct pelvic plate with a bow-shaped extension, resembling the reversed letter omega. This part of the plate features three holes that allow shaping of the plate and using the fixation screw in the rear of the arch. The centre hole is not designed for screw insertion; it serves as a support for an instrument – ball spike, at the repositioning and fixation of the plate.

Two pressure fixings above the plate arch stabilise fragments above the *linea arcuata* and serve as inverted „spring plates“. Dorsal part of the plate features four oval holes with one fixing. Front part of the plate feature six holes for screws and four fixings.

b) OMEGA ILIAC Pelvic Plate:

OMEGA ILIAC Pelvic Plate, left 397 129 70 4190

OMEGA ILIAC Pelvic Plate, right 397 129 70 4200

The plate is designed for acetabular fractures extending into the posterior column. Using the attached iliac access you can insert a long screw through one of the dorsal fixings and stabilise simple fractures in the posterior column area of the acetabulum (Fig. 9).

ILIAC plate design is based on the basic design of OMEGA plate. Its dorsal part is extended by two more fixings.

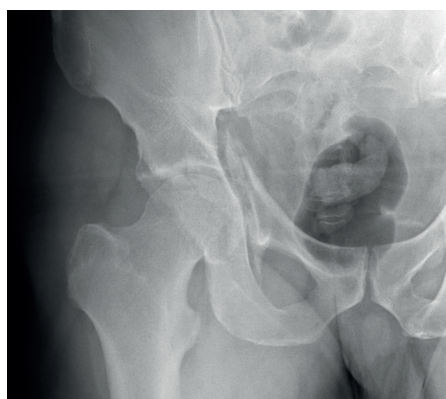
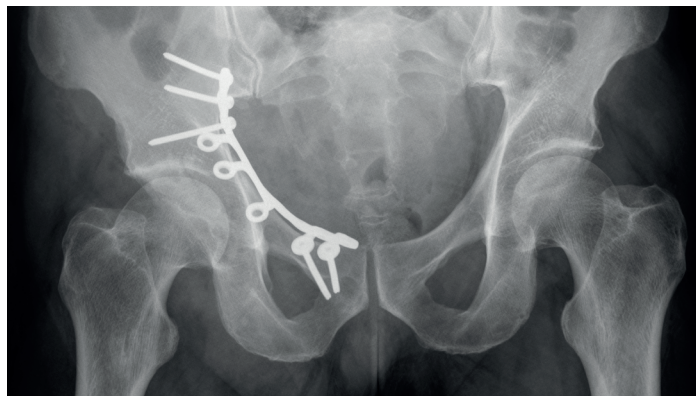
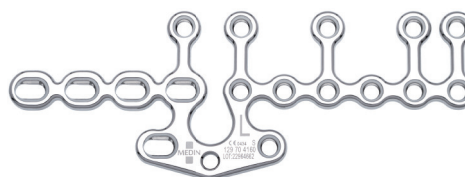


Fig. 1 a, b: X-ray images



OMEGA basic Pelvic Plate



left
129 70 4160



right
129 70 4170

OMEGA ILIAC Pelvic Plate



left
129 70 4190



right
129 70 4200

OMEGA PELVIC PLATES

c) OMEGA LONG Pelvic Plate:

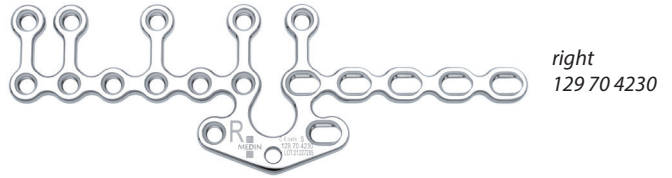
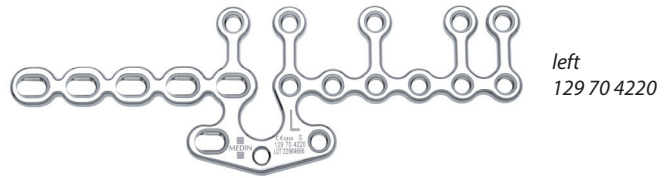
OMEGA LONG Pelvic Plate, left 397 129 70 4220

OMEGA LONG Pelvic Plate, right 397 129 70 4230

The plate is designed for large pelvises in cases where the basic design of OMEGA pelvic plate is not sufficient.

LONG plate design is based on the basic design of OMEGA plate. Its dorsal part is extended by an additional oval hole in the body of the plate.

OMEGA LONG Pelvic Plate



d) OMEGA MAXI Pelvic Plate:

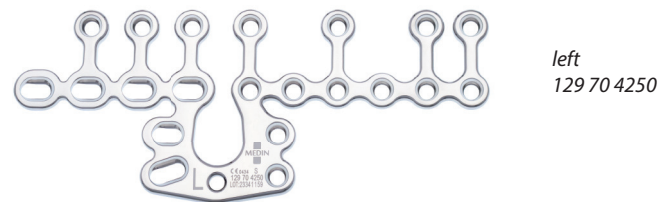
OMEGA MAXI Pelvic Plate, left 397 129 70 4250

OMEGA MAXI Pelvic Plate, right 397 129 70 4260

The plate is designed for the severe damage of the quadrilateral area. In appropriate indications the implant can only be used to stabilise the posterior column using the modified Stoppa's approach, where two screws are introduced through two holes of the posterior arch of the plate.

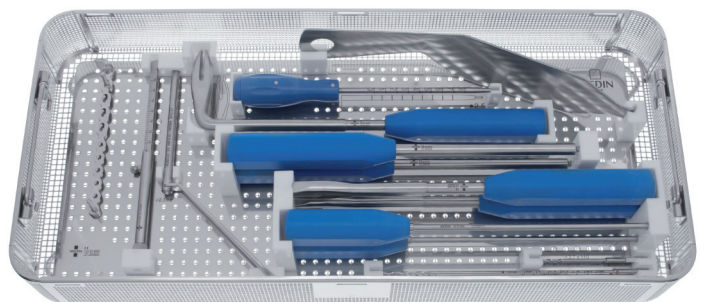
MAXI plate design is based on the design of OMEGA ILIAC pelvic plate. Omega-shaped extension is magnified and allows insertion of screws into the two posterior holes of the plate arch, with the lower edge hole positioned at an angle.

OMEGA MAXI Pelvic Plate



Instrumentarium for OMEGA plate

Instrumentarium is selected so as to allow shaping of the plate and the introduction of fixing screws. Special instruments for plate shortening or special benders are not included in the instrumentarium.



Acetabular fracture surgery using OMEGA Pelvic Plate

1. Indication

OMEGA plate is indicated for the fractures listed below:

- Transverse acetabular fractures
- T-shaped fractures of the acetabulum
- Fractures of the anterior wall and anterior column of the acetabulum
- Complex fractures of the acetabulum
- Fractures of the posterior wall and posterior column of acetabular cup

2. Contraindication

- Insufficient quantity or quality of bone, which may prevent correct fixation of bone.
- Any fully developed or purported latent infection in the surgical area or in its vicinity.
- Previous stages of infections.
- Any mental disorder or neuromuscular disease of the patient, which may result in unacceptable risk related to fixation failure or complications in the postoperative period.
- Reduced bone stock, impaired by disease, infection or prior implantation, which cannot provide proper support for implants.
- Impaired vascularity, which may prevent the necessary blood supply to the fracture or surgery site.
- Malignant growths in the fracture site.
- All cases where the medical product is in conflict with anatomical structures or physiological functions.
- Using a steel implant if the patient is allergic to nickel (documented or suspected allergy).
- Obesity or overweight patient.

3. Preoperative planning and preparation of the implant

3.a. CT-defined (CTD) projection of the pelvic entrance

Exact CT projection of pelvic entrance with the mark of the centre of the acetabulum is obtained from computer processing of the preoperative CT examination. CTD projection of the pelvic entrance uses anatomical correlates, usually based on uninjured side of the pelvis. Slice thickness is 5 mm, the angle of the slice is determined by the line that begins on the upper edge of the symphysis in its anterior part and extends to 10 mm below the level of the tympanic promontory in its posterior part. Then the slice is moved symmetrically in bilateral distal direction with the centre on the upper quarter of the femoral head (Fig. 2, 3). CTD projection of the pelvic entrance after its modification to the real size (using the scale on the CT image) and after mirror inversion allow precise shaping of the plate before surgery. Correct size of the plate is determined by precise measuring from the centre of the acetabulum dorsally and ventrally. Using the plate modelled based on mirrored CTD projection of the uninjured pelvis side is accurate in 68 %. Minor differences in the length (up to 4 mm) are not very significant, minor differences in curvature (up to 3 mm) are compensated by the flexibility of the plate. These two categories include 82 % of all patients. Adjustment of greater differences between the modelled plate and anatomy and possible modification of the angle of the pressure fixings facilitates the surgical procedure, which allows repeated removal and modification of the plate shape using the appropriate instrumentarium.

3.b. Shaping of the OMEGA plate before surgery

Plate type must be selected and precisely modelled before the surgery based on the CT-defined projection of the pelvic entrance. Pressure fixings of the plate above the acetabulum are bent at an angle of about 70°. Fixings with screw holes in the pubic bone's upper branch level are bent at an angle of almost 90° (Fig. 4). In detail below: 5. Preoperative modelling of the plate.

Note: The Company MEDIN a.s. in Nové Město na Moravě, offers accurate bending of plates and fixings based on received CTD projections of the pelvic entrance. If interested, please contact our sales representative.

Fig. 2: process to obtain a CT-defined projection

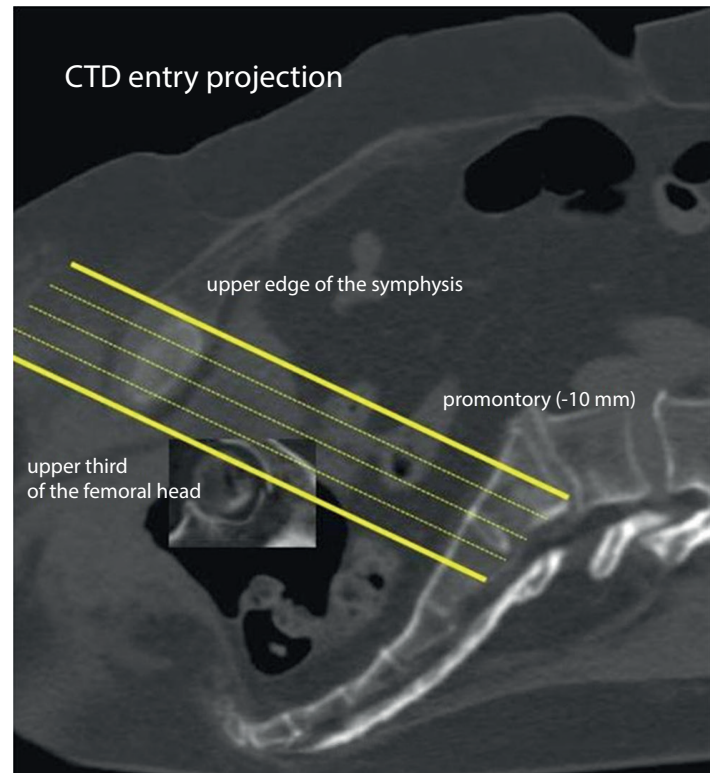


Fig. 3: resulting projection

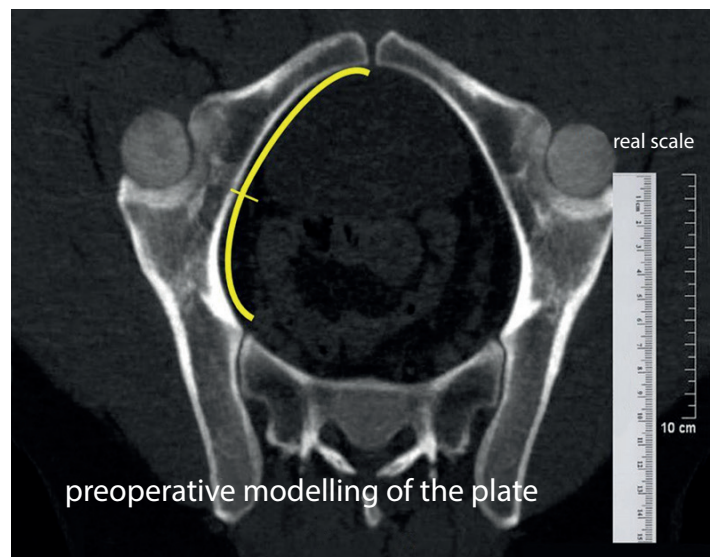


Fig. 4: shaped OMEGA plate



4. Surgical technique

4.a. Position of the patient

For surgery performed using Stoppa's approach only, the patient lies on the operating table in the supine position. The position of the patient must enable the use of a mobile X-ray equipment to perform basic projections (anteroposterior and lateral) and oblique projections (inlet, outlet and both oblique projections of the operated acetabulum).

4.b. Surgical approach

In multiple displaced fractures of the posterior column, the surgery usually starts from the back Kocher-Langenbeck approach. Exact repositioning and stabilization of fragments then usually follows using the plate technique. When inserting the screws into the proximal plate holes, it is necessary to ascertain possible future conflict with the dorsal screws of OMEGA plate.

If surgery is not necessary from the posterior approach, then according to the type of acetabulum fracture, fracture repositioning in the area of *crista iliaca* should first be performed, where individual fragments are repositioned and fixed through an open approach. The surgeon will consider, whether to perform rigid internal fixation using a plate or semi-rigid surgery, for example 2 screws with cerclage, which allows additional correction of repositioning after using modified Stoppa's approach. Depending on fracture type, K-wires or a single cannulated screw may be inserted in the anteroposterior direction percutaneously in the supra-acetabular area.

Using the modified Stoppa's approach (Fig. 5, 6) fragments of the upper branch of the pubic bone, fractures in the anterior acetabular column, quadrilateral area fractures and those around *linea arcuata* are subsequently repositioned and temporarily fixed with K-wires. OMEGA plate is also introduced using this approach.

Fig. 5: placement of hooks: A – Hohmann's hook with a sharp spike driven into the area above *linea arcuata*, B – Special blunt-tipped wide hook introduced almost into foramen infrapiriforme, C – Perpendicular hook protects and pulls away *vasa iliaca ext.* (adopted from: Léčení zlomenin pánve a acetabula.)

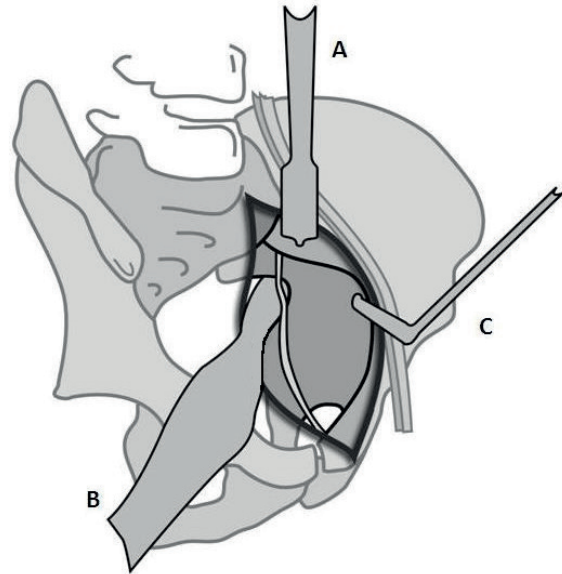
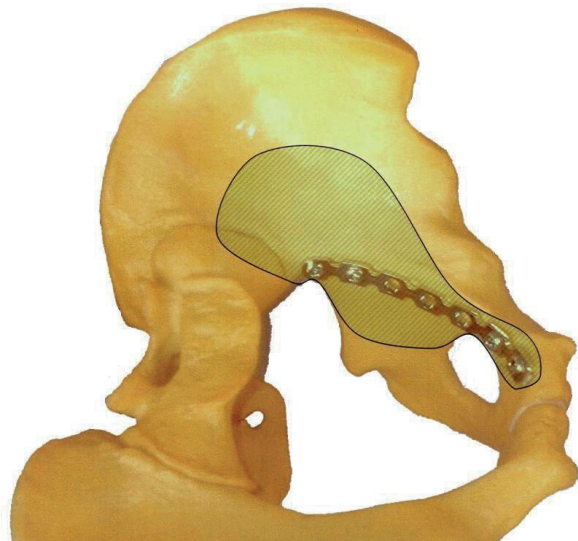


Fig. 6: range of area accessible by Stoppa's approach



4.c. Repositioning

For precise final repositioning it is very convenient to shape the plate prior to surgery based on the CT image of the other, uninjured side of the pelvis. This allows for faster and easier surgery, as well as more accurate repositioning of individual bone fragments.

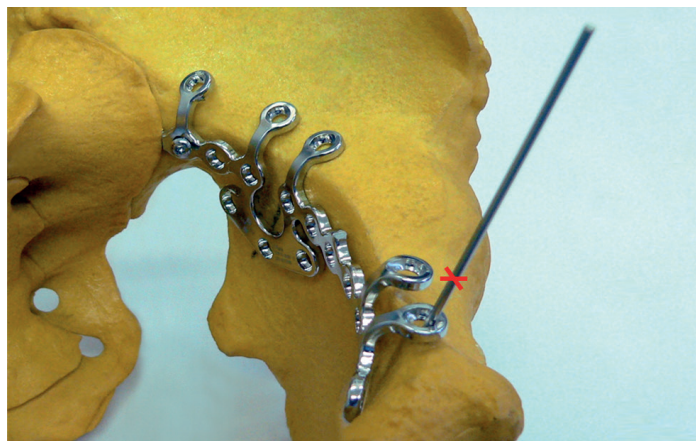
4.d. Final shaping of the plate

If the plate has not been shaped prior to the surgery (recommended), then use of a shaping tape which is included in the instrumentarium can facilitate shaping of the plate during the surgery. This can be easily modelled based on the anatomy and then shape the plate accordingly. **The tape, however, must never be used as an implant.**

4.e. Plate Location

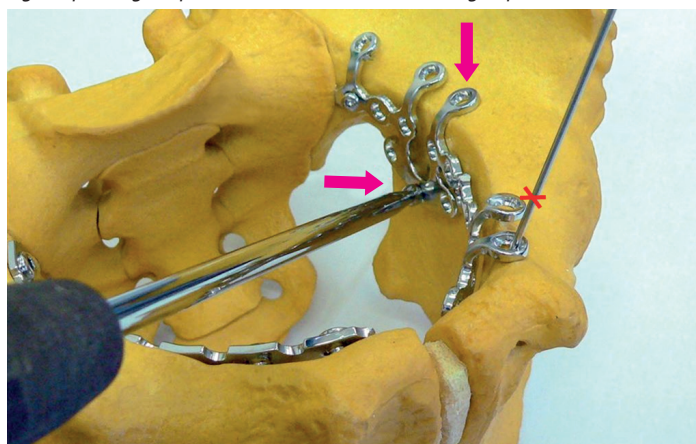
After marking the symphysis location, e.g. using the injection needle, the pre-modelled plate **OMEGA L/R**, or **OMEGA LONG L/R** is inserted into the area below *linea arcuata*. The front plate fixing located just next to the symphysis is temporarily fixed with a K-wire, thus providing accurate centring of the plate (Fig. 7 a).

Fig. 7a: plate insertion and fixation with a K-wire



Any necessary correction of plate shape and degree of fixings bending can be done by removing the plate when leaving the already inserted and shortened K-wire in place. Using the pelvic spike, the pelvic arch of the plate is pushed to the quadrilateral area and at the same time, the pressure fixings are pushed above the upper edge of *linea arcuata*. Intense pressure on pelvic spike is used to complete the final repositioning (Fig. 7 b).

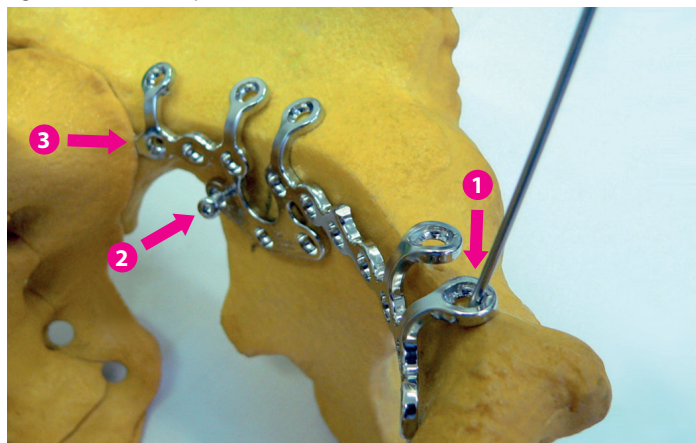
Fig. 7b: pushing the plate in the arrows' direction using a spike



4.f. Fixation of the plate with bone screws

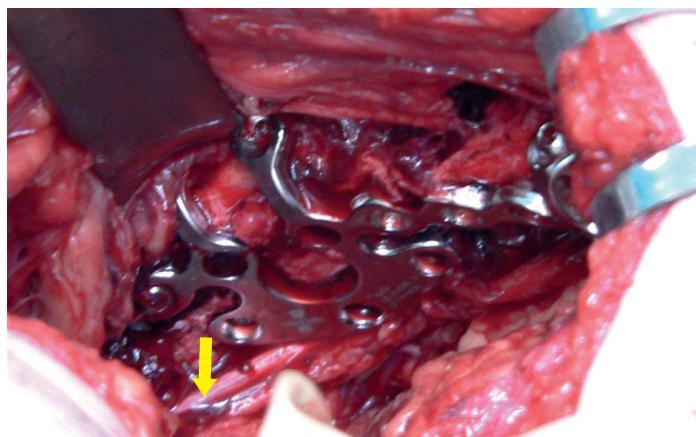
The plate is fixed with the first screw, which is inserted into the fixing just next to the symphysis and not fully tightened. The next screw inserted through the hole in the posterior part of the OMEGA plate arch to the posterior acetabular column pushes the plate arch firmly against the quadrilateral area, while the pressure fixings stabilise the fragments above *linea arcuata* (Fig. 7 c).

Fig. 7c: fixation of the plate with screws



Screws into the dorsal part of the OMEGA plate and other screws follow. During the entire surgery *nervus obturatorius* must be carefully protected (Fig. 8).

Fig. 8: plate in situ with highlighted location of *n. obturatorius*



4.g. Plate type selection

When choosing the type of OMEGA pelvic plate, follow the recommendations above in the description of individual types of plates.

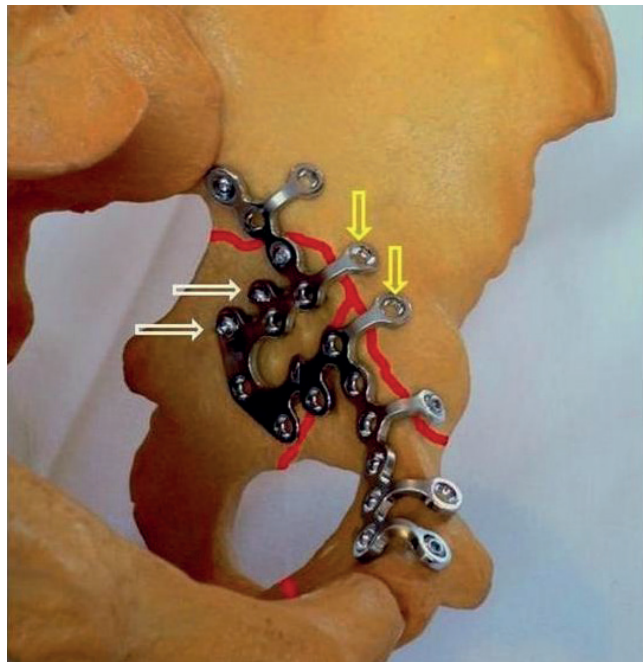
Using the attached iliac access one can insert a long screw through one of the dorsal fixings of **OMEGA ILIAC** pelvic plate and stabilise simple fractures in the posterior column area of the acetabulum (Fig. 9). The correct position of the screw introduced into the posterior column must be checked visually and with C-arm.

Fig. 9: model of the pelvis with a screw inserted into the posterior column



In appropriate indications the plate with enlarged posterior arch **OMEGA MAXI** can be used to stabilise the posterior column using only the modified Stoppa's approach, where two screws are introduced through both holes of the posterior arch of the plate (Fig. 10).

Fig. 10: stabilization of the posterior column using plate OMEGA MAXI



Basic principles of proper function of OMEGA plate:

The basic condition for the proper function of the OMEGA plate is its secure fixation against stable parts of the pelvic ring. In the posterior segment, it is necessary to introduce the screws into the bone, which is firmly connected to an intact sacroiliac joint or the bone, which is already stable after internal fixation. You can also consider the possibility of fixation of the last dorsal screw into the lateral part of the sacrum.

In the front section of the plate, secure fixation to the upper branch of the pubic bone, which is connected to a fixed symphysis, is fundamental.

During the entire surgery *nervus obturatorius* must be carefully protected.

Acetabular osteosynthesis of the pelvis can be supported by straight or curved pelvic plates. Percutaneously introduced cannulated screws can also be used.

OMEGA pelvic plate is not a fully supportive implant. It only serves as a fixation element for the healing period. It is allowed to fully bear weight on the injured pelvis after the bone has completely healed.

5. Customized modelling of the plate based on CTD image

Only at the request of the hospital.

- Accurately determine the correct size of the pelvic entrance by comparing pelvic entrance CTD projection scale with a real measure (Fig. 11);
- The modelling is usually carried out based on the uninjured side, be careful not to swap sides;
- Define the centre of the acetabulum (the point of greatest bone thinning) based on the real size of the pelvic entrance, determine the symphysis and sacroiliac joint;
- Optimal position:** centre of the OMEGA Plate arch should be in the centre of the acetabulum, with the ventral plate part just next to the symphysis;
- Variation:** it is possible to move the centre of the arch of OMEGA Plate from the acetabular centre by circa 5 mm in ventral direction and by 10 mm in dorsal direction to achieve location of the plate just next to the symphysis;
- In case of inappropriate anatomical proportions, it is necessary to keep the centre of the arch of the OMEGA Plate at the acetabular centre. Then you must **determine precisely** in mm the **distance between the ventral part of the plate and symphysis** (red marked – Fig. 12);
- Bend the fixings in the ventral part of the plate at an angle of about 80 °, fixings above the arch (pressure fixings) at an angle of about 70 °, fixings in the dorsal part of the plate (ILIAC type) at an angle of about 55 °;
- The length of the dorsal section is decisive in terms of using the OMEGA LONG type. Unless there are compelling reasons, the dorsal plate end **should not exceed the sacroiliac joint**;
- Consider using the variants of the OMEGA plates ILIAC or MAXI.

Notes:

- when modelling the plate, avoid reverse bends of the plate
- perform bends in the largest arch possible

Fig. 11: real scale matched to the CTD pelvic screening scale. Determining the center of the acetabulum (transverse line), symphysis and sacroiliac joint.

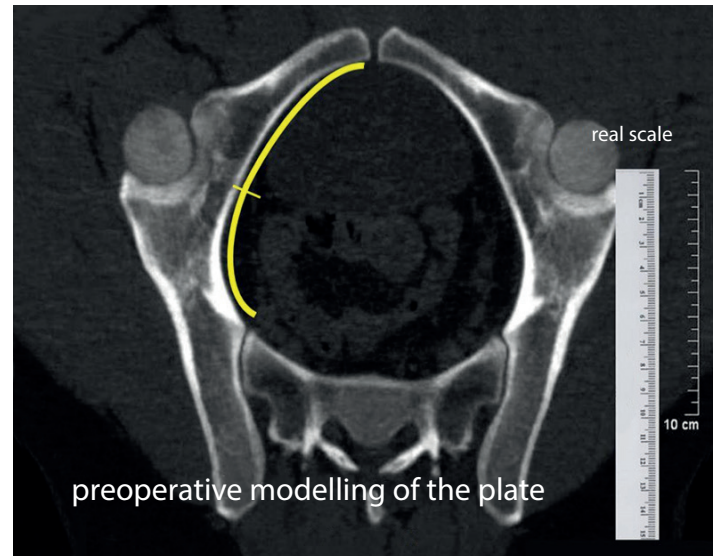
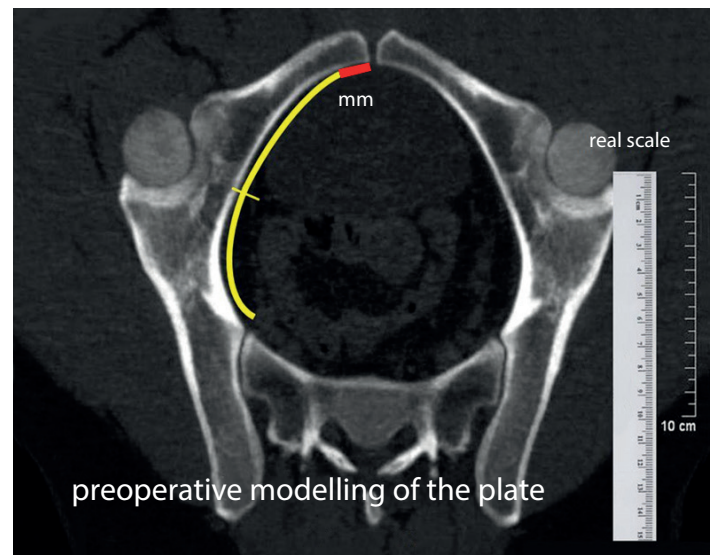


Fig. 12: optimal position of the OMEGA plate and measurement of the distance from the symphysis (marked in red)



7) Extraction of the implant

If the implant does not extend over moving sections of the pelvic ring, it is not necessary to remove it after the fracture has healed. The advantage of the OMEGA plate is that it can be left in situ at any late application of TEP.

8) Storage of implants

Prevent deformation and scratches to the implant; avoid contact with other metallic materials and chemicals when handling the implant. Implant with mechanical damage must not be used.

The implant must be stored in a dry place without direct exposure to chemicals.

9) Recommended method of cleaning and disinfection

Implants are cleaned by the manufacturer, and therefore there is no need to clean or disinfect them. Should it be necessary to re-sanitize an unused implant, a disinfectant that contains no chloride ions and is suitable for steel instruments has to be used. The implant must not be damaged (scratched) during disinfection.

We recommend either a device for washing and thermal or /thermo-chemical disinfection or hand washing of implants after chemical disinfection with a virucidal disinfectant; it is possible to combine both stages using the disinfectants with combined detergent effect. Disinfectants can be used in accordance with the instructions on the product label. During the preparation of disinfectants and cleaning solutions, the procedures specified by the manufacturer must be followed. Implants that are designed for disassembly, are dismantled and each part is further considered as individual. After disinfection, implants are to be rinsed with demineralised water to remove chemical residues remaining on the implant.

Recommended products: Sekusept pulver, NeodisherseptoMED.

10) Recommended method of sterilization

We recommend that implants are sterilised separately from other instruments. Unless otherwise stated in a special notification, it is advisable to use steam sterilization in a steam steriliser equipped with antibacterial filter at 121 °C, pressure 205 kPa for 20 minutes or at 134 °C, pressure 304 kPa for 10 minutes. If the special notification includes recommendations on hot air sterilization, it must be carried out in devices with forced air circulation at 160 °C for 60 minutes or at 170 °C for 30 minutes or at 180 °C for 20 minutes, unless otherwise indicated. Hot air steriliser should be opened after the end of the cycle after cooling down to 80 °C at least.

11) Instruction for the patient

- Tell the patient that they must strictly follow instructions of the attending physician.
- Inform the patient about the surgery procedure, possible risks and rehabilitation program.
- To prevent damage to the implant, instruct the patient when it is possible to fully bear weight on the bone with internal fixation.



12) Preventive measures

The implant should never be re-used! Previous stress can reduce the fatigue strength and the re-implantation may cause failure of osteosynthesis.

- Used implant may be contaminated and its re-use can cause an inflammatory response to the body. It can also serve as a medium for disease of the previous patient.
- Use only the specified instrumentarium for the surgery; it must not be damaged.
- If it is necessary to change the shape of the implant, it can only be performed as specified.

- Do not use implants from different materials in one patient because contact between different metals may accelerate the corrosion process, which may lead to a premature reduction in the efficiency and life of the implant, as well as an increased amount of metal compounds released into the body of the patient that may cause toxic reaction.
- Prevent deformation and scratches to the implant, avoid contact with other metallic materials and chemicals when handling the implant.
- Make sure all shapes and sizes of implants that are likely to be used are available at the medical facility.
- The surgeon must be familiar with the surgery procedure and use of the specified instrumentarium.
- Consider the use of implants in patients where there is no certainty that they will co-operate with their physician after the surgery (such as alcoholics, drug addicts, and the mentally ill).
- Consider additional preventive measures that reduce the weight bearing stress in order to minimize premature weight stress of the fracture fixation device, until the X-ray proves bone healing.
- After solid bone healing it is necessary to consider implant removal in younger patients. Absolute indications for removal are implants that bridge movable parts of the pelvis (symphysis and sacroiliac joint). Removal in other locations is to be assessed by the surgeon. In older patients, the implants are usually left in situ after healing. Risks during implant removal surgery are relatively high.
- Choose early removal of the implant when suspecting poor healing of the bone, or that the implant may loosen, bend or break. This could lead to serious injury to the patient.
- When using imaging techniques such as X-RAYS, CT scans, MR methods etc., the instructions of the manufacturer of these devices must be followed.
- The manufacturer is not liable if the product is not used in accordance with the instruction manual or surgical procedure.
- The manufacturer is not liable if the product is used in combination with implants from other manufacturers.

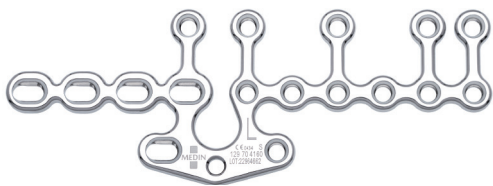
13) Possible side effects of surgical procedure

- Incorrect fixation of individual fracture fragments, osteoporosis, impaired vascularization and slowed formation of new bone tissue can cause implant loosening, bending or breakage or premature loss of solid bone fixation.
- Poor healing of fractures caused by improper repositioning.
- Overgrowth of fibrous tissue around the fracture site in unstable fractures, with the potential risk of non-union.
- Early or late infection, both deep and superficial.
- Avascular necrosis of bone.
- The healing process may result in shortened bone in the area of fracture.
- Iatrogenic nerve damage as a result of surgery.
- Allergy to nickel.
- The risk of misdiagnosis when using CT or MRI diagnostic devices, where the presence of steel implant in that area will result in poor display.

In surgery intended to remedy consequences of multiple injuries, severe complications may occur, much like in any surgical procedure. These complications include genitourinary, gastrointestinal and vascular disorders including thrombosis; bronchopulmonary disorders including embolism, myocardial infarction and death.

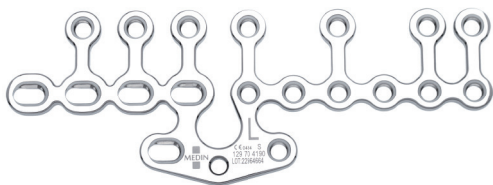
14) Implant disposal

The implant is considered hazardous waste after its use. User is responsible for implementing measures of safe handling and disposal of the product. After drying, used implants are discarded and disposed of as potentially hazardous waste.



OMEGA basic pelvic plate

SSt	type	
129 70 4160	left	129 × 48 mm
129 70 4170	right	129 × 48 mm



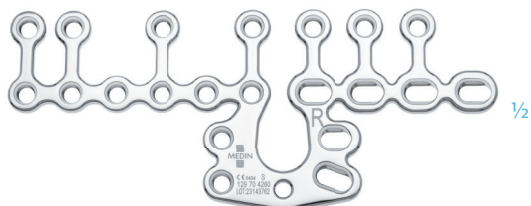
OMEGA ILIAC pelvic plate

SSt	type	
129 70 4190	left	129 × 48 mm
129 70 4200	right	129 × 48 mm



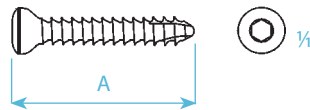
OMEGA LONG pelvic plate

SSt	type	
129 70 4220	left	143 × 48 mm
129 70 4230	right	143 × 48 mm



OMEGA MAXI pelvic plate

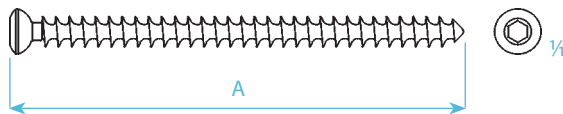
SSt	type	
129 70 4250	left	129 × 62 mm
129 70 4260	right	129 × 62 mm



drill bit for threaded hole	Ø 2.7 mm
screwdriver	Ø 2.5 mm

Self-tapping cortical bone screw HA 3,5

SSt	A
129 79 5241	16 mm
129 79 5251	18 mm
129 79 5261	20 mm
129 79 5271	22 mm
129 79 5281	24 mm
129 79 5291	26 mm
129 79 5301	28 mm
129 79 5311	30 mm
129 79 5321	32 mm
129 79 5331	34 mm
129 79 5341	36 mm
129 79 5351	38 mm
129 79 5361	40 mm
129 79 5371	42 mm
129 79 5441	44 mm
129 79 5451	46 mm
129 79 5461	48 mm
129 79 5391	50 mm
129 79 5401	55 mm
129 79 5411	60 mm
129 79 5421	65 mm
129 79 5431	70 mm



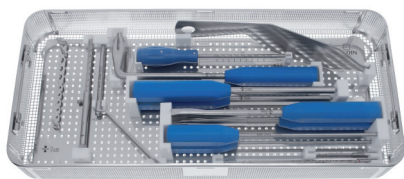
drill bit for threaded hole	Ø 2.0 mm
screwdriver	Ø 2.5 mm

Cancellous bone screw HB 4

SSt	A
129 79 6010	16 mm
129 79 6020	18 mm
129 79 6030	20 mm
129 79 6040	22 mm
129 79 6050	24 mm
129 79 6060	26 mm
129 79 6070	28 mm
129 79 6080	30 mm
129 79 6090	32 mm
129 79 6630	34 mm
129 79 6640	36 mm
129 79 6650	38 mm
129 79 6110	40 mm
129 79 6660	42 mm
129 79 6670	44 mm
129 79 6680	46 mm
129 79 6690	48 mm
129 79 6130	50 mm
129 79 6140	55 mm
129 79 6150	60 mm

OMEGA PELVIC PLATES

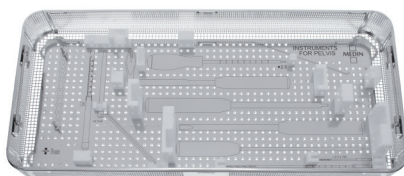
INSTRUMENTS FOR OMEGA PELVIC PLATES



139 09 0695 Set of instrumentation for pelvic plates with a sieve
540 × 240 × 90 mm
including instruments



139 09 0690		set	pcs
1	129 69 5800	Screwdriver; hexagon 2.5 mm	1
2	129 69 6270	Bender, pin-type	1
3	129 69 6291	Drill 2.7 × 230 mm	1
4	129 69 8440	Bender, fissure-type	2
5	129 69 8450	Spike	2
6	129 69 8610	Hip hook	1
7	129 69 8620	Tape	1
8	129 69 8630	Curved lever, fissure -type	1
9	129 69 8640	Protecting sleeve	1
10	129 69 8910	Drill 2,7 × 110 mm	1
11	129 69 9070	Bender, pin-type	1
12	129 79 8900	Depth gauge	1



129 69 8660 Sieve for pelvic plates instrumentation
540 × 240 × 90 mm
without instruments



Bending pliers
for plates, 11 mm width

129 08 4960 290 mm



HERCULES
Wire cutting forceps
for wires up to 3.0 mm in diameter

116 91 0539 230 mm

REFID