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MEDICAL SOLUTIONS

Surgical Technique

INTEOS® Distal Radius System M4

INTEOS® Distal Radius Plate palmar & palmar - Watershed

Preface

This document provides information about handling the Hofer Medical Solutions implants and instruments.

This manual of surgical technique is an addition and must not be considered as a substitute to existing literature about surgical methods within orthopaedics and traumatology.

The content shall be regarded as a recommendation for a standardized procedure of how to apply the products without addressing the issues of any further required measures, additional surgical interventions and possible extensions of the surgical technique.
The actual selection of the most suitable implant and its implantation method must happen exclusively by the surgeon based on his education and the individual diagnostic findings.

All illustrations printed here have a purely symbolic character to support the description of the surgical technique and can vary.

This surgical instruction does not contain any details on the use of the instruments.
Corresponding documents are available in the form of

- instructions for use of instruments: intra- and postoperative handling
- instructions for use of implants (is enclosed with each implant)

Please note that both the diagnosis and the determination of the treatment strategy rest solely with the surgeon.

Hofer Medical Solutions gladly offers detailed training in safe handling and various surgical techniques.

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Warning
This description does not suffice for immediate usage of the implants and instruments.
A briefing by a surgeon experienced in this field in handling these instruments is highly recommended.

Legend

System S


Hole angle stable &
limited angle variable

Titan

Packaging unit

Plate thickness

ATTENTION: available as
left and right variation

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Contents

The INTE**OS**® system of the company Hofer Medical Solutions is a multi directional and angle stable implant system for small fragments based on the internal fixateur principle.

The INTE**OS**® system is designed to treat diaphyseal, metaphyseal as well as intra-articular (epiphyseal) fractures of small bones.

All Hofer Medical Solutions products are the result of joint development by experienced surgeons and our engineers. This successful cooperation results in products that meet the anatomical and functional requirements due to the anatomically preformed, low-profile design and the wide range of treatment options, from simple fractures to comminuted fractures.

General advantages of the system:

- Minimization of irritations of ligaments and soft tissue due to the flat plate and screw design
- Screw heads countersunk to a large extent
- High angular variability of up to 70° with full angular stability
- High flexibility of treatment due to the sieve design of respective plates
- Angular stability in the shaft area: high security in case of bone instability
- System added value: compatibility of screws and instruments with many other INTE**OS**® plates
- 3-point support (transformation of bending stress into tensile and compressive stress) is possible

Indication:

- Treatment of malposition or instability of wrist fracture at a typical site (radius fracture loco typico) with and without joint involvement.
- Corrective osteotomy in the area close to the joint in case of malposition after fracture/fracture healing of the wrist.

Absolute contraindications:

- Possible or existing sensitivity to the material
- Application to the spine
- A (mainly) ulnar-dorsally located and displaced joint, which may not be sufficiently reduced and fixed from the flexor side (Barton fracture, AO classification B2)
- Open wrist fracture grade 2 or grade 3 with contamination of the wound without sufficiently cleansing or soft tissue coverage intra-operatively

Relative contraindications:

- Infections or inflammations (acute, chronic, local)
- Decreased blood flow to the affected area
- Reduced bone stability for correct implant fixation
- Patients with little or no compliance in terms of adherence with postoperative rehabilitation recommendations
- Obesity
- For bone plates, cannulated screws and OSTYS compression screws: Patients with open epiphysial plates
- Inadequate soft tissue coverage
- Open soiled fractures with inadequate possibility of cleansing

Warning:

- See instructions for use IMPLANTS - TITANIUM

Patient positioning and accesses:

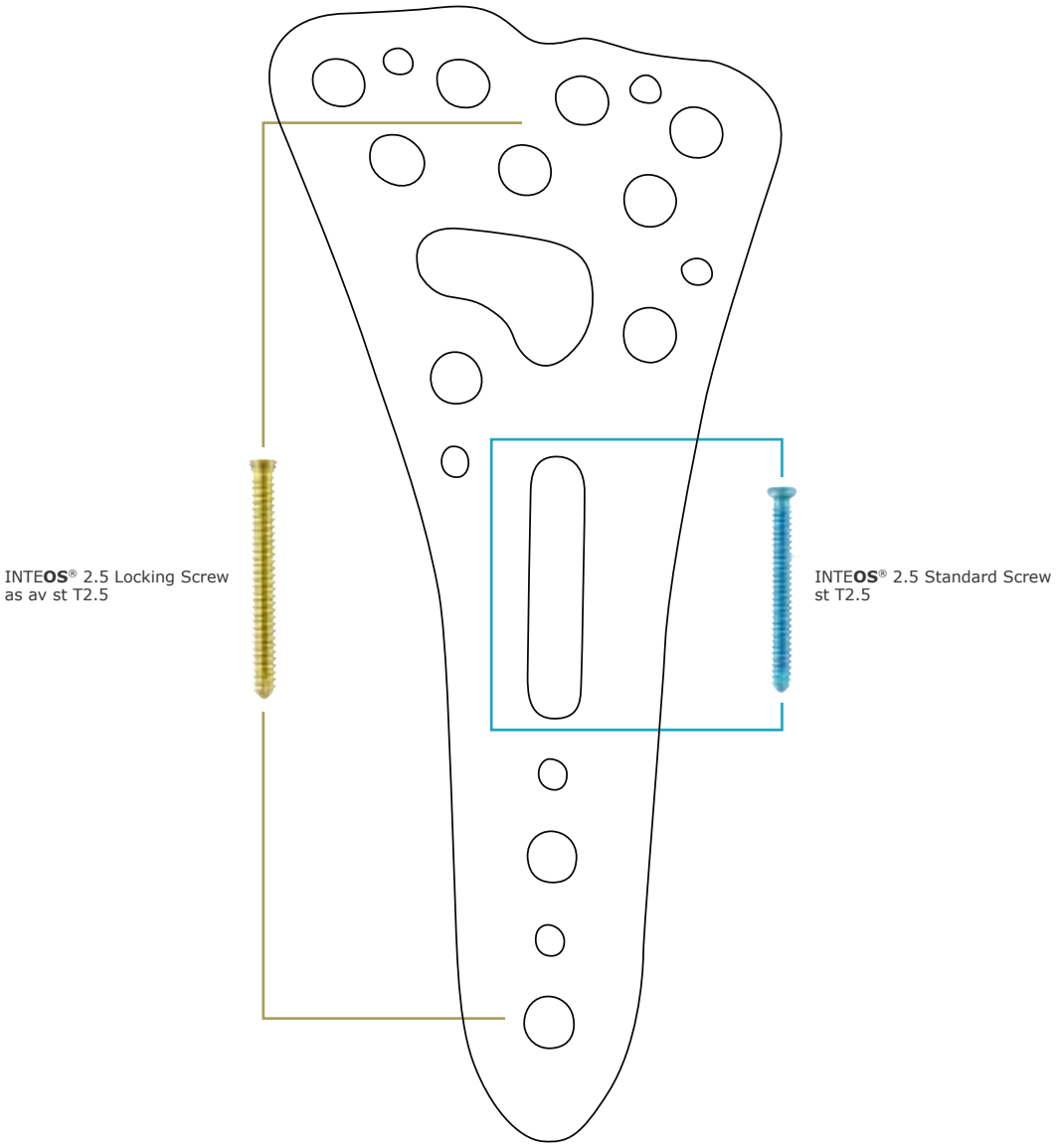
- Standard
- Standard flexor side

Plate specific details:

- Epiphyseal up to 9 polyaxial/angular stable screws to be placed for optimal joint reconstruction and fixation
- Kirschner wire holes for K-wires up to a thickness of 1.2 mm for temporary fixation of the plate to the bone, temporary fixation of reduced bone pieces to the plate, reduction of bone pieces in malposition using the K-wires, fixation of the capsular ligament apparatus using sutures to the plate
- Oblong hole for primary variable fixation of the plate to the radius
- Window for possible fracture repositioning with the instrument through the plate
- Third row of screws, which can provide additional support/stabilization in the case of extremely unstable fractures.
- Extremely high stability against bending (subsidence of a fracture set up by using a plate is hardly possible, thus extension-side support is seldom necessary in the case of comminuted fracture).
- Direct fixation of the styloid to the plate
- Low-profile design, minimal screw head protrusion

Additional specifications for WSL:

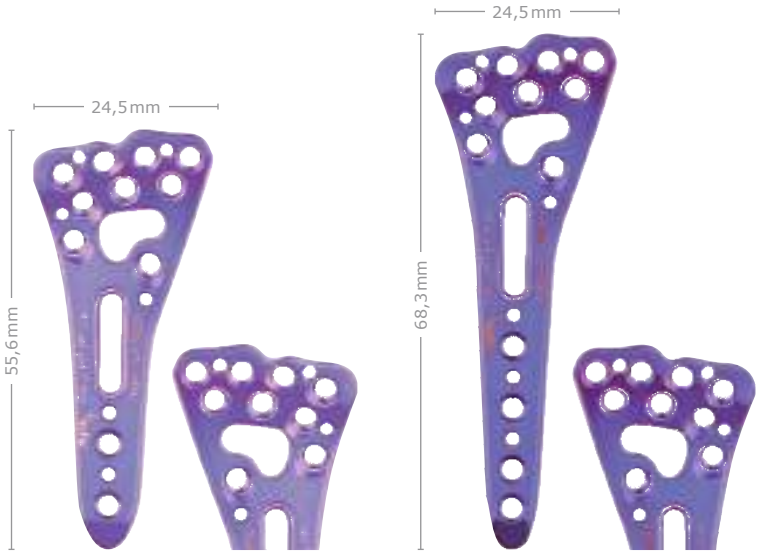
- The best possible anatomical pre-bending ensures an extremely distal plate position, taking into account the anatomy of the promontory radii. Predefined screw angle in the screw row close to the joint (largely avoidance of an intra-articular screw position with optimum support of the joint surface), adaptation of the plate to the ulnar anatomy of the radius (the best possible addressing of the ulnar key fragments)
- High security of supply due to pre-angled wells



Compatibility screws and drills

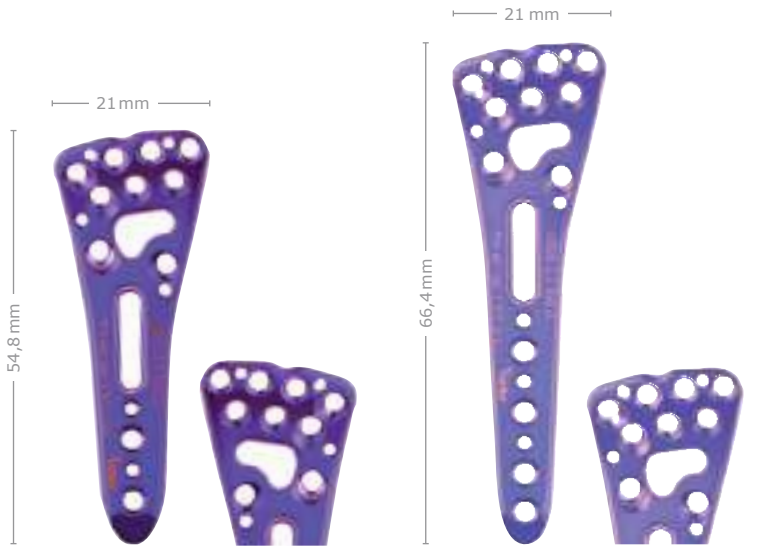
Screw diamter	 ø 2,5 mm	 ø 2,5 mm
Drill diameter Standard	 ø 2,0 mm	 ø 2,0 mm
Drill diameter poor bone quality, e.g. osteoporosis	 ø 1,8 mm	 ø 1,8 mm

*INTE**OS**® Distal Radius System M4*
Implant overview



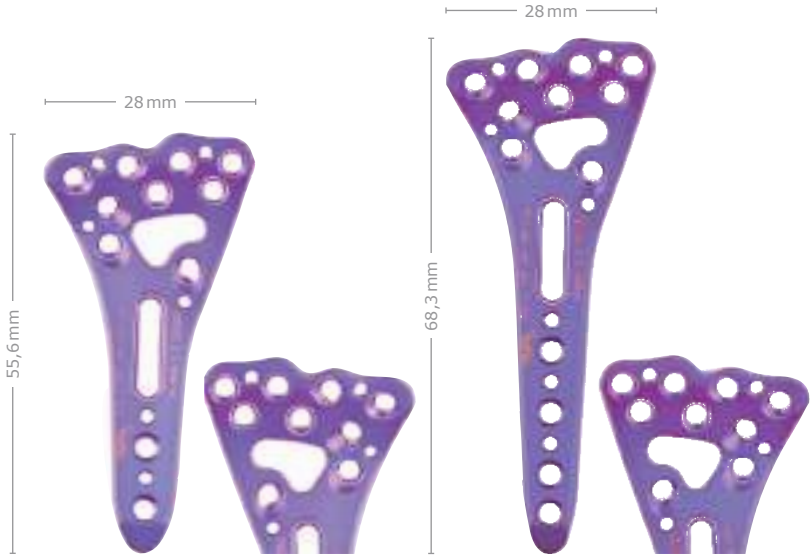
INTE**OS**® Distal Radius Plate palmar -
Watershed L/R

S | Ti | 2.0 | 1 unit | L/R



INTE**OS**® Distal Radius Plate palmar -
Watershed narrow L/R

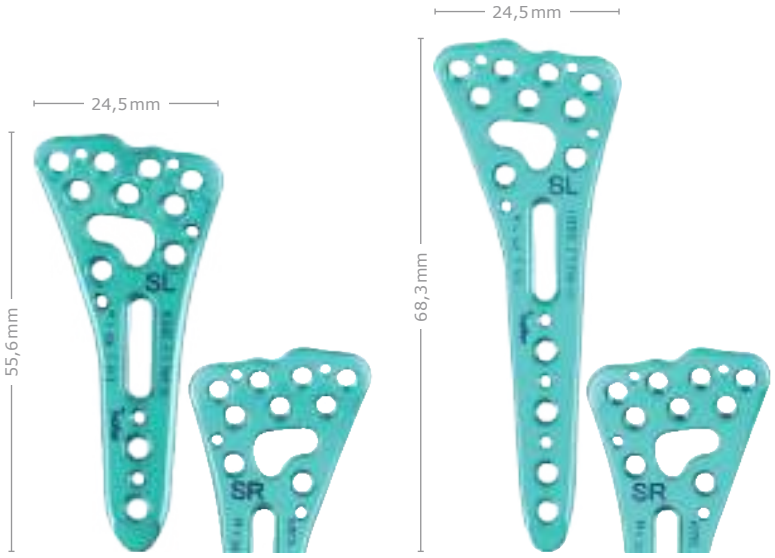
S | Ti | 2.0 | 1 unit | L/R



INTE**OS**® Distal Radius Plate palmar -
Watershed wide L/R

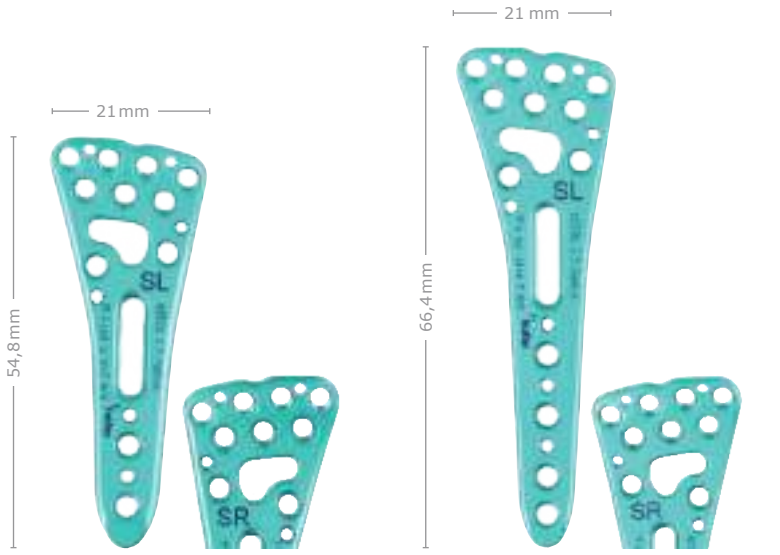
S | Ti | 2.0 | 1 unit | L/R

*INTE**OS**® Distal Radius System M4*
Implant overview



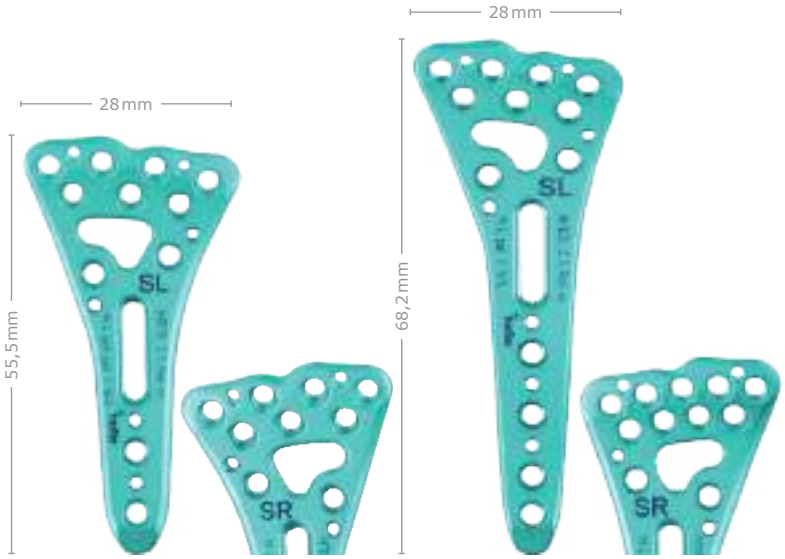
INTE**OS**® Distal Radius Plate palmar
SL/SR

S | Ti | 2.0 | 1 unit



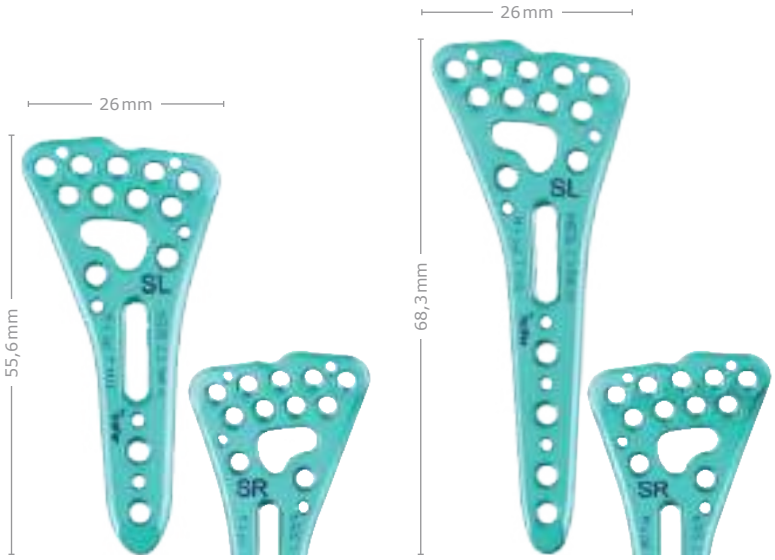
INTE**OS**® Distal Radius Plate palmar –
narrow SL/SR

S | Ti | 2.0 | 1 unit



INTE**OS**® Distal Radius Plate palmar –
wide SL/SR

S | Ti | 2.0 | 1 unit



INTE**OS**® Distal Radius Plate palmar –
multihole SL/SR

S | Ti | 2.0 | 1 unit

Preparatory measures for the use of Hofer Medical Solutions implants require careful preparation of the surgical site. Particular care is required for nearby nerve bundles and blood vessels. Before using Hofer Medical Solutions implants, an adequate reduction of the anatomical structure must primarily have been performed.

Insertion of the implant

After reduction of the fracture zone, the plate can be placed. This step does not require a special insertion instrument.

Temporary fixation

Temporary fixation of the plate can be achieved either via the Kirschner wire holes or the oblong hole, depending on the plate type. In the case of Kirschner wires, these can additionally be used like a "joy stick" if further reduction of the fragments is required. In the case of the oblong hole, it is recommended to use a non-angular stable standard screw.

Alignment of the implant

The implant is aligned according to the existing anatomy.
When using the oblong hole: As long as the standard screw is not yet tightened, the plate can still be brought into the final position.

Screw placement

The insertion of an angle-stable or non-angle-stable screw works in the same way. The number of screws, their position and orientation must be selected according to the situation. Use a depth gauge to measure the hole depth and determine the required screw length. Bicortical screw fixation is recommended.

Removal of temporary fixation or instruments

If the temporary fixation was made via the oblong hole, the screw already inserted can be left in place for additional fixation of the plate. The screw must be tightened for this purpose.

Wound closure

Postoperative treatment

An intraoperatively applied splint supports postoperative analgesia. The start of functional postoperative treatment should be selected according to the type of fracture and the stability achieved intraoperatively.

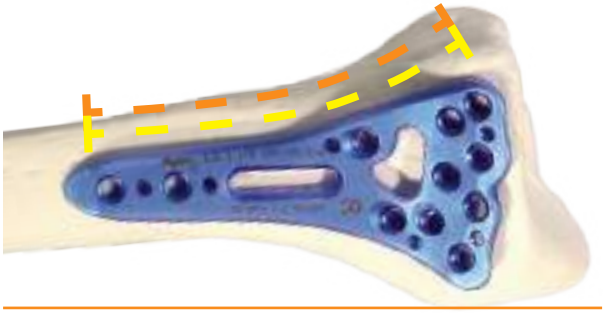
Material removal

If the bony build-up is secured, material removal must be decided on a case-by-case basis by the attending physician. Careful exposure of the screw heads must be ensured during removal!

Please note that the reduction techniques as described below are fully valid for both INTE**OS**® Radius M4 plate types (plate violet, plate turquoise). The techniques are exemplified using the INTE**OS**® Radius watershed.

Annotation:

- The implant is anatomically pre-shaped. However, if adaptation to anatomical conditions is necessary, the plate can be shaped using appropriate bending pliers.
- The screw connection should always be implanted in the shaft area
- It is important to control the correct deflection of the screws according to the pre-angulation
- No placement of plates distal to the watershed line.
- Screws must be inserted as far as possible into the plate.



The INTE**OS**® Distal Radius Plate palmar, as well as the wider INTE**OS**® Distal Radius Plate palmar – watershed, are applied at the ulnar edge of the radius.

Malposition with dorsally tilted joint surface.

Kirschner wire shows the ideal position of the joint surface.

Technique 1

Repositioning via Kirschner wire or screw hole

1

Screwing the plate in good position, on the shaft in the oblong hole

2

Reduction using Kirschner wires via Kirschner wire or screw holes

3

It is recommended to perform temporary fixation at least with 2 pieces of Kirschner wires diameter 1.2 mm

Technique 2

Reduction by screwing onto the shaft

1

Aligning the plate to the distal fragment.
Fixation of the plate over:

- Kirschner wire hole by means of a Kirschner wire diameter 1.2 mm or
- in the oblong hole by means of a non-angularly stable screw or

Note:
For temporary fixation of the plate with freely selectable distance to the bone at the proximal end of the plate, an additional instrument set is also available on request.

2

- Pre-drilling of the pre-angulated distal screw row
- Fill the predrilled distal screw row with at least two angle-stable screws

3

Fracture reduction by screwing the plate to the shaft using a standard screw

Ensure that the fracture gap on the flexural side is closed!

4

- Final tightening of the non-locking screw in the oblong hole with the flexion-side fracture gap closed

Now the non-locking screws (except for the oblong hole) are replaced with the locking screws!

Technique 3

Reposition via traction technique

1

- Screw the plate into the oblong hole in a good position on the shaft

2

- Placement of the distal angle-stable screw under image change control without locking with the plate
- Reduction of the fracture using the SafeLock T6 instrument

SafeLock:
Please observe the operating instructions as well as the instructions for use

3

- Pulling the fragment towards the plate by slowly tightening the distal screw without loosening the locking, between the screw head and the SafeLock T6

4

- Loosen the connection between SaveLock T6 and screw head. Then fully lock the screw using ForceDRIVE T6

5

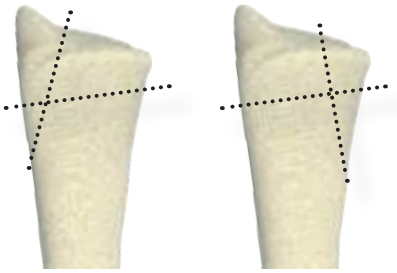
- Angular stable locking of the remaining screws in the plate

Shape-left and shape-right, the new flexibility of the INTE**OS**® Radius Plate pal from Hofer Medical Solutions - more leeway is not possible.

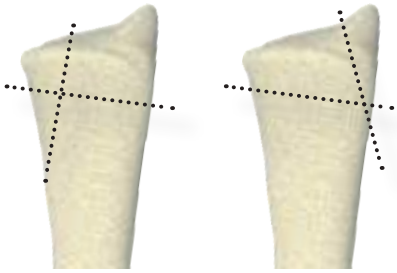
You decide during the operation which INTE**OS**® Radius Plate pal is best suited for the respective fracture type. This is possible thanks to the special plate design and the high anatomical and functional standards of this Hofer Medical Solutions implant. This allows you to use the marked plate **(SL)** on both the left and right radius - and to place the plate **(SR)** on both the right and left radius.

Symbolic representation of the different variants

Radius left



Radius right



Fracture line course

Radius Plate
Shape-left (SL)

Radius Plate
Shape-right (SR)

Radius Plate
Shape-left (SL)

Radius Plate
Shape-right (SR)

Aiming device for
Radius Plate (SL)

Aiming device for
Radius Plate (SR)

Aiming device for
Radius Plate (SL)

Aiming device for
Radius Plate (SR)

Depending on the selected shape, the INTE**OS**® Distal Radius System pal offers anatomically pre-aligned target burr blocks to support the surgeon intraoperatively target drilling blocks.

Application:

- Depending on the selected shape, there are anatomically pre-angulated aiming devices. The selected INTE**OS**® Radius Plate with Shape-left (SL) or Shape-right (SR) as well as the radius to be supplied left (L) or radius right (R) define the aiming device to be selected as a combination specification (SL-R, SL-L, SR-R, SR-L)
- The aiming device is attached to the INTE**OS**® Radius Plate in the distal area using a click mechanism. A screw connection is not necessary
- By means of the drill sleeve, which can be plugged into the aiming device, the hole for the screw core can be pre-drilled in the corresponding direction / position / angle

Please note that different target drill blocks must be used for the INTE**OS**® Radius Plate width (narrow, standard, wide, multi-hole)

Deflection of the distal screw row by means of a target drill block:

1

- The INTE**OS**® Distal Radius Plate palmar as well as the wider INTE**OS**® Distal Radius Plate - wide are applied according to the requirements of the fracture

2

- The aiming device is placed on the distal end of the plate. The "click" signals the fixation of the aiming device

3

- The aiming drill sleeve fits loosely into the aiming device. It must not be possible to feel any jamming during insertion

4

- The target drill sleeve is used to drill the hole for the screw.

5

- The INTE**OS**® depth gauge fits perfectly into the target block, so it is easy to measure over the target block without any problems …

6

- … the desired screw length can be read off directly

7

- The screwdriver to screw connection can be described as "stick-fit" i.e. the screw is positively engaged with the screwdriver

8

- Make sure that the screw is completely and firmly locked to the plate

Representation plate position palmar

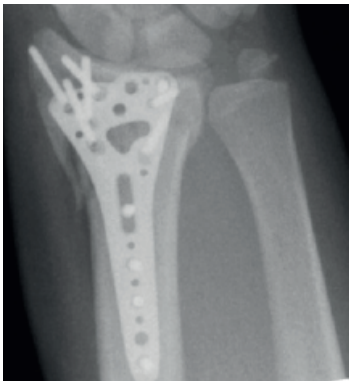
Note:
Shaft screws are not shown for demonstration purposes

Representation screw position dorsal

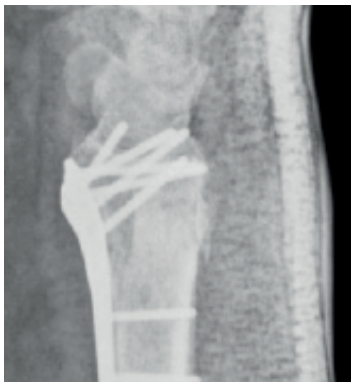
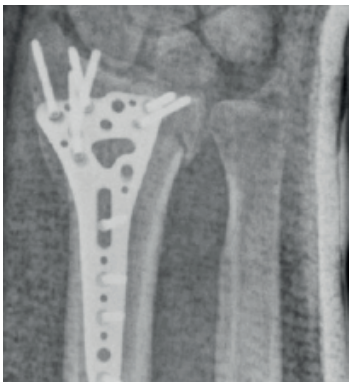
Note:
the screws were chosen too long for demonstration purposes

The following pictures show a distal radius fracture treated with the INTE**OS**® Distal Radius System.


Fracture

Operation

2nd postop. Week


3rd postop. Month

After fracture healing, the implant loses its function and can be removed. Especially in case of a long duration of the implantation, the bone–titanium contact can become quite tough. Therefore, it is recommended to remove the material as soon as a clinically acceptable bony support got established.

In such a situation of a strong bond

between a bone screw and the bone, the following procedure can be recommended for a quick removal:

- Clean screw heads and plate
- Exact exposure of the ForceDRIVE connection in the screw head
- Attach screwdriver
- Perform some slight strikes in axial direction onto the attached screwdriver and simultaneously turn it left and right
- Perform stepwise unlocking of the screw according to picture

Hold till screw does not show counter torque, then next **1/8 – 1/4** turn

In case of extremely strong connection

Expand stepwise unlocking by partial re-locking

If the screw breaks,

standard extraction instruments can be applied to remove it. Please note that the plate has to be removed first.

Required instruments

Screwdriver ForceDRIVE with Shaft T6

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