Design Features and Claims of the NCB® Periprosthetic Femur Plate System

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Abbreviations:
NCB: Non-contact bridging **PPF:** Periprosthetic Femur

Background

Periprosthetic femur (PPF) fracture is a rare pathology. However, the frequency of PPF fracture has been increasing in recent years due to increase of life expectancy and revision surgery leading to a significant increase in the number of hip and knee joint replacements in an aging population, most of them are suffering from additional risk factors and osteopenia.[1, 2] Osteoporotic patients are additionally affected by biological and mechanical issues, such as multiple medical co-morbidities, multiple fracture planes with lower-energy injuries, and difficulty with postoperative mobilization.[1] The incidence rates after revision arthroplasty procedures is up to more than ten times higher when compared to primary interventions: periprosthetic fracture around total hip and knee arthroplasty occurs in 0.3% to 2.5% of primary arthroplasty patients and in 1.5% to 38% of revision arthroplasty patients.[3-7]

During the last decades, there was a significant evolution of devices for the treatment of periprosthetic fractures of the femur. In the presence of hip and knee prosthetic devices, the use of intramedullary nails might be impossible for fracture treatment. Historically, PPF fracture treatment with conventional non-angle stable plating systems resulted in high failure rates[8] with up to 100% non-union.[1]

The development of locking plates with low-contact technology, e.g. LISS, LCP (both Synthes) lead to a significant reduction of non-union, mal-malalignment, and reoperation and fixation failure[8, 9]. Monoaxial locking plates often require screw placement in regions with poor bone quality and in regions with interference with prosthesis stems, making bicortical screw fixation impossible.[10]

The NCB® Periprosthetic Femur Plate System (NCB PPF) features further improvement to support a successful treatment of challenging PPF fractures, including an anatomical plate design, non-contact bridging technology designed for the protection of the periosteal blood supply, polyaxial screw placement options and offset holes designed for easier bicortical screw fixation and a stable plate-bone construct.

The following paragraphs detail the main NCB PPF design aspects and provide references of peer reviewed published articles detailing outcomes of clinical series, other clinical experience, and biomechanical testing results with the NCB PPF System.

The specific NCB Periprosthetic Femur Plate System Design Characteristics

Polyaxiality

The NCB Plate Technology allows polyaxial screw placement (30° cone) with screw locking achieved through the use of locking caps that are threaded into the plate holes. The locking construct improves stability especially in poor bone quality.

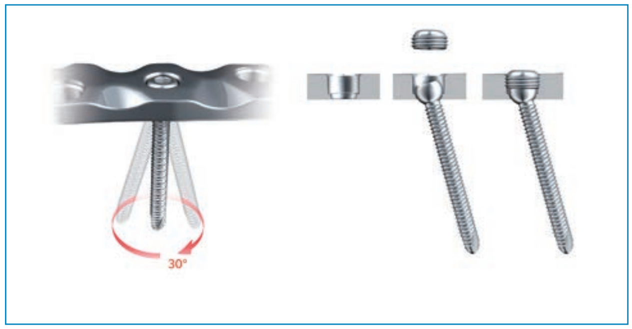

Figure 1. The NCB 30° Cone Polyaxiality and the principles of NCB angular stability with locking caps.

The NCB PPF Plates include the innovative design features of the NCB Plates. The NCB technology was introduced to the markets in 2003 with the NCB Distal Femur Plate and since then implemented in other plates designed for long bone fracture treatment in the femur, the tibia and the humerus. A central characteristic of the NCB plates includes the combination of free screw placement within a 30° cone and the possibility for locking of these screws, achieving a polyaxial fixed-angle construct. A NCB screw can be freely placed within a 30° cone, and being locked after final screw placement.

This includes several aspects[11, 12]: The polyaxiality (placement of screws in different non-parallel directions) leads to higher pull-out strength compared with screws set in parallel. The polyaxiality further enables or facilitates bicortical screw placement in the presence of prosthesis stems, around the prosthesis. Bicortical screw fixation has shown to further improve stability of the plate-bone construct. The placement of a locking cap after definitive screw placement not only facilitates screw placement, it further increases construct stability as it holds the screws in a fixed angle to the plate. The fatigue strength of screws locked with a locking cap in a 15° position was shown not being different from a screw placed in neutral position and for all angles, fatigue strength with the locking cap system was significantly superior when compared to a standard cross-threaded locking mechanism.[13]

The improved plate-bone construct stability is of special importance in patients with poor bone quality. Such conditions are frequently seen in people suffering from periprosthetic fractures, thus, in the population disposed to the treatment with the NCB PPF Plate System.

Diagonal Three Hole Pattern

All NCB Periprosthetic Plates provide a diagonal three hole pattern, which allows for multiple screw options:

- Offset holes allow for easier screw placement around the prosthesis and may allow bicortical fixation.
- The central screw holes can accommodate unicortical screws, cable buttons and cables

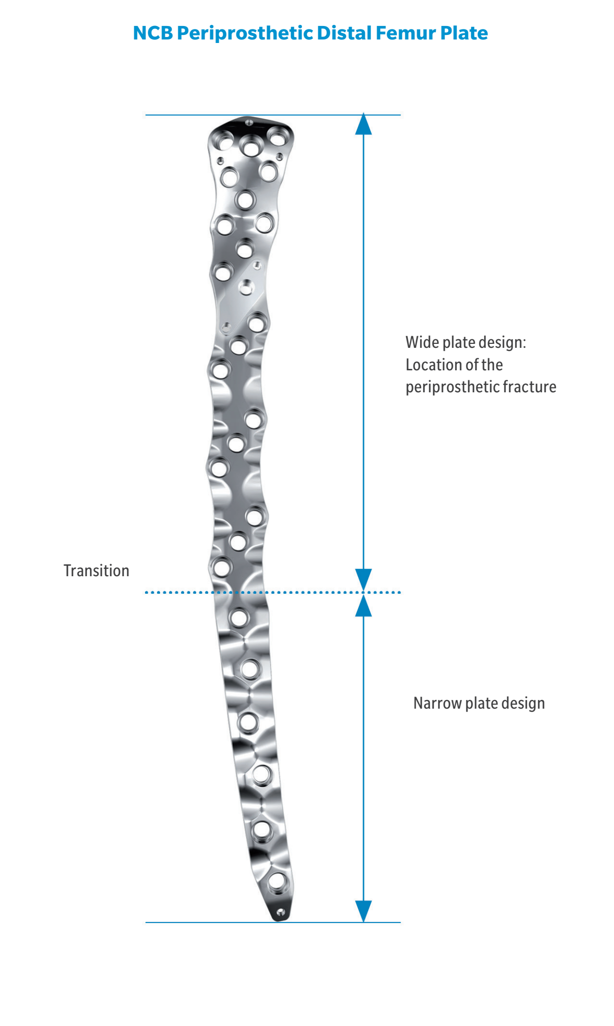

Figure 2. The NCB diagonal three hole pattern in the wide area of a Periprosthetic Proximal Femur Plate, where screws are potentially interfering with prosthesis stems.

The Periprosthetic Proximal and Distal Plates are of a wider plate design and host screw holes in the margin of the plate. Screws set in these zones of wider plate design are potentially interfering with a prosthesis stem. The screw holes are aligned in a diagonal pattern with a central screw hole. The position of the screw holes in combination with the polyaxiality allows easier bicortical screw fixation around the hip or knee prosthesis stem and thus, helps to improve the stability of the plate-bone construct. Screws should be placed both anterior and posterior to the prosthesis. The advantages resulting from the three-hole pattern have been confirmed in clinical practice and described in peer-reviewed published literature.[11, 19]

Plate Stiffness

Differently Shaped Scallops allow for reduced and uniform plate stiffness.

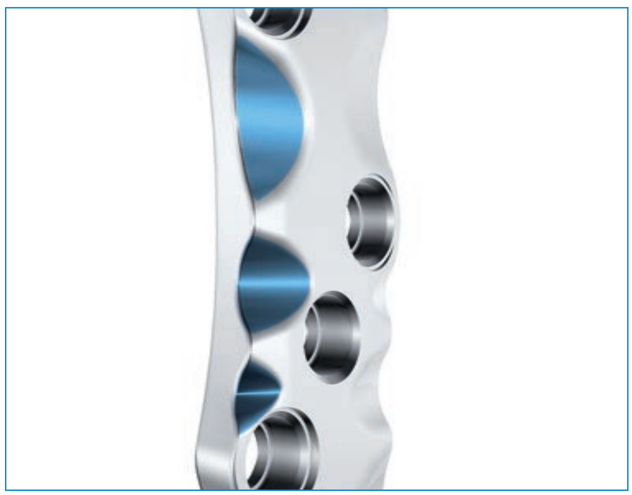

Figure 3. The scallops in the wide plate area.

To accommodate the diagonal three hole pattern, the NCB PPF plates have a wider plate design in the area where screws might interfere with a prosthesis stem. With constant plate thickness and unchanged material (Ti6Al4), the wider plate will cause increase in stiffness. However, it has been described in published literature that within a defined range, plate stiffness will enhance callus formation and bone healing process, as it allows interfragmentary motion.[22, 23] To bring back the plate stiffness into a range more convenient for callus formation and bone healing, the NCB PPF was designed with scallops. These specifically designed scallops in the proximity of the diagonal three-hole pattern screw holes are intended to reduce the plate stiffness in the area intended to span the fracture, they furthermore allow for a uniform plate stiffness along this transition zone.

In a biomechanical study [24] it has been shown that the plate stiffness of the Proximal, the Distal and the Curved NCB PPF plates is within the range of other commercially available plating systems for the treatment of long bone fractures, with confirmed long term clinical performance.
Biomechanical studies: [24]

Anatomical Plate Design / Contouring

Due to the anatomical shape of the NCB PPF Plate, no additional contouring is required for most patients. If required, better plate contouring across solid cross-sections, away from holes.

Figure 4. The bending press with insert. It allows anatomical adaptation of the plate.

The Proximal, Distal, and Curved NCB PPF Plates have a specific anatomical fit to the bone. Due to the anatomical shape of the NCB PPF Plates, no additional contouring is required for a high number of patients. Although, if additional contouring might be required in some situations, this can be done by using the Bending Press and the corresponding Bending Press Inserts.

Caution is required when bending the plate: it might decrease its fatigue strength, and furthermore, the locking mechanism of the NCB Screw hole might be damaged the way it will not be available for screw insertion. However, plate contouring across solid cross sections, away from holes, will help to reduce the risk of damaging the locking mechanism of the NCB plate. [24]

Cable Fixation Options

The products from the Cable-Ready® Cable Grip System are compatible with the NCB Periprosthetic Femur System.

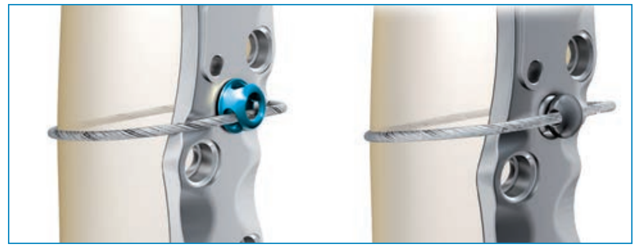

Figure 5. Cable fixation with the blue button of the Cable-Ready® Cable Grip System (left), and with a Hex button (right).

Fixation using cables and cable buttons is possible for those cases where bicortical screw fixation cannot be achieved. Both techniques (locking screws and cables) may also be combined.

The Cable-Ready® Cable Grip System Button implants are designed to be used in conjunction with NCB® Polyaxial Locking, NCB Periprosthetic and Zimmer® Periarticular Locking Plates and cerclage cables. The blue Cable Buttons (REF 47-2232-060-01) are compatible with the NCB PPF Plates, they have to be inserted with a 2.5 mm Hex screw driver into NCB Screw Holes.

Alternatively, Hex Buttons (REF 00-2232-002-35) fit into the standard hex in the NCB screw head and into the NCB locking cap by means of a 3.5mm hex. Therefore, hex buttons can also be inserted where a NCB Screw, locking cap or blind screw insert has already been set. Furthermore, the hex buttons fit directly to the specific holes of the NCB Periprosthetic Trochanter Plate, if additional cerclage cable fixation around the trochanter should be required (see next section).

Periprosthetic Trochanter Plate[25]

The NCB Periprosthetic Trochanter Plate is designed to reattach the greater trochanter in combination with a polyaxial NCB Periprosthetic Proximal Femur Plate.

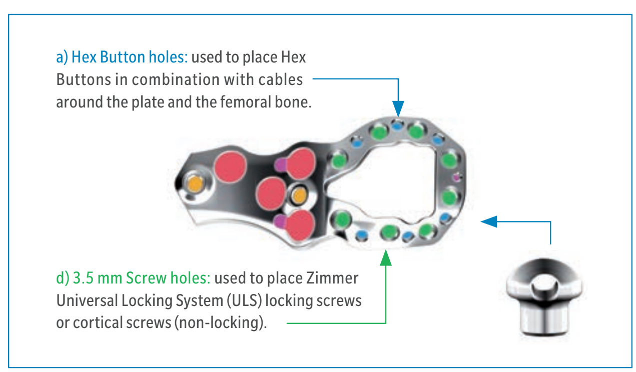

Figure 6. Fixation options with the Periprosthetic Trochanter Plate.

For the fixation of periprosthetic fractures in the trochanter area, the NCB PPF Plating System offers the NCB Periprosthetic Trochanter Plate. It is available in two different sizes (two different widths), while the height is the same. Due to the anatomical shape of the proximal femur, a left and a right version are offered. The Trochanter Plate has to be used in combination with and attached to a Proximal Femur Plate with Connection Screws.

The Trochanter Plate features two different types of holes: 3.5mm screw holes and Hex Button holes are alternating along the Trochanter Plate arch. The eight 3.5mm screw holes are designed for insertion of two different screw types:

a. (Standard, non-locking cortical screws which allow anatomical reduction of the fracture fragments, and

b. Locking screws with a built in screw technology which gives surgeons the option to create a fixed-angle con struct while using familiar plating techniques. The locking screw heads comprise male threads, while the holes in the plate are designed with female threads. This allows the screw head to be threaded into the plate hole, locking the screw into the plate. The heads are designed to create a nearly flush profile on the plate, which helps to decrease soft tissue irritation.

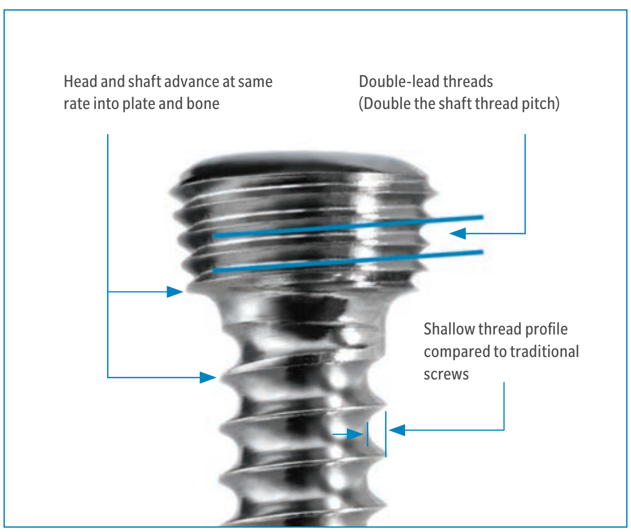

Figure 7. Screw head design of the Locking ULS Screws with 03.5mm for use with the NCB Periprosthetic Trochanter Plate.

The seven Hex Button holes can be used to place Hex Buttons in combination with cables around the plate and the femoral bone, in case of the trochanteric fragment is small, when further stabilization is required, and for fracture reduction.

Non-Contact Bridging

In the locked mode the NCB Periprosthetic Plate acts as an internal fixator without contact between the plate and the bone surface, which may reduce the risk of impairment to the periosteal blood supply.

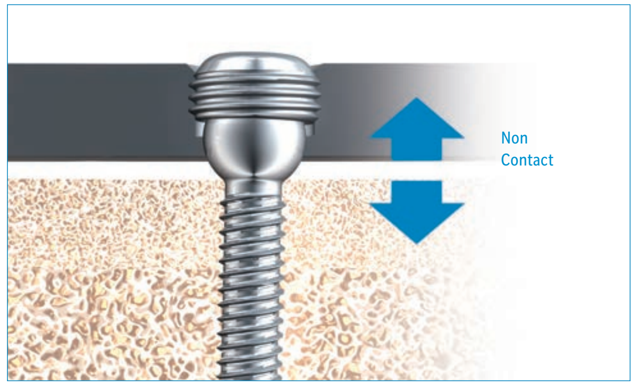

Figure 8. The mechanism of non-contact bridging with the NCB Plate Systems.

Surgeons using early generations plating systems experienced high rates of non-union, mal-union and delayed union. A principal driver for lower success rates with these conventional plating systems discussed in published literature, is the impairment of periosteal blood supply when the plate is pressed against the bone with these systems. In contrast, with modern non-contact bridging plating systems, these mechanisms for impairment of periosteal blood supply do not exist any longer. [28-30]

The NCB Plate Systems offer a unique way to achieve non-contact bridging along the whole plate. When locking an NCB screw by means of a locking cap, the screw head will be pressed against the bone surface and the plate is lifted off from the bone. This unique NCB design characteristic for achieving non-contact bridging is easy to perform during the surgery. Furthermore, with the help of previously inserted spacers, it allows for non-contact bridging along the whole plate.

Patients suffering from periprosthetic fractures oftentimes belong to a vulnerable elderly population with multiple medical comorbidities and poor bone quality. Biologic causes of poor blood flow and poor bone healing include diabetes, peripheral vascular disease, vitamin D deficiency, renal insufficiency, and medications (steroids, NSAIDs, opiates). [31] For those, to reduce the risk of impairment to the periosteal blood supply, may be of special importance.

Broad Screw Options

Five different NCB Screw types are offered with the NCB Periprosthetic Femur System, to allow both bicortical and unicortical fixation.

There are five different NCB screw types available, which cover the need for screw fixation: 5 mm bicortical, monocortical and cancellous screws, and 4 mm bicortical standard thread and deep thread screws (Table 1).

Furthermore, 5 mm MotionLoc™ screws are available for use with the NCB PPF Plate System. The MotionLoc screws allow for far cortical locking, which is known to enhance bone healing in the near cortex of locking plates.[33-36] The MotionLoc screws feature the same aspects of polyaxiality and locking mechanism as with the NCB screws.

The portfolio is completed by 3.5 mm ULS screws for use with the NCB Periprosthetic Trochanter Plate.

bicortical			NCB screws		NCB screws
SCREW TYPE	**Cortical 5 mm**	**Cortical 4 mm**	**Cortical 4 mm Deep Thread**	**Cancellous Partly Thread**	**Cortical Blunt Tip**
PICTURE					
OUTER Ø	5 mm	4 mm	4 mm	5 mm	5 mm
CORE Ø	4.4 mm	3.4 mm	2.9 mm	2.9 mm	4.4 mm
LENGTH	22 - 100 mm	20 - 65 mm	20 - 65 mm	50 - 100 mm	10 - 20 mm
APPLICATION	Close to the fracture area, in the shaft area, or where there is no risk of hitting the prosthesis	Away from the fracture area to achieve bicortical fixation around the prosthesis	Away from the fracture area to achieve bicortical fixation around the prosthesis when fixation even with the 4.0 mm cortical standard screws is impossible	Metaphyseal area of the Distal Femur	For use when bicortical fixation cannot be achieved
DRILL BIT Ø	4.3 / 4.5 mm	3.3 / 3.5 mm	3.0 mm	2.5 mm	4.3 / 4.5 mm

Table 1. The different NCB PPF screw types and their main characteristics.

Specific Instruments for Periprosthetic Fractures

Slightly oversized drill bits and drill guides are offered with the NCB Periprosthetic Femur System, to help reducing the risk of cracks in the cement mantle when placing screws around a cemented prosthesis.

Figure 9. NCB PPF drill bits and drill guides.

Overdrilling by using drill bits of a slightly larger diameter (0.2mm) may reduce the risk for cracks in the cement mantle during screw insertion. In the NCB PPF set a 3.5 mm drill bit (REF 02.00024.325) can be used in place of the 3.3 mm drill bit, and a 4.5mm drill bit can be used in place of the 4.3 mm drill bit. These drill bits are offered together with their corresponding drill guides.

In a biomechanical study, overdrilling the cement mantle by 0.2 mm (4.5 mm instead of 4.3 mm) reduced the risk for cracks from 62.5% to 37.5%.[37] On the other hand, overdrilling the cement mantle by 0.2mm also reduced the pull out strength by about 20%.[37] However, within the cement mantle pull out strength with a bicortical screw still leaves a 1.8 times higher pull-out strength than with the unicortical screw.[37] Clinical experience with the specific drilling instruments confirmed the in vitro findings and the usability of these instruments.[7, 20, 21]

NCB Distal Femur Plate - 95° Angled Distal Hole

The most distal central plate hole is angled at 95° to the plate shaft to allow screw insertion parallel to the joint. This may help reduce the fracture and facilitate realignment of the anatomic axis of the femur.

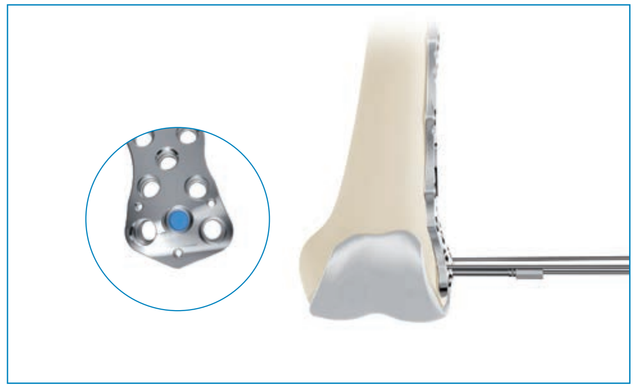

Figure 10. The position of the 95° angled distal hole of the Distal NCB PPF Plate.

The 95° angled distal hole provides an option to achieve correct plate alignment. Furthermore, the two distal k-wire holes are aligned at 95° to the plate shaft and are parallel to the most distal central screw hole to facilitate realignment of the shaft to the anatomic axis of the femur.

Fracture Reduction

Before locking, NCB Screws can also act as lag screws. Therefore, NCB Screws may be used for fracture reduction and to apply interfragmentary compression, a feature not offered with conventional locking systems

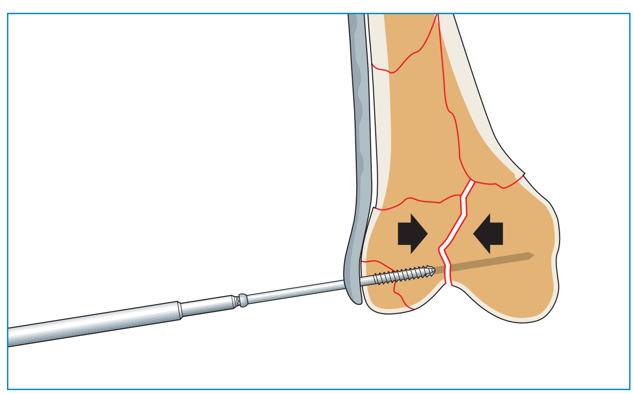

Figure 11. Fracture reduction by insertion of a NCB screw.

The NCB technology allows to achieve two goals with the placement of one NCB Screw: fracture reduction and angle-stable locking mechanism. This unique NCB design feature increases the options to achieve high construct strength and most favorable axis alignment.

NCB screws can act as lag screws and thus, can be used for fracture reduction and interfragmentary compression, when required. After repositioning / compression of the fragments the screw head of any NCB Screw can be finally locked in the desired fixed-angle position by insertion of a locking cap. The locking of the screws considerably increases the stability of the plate-bone construct.[12] If correction should be required, a locked screw can be unlocked and relocked interoperatively at any time.

Conclusion

The NCB PPF Plate System includes numerous design features and characteristics. Each of these aspects has a potential value on its own, for successful treatment of periprosthetic fractures of the femur, as laid out above.

As a result of this, the multitude and combination of these aspects is a further strength of the NCB PPF Plate System, as it makes it flexible and easy to handle. It makes the system adaptive to the challenging patient conditions the surgeon needs to cope with, as these will often not be recognized in detail before surgery.

In this context, we conclude with some feedback in published literature from experienced surgeons in the field of periprosthetic fracture treatment of the femur:

“The complexity of the fracture biology and the frail patient population require the full range of options necessary to optimise healing.” [26]

“The learning curve in the use of NCB plates, in an experienced surgeon, is very fast, the instruments are simple and complete.” [7]

“NCB plates, compared to the means of synthesis used in the past, are technologically innovative tools, much more resistant, conceptually better, and easier to apply in the operating field. Their flexibility helps to solve practically all the technical problems that are typical of their osteosynthesis.” [7]

“The NCB system, with its 30° polyaxial locking mechanism, allows for the positioning of a mean of 5 locked bicortical screws around an intramedullary implant and enables the use of every screw as a lag screw through the plate when it is appropriate. In the less invasive technique, long plates can be applied with low rates of soft-tissue complication and implant failure. Accordingly, no failure of fixation was seen in any of the 41 study patients.” [5]

References

Clinical studies: 1, 4, 5, 6, 7, 8, 10, 14, 15, 16, 17, 18, 20, 21, 25, 26, 27

Biomechanical studies: 11, 12, 19, 24, 28, 29, 30, 37

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Pioneer Surgical Technology, is the responsible manufacturer of the DVR Crosslock Wrist Spanning Plate For complete product information, including indications, contraindications, warnings, precautions, and potential adverse effects, see the package insert and www.zimmerbiomet.com or contact your local Zimmer Biomet sales representative; fo addtional product information, visit www.zimmerbiomet.com.

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