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CONTOURS PHP
Proximal Humeral Plate

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- Fine thread designed to improve osteointegration
- Self-drilling tip

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Features

- Triangular configuration (of the Main Locking Screw and the Fine Threaded Screws)
- Designed to reduce the amount of bone stock removed from the humeral head
- Low head profile designed to avoid impingement
- Anatomically shaped: designed both for the right and the left humerus
- Made of Titanium Alloy
- Suture holes with large groove designed for easy needle insertion

1. Introduction

The Contours PHP-Proximal Humeral Plate is a locking titanium plate intended for the treatment of fractures, osteotomies and non-unions of the proximal humerus, particurarly in osteopenic bone.

This document gives a comprehensive description of Contours PHP's technical and biomechanical features. The innovative technical aspects of the components and the whole system are presented, thus demonstrating the unique advantages and benefits that Contours PHP offers.

2. System Components

2.1 The Plate

2.1.1 Right and left designs

The plate is available in two different anatomically shaped designs for the right and left humerus (Fig. 2).

Fig. 1 Plate dimensions

Fig. 2 Plate: right and left designs

2.1.2 Plate features

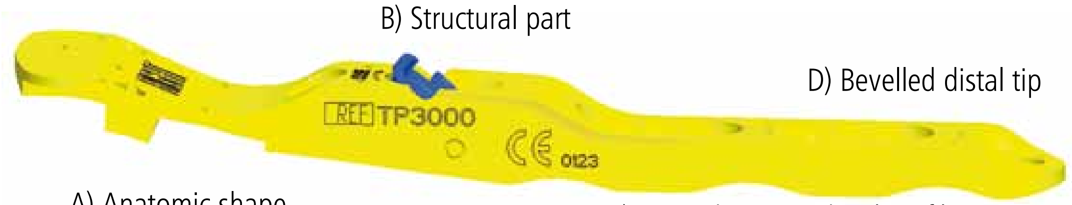


Fig. 3 Plate main features

A) The anatomic shape

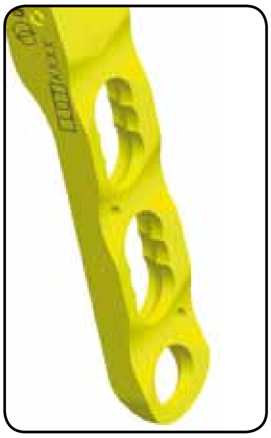
The proximal part of the plate is characterized by an anatomic shape.

Obtaining a correct anatomic reduction has an influence on the final clinical result [1] and can reduce the risk of complications [2].

B) The structural part

The structural part locked with the main locking screw provides frontal stability by allowing the load transfer from the head to the diaphysis of the humerus.

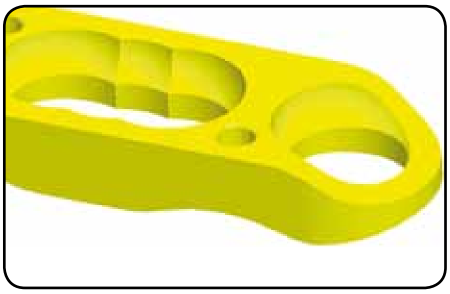
C) The limited contact distal profile



Impairment of periosteal blood supply due to plate fixation can induce formation of cortical porosis that increases the risk of poor fracture healing and refracture after plate removal [3]. Reducing the contact area between plate and bone provides reduced disturbance of blood supply [4].

The Contours PHP has been designed with a limited contact distal profile to permit correct periosteal vascularization to decrease the risk of cortical porosis.

D) The bevelled distal tip



In the treatment of proximal humerus fractures careful soft tissue management is considered a predictor of success [5].

The distal part of the plate has been designed with a bevelled tip with the aim of facilitating plate insertion under the soft tissues.

2.1.3 Plate holes

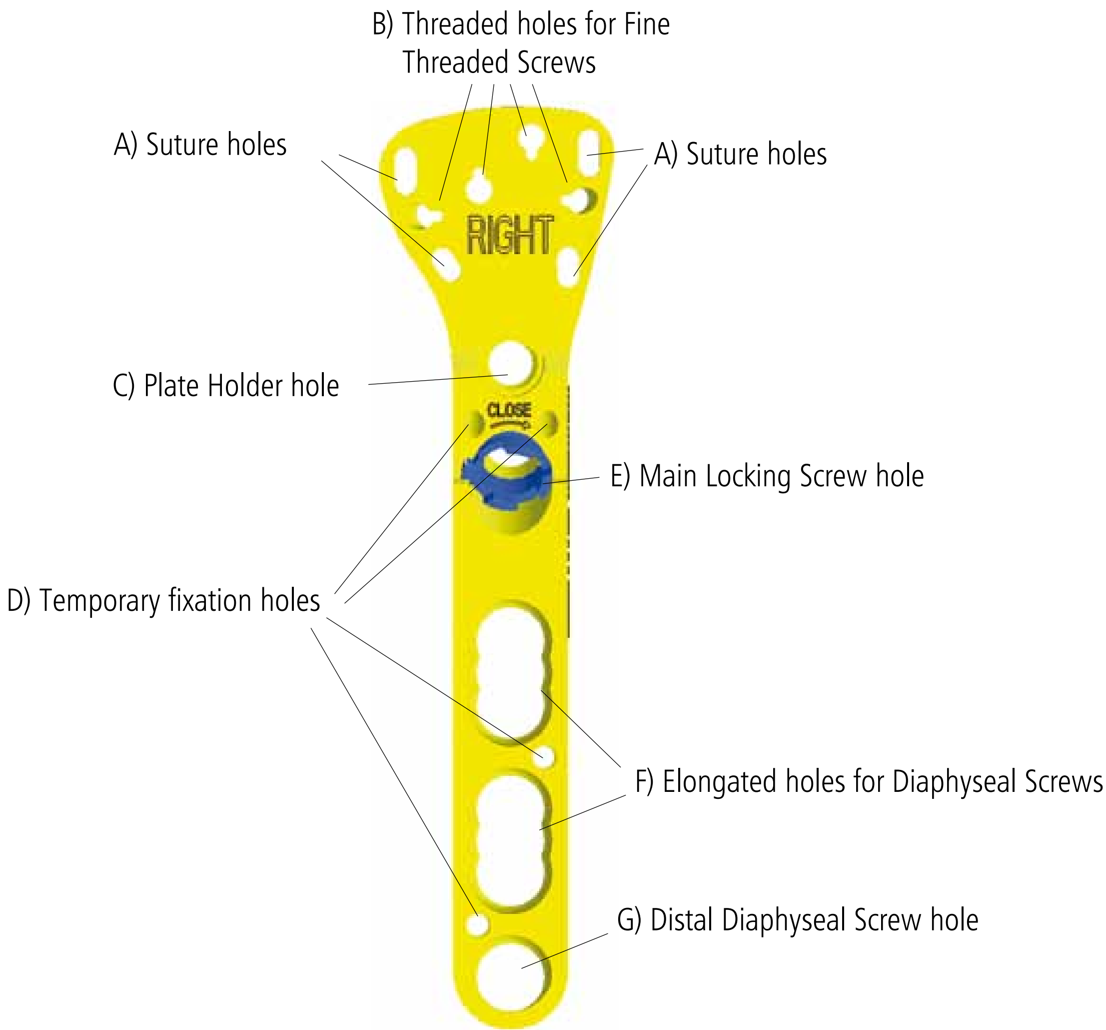


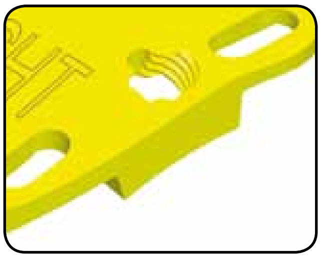
Fig. 4 Frontal view of the plate

A) The suture holes

Use of additional sutures has been suggested to reduce and fix the tuberosities in osteoporotic bone [6].

The 4 oblong suture holes are connected to large grooves on the reverse side of the plate which permit easy passing of the suture needle. This design feature has been implemented to facilitate suturing and cerclage procedures.

B) The threaded holes for Fine Threaded Screws

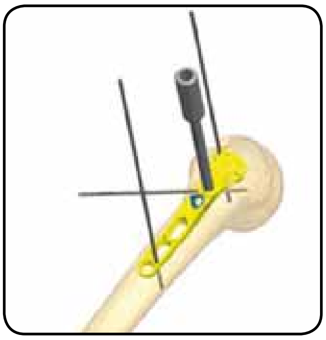


The plate is supplied with threaded holes for locking of Fine Threaded Screws.

C) The Plate Holder hole

The plate has a threaded hole for the Plate Holder that is used during the plate application.

D) The temporary fixation holes

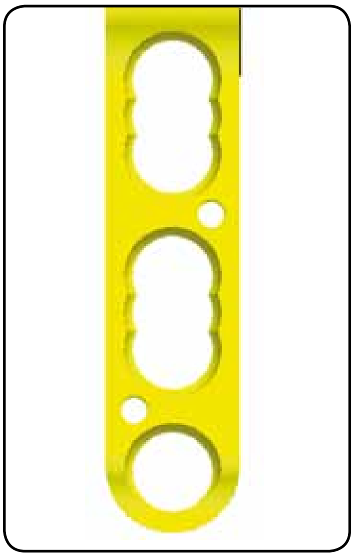


Prior to definitive fixation, the plate is temporarily fixed by using K-wires that prevent sliding and detaching of the plate. K-wires are also used to keep the fracture reduced during the application of the plate.

E) The Main Locking Screw hole

The hole for the Main Locking Screw has a cam* which securely locks the Main Locking Screw. The cam is an alternative to a threaded hole: the main screw is locked tightly to the plate, so that the plate and screw result in a unique piece. Cold welding of the locking titanium screws in the threaded plate holes is a well-known problem that can occur at the time of screw tightening and can significantly complicate subsequent plate removal [7]. Because of its specific closure mechanism, the use of a cam avoids titanium cold welding.

F) The elongated holes for Diaphyseal Screws



Proper plate placement is considered fundamental to treat successfully proximal humerus fractures [1, 5].

The elongated holes for Diaphyseal Screws permit plate fine tuning on the longitudinal axis to get its optimal positioning.

These holes are also used for Revision Screws in case of osteoporotic bone.

***Cam =** A mechanical device for converting a rotating motion into a locking motion; specifically, after that the screw in inserted, the cam is rotated into a locking position, fixing the screw firmly into the plate.

2.2 The Main Locking Screw

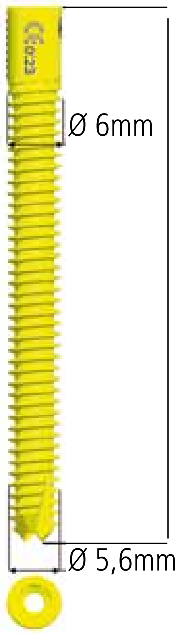


Fig. 5 Main Locking Screw dimensions

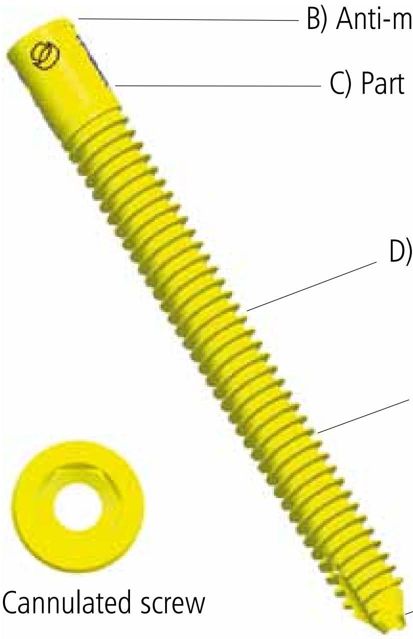
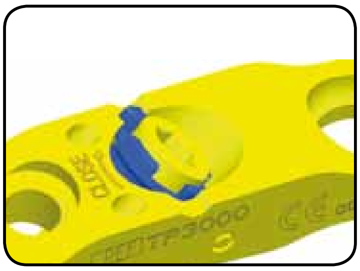


Fig. 6 Main Locking Screw features

A) Cannulated screw

The Main Locking Screw is cannulated to allow a guidewire to be run through. This feature helps to put the screw into position. The Main Locking Screw, working as a hip screw, transfers the primary load from the head to the diaphysis of the humerus.

B) The anti-migration collar



With angle-stable plate systems screw migration leading to perforation of the humeral head and reoperation is a common complication [1, 6, 2].

The Main Locking Screw has been created with an anti-migration collar. During the insertion, when the screw is completely inserted, the screwdriver is automatically released.

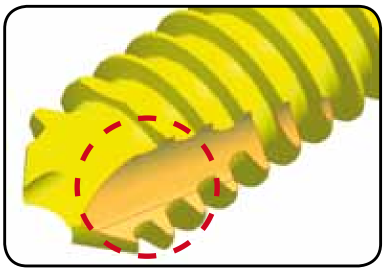
C) The part in contact with the cam

The Main Locking Screw has a smooth cylidrical part which locks to the cam without cold welding.

D) The conical shape

The diameter of the thread increases from 5,6mm to 6mm. The conical shape is designed to produce radial preload* with the following mechanism: as the screw is inserted, the thinner distal end makes the initial path through the bone. As the screw advances, its diameter increases exerting radial pressure* on the near cortex. This is designed to improve the holding power of the screw.

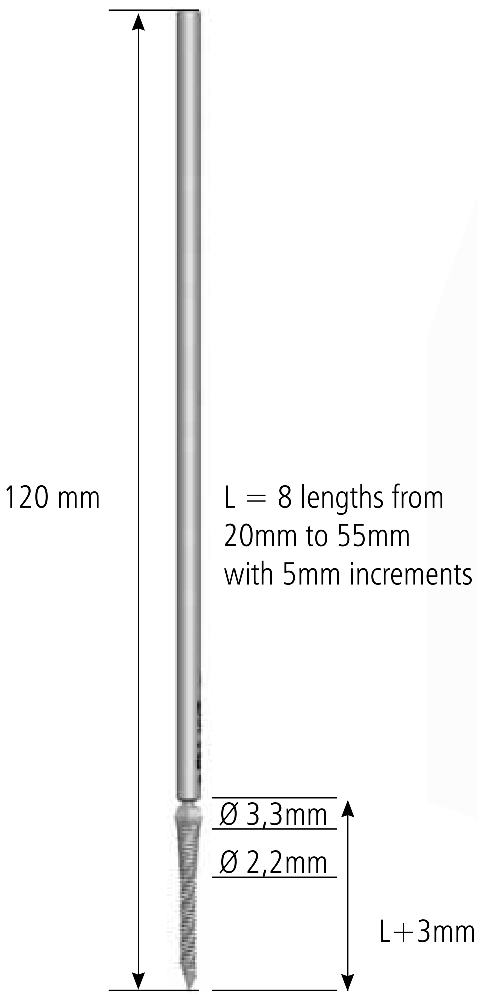
F) The self-drilling tip



The tip of the screw and the cutting angles have been optimized to provide easy entry and stable contact between the screw and the bone surface.
The flutes have been designed to offer efficient cutting and removal of the bone chips.

***Radial preload** = a compressive force perpendicular to the screw axis produced during the insertion of the screw
***Radial pressure** = pressure perpendicular to the screw axis

2.3 The Fine Threaded Screws



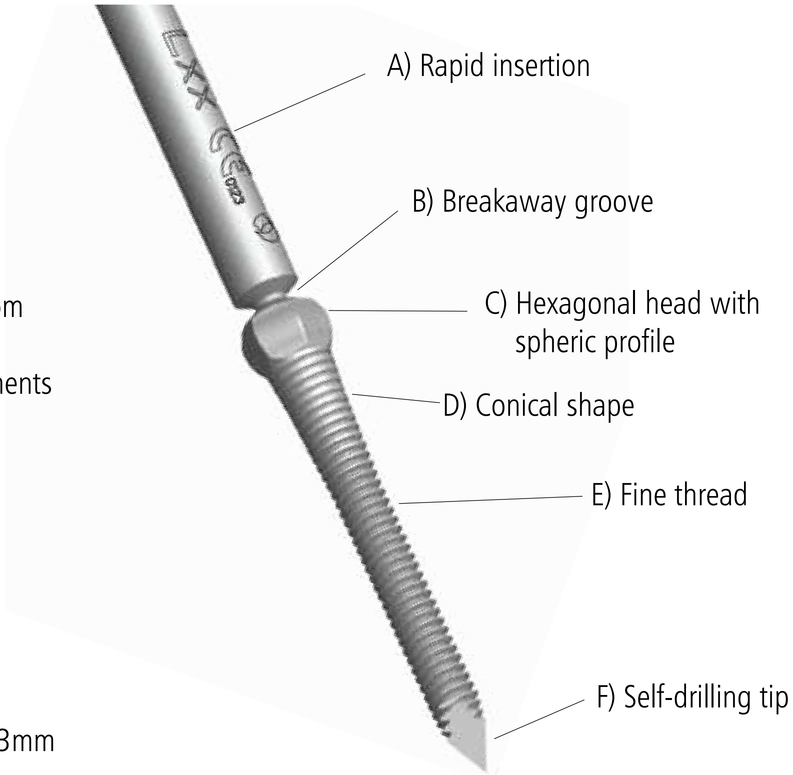


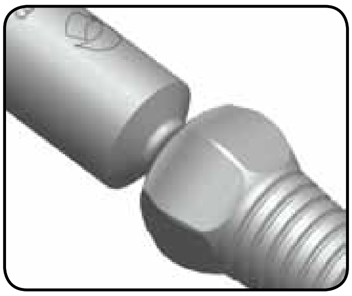
Fig. 7 Fine Threaded Screw dimensions

Fig. 8 Fine Threaded Screw features

A) Rapid insertion

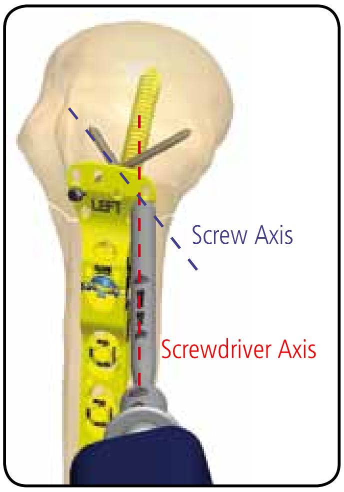
The Fine Threaded Screws are rapidly inserted with the use of a power drill. Differently from other systems on the market, in which screw insertion has to be done with a screwdriver, this solution has been conceived to reduce the time needed for screw application.

B) The breakaway groove



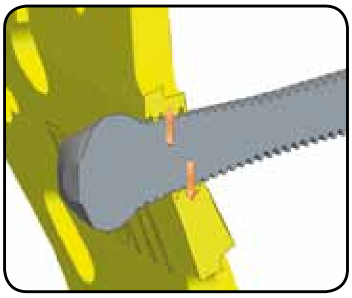
The groove has been designed with a particular geometry to permit the automatic breakaway of the shank from the screw implanted in the bone. The breakage occurs at a defined closure torque* [internal reports].

C) The hexagonal head with spheric profile



The particular hexagonal head with spheric profile of the Fine Threaded Screws is designed to allow the screw removal even if the screwdriver and the screw head are not coaxial*. The screw head remains external; therefore, it can be easily seen, cleaned from the newly formed bone and grabbed. In addition, since the screw head has an external 3,5mm hexagon, it allows an easy grabbing with pliers or similar instruments.

D) The conical shape



The conical part of the Fine Threaded Screws has a larger diameter than the hole diameter in the plate; therefore, it generates a lateral pressure on the plate. This has been designed to provide an optimal grip with the hole and to reduce the risk of screw backing out, a complication that can be frequently seen with other systems [11].
In addition, the conical shape guarantees the coupling between the screw thread and the hole thread also when screws are oriented up to $\pm 15°$.

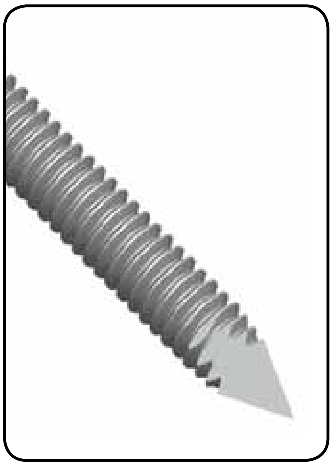
***Closure torque =** force required to fasten a screw
***Coaxial =** having a common axis

E) The fine thread and osteointegration

The Fine Threaded Screws are characterized by:

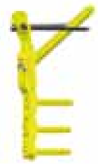
- *Fine thread pitch and low thread profile:*
  The low thread together with the fine thread pitch provide attenuates stripping effect during insertion an increase in the screw-bone contact interface. This improves fixation, holding power and osteointegration [9, 10, 12].

F) The self-drilling tip

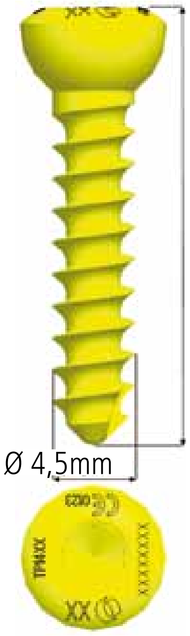


The three cutting edges and the small diameter of the screw make the tip self-drilling.

The Fine Threaded Screws have greater mechanical efficiency and significantly better holding power compared to other commercial cortical screws, furthermore, titanium surface encourages osteointegration of bone screws [10, 12, 13].



2.4 The Diaphyseal Screws



8 available lengths
from 22mm to 36mm
with 2mm increments

Features:
- 3,5mm hexagon
- Spherical head
- Non locking screw to feel screw stability and gripping into the bone

2.5 The Revision Screws

5 available lengths
from 26mm to 34mm with
2mm increments

Features:
- 3,5mm hexagon
- Spherical head
- Wider crests for poor quality bone
- Non locking screw to feel screw stability and gripping into the bone

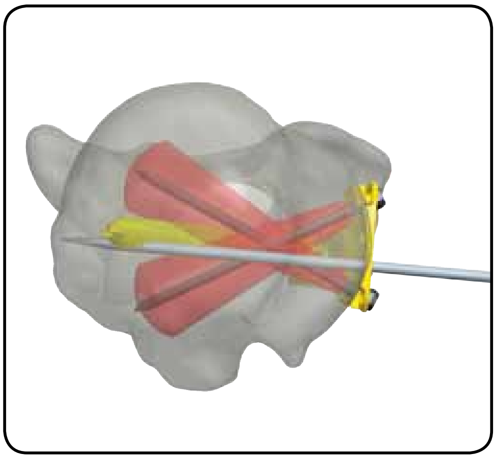
3. The Contours PHP System

The Contours PHP was designed to have the following features:

- Triangular configuration (of the Main Locking Screw and the Fine Threaded Screws)
- Designed to reduce the amount of bone stock removed from the humeral head
- Low head profile designed to avoid impingement
- Anatomically shaped: designed both for the right and the left humerus
- Made of Titanium Alloy
- Suture holes with large groove designed for easy needle insertion

3.1 Stability

With Contours PHP, stability is obtained with the triangular configuration of the Main Locking Screw and the angulated Fine Threaded Screws.
Principal stabilization is achieved by the Main Locking Screw, which is inserted in the calcar area.
By providing mechanical support of the inferomedial region of the proximal humerus head, characterized by maximum bone quality and quantity [14], the risk of secondary loss of reduction and screw fixation failure is reduced [15].



The Fine Threaded Screws angulated in convergent directions up to ±15° contribute to pullout strength and fixation strength. Although characterized by a diameter of 2,2mm, they are as stable as Ø 3,5mm screws as described by [16] (Fig. 9).

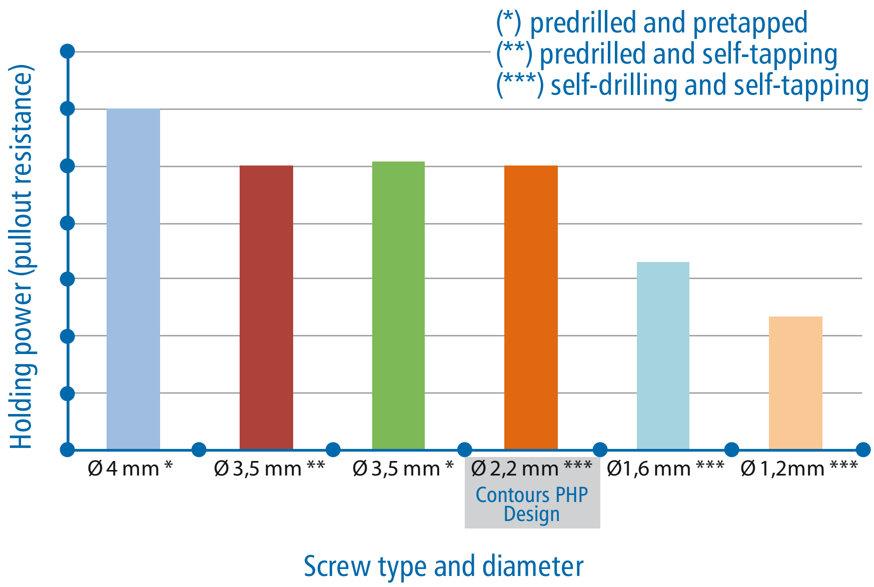


Fig. 9 Holding power of different screws. Adapted from [15].
There is no significant difference between the maximum holding power of the 2,2mm fine machine thread screws and the 3,5mm cortical screws.

3.2 Reduced amount of metal content

"Avascular necrosis is initiated by the fracture pattern, that almost unavoidably damages the delicate blood supply of the humeral head" [17]. Contours PHP has been designed to decrease the invasiveness in terms of metallic content in the humeral head and reduce further damages of the vascularity.

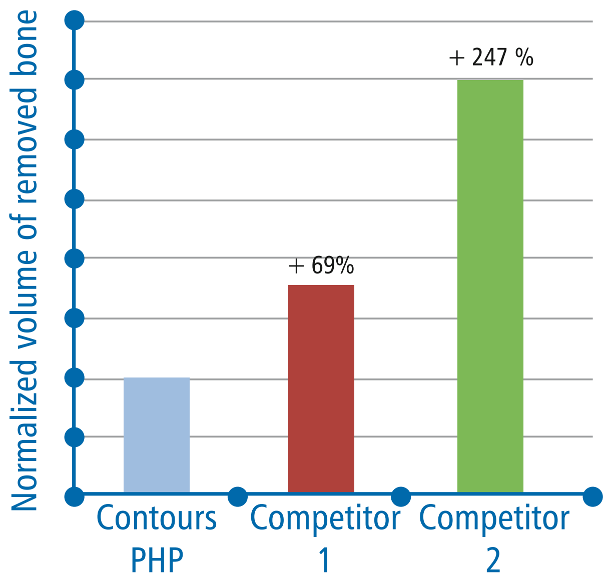


Fig. 10 Relative amount of removed bone
With the Contours PHP the amount of bone removed from the humeral head is lower in comparison to other systems in the market.

3.3 Low Plate Positioning

Low head profile and low plate positioning have been conceived to reduce the risk of subacromial impingement, which frequently occurs when plates are not low contoured or placed too superiorly [18, 19].
In addition, lower plate positioning allows the use of anatomical landmarks (e.g., insertion of the pectoralis major muscle) located far from the fracture zone.

3.4 Easy Application and Removal

Contours PHP has been developed to be easy to apply and remove.

Removal of titanium angle-stable plates can be troublesome. The main problems are generally related to the removal of the screws anchored in the bone [20, 21, 22].
To remove Contours PHP only two instruments are necessary: a standard 3,5mm hexagonal screwdriver for the main locking screw and distal screws and a 3,5mm quick connect screwdriver for the fine threaded screws. The hexagonal head of the Fine Threaded Screws and the cam facilitate plate removal.

3.5 Biomechanical Tests

A series of biomechanical tests has been performed in an external certified laboratory to compare the mechanical behaviour of the Contours PHP with its main competitor.

The following tests were performed:
- Torsion test
- Flexion test

The results demonstrate that the Contours PHP has similar torsional and superior bending biomechanical characteristics to its main competitor.

3.5.1 Torsion test

Aim of the test:
Comparison of the torsional stiffness between the Contours PHP and its main competitor.

Set-up:

The plates were mounted as shown in Fig. 11 and tested according to [23, 24]. Torsional stiffness was evaluated by measuring the angular excursion of the system (plate + sawbones) subjected to a symmetrical torque for 1000 cycles.
The bigger the angle, the lower the torsional stiffness.

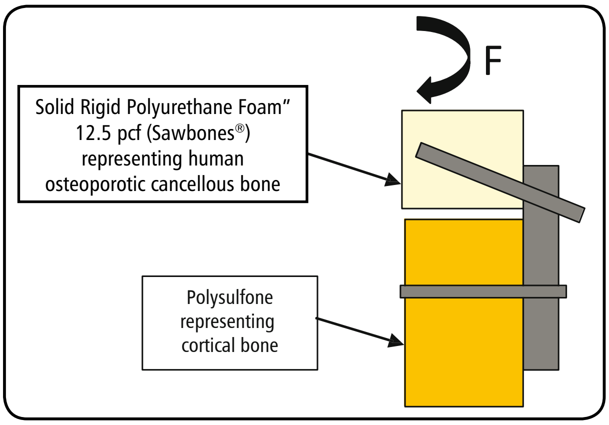


Fig. 11 Scheme of the tested specimens

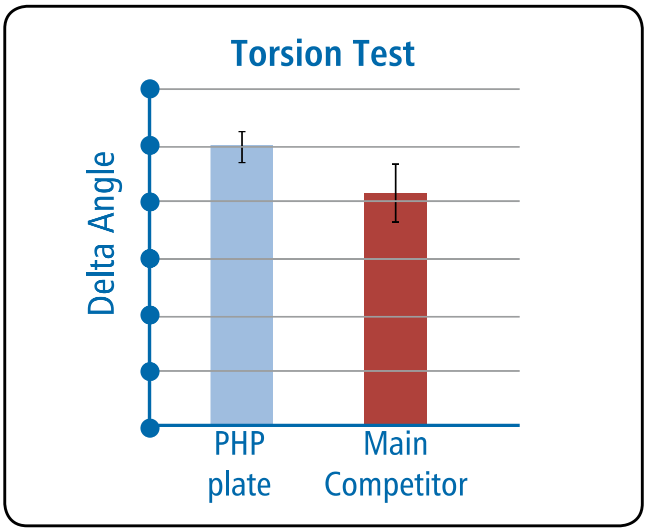


Fig. 12 Mean total angular excursion
The difference between the two plates is not significant.

Results:

Screw migration did not occur; Contours PHP showed a **constant** total angular excursion, which indicates a good torsional stiffness.

The results show that the Contours PHP consisting of 1 Main Locking Screw, 3 Diaphyseal Screws and 4 Fine Threaded Screws is characterized by a torsional performance comparable to its main competitor (Fig. 12).

3.5.2 Flexion test

Aim of the test:
Comparison of the bending stiffness between the Contours PHP and its main competitor.

Set-up:

The plates were mounted as shown in Fig. 13 and tested according to [25]. A load was applied for 5000 cycles. The displacement of the system (plate + sawbones) was measured at every cycle.

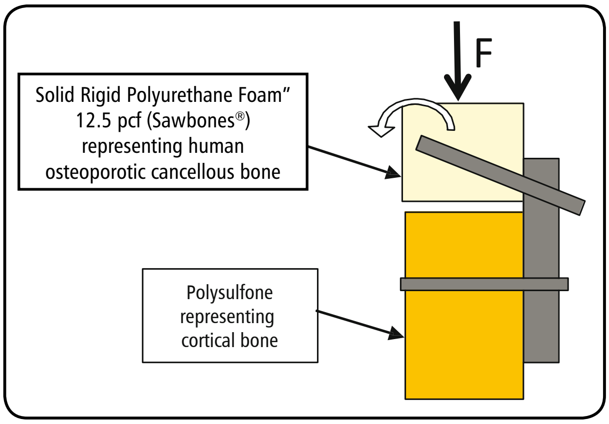


Fig. 13 Scheme of the tested specimens

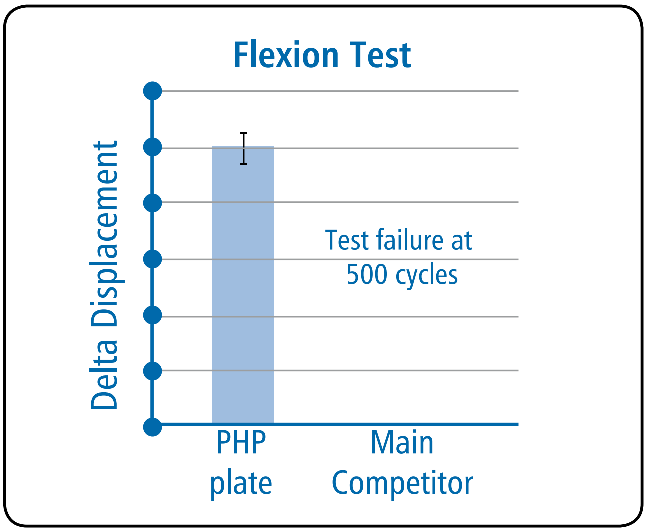


Fig. 14 Mean displacement
The competitor plate failed during the test

Results:

The competitor plate showed low bending stiffness and failed. On the contrary, the Contours PHP showed higher bending stiffness.

The results indicate that in comparison to the competitor plate the Contours PHP is able to resist to higher loads (Fig. 14).

4. Conclusions

This document was created to present the technical and biomechanical features of the Contours PHP system.

The technical solutions studied for this system were designed to solve typical problems that can occur during angle-stable plate fixation. Biomechanical tests prove that Contours PHP performance is comparable to or better than the market leader plate performance.

In conclusion, Contours PHP is a unique innovative system for the treatment of acute fractures of the proximal humerus.

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Manufactured by: ORTHOFIX Srl
Via Delle Nazioni 9
37012 Bussolengo (Verona)
Italy

Telephone +39-0456719000
Fax +39-0456719380

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