

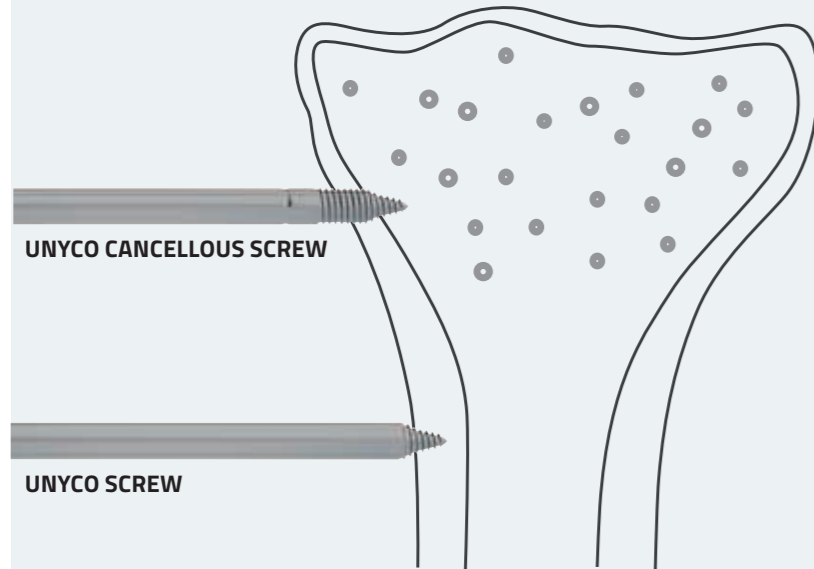


QUICK REFERENCE GUIDE FOR GALAXY UNYCO DIAPHYSEAL STERILE KIT 99-93506

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



INTRODUCTION



There are 2 variants of the UNYCO screws; both of them must be inserted with the Power Drill Torque Limiter:

- one designed for diaphyseal bone (UNYCO Screw).
- one for metaphyseal bone (UNYCO Cancellous Screw).

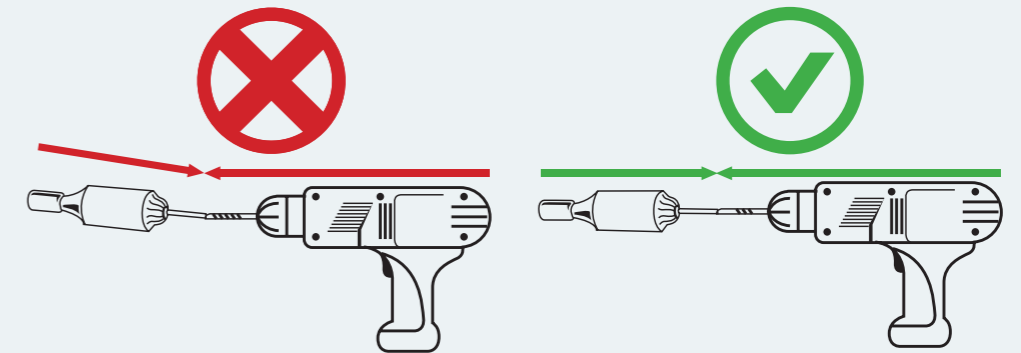
In **Cancellous Bone**, where the UNYCO Cancellous Screw should be used, drilling must be stopped visually by the surgeon when the soft tissue reference line reaches the skin.

There will be instances when the cortex of the cancellous bone is sufficiently hard such that the torque limiter will activate on reaching the required torque and decouple the drilling.

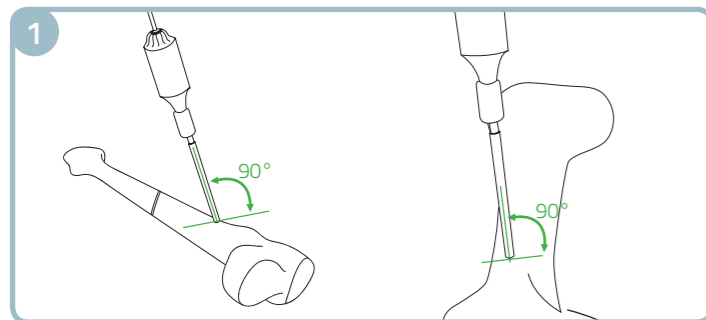
In **Cortical Bone**, when the UNYCO Screw is correctly inserted into the first cortex, the Power Drill Torque Limiter will stop the rotation of the screw automatically.

PRECAUTION: The system stability is guaranteed only with 4 UNYCO screws coupled with the Large Multiscrew Clamp in each segment.

The sterile packed Power Drill Torque Limiter is included in the same cardboard box together with the sterile peel pack.

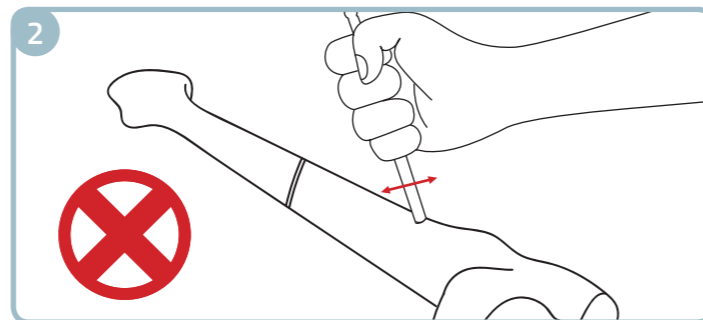


If the power drill used for the surgery does not have the Quick Connection system, please **make sure the Power Drill Torque Limiter is coaxially inserted.**



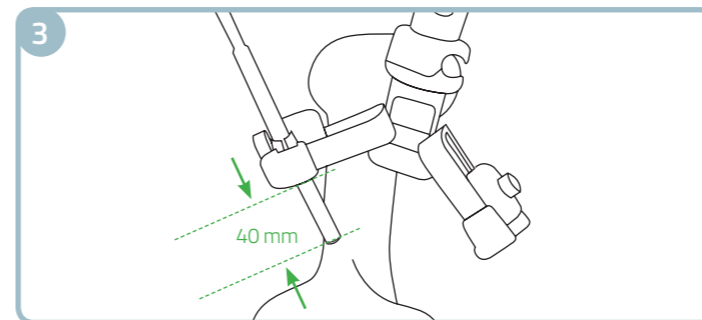
- Make a 5 mm puncture in the skin.
- Insert the first screw freehand, without the clamp, just medial the tibial crest or directly over it.

PRECAUTION: Uni-cortical screws must be inserted perpendicular to the bone surface using low rotation speed and a steady thrust to ensure optimal bone purchase.



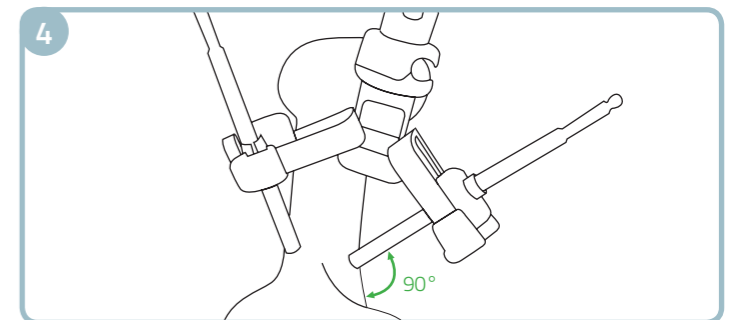
Proper unicortical screw insertion should NOT be checked by bending the single screws.

PRECAUTION: During and after insertion, ensure correct positioning of the implants under image intensification. Check screw insertion both in the AP and lateral planes.



Apply the Large Multiscrew Clamp for UNYCO Screws (93566) on the first screw.

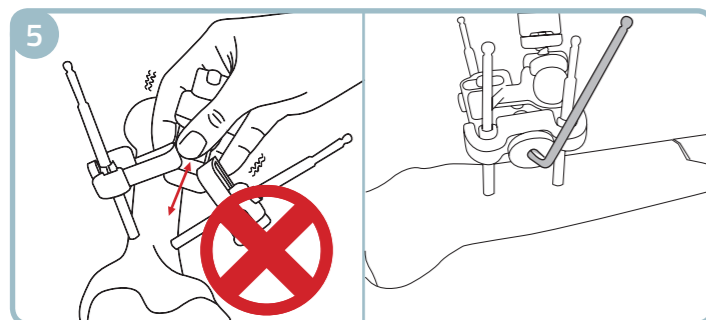
PRECAUTION: Once converging uni-cortical screws have been inserted, the distance of the clamp from the soft tissue surface cannot be altered. It is therefore important to determine the final distance of the fixator from the skin before inserting the second screw in the clamp.



Make sure to tighten the metal ring on the arm clockwise. Using the Large Multiscrew Clamp for UNYCO Screws (93566) as a template for screw insertion, insert the second screw in the contralateral arm, **trying to be as perpendicular as possible to the bone surface.**

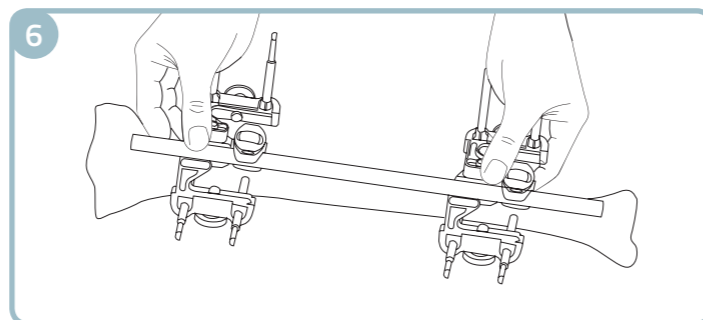
PRECAUTION: Uni-cortical screws must be inserted perpendicular to the bone surface using low rotation speed and a steady thrust to ensure optimal bone purchase.

Before drilling the UNYCO Screw into the bone, if necessary, partially tighten the metal ring on the clamp clockwise so that the screw within its seat is free to move but without excessive play.



The clamp should not be pulled/pushed after the second screw is inserted.

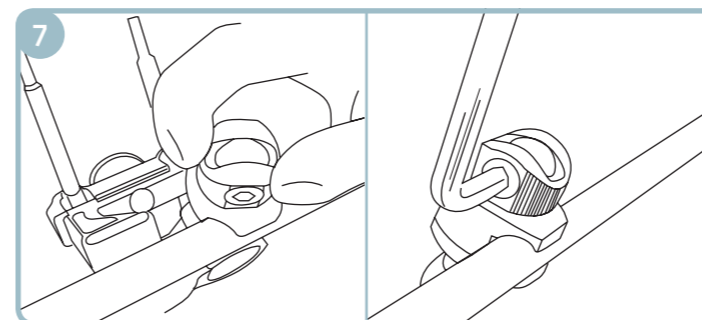
Once all screws in each arm have been inserted, tighten both metal rings fully with the 5 mm Allen Wrench (30017).



- Follow steps 2-5 to apply the second Large Multiscrew Clamp for UNYCO Screws in the distal segment.
- Join both Large Multiscrew Clamps for UNYCO Screws with the rod leaving the clamps loosened to facilitate fracture reduction.
- Reduce the fracture, with X-ray guidance as necessary, holding the clamps to facilitate the reduction maneuvers.

Fracture reduction should only be undertaken once four unicortical screws have been inserted in each Large Multiscrew Clamp for UNYCO Screws. Fracture reduction should only occur by manipulating the clamps (not via individual screw manipulation).

PRECAUTION: The system stability is guaranteed only with 4 UNYCO Screws coupled with the Large Multiscrew Clamp in each segment. The Large Multiscrew Clamp for UNYCO Screws should never be applied across the fracture line.



- Lock the clamps first manually by turning the knurled metal ring clockwise.
- If reduction is satisfactory, finally lock all the clamps firmly by tightening the cams with the 5 mm Allen Wrench.

TIPS

When treating intermediate fragments of segmental fractures, should the UNYCO Screw length be insufficient, the UNYCO Cancellous Screws are recommended (as they are 10 mm increased in length).

Initial maneuvering of the clamps may lead to the adjustment of clamp components. Check the tightening of the nuts and metal rings prior to and after the reduction.

Retighten all the nuts and metal rings after 24 hours, and check daily that they remain tightly closed. In case the metal rings are slightly released, re-close them tightly with a 5 mm wrench.