



BioPro[®]
HBS[®]

Headless
Bone
Screw

BIOLOGICALLY ORIENTED PROSTHESES

BIOPRO



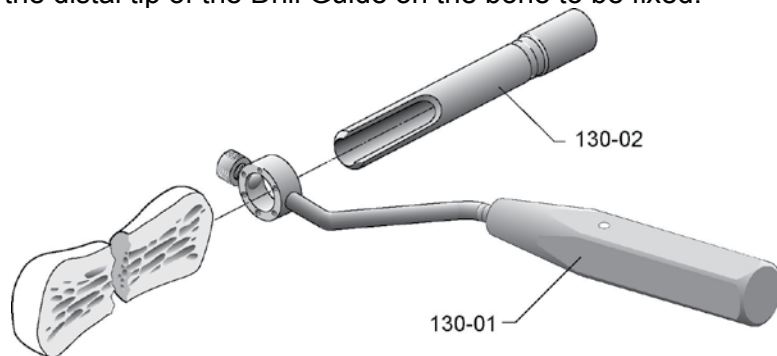
ISO 13485
FM 77447

STEP ONE:

Prepare the patient for surgery following accepted procedures. The skin incision is the surgeon's choice and will be dictated by the type of procedure being performed.

STEP TWO:

Assemble the Drill Guide Assembly (place 130-02 into 130-01) and carefully position the distal tip of the Drill Guide on the bone to be fixed.

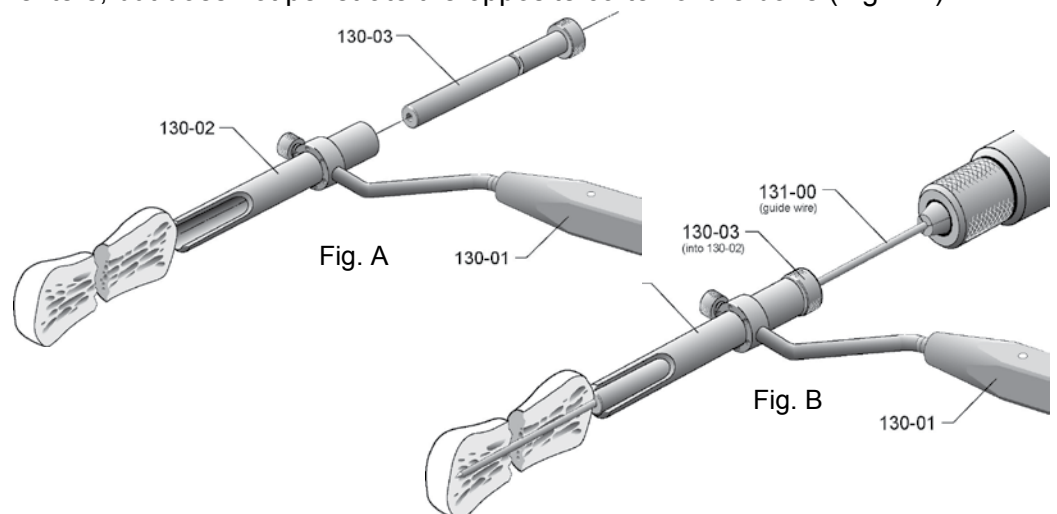


NOTE: Care must be taken to carefully remove any soft tissue overlying the bone so as to enable the points on the tip of the Drill Guide to engage with bone directly. Doing so will prevent wandering of the Drill Guide during drilling and will enable accurate screw length measurement.

NOTE: The position and alignment of the Drill Guide may be checked on an image intensifier to confirm that the tip of the Drill Guide is positioned for optimal placement of the Guide Wire.

STEP THREE:

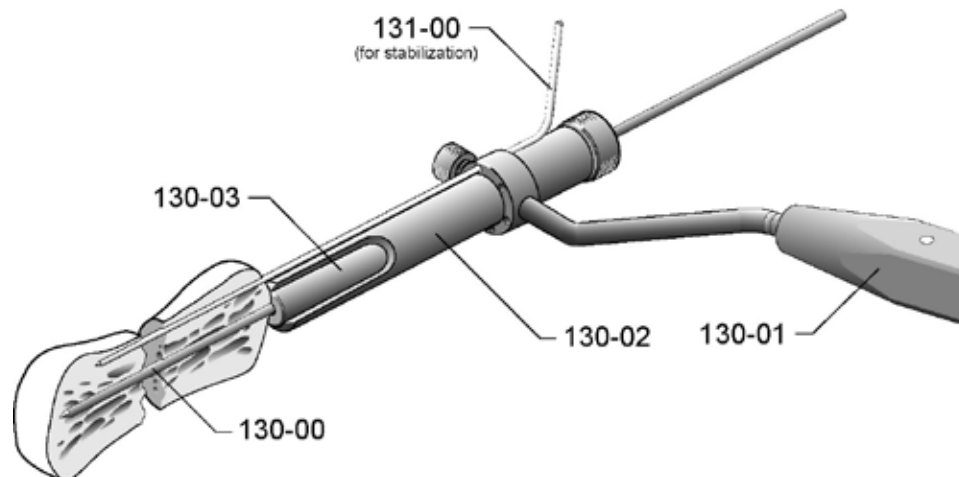
Upon attaining optimum positioning of the Drill Guide Assembly, the Reduction Sleeve (130-03) is placed into the Drill Guide (130-02) (Fig. "A"). The Reduction Sleeve allows the Surgeon to accurately control the position of the Guide Wire (131-00) during insertion. The Guide Wire is advanced slowly under image control to ensure it is positioned perpendicular to the fracture/fusion in the mid-axis of the bone. The distal tip of the Guide Wire is advanced to the point where it enters, but does not penetrate the opposite cortex of the bone (Fig. "B").



NOTE: Insertion of the Guide Wire is best done using a suitable, slow speed, smaller power instrument.

STEP FOUR:

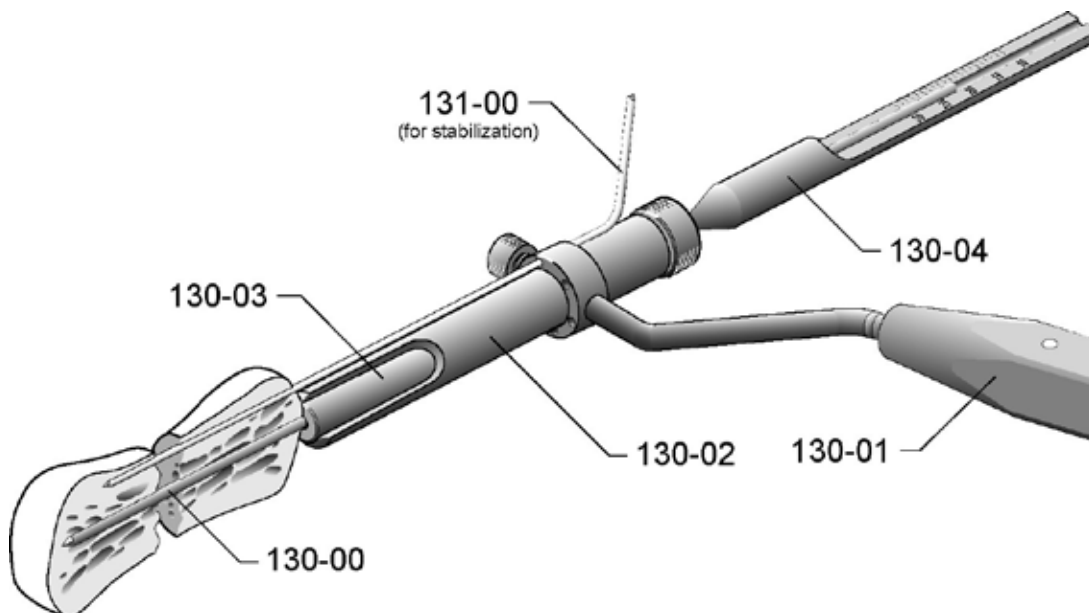
Following the positioning of the Guide Wire (130-00) additional stabilization Guide Wire(s) (use 130-00) are passed through any one of the six peripheral holes on the collar of the Guide Handle (130-01). The stabilization Guide Wire(s) are advanced across the fracture/fusion site under image control and allow for optimal reduction to be obtained during insertion of the screw. Once the stabilization Guide Wire(s) are positioned satisfactorily, the protruding end of the Guide Wire(s) should be bent so as not to interfere with the Surgeon's access to the Drill Guide Assembly. At the end of the procedure the stabilization Guide Wire(s) should be removed.



NOTE: Insertion of the Stabilization Guide Wire(s) is best done using a suitable, slow speed, smaller power instrument.

STEP FIVE:

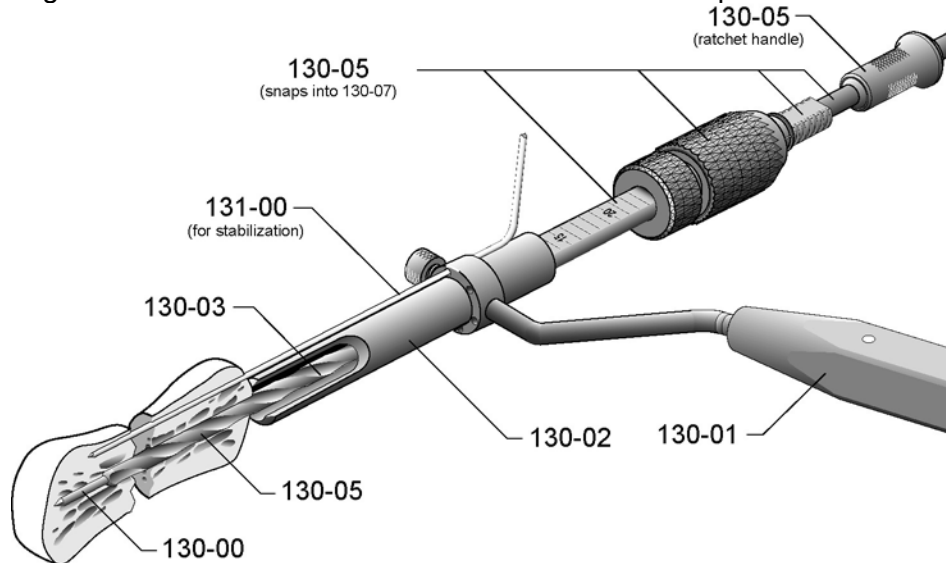
Once the Guide Wire (130-00) is optimally positioned, the Measuring Sleeve (130-04) is passed over the proximal end of the Guide Wire to obtain a direct measurement of the length of screw required. Once the measurement is obtained, drive the Guide Wire 5-10mm deeper before moving on to Step Six. This will ensure the Guide Wire doesn't pull out with the Cannulator Drill Bit during Step Six.



NOTE: To ensure accurate measurement, attention must be given to ensuring the tip of the Drill Guide (130-02) remains firmly in contact with the surface of the bone and the distal end of the Measuring Sleeve (130-04) abuts top of the Reduction Sleeve (130-03).

STEP SIX:

Following screw length measurement, the Reduction Sleeve (130-03) is removed from the Drill Guide (130-02) by passing it over the Guide Wire (131-00). The Cannulated Drill Bit (130-05) is passed over the Guide Wire with the drill stop having been set at the depth indicated by the Measuring Sleeve (130-04). The Cannulated Drill Bit is carefully advanced along the Guide Wire under image control until the drill stop abuts the top of the Drill Guide, indicating that the Cannulated Drill Bit has reached its full depth.

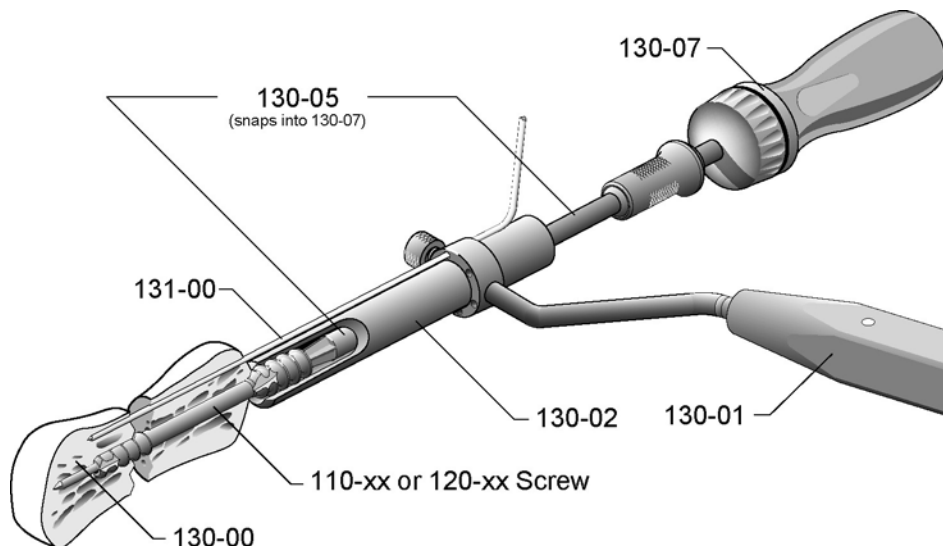


NOTE: Drilling is best done using a suitable, slow speed, smaller power instrument. If none is available, drilling may be accomplished by hand using the Ratcheting Handle (130-07) with the Cannulated Drill Bit.

CAUTION: It is recommended that the Cannulated Drill Bit is withdrawn and cleaned one or more times during drilling to prevent binding with the Guide Wire. Should binding occur, the Guide Wire may withdraw with the drill. Should the Guide Wire be inadvertently withdrawn, it should be repositioned (using the Reduction Sleeve if necessary) before moving to the next step.

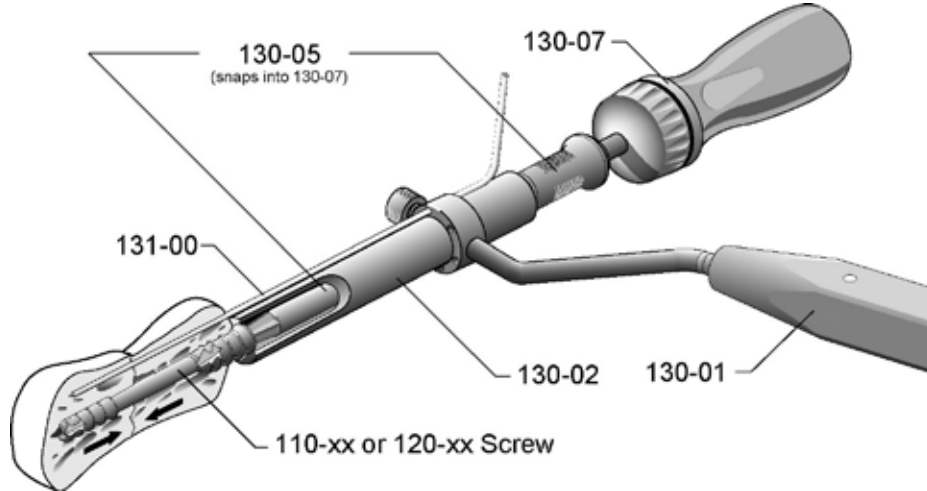
STEP SEVEN:

The Cannulated Screwdriver Bit (130-05) is inserted into the Ratcheting Handle (place 130-05 into 130-07) and is used to lift a Screw of correct length from the screw rack. The Screw is passed over the Guide Wire (131-00) and inserted until increased resistance is felt as the trailing thread enters the bone.



STEP EIGHT:

Upon increased resistance being felt as the trailing thread enters the bone, the Screw Guide Wire (131-00) should be removed. **Note: Do not remove the Stabilization Guide Wire yet as this keep the drill guide assembly lined up with the screw.** Following removal of the Guide Wire, the Screw should be reengaged with the driver tip of the Cannulated Screwdriver Assembly (130-05 into 130-07). The Screw should be advanced until the Cannulated Screwdriver Assembly stop abuts on the top of the drill guide.



CAUTION: The Guide Wire should always be removed before the Screw is fully tightened. Not removing the Guide Wire at this stage could cause the tip of the Guide Wire to become bent making it impossible to remove.

STEP NINE:

Fixation is now complete. The Stabilization Guide Wire can now be removed and the surgical site should be closed in the usual manner.

