

HDC

Health Development Company

Thank you for choosing another high quality product from HDC. In order to use this product correctly please read completely and follow the underwritten instructions for use carefully. These written instructions cannot cover all eventualities during the procedure.

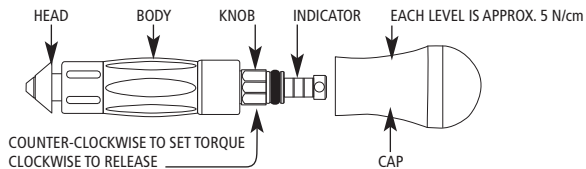
PRODUCT INFORMATION

The Torque Driver Body (DST-1600) is a manual Spider Screw placement driver to help you avoid Spider Screw breakage. The Torque Driver has a pre-set torque value of 5 Ncm and the torque can be adjusted incrementally up to 20 Ncm, the tolerance is +/- 1 Ncm. The torque settings are dependent upon the placement site, bone quality and/or other circumstances. The average torque required for placement of the K1 Spider Screw into the maxilla is between 5 and 15 Ncm. In the mandible where the bone is usually denser, the torque value may need to be set to 20 Ncm. The torque required for Spider Screw placement is lower for soft, spongy bone (maxilla) and higher for hard, dense bone (mandible, posterior). The breakage point for K1 Spider Screws is approximately 25 Ncm, however if the tip of a screw comes in contact with a root the breakage point is approximately 12-15 Ncm. The Torque Driver is manufactured from anodized aluminum, the internal mechanism and all the other parts are manufactured from stainless steel. The Torque Driver Body consists of three main parts: head, handle body and adjusting knob (see diagram below).

DIRECTIONS FOR USE (see diagram)

1. To begin place the Pick-up Driver Shaft (DSP-5052N) in to the Torque Driver Body (DST-1600). Simply pull back completely on the head of the Torque Driver and hold it back. Place the shaft into the Torque Driver Body tip. Due to hexagonal shape of the connection, rotate the shaft slightly to the left and right to find the correct locking position, you will feel the shaft connect into position. Push the Pick-up Driver Shaft in completely and release the head. Pull on the shaft, if correctly inserted it will be locked into position. If the shaft comes out pull back and replace to lock into position.

2. The Torque Driver has a torque range of 15 Ncm. The torque is pre-set at 5 Ncm (+/- 1 Ncm) and the maximum torque setting is 20 Ncm (+/- 1 Ncm). To adjust the torque, first remove the Indicator Cover Cap. Then rotate the knob counter-clockwise to the desired indicator level. Each indicator line measures approximately 3mm and each 3mm increment is about 5 Ncm of torque. The Torque Driver can also be rotated clockwise to lower or release the torque. A complete radiographic evaluation is required to determine bone quality, density and placement site which will determine torque settings.



3. Replace the cap after setting the torque and prepare for Spider Screw placement. For initial insertion if it is necessary during the first 2 or 3 turns you may push with a light hand, to guide placement, after the initial turns do not push on the driver, let the screw do the work. If during placement you reach the set torque value, the mechanism inside of the Torque Driver will release and you will hear an audible click, the handle will continue to rotate but the screw cannot be inserted any further because the shaft has stopped.

4. If the set torque value has been reached you must stop and assess the situation. You cannot go on with insertion or the screw may break. It is possible you may have hit a root or the bone is more dense than expected. If you have come in contact with a root you must adjust your insertion site. If the site is acceptable you must remove the Spider Screw and drill a pilot hole. After making the pilot hole, release the Torque Driver (see important note below) and reset to the desired torque level and continue with placement.

IMPORTANT: After EVERY use, you must remove the cap and rotate the knob clockwise completely to release the spring. The spring must be released each time the Torque Driver is used. The knob must be returned to the starting position or the Torque Driver will remain loaded and will not function properly.

IMPORTANT: The Torque Driver must be calibrated by the manufacturer every year in order to maintain the internal pre-loaded spring and functionality of the driver. Please contact Ortho Technology each year from the date of purchase to set up your annual calibration. Do not attempt to adjust the internal spring mechanism within the Torque Driver, it is only to be adjusted by the manufacturer.

Sterilize before use.

1. Before use of surgical instruments sterilization is required.
 - a. A steam sterilizer (Class B) is suggested with a sterilization process of 134°C (273°F) for 5 minutes or 121°C (273°F) for 15 minutes.
2. Sterilize prior to every surgical operation.
3. Correct and complete cleaning of the instrument it is strictly required.
4. After the sterilization process has been performed, a disinfection of the instrument before use is suggested (aerobic prevention).

HDC Torque Driver is a placement tool to help you avoid screw breakage during insertion and has a tolerance of +/- 1 Ncm.

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