

Torque Controlled Screwdriver Handles – AC0027-1, AC0032-A, AC0032-B, AC0032-C, AC0051-1-A, CAT4014, PBZ0014, PS0003-1, SL0007, CB0073-1

Product Description and Precautions:

The product is a torque-controlled screwdriver handle. It is pre-set for a maximum insertion torque (+/- 10% tolerance):

- AC0027-1 with 5 Nm
- AC0032-A with 11 Nm
- AC0032-B with 11 Nm
- AC0032-C with 11 Nm
- AC0051-1-A with 2.5 Nm
- CAT4014 with 9 Nm
- PBZ0014 with 3.6 Nm
- PS0003-1 with 2 Nm
- SL0007 with 3 Nm
- CB0073-1 with 3 Nm

The instrument must be serviced regularly to ensure that the torque remains constant throughout its service life.

The instrument must be returned to SIGNUS Medizintechnik GmbH for service every 3 years or after 250 autoclave cycles (whichever comes first). Torque-limited screwdriver handles that have not been serviced in good time may no longer be used. A fixed service charge will apply.

The instrument must be fitted with a specially designed blade for the intended use of tightening screws to the pre-set torque. The blade can be inserted into the handle by retracting the coupling. The instrument is then ready for use.

A torque-controlled screwdriver handle is not intended for insertion or removal of screws. It is designed to tighten the screw to the final torque after the screw has been inserted by another screwdriver.

The internal mechanism can be felt to disengage when the pre-set torque is reached. The screw is inserted with the correct torque.

Torque-controlled screwdriver handles should be used with SIGNUS products only.

- Completely remove all components of the packaging prior to reprocessing.
- All non-sterile instruments must be reprocessed in the SIGNUS trays.
- Observe the validated reprocessing procedure in the instructions included with the tray (valid version: eifu.signus.com).
- Products with cavities as well as gaps, threads, joints and springs must be placed in an ultrasonic bath for 10 minutes at 40°C in a 0.5% alkaline cleaning solution and then rinsed/flushed for 20 seconds with cold mains water at about 4 bar static pressure (mains pressure).

- During sterilisation the following must be noted:

- Method: Steam sterilisation (fractionated vacuum method)
- Temperature: Minimum 132°C, maximum 137°C
- Cycles: At least 4 pre-vacuum pulses
- Sterilisation duration: At least 4 minutes
- Drying time: Adjust the drying time in accordance with the loading of the steriliser; the items to be sterilised must be dry

- The implant and instrument tray must undergo a validated cleaning process before being returned to SIGNUS. This must be documented on the delivery note provided, which must be enclosed with the return shipment.

Please fill in (see delivery documentation):

REF-no.: _____

Next service date: _____

Serial-no.: _____

Product warranty:

SIGNUS Medizintechnik GmbH guarantees that every torque-controlled screwdriver has been manufactured, packaged and tested with the greatest possible care using selected materials and that all processes involved are subject to continuous quality control. Since SIGNUS Medizintechnik GmbH has no influence on the conditions under which a screwdriver is applied and used, nor on the diagnosis of the patient, the method of application or the handling of the screwdriver after it has left the factory, SIGNUS Medizintechnik GmbH gives no warranty either for the success of the procedure or for the non-occurrence of complications. Please inform SIGNUS immediately of any (potential) malfunction of which the user is aware, including the REF-no. and the Serial-no..