SURGI-TEC

ENGLISH	**Instructions for Use - Surgi-Tec Surgical Instruments** intended for use with **TPD** (Classic, All-in-one, Neo) **/ TMD / OS Screws & Plates / OBA**	ENGLISH

This document is intended to give general guidance on how standard reusable surgical instruments supplied by Surgi-Tec may be processed to prepare them for use.
A surgeon should not begin clinical use of the surgical instrument without reading the instructions for use.

Intended use
Surgi-Tec surgical instruments are intended for use during surgical procedures by using one of the following Surgi-Tec medical devices: Distraction devices such as TPD (Classic, All-in-one, Neo) / TMD / Skeletal anchorage systems and osteosynthesis screws and plates. Surgi-Tec surgical Instruments can be reused after appropriate cleaning, disinfection and sterilization.

Intended users
Surgi-Tec's surgical instruments are intended for use by suitably trained and qualified oral and maxillofacial surgeons.

Intended environment
The intended environment for the use of surgical instruments is Hospitals and Clinics.

Performance characteristics

Ref	Description	Performance characteristic
99-901A	Handpiece for all inserts	Surgi-Tec instrument handle to lock specific inserts and provide torque for insertion.
99-101A	Screwdriver-Internal Pentagon	Surgi-Tec surgical screwdriver for inserting and removing Surgi-Tec's screws with internal pentagon design
99-906A	Screwdriver - Micro Internal Pentagon	Surgi-Tec surgical screwdriver for inserting Surgi-Tec' micro screws with internal pentagon design
99-906S	Insert - Micro Internal Pentagon	Surgi-Tec surgical insert to be used with handpiece for inserting Surgi-Tec's micro screws with internal pentagon design
99-907A	Screwdriver - Micro External Pentagon	Surgi-Tec surgical screwdriver for removing Surgi-Tec's micro screws with external pentagon design
99-909S	Insert - Internal Pentagon	Surgi-Tec surgical insert to be used with handpiece for inserting Surgi-Tec's screws with internal pentagon design
99-910S	Insert - External Pentagon	Surgi-Tec surgical insert to be used with handpiece for removing Surgi-Tec's screws with external pentagon design
99-915S	Insert - Slotted	Surgi-Tec surgical insert to be used with handpiece for inserting Surgi-Tec's screws with slotted design
03-751A	TPD NEO - Hinged Key	Surgi-Tec's reusable dental torque wrenches for use with TPD NEO
03-951A	TPD All-In-One / Classic - Hinged key	Surgi-Tec's reusable dental torque wrenches for use with TPD All-In-One / Classic

Material information

Device	Material info
99-901A : Handpiece for all inserts	PROPYLUX HS DARK BLUE CW614N X2CrNiMo18-14-3 Inox 302 mat - EN 10270-3 RVS 316
99-101A : Screwdriver-internal pentagon	X17CRNI162 , AISI431 PROPYLUX HS DARK BLUE
99-906A : Screwdriver - Micro Internal Pentagon	X17CRNI162 , AISI431 PROPYLUX HS DARK BLUE
99-906S : Insert - Micro Internal Pentagon	X17CRNI162 , AISI431
99-907A : Screwdriver - Micro External Pentagon	X17CRNI162 , AISI431 PROPYLUX HS DARK BLUE
99-909S : Insert - Internal Pentagon	X17CRNI162 , AISI431
99-910S : Insert - External Pentagon	X17CRNI162 , AISI431

99-915S : Insert - Slotted	X17CRNI162 , AISI431
03-751A : TPD NEO - Hinged Key	X2CrNiMo17-10-2 X2CrNiMo18-14-3
03-951A : TPD All-In-One / Classic - Hinged key	X2CrNiMo17-10-2 X2CrNiMo18-14-3

Indications
Surgi-Tec's surgical instruments are accessories to be used with following Surgi-Tec devices:
- Distraction devices
- Orthodontic Bone Anchors
- Osteosynthesis plates
- Osteosynthesis screws

Contra-indications
Pre-existing or suspected infection at or near the implantation site.
Known allergies and/or hypersensitivity to foreign bodies.
Inferior or insufficient bone quality to securely anchor the implant.

Possible adverse effects
In most cases, potential complications have a clinical source as opposed to arising from the instruments.
These include among other things:
- Hypersensitivity to metal or allergic reactions.
- Soft tissue irritation and/or nerve damage through surgical trauma.
- Early or late infection, both superficial and deep.
- Elevated fibrotic tissue reaction around the surgical area.

Warnings and precautions
- The products may only be used by medical personnel who hold the correct professional qualifications.
- Surgi-Tec, as manufacturer, recommends that the user reads all available documents before first use and contacts other users who have practical experience.
- Never use products that have been damaged by transport, improper handling in the hospital, or in any other way.
- The user may not alter any of the components or replace them with an instrument or product from another manufacturer even if the size or shape is similar or exactly corresponds to that of the original product.
- The sterilizing cases and instrument trays shall not be vigorously shaken or tipped over since the individual components may become damaged or fall out.
- Use the indicated screwdriver for the respective system. Make sure that the screwdriver/screw head connection is precisely vertically aligned. If not, there is a greater risk of damage to the implant and screwdriver blade. When inserting the screw, ensure that a sufficient axial force is used between blade and screw. At the same time, the axial force should be in certain limits in order not to damage the bone structure.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of your EU member state.
- Instruments that are damaged or have reached their maximum reprocessing cycles have to be disposed as medical waste in a dedicated container, in accordance with all local guidelines and/or your institution 's safety program

Preparation for use
- Empty the instrument trays and remove the lid if applicable.
- Disassemble and open the instruments as far as possible.
- Remove damaged instruments.

Automated cleaning and disinfection

- All surgical instruments of Surgi-Tec are delivered **'non-sterile'** and must be cleaned, disinfected and sterilized before use. This also applies to the first use after delivery. All packaging must be removed before preparation.
- Thorough cleaning and disinfection are essential for effective sterilization.
- All instrument components are intended to be reused.
- It is your responsibility to ensure that the surgical instruments are completely sterile when used, to use device- and product-specific procedures for cleaning/disinfection and sterilization that are sufficiently validated, to regularly service and inspect the employed devices (disinfector, sterilizer), and to ensure that the validated and/or manufacturer's recommended parameters are maintained for each cycle.
- The statutory regulations applicable in your country and the hospital's hygiene requirements must also be observed. This applies in particular to the various instructions for effectively deactivating prions.

- Surgi-Tec has used “Neodisher MediClean forte” for the validation process of the automated cleaning and disinfection and has followed the instructions of the manufacturer (instruction Dr. Weigert). The validation was carried out according to table below.
- For the remainder of this document, please use the following definitions regarding water temperature:
  Cold water: T < 40°C
  Warm water: T > 40°C
- When selecting the disinfector, make sure that the cleaning process includes the following phases in accordance with EN ISO 15883:
- The following precleaning steps will be performed: Rinsing the test items under cold running tap water for 5 minutes; NOTE: the inserts should be removed from the handpiece before cleaning

Phase	Temperature	Duration	Action
Pre-rinsing	Not applicable	Soaking time *>120 sec / 2 min*	*Cold tap water* (temperature <40°C)
Cleaning cycle	Cleaning temperature - *45°C*	Soaking time > *300 sec / 5 min*	*Warm tap water* (temperature >40°C) Recommended Detergent - *Neodisher Mediclean Forte* Concentration - *0.6% (v/v)*
Cleaning cycle	Cleaning temperature - *55°C*	Soaking time > *300 sec / 5 min*	*Warm tap water* (temperature >40°C) Recommended Detergent - *Neodisher Mediclean Forte* Concentration - *0.6% (v/v)*
Post-rinsing 1	Rinsing temperature *>40°C*	Rinsing time > *60 sec/ 1 min*	*Warm tap water* (temperature >40°C)
Post-rinsing 2	Rinsing temperature *<40°C*	Rinsing time > *60 sec/ 1 min*	*Cold tap water* (temperature <40°C)
Thermal disinfection	Disinfection temperature *≥ 90°C (194°F)*	Soaking time *> 60 sec/ 1 min (A_0 value > 600)*	*With demineralized (DI water) and/or purified water; do not add additional detergent*
Drying	Drying temperature > 110°C	Drying time > *1500 sec / 25 min**	*Drying process*
(*) Corresponds to worst case item validated			

- The information provided is based on the use of “Neodisher MediClean forte” by Dr. Weigert; validation was performed with a concentration of 0.60 % v/v at 55°C; if a different detergent is used, exposure times, concentrations and temperatures may vary; the relevant manufacturer’s instructions must be observed.
- The products must be completely dried directly afterwards. It is recommended to dry the products using medical compressed air; this is especially gentle and effective. Otherwise lint-free disposable wipes (e.g. Perform classic from Schülke & Mayr) can be used. If applicable, the products have to be stored in a clean environment until they are completely dry.

Inspection
- In general sufficient cleanliness is the basic requirement for a successful sterilization. Before the products are packaged for sterilization they have to be inspected visually. (Recommendation: use working place light fixtures ideally with magnifiers).
- Check the surgical instruments after cleaning and disinfection for damages and contamination.
- See if all moving parts are functional.

Packaging
- Surgi-Tec recommends wrapping the surgical instruments in hospital common sterilization packaging (paper/film packaging, according to DIN EN ISO 11607-1 and DIN EN 868-2).
- If the surgical instruments are sterilised in trays, the hospital is responsible for the validation of the packaging composition variations

Sterilization of Products labelled as ‘non sterile’
- For the sterilization process the instructions of the appropriate sterilizers have to be followed.
- All NON-STERILE products can be sterilized in an autoclave. The autoclaves must be in accordance with EN285 respectively EN13060 regarding validation, servicing, maintenance and controlling.
- Steam sterilization should be performed after the recommended cleaning, disinfection, inspection and packaging.

- Surgi-Tec recommends that sterilization is performed in accordance with following EN ISO 17665 validated process parameters
- For both initial and subsequent sterilization, the following parameters were validated by Surgi-Tec in accordance with the requirements of the current sterilization standards, EN ISO 17665 and ANSI/AAMI ST79.
- **Cycle: Pre-Vacuum (Dynamic air removal)**

Procedure	Fractionated and dynamic pre-vacuum process
Exposure time	≥ 5 minutes *(Minimum 5 minutes at 134°C)*
Temperature	Temperature ≥ 134°C
Drying time	≥ 20 minutes - 30 minutes (in autoclave chamber)

- Surgi-Tec recommends that sterilization is performed in accordance with the above validated processes. If the user utilizes other processes (e.g. flash sterilization), these must be validated by the user. The ultimate responsibility for validation of sterilization techniques and equipment lies with the user.
- The responsibility for the maintenance and qualification of the sterilization equipment used and the validation of user specific sterilization process lies with the user.
- After sterilization, the products must be stored in a dry and dust-free environment.
  The maximum storage time is dependent on different factors such as the sterile barrier employed, storage manner, environmental conditions and handling.
- The user should define a maximal storage time for sterile products until use. Within this defined time the products have to be used or reprocessed again.
- Do not use hot-air sterilization, radiation sterilization, formaldehyde sterilization, ethylene oxide sterilization or substitute procedures for sterilizing thermolabile products such as plasma or peroxide sterilization for Surgi-Tec products.

These IFU and additional information can be found on the internet at www.surgi-tec.com/instructions.
The summary of safety and performance can be found in EUDAMED public website:
https://ec.europa.eu/tools/eudamed

Reusability of instruments

The surgical instruments can be reused if Surgi-Tec's instructions are followed and if they are undamaged and uncontaminated. It is also necessary to check the functionality of the instrument.
If surgical instruments come in contact with pathogens that are difficult to identify such as variations of Creutzfeldt-Jakob's disease (confirmed or suspected pathogen), they must be discarded. Those surgical instruments must not be reused.
Surgi-Tec recommends reusing its surgical instruments up until 100 times. Surgi-Tec has tested the performance, safety and functionality of reusable surgical instruments for 100 cycles of automated cleaning, disinfection and sterilization.

Explanation of symbols:

	Please observe instructions for use
	Caution
	Reference number
	Lot number
	Manufacturer
	Non sterile product
	Do not use if package is damaged
	Medical device
	Unique device identifier

1639

Medical device Class Ir

BASIC UDI-DI : 540700775CHINST6V

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