ENGLISH	**Instructions for Use - Surgi-Tec Standard 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 surgical instruments supplied by Surgi-Tec may be processed to prepare them for use.
A surgeon should not begin clinical use of the instrument without reviewing the instructions for use.

Description
Surgi-Tec Standard 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 Standard Instruments can be reused after appropriate cleaning, disinfection and sterilization.
TPD and TMD Patient wrenches are used by the patient after the surgical procedure.

Contraindications
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 relevant qualifications.
- TPD and TMD Patient wrenches may only be used by the patient after clear instructions given by the surgeon.
- 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 size. 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.

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.

Manual cleaning and disinfection
Cleaning Procedure:
1. Prepare an ultrasonic bath with a cleaning solution at the concentration and temperature specified in the detergent manufacturer´s instructions.
2. Immerse the device completely and activate the bath for at least the time specified in the detergent manufacturer´s instructions.
3. Using suitable brushes (only soft brushes, never metal brushes or steel wool) to clean the device paying particular attention to rough surfaces and features that may be shielded from the brushing action.
4. Rinse in properly monitored demineralized or purified water until all traces of cleaning solution are removed.
5. If, after completion of the cleaning step in the ultrasonic bath, encrusted soil remained on the device which had to be removed with the brush, the cleaning step must be repeated as described above.

Disinfection Procedure:

1. Prepare a disinfection bath with a disinfectant solution at the concentration and temperature specified in the detergent manufacturer´s instructions.
2. Immerse the device completely for at least the time specified in the detergent manufacturer´s instructions.
3. Rinse in demineralized water until all traces of disinfectant solution are removed.
4. Dry the medical device using medical compressed air and clean and lint-free single use wipes (if required supplemented by post drying at a clean place for up to 2 hours) or by heating in an oven below 110°C.
5. Visually inspect and repeat complete manual cleaning and disinfection if necessary.

Automated cleaning and disinfection

1. Load the medical devices into the washer-disinfector with approved efficiency (according to ISO 15883) properly installed, qualified and regularly subjected to maintenance and testing.
2. Avoid contact between devices (movement during washing could cause damage, and washing action could be obstructed).
3. Select disinfection program as recommended by the washer-disinfector equipment manufacturer
4. Operate the washer-disinfector cycle.
5. On completion unload the washer disinfector.
6. Visually inspect each device for remaining soil and dryness. If soil remains repeat the cleaning process including the pre cleaning stage.
7. Remaining wetness may be removed with medical grade compressed air, clean and lint free single use wipes (if required supplemented by post-drying at a clean place for up to 2 hours) or by heating in an oven below 110°C.

Sterilization

- Surgi-Tec Standard Instruments are steam sterilized.
- The steam autoclaves must be in accordance with EN285 respectively EN13060 regarding validation, servicing, maintenance and control.
- Surgi-Tec recommends that sterilization is performed in accordance with following process parameters
  -Cycle : Pre-Vacuum (Dynamic air removal)
  -Temperature : 134°C - 137°C
  -Exposure time : minimum 3 minutes
  -Drying time : 30 minutes (in autoclave chamber).
- The responsibility for the maintenance and qualification of the sterilization equipment used by the user and the validation of user specific sterilization processes 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.

Packing/Storage/Transportation

Instruments can be sterilized in transparent sterilized packages. If they are packed in a pouch bag then this should be large enough so that the sealing is not under tension.

Reusability of instruments

The instruments can be reused if Surgi-Tecs instructions are followed and if they are undamaged and uncontaminated.
If 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 products must not be reused.

Explanation of symbols

Please observe instructions for use

Reference number

Lot number

Manufacturer

Non sterile product

Do not use if package is damaged

CE

Medical device Class I

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