SURGI-TEC

ENGLISH	Instructions for Use Surgi-Tec TPD measuring templates (Dummies) Surgi-Tec TPD /TMD patient key	ENGLISH

This document is intended to give general guidance on how TPD measuring templates (dummies) and TPD et TMD patient keys supplied by Surgi-Tec are to be handled before and during use.

Description
Surgi-Tec measuring templates (dummies) are used to determine the TPD distractor size before or during surgical procedure.
TPD and TMD Patient keys are used by the patient to activate the distractor after the surgical procedure.

Contra-indications
None

Possible adverse effects
Hypersensitivity to metal or allergic reactions.

Warnings and precautions
- Read all available documents before first use.
- The dummies may only be used by medical personnel, who hold the correct professional qualifications.
- TPD and TMD Patient Keys may only be used by the patient after clear instructions given by the surgeon.
- 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.

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, 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 TPD measuring templates (dummies) and TPD et TMD patient keys 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 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 patient keys can only be reused by the same patient.
- The dummies can be reused if Surgi-Tec's instructions for cleaning, disinfection and sterilization are followed and if they are undamaged.
- If dummies come in contact with pathogens that are difficult to identify such as variations of Creutzfeldt-Jakob's disease (confirmed or suspected pathogen), they 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

 Medical device

 Unique device identifier

CE

Medical device Class I
BASIC UDI-DI: 540700775INSTBW

MANUFACTURED BY

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