Instructions for use

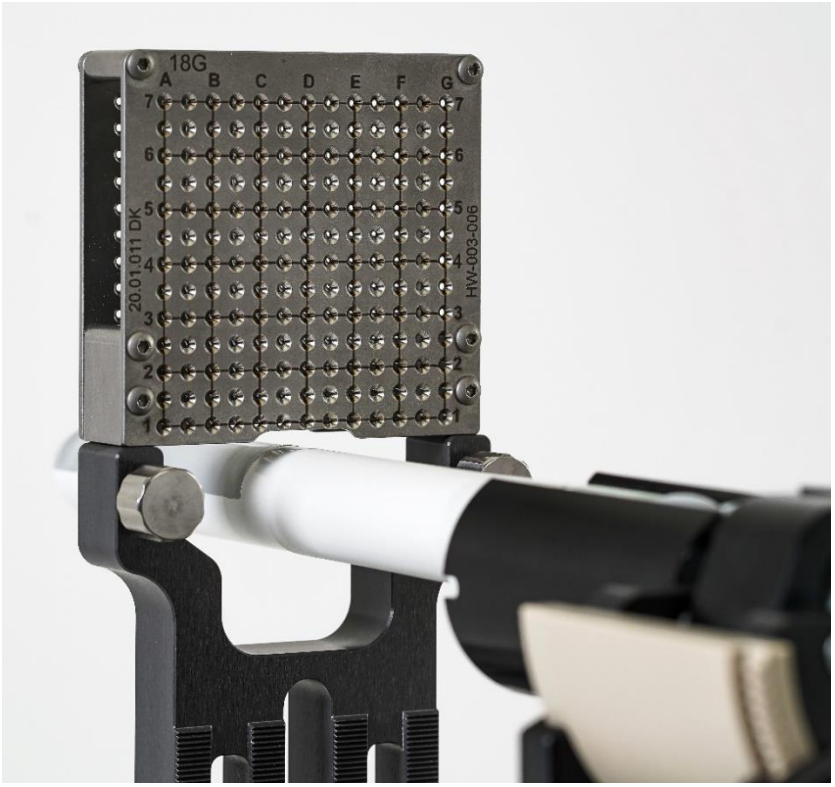
Stainless steel template

Versions 18G, 17G, 16G, 15G, 14G, 13G

Art.-No.: HW-005-002 to -014

Language version(s):

EN



Vers. 01

2023-06-28

CE

MTT

Thank you for purchasing your MTT product. It is used to assist in the manual positioning of needles in ultrasound guided transperineal biopsies or focal therapies (such as cryotherapy) as well as LDR brachytherapy of the prostate.

WARNING! Improper handling and improper use can cause danger and damage. Therefore, we ask you to read these instructions for use and to follow them carefully. Always keep them handy. To avoid personal injury and property damage, please also observe the safety instructions.

If you have any questions about the content of these instructions for use or the use of the product, please contact us or our specialist dealer through whom you purchased this product.

Your MTT Team

Version of the instructions for use

The version of these instructions for use can be found on the cover page. All versions of the instructions for use can be requested from MTT:

www.medical-tt.com

Scope

This instruction manual applies to the following products as well as product versions and variants:

Product	Version
Stainless steel template	18G, 17G, 16G, 15G, 14G, 13G

Contact details of the manufacturer

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Table of contents

1. Information on how to use these instructions for use

1.1. Explanations of the warnings in these instructions for use

Signal word	Description
DANGER!	An immediate danger situation exists, and serious damage or death is possible
WARNING!	Possible hazard with serious damage or death as a result
CAUTION!	Possible hazard with mild or moderate damage as a result
HINT	Operating errors can cause damage to the product

1.2. Presentation conventions in this instruction manual

Representation	Description
italic	Italic font marks cross-references
Bold	Bold font indicates controls, controls, switches, window titles, menu items, functions, etc.

1.3. Copyright, Disclaimer, License Terms, Warranty, Miscellaneous

The warranty claim for products included in these instructions for use is 12 months from delivery of the products.

1.4. Feedback on the instructions for use

Please contact MTT with any feedback for improvement with this manual. Your opinion matters, and we will evaluate the content for updated version.

2. Purpose

2.1. Medical purpose

The stainless-steel template assists in the manual positioning of needles in ultrasound-guided, trans-perineal prostate biopsies or focal therapies (e.g., cryotherapy) as well as LDR brachytherapy of the prostate. Using the recorded coordinates on the templates, needles can be positioned at specific points, e.g. specified by planning software or determined by the user on the basis of the matching display on the ultrasound device.

2.2. Clinical benefit

Depending on the localization of the lesion to be hit in the biopsy, the needles can precisely target the ROI (*region of interest*) through the needle guide grid. In focal therapy, the coordinates of the ROI are usually calculated using a planning software. In brachytherapy, the brachy needles can be placed in a planned manner to cover the entire organ as accurately as possible.

2.3. Indication(s)

Need for a prostate biopsy due to the suspicion of prostate cancer or the presence of the disease and thus the need for therapy of the prostate.

2.4. Contraindications / exclusions / limitations

No contraindications known.

2.5. Intended patient target group(s)

All patients intended for transperineal biopsy or prostate therapy. Physical characteristics, limitations and requirements are secondary and identical to the attributes for the application.

2.6. Intended users

The stainless-steel template must be used by urological specialists with appropriate medical training. Users should have experience with the respective prostate application. If the needle guide grid is used in conjunction with planning software, training in the respective software used is required.

2.7. Intended usage environment(s)

The template may only be used in operating theatres and urological practices.

3. Important safety instructions

IMPORTANT! Read all safety instructions carefully before using the product. Follow safety instructions to avoid injury and life-threatening situations.

Caution! The stainless-steel templates are not sterilely packaged. They must be disinfected and sterilized before each use. See chapter 8

Caution! When using the templates with the BioJet system or a planning software, the correct calibration of the guide grid in the software must be checked during the application. In case of a deviation of the calibration, the needle guide grid should not be used. In this case, contact MTT or your distributor.

Caution! The template only assists with the positioning of the needle. The exact position of the needle can only be detected in the live ultrasound image.

Caution! The template is not intended for direct patient contact.

3.1. Reporting obligation

Report any serious incidents related to the product (damage, injuries, infections, etc.) to the distributor responsible for you or MTT and the competent authority.

3.2. Product Lifetime

Under normal intended use, the stainless steel templates have a service life of 5 years from the time they are made available on the market. However, this depends on the (maintenance) condition of the product. Improper cleaning or dropping can lead to reduced lifespan.

4. Product description

4.1. Functional principle of the product and process overview

The stainless steel template has two hole grids, which are held together and aligned by spacers. When a straight needle is pushed through a hole of the front plate, the same hole on the rear plate is hit. Both holes together guide the needle to the selected position in the patient's prostate. The depth of penetration of the needle is tracked by live ultrasound.

4.2. Product Compliance

The product meets the following regulatory requirements:

- (EU) 2017/745 (MDR)
- ISO 14971:2019
- IEC 62366-1:2015 + AMD:2020
- ISO 13485:2016
- ISO 17664-1:2021

4.3. Scope of delivery

Packaging contents	Article	Number
Instructions for use	/	1
Needle guide grid	HW-005-002 to -14	1

4.4. Combination with other products

The stainless-steel template must be used in conjunction with a template holder that corresponds to the geometric dimensions of the feet of the templates and offers a possibility of fixation.

Combination product	Manufacturer – Article number	Description
Template holder	MTT – HW-004-003	Holder for brachy and biopsy templates for Stepper A-TP

4.5. Product overview

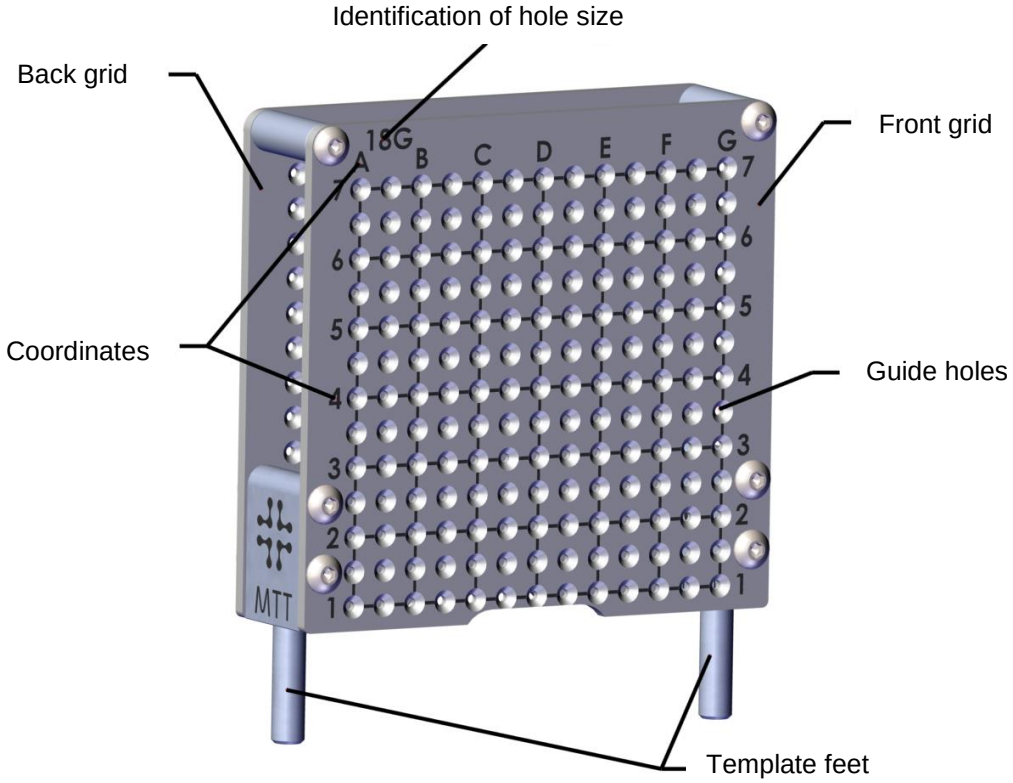

Figure 1: Product Overview

The template has two perforated plates with 13x13 holes at a distance of 5 mm each with corresponding hole size and coordinates for the planned placement of needles, as well as two template feet for fixing the template on a template holder.

5. Transport, storage

The stainless steel templates are shipped in a well-padded cardboard box. This is not necessary for on-site storage. After sterilization, packaging in a sterile barrier system is recommended (see chapter8

5.1. Packaging dimensions, weight

Category	Specification
Packaging dimensions (H x W x D)	250 x 170 x 60 mm
Weight including packaging	approx. 300 g

6. Installation / Preparations

6.1. Calibration

When using biopsy or planning software, the system is calibrated to the templates (more precisely: the combination of template and template holder). See the corresponding instructions for use of the software system.

Caution! Check proper calibration before use.

6.2. Sterilization

The stainless steel template is delivered non-sterile. Before the first and before each subsequent use, the needle guide grid must be cleaned, disinfected and sterilized. For detailed instructions, see chapter 8.

7. Use of the product

The template is placed and fixed on the corresponding template holder with the feet in the recesses provided for this purpose. The details can be found in the corresponding instructions for use of the template holder.

Caution! Always make sure to use the appropriate needles for the hole size: 18G template with 18G needle etc. The hole size is marked on the templates.

- ➔ The use of a needle that is too large is either prevented by the hole size in the template (the treatment may have to be discontinued) or leads to jamming of the needle.
- ➔ The use of needles that are too small reduces the accuracy of the needle guide.

Caution! The template is not intended for direct patient contact.

8. Reprocessing: cleaning, disinfection, sterilization

The stainless-steel template muss be cleaned immediately after each use, so that no liquids can dry on it.

Before and after each cleaning, disinfection, and sterilization, check the templates for completeness, damage, and excessive wear.

Caution! The templates must be packaged in such a way as to ensure the necessary cleaning, disinfection, and steam penetration as well as thorough drying.

8.1. Preparation instructions according to DIN EN ISO 17664

Warnings	• The templates are not sterile packed. The device must be sterilized before each use. • To avoid contamination of patients and users, the templates must be cleaned, disinfected, and sterilized before and after each use. • Under no circumstances should the product be cleaned in an ultrasonic cleaner.
Processing restrictions:	• It is recommended to prepare the used products no later than 2 hours after use.

Risk assessment and classification of medical devices before reprocessing:
The type and extent of reprocessing depend on the use of the medical device. For this reason, the operator is responsible for the correct classification of the device and thus also for determining the type and scope of reprocessing (see KRINKO/BfArM recommendation, section 1.2.1 Risk assessment and classification of medical devices before preparation). Based on this user-dependent classification, the user can specify which reprocessing steps must be carried out from the following reprocessing steps.

Instructions:	
At the place of use:	Equipment: Personal protective equipment (gloves, water repellent clothing, face protection or goggles, tap water (at least drinking water quality). Visible dirt on the template should be removed at the point of use to prevent impurities and contamination from drying up in and on the template. Rinse the template under cold tap water to remove blood or other substances from boreholes, gaps, joints, surfaces, and other hard-to-reach areas of the templates. If there is still visible dirt adhering to the templates, please continue the process according to pre-cleaning (see below).
Storage and Transport:	It is recommended to transport contaminated products in a closed clean box/container.
Preparation for decontamination:	Personal protective equipment (gloves, water repellent protective clothing, face mask or goggles, see also manufacturer's instructions for detergents and disinfectants). **Caution!** Do not loosen screws on the template.
Pre-cleaning:	Equipment: Nylon brush (e.g., Interlock #09050), tap water (20± 2°C) at least in drinking water quality (according to the RKI guidelines) 1) Rinse the template for at least 1 minute under running tap water and remove visible dirt from the hard-to-reach places with a nylon brush
Machine cleaning and disinfection:	If visible dirt is still present in the interior, gaps, holes, bearings, clamps, joints, threads, screws, and other hard-to-reach areas: Repeat the pre-cleaning (see pre-cleaning above). Equipment: Washing disinfection according to DIN EN ISO 15883-1 + -2 with a thermal program (temperature 90°C -93°C), low alkaline detergent (e.g., Sekumatic® MultiClean 200 ml), air gun with compressed air of medical quality (in accordance with the legal regulations).

	1) Place the product on a suitable carrier in a carrier module and then in the mechanical disinfector so that all internal and external surfaces can be cleaned and disinfected. 2) After closing the door, start the thermal program. The program parameters are listed in the following table. 3) After the program is finished, remove the product. 4) Check that the product is completely dry. If necessary, dry the product with a lint-free wiper or towel or dry it with compressed air by an air gun.

Mechanical cleaning and disinfection steps:

Program step	Water	Dosage	Time	Temperature
Pre-rinse	Cold		5 min	
Dosage of the cleaner		According to the manufacturer's specifications		According to the manufacturer's specifications
Cleaning	Deionized water		10 min	55 °C
Rinsing	Deionized water		2 min	
Disinfection	Deionized water		A_0 Value >3000[1] (e.g., 5 min, 90 °C) [1] (Authorities may impose other implementing rules (disinfection performance parameters) in their area of competence.)	
Drying			15 min	Up to 120 °C

Maintenance, inspection and testing:	• Check all components of the product for dirt under normal lighting. Repeat manual cleaning and automated cleaning and disinfection unless all components are visibly clean. • Check the product for completeness, damage and wear after each cleaning, disinfection, and sterilization cycle. • Check for damage and functionality before using the product. • Do not use the product if damage or malfunction is detected.
Packaging:	• Packaging in a sterile barrier system according to DIN EN ISO 11607 or DIN 58953.
Sterilization:	• Use autoclave according to DIN EN 13060 and/or DIN EN 285. • Pre-vacuum procedure, 134°C and sterilization time at least 3 min (longer holding times and higher temperatures are possible) 1) Place the packaged product in the sterilization chamber. 2) Start the program (sterilization over 3 min. at 134°C). 3) After the program is finished, remove the product and let it cool. 4) Check that the package is closed and sealed and that the package is dry.
Storage:	Storage and shelf life according to the conditioner's instructions
Additional information:	Only validated processes may be used for the reprocessing of medical devices.

The above instructions have been validated MTT as an appropriate method for reprocessing the medical device for reuse. It is the responsibility of the processor to ensure that the actual reprocessing of the medical device using equipment, material and personnel of the conditioner achieves the desired and

necessary result. This requires validation and routine monitoring of the processes. Likewise, any change in the listed treatment steps must be accurately assessed and evaluated with regard to their effectiveness and potentially adverse consequences.

9. Disposal

At the end of the usage phase, dispose of stainless steel templates in accordance with local regulations or, if applicable, legal regulations.

To initiate a return and disposal of the templates via MTT, please contact us. By phone at +49 (0) 4133 510 185 or via the website www.medical-tt.com.

10. Specifications

10.1. Performance data

Category	Specification
Needles	Depending on the hole size (see marking on the template)

10.2. Measurement accuracy / scale

Category	Specification
Hole spacing	5 mm vertical, 5 mm horizontal, 13x13 holes
Scale	pictured: A-G; complete: A-a-B-b-C-c-D-d-E-e-F-f-G pictured: 1-7; complete: 1-1.5-2-2.5-3-...-6-6.5-7

10.3. Materials

Category	Specification
Stainless steel template	Stainless steel 1.4301 / 1.4305

10.4. Dimensions / weight of the product

Category	Specification
Dimensions (H x W x D)	85 x 85 x 20 mm
Weight	200 g

11. Symbols used on the product and the label

Symbol	Meaning
	Manufacturer
	Labelling as a *medical device*
	CE mark
	Article number
	Serial number
	Follow the instructions for use
	UDI Carrier
	Observe warnings
	Non-sterile