Healing caps & gingiva formers

Prosthetic procedure

Instructions for use THM61116

Version 004_AA, Issue date 08/22

THOMMEN Medical

1. At a glance

These instructions apply to all healing caps and gingiva formers (excluding customizable gingiva formers), as listed in the product catalog (www.ifu-tm.com/THM31111). You can also find information on the identifying elements (geometry, dimensions) of the individual components in this brochure.

Components	Material	Reusable	Sterile delivery
Healing cap in the implant pack	Pure titanium grade 4	No	Yes
Healing cap SE	Pure titanium grade 4	No	No
Gingiva former	Pure titanium grade 4	No	No
Gingiva former+	Pure titanium grade 4	No	No
Gingiva former narrow	Pure titanium grade 4	No	No

Restrictions for use

See the general restrictions of use (page 7).
Modification of gingiva formers and healing caps is not permitted.

Indication for use

Thommen Medical prosthetic components are used in conjunction with the Thommen Medical Dental implant system in the partially / fully edentulous maxillary and mandibular arch to restore the chewing function.

Intended use

Thommen Medical prosthetic components are to be used in conjunction with the Thommen Medical dental implant system in the maxillary and mandibular jawbone for implant-supported dentures.

2. Application and handling

Clinical use

Healing caps are screwed on implants for the soft tissues to heal before final restoration. Gingiva formers are used to form the soft tissues around an implant before final restoration.

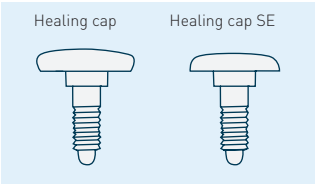
Before the insertion and attachment of prosthetic components, the implant shoulder and the inner configuration must be free of contamination and overhanging soft tissue.

Torque value for the permanent attachment of healing caps and gingiva formers (see also www.ifu-tm.com/THM61122):
· 10 Ncm for all platforms

Healing caps or gingiva formers must not be subjected to any stress loading during the entire healing phase and, therefore, must be kept entirely out of occlusion.

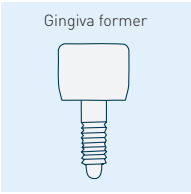
Screw in the healing cap/gingiva former by hand until it is in slight contact with the implant shoulder. Always avoid non-axial forces on the screwdriver.

When tightening, the torque ratchet may only be used with a maximum torque of 10 Ncm.



Healing caps

In addition to the healing cap in the implant container, Thommen Medical also offers healing caps separately which because of their rounded edges enable a better adaption of the mucosal flap particularly in thin soft tissue conditions (healing cap SE, smooth edge).

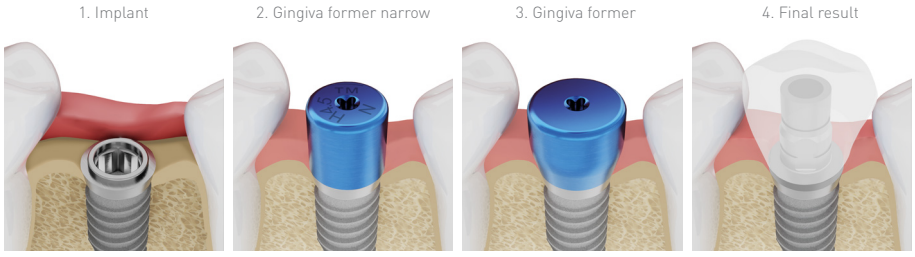


Gingiva former

The gingiva former allows the shaping of the peri-implant soft tissue for all implant platforms. Five different heights (2.0/3.2/4.5/5.7 and 7.0 mm) ensure optimal soft tissue conditioning.

Gingiva former narrow

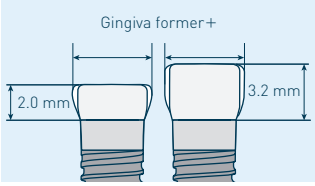
The gingiva former narrow should be used in combination with the gingiva former in a two-stage procedure. Five different heights (2.0/3.2/4.5/5.7 and 7.0 mm) ensure optimal soft tissue conditioning for all implant platforms.



After inserting the implant (Fig. 1), the gingiva former narrow is inserted (Fig. 2). After the healing phase or during the 2nd session, the narrow gingiva former is replaced by the standard gingiva former (Fig. 3) in order to exert a graduated compression and to prepare the soft tissue for the subsequent final restoration (Fig. 4).

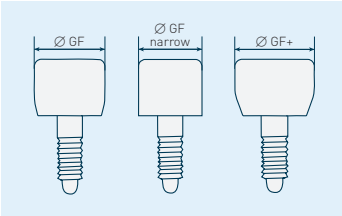
Note:
In order to guarantee an accurate and unobstructed fit of the abutment, the bone contouring instrument must be used for implants in a crestal or subcrestal position.

Gingiva former +



The gingiva former+ is available for PF 3.5 and features a slightly larger outer diameter (4.5 mm instead of 4.0 mm) compared to the standard gingiva former. The gingiva former+ is available in the heights of 2 mm and 3.2 mm and is ideally used for shaping the gingiva in edentulous patients and in combination with the SPI®ELEMENT LC implant. The gingiva former is ideally used in a partially edentulous jaw. Due to the larger outer diameter, the gingiva former+ should not be used if teeth are positioned closely together.
Healing caps and gingiva formers are sold separately and are non-sterile, and must be sterilized prior to use.

Overview of gingiva former (GF) diameters



	PF 3.5			PF 4.0		PF 4.5		PF 5.0		PF 6.0	
Height	∅ GF	∅ GF narrow	∅ GF+	∅ GF	∅ GF narrow	∅ GF	∅ GF narrow	∅ GF	∅ GF narrow	∅ GF	∅ GF narrow
2.0 mm	4.0 mm	3.6 mm	4.5 mm	4.6 mm	4.1 mm	5.1 mm	4.6 mm	5.6 mm	5.1 mm	6.6 mm	6.1 mm
3.2 mm	4.0 mm	3.6 mm	4.5 mm	5.0 mm	4.1 mm	5.5 mm	4.6 mm	6.0 mm	5.1 mm	7.0 mm	6.1 mm
4.5 mm	4.0 mm	3.6 mm		5.0 mm	4.1 mm	5.5 mm	4.6 mm	6.0 mm	5.1 mm	7.0 mm	6.1 mm
5.7 mm	4.0 mm	3.6 mm		5.0 mm	4.1 mm	5.5 mm	4.6 mm	6.0 mm	5.1 mm	7.0 mm	6.1 mm
7.0 mm	4.0 mm	3.6 mm		5.0 mm	4.1 mm	5.5 mm	4.6 mm	6.0 mm	5.1 mm	7.0 mm	6.1 mm

Cleaning, disinfection and sterilization

Single-use products:
All products, which are supplied in a non-sterile state, must be sterilized before first use, unless stated otherwise. If prosthetic components have not been reprocessed, no cleaning and disinfection is necessary.

Multiple-use products:
All multiple-use products must be cleaned, disinfected and sterilized before first use. An effective cleaning and disinfection are absolutely necessary requirements for an efficient sterilization for re-use.

Steam sterilization is recommended:
- Fractionated vacuum process with at least 3 vacuum steps (with adequate product drying)
- A steam sterilizer compliant with DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- Maximum sterilization temperature 138°C (280°F), (plus tolerance in compliance with DIN EN ISO 17665)

Sterilization time (exposure time at the sterilization temperature) of at least 4 minutes (or 18 minutes, prion inactivation, not relevant for USA) at 132 °C (270 °F)/134 °C (273 °F)

For further instructions on the sterilization of prosthetic components, please refer to the valid Thommen Medical processing instructions (www.ifu-tm.com/THM61131).

3. General notes

THOMMEN IMPLANT SYSTEM

THOMMEN Medical

Manufacturer: Thommen Medical AG
Neckarsulmstrasse 28
2540 Grenchen, Switzerland
www.thommenmedical.com

LOT	Batch code
	Use by date
	Date of manufacture
STERILE R	Sterilized using irradiation
	Simple sterile barrier system
	Simple sterile barrier system with protective packaging on the inside
21	No more than 20 processing cycles
EC REP	EU authorized representative
	Temperature limitation
	Do not re-use
NON STERILE	Non-sterile
	Caution
REF	Article number
CE 0297	Conformity mark according to Directive MDD 93/42/EEC or Regulation (EU) 2017/745 MDR (see corresponding declaration of conformity)
	Consult instructions for use
STERILIZE	Do not resterilize
	Do not use if package is damaged
	Atmospheric pressure limitation
	Manufacturer
	Keep away from sunlight
Rx Only	May only be sold to and prescribed by physicians (USA)
MD	Medical device
UDI	Single product code

COLORED WARNING STICKER
Application was changed – follow the directions in the corresponding instructions for use.

NEW HANDLING
New design – the application has not been changed.

NEW DESIGN

PRODUCT INFORMATION The information in this document describes the application of the Thommen Medical implant system. This information is available in electronic form online at: www.ifu-tm.com. The responsible country representative or distributor for Thommen Medical AG is available to provide technical advice.

COLOR CODE Each implant platform diameter has a color code, which can be found on all implant packagings, on the impression items and on most diameter-specific instruments.

TRACEABILITY
In order to ensure the traceability of the implantable products as well as the manufacturer, product type and product dimensions also for a later prosthetic re-restoration, each product package comes with three patient labels. These labels should be used in the practice for documentation and for the implant passport.

Brown	=	PF 3.0
Yellow	=	PF 3.5
Green	=	PF 4.0
Blue	=	PF 4.5
Grey	=	PF 5.0
Purple	=	PF 6.0

AVAILABILITY Not all of the Thommen Medical products mentioned in these instructions for use are available in all countries. The responsible country representative or distributor for Thommen Medical AG can provide information about availability of Thommen Medical products for the country in question.

GENERAL RESTRICTIONS OF USE Reconstructions with cantilevers to individual implants are not recommended. Individual restorations with angled abutments should not be used in regions with high mechanical stress. For implants with a small diameter (PF 3.0 and 3.5), the prosthetic restoration should be constructed in such a way that a large bending moment does not occur.

CONTRAINDICATION The Thommen Medical products may not be used on patients who are known to have allergies to the corresponding materials.

POSSIBLE COMPLICATIONS A stressed loading of the implant or abutment over and above its functional capacity can lead to excessive bone loss or fracture of the implant or restoration. The clinician must supervise the occlusion and functional loading of the prosthetic supraconstruction very carefully.

SIDE EFFECTS The patient should be informed about the possible side effects, interactions, precautionary measures and complications associated with Thommen Medical products.
Potential complications can occur immediately after insertion of dental implants:
Temporary symptoms: swelling, difficulties with speaking, gum inflammations, pain.
Longer lasting symptoms: chronic pain connected with the dental implant, localized or systemic infections, dysesthesia, loss of alveolar ridge (upper and lower jaw), oroantral or oronasal fistulas, irreversible damage to neighboring teeth, esthetic problems, nerve damage, hyperplasia. Possible additional side effect: Implant loss.

WARNINGS All Thommen Medical products that come into effect inside the oral cavity must be protected against aspiration. Thommen Medical products have not been tested for safety and compatibility in an MR environment. Thommen Medical products have not been tested for heating or migration in the MR environment. The safety of Thommen Medical products in the MR environment is unknown. Magnetic resonance tomographic examinations of patients, who have been treated with Thommen Medical products, may result in patient injuries.

RESPONSIBILITY/LIABILITY As a part of an overall scheme, Thommen Medical products may be used only with the related original components and instruments in accordance with the instructions for use provided by Thommen Medical. The use of non-system parts may compromise the performance of Thommen Medical products and lead to failures. Users must have appropriate knowledge and information about the handling of Thommen Medical products in order to use the products safely and correctly. The user is obliged to use the Thommen Medical products according to the instructions for use and to check whether the product is suitable for the individual patient situation. The use of Thommen Medical products is the responsibility of the user, as such, beyond the control of Thommen Medical AG. We refuse to accept any responsibility or liability for any damage due to incorrect utilization of the product. Products labeled "Do not re-use" may not be refurbished and/or reused. The refurbishment and/or reuse of these products can affect their function (e.g. fitting and/ or cutting properties) as well as their safe use (e.g. risk of infection, disease transmission, fading of the laser or color marks, corrosion). Detailed information about the possible consequences, which may result from incorrect use, is available from the responsible country representative or distributor of Thommen Medical AG. All serious incidents which have occurred in connection with the product must be reported to the manufacturer and the user's local competent authority.

GUARANTEE The comprehensive guarantees can be found in the country-specific guarantee leaflets.

TRANSPORT AND STORAGE Please note the specifications on the labels and instructions for use regarding transportation, storage and handling. If the packaging is damaged, the products must not be used; a visual inspection is necessary. Under no circumstances may Thommen Medical products be used beyond the expiry date, as proper functioning or sterility of sterile packaged products cannot be guaranteed by the manufacturer.

APPLICATION The following descriptions are not intended as comprehensive for the. immediate use of the Thommen Medical Implant System. Training by a specialist experienced in the use of this system is recommended

GUARANTEE OF STERILITY In general, products of the Thommen Implant System supplied in sterile packaging must not be re-sterilized Sterile-packed products, whose packaging is damaged, must not be used under any circumstances. Sterile-supplied products, which have not been used for the surgical operation, whose packaging has been opened are considered as having been used and must not be used thereafter. In the event of resterilization, proper function and the sterility cannot be guaranteed by the manufacturer. The products intended for single use must never be reprocessed, sterilized or reused and must be disposed of safely and properly after use in compliance with all applicable legal and regulatory requirements. Reusable products must be reprocessed according to the instructions for use and, if used on patients, sterilized. They must be checked for their integrity before each use. Any damage (for example, scratches, cracks, nicks, dents), as well as bent parts, means that they must not be used any longer. The number of reprocessing cycles is limited and must be monitored. If the number of cycles is exceeded, proper function and sterility of the product are not guaranteed by the manufacturer anymore.

DISPOSAL In the case of cutting products, there is always a risk of injury, therefore the products must be disposed of safely and properly after use, observing all applicable legal and regulatory requirements. For products and their accessories, which have been used on a patient, there is a risk of an infection. Our products are designed and produced so that they can be disposed of safely and correctly after use in compliance with all valid legal and regulatory requirements.

VALIDITY Thommen Medical AG. All previous versions lose their validity with the publication of this instruction for use.

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