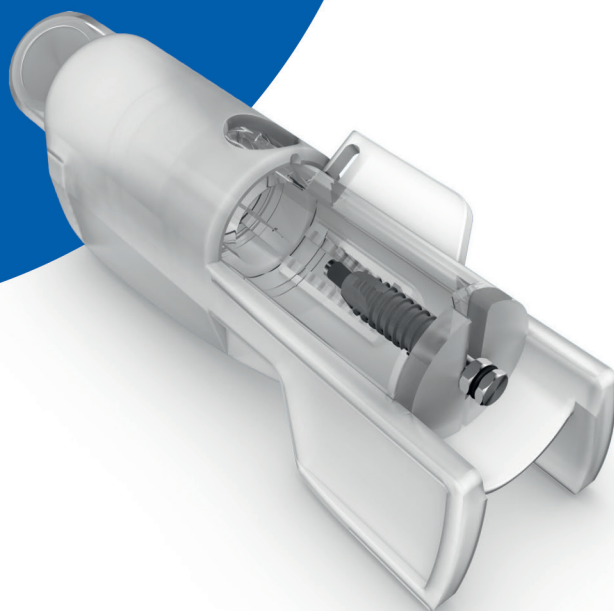


SPI[®]ELEMENT/ CONTACT INICELL[®] APLIQUIQ[®] implant.

Instructions for use THM61112



1. At a glance

Essentials: The SPI®ELEMENT INICELL® implant and the SPI®CONTACT INICELL® implant are referred to as the implant in this document for the sake of simplification.



Important: The following information relates to the indications, contraindications, clinical application and restrictions of use for the implants PF 3.5 - 6.0 with the INICELL® surface. However, this information is not intended as a set of instructions and is insufficient for the immediate use of the Thommen implant system. Training by a specialist experienced in the use of this system is recommended

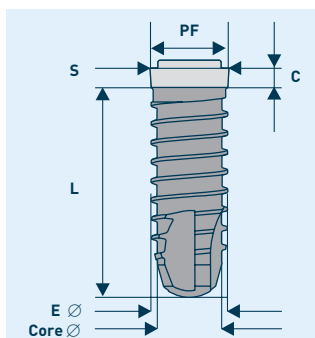
Note: More information on surgical procedures for implants PF 3.5 - 6.0 can be found at: www.ifu-tm.com/THM61141.

Note: More information on the indication/contraindications, clinical use and surgical/prosthetic procedure for the Thommen 3.0 implant system can be found at: www.ifu-tm.com/THM61146.

2. General information

The implants are available in various diameters and lengths, as listed in the product catalogue (www.ifu-tm.com/THM31111).

The clinically relevant properties of Thommen Medical implants are defined as follows:



PF = platform

Refers to the implant-abutment connection, which constitutes the connection geometry to the abutment. The platform diameter is a key parameter for the selection of the prosthetic components (see next page).

C = collar

Collar height – refers to the absolute height of the machined collar. At 0.5 mm in length, the collar of the MC implant (Minimized Collar) is shorter than the Regular Collar (RC). The LC implant (Long Collar) at 2.5 mm has the longest collar.

S = shoulder

Refers to the coronal level of the implant. For MC implants it is the level that is positioned crestally. The shoulder diameter corresponds to the platform diameter.

L = endosseous length

Length of the implant without the collar height (except for MC implants, in which the collar height is included in the total length L). The length L thus always corresponds to the endosseous insertion depth (drilling depth) when preparing the implant bed.

E Ø = endosseous diameter

Refers to the largest external diameter of the implant thread (in the parallel-walled part of the implant).

Core Ø = core diameter

The core diameter corresponds to the drilling diameter.

Material

All implants are made of pure titanium (grade 4) in accordance with ASTM F 67 / ISO 5832-2.

Labels

Implant line: SPI®ELEMENT RC INICELL®

Surface type: RC

Collar height: C 1.0

REF 4.23.123 Qty.: 1 Mat.: Titan

LOT XXXXX

JJJJ-MM-TT Rx Only

JJJJ-MM-TT STERILE R

www.ifu-tm.com/THM61112

110 kPa

65 kPa

L 9.5

E Ø 4.0 (mm)

THOMMEN Medical

UDI (01)07640156471243 (11)JJJJ-MM-TT (17)JJJJ-MM-TT (10)XXXXX

CE 0297 MD

EC REP Thommen Medical Deutschland GmbH | Am Rathaus 2 | 79576 Weil am Rhein | Germany

Reference to electronic Instructions for use

Surface and conditioning for INICELL®

The surface of the endosseous portion of the implants is sandblasted and acid-etched. INICELL® is created during the conditioning process. The cartridge is pushed in and shaken at least five times. The effect of INICELL® lasts after conditioning during the treatment time of the patient.



Caution: The conditioning fluid is an irritant, do not ingest (contains 0.05 M NaOH). Avoid contact with eyes, in case of eye contact rinse immediately with plenty of water while keeping eyelids open and seek medical attention. If swallowed, dilute with copious amounts of water.

3. Intended purpose

Thommen Medical implants are used in the upper and lower jaw for implant-borne reconstructions.

4. Indication

Thommen Medical implants are inserted into partially edentulous/edentulous upper and lower jaws for restoration of masticatory function.

5. Contraindications

Implantation is contraindicated under the following conditions:

- insufficient bone volume or poor bone quality, which cannot guarantee a stable fit for the implant (primary stability)
- acute or chronic infections
- subacute chronic osteitis of the jaws
- diseases which cause microvascular disorders
- systemic diseases
- poor general health of patient
- addictions (abuse of alcohol, tobacco, drugs)
- inadequate oral hygiene as well as poorly motivated, uncooperative patients
- titanium allergy

Note: Take account of all generally applicable contraindications in implant dentistry. Poor periodontal conditions must be remedied before implantation.

6. Clinical use

The Thommen Implant System with INICELL® surface is suitable for use in one-stage and two-stage surgical techniques. The Thommen INICELL® implant is intended for immediate implantation and restoration in case of replacement of individual teeth or several teeth to restore masticatory function. Prerequisites are good primary stability and appropriate occlusal loading. Multiple restorations can be rigidly splinted. For edentulous patients at least four implants must be used for an immediate loading.

Implants with reduced diameter (PF 3.5)

Implants with reduced diameter should only be used if the available bone precludes a larger diameter (minimum width of alveolar ridge 5 – 6 mm). We also recommend that endosseous implants with reduced diameter should be splinted whenever possible.

– Partially edentulous lower and upper jaw:

The implants PF 3.5 are indicated for alloplastic replacement of the lateral incisors of the upper jaw and the central and lateral incisors of the lower jaw.

– Edentulous lower and upper jaw:

For solid reconstructions, implants with a reduced diameter must be combined with other implants, which have the same platform size and / or a larger diameter.

7. Restrictions of use

General restrictions of use, see Page 11.

Restrictions of use for implants PF 3.5 (reduced diameter):

The use of PF 3.5 implants is not permitted for:

- the posterior region in the upper jaw (UJ) and lower jaw (LJ)
- single tooth replacement of canines
- single tooth replacement of central incisors in the UJ
- any applications involving the use of retentive anchors
- use in areas where pronounced rotational and translational movements occur, which results in the danger that the implants are subjected to large bending moments, should be avoided (e.g. single tooth replacement of canines)

Restrictions of use for SPI® ELEMENT INICELL® of length 6.5 mm

Because of the reduced mechanical anchorage in the bone, these short implants must only be used for the following clinical uses:

- as an additional implant in combination with longer implants to support implant-borne reconstructions
- as auxiliary implant for implant-borne bar constructions supporting full dentures in a seriously atrophied mandible

8. Specific information on implant types

SPI® ELEMENT INICELL®

The ELEMENT INICELL® implant is an endosseous screw implant with cylindrical design and self-tapping thread.

Clinical use

The ELEMENT INICELL® implant with a collar height of 1.0 mm (RC, Regular Collar) and 0.5 mm (MC, Minimized Collar) allows a supracrestal and crestal located implant platform, with which a high esthetic standard can be achieved, particularly in the anterior region. The collar height of 2.5 mm (LC, Long Collar) is suitable for transgingival use.

SPI® CONTACT INICELL®

The CONTACT INICELL® implant is an endosseous screw implant with conical-cylindrical design and self-tapping thread.

Clinical use

The CONTACT INICELL® implant with a collar height of 1.5 mm (RC, Regular Collar) is intended for supracrestal and transgingival use. The CONTACT implant with a collar height of 0.5 mm (MC, Minimized Collar) allows a crestal located implant platform, with which a high esthetic standard can be achieved, particularly in the anterior region. The CONTACT INICELL® implant is suitable for special anatomical situations, such as convergent roots of adjacent teeth as well as a concave alveolar ridge. Care must be taken that despite the conical-cylindrical design it may only be implanted where there is sufficient bone volume available. Due to its conical-cylindrical design, the CONTACT INICELL® implant is particularly suitable for immediate or delayed implantation in extraction alveoli.

Note: In preoperative planning one should consider that explantation of a CONTACT INICELL® implant can be difficult because of its conical-cylindrical design, if the apical end of the implant is implanted close to the roots of adjacent teeth.

SPI® CONTACT INICELL® surgical techniques

The conical-cylindrical shape of the CONTACT INICELL® implant requires a specific drilling protocol. A CONTACT profile drill must be used to prepare the conical portion of the implant bed (see: www.ifu-tm.com/THM61141).

Important: The CONTACT INICELL® implant must never be inserted deeper than planned, measured and pre-drilled. Incorrectly inserted implants or where the implant bed could not be correspondingly prepared with the profile drill may exert a lateral pressure on the bone because of the partially conical form, which can jeopardize osseointegration or cause the bone to fracture.

9. Possible complications

Intraoperative

- Inadequate preoperative planning and / or non-observance of the surgical technique may cause complications and implant failure.
- Failure to recognize or take account of the physical or psychological preconditions listed as contraindications may cause complications and implant failure.

Postoperative

If the implant or abutment is loaded beyond its functional capacity, excessive bone loss or breakage of implant or restoration may occur. Clinicians must monitor patients closely to determine any possible periimplant loss of bone, changes to implant's response to percussion, or radiologic changes to the bone-to-implant contact along the length of the implant. If the implant has mobility or more than 50% bone loss, the implant should be evaluated for possible removal.

Note: Patients should avoid exposing their bodies to strenuous physical activity after surgery. Despite high success rates for dental implants, the possibility of failure can never be eliminated. The causes of such failures often cannot be determined, are specific to each case or patient-related. They should be documented and reported to the manufacturer.

10. MRI safety information

See Warnings on page 11.

11. Immediate loading

The implants can be subjected to immediate loading with good primary stability and appropriate occlusal loading. At least 4 Thommen implants must be combined for edentulous lower and upper jaw.

12. Healing phases

We recommend a healing phase of at least

3 weeks:

- with good bone quality and adequate bone volume
- with implants of lengths from 8.0 mm and endosseous \varnothing of 4.0 mm and larger

We recommend a healing phase of at least

8 weeks:

- with cancellous bone quality
- with implants of length of 6.5 mm
- with implants of endosseous \varnothing of 3.5 mm

We recommend a healing phase of at least

12 weeks:

- for CONTACT implants PF 3.5 of endosseous \varnothing of 2.7 mm

The recommended healing phases are the same for the maxilla and mandible. In situations where the sandblasted and acid-etched surface is not completely in contact with the bone, or where bone augmentation measures are necessary, a healing phase in accordance with the situation must be planned. An radiographic check is recommended after a healing phase of 3– 12 weeks before starting the prosthetic restoration.

13. Packaging

Open the protective pack (cardboard box) only immediately before implantation. Inspect the sterile packaging for damage before opening. Damage to the sterile packaging may compromise the sterility of the products contained.

14. Sterilization method

Gamma radiation of at least 25 kilograys (kGy) is used to sterilize the implant and all other components in the sterile pack.

15. Storage

Implants must be stored in their original protective pack at room temperature, and protected from direct sunlight.

16. Documentation/Traceability

The manufacturer recommends complete clinical, radiologic, photographic and statistical documentation. Implant traceability must be guaranteed.

Note: Use adhesive labels enclosed in the protective pack for the documentation in the respective patient's medical records (art. no./lot. no.).

17. Link to summary report on safety and clinical performance

The report on the safety and clinical performance (Summary of Safety and Clinical Performance) for the products listed in these instructions for use is available in the Download Center at: www.thommenmedical.com.

18. Implant card for implantable devices

Fill out the implant card as shown on: www.ifu-tm.com/THM61154 and give the completed implant card to the patient. If anything is unclear please contact the responsible member of the sales force.

Product list

Article number	Description	Material *	Single use	Sterile	UDI-DI
4.23.112	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 3.5, endosseous Ø of 3.5 mm, L 8.0 mm	Titanium Grade 4	yes	yes	07640156472967
4.23.113	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 3.5, endosseous Ø of 3.5 mm, L 9.5 mm	Titanium Grade 4	yes	yes	07640156471304
4.23.114	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 3.5, endosseous Ø of 3.5 mm, L 11.0 mm	Titanium Grade 4	yes	yes	07640156471298
4.23.115	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 3.5, endosseous Ø of 3.5 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156471281
4.23.116	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 3.5, endosseous Ø of 3.5 mm, L 14.0 mm	Titanium Grade 4	yes	yes	07640156471274
4.23.117	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 3.5, endosseous Ø of 3.5 mm, L 17.0 mm	Titanium Grade 4	yes	yes	07640156471267
4.23.121	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 4.0, endosseous Ø of 4.0 mm, L 6.5 mm	Titanium Grade 4	yes	yes	07640156470888
4.23.122	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 4.0, endosseous Ø of 4.0 mm, L 8.0 mm	Titanium Grade 4	yes	yes	07640156471250
4.23.123	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 4.0, endosseous Ø of 4.0 mm, L 9.5 mm	Titanium Grade 4	yes	yes	07640156471243
4.23.124	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 4.0, endosseous Ø of 4.0 mm, L 11.0 mm	Titanium Grade 4	yes	yes	07640156471236
4.23.125	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 4.0, endosseous Ø of 4.0 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156471229
4.23.126	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 4.0, endosseous Ø of 4.0 mm, L 14.0 mm	Titanium Grade 4	yes	yes	07640156471212
4.23.131	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 4.5, endosseous Ø of 4.2 mm, L 6.5 mm	Titanium Grade 4	yes	yes	07640156470871
4.23.132	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 4.5, endosseous Ø of 4.2 mm, L 8.0 mm	Titanium Grade 4	yes	yes	07640156471205
4.23.133	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 4.5, endosseous Ø of 4.2 mm, L 9.5 mm	Titanium Grade 4	yes	yes	07640156471199
4.23.134	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 4.5, endosseous Ø of 4.2 mm, L 11.0 mm	Titanium Grade 4	yes	yes	07640156471182
4.23.135	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 4.5, endosseous Ø of 4.2 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156471175
4.23.136	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 4.5, endosseous Ø of 4.2 mm, L 14.0 mm	Titanium Grade 4	yes	yes	07640156471168
4.23.137	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 4.5, endosseous Ø of 4.2 mm, L 17.0 mm	Titanium Grade 4	yes	yes	07640156471151
4.23.141	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 5.0, endosseous Ø of 5.0 mm, L 6.5 mm	Titanium Grade 4	yes	yes	07640156470864
4.23.142	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 5.0, endosseous Ø of 5.0 mm, L 8.0 mm	Titanium Grade 4	yes	yes	07640156471144
4.23.143	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 5.0, endosseous Ø of 5.0 mm, L 9.5 mm	Titanium Grade 4	yes	yes	07640156471137
4.23.144	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 5.0, endosseous Ø of 5.0 mm, L 11.0 mm	Titanium Grade 4	yes	yes	07640156471120
4.23.145	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 5.0, endosseous Ø of 5.0 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156471113
4.23.146	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 5.0, endosseous Ø of 5.0 mm, L 14.0 mm	Titanium Grade 4	yes	yes	07640156471106
4.23.151	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 6.0, endosseous Ø of 6.0 mm, L 6.5 mm	Titanium Grade 4	yes	yes	07640156470765
4.23.152	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 6.0, endosseous Ø of 6.0 mm, L 8.0 mm	Titanium Grade 4	yes	yes	07640156470772
4.23.153	SPI@ELEMENT impl. RC INICELL®, incl. healing cap, PF 6.0, endosseous Ø of 6.0 mm, L 9.5 mm	Titanium Grade 4	yes	yes	07640156470758

* according to [ISO5832-2]

Article number	Description	Material *	Single use	Sterile	UDI-DI
4.23.154	SPI®ELEMENT impl. RC INICELL®, incl. healing cap, PF 6.0, endosseous Ø of 6.0 mm, L 11.0 mm	Titanium Grade 4	yes	yes	07640156470741
4.23.155	SPI®ELEMENT impl. RC INICELL®, incl. healing cap, PF 6.0, endosseous Ø of 6.0 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156470734
4.23.214	SPI®CONTACT impl. RC INICELL®, incl. healing cap, PF 3.5, endosseous Ø of 2.7 mm, L 11.0 mm	Titanium Grade 4	yes	yes	07640156471090
4.23.215	SPI®CONTACT impl. RC INICELL®, incl. healing cap, PF 3.5, endosseous Ø of 2.7 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156471083
4.23.216	SPI®CONTACT impl. RC INICELL®, incl. healing cap, PF 3.5, endosseous Ø of 2.7 mm, L 14.0 mm	Titanium Grade 4	yes	yes	07640156471076
4.23.223	SPI®CONTACT impl. RC INICELL®, incl. healing cap, PF 4.0, endosseous Ø of 3.5 mm, L 9.5 mm	Titanium Grade 4	yes	yes	07640156471069
4.23.224	SPI®CONTACT impl. RC INICELL®, incl. healing cap, PF 4.0, endosseous Ø of 3.5 mm, L 11.0 mm	Titanium Grade 4	yes	yes	07640156471052
4.23.225	SPI®CONTACT impl. RC INICELL®, incl. healing cap, PF 4.0, endosseous Ø of 3.5 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156471045
4.23.226	SPI®CONTACT impl. RC INICELL®, incl. healing cap, PF 4.0, endosseous Ø of 3.5 mm, L 14.0 mm	Titanium Grade 4	yes	yes	07640156471038
4.23.233	SPI®CONTACT impl. RC INICELL®, incl. healing cap, PF 4.5, endosseous Ø of 3.5 mm, L 9.5 mm	Titanium Grade 4	yes	yes	07640156471021
4.23.234	SPI®CONTACT impl. RC INICELL®, incl. healing cap, PF 4.5, endosseous Ø of 3.5 mm, L 11.0 mm	Titanium Grade 4	yes	yes	07640156471014
4.23.235	SPI®CONTACT impl. RC INICELL®, incl. healing cap, PF 4.5, endosseous Ø of 3.5 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156471007
4.23.236	SPI®CONTACT impl. RC INICELL®, incl. healing cap, PF 4.5, endosseous Ø of 3.5 mm, L 14.0 mm	Titanium Grade 4	yes	yes	07640156470994
4.23.237	SPI®CONTACT impl. RC INICELL®, incl. healing cap, PF 4.5, endosseous Ø of 3.5 mm, L 17.0 mm	Titanium Grade 4	yes	yes	07640156470987
4.23.243	SPI®CONTACT impl. RC INICELL®, incl. healing cap, PF 5.0, endosseous Ø of 4.2 mm, L 9.5 mm	Titanium Grade 4	yes	yes	07640156470970
4.23.244	SPI®CONTACT impl. RC INICELL®, incl. healing cap, PF 5.0, endosseous Ø of 4.2 mm, L 11.0 mm	Titanium Grade 4	yes	yes	07640156470963
4.23.245	SPI®CONTACT impl. RC INICELL®, incl. healing cap, PF 5.0, endosseous Ø of 4.2 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156470956
4.23.246	SPI®CONTACT impl. RC INICELL®, incl. healing cap, PF 5.0, endosseous Ø of 4.2 mm, L 14.0 mm	Titanium Grade 4	yes	yes	07640156470949
4.23.247	SPI®CONTACT impl. RC INICELL®, incl. healing cap, PF 5.0, endosseous Ø of 4.2 mm, L 17.0 mm	Titanium Grade 4	yes	yes	07640156470932
4.23.253	SPI®CONTACT impl. RC INICELL®, incl. healing cap, PF 6.0, endosseous Ø of 5.0 mm, L 9.5 mm	Titanium Grade 4	yes	yes	07640156470925
4.23.254	SPI®CONTACT impl. RC INICELL®, incl. healing cap, PF Ø 6.0 mm, endosseous Ø 5.0 mm, L 11.0 mm	Titanium Grade 4	yes	yes	07640156470918
4.23.255	SPI®CONTACT impl. RC INICELL®, incl. healing cap, PF 6.0, endosseous Ø of 5.0 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156470901
4.23.256	SPI®CONTACT impl. RC INICELL®, incl. healing cap, PF 6.0, endosseous Ø of 5.0 mm, L 14.0 mm	Titanium Grade 4	yes	yes	07640156470895
4.23.512	SPI®ELEMENT impl. MC INICELL®, incl. healing cap, PF 3.5, endosseous Ø 3.5 mm, L 8.0 mm	Titanium Grade 4	yes	yes	07640156470345
4.23.513	SPI®ELEMENT impl. MC INICELL®, incl. healing cap, PF 3.5, endosseous Ø 3.5 mm, L 9.5 mm	Titanium Grade 4	yes	yes	07640156470321
4.23.514	SPI®ELEMENT impl. MC INICELL®, incl. healing cap, PF 3.5, endosseous Ø 3.5 mm, L 11.0 mm	Titanium Grade 4	yes	yes	07640156470307
4.23.515	SPI®ELEMENT impl. MC INICELL®, incl. healing cap, PF 3.5, endosseous Ø 3.5 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156470284
4.23.516	SPI®ELEMENT impl. MC INICELL®, incl. healing cap, PF 3.5, endosseous Ø 3.5 mm, L 14.0 mm	Titanium Grade 4	yes	yes	07640156470260

Article number	Description	Material *	Single use	Sterile	UDI-DI
4.23.522	SPI@ELEMENT impl. MC INICELL®, incl. healing cap, PF 4.0, endosseous Ø 4.0 mm, L 8.0 mm	Titanium Grade 4	yes	yes	07640156470239
4.23.523	SPI@ELEMENT impl. MC INICELL®, incl. healing cap, PF 4.0, endosseous Ø 4.0 mm, L 9.5 mm	Titanium Grade 4	yes	yes	07640156470215
4.23.524	SPI@ELEMENT impl. MC INICELL®, incl. healing cap, PF 4.0, endosseous Ø 4.0 mm, L 11.0 mm	Titanium Grade 4	yes	yes	07640156470192
4.23.525	SPI@ELEMENT impl. MC INICELL®, incl. healing cap, PF 4.0, endosseous Ø 4.0 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156470178
4.23.526	SPI@ELEMENT impl. MC INICELL®, incl. healing cap, PF 4.0, endosseous Ø 4.0 mm, L 14.0 mm	Titanium Grade 4	yes	yes	07640156470154
4.23.532	SPI@ELEMENT impl. MC INICELL®, incl. healing cap, PF 4.5, endosseous Ø 4.2 mm, L 8.0 mm	Titanium Grade 4	yes	yes	07640156470130
4.23.533	SPI@ELEMENT impl. MC INICELL®, incl. healing cap, PF 4.5, endosseous Ø 4.2 mm, L 9.5 mm	Titanium Grade 4	yes	yes	07640156470123
4.23.534	SPI@ELEMENT impl. MC INICELL®, incl. healing cap, PF 4.5, endosseous Ø 4.2 mm, L 11.0 mm	Titanium Grade 4	yes	yes	07640156470116
4.23.535	SPI@ELEMENT impl. MC INICELL®, incl. healing cap, PF 4.5, endosseous Ø 4.2 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156470109
4.23.536	SPI@ELEMENT impl. MC INICELL®, incl. healing cap, PF 4.5, endosseous Ø 4.2 mm, L 14.0 mm	Titanium Grade 4	yes	yes	07640156470093
4.23.542	SPI@ELEMENT impl. MC INICELL®, incl. healing cap, PF 5.0, endosseous Ø 5.0 mm, L 8.0 mm	Titanium Grade 4	yes	yes	07640156470086
4.23.543	SPI@ELEMENT impl. MC INICELL®, incl. healing cap, PF 5.0, endosseous Ø 5.0 mm, L 9.5 mm	Titanium Grade 4	yes	yes	07640156470079
4.23.544	SPI@ELEMENT impl. MC INICELL®, incl. healing cap, PF 5.0, endosseous Ø 5.0 mm, L 11.0 mm	Titanium Grade 4	yes	yes	07640156470062
4.23.545	SPI@ELEMENT impl. MC INICELL®, incl. healing cap, PF 5.0, endosseous Ø 5.0 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156470055
4.23.546	SPI@ELEMENT impl. MC INICELL®, incl. healing cap, PF 5.0, endosseous Ø 5.0 mm, L 14.0 mm	Titanium Grade 4	yes	yes	07640156470048
4.23.552	SPI@ELEMENT impl. MC INICELL®, incl. healing cap, PF 6.0, endosseous Ø 6.0 mm, L 8.0 mm	Titanium Grade 4	yes	yes	07640156470031
4.23.553	SPI@ELEMENT impl. MC INICELL®, incl. healing cap, PF 6.0, endosseous Ø 6.0 mm, L 9.5 mm	Titanium Grade 4	yes	yes	07640156470024
4.23.554	SPI@ELEMENT impl. MC INICELL®, incl. healing cap, PF 6.0, endosseous Ø 6.0 mm, L 11.0 mm	Titanium Grade 4	yes	yes	07640156470017
4.23.555	SPI@ELEMENT impl. MC INICELL®, incl. healing cap, PF 6.0, endosseous Ø 6.0 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156470000
4.23.615	SPI@CONTACT impl. MC INICELL®, incl. healing cap, PF Ø 3.5 mm, endosseous Ø 2.7 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156470710
4.23.616	SPI@CONTACT impl. MC INICELL®, incl. healing cap, PF 3.5, endosseous Ø 2.7 mm, L 14.0 mm	Titanium Grade 4	yes	yes	07640156470697
4.23.617	SPI@CONTACT impl. MC INICELL®, incl. healing cap, PF Ø 3.5 mm, endosseous Ø 2.7 mm, L 15.5 mm	Titanium Grade 4	yes	yes	07640156470673
4.23.624	SPI@CONTACT impl. MC INICELL®, incl. healing cap, PF Ø 4.0 mm, endosseous Ø 3.5 mm, L 11.0 mm	Titanium Grade 4	yes	yes	07640156470659
4.23.625	SPI@CONTACT impl. MC INICELL®, incl. healing cap, PF Ø 4.0 mm, endosseous Ø 3.5 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156470635
4.23.626	SPI@CONTACT impl. MC INICELL®, incl. healing cap, PF Ø 4.0 mm, endosseous Ø 3.5 mm, L 14.0 mm	Titanium Grade 4	yes	yes	07640156470611
4.23.627	SPI@CONTACT impl. MC INICELL®, incl. healing cap, PF Ø 4.0 mm, endosseous Ø 3.5 mm, L 15.5 mm	Titanium Grade 4	yes	yes	07640156470598
4.23.634	SPI@CONTACT impl. MC INICELL®, incl. healing cap, PF 4.5, endosseous Ø 3.5 mm, L 11.0 mm	Titanium Grade 4	yes	yes	07640156470574
4.23.635	SPI@CONTACT impl. MC INICELL®, incl. healing cap, PF 4.5, endosseous Ø 3.5 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156470550

Article number	Description	Material *	Single use	Sterile	UDI-DI
4.23.636	SPI@CONTACT impl. MC INICELL®, incl. healing cap, PF 4.5, endosseous Ø 3.5 mm, L 14.0 mm	Titanium Grade 4	yes	yes	07640156470536
4.23.637	SPI@CONTACT impl. MC INICELL®, incl. healing cap, PF 4.5, endosseous Ø 3.5 mm, L 15.5 mm	Titanium Grade 4	yes	yes	07640156470512
4.23.644	SPI@CONTACT impl. MC INICELL®, incl. healing cap, PF 5.0, endosseous Ø 4.2 mm, L 11.0 mm	Titanium Grade 4	yes	yes	07640156470499
4.23.645	SPI@CONTACT impl. MC INICELL®, incl. healing cap, PF 5.0, endosseous Ø 4.2 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156470475
4.23.646	SPI@CONTACT impl. MC INICELL®, incl. healing cap, PF 5.0, endosseous Ø 4.2 mm, L 14.0 mm	Titanium Grade 4	yes	yes	07640156470451
4.23.647	SPI@CONTACT impl. MC INICELL®, incl. healing cap, PF 5.0, endosseous Ø 4.2 mm, L 15.5 mm	Titanium Grade 4	yes	yes	07640156470437
4.23.654	SPI@CONTACT impl. MC INICELL®, incl. healing cap, PF Ø 6.0 mm, endosseous Ø 5.0 mm, L 11.0 mm	Titanium Grade 4	yes	yes	07640156470413
4.23.655	SPI@CONTACT impl. MC INICELL®, incl. healing cap, PF 6.0, endosseous Ø 5.0 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156470390
4.23.656	SPI@CONTACT impl. MC INICELL®, incl. healing cap, PF 6.0, endosseous Ø 5.0 mm, L 14.0 mm	Titanium Grade 4	yes	yes	07640156470376
4.23.657	SPI@CONTACT impl. MC INICELL®, incl. healing cap, PF 6.0, endosseous Ø 5.0 mm, L 15.5 mm	Titanium Grade 4	yes	yes	07640156470352
4.23.712	SPI@ELEMENT impl. LC INICELL®, incl. healing cap, PF 3.5, endosseous Ø 3.5 mm, L 8.0 mm	Titanium Grade 4	yes	yes	07640156470338
4.23.713	SPI@ELEMENT impl. LC INICELL®, incl. healing cap, PF 3.5, endosseous Ø 3.5 mm, L 9.5 mm	Titanium Grade 4	yes	yes	07640156470314
4.23.714	SPI@ELEMENT impl. LC INICELL®, incl. healing cap, PF 3.5, endosseous Ø 3.5 mm, L 11.0 mm	Titanium Grade 4	yes	yes	07640156470291
4.23.715	SPI@ELEMENT impl. LC INICELL®, incl. healing cap, PF 3.5, endosseous Ø 3.5 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156470277
4.23.716	SPI@ELEMENT impl. LC INICELL®, incl. healing cap, PF 3.5, endosseous Ø 3.5 mm, L 14.0 mm	Titanium Grade 4	yes	yes	07640156470253
4.23.721	SPI@ELEMENT impl. LC INICELL®, incl. healing cap, PF Ø 4.0 mm, endosseous Ø 4.0 mm, L 6.5 mm	Titanium Grade 4	yes	yes	07640156470246
4.23.722	SPI@ELEMENT impl. LC INICELL®, incl. healing cap, PF Ø 4.0 mm, endosseous Ø 4.0 mm, L 8.0 mm	Titanium Grade 4	yes	yes	07640156470222
4.23.723	SPI@ELEMENT impl. LC INICELL®, incl. healing cap, PF 4.0, endosseous Ø 4.0 mm, L 9.5 mm	Titanium Grade 4	yes	yes	07640156470208
4.23.724	SPI@ELEMENT impl. LC INICELL®, incl. healing cap, PF Ø 4.0 mm, endosseous Ø 4.0 mm, L 11.0 mm	Titanium Grade 4	yes	yes	07640156470185
4.23.725	SPI@ELEMENT impl. LC INICELL®, incl. healing cap, PF 4.0, endosseous Ø 4.0 mm, L 12.5 mm	Titanium Grade 4	yes	yes	07640156470161
4.23.726	SPI@ELEMENT impl. LC INICELL®, incl. healing cap, PF 4.0, endosseous Ø 4.0 mm, L 14.0 mm	Titanium Grade 4	yes	yes	07640156470147

General notes

THOMMEN IMPLANT SYSTEM



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



Batch code



Use by date



Date of manufacture



Sterilized using irradiation



Simple sterile barrier system



Simple sterile barrier system with protective packaging on the inside



No more than 20 processing cycles



EU authorized representative



Temperature limitation



Do not re-use



Non-sterile



Caution



Article number



Conformity mark according to Directive MDD 93/42/EEC or Regulation (EU) 2017/745 MDR (see corresponding declaration of conformity)



Consult instructions for use



Do not re-sterilize



Do not use if package is damaged



Atmospheric pressure limitation



Manufacturer



Keep away from sunlight



May only be sold to and prescribed by physicians (USA)



Medical device



Single product code

COLOR 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.

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

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