FB290 Summary of the Safety and Clinical Performance (SSCP)

Summary of the safety and clinical performance intended for users/healthcare professionals

1. Device identification and general information

This summary of safety and clinical performance applies to:

Device trade name	Hipp medical TITANIUM PINS AND MICRO SCREWS
Manufacturer; name and address	Hipp Medical AG Wilhelmstrasse 19 78600 Kolbingen E-Mail info@hipp-medical.com Website www.hipp-medical.com
Manufacturer's single registration number (SRN)	DE-MF-000010276
Basic UDI-DI	42556531Membrane-Fix.WA
Class/ Rule	IIb / 8
Category / MDN/MDA Codes	1102
UMDNS Code	16-085
GMDN Code	46645
CND / EMDN Code	P09120402
Year when the device was first CE-marked	2012
Authorised representative if applicable; name and the SRN	NA
NB's name (the NB that will validate the SSCP) and the NB's single identification number	MDC MEDICAL DEVICE CERTIFICATION GMBH 0483

as required by the Regulation (EU) 2017/745 of the European Parliament and of the Council (EU MDR).

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.
The SSCP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

2. Intended use of the device

Intended purpose	TITANIUM PINS AND MICRO SCREWS are used to fix resorbable and non-resorbable membranes in regenerative and surgical procedures in the field of oral and maxillofacial surgery.
Indications	TITANIUM PINS AND MICRO SCREWS generally support the treatment and healing process of reconstructive surgery (osteosynthesis, correction of degenerative diseases). However, the implants are not suitable to replace normal body structures. The products are being used in dental surgery for: • Guided bone regeneration before implantation. • Guided bone regeneration with immediate implant placement. • Guided bone regeneration for fenestration and dehiscence defects. • Guided tissue regeneration
Target population	The group of patient population is not limited to an age. Restrictions in the patient population are only represented by allergies to material components.
Contraindications and/or limitations	• All concomitant illnesses that may jeopardize/compromise fixation or the success of the intervention • Poor bone substance/structure which endanger or interfere with safe fixation of the implants • Severe muscular, neurological or vascular conditions that endanger or compromise the success of the intervention/surgery • Allergy patients who are inclined to allergic shock/soft tissue reactions due to the relevant materials used in the implant • Acute or chronic, local or systemic infections • Infections • Nicotine, which can endanger the success of the intervention/surgery by delaying bone/wound healing • Physically or mentally unstable patient

3. Device description

Device description	Hipp medical TITANIUM PINS AND MICRO SCREWS are offered in the following variants: Pins: Diameter: 0.6mm Length: 3mm Material: Titanium Alloy Ti6Al4V (EN ISO 5382-3) Micro Screws: Diameter: 1.0mm – 1.5mm Length: 4mm – 13mm Material: Titanium Alloy Ti6Al4V (EN ISO 5382-3) Stainless Steel 1.4441 (EN ISO 5832-1)
A reference to previous generation(s) or variants if such exist, and a description of the differences	Hipp medical TITANIUM PINS AND MICRO SCREWS are marketed successfully in Europe since 2012. No changes have been made to the design since initial release to market. No previous generation(s) or variants exist.
Description of any accessories which are intended to be used in combination with the device	NA
Description of any other devices and products which are intended to be used in combination with the device	NA

4. Risks and warnings

Residual risks and undesirable effects	The use of HIPP medical Titanium Pins for the fixation of membranes requires the following, general indications: • The patient is in a good condition • Good neurovascular condition • Accustomed to adequate oral hygiene before the treatment • Good bone substance for the implants • Post-operative care is possible • Patient is cooperative

Warnings and precautions	The following warnings and precautions are listed in the instructions for use. These statements are taken from technical design specifications, guidelines and scientific publications and are intended to ensure the highest level of safety during surgery and the retention of the implant in the body. • The product is intended for single use only. It must not be reused. • Implants that have come into contact with soft tissues, bone, blood or other body fluids must not be reused and must be disposed of by hospital staff in accordance with the guidelines for the disposal of contaminated products. Contamination residue on implants may result in injury or infection to the patient or user. • An implant that has already been implanted must not be reused, as the risks of material fatigue damage and infection are very high. HIPP medical assumes no liability here in the event of non-compliance. • Implants or instruments must not be used if damage has been detected during use or implantation. • During the time the implant is in the patient's body, the patient should be checked regularly for infections. • These implants are designed for temporary use and should be removed after fracture healing is complete. • The factors described under "General Indications" should be considered when selecting a patient. • The implants do not need to be, and should not be, mechanically processed or modified. • There are several risks associated with the use of TITANIUM PINS AND MICRO SCREWS in an MRI environment unless the implant is labeled "MR safe" or "MR conditional." These include, but are not limited to: - Heat generation and/or migration of the implant - Artifacts caused by the implant. HIPP medical implants are not tested for MRI compatibility.

Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable	NA

5. Summary of clinical evaluation and post-market clinical follow-up

Summary of clinical data related to equivalent device, if applicable	The evaluation of clinical data for medical device Hipp medical TITANIUM PINS AND MICRO SCREWS was per-formed by taking into account the relevant state of the art standards and demonstration of equivalence to commercially available devices. Equivalence is demonstrated considering clinical, technical and biological characteristics with no clinically significant difference in the safety and clinical performance of the device. The Clinical Evaluation of Hipp TITANIUM PINS AND MICRO SCREWS is based on clinical data relating to a device for which equivalence to the device in question can be demonstrated. Hipp medical TITANIUM PINS AND MICRO SCREWS are equivalent to • Botiss (Straumann) – Ti-Pins • Ustomed – Membrane and Micro Screw whose biological, physical and technological characteristics are well-known and set the standard for claiming clinical equivalence.
Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable	NA, there is no independently published clinical data for the medical device Hipp medical TITANIUM PINS AND MICRO SCREWS available. Stable, well-established technologies that perform as intended and are not associated with safety concerns, and where there has been no innovation, are less likely to be the subject of research, and therefore literature data is limited or non-existent. The common features of the devices which are well-established technologies are that they all have: 1. relatively simple, common and stable designs with little evolution;

2. their generic device group has well-known safety and has not been associated with safety issues in the past;
3. well-known clinical performance characteristics and their generic device group are standard of care devices where there is little evolution in indications and the state of the art;
4. a long history on the market.

Hipp medical TITANIUM PINS AND MICRO SCREWS meet all these criteria may be considered “well-established technologies”. See following how the above listed common features are fulfilled.

Ad 1. Relatively simple, common and stable designs with little evolution

The principle of guided bone regeneration is based on the fact that the separation between hard and soft tissue is realized by a barrier membrane. To secure the barrier during the active healing phase, it is recommended to stabilize and fix it three-dimensionally with mechanical retention aids. The fixation of the membrane improves the therapy prognosis and can be achieved most easily with TITANIUM PINS AND MICRO SCREWS.

Ad 2. The generic device group has well-known safety and has not been associated with safety issues in the past

The devices belong per definition of MDR 2017/745 Article 52 (4)
that are sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors for which the clinical evaluation is based on sufficient clinical data and is in compliance with the relevant product-specific CS, where such a CS is available.
Devices in the exemption list are required to possess a "well-established technology" per MDR 2017/745 Article 52 (5).

Post market surveillance data confirms that the products are safe in use and that the benefit of TITANIUM PINS AND MICRO SCREWS overweighs the risks for

	the use. For details see section 10 Post Market Activities. Ad 3. Well-known clinical performance characteristics and their generic device group are standard of care devices where there is little evolution in indications and the state of the art Surgical procedures for TITANIUM PINS AND MICRO SCREWS are state-of-the-art. The principle of GBR was first studied in rats by Dahlin et al. 1988. The selective ingrowth of bone-forming cells into a bone defect could be improved - also according to a study by Kostopoulos and Karring (1994) - if the surrounding tissue is kept away with a membrane. The principle of guided bone regeneration is based on the fact that the separation between hard and soft tissue is realized by a barrier membrane. To secure the barrier during the active healing phase, it is recommended to stabilize and fix it three-dimensionally with mechanical retention aids. Micro-movements can prevent the differentiation of mesenchymal stem cells into osteoblasts and instead lead to the formation of fibroblasts. The fixation of the membrane improves the therapy prognosis and can be achieved most easily with TITANIUM PINS AND MICRO SCREWS. In the case of large bone defects with continuous multi-tooth positions, it is the first choice to use a large number of pins to fix the membrane and grafts. Ad 4. A long history on the market The medical device TITANIUM PINS AND MICRO SCREWS received the CE mark in the year 2012 and has been marketed successfully in Europe since 2012. No significant changes to the design like • Change of the intended purpose, user group, patient population, or clinical use • Design changes related to corrective actions or new risks identified • Change of design or performance specification requiring further clinical or usability data to support safety and performance • Change in material

	• Change to terminal sterilization method of the device or packaging design with impact to the sterilisation have been implemented for TITANIUM PINS AND MICRO SCREWS since initial release to market back in 2012.
Summary of clinical data from other sources, if applicable	All information from the literature search and associated evaluation during the assessment period was evaluated for its impact on product risk and clinical use data. A general risk using Hipp medical TITANIUM PINS AND MICRO SCREWS or new risks or information were not identified.
An overall summary of the clinical performance and safety	Hipp medical has elected to demonstrate conformity of this device with REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017 ON MEDICAL DEVICES Article 61 and Part A of Annex XIV via the provision of a written critical evaluation of relevant scientific literature. Given that 1. Hipp medical TITANIUM PINS AND MICRO SCREWS are manufactured from well-established materials recognized for use for implants. 2. Hipp medical TITANIUM PINS AND MICRO SCREWS are state of the art devices used in osteosynthesis within well established procedures. 3. The residual risks for the use of Hipp medical TITANIUM PINS AND MICRO SCREWS are rather user and procedure (off-label) than device related. It is considered that the clinical data requirements under REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017 ON MEDICAL DEVICES Article 61 and Part A of Annex XIV have been satisfied in respect of the manufacturer's claims relating to the clinical safety and performance of Hipp medical TITANIUM PINS AND MICRO SCREWS and that, as a result of this, a clinical investigation to demonstrate satisfactory clinical performance and safety is not required.

	Hipp medical concludes that 1. The device performs as intended when used in accordance with the instructions from use and operated by professionals, 2. The device does not pose undue safety concerns to either the recipient or end user, 3. And risks associated with the use of the device are acceptable when weighed against the benefits to the patient. Although there are general risks related to the Hipp medical TITANIUM PINS AND MICRO SCREWS, which cannot be completely reduced, there is obvious compliance of Hipp medical TITANIUM PINS AND MICRO SCREWS compared to the other available implant systems for cranial osteosynthesis on the market. Safety and performance characteristics of Hipp medical TITANIUM PINS AND MICRO SCREWS are demonstrated.
Ongoing or planned post-market clinical follow-up	NA - the decision for not performing a PMCF is still justified as for the product safety and efficacy is demonstrated by historic data. Hipp medical TITANIUM PINS AND MICRO SCREWS are in the market since 2012 with good clinical results proven by the fact that there are no complaint reports related to clinical problems on file. Registries are not available for this type of device.

6. Possible diagnostic or therapeutic alternatives

Alternative methods are no additional fixation of the membrane or using suturing techniques for membrane fixation.
The technique utilizing periosteal vertical mattress suture (PVMS) for the fixation of grafts and membranes has been proposed for single implant sites.

Similar to PVMS, continuous periosteal strapping sutures (CPSS) have been used to fix the grafts and absorbable membranes for buccal ridge augmentation.
However, all this suture techniques are all limited by the tensile strength and the resorption rate of the sutures, the time of fixation is also limited by the biodegradation period of the absorbable suture material. Another limitation is that the linear-guided suture may result in possible migration of the particulate graft material in an apicocoronal direction. Moreover, the PVMS technique may not provide enough stability for grafts in large defects, and for large ridge defects the use of pins is still recommended.

7. Suggested profile and training for users

Hipp medical TITANIUM PINS AND MICRO SCREWS are designed only for qualified doctors with sufficient experience in the field of orthopedic surgery.

8. Reference to any harmonised standards and CS applied

- EN ISO 13485:2016 + AC:2018 + A11:2021
- EN ISO 14971:2019 + A11:2021 + A11:2021
- EN 62366-1:2015+COR1:2016+A1:2020
- ISO/TR 20416:2020
- EN ISO 20417:2021
- EN ISO 15223-1:2021
- EN ISO 10993-1:2020
- EN ISO 5832-1:2019
- EN ISO 5832-3:2021
- ISO 19227:2018
- EN ISO 11607-1:2020
- EN ISO 11607-2:2020
- EN ISO 11137-1:2015 + A2:2019
- EN ISO 11137-2:2015
- EN ISO 14644-1:2015
- EN ISO 17664-1:2021
- EN ISO 17665-1:2006

9. Revision History

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
01	17.03.2023	Initial version	☐ Yes Validation language: ☒ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
			☐ Yes Validation language: ☐ No