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 Kirschner Wires and Guide Wires
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	42556531K-WireY4
Class/ Rule	IIb / 8
Category / MDN/MDA Codes	1102
UMDNS Code	16-104
GMDN Code	61690
CND / EMDN Code	P09120301
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	Temporary repos1tion and guide wires for surgery and for short-term fixation of fractures, osteotomies, fusions of the upper and lower extremities. The aim of treating osteosyntheses and fixations with Kirschner wires and guide wires is: • Achieve stable fixation of bone fragments in a fracture, fusion, or osteotomy to allow early weight-bearing mobilization. • Restore correct alignment of bone fragments and parts to prevent malalignment, shortening and rotational errors.
Indications	Kirschner wires and guide wires are used for fixation of fractures, fusions for osteoarthritis or correction procedures for anatomical malpositions, osteotomies for malpositions, and reconstructions of the extremities. Specific indications include • Reposition and fixation of metaphyseal fractures • Diaphyseal fractures and dislocations of the hand and foot bones (often referred to as CRIF- closed reduction and internal fixation) by transcutaneous insertion) • Temporary arthrodesis of small joints • Temporary intraoperative fixation of fracture fragments
Target population	The group of patients is not limited to a certain age. There are only therapeutic alternatives that must be considered by surgeons. E.g., rigid fixation should not be used if epiphyseal growth is not complete, as this will stop bone growth.
Contraindications and/or limitations	• All concomitant diseases that can endanger/ interfere with the fixation or the success of the surgery. • Poor bone substance/ structure which endangers or has a negative effect on the secure fixation of implants • Serious muscular, neurological or vascular diseases that endanger or have a negative effect on the success of the procedure / surgery

	• Patients with allergies susceptible to allergic shock/ soft tissue reactions because of the material used in the implant • Acute or chronic, local or systematic infections. • Inflammations • Smoking which can endanger the success of the procedure / surgery by delayed bone healing / wound healing. • Physically or mentally unstable patient • Option of conservative treatment • Growing patient with open epiphyses • Patient with high level of activity

3. Device description

Device description	Hipp medical Kirschner Wires and Guide Wires are offered in the following variants: Diameters: 0,9mm, 1,0mm, 1,2mm, 1,4mm, 1,5mm, 1,6mm, 1,8mm, 2,2mm, 2,4mm, 2,5mm, 3,0mm, 3,2mm Length: 150mm, 200mm, 230mm, 250mm, 255mm, 280mm, 300mm, 310mm, 350mm, 360mm, 380mm, 400mm, 430mm Material: stainless steel 1.4441 (X2CrNiMo18-15-3) acc. EN ISO 5832-1 Shape: • with trocar or with drill tip • with eyelet or without eyelet
A reference to previous generation(s) or variants if such exist, and a description of the differences	Hipp medical Kirschner Wires and Guide Wires 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 Kirschner Wire Implants for treating fractures, fusions, osteotomies and reconstructions of extremities requires the following, general indications: • The patient is in a good condition • Good neurovascular condition • Sufficient skin cover • 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 Kirschner wires and drill wires 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 Kirschner Wires and Guide Wires was performed 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 medical Kirschner Wires and Guide Wires is based on clinical data relating to a device for which equivalence to the device in question can be demonstrated. Hipp medical Kirschner Wires and Guide Wires are equivalent to • Medartis – APTUS K-WIRE SYSTEM • Depuy Snthes – K-Wire 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 Kirschner Wires and Guide Wires 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 Kirschner Wires and Guide Wires 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 Kirschner wire osteosynthesis was developed as early as 1920 by Dr. Martin Kirschner and is still used today. It is thus one of the oldest, regularly used procedures in the surgical treatment of fractures. 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 KIRSCHNER WIRES AND GUIDE WIRES 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 Hipp medical Kirschner Wires and Guide Wires are state-of-the-art. The Kirschner Wires are designed in accordance with the AO Surgery Reference [02] for the management of fractures, based on current clinical principles, practices and available evidence. The AO Foundation (Arbeitsgemeinschaft für Osteosynthesefragen), is a medical non-profit organization with international research and educational activities led by surgeons specialized in trauma (orthopaedic), spinal, craniomaxillofacial, and veterinary surgery. Its mission is to foster and expand its network of healthcare professionals in education, research, development, and clinical investigation to achieve more effective patient care worldwide. Founded in 1958, the AO today represents the world's leading knowledge organization in this field. It comprises one of the most important and extensive networks in medicine with more than 10,000 surgeons, and an international faculty of over 3,000 experts in more than 100 countries. The AO principles (principles of osteosynthesis) are: • Fracture reduction and fixation to restore anatomical relationships • Stability by fixation or splintage, according to the personality of the fracture and the injury

	• Preservation of the blood supply to soft tissues and bone by careful handling and gentle reduction techniques. • Early and active mobilization. These principles have been established back in 1958, further developed over the past 50 years, and do represent today the golden standard in modern trauma and orthopedic surgery. The lower extremities implants are established in the medical device market for years. Bone fracture fixation / Fusion / Osteotomies, using Kirschner Wires is a state-of-the-art procedure.
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 Kirschner Wires and Guide Wires 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 Kirschner Wires and Guide Wires are manufactured from well-established materials recognized for use for implants. 2. Hipp medical Kirschner Wires and Guide Wires are state of the art devices used in osteosynthesis within well established procedures. 3. The residual risks for the use of Hipp medical Kirschner Wires and Guide Wires 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 Kirschner Wires and Guide Wires 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 Kirschner Wires and Guide Wires, which cannot be completely reduced, there is obvious compliance of Hipp medical Kirschner Wires and Guide Wires compared to the other available implant systems for cranial osteosynthesis on the market. Safety and performance characteristics of Hipp medical Kirschner Wires and Guide Wires 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 Kirschner Wires and Guide Wires 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

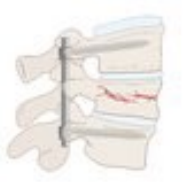
Bone fractures range from thin, hairline cracks to broken bones. A common help with this condition is giving the patient a splint or a cast. This keeps the bone immobilized, allowing a patient's body to repair the fracture.
For severe fractures, getting surgery may be necessary. Surgical treatment for broken bones is typically necessary when a fracture has resulted in multiple bone fragments or misalignment of bone fragments. In such a situation, the pieces of bone or secure bone fragments will need to set in place using screws or pins.

Typical treatments are:

Open reduction internal fixation

Definition: a surgical procedure to repair a fracture and/or dislocation through operative (open) repositioning (reduction), followed by fixation with rods, nails, plates, and/or screws.

Indications



- Failed closed reduction
- Multiple trauma
- Open fractures
- Fractures with vascular injuries
- Nonunion

Lag screw fixation

Definition: the fixation of a fracture using lag screws either on their own or in combination with other devices (e.g., plates)

Indications:: most types of fractures (e.g., articular fractures, slipped capital femoral epiphysis)

Principles: fixation and compression of the fracture gap

Types of hardware involved

- Cortical screws: fixation of the fracture gap
- Cancellous screws: compression and fixation of the fracture gap

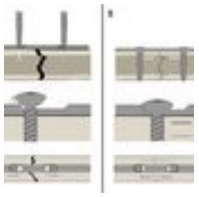
Plate fixation

Definition: a surgical procedure in which stainless steel or titanium plates are used in combination with screws for the fixation of a fracture

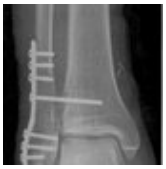
Indications: comminuted fractures (e.g., unstable articular fractures, osteoporotic fractures)

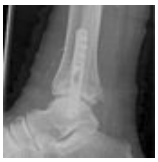
Principles: neutralization and stabilization of the malposition for quicker postoperative functional rehabilitation

Types of hardware involved



- Buttress (antiglide) plates: compensate for shear forces
- Compression plates: compress the fracture gap
- Neutralization plates: neutralize bending, torsional, and shear forces
- Tension-band plates: convert tensile forces into compression forces
- Bridge plates: connect the intact bone ends of comminuted fractures or bony defects, bypassing the intermediate fracture zone





Intramedullary nail fixation

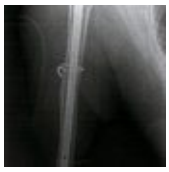
Definition: a surgical procedure in which a metal rod is inserted into the medullary cavity of a bone to internally fix a fracture

Indication

- Diaphyseal fractures of the long bones (e.g., tibial shaft, distal femur, humerus shaft)
- Metaphyseal fractures

Principle

- Stabilization of the bone
- Preservation of bone length
- Limitation of rotation



7. Suggested profile and training for users

Hipp medical Kirschner Wires and Guide Wires 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
- 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	15.03.2023	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