Summary of the Safety and Clinical Performance

intended for
Users / Healthcare Professionals

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This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an up-dated summary of the main aspects of the safety and clinical performance of HIPP medical KIRSCHNER WIRES AND GUIDE WIRES.

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.

FB290 Summary of Safety and Clinical Performance (SSCP)

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 Germany 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	to (EU) 2017/745, Appendix VIII
Category / MDN/MDA Codes	MDN 1102	Non-active osteo- and orthopaedic implants
UMDNS Code	16-104	Wires, Bone
GMDN Code	32854	Orthopaedic bone pin, non-bioabsorbable
CND / EMDN Code	P09120301	KIRSCHNER BONE WIRES
Year when the device was first CE-marked	2012	
Authorized repre-sentative 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.

2. Intended use of the device

Intended purpose	• Temporary reposition and guide wires for surgery • Closed Reposition and fixation of fractures, osteotomies and 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. The use of HIPP medical KIRSCHNER WIRES AND GUIDE WIRES 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
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 patients • 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:

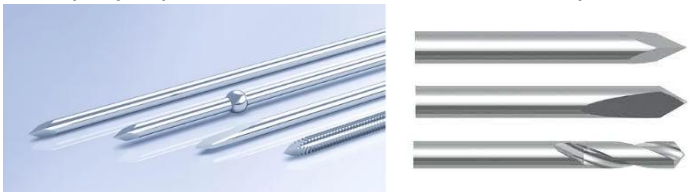
Diameters: 0,9mm, 1,0mm, 1,2mm, 1,4mm, 1,5mm, 1,6mm, 1,8mm, 2,2mm, 2,4mm, 2,5mm, 3,0mm, 3,2mm

Length: 150mm, 200mm, 230mm, 250mm, 255mm, 280mm, 300mm, 310mm, 350mm, 360mm, 380mm, 400mm, 430mm

Material: medical grade stainless steel 1.4441 (X2CrNiMo18-15-3) acc. EN ISO 5832-1

Shape: with trocar or with drill tip
with eyelet or without eyelet

Exemplary representation of the variants of the tip



HIPP medical KIRSCHNER WIRES AND GUIDE WIRES are one-piece products.

The application is

- Long-term exposure for the application as
  Closed reposition and fixation of fractures, osteotomies and fusions of the upper and lower extremities.

and

- Limited / short term exposure in case of use as
  Device for temporary reposition and guide wires for surgery.

Kirschner Wires are mainly used as implants for primary fixation, reduction support and as guide wires for inserting cannulated screws. Also, in the temporary extension table reduction the Kirschner Wires are used to keep the fracture stable for a couple of days before the operation takes place.
They are also referred to as “spiking wires” for wire lacing; here, small bone fragments or bone grafts are fixed with wire spikes. Similarly, fractures of small bones are treated in fracture fixation procedure in the sense of wire splinting by percutaneously drilled Kirschner wires.

With the Kirschner wire it is possible to fix the bone fragments in a minimally invasive, punctual way without compression effect.

Kirschner wire osteosynthesis was introduced in 1909 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. Guide wire (also drill wire or bone drill wire) is a wire made of stainless implant steel used in medicine, particularly in the context of osteosynthesis, which is screwed directly through or into a bone with a drill.
It can be used as a guide wire for placing a cannulated implant or for fixing bone fractures (Kirschner wire according to Martin Kirschner). Drill wires usually have a trocar tip. Threaded drill wires are also used for fixation by means of an external fixator.

	Kirschner Wires are intended for multiple applications including, but not limited to: • Fracture Fixation • Fracture Reduction • Reduction and fixation of metaphyseal fractures • Diaphyseal Fractures und luxation of small bones • Temporary arthrodesis of small joints • Primary operation fixation • Temporary extension table fixation • Guide wire HIPP medical KIRSCHNER WIRES AND GUIDE WIRES do not contain any drugs, and/or substances or derivatives of human blood.
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 or the intended purpose 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 risk analysis for HIPP medical KIRSCHNER WIRES AND GUIDE WIRES has shown that none of the identified risks and side-effects result in unacceptable harm to the patient, the user, or other people in the environment where the product is used. Therefore, all risks were classified as acceptable after implementation of the risk control actions. All known and predictable use errors of HIPP medical KIRSCHNER WIRES AND GUIDE WIRES have been mitigated at the user-product level and/or in the context of instructions for use. The analysis of the literature did not reveal any further hazards attributable to the treatment with KIRSCHNER WIRES AND GUIDE WIRES. The literature, as well as the analysis of clinical experience data, did not identify any incidents that were caused due to improper use. Based on the results of literature studies, clinical experience data, and risk analysis, the benefits to the patient from treatment with the KIRSCHNER WIRES AND GUIDE WIRES far outweigh the likelihood of patient harm. Therefore, benefit-risk profile is acceptable.

The following risks and side effects are known so far for treatment with HIPP medical KIRSCHNER WIRES AND GUIDE WIRES:

Risks and Side Effects	Probability of occurrence after measure out of risk management	Clinical parameter and literature reference out of current clinical evaluation report
Bone fractures / refracture - iatrogenic fracture: bone fracture that occurs as a direct result of the medical procedure itself. - refracture: occurrence of a new fracture at the site of a previously healed fracture or a fracture in healing process.	Unlikely: ≤1 of 10.000	-
Improper bone healing - delayed union: bone fracture that takes longer than usual to heal. - non-union: fractured bone fails to heal properly. - malunion: fractured bone heals in an incorrect position (e.g., pseudoarthrosis, deformity)	Unlikely: ≤1 of 10.000	Delayed union / Non-union: 5,20% [1], [5], [14], [15], [18] Malunion: 2,05% [3], [5], [18] Rate of union / Time to union: 95,60% / 553,34d [1], [2], [3], [5], [6], [7], [13], [15]
Infection diseases An infection is the invasion and multiplication of harmful microorganisms, such as bacteria, viruses, or parasites, within a host organism. Most common is the pin site infection, which could lead to failure of fixation, malunion and osteomyelitis.	Unlikely: ≤1 of 10.000	Infection: 5,95% [1], [2], [3], [4], [5], [6], [7], [8], [9], [10], [11], [12], [13], [14], [15], [16], [17], [18], [19], [20], [21], [22]
Postoperative wound complications Unproper wound healing. Factors that can impair wound healing and lead to complications include bacterial infection, necrotic tissue, foreign bodies, diabetes, smoking, malignancy, malnutrition, poor blood supply, global hypotension, hypothermia, immunosuppression (including steroids), emergency surgery, ascites, severe cardiopulmonary disease, and intraoperative contamination	Unlikely: ≤1 of 10.000	-
Inflammation / hypersensitivity reaction The body's natural response to injury or infection. Inflammation can occur without infection, such as in response to surgical trauma, but infection almost always causes inflammation. A hypersensitivity reaction is e.g., hardware intolerance.	Unlikely: ≤1 of 10.000	Hardware intolerance: 0,00% [1], [2], [3], [4], [5], [6], [7], [8], [9], [10], [11], [12], [13], [14], [15], [16], [17], [18], [19], [20], [21], [22]
Neurovascular compromise - Nerve injury: Damage to nearby nerves during the insertion of K-wires, leading to symptoms like numbness, tingling, or loss of motor function. - Nerve lesion: A nerve lesion in K-wire treatment refers to damage or injury to a nerve that occurs during the insertion, positioning, or removal of K-wires. - Vascular injury: Damage to blood vessels, which can result in bleeding, hematoma formation, or compromised blood flow to the affected area. - Ischemia: Reduced blood supply to tissues, which can cause pain, pallor, and in severe cases, tissue death.	Unlikely: ≤1 of 10.000	-

Soft tissue injury Soft tissue injury refers to damage to the muscles, tendons, ligaments, or skin that can occur during the insertion, positioning, or removal of K-wires.	Unlikely: ≤1 of 10.000	-
Avascular necrosis Avascular necrosis (AVN), also known as osteonecrosis, is a condition where bone tissue dies due to a lack of blood supply.	Unlikely: ≤1 of 10.000	-
Pain - Manipulation of a fracture is painful, so this is usually carried out using local, regional, or general anaesthesia - Post-operative pain: Can occur e.g., from infections, soft tissue irritation. Effective pain management strategies are crucial to help patients recover comfortably.	Unlikely: ≤1 of 10.000	Patient-Rated Wrist Evaluation score: 24,96 [15], [16], [20], [21], [22] Visual Analogue Scale score: 3,48 [1], [2], [11], [17], [18]
Cosmetic complications - Scarring: The insertion points of the K-wires can leave scars on the skin - Skin Necrosis: Poor management of the soft tissue around the K-wire can lead to skin necrosis, where the skin tissue dies due to lack of blood flow.	Unlikely: ≤1 of 10.000	-
Joint immobility Inability to move a joint normally due to stiffness or restriction.	Unlikely: ≤1 of 10.000	Disabilities of the Arm, Shoulder and Hand score: 16,76 [16], [19], [20], [21] American Orthopaedic Foot and Ankle Society Ankle-Hindfoot score: 51,09 [2], [11], [17] Range of motion: 0,27 [1], [2], [3], [7], [12], [13], [14], [18], [19]
Hardware displacement / instability - Migration: movement of the K-wire from its original position. - Exposure of metal ware: K-wire becomes visible through the skin. - Loosening: K-wire becomes unstable and loses its secure position within the bone	Unlikely: ≤1 of 10.000	-
Operation structure failures Several factors can contribute to wrong approaches and destroying of important soft tissues and nerves.	Unlikely: ≤1 of 10.000	-
Implant failure - Breakage during and after treatment. - Repeated bending back and forth will cause fatigue or breakage of the implant. - Notches and pressure points also significantly reduce the mechanical strength of the implant	Unlikely: ≤1 of 10.000	Failure to product: 0,24% [2], [3], [8], [9], [10], [12], [14], [20], [21]
Needle-stick injury Needle-stick injury occurs when the sharp end of the K-wire accidentally punctures the skin of medical personnel.	Unlikely: ≤1 of 10.000	-

	Due to the different number of patients per publication, all parameters were assessed using the weighted mean value.
Warnings and Precautions	HIPP medical KIRSCHNER WIRES AND GUIDE WIRES are single-use products. They must not be reused. KIRSCHNER WIRES AND GUIDE WIRES that have been in contact with bone tissue, soft tissue, blood, synovial fluid, and skin must not be reused and must be disposed of by clinical staff according to the guidelines for disposal of contaminated products. Contamination residues on the implants can lead to injuries or infections in the patient or the user. KIRSCHNER WIRES AND GUIDE WIRES that have already been implanted must not be reused, since the risks of material fatigue damage and infection are very high. Reuse or clinical reprocessing (for example, cleaning and re-sterilisation) of single-use devices may compromise the structural integrity of the device and/or lead to device failure and result in patient injury, illness, or death. Furthermore, the reuse or clinical reprocessing of single-use products increases the risk of contamination, for example through germ transmission from patient to patient. This may also result in injury, illness or death to the patient or user. HIPP medical advises against the clinical reprocessing of contaminated KIRSCHNER WIRES AND GUIDE WIRES. HIPP medical products contaminated by bone tissue, soft tissue, blood, synovial fluid, and skin must not be reused under any circumstances and must be disposed of in accordance with hospital policies and regulations. Even if components appear externally intact after use, minor defects and invisible material damage can cause material fatigue. KIRSCHNER WIRES AND GUIDE WIRES should be accepted only if their packaging and labeling are undamaged. They must not be inserted if damage has been detected during insertion or implantation. They must not be used if the sterile packaging is damaged. They must not be inserted in case of overdue expiration date. <u>Reprocessing</u> KIRSCHNER WIRES AND GUIDE WIRES supplied in a sterile state can be reprocessed according to the specification listed in the instructions for use if they become non-sterile during surgery and have not yet been modified, have not yet been implanted and have not been in contact with bone tissue, soft tissue, blood, synovial fluid, and skin. Non-sterile KIRSCHNER WIRES AND GUIDE WIRES must be cleaned, and steam sterilised prior to operative use. Prior to cleaning, the original packaging is to be completely removed. Prior to steam sterilisation, pack the products in a validated packaging system (sterilisation wrap or sterilisation container). Instructions for reprocessing are described in instructions for use. <u>Information for the user / treating physician / precautions</u> The instructions for use contain important warnings and cautions for operation. It must be available to the user and clinic staff at all times. It must be read in full, and the products may be used if you the user has understood these instructions. The user / attending physician must be familiar with the surgical technique to be used. HIPP medical AG cannot be held liable for complications arising from the use of the products that are beyond the control of HIPP medical AG, including but not limited to product selection and deviations in application / handling and surgical technique. When selecting a patient, the factors described in the instructions of use under “Indications” and “Contraindications” should be considered. The patient should be tested for infections at regular intervals for the duration that the implant is in the body. KIRSCHNER WIRES AND GUIDE WIRES are designed for temporary use and should be removed once healing is complete. The use of KIRSCHNER WIRES AND GUIDE WIRES in an MRI environment poses several risks unless the implant is labeled “MR safe” or “MR conditional”. These include:

- Heat generation and/or migration of the implant
- Artifacts caused by the implant.

Implants of HIPP medical are not tested for MRI compatibility.

Intraoperative phase

The KIRSCHNER WIRES AND GUIDE WIRES must not come into contact with objects that could damage their surface. They must not be mechanically processed or otherwise modified unless the design and surgical technique explicitly provide for this. In this case, the modification must be carried out with the appropriate instruments in accordance with the references.

The mechanical processing of KIRSCHNER WIRES AND GUIDE WIRES by the user involves several important steps and techniques to avoid damaging the product, to ensure optimal fixation and healing of the fracture:

- Adjusting the length:
  KIRSCHNER WIRES AND GUIDE WIRES can be cut to the re-quired length before use. This must be done with special wire cutters.
- Bending and shaping:
  Depending on the type and location of the fracture, it may be necessary to bend or shape the KIRSCHNER WIRES AND GUIDE WIRES to achieve optimal stability. This must be done manually or with special instruments.

If the KIRSCHNER WIRES AND GUIDE WIRES are bent with the necessary care, the implant will not be damaged. Extreme deformation of the implant must be avoided at all costs.

The user is responsible for sterility of the modified KIRSCHNER WIRES AND GUIDE WIRES.

It is extremely important to handle the HIPP medical KIRSCHNER WIRES AND GUIDE WIRES correctly. If shaping of the implant is necessary, excessive bending, bending against the original shape, notching, or scratching should be avoided. Such manipulations combined with improper use can lead to defects on the surface and/or a structural change in the material, ultimately resulting in product failure.

Repeated bending back and forth will cause fatigue or breakage of the implant. Notches and pressure points also significantly reduce the mechanical strength of the implant.

The physician should inform the patient about the load limits of his or her implant and provide instructions for post-operative behaviour, and gradual load build-up. Failure to do so may result in malpositioning, delayed bone healing, implant failure, infection, thrombophlebitis and/or wound hematoma.

Post-operative care

The physician should inform the patient about the load limits of his or her implant and provide instructions for post-operative behaviour, and gradual load build-up. Failure to do so may result in malpositioning, delayed bone healing, implant failure, infection, thrombophlebitis and/or wound hematoma.

The final decision on when to remove the implant is the responsibility of the treating physician. It is recommended – if possible and applicable for the individual patient – to remove the fixation products after the healing process is fully completed. This is especially true with young and active patients. The risk of adverse effects such as secondary infection, allergies, material fatigue fractures, implant failure and/or impaired blood circulation increases with the duration of the implant in the body.

Compatibility

	For the application of HIPP medical products, their compatibility is guaranteed. The use of HIPP medical products together with products from other manufacturers is not recommended, due to the mismatched designs, materials, mechanics, and structures.
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	According to Regulation (EU) 2017/745 of the European Parliament and of the Council, Article 61, Section 8 and MDCG 2020-6 for well-established devices, the clinical evaluation was based on data generated with comparable devices. A comparison of HIPP medical KIRSCHNER WIRES AND GUIDE WIRES and similar products on the market was performed to demonstrate that HIPP medical KIRSCHNER WIRES AND GUIDE WIRES are comparable to similar medical devices on the market and are therefore state-of-the-art.
Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable	NA, no pre-market clinical investigations have been performed to support safety and performance of the HIPP medical KIRSCHNER WIRES AND GUIDE WIRES. HIPP medical KIRSCHNER WIRES AND GUIDE WIRES meet all criteria to be considered "well-established technologies", because <u>MDCG 2020-6 Ad 1. Relatively simple, common and stable designs with little evolution</u> Kirschner wire osteosynthesis was introduced in 1909 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. <u>MDCG 2020-6 Ad 2. The generic device group has well-known safety and has not been associated with safety issues in the past</u> The devices belong to the per Regulation (EU) 2017/745 of the European Parliament and of the Council , Article 52 (4) form section 4 Annex IX except device group 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 Regulation (EU) 2017/745 of the European Parliament and of the Council , 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. <u>MDCG 2020-6 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</u> Surgical procedures for KIRSCHNER WIRES AND GUIDE WIRES are state-of-the-art. The Kirschner Wires are designed in accordance with the AO Surgery Reference 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 orthopaedic 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.

<u>MDCG 2020-6 Ad 4. A long history on the market</u>
The medical device KIRSCHNER WIRES AND GUIDE WIRES 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 KIRSCHNER WIRES AND GUIDE WIRES since initial release to market back in 2012.

<u>Manufacturing technologies are state-of-the-art</u>
Regarding the manufacturing technologies for KIRSCHNER WIRES AND GUIDE WIRES are made of stainless steel. No changes have been made to the manufacturing technology of KIRSCHNER WIRES AND GUIDE WIRES since initial release to market. The manufacturing technologies used for KIRSCHNER WIRES AND GUIDE WIRES have been applied since decades and therefore are considered state-of-the-art.

Summary of clinical data from other sources, if applicable

Clinical data supporting the safety and performance of the HIPP medical KIRSCHNER WIRES AND GUIDE WIRES have been derived from the following sources:

Publications identified by Literature Search / Benchmark state-of-the-art Literature Review
A comprehensive systematic literature search to identify clinical performance and clinical safety data not held by the manufacturer was conducted using MEDLINE / PubMed, Science Direct databases, and Cochrane library for the period from 2018 to 2024. A total of 22 articles (without duplicates) were identified addressing the state of the art (see section 9).

In the reviewed clinical literature, a total of roughly 2.190 patients/treatments with KIRSCHNER WIRES AND GUIDE WIRES (with different diameters and lengths) and a total of roughly 1.171 patients/treatments with state of the art products to be evaluated. The authors did not report any performance or safety issues related to the use of the KIRSCHNER WIRES AND GUIDE WIRES. It can thus, be stated that all KIRSCHNER WIRES AND GUIDE WIRES demonstrated the safety and performance as intended.

The clinical benefits and residual risks of the KIRSCHNER WIRES AND GUIDE WIRES have been discussed in detail. Clinically relevant parameters were established to be able to demonstrate the general safety and performance of the KIRSCHNER WIRES AND GUIDE WIRES as well as the claimed benefit, and to prove the device-specific claims.13 direct und surrogate parameters to evaluate the success of the use and/or application of the KIRSCHNER WIRES AND GUIDE WIRES have been defined, assessed and confirmed throughout the literature search and subsequent evaluation of benefit-risk ratio. Due to the different number of patients per publication, all parameters were assessed using the weighted mean value:

1. Delayed union / non-union
2. Hardware removal time
3. Rate of union (time to union)
4. DASH score
5. AOFAS ankle-hindfoot score
6. Malunion
7. Infection
8. Range of Motion (ROM)
9. Hardware intolerance
10. VAS score
11. PRWE score
12. Duration of surgery
13. Failure to product

All clinical parameters have been evaluated as acceptable. The benefit-risk ratio of KIRSCHNER WIRES AND GUIDE WIRES was considered positive. The benefits of using KIRSCHNER WIRES AND GUIDE WIRES out-weigh the potential risks, as evidenced. Identified issues related to performance and safety are already known and addressed in risk assessment. Clinical claims are confirmed. To assess the performance and safety of the evaluated medical device, the number and quality of publications assessed as relevant was considered sufficient.

Monitoring of Product Databases / Complaint Trending and Analysis

Post-market surveillance was performed continuously, with reviews occurring at regular, defined intervals to track and identify trends in device complaints. Other post-market surveillance activities included on-going monitoring and investigation of field events such as physician or patient concerns or comments, complaints, customer reported adverse clinical events, adverse events identified through regular, periodic literature reviews, and the routine trending of events reported in all commercially released products.

The recent vigilance search was conducted for the years 2020 – 2023 in the following medical device databases

- “Manufacturer and User Facility Device Experience (MAUDE) Database” maintained by the United States’ Food and Drug Administration,
- the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) database of Field Corrective Actions,
- database maintained by swissmedic for Switzerland,
- database for alerts, recalls and safety information maintained by Medicines and Healthcare products Regulatory Agency, UK as well as
- database of Adverse Event Notifications (DAEN) – medical devices maintained by Therapeutic Goods Administration (TGA), Australia

were searched for clinical data on the KIRSCHNER WIRES AND GUIDE WIRES during the preparation of the clinical evaluation report. The search resulted in 71 hits for the evaluating product / similar products. The results of this reviews were consistent with the findings of previous evaluations with regard to cases of error and the resulting complications or risks for the patient. The assessment therefore does not provide any new or significantly changed findings with regard to product or procedure-specific risks and complications. The searches in the database did not yield any records regarding serious incidents caused by KIRSCHNER WIRES AND GUIDE WIRES and the similar devices.

Furthermore, there have been no reportable complaints and no reportable events for HIPP medical KIRSCHNER WIRES AND GUIDE WIRES for the reporting period and since 2012. The frequencies of complaints, reportable complaints, and their associated reported complications (complaint type) did not present any new risks or unanticipated frequency of risks associated with use of the HIPP medical KIRSCHNER WIRES AND GUIDE WIRES. The on-market experience reinforced, that potential risks have been reduced as far as possible, that the potential benefits of the device outweigh the overall and individual potential risks, and that the potential risks remain acceptable.

Pre- and non-clinical Data
In terms of biological safety, the following assumptions, preclinical evaluations, and test reports were considered:

- The used material for the medical device covered by the clinical evaluation is stainless steel 1.4441 in accordance with EN ISO 5832-1.
- The material is intended to be used as implant materials according to the standards listed above by following justification given in both standards:
  “No known surgical implant has ever been shown to cause absolutely no adverse reactions in the human body. However, long-term clinical experience of the use of material referred to in this part of ISO 5832 has shown that an acceptable level of biological response can be expected, when the material is used in appropriate applications.”

Given the inherent acceptable biocompatibility profile of stainless steel 1.4441 when implanted in contact with bone and tissue, the principle risk of eliciting an adverse biological response stem from the presence of surface impurities, which could leach out into the surrounding tissue after implantation of the device.
These impurities may arise from a variety of sources, either:

- residual contaminants from the manufacturing process
- Contaminants from the implant packaging materials that are in direct contact with the implant.

All risks were mitigated by tests and clinical experience and were assessed as safety-related state-of-the-art. The biocompatibility risks presented by contaminants in the packaging materials that are in direct contact with the devices were addressed through the operation of quality assurance specifications. HIPP medical AG uses only packaging materials that are specifically intended by their suppliers for use in the packaging of medical devices or food applications. Therefore the evaluation considered biological hazard identification with regard to material, processing, packaging and the characterization of non-chemically mediated hazards.
The tests carried out and the justifications given do not indicate any negative effects and show no release of potentially hazardous compounds. Safe clinical use is not at risk. Long-term toxicological effects were assessed as unlikely.

Post-market Clinical Follow-up (PMCF) / Clinical Investigation Data
Although per definition of MEDDEV 2.12/2 a PMCF study is indicated, no PMCF study has been performed in the past nor is planned. The decision for not performing a comprehensive PMCF study in accordance with MDCG Guidance 2020-7 and 2020-8 was justified as for the product safety and efficacy is demonstrated by historic data. The product group

	is in the market since 2012 with good clinical results proven by the fact that there were no complaint reports related to clinical problems on file.
An overall summary of the clinical performance and safety	A comprehensive, systematic, and critical evaluation of the pertinent clinical data in relation to the HIPP medical KIRSCHNER WIRES AND GUIDE WIRES has been carried out and documented in the clinical evaluation report. Based on the results of that evaluation, it was considered that: a) Conformity with relevant general safety and performance requirements set out in Regulation (EU) 2017/745 of the European Parliament and of the Council, Annex I under the normal conditions of the intended use of the device has been confirmed. b) Undesirable side-effects and acceptability of the benefit-risk ratio have been evaluated and are acceptable according to the current knowledge/the state of the art in the medical fields concerned and according to available medical alternatives. c) The information materials supplied by HIPP medical AG, and the risk reduction measures are adequate taking into account the intended purpose of the device. d) Usability aspects have been adequately considered and the HIPP medical KIRSCHNER WIRES AND GUIDE WIRES, including the IFUs, are suitable for the intended users. e) The claims foreseen in the information materials provided with the clinical evaluation report is adequate taking into account the intended purpose of the device. f) The information materials supplied and the risk management documentation for the device under evaluation are consistent with the clinical data presented in the clinical evaluation report and with the current knowledge/state-of-the-art. On the basis of existing findings and the results of current literature research clinically relevant parameters were established to be able to demonstrate the general safety and performance as well as the claimed benefit of HIPP medical KIRSCHNER WIRES AND GUIDE WIRES, and to prove the device-specific claims. The benefit-risk ratio of HIPP medical KIRSCHNER WIRES AND GUIDE WIRES is considered positive. The benefits of using HIPP medical KIRSCHNER WIRES AND GUIDE WIRES outweigh the potential risks, as evidenced. HIPP medical has elected to demonstrate conformity of this device with Regulation (EU) 2017/745 of the European Parliament and of the Council, 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 , 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 AG concludes that 1. The devices perform as intended when used in accordance with the instructions from use and operated by professionals, 2. The devices do 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.

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 KIRSCHNER WIRES AND GUIDE WIRES for

- temporary reposition and guide wires for surgery and
- closed Reposition and fixation of fractures, osteotomies, and fusions of the upper and lower extremities

on the market.

According to the clinical data presented in the scientific literature, the information gained from post-market surveillance and post-market clinical follow-up measures as well as the risk analysis, it can be concluded that risks which may be associated with the intended use of the HIPP medical KIRSCHNER WIRES AND GUIDE WIRES constitute acceptable risks when weighed against the benefits to the patient. Further, it can be concluded that for patients carefully selected for this treatment, undesirable side-effects constitute an acceptable risk when weighed against the performance intended by the professional user in charge. The main risks are described and documented in detail in the scientific literature, thus being known to trained professional user. There is sufficient data to establish the continued safety and efficacy profile of the subject device(s) when used as intended. Risk reduction measures, as well as monitoring by HIPP medical of post-market data, will continue in an effort to mitigate some of the harms or complications presented in this report, and to improve the overall safety of the subject device. Therefore, by complying with all warnings and precautions, the HIPP medical KIRSCHNER WIRES AND GUIDE WIRES offer an acceptable benefit-risk profile and meets the requirement for an acceptability of side effects and acceptable benefit-risk profile.

Post-market surveillance will continue to be performed and reported in Periodic Safety Update Reports to evaluate any new risks (including hazards or hazardous situations) and changes to benefit-risk determination that require action.

Overall, it is concluded that the risks associated with the use of the HIPP medical KIRSCHNER WIRES AND GUIDE WIRES are acceptable when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art; that the intended clinical performances are achieved by the device; and that known and foreseeable risks and undesirable side effects are considered acceptable when weighed against the benefits from performance achieved by the device. The results of risk management, Instructions For Use and user reports with KIRSCHNER WIRES AND GUIDE WIRES confirm the clinical safety and performance of HIPP medical KIRSCHNER WIRES AND GUIDE WIRES.

The medical safety and performance of the HIPP medical KIRSCHNER WIRES AND GUIDE WIRES were demonstrated with the clinical evaluation. The clinical evaluation report demonstrates that KIRSCHNER WIRES AND GUIDE WIRES complies with the relevant GSPRs according to Annex I of the Regulation (EU) 2017/745 of the European Parliament and of the Council.

Ongoing or planned post-market clinical follow-up

To continuously monitor the product's safety and performance, the clinical evaluation of the HIPP medical KIRSCHNER WIRES AND GUIDE WIRES is regularly updated with newly acquired clinical data throughout the device's life cycle. The decision for not performing a comprehensive 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.

The post-market surveillance system of HIPP medical AG is based on a systematic planning and reporting system for products or product families of different risk classes. Post-

market surveillance is an ongoing, continuous process in which HIPP medical AG collects, analyses and evaluates clinical data resulting from the use of a device and placed on the market in accordance with its intended purpose. The analysis of the collected data takes place in the clinical evaluation. If new risks, complications, or unexpected product failures are identified, the risk-benefit balance is updated. If no new events are identified, the update frequency is carried out according to the specifications from the required reports (e.g., PMS / PSUR / Trends / SSCP / etc.) and the risk class of the medical devices.

There are currently no unanswered questions relating to the use of the device that need to be investigated. If there are any emerging risks, complications, or unexpected device failures these will feed into the risk analysis and be investigated.

HIPP medical AG will conduct the following activities in post-market, including general and specific methods/procedures, for the HIPP medical KIRSCHNER WIRES AND GUIDE WIRES:

Clinical Literature Review
Proactive continuous monitoring of scientific literature concerning HIPP medical KIRSCHNER WIRES AND GUIDE WIRES and equivalent or similar products in order to identify scientific literature with regard to the specific product and the state-of-the-art of application of the device. Additionally, the monitoring of scientific literature allows the identification and evaluation of safety and performance issues (e.g., possible off-label-use).

Complaint Trending and Analysis
To confirm the safety of the HIPP medical KIRSCHNER WIRES AND GUIDE WIRES and to identify previously unknown side-effects (related to the procedures or to the medical devices) as well as to monitor the identified side-effects and contraindications all complaints related to marketed product are captured in our quality management system from clinician users and/or distributors of the subject devices.
Limitations: Without knowing the sales volumes of the similar devices, it may be difficult to compare the adverse event occurrence rates, but the overall numbers of events and the types of events can be compared.

Monitoring of Product Databases
Proactive continuous monitoring of medical product databases concerning the HIPP medical KIRSCHNER WIRES AND GUIDE WIRES and equivalent or similar products e.g. “Manufacturer and User Facility Device Experience (MAUDE) Database” maintained by the United States’ Food and Drug Administration as well as the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) database of Field Corrective Actions. This measure will provide data on safety aspects which also may be relevant for the application of HIPP medical KIRSCHNER WIRES AND GUIDE WIRES.

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.

Purpose / Indication	Alternative procedure
Radius fractures Distal, lateral, medial, radial neck	Plate osteosynthesis
	External fixator
	Conservative treatment (closed reduction and immobilization – plaster cast)
	Elastic nails
Humerus fractures Lateral, supracondylar	Different techniques (free-lying versus recessed K-wire technique)
Metacarpal / phalanx fractures	23-gauge hypodermic needle
	Mini plate osteosynthesis
Clavicle fractures medial	Klavikula / Clavicle pins
	Screw-plate osteosynthesis
	Locking plates
	Bone screws
	Suture material
	Conventional (non-surgical) therapy
Scaphoid fractures	Herbert Screw

Typical treatments in accordance with AO Surgery Reference:

- Tension-band Wiring, a surgical procedure using Kirschner wires and a tension band to internally fixate and com-press fractures.
  Indications: Greater tuberosity fractures, Olecranon fractures, Greater trochanter fractures, Patella fractures, Lateral malleolus fractures

- Open Reduction and Internal Fixation (ORIF), a surgical procedure to repair a fracture and/or dislocation through operative (open) repositioning (re-duction), followed by fixation with rods, nails, plates, and/or screws.
  Indications: Failed closed reduction, Multiple trauma, Open fractures, Fractures with vascular injuries, Non-union

- Lag Screw Fixation, 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).

- Plate Fixation, 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).

- Intramedullary Nail Fixation, a surgical procedure in which a metal rod is inserted into the medullary cavity of a bone to internally fix a fracture.
  Indications: Diaphyseal fractures of the long bones (e.g., tibial shaft, distal femur, humerus shaft), Metaphyseal fractures

7. Suggested profile and training for users

HIPP medical KIRSCHNER WIRES AND GUIDE WIRES are designed only for qualified doctors / physicians / traumatologists in the field of trauma surgery and healthcare professionals (surgical assistants) with sufficient knowledge of the identification, selection, provision, and aseptic handling of instruments during surgical procedures.

The user / attending physician must be familiar with the surgical technique to be used. No additional training is required. Specifically, experience is required in fixation of fractures, fusions for osteoarthritis or correction procedures for anatomical malpositions, osteotomies for malpositions, and reconstructions of the extremities.

Intended user groups are

Surgeons	The specialist responsible for performing the surgery.
Supporting personnel in the operating room	Refers to those who assist the physician and are expected to perform some of the tasks during the procedure, especially setup and preference setting. This profile includes the resident, operating room nurses, and clinical support professionals.

8. Reference to any harmonized standards and CS applied

- EN 62366-1:2015+COR1:2016+A1:2020
- EN ISO 11137-1:2015 + A2:2019
- EN ISO 11137-2:2015 + A1:2023
- EN ISO 11607-1:2020 + A1:2023
- EN ISO 11607-2:2020 + A1:2023
- EN ISO 13485:2016 + AC:2018 + A11:2021
- EN ISO 14644-1:2015
- EN ISO 14971:2019 + A11:2021 + A11:2021
- EN ISO 15223-1:2021
- EN ISO 17664-1:2021
- EN ISO 17665-1:2006
- EN ISO 20417:2021
- EN ISO 5832-1:2024
- ISO 10993-1:2018
- ISO 19227:2018
- ISO/TR 20416:2020

9. Literature

1. Senesi, L., Marchesini, A., Pangrazi, P. P., De Francesco, M., Gigante, A., Riccio, M., & De Francesco, F. (2020). K-wire fixation vs 23-gauge percutaneous hand-crossed hypodermic needle for the treatment of distal phalangeal fractures. BMC Musculoskeleta
2. Hegazy, G., Alshal, E., Abdelaal, M., Abdelaziz, M., Moawad, M., Saqr, Y. M., … & El-Barody, M. (2020). Kirschner wire versus Herbert screw fixation for the treatment of unstable scaphoid waist fracture nonunion using corticocancellous iliac bone graft:
3. Ahmed, Z., Haider, M. I., Buzdar, M. I., Chugtai, B. B., Rashid, M., Hussain, N., & Ali, F. (2020). Comparison of Miniplate and K-wire in the Treatment of Metacarpal and Phalangeal Fractures. Cureus, 12(2).
4. Ormsby, N. M., Walton, R. D., Robinson, S., Brookes-Fazakerly, S., Chang, F. Y., McGonagle, L., & Wright, D. (2016). Buried versus unburied Kirschner wires in the management of paediatric lateral condyle elbow fractures: a comparative study from a tertiar
5. Ganeshalingam, R., Donnan, A., Evans, O., Hoq, M., Camp, M., & Donnan, L. (2018). Lateral condylar fractures of the humerus in children: does the type of fixation matter?. The bone & joint journal, 100(3), 387-395.
6. Thapa, P., Sapkota, K., Wahegaonkar, K., Ranjeet, N., Onta, P. R., & Thapa, U. J. (2019). Comparison of Kirschner wires and Cannulated screw internal fixation for displaced lateral humeral condyle fracture in children. Asian Journal of Medical Sciences, 1
7. Afaque, S. F., & Singh, A. (2020). Outcome of Cancellous screw vs K wire fixation for management of neglected lateral condyle fracture of humerus in children. Doi: https://doi. Org/10.33518rthrohor, v4.
8. Khaled, M., Fadle, A. A., Hassan, A. A., Khalifa, A., Nabil, A., Hafez, A., & Oyoun, N. A. A. (2022). To bury or not to bury the k-wires after fixation of a pediatric both bone forearm fracture, a randomized controlled trial.2

9. Khan, H., Adil, A., Ain, N. U., Qureshi, B. A., Chishti, U. F., & Malik, T. S. (2022). Outcome of Buried Versus Exposed Kirchner Wires in Terms of Infection in Fractures of Phalanges and Metacarpal Bones of Hand. Cureus, 14(2).
10. Ohshima, K., Tokutake, K., Takegami, Y., Asami, Y., Matsubara, Y., Natsume, T., … & Imagama, S. (2023). Longer time of implantation using the buried pin technique for intramedullary nailing would decrease refracture in the diaphyseal forearm fracture2
11. Xie, W., Li, H., Zhang, C., Cui, X., Zhang, S., Rui, Y., & Chen, H. (2023). Comparison of temporary external and percutaneous k-wire fixations for treatment of ankle fracture–dislocations. BMC Musculoskeletal Disorders, 24(1), 880.
12. Leopold, V. J., Conrad, J., Zahn, R. K., Hipfl, C., Perka, C., & Hardt, S. (2023). Fixation stability and implant-associated complications in periacetabular osteotomy: A comparison of screw and K-wire fixation. Archives of Orthopaedic and Trauma Surgery,
13. Mohamed Husin Oraby, A., Mohamed Bissar, M., & Fathy El-Halawany, M. (2023). K-WIRE FIXATION VERSUS, VOLAR PLATE FOR EXTRA-ARTICULAR DISTAL RADIUS FRACTURE IN ELDERLY. Al-Azhar Medical Journal, 52(1), 87-102.
14. Kim, D. E., Lee, T. J., Na, Y., & Noh, Y. G. (2023). Comparative Evaluation of the Efficacy of Combined Intramedullary Pinning with K-Wires Pinning in the Treatment of Fifth Metacarpal Neck Fractures versus Conventional Techniques—K-Wires Pinning and Intr
15. Cummings, J. L., Schwabe, M. T., Rivera, A. E., Sanders, J., Denning, J. R., Neal, K., ... & Hosseinzadeh, P. (2023). K-wire versus screw fixation in displaced lateral condyle fractures of the humerus in children: a multicenter study of 762 fractures. Jou
16. Khalilizad, M., Ghezelsofla, F., Mouodi, S., Jokar, R., Ganji, S. M. E., Bahrami, M., ... & Khafri, S. (2024). Wrist Radiographic Indices and Patients' Performance Following Three Surgical Methods for Management of Distal Radius Fractures: A Randomized Si
17. Caravelli, S., Gardini, G., Pungetti, C., Gentile, P., Perisano, C., Greco, T., ... & Mosca, M. (2022). Intra-Articular Calcaneal Fractures: Comparison between Mini-Invasive Approach and Kirschner Wires vs. Extensive Approach and Dedicated Plate—A Retrosp
18. Singh, V., Ahmad, S., Singh, G., Singh, S., Gupta, K., & Kalia, R. B. (2023). Jo'hi's External Stabilization System and K-wire Fixation in the Management of Hand Fractures–A Prospective Comparative Study. Journal of Orthopaedic Diseases and Traumatology,
19. Pandey, R., Soni, N., Bhayana, H., Malhotra, R., Pankaj, A., & Arora, S. S. (2019). Hand function outcome in closed small bone fractures treated by open reduction and internal fixation by mini plate or closed crossed pinning: a randomized controlled trail
20. Costa, M. L., Achten, J., Rangan, A., Lamb, S. E., & Parsons, N. R. (2019). Percutaneous fixation with Kirschner wires versus volar locking-plate fixation in adults with dorsally displaced fracture of distal radius: five-year follow-up of a randomized con
21. van Bussel, E. M., Houwert, R. M., Kootstra, T. J., van Heijl, M., Van der Velde, D., Wittich, P., & Keizer, J. (2020). Second Place Award: Long-term patient-reported outcomes after intramedullary Kirschner-wire fixation for displaced subcapital fractures
22. Costa, M. L., Achten, J., Ooms, A., Png, M. E., Cook, J. A., Lamb, S. E., ... & Dias, J. (2022). Surgical fixation with K-wires versus casting in adults with fracture of distal radius: DRAFFT2 multicentre randomised clinical trial. bmj, 376.

10. Revision History

Rev. No.	Date issued	Change description	Revision validated by the Notified Body
01	01.10.2025	Initial version	☒ Yes Validation language: English ☐ No