1 Device identification and general information

1.1 Device trade name(s)

Kirschner wires; Steinmann pins; bone wires

1.2 Manufacturer's name and address

RUDOLF Medical GmbH+ Co. KG phone: +49 (0)7463 9956-0
Zollerstrasse 1
78567 Fridingen an der Donau E-mail: sales@rudolf-med.com
Germany Internet: www.rudolf-med.com

1.3 Manufacturer's single registration number (SRN)

SRN DE-MF-000005515

1.4 Basis UDI-DI

4049356TD-010GR

1.5 European Medical Device Nomenclature (EMDN) description / text

- EMDN Code: P091203 – Implantable Prosthetic Devices and Osteosynthesis Devices
- Sub EMDNs: P09120301 Kirschner bone wires (includes Steinmann pins); P09120302 cerclage devices, wires and binders

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1.6 Risk class of device

1.6.1 Risk classification

Definition	Description	Applicable	
		yes	no
Duration of Use			
Transient	'Transient' means normally intended for continuous use for less than 60 minutes.	☐	☒
Short Term	'Short term' means normally intended for continuous use for between 60 minutes and 30 days.	☐	☒
Long Term	'Long term' means normally intended for continuous use for more than 30 days.	☒	☐
Nature of Body Contact			
Surgically Invasive Device	A device, which penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation; and (b) a device which produces penetration other than through a body orifice.	☒	☐
Body Orifice	Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.	☐	☒
Implantable Device	Any device (partially /wholly absorbed) which is intended: • to be totally introduced into the human body or, • to replace an epithelial surface or the surface of the eye, by clinical intervention which is intended to remain in place after the procedure. Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.	☒	☐
Injured Skin or Mucous Membrane	An area of skin or a mucous membrane presenting a pathological change or change following disease, a wound or a scar.	☒	☐
Reusable Surgical Instrument			
Reusable Surgical Instrument	Instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilization have been carried out.	☐	☒
Active Medical Device			
Active Medical Device	Any medical device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices. Software is also considered to be an active medical device.	☐	☒

Definition	Description	Applicable	
		yes	no
Active Therapeutic Device			
Active Therapeutic Device	Any active device, whether used alone or in combination with other devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.	☐	☒
Active Device Intended for Diagnosis and Monitoring			
Active Device Intended for Diagnosis and Monitoring	Any active device, whether used alone or in combination with other devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.	☐	☒
Central Circulatory System			
Central Circulatory System	'Central circulatory system' means the following blood vessels (see MDR): arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior.	☐	☒
Central Nervous System			
Central Nervous System	'Central nervous system' means the brain, meninges and spinal cord.	☐	☒
Device Combination			
Device Combination	If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories for a medical device and for a product listed in Annex XVI shall be classified in their own right separately from the device with which they are used.	☐	☒
Software			
Software	Software, which drives a device or influences the use of a device, falls within the same class as the device.	☐	☒
Several applicable rules			
Several Rules	If several rules, or if, within the same rule, several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and sub-rule resulting in the higher classification applies.	☐	☒

1.6.2 Classification rules according to Annex VIII, Chapter III of the Regulation (EU) 2017/745

<table>
<tr><th>Rule</th><th>Applicable definition</th><th>Class</th></tr>
<tr><td>8</td><td>Applicable definition: All implantable devices and long-term surgically invasive devices are classified as class IIb, unless they are:
<table>
<tr><th></th><th colspan="2">Applicable</th></tr>
<tr><th></th><th>Yes</th><th>No</th></tr>
<tr><td>— are intended to be placed in the teeth, in which case they are classified as class IIa,</td><td></td><td>X</td></tr>
<tr><td>— are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified as class III,</td><td></td><td>X</td></tr>
<tr><td>— have a biological effect or are wholly or mainly absorbed, in which case they are classified as class III,</td><td></td><td>X</td></tr>
<tr><td>— are intended to undergo chemical change in the body in which case they are classified as class III, except if the devices are placed in the teeth</td><td></td><td>X</td></tr>
<tr><td>— are intended to administer medicinal products, in which case they are classified as class III,</td><td></td><td>X</td></tr>
<tr><td>— are active implantable devices or their accessories, in which cases they are classified as class III,</td><td></td><td>X</td></tr>
<tr><td>— are breast implants or surgical meshes, in which cases they are classified as class III,</td><td></td><td>X</td></tr>
<tr><td>— are total or partial joint replacements, in which case they are classified as class III, with the exception of ancillary components such as screws, wedges, plates and instruments; or</td><td></td><td>X</td></tr>
<tr><td>— are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class III with the exception of components such as screws, wedges, plates and instruments.</td><td></td><td>X</td></tr>
</table></td><td>IIb</td></tr>
</table>

1.7 Year when the device was first CE-marked under Regulation (EU) 2017/745 covering the device

The bone implants are not yet CE-marked under Regulation EU 2017/745. They have been CE-marked under MDD since October 2007.

1.8 Authorized representative

Not applicable

1.9 Notified Body

DQS Medizinprodukte GmbH, August-Schanz-Strasse 21, 60433 Frankfurt am Main, Germany; ID: 0297

2 Intended purpose and other indications

The information provided in this Safety and Clinical Performance Summary (SSCP) is tailored to the user. Patient-specific information is provided by the user during the pre-procedure consultation.

2.1 Intended Purpose

Bone implants are used in osteosynthesis and for the correction of degenerative changes in the skeleton.

2.2 Surgical techniques

Kirschner Wires and Steinmann Pins

Kirschner wires and Steinmann pins are used for open reduction and fixation of a fracture.

Procedures of surgical fracture treatment:

- Percutaneous intramedullary nailing, e.g., of the metacarpal bones
- Percutaneous “pinning” to stabilize a fracture by inserting a Kirschner wire, and, if possible, securing the wire in the opposite cortical bone, including the use of an external fixator

Bone wire

- Bone wires are used to treat fractures by wrapping the wire around the bone. The soft wire is usually wrapped around the bone several times and tightened by twisting it.

2.3 Indications and target populations

Indications

- Bone fracture treatment
- Repositioning and fixation of metaphyseal fractures
- Diaphyseal fractures and dislocations of the hand and foot bones
- Temporary arthrodesis of small joints
- Temporary intraoperative fixation of fracture fragments
- Fractures of the musculoskeletal system
- Closed / open fracture

2.4 Patient population

There are no restrictions concerning the patient population. It may be left to the discretion and experience of the medical professional to decide whether the benefit outweighs the risk in the given population.

The choice of treatment is influenced by factors such as fracture type, comorbidities, biological age, and the overall physical and mental condition of the patient.

2.5 Contra-indications and/or limitations

Contra-indications

The medical devices are not intended for the use on the central nervous and circulatory system.

Medical conditions that preclude adequate implant support or hinder the healing process include, among others:

- Fractures of spine
- Impairment of blood supply
- Insufficient bone quality or quantity (osteoporosis)
- Extreme adiposity
- Acute and chronic, local or systemic infections
- Deep and superficial infections
- Twisting or strong inclination of the fracture
- Muscle, nerve or vascular diseases that endanger the affected extremity
- Local bone tumors
- Systemic diseases and metabolic dysfunctions
- Severe deformities
- Serious falls
- Mental conditions that make participation in the rehabilitation program impossible (Parkinson's disease, alcoholism, drug use, etc.)
- Great physical activities and those involving strong vibrations, where the implants are subjected to blows and/or excessive loads (e.g., heavy physical work)
- Allergies or other reactions to the material used (see the “Risks / intolerances” section)
- Fusion of the proximal interphalangeal joint

2.6 Application requirements

Physiological or anatomical differences that can affect the intended function of the implant must be taken into account, e.g.:

- The patient's physique (height, body weight)
- The patient's age
- Pathological conditions
- Bone quality
- Vitality and condition of the surrounding tissue
- Load conditions
- Implantation method
- Patient's activity level

Certain circumstances can limit the use of the implant or require special caution during clinical use. The function of the implant can also be affected by patient-specific circumstances.

3 Product description

-  The RUDOLF Medical bone implants are placed on the market as single-use products and are intended for single use only.
- These single-use products must not be reused, as they no longer function as intended after their first use.
- The bone implants are delivered non-sterile and must be cleaned, disinfected, and sterilized before use. Protective caps and transport packaging must be removed beforehand; those are not suitable for sterilization.
- The bone implants are manufactured from stainless steel according to DIN EN ISO 5832-1: implant steel 1.4441. They are suitable for MRI. However, artefacts are created.
- If a patient has a confirmed allergy to nickel, cobalt, or chromium, implants made of implant-grade steel (material number 1.4441 according to DIN EN ISO 5832-1) must not be used.
- **Kirschner Wires and Steinmann Pins:**
  Kirschner wires and Steinmann pins are semi-rigid wires of various diameters and lengths with different end configurations.
- **Bone wire:**
  Bone wires are malleable wires and are supplied on 10-meter coils.
-  If the implants are used outside their intended purpose this can result in complications or harm to the patient; in some cases, the surgery must be redone. Orthopedic implants can only be used in procedures where the intended purpose of the implant is explicitly required and defined.
- The bone implants do not contain the following:
  - Tissue of human or animal origin
  - Medicinal components
  - Software

3.1 Product Description

3.1.1 Kirschner Wires and Steinmann Pins

- Kirschner wires and Steinmann pins are semi-rigid wires of various diameters and lengths with different end configurations.
- The Kirschner wires have a smaller diameter than the Steinmann pins.
- The length is cut to size as needed by the user.
- All available variants are listed in the product list and in the catalog.

Designs:

Kirschner – Trocar point with a flat end

Kirschner – Trocar point with a round end

Kirschner – Trocar point with a trocar end

Kirschner – Trocar point with a thread

Steinmann – Trocar point with a triangular end

3.1.2 Bone Wires

- Bone wires are malleable wires and are supplied on 10-meter coils. Their diameter lies between 0.2-1.5mm.

Bone wire on 10-meter coils

3.1.3 Processing

Important:
- Cable ties used to hold the bone wires (rolls) together must be removed before sterilization.
- Do not use any of the following sterilization methods: hot-air sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization, or plasma sterilization.

Automated cleaning and disinfection

- Clean and disinfect the medical devices only in suitable washer-disinfectors (WD) and with a procedure / program validated for the WD and medical devices (EN ISO 15883 for the WD and DIN EN ISO 17664-1 for the procedure).
- The operating and loading instructions of the WD manufacturers must be observed.
- When choosing the detergent, consider the material and properties of the device and the cleaning agents recommended by the WD manufacturer for the respective application.

Detergent and WD for the automated cleaning and disinfection

Detergent for the automated cleaning	neodisher MediClean forte by Dr. Weigert Concentration: 0.5%
Disinfection process	Thermal disinfection (no chemothermal disinfection)
WD	Miele PG 8535

Automated cleaning program with thermal disinfection in a WD with an alkaline detergent

Step	Cleaning agents	Time (min)	Temp. (°C)
Pre-rinsing	Tap water	1	Cold
Pre-rinsing	Tap water	1	Cold
Cleaning	Tap water, 0.5% alkaline detergent	5	55
Post-rinsing	Demineralized water	2	Cold
Disinfection	Demineralized water	> 5	> 90

Sterilization

- The sterilizers are validated according to DIN EN 13060 and DIN EN 285, respectively; the sterilization process is validated according to DIN EN ISO 17665.
- Please observe the manufacturer's instructions of the sterilizer.

The following parameters of the steam sterilization (fractionated vacuum method) have been validated:

Sterilization validated according to DIN EN ISO 17665:

Sterilization temperature	Minimum holding time (exposure time)	Drying time
134°C, minimum 132°C; maximum 137°C	4 minutes	Minimum 10 minutes

or

Sterilization according to ANSI AAMI ST79:

Sterilization temperature	Minimum holding time (exposure time)	Drying time
132°C – 135°C	4 minutes	20 minutes

Information regarding the validation of the reprocessing procedure

The following materials and machines have been used during the validation procedure:

Manual pre-cleaning in the ultrasonic bath	• Detergent: neodisher MediClean forte by Dr. Weigert, alkaline, concentration 0.5% • Ultrasonic bath device: Elmasonic S 300H by Elma Schmidbauer GmbH • Temperature: < 40°C • Duration: 10 minutes
Automated cleaning and disinfection	• Detergent: neodisher MediClean forte by Dr. Weigert, alkaline, concentration 0.5% • Thermal disinfection (no chemothermal disinfection) • Washer-disinfector: Miele PG 8535
Sterilization	• Steam sterilization, fractionated vacuum method • Sterilizer: HX-320 2D by Systec GmbH & Co. KG

3.2 Previous generations and variants

The bone implants have been manufactured and marketed with the CE mark without change since 2007. They are considered state-of-the-art devices and are clinically established. All available variants are listed in the product list and in the catalog.

3.3 Accessories which are intended to be used in combination with the device

Not applicable

Note:

- Depending on the surgical technique, various application instruments are used to insert the implants, such as a drill with an appropriate chuck, wire cutting pliers, bone-holding forceps, or external fixators (e.g., the Böhler traction bow). The user must verify the selection and combination of these application instruments prior to clinical use.

3.4 Other devices and products which are intended to be used in combination with the device

Not applicable

Notes:

- Depending on the surgical technique, various application instruments are used to insert the implants, such as a drill with an appropriate chuck, wire cutting pliers, bone-holding forceps, or external fixators (e.g., the Böhler traction bow). The user must verify the selection and combination of these application instruments prior to clinical use.
- Depending on the type of fracture treatment, these bone implants are used in combination with other medical devices—such as external fixators, plates, or screws—as part of a comprehensive fracture treatment plan. The treating physician selects the appropriate combination based on the type of fracture, the required stability, and the individual patient factors.

4 Reference to any harmonized standards and CS applied

Please see the list of applicable standards and guidances in the “Regulatory Requirements” section below.

5 Residual risks, warnings and precautions

As part of the risk management process, all foreseeable and known risks were assessed, and risk control measures were implemented to reduce the risk as far as possible. Any residual risks were accepted and communicated to the user via the instructions for use to ensure the safety of both the patients, users, and third party. The literature review did not identify any new risks that had not already been considered in the risk management process. The benefits of the product clearly outweigh any potential residual risks.

5.1 Residual risks and undesirable effects

Risks / intolerances:

- After the implantation of metal implants, an inflammatory reaction of varying severity can occur. Other symptoms could be: localized or generalized eczema, impaired wound healing, and pain.
- If a patient has a confirmed allergy to nickel, cobalt, or chromium, implants made of implant-grade steel (material number 1.4441 according to DIN EN ISO 5832-1) must not be used.
- Inadequate cleaning and sterilization can lead to infections in the patient.
- Improper reprocessing procedures can lead to surface discoloration or corrosion of the implant.
- Improper application during implantation or excessive stress on the implant during and after the implantation can lead to fractures or deformation of the implant. This can cause harm to the patient.
- The physician must carefully weigh any potential risks posed by external electrical and electromagnetic influences (radiation, magnetic fields) in connection with diagnostic and therapeutic procedures (e.g., X-rays, MRI) prior to the examination.

Complications:

The following complications have been observed in various cases and therefore require special attention from the treating physician:

- Bending, breaking, loosening or detachment of the implant
- If the fracture does not heal properly, secondary dislocation of the fracture can occur.
- Superficial and deep infections
- The procedure and the use of bone implants can result in vascular injuries caused by implantation or migration, such as thrombophlebitis, pulmonary embolism, hematomas, and non-vascular necrosis of the femoral neck.
- Allergies, tissue and foreign body reactions can occur near the bone implants.
- Delayed or incomplete fracture healing
- Bone deformity and refracture
- Displacement of the bone implant
- Cardiovascular dysfunction
- Nerve injuries caused by implantation or migration
- CRPS (complex regional pain syndrome) resulting from trauma
- Dysesthesia
- Pseudoarthrosis

- Pin-site infection: infections at the implant entry sites
- Reoperation/symptomatic implant removal: the need for reoperation or premature implant removal
- Postoperative arthritis: particularly in fractures near joints

5.2 Reporting serious incidents

All serious incidents related to the product must be reported to the manufacturer and to the competent authority of the country in which the user and/or patient is located.

5.3 Warnings and precautions

- If the implants are used outside their intended purpose this can result in complications or harm to the patient; in some cases, the surgery must be redone. Orthopedic implants can only be used in procedures where the intended purpose of the implant is explicitly required and defined.

Important notes for surgeons and operating room staff

- The bone implants must be used exclusively for their intended purpose in the corresponding medical specialties by sufficiently qualified personnel.
- The implants are intended for single use only. If the implant becomes deformed or damaged during implantation, it must not be implanted. In this case, a new implant must be used.
- Be careful when handling sharp tips and cutting edges as there is a risk of injury.
- The drill wires must not be cleaned while they are in a sterilization container (sterilization tube). However, for the sterilization process they are placed in the sterilization tubes.
- For patients with incurable infections such as CJD (Creutzfeldt-Jakob disease), hepatitis, HIV, possible variants of these infections, or suspected infections, the applicable national regulations regarding the disposal and reprocessing of the medical devices must be applied.
- RUDOLF Medical assumes no liability for damages or consequential damages resulting from improper use, handling, or improper reprocessing and sterilization.

Patient

- To ensure full traceability, the REF number (item or order number) and the LOT number (batch number) of the orthopedic implant used must be documented in the surgical report.
- **Implant selection:**
  - The user is responsible for selecting the bone implant suitable for the specific application or surgical procedure, for receiving adequate training and information, and for having sufficient experience in handling the bone implants.
  - For implants with a deliberately roughened surface (e.g., threads or knurling), the increased diameter must be taken into account.
  - Before use, the diameter of the implant must be checked using a suitable measuring device or template. Selecting an implant that is too thin for the indication poses a risk of fracture.
  - It is the user's responsibility to assess the extent of the injuries or changes requiring surgical treatment and to select the appropriate implants.
  - The appropriate implant type and size must be tailored to the patient. The patient's weight and activity level must be taken into account, as well as the fracture to be treated.
  - Using the largest possible bone implant and ensuring proper positioning prevents bending, breaking, cracking, and loosening of the bone implant. This also minimizes the force transmitted to the bone.
  - Selecting the wrong implant can lead to implant failure.
  - Before a surgery, it must be determined whether the patient might have an unusually sensitive reaction or a potential allergy to the implant material.
- **Postoperative risks and care:**
  - The bone implants can never bear the full load of the treated bone segment. The patient must be informed of the load limits. Appropriate postoperative behavior must be prescribed.
  - In general, the patient must be informed about indications, contra-indications, adverse side effects, and postoperative care. This must be documented.
  - After implantation, regular medical follow-up should take place.

- Early weight-bearing increases the stress on the implant and can lead to fracture, bending, or loosening of the implant. In patients who are exposed to heavy loads or who suffer from delayed healing or delayed bone union this requires special attention. Weight-bearing can then be considered if the fracture is stable with good bone-to-bone contact. Full weight-bearing before complete fracture healing is contraindicated.

Implantats

- Before each procedure, the implant must be inspected by trained medical personnel. If the implant shows signs of damage or deformation, particularly at the sharp tips, it must not be used.
- It is absolutely essential that the user, surgeon, and operating room staff are familiar with the appropriate surgical technique for the instruments and implants being used.
- Modifications of the bone implants must only be performed by trained users using the appropriate instruments. Before beginning treatment, ensure that the necessary instruments are available and suitable for the use with our bone implants. Material fatigue must be avoided.
- **Compatibility**:
  - **Application instruments and implants:**
    - Depending on the surgical technique, various application instruments are used to insert the implants, such as a drill with an appropriate chuck, wire cutting pliers, bone-holding forceps, or external fixators (e.g., the Böhler traction bow). The user must verify the selection and combination of these application instruments prior to clinical use.
  - **Combining the implants with other implants:**
    - Depending on the type of fracture treatment, these bone implants are used in combination with other medical devices—such as external fixators, plates, or screws—as part of a comprehensive fracture treatment plan. The treating physician selects the appropriate combination based on the type of fracture, the required stability, and the individual patient factors.
    - ⚠ When different implants are combined observe the following: For example, if a bone wire is additionally secured to the bone with a bone plate, the bone wire and bone plate must not be damaged in the process. In the case of the bone wire, there is a risk that the bone wire's original properties will be adversely affected.
    - For metallurgical, mechanical, and design reasons, implants made of different materials must not be combined.
- **Handling:**
  - Drill wires with partial or full threads, as well as those with drill tips, might break if used improperly. We as the manufacturer assume no liability for such damage.
  - Appropriate drilling devices with a three-jaw chuck must be used when implanting these wires.
  - The bone implants must not come into contact with objects that could damage the implant surface.
  - The bone implants must not be mechanically modified or manipulated in any way, unless the design and surgical technique expressly require this. In the latter case, the modification must be performed using the appropriate instruments.
  - Bending the bone implants must be done with care. Extreme deformation of the bone implant must be avoided at all costs.
  - Repeated bending back and forth leads to fatigue or fracture of the bone implant. Notches and pressure marks also significantly reduce mechanical strength.
  - Surgical technique: The rules of art and science, as well as scientific publications, are authoritative.

Implanting the bone implants

- The choice of surgical procedure depends on the patient's general condition, severity of the fracture, bone quality, closed or open soft tissue injuries, concomitant injuries, the patient's motivation and compliance, the expected functional load as well as surgeon's preference.
- The placement of the implant is monitored and verified radiologically in accordance with the current state of the art.
- The Kirschner wire or Steinmann pin is inserted mechanically using a surgical drill. To do this, the wire is clamped into the appropriate holder (e.g., a three-jaw chuck). Contraindications are the same as those for osteosynthesis. The insertion depth is monitored radiologically using a mobile X-ray image intensifier (C-arm) (typically involving bicortical bone fixation).
- In some surgical procedures involving Steinmann pins, a Böhler traction bow is used.
- Bone wire is wrapped around the bone.

Removal of the bone implants

- Wire removal can be performed once the goal of the surgery has been achieved, i.e., once the fracture has healed. If the wires become loose, prompt removal is necessary; otherwise, the wires can pierce the skin from the inside, break, or migrate, thereby damaging tendons, nerves, and/or blood vessels. If left in the body for too long, the wires become difficult or impossible to remove.
- Given the wide variety of possible locations where an implant can be placed in a patient, it is impossible to provide exhaustive instructions for removing a specific implant. Common instruments used to remove implants include flat-nose pliers and the wire-holding forceps.

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

Not applicable

6 Summary of performance evaluation and post-market performance follow-up (PMCF)

6.1 Summary of performance data from the equivalent device, if applicable

Within the scope of the clinical evaluation of RUDOLF Medical's bone implants, an equivalent device as defined in the requirements of Regulation (EU) 2017/745 (MDR) was not evaluated.

The clinical evaluation is based on the approach set forth in Article 61(8) of the MDR in conjunction with MDCG 2020-6 for "well-established technology" devices. The Kirschner wires (K-wires), Steinmann pins and bone wires are considered generic device groups according to article 2 (7), Regulation (EU) 2017/745. The commonality of the technology, materials, design, and application principles means that the products within this generic product group are to be considered equivalent. There are no significant technical differences that would lead to specific performance or safety issues. The clinical data available for the generic product group are therefore applicable to the products of RUDOLF Medical GmbH + Co. KG.

The clinical data used for the evaluation are derived from published studies covering the entire generic product group. The scientific literature generally does not specify either the manufacturer or the material specifications of the bone implants used. This fact underscores that these products are established standard products in orthopedics and trauma surgery, whose general safety and clinical performance do not depend on a specific manufacturer.

6.2 Summary of performance data from conducted studies of the device prior to CE-marking, if applicable

Not applicable

6.3 Summary of performance data from other sources, if applicable

A systematic literature review was planned and conducted. The search was performed in the PubMed database. The search targeted the generic product groups “Kirschner wires,” “Steinmann pins,” and “bone wires.” The literature search focused on fracture treatment and osteosynthesis. Relevant references were additionally reviewed for further relevant citations through a manual search.

No clinical data directly related to RUDOLF Medical’s products could be identified. A total of 40 publications were identified that refer to comparable products as representatives of the generic product group of bone pins and wires. These data represent the best available evidence for the evaluated products as representatives of the generic product group.

The majority of publications that mention the use of Kirschner wires, Steinmann pins, or bone wires address clinical issues that are not directly related to the products themselves. However, this is to be expected, as these are established standard products in orthopedic surgery. They have been in clinical use for several decades without significant changes in design, material properties, or principles of application. The application, performance, and safety characteristics of these products are covered in modern textbooks, are widely known, and are not the focus of current scientific research.

The commonality of the technology classifies bone pins and wires as a generic group of medical devices that are inherently equivalent. Consequently, the evaluated data can be used to verify the general safety and clinical performance of the bone implants manufactured by RUDOLF Medical GmbH + Co. KG.

6.4 An overall summary of the performance and safety

The clinical benefit of bone implants lies in their primary purpose: the fixation of bone, either by wrapping around the bone or by drilling into it. The advantages of Kirschner wire osteosynthesis include minimally invasive implantation, reduced soft tissue trauma, ease of removal, and versatility across a wide range of fracture types and anatomical locations. Furthermore, the technique provides stable fixation that supports early mobilization, thereby preventing joint stiffness and promoting functional recovery.

Clinical performance:

In the identified published literature, a total of at least 7,197 K-wires and 157 Steinmann pins were used in 3,707 and 157 patients, respectively. Throughout the reviewed publications regarding bone/cerclage wires, over 800 patients were included. Bone/cerclage wires were predominantly used in conjunction with other devices or implants, particularly intramedullary nails, to enhance fracture stability and improve surgical outcomes.

The following clinical performance parameters were derived from the literature reviewed:

The following validated clinical outcome scores were used to assess the clinical performance: Visual Analogue Scale (VAS) for pain assessment, Disabilities of the Arm, Shoulder and Hand Score (DASH) and Patient-Rated Wrist and Hand Evaluation (PRWHE) for functional outcome, and Range of Motion (ROM) for joint mobility.

Parameter	**Results**	**Literature**
Clinical performance *parameters – Kirschner wires and Steinmann pins*		
Union rate	91%–100%	Rocchi et al. 2018; van Bussel et al. 2019; Galal Hegazy et al. 2020
Time to fracture healing	4.7–14 weeks	Rocchi et al. 2018; Galal Hegazy et al. 2020; Kim et al. 2021
VAS (pain, postoperative)	1–5	Galal Hegazy et al. 2020; El-Azab et al. 2022
DASH Score	5–33	Costa et al. 2014; Rocchi et al. 2018; van Bussel et al. 2019; Mishra et al. 2021
PRWHE Score	7–19	van Bussel et al. 2019; Rocchi et al. 2018; Mishra et al. 2021
Range of motion	95%–98% of the healthy side	Moon et al. 2016; Pandey et al. 2019

Parameter	Results	Literature
Clinical performance *parameters – cerclage / bone wire*		
Anatomical reduction	95.23% (vs. 74.07% without cerclage)	Trikha et al. 2018
Union rate	78%–100%	Trikha et al. 2018; Collado et al. 2022

The efficacy of the Kirschner wires, Steinmann pins, and bone wires is well established in the scientific literature and clinical practice and is not questioned.

In the literature reviewed, cerclage/bone wires were associated with better anatomical reduction, a reduced risk of pseudarthrosis, and lower rates of implant failure compared to techniques without cerclage. The use of cerclage wires in difficult subtrochanteric fractures improves fracture reduction, increases the stability of the construct, and reduces complications (Trikha et al. 2018; Panteli et al. 2022).

The results confirm that Kirschner wire fixation achieves clinical outcomes comparable to those of alternative osteosynthesis techniques (palmar locking plates, external fixation, screw osteosynthesis). Several randomized controlled trials showed no significant differences between Kirschner wire fixation and plate osteosynthesis in terms of functional outcomes (Costa et al. 2014; Pandey et al. 2019; Mishra et al. 2021).

Safety:

The safety and effectiveness of Kirschner wires, Steinmann pins, and bone wires have been demonstrated across a broad spectrum of patient demographics, including variations in age, weight, health status, and ethnicity. The risks associated with the use of these products are primarily related to osteosynthesis in general. Most complications are not limited exclusively to Kirschner wires, Steinmann pins, and bone wires; they can also occur with other osteosynthesis implants. Complications such as infections, wire migration, or implant fracture are well documented and addressed in clinical guidelines. Complication rates are relatively low, and established measures exist to minimize risk.

The following complication rates are based on a systematic review of the published scientific literature conducted as part of the clinical evaluation. The majority of the publications evaluated had a follow-up period of ≥ 12 months.

The risks associated with the use of bone implants can be divided into procedure-related and device-related complications. Most of these complications are not limited exclusively to Kirschner wires and Steinmann pins; they can also occur with other osteosynthesis implants such as plates, screws, and external fixators.

Procedure-related complications

Each surgical intervention is associated with a number of principle risks, which mainly derive from anesthesia, thrombosis/embolism, bleeding, damage of soft tissue/bone tissue. The surgical procedure or the implant itself may impact on adjacent anatomical structures.

- Wound healing disorders/infections: 0.4%–9.8%
- Nerve and vessel injury: 3.3%: Rarely, but severe. All reported nerve injuries were transient and resolved within 12 months.
- CRPS (Complex Regional Pain Syndrome): 1.1%–6.3%
- Loss of reduction: about 4% (can occur due to inadequate stabilization or early mobilization)
- Secondary dislocation: 2.1%–5.8% (Depending on the type of fracture and the stability of the fixation)
- Postoperative arthritis: 1.3%
- Pseudoarthrosis (nonunion): 6.2%
- Bone deformity and refracture: isolated cases
- Vascular complications (thrombophlebitis, hematoma): isolated cases

Device-related complications

- Pin-site infection (wire infection): 6.8%
- Wire migration: 5.3%
- Implant failure (breakage/loosening): 6.1%
- Reoperation / premature implant removal: 5.7%–5.9%
- Allergies / foreign body reactions: isolated cases

Notes on data interpretation

- Actual complication rates can be higher than the published figures due to underreporting.
- Approximately 70% of RCTs (randomized clinical trials) on fracture treatment do not provide a standardized definition of infection, which limits comparability.
- The complication rates are derived from studies with heterogeneous patient populations. Individual risks can vary.

Experienced orthopedic surgeons and trauma surgeons are familiar with these complications and know how to prevent and treat them. Post-Market Surveillance data do not indicate any performance or safety issues with RUDOLF Medical's bone implants. The reviewed literature has not identified any new residual risks, side effects, or complications that have not already been addressed in risk management.

Benefit-risk assessment:

The clinical benefit was confirmed in the clinical evaluation using relevant clinical data from the literature. The realization of the clinical benefit depends primarily on correct use. The reviewed literature did not identify any new residual risks, side effects, or complications. The known complications are well documented, established in clinical practice, and addressed in guidelines.

A positive benefit-risk ratio was determined as part of the risk management process. All foreseeable and known risks were assessed, and risk control measures were implemented to reduce the risk as far as possible. Residual risks are acceptable and are communicated to the user in the instructions for use.

After evaluating the patient's individual condition and any relative contraindications, the benefits of bone implants clearly outweigh the remaining residual risks.

The use of RUDOLF Medical bone implants is state of the -art and has been established in medicine for decades. The benefits for the various indications are sufficiently substantiated by the use of the products and relevant data from the literature. The residual risks that remain after all risk-minimizing measures have been taken are well known and are considered acceptable in comparison to the benefits of using bone implants for the patient. The proven benefits of the products outweigh the existing residual risks. The benefit-risk profile is positive and justifiable.

6.5 Ongoing or planned post-market performance follow-up (PMCF)

Post-market surveillance is conducted on a regular basis, evaluating the following sources: complaints, databases (BfArM, FDA Maude and recalls; the corresponding module of the EUDAMED database is not yet operational), customer feedback, and publicly available information on similar medical devices.

Based on the rationale outlined above—post-market surveillance, risk management, and data from database and literature searches—no additional PMCF study is required. The planned post-market activities are considered sufficient to demonstrate the safety and performance of our products.

Residual risks, possible complications, and contraindications are listed in the products' instructions for use.

The benefits of the products outweigh the expected residual risks.

7 Possible diagnostic or therapeutic alternatives

Possible diagnostic or therapeutic alternatives should be discussed with a doctor or healthcare professional who can take the patient's individual situation into account.

If alternative treatments are being considered, this should also be discussed with a doctor who can take the patient's individual situation into account.

7.1 Conservative, Non-Surgical Treatment of Fractures

An alternative conservative treatment of fractures typically begins with closed reduction of the fracture, which is then immobilized in a plaster cast or orthosis. Immobilization allows the bone fragments to heal together permanently, thereby promoting fracture healing. Appropriate pain management is crucial for the patient's well-being. Following initial immobilization, physical therapy can be used to promote mobility and restore function (Schüttrumpf et al. 2020). Conservative treatment is often indicated for stable extra-articular fractures with little or no displacement. This is particularly true for older patients, in whom the functional difference between surgical and non-surgical treatment is often minimal (Dresing 2021; Gutiérrez-Espinoza et al. 2022). In children, conservative treatment is often preferred, particularly for proximal humerus fractures, due to the high potential for spontaneous correction. Immobilization is achieved using a Gilchrist or Desault splint for 2–3 weeks (Gressing 2021).

Conservative treatment can be associated with the following complications and risks: secondary fracture dislocation, effusion, thrombosis/embolism, retropatellar cartilage damage, post-traumatic osteoarthritis, CRPS (Schüttrumpf et al. 2020), acute carpal tunnel syndrome, rotational axis deviations, delayed healing, and pseudarthrosis (Dresing 2021).

7.2 Surgical Treatment (Alternative Osteosynthesis Techniques)

Both treatment methods (conservative and surgical) involve reduction, fixation, and rehabilitation; however, surgical treatment using osteosynthesis generally offers better reduction outcomes, often more stable postoperative fixation, and faster mobilization compared to conservative treatment (Bäcker et al. 2022).

In addition to Kirschner wire osteosynthesis, the following alternative surgical procedures are available (Dresing 2021):

- Conventional plate osteosynthesis
- Angle-stable osteosynthesis using plate and screw implants
- Screw osteosynthesis
- Intramedullary nail osteosynthesis
- External fixator
- Intrafocal osteosynthesis / Kirschner wire pinning according to Kapandji

The various methods can also be combined, e.g., internal and external techniques, or—in the case of C3 fractures—the combination of plate osteosynthesis with Kirschner wires, as well as palmar and dorsal plate osteosynthesis (Dresing 2021).

Conventional plate osteosynthesis:

Conventional plate osteosynthesis involves the use of metal plates and screws to stabilize fractures. This technique requires an open surgical approach to allow for anatomical reduction of the fracture, which is achieved through direct visualization. The plate is affixed to the bone, providing stable fixation and allowing for compression at the fracture site (Bäcker et al. 2022). Plate osteosynthesis is particularly indicated for comminuted fractures, fractures with a narrow femoral shaft, and periprosthetic fracture (Dresing 2021). The risks associated include potential reduction in periosteal circulation, stress shielding, inadequate healing response, pseudarthrosis, implant failure, bleeding, malalignment, and infection (Dresing 2021; Bäcker et al. 2022).

Intramedullary fixation:

In intramedullary (IM) fixation, an intramedullary nail is inserted into the medullary canal of a bone. This method is primarily used for fractures of long bones (femur, tibia, humerus). Compared to plate osteosynthesis, IM fixation offers greater biomechanical stability and lower rates of pseudarthrosis. Due to its minimally invasive nature, it is less prone to access-related complications such as soft tissue damage, bleeding, or postoperative infections, but is more prone to fat embolisms. A rare but serious complication is implant failure (Bäcker et al. 2022). According to the DGU (German Society for Trauma Surgery) guideline “Distal Radius Fracture,” intramedullary nail osteosynthesis is indicated, for example, for non-complex intra-articular fractures and yields results identical to those of plate osteosynthesis (Dresing 2021).

The following table provides an overview of the advantages of various treatment methods for distal radius fractures according to the DGU guideline:

Table 1: Overview of the benefits of various treatment approaches for distal radius fractures according to the DGU Guidelines (Dresing 2021). Abbreviations: DASH: Disabilities of the Arm, Shoulder, and Hand; MIPO: Minimalinvasive Plattenosteosynthese; PRWE: Patient-Related Wrist Evaluation; ROM: Range of Motion

Procedure I vs. Procedure II	Evidence	Outcome
K-wire vs. volar locking plate osteosynthesis	IV	Short-term results/function >II Long-term results identical
K-wire vs. volar locking plate osteosynthesis	III	II better radiographic anatomy (radial inclination, volar tilt, radial length), no evidence for better function than I
K-wire vs. percutaneous volar locking plate osteosynthesis	Ia	II advantages in unstable fractures
K-wire vs. percutaneous volar locking plate osteosynthesis	Ia	II slightly better function, no radiological differences (radial inclination, radial height, volar tilt)
K-wire vs. percutaneous volar locking plate osteosynthesis	Ia	No significant differences, II fewer complications, > grip strength, > range of motion, < infections
External fixator vs. volar locking plate osteosynthesis	Ia	II slightly better early function, better grip strength after 3 months, no difference thereafter
External fixator vs. volar locking plate osteosynthesis	Ia	II better early function, DASH after 3 and 6 months, grip strength, flexion, extension after 3 months, II slightly fewer complications at 12 months
External fixator vs. volar locking plate osteosynthesis	Ib	Patients < 50 years: after 12 months I significantly better ROM, grip strength
External fixator vs. volar locking plate osteosynthesis	Ia	AO type C fracture, II maintains reposition, no significant difference in outcome, volar tilt, ulnar variance, II slightly better radial inclination
External fixator vs. internal osteosynthesis (mainly volar locking plate osteosynthesis)	Ia	II better functional outcome, supination, restoration of volar tilt and radial inclination, faster recovery
External fixator vs. volar locking plate osteosynthesis	IIb	No difference in DASH, PRWE, ROM, grip strength, radial arthritis signs
External fixator vs. internal osteosynthesis (mainly volar locking plate osteosynthesis)	Ia	No difference in long-term analysis
External fixator vs. volar locking plate osteosynthesis	III	II better outcome, more expensive, possible metal removal
External fixator vs. plate osteosynthesis	Ia	II better DASH, better restoration of radial length, fewer infections

Procedure I vs. Procedure II	Evidence	Outcome
External fixator vs. volar locking plate osteosynthesis	Ib	Unstable distal radius fractures: no difference in DASH, PRWE, grip strength, ROM after 3 years
Intramedullary nail vs. volar locking plate osteosynthesis	Ib	I same as II in grip strength, clinical outcome, no change in complications
Intramedullary nail vs. volar locking plate osteosynthesis	Ia	Identical clinical, functional, radiological outcomes; less carpal tunnel syndrome after I
Intramedullary nail vs. volar locking plate osteosynthesis	III	I better restoration of volar tilt, II better supination, radio-ulnar variance
Non-operative, closed + cast immobilization vs. volar locking plate osteosynthesis	Ib	No significant superiority for any procedure
Non-operative, closed + cast immobilization vs. plate osteosynthesis	Ia	No clinical difference after 1 year
Non-operative, closed + cast immobilization vs. percutaneous procedures	Ia	II same quality of life as I, I fewer complications than II
Non-operative, closed + cast immobilization vs. volar locking plate osteosynthesis	III	In complex AO C fractures, > 60 years: no statistical differences in function after 16 months; II better in grip strength, radial inclination, radial height, joint steps
Non-operative, closed + cast immobilization vs. volar plate osteosynthesis	Ib	In extra-articular radius fractures, II functionally better after 12 months
Non-operative, closed + cast immobilization vs. volar locking plate osteosynthesis	Ib	Dorsally unstable distal radius fractures: II better DASH, PRWE after 3 and 12 months
Non-operative, closed + cast immobilization vs. volar locking plate osteosynthesis	Ib	No difference in DASH, PRWE after 12 months
Non-operative vs. operative	Ia	No difference in clinical outcome in moderately displaced fractures
Non-operative, cast immobilization vs. volar plate osteosynthesis	Ib	In acceptably repositioned intra-articular fractures: II better outcome in DASH after 12 months
MIPO vs. volar locking plate osteosynthesis	Ia	I greater patient satisfaction, no differences in grip strength, clinical scores, ROM, radial inclination, volar tilt
Nail osteosynthesis vs. MIPO	III	In extra-articular unstable fractures, II shorter incision, better clinical outcomes after 6 months

The choice of procedure depends on the patient's general condition, the severity of the fracture, bone quality, open or closed soft tissue injuries, associated injuries, the patient's motivation and compliance, the expected functional demands, and the surgeon's preference.

8 Suggested profile and training for users

Bone implants must only be used by individuals who have the necessary training, knowledge, and experience. The treating physicians are responsible for ensuring that they have received appropriate training and have sufficient experience in handling bone implants.

Before using a bone implant, the user must verify that the product is in good working order and in proper condition and must follow the instructions for use.

9 Regulatory requirements (in addition to the standard requirements)

Standard	Title	Revision	Applicable
ISO 5838-1	Implants for surgery - Metallic skeletal pins and wires - Part 1: General requirements	2013-03	☒ full ☐ partial
ISO 5838-2	Implants for surgery; skeletal pins and wires; part 2: Steinmann skeletal pins; dimensions	1991-01	☒ full ☐ partial
ISO 5838-3	Implants for surgery; skeletal pins and wires; part 3: Kirschner skeletal wires	1993-09	☒ full ☐ partial
DIN EN ISO 14602	Non-active surgical implants - Implants for osteosynthesis - Particular requirements	2012-06	☒ full ☐ partial
DIN EN ISO 14630	Non-active surgical implants - General requirements	2025-03	☒ full ☐ partial
DIN EN ISO 5832-1	Implants for surgery - Metallic materials - Part 1: Wrought stainless steel	2024-07	☒ full ☐ partial
ISO 10334	Implants for surgery - Malleable wires for use as sutures and other surgical applications	1994-08	☒ full ☐ partial
ISO 19227	Implants for surgery - Cleanliness of orthopedic implants - General requirements	2018-03	☒ full ☐ partial
DIN EN ISO 15223-1	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	2022-02	☐ full ☒ partial
DIN EN ISO 14971	Medical devices - Application of risk management to medical devices	2022-04	☒ full ☐ partial
DIN EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process	2025-11	☒ full ☐ partial
DIN EN ISO 17664-1	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices	2021-11	☒ full ☐ partial

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11 Revision History

Revision	Date issued (*DD.MM.JJJJ*)	Change description	Author	Revision validated by the Notified Body
A	08.03.2023	First issue	Ayfer Bektas	☒ Yes Language of the validated SSCP: German ☐ No
B	14.07.2026	Update after technical file review and after update of risk management, post market surveillance, and clinical evaluation	Dr. rer.nat Natalja Klymov; Ayfer Bektas	☐ Yes Language of the validated SSCP: ☐ No