	<p style="text-align: center;">INSTRUCTIONS FOR USE KNEE ARTHROSCOPY SYSTEM (EO STERILE)</p>	<p>KAUL-Medizintechnik GmbH Königsberger Straße 40 56269 Dierdorf, Germany</p>
--	---	---

INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

DEVICE SYSTEM NAME

Knee Arthroscopy System

DEVICE DESCRIPTION

KAUL-Medizintechnik GmbH's Knee Arthroscopy System includes KR-2 Buttons, KR-2 Interference Screws, Meniscus Repair options (K-Meni & K-Fix) and Ligament staples. The KR-2 knee arthroscopy system are the suspensory devices indicated for fixation of ligament repair and reconstructions. The interference screws are cannulated indicated for ligaments fixations in soft tissue or bone tendon bone application. The system provides an excellent combination of strength and stiffness required for successful cortical fixation. There are various types of devices included in the knee Arthroscopy which are as follows:

1. KR-2 NAKED BUTTON

KR-2 Naked button is made up of titanium alloy. The system provides an excellent combination of strength and stiffness required for successful cortical fixation. The large naked buttons of KR-2 Naked button may eliminate the need for a stepped tunnel technique and are considered to be an excellent choice for revision surgeries.

- KR-2 Mini Naked Button L:12mm, W: 3.9mm, Sterile
- KR-2 Large Naked Button L: 16.5mm, W: 4.4mm, Sterile
- KR-2 Ultimate Mini Naked Button L: 12mm, W: 3.9mm, Sterile
- KR-2 Ultimate Large Naked Button L: 16.5mm, W: 3.9mm, Sterile

2.a. KR-2 ADJUSTABLE LOOP BUTTON

KR-2 Ultimate Mini is an adjustable loop with an oblong shaped titanium button used for Cruciate Graft Reconstructions. KR-2 Ultimate provides a double locking mechanism which eliminates the need for knot tying.

KR-2 Ultimate Mini provides three sutures (UHMWPE):

Adjustable Suture (USP 7, White/Blue): It allows the surgeon to maximize the amount of graft inside the femoral tunnel, thereby optimizing the healing process. It also enables calibration of the loop to its optimum size.

Pulling Suture (USP 5, White): It is available to pull the graft inside the tunnel.

Flipping Suture (USP 5, White/Black): It ensures the flipping of the button.

- KR-2 Ultimate Mini Button, Button L: 12mm, W: 3.9mm, Adjustable Loop, Sterile

KR-2 Ultimate Large is an adjustable loop with an oblong shaped titanium button used for Cruciate Graft Reconstructions. KR-2 Ultimate provides a double locking mechanism which eliminates the need for knot tying. Hence, KR-2 Ultimate Large is considered as an excellent choice for revision surgeries. KR-2 Ultimate Large provides three sutures (UHMWPE):

Adjustable Suture (USP 7, White/Blue): It allows the surgeon to maximize the amount of graft inside the femoral tunnel, thereby optimizing the healing process. It also enables calibration of the loop to its optimum size.

Pulling Suture (USP 5, White): It is available to pull the graft inside the tunnel.


Flipping Suture (USP 5, White/Black): It ensures the flipping of the button.

- KR-2 Ultimate Large Button, Button L: 16.5mm, W: 3.9mm, Adjustable Loop, Sterile

2.b. KR-2 MINI LOOP BUTTON

KR-2 Mini is a fixed/Closed loop with an oblong shaped button used for Graft Fixations in ACL/PCL Reconstruction. Being a continuous loop without any joint, KR-2 Mini provides a stronger fixation while eliminating the need for knot



	<p style="text-align: center;">INSTRUCTIONS FOR USE KNEE ARTHROSCOPY SYSTEM (EO STERILE)</p>	<p>KAUL-Medizintechnik GmbH Königsberger Straße 40 56269 Dierdorf, Germany</p>
--	---	---

INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

tying. The pre-loaded pulling and flipping braided sutures are available to ensure controlled pulling and flipping of the button in the transosseous tunnel. A 4.5mm cannulated headed reamer is provided in the instrument set for drilling the tunnel, allowing the KR-2 Mini button to pass easily into it. The fixed loop is made of UHMWPE (Ultra High Molecular Weight Polyethylene).

Pulling Suture (USP 5, White): It is available to pull the graft inside the tunnel.

Flipping Suture (USP 5, White/Black): It ensures the flipping of the button.

Following are the variants of KR-2 Mini Button:

- KR-2 Mini, Loop: 12mm to 55mm, Button L: 12mm, W: 3.9mm, Sterile

2.c. KR-2 LARGE LOOP BUTTON

KR-2 Large is a fixed/Closed loop with an oblong shaped button used for Graft Fixations in ACL/PCL Reconstruction. Being a continuous loop without any joint, KR-2 Large provides a stronger fixation and also eliminates the need for knot tying. The KR-2 Large includes a larger button compared to KR-2 Mini which eliminates the need for a stepped tunnel technique. Hence, KR-2 Large is considered as an excellent choice for revision surgeries. The pre-loaded pulling and Flipping braided sutures are available to ensure controlled pulling and flipping of the button in the transosseous tunnel. KR-2 Large is available in various pre-measured loop sizes. The fixed loop is made up of UHMWPE (Ultra High Molecular Weight Polyethylene) while the oblong button is made up of titanium material.

Pulling Suture (USP 5, White): It is available to pull the graft inside the tunnel.

Flipping Suture (USP 5, White/Black): It ensures the flipping of the button.

Following are the variants of KR-2 Large Button:

- KR-2 Large, Loop: 12mm to 55mm, Button L: 16.5mm, W: 4.4mm, Sterile

3. KR-2 BUTTON EXTENDER

KR-2 Button Extender is an extension device designed to provide extended surface area during cruciate graft reconstructions. It can be used in conjunction with the KR-2 Mini and KR-2 Ultimate Mini button providing an effective solution for cortical blowouts. It also helps overcome intraoperative complications seen in revision surgeries.

- KR-2 Button Extender L: 18mm, W: 5.0mm, Sterile

4. KR-2 NO-BUTTON ADJUSTABLE LOOP

KR-2 No-Button is an adjustable loop without button used for Cruciate Graft Reconstructions. The adjustable Loop is made of UHMWPE (Ultra High Molecular Weight Polyethylene).

Adjustable Suture (USP 7, White/Blue): It allows the surgeon to maximize the amount of graft inside the femoral tunnel, thereby optimizing the healing process. It also enables calibration of the loop to its optimum size.

- KR-2 No-Button Adjustable Loop, Sterile

5. KR-2 CONCAVE BUTTON

The KR-2 Concave Button is an attachable Button System that has revolutionized tibial fixation of ACL and PCL grafts. KR-2 Concave Button can be used on all graft types and attached to a variety of button configurations for fixation over sockets or full tunnels. The advantages of the KR-2 Concave Button implant include: Maximum graft-to-bone contact improves incorporation and healing the ability to retention grafts after fixation and knee cycling Several different button options for sockets and full tunnels.



INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

- KR-2 Concave Button 11mm with 4mm Collar, Sterile
- KR-2 Concave Button 14mm with 7mm Collar, Sterile
- KR-2 Concave Button 20mm with 9mm Collar, Sterile
- KR-2 Round Button without Collar, 14mm, Sterile

6. KR-2 PEEK CF INTERFERENCE SCREW

The PEEK CF Interference Screw is made of A carbon fiber reinforced PEEK OPTIMA from Invibio, USA. The polymer in PEEK CF enhances the physical strength by nearly twice as much as natural PEEK. Its mechanical properties are much closer to the cortical bone than the natural PEEK, PLLA or Titanium. The PEEK CF Interference Screw has a fully threaded design which provides strong mechanical fixation for both bone tendon bone (BTB) and soft tissue grafts. It is renowned for its radiolucent properties, less imaging artefact and for being MRI safe. PEEK CF interference screw offers revision ability of an absorbable screw. The screws vary from diameter 7mm to 12mm and length varies from 20mm to 35mm.

- KR-2 PEEK CF Interference Screw (Dia. 7mm to 12mm and Length 20mm to 35mm), Sterile

7. KR-2 PEEK OPTIMA INTERFERENCE SCREW

The PEEK OPTIMA (From Invibio, USA) interference screw is made up of PEEK (Poly-Ether-Ether-Ketone). PEEK is a thermoplastic material and has radiolucent properties for easy artefact free monitoring and assessment of the healing site with X-ray, CT or MRI. It also offers a revision ability of an absorbable screw. PEEK OPTIMA Interference Screw has a fully threaded design. It provides strong mechanical fixation for both Bone-Tendon-Bone (BTB) and soft tissue grafts. PEEK OPTIMA is considered to be extremely strong, durable, and highly resistant to creep & fatigue. The bone like modulus helps minimize stress shielding and also stimulates bone healing. The screws vary from diameter 7mm to 12mm and length varies from 20mm to 35mm.

- KR-2 PEEK OPTIMA Interference Screw (Dia. 7mm to 12mm and Length 20mm to 35mm), Sterile

8. KR-2 TITANIUM INTERFERENCE SCREW

The Titanium interference screw is made up of Titanium alloy. The screw has a fully threaded design which provides strong mechanical fixation for both Bone-Tendon-Bone (BTB) and soft tissue grafts. The rounded edge of the threads protects tissue used with guide wire and cannulated screw driver. The screws vary from diameter 7mm to 12mm and length vary from 20mm to 35mm.

- KR-2 Titanium Interference Screw (Dia. 7mm to 12mm and Length 20mm to 35mm), Sterile

9. KT LIGAMENT STAPLE

The Ligament staple is made up of titanium alloy. It can be used for attaching soft tissue to the bone. Low-profile, wide staple base provides better load distribution while impacting. Spike-post leg design encourages uninterrupted vascular flow to the underlying tissue. Sharp leg points for easier penetration into cortical bone. The ligament staples are available in different sizes. The staple impactor is provided in the instrument set for the staple holding and easier staple insertion into the bone. The following are the variants of ligament staple:

- KT Ligament Staple, 8mm x 13mm x 20mm, Titanium, Sterile
- KT Ligament Staple, 6mm x 11mm x 25mm, Titanium, Sterile
- KT Ligament Staple, 8mm x 13mm x 25mm, Titanium, Sterile
- KT Ligament Staple, 11mm x 16mm x 25mm, Titanium, Sterile
- KT Ligament Staple, 16mm x 21mm x 25mm, Titanium, Sterile



INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

10. KR-2 K-MENI INSIDE-OUT MENISCAL REPAIR NEEDLE

KR-2 K-Meni Inside-out system is specifically designed for inside-out meniscal repair procedures features cannulas, needles and rasps. Five pre-bent Single Lumen cannulas provide optimum access to all zones of the meniscus with funnel ends that make the loading of needles safe and easy. Double-arm meniscal repair needles are thin, strong and flexible for easy passage. The needles are available with Pre-attached USP 2-0, USP 0 K-Braid Suture & 1.0mm Suture Tape. Meniscal repair needles are made of Stainless Steel and have a large eyelet at one end to permit easy threading of suture material.

- KR-2 K-Meni Inside-Out Meniscal Repair Needle With USP 2-0 K-Braid: White/Blue, Length 91.4cm (36inch), Needle Length 25cm, Sterile
- KR-2 K-Meni Inside-Out Meniscal Repair Needle With USP 0 K-Braid: White/Blue, Length 91.4cm (36inch), Needle Length 25cm, Sterile
- KR-2 K-Meni Inside-Out Meniscal Repair Needle With 1.0mm Suture Tape: White/Blue, Length 91.4cm (36inch), Needle Length 25cm, Sterile

11. KR-2 K-FIX ALL-INSIDE MENISCAL REPAIR

MENI-FIX All-Inside Meniscal Repair includes two 0.9mm PEEK anchors with a pre tied, self-sliding knot comprised of USP 2-0, UHMWPE K-braid Suture. The delivery needles are available in Curved, Straight, and Reverse Curved designs. The Curved and Reverse Curved designs allow the surgeon to rotate the needle tip away from the neurovascular structures when penetrating the meniscus, further reducing the risk of neurovascular injury. The Curved delivery needle is optimally shaped to allow vertical mattress sutures to be inserted on either the femoral or tibial surfaces of the meniscus. The Reverse Curved delivery needle is most useful for repairing tears on the tibial surface and more anterior located tears. The built-in, adjustable depth penetration limiter is adjustable from 8mm to 18mm from the tip of the needle. Use of the meniscal depth probe in conjunction with the adjustable depth penetration limiter allows controlled delivery of the implants.

- KR-2 K-Fix All-Inside Meniscal Repair - Straight Needle, Sterile
- KR-2 K-Fix All-Inside Meniscal Repair - 12° Curve Needle, Sterile
- KR-2 K-Fix All-Inside Meniscal Repair - 12° Reverse Curve Needle, Sterile


12. KR-6 K-BRAID SUTURE

K-Braid Sutures are braided sterile sutures prepared from Ultra High Molecular Weight Polyethylene (UHMWPE). They can be used in soft tissue approximations along with allograft tissues in arthroscopy procedures. K-Braid sutures are non-absorbable and do not impose any significant changes in tensile strength retention known to occur in vivo. K-Braid sutures are available in a variety of colour combinations for easy suture management in complicated repairs. To achieve best results, do not use any of the KAUL-Medizintechnik GmbH's Knee Arthroscopy System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another KAULMED document. As with all Arthroscopy implants, none of the KAUL-Medizintechnik GmbH's Knee Arthroscopy System components should ever be reused under any circumstances. Reuse may lead to infection and cross infection.

13. KR-6 K-BRAID SUTURE TAPE

K-Braid Suture Tape is a flat, braided, sterile suture prepared from Ultra High Molecular Weight Polyethylene (UHMWPE). It is intended for use in soft tissue approximation, fixation, and reinforcement, including use with allograft



	<p style="text-align: center;">INSTRUCTIONS FOR USE KNEE ARTHROSCOPY SYSTEM (EO STERILE)</p>	<p>KAUL-Medizintechnik GmbH Königsberger Straße 40 56269 Dierdorf, Germany</p>
--	---	---

INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

tissues in arthroscopic procedures. K-Braid suture tape is non-absorbable and does not undergo any significant changes in tensile strength retention known to occur in vivo. The flat, wider profile of the tape allows for improved load distribution across soft tissues, potentially reducing tissue cut-through in high-stress repairs. To achieve optimal results, do not use any KAUL-Medizintechnik GmbH Knee Arthroscopy System implant components with components from any other system or manufacturer, unless specifically permitted in this or another KAULMED document. As with all arthroscopy implants, none of the KAUL-Medizintechnik GmbH's Knee Arthroscopy System components should ever be reused under any circumstances. Reuse may lead to infection and cross-infection.

14. KR-6 K-BRAID INFINITY LOOP NEEDLE

K-Braid Infinity Loop Needle is a sterile, braided, continuous-loop suture prepared from Ultra High Molecular Weight Polyethylene (UHMWPE) and supplied pre-attached to a surgical needle. It is intended for use in soft tissue approximation, fixation, and reinforcement, including use with autograft or allograft tissues in arthroscopic procedures. The Infinity Loop Suture is non-absorbable and does not undergo any significant changes in tensile strength retention known to occur in vivo. The continuous closed-loop design provides uniform load distribution, secure graft fixation, and eliminates free suture ends, thereby facilitating efficient suture management during complex repairs.

The K-Braid Infinity Loop Needle consists of a K-Braid Infinity Loop Suture and a compatible surgical needle. To achieve best results, do not use any of the KAUL-Medizintechnik GmbH's Knee Arthroscopy System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another KAULMED document. As with all Arthroscopy implants, none of the KAUL-Medizintechnik GmbH's Knee Arthroscopy System components should ever be reused under any circumstances. Reuse may lead to infection and cross infection.

PURPOSE

The KAUL-Medizintechnik GmbH's Knee Arthroscopy System is indicated for used in the surgical procedures related to the Knee Ligament and meniscus fixation.

MATERIALS

The KAUL-Medizintechnik's Knee Arthroscopy System implant components are fabricated from Titanium Alloy (Ti-6Al-4V) as per ISO 5832-3:2021, PEEK OPTIMA as per ASTM F2026 and PEEK CF as per ASTM F3333, Stainless Steel as per ISO 7153-1 and UHMWPE Yarn/Suture (K-Braid) as per ASTM F2848.

The KAUL-Medizintechnik's Knee Arthroscopy System making direct contact with Knee Joint and Surrounding tissues.

INDICATION USE

The KAUL-Medizintechnik GmbH's Knee Arthroscopy System is indicated for used in reconstruction or repair of Knee ligament (ACL, PCL). These devices are also used for treating meniscal tears in the anterior, middle and posterior portion of the meniscus.

CONTRAINDICATIONS

Contraindications may be relative or absolute. The conditions listed below may preclude or reduce the chance of a successful outcome:

- Any case not described in the indications.
- In patients where there is a possibility for conservative treatment.



KAULMED	INSTRUCTIONS FOR USE KNEE ARTHROSCOPY SYSTEM (EO STERILE)	KAUL-Medizintechnik GmbH Königsberger Straße 40 56269 Dierdorf, Germany
----------------	--	--

INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

- Active, suspected or latent infection in the affected area.
- Blood supply limitations or other systemic conditions that may retard healing.
- Foreign body sensitivity, if suspected.
- Fever or leukocytosis.
- Patient's inability or unwillingness to follow surgeon's prescribed post-operative regimen.
- Any situation that would compromise the ability of the user to follow the instructions for use or using the device for an indication other than those listed.

WARNINGS & PRECAUTIONS

- This product should only be used by or on the order of a surgeon.
- The fixation provided by this device should be protected until healing is complete. Failure to follow the postoperative regimen prescribed by the surgeon could result in the failure of the device and compromised results.
- Any decision to remove the device should consider the potential risk of a second surgical procedure. Adequate postoperative management should be followed after implant removal.
- The patient should be advised of the use and limitations of this device.
- Pre-operative planning and evaluation, surgical approaches and technique, and familiarity of the implant, including its instrumentation and limitations are necessary components in achieving a good surgical result.
- This device must never be reused. Reuse or re-sterilization may lead to changes in material characteristics such as deformation and material degradation which may compromise device performance. Reprocessing of single use devices can also cause cross- contamination leading to patient infection.
- This device must never be re-sterilized.
- Appropriate instrumentation should be used to implant this device.
- Use only the KAULMED's instruments with KAULMED Implant to make the surgery convenient as KAULMED Instruments are only compatible KAULMED Implants.
For all the implants there is a single instrument set available except for All-inside meniscal repair implant and Inside-out meniscal repair implant. For these two implants (All-inside meniscal repair and Inside-out meniscal repair) two specific instrument sets are available

GRAFT SELECTION:

A patient's own tissue - an auto-graft - can often be used for a surgical reconstruction procedure. It may be Autograft BTB, Hamstring or Quadriceps.

BTB Graft

- Considered gold standard (Ease of Harvest, Consistent Size & Shape, Strong bone-Tendon Interface, Strong Bone to Bone Fixation, Good Healing).
- Middle third of patellar tendon harvested.
- 2.5mm bone plug from patella and tibial tuberosity.

Hamstring Graft

- Quadrupled Semi-T/ Doubled SemiT + Gracilis
- 4 strands of Hamstrings = 250% strength of native ACL
- Hamstring Graft is a stronger graft and requires smaller incision.



KAULMED	INSTRUCTIONS FOR USE KNEE ARTHROSCOPY SYSTEM (EO STERILE)	KAUL-Medizintechnik GmbH Königsberger Straße 40 56269 Dierdorf, Germany
----------------	--	--

INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

Quadriceps Tendon Graft

Bony end on one side and soft tissue strip on other Cross-sectional area thicker than BTB. It have comparatively less harvest site morbidity.

TARGET PATIENT GROUP

Male or Female, aged between 18 to 75 years and skeletally mature patient.

INTENDED USER GROUP

All qualified and well-trained/experienced Surgeons can use this device.

SURGEON NOTE

Although the surgeon is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.

CAUTION

- To be used by Qualified and Trained Surgeon Only.
- Federal law restricts this device to sale by or on the order of a physician

MRI COMPATIBILITY

The KAUL-Medizintechnik GmbH’s Knee Arthroscopy System have not been evaluated for safety and compatibility in the MR environment. The KAUL-Medizintechnik GmbH’s implants have not been tested for heating or migration in the MR environment. Patients should seek the opinion of medical Experts before entering the MRI (Magnetic Resonance Imaging) environment.

CLINICAL BENEFITS

The expected clinical benefits of suspensory devices when used in accordance with the recommended technique and instructions for use are to achieve graft/tissue/ligaments healing by achieving anatomical stabilization of the knee joint and reducing pain (VAS Score Evaluation), maintaining Range of Motion.

PERFORMANCE CHARACTERSTICS

The KAUL-Medizintechnik GmbH’s Knee Arthroscopy System has adequate fixation strength, Stiffness, flexibility, it is also biocompatible for use and are capable of undergoing to bear the deformation load and have sufficient strength to allow the healing of the Joint.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The Summary of Safety and Clinical Performance (SSCP) has been uploaded on the KAUL-Medizintechnik's Website. It can be assessed with link " <https://www.kaulmed.com/sscp-report/>". Once the EUDAMED Database is fully functional, the SSCP will be uploaded on EUDAMED Database also.

POTENTIAL ADVERSE EVENTS

A listing of possible adverse events includes, but is not limited to:

- Infection, both deep and superficial.
- Allergies and other reactions to device materials.
- Risks due to anaesthesia.



KAULMED	INSTRUCTIONS FOR USE KNEE ARTHROSCOPY SYSTEM (EO STERILE)	KAUL-Medizintechnik GmbH Königsberger Straße 40 56269 Dierdorf, Germany
----------------	--	--

INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

NOTE:

Additional surgery may be necessary to correct some of these anticipated adverse events.

OTHER PREOPERATIVE, INTRAOPERATIVE, AND POSTOPERATIVE WARNINGS ARE AS FOLLOWS

PATIENT SELECTION

The proper selection and compliance of the patient will greatly affect the results.

IMPLANT SELECTION

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human ligaments/tissue/bone. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

DEVICE FIXATION

Refer to the KAUL-Medizintechnik GmbH’s Knee Arthroscopy System surgical technique. KAUL-Medizintechnik GmbH’s Knee Arthroscopy System instrumentation contains instrument set and implants, which are intended to be used with device specific instruments.

PREOPERATIVE:

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and/or predispositions such as those addressed in the contraindications mentioned above should be avoided.
- An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The KAUL-Medizintechnik GmbH’s Knee Arthroscopy System components (described in the DESCRIPTION section) are not to be combined with the components from another manufacturer.


INTRA-OPERATIVE:

- Extreme caution should be used around the implantation site.
- Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
- Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.

POST-OPERATIVE

- To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.



	<p style="text-align: center;">INSTRUCTIONS FOR USE KNEE ARTHROSCOPY SYSTEM (EO STERILE)</p>	<p>KAUL-Medizintechnik GmbH Königsberger Straße 40 56269 Dierdorf, Germany</p>
--	---	---

INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

- Patients should be advised to avoid excessive and repeated stress on the body as it may cause the loosening/migration of an implant which may leads to the failure of the treatment and delayed healing into the patient.
- The surgeon should inform to the patients that temporary Pain, discomfort, or abnormal sensations due to the presence of the device might occur just after the surgery.

More of the following complications may occur:

- (1) Corrosion, with localized tissue reaction or pain, (2) Migration of implant position, possibly Resulting in injury, (3) Risk of additional injury from postoperative trauma, (4) Possible increased risk of infection. In such complications re-surgery/removal of an Implant may needed.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all Arthroscopic implants, the KAUL-Medizintechnik GmbH’s Knee Arthroscopy System components should never be reused under any circumstances. Reuse may lead to infection and cross infection. The reuse of implants after re-sterilization may not result in the same responses.
- Arthroscopic surgeries do not generally involve major risks and complications. Orthopaedic Surgeons are properly trained to avoid potential difficulties which might occur during an intervention, as well as to efficiently correct such problems if they appear. However, some of the risks and complications which may accompany an orthopaedic surgical procedure are:

Postoperative infections: In order to avoid this complication, patients will be administered Antibiotics before, during and after the surgery.

Bleeding

Blood clots: They may occasionally appear after orthopaedic surgery. Blood clots can be avoided with appropriate medication and physical exercise.

Blood vessel damage: This complication may appear if blood vessels located in proximity to the implant are affected during the procedure.

Allergic reactions: The patient might experience an allergic reaction.

PACKAGING

Packages for each device should be intact upon receipt. All implants should be carefully checked for lack of damage before use. Damaged packages or products should not be used and should be returned to KAUL-Medizintechnik GmbH.

NOTE:

Implants are supplied sterile; no sterilization is required for implants.

STERILIZATION

Ethylene Oxide (EO) Sterilization-" KAUL-Medizintechnik GmbH’s Knee Arthroscopy System implants are supplied in sterile condition. A sterility assurance level is SAL of 10⁻⁶ was achieved using Ethylene Oxide (EO) sterilization with the exposure time of 180 minutes in ETO sterilizer, Complete cycle running time including pre conditioning & aeration is ~8 hours." Shelf life of the implants is 5 Years.

STORAGE

Store the implants in a dry location. Handle and store the implant components with care to prevent any scratches or damage. Implants and instruments must be protected during storage, particularly from corrosive environments. The implant surfaces should remain free from scratches or notches, as these may compromise the functional strength of the



KAULMED	INSTRUCTIONS FOR USE KNEE ARTHROSCOPY SYSTEM (EO STERILE)	KAUL-Medizintechnik GmbH Königsberger Straße 40 56269 Dierdorf, Germany
----------------	--	--

INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

construct. The recommended storage temperature range is between 10°C and 25°C.

Lifetime of the Product

Knee Arthroscopy implants are manufactured from non-biodegradable materials with long-term mechanical and chemical stability in the human body. Such implants are intended to remain permanently in-situ and outlast the patient’s lifetime.

DISPOSAL

The Orthopaedics implant is to be disposed off as per the Hospital and Regulatory norms.

PRODUCT COMPLAINTS

Customers or users of products, who have any complaints or who have experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the Manufacturer, KAUL-Medizintechnik GmbH. Further, if any of the implanted KAUL-Medizintechnik GmbH’s Knee Arthroscopy System ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the Manufacturer and Competent Authority of the member state in which the user and/or patient established should be notified immediately.

If any KAUL-Medizintechnik GmbH’s product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor, Manufacturer and Competent Authority of the member state in which the user and/or patient is established should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

Implant Card

An implant card is provided with every device. The surgeon must fill the details of implant and patient at the time of implantation and hand over to the patient.


The implant card contains essential information including device name, model, lot/serial number, UDI, and manufacturer details.

Patients must always keep the implant card with them and present it to healthcare professionals whenever medical care is required (including diagnostic imaging, surgery, or emergency care). This information is critical for ensuring safe follow-up and treatment.


FURTHER INFORMATION

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact your representative or distributor or contact the manufacturers direct at <https://www.kaulmed.com/> where IFU, Surgical Technique and Catalogue are also available.









DETAILS OF VARIOUS SYMBOLS USED IN LABELING

Symbol	Symbol Title	Description	Standard Title	Reference Number
	Date of Manufacture	Indicates the date when the medical device was manufactured.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—	5.1.3











	<p align="center">INSTRUCTIONS FOR USE KNEE ARTHROSCOPY SYSTEM (EO STERILE)</p>	<p>KAUL-Medizintechnik GmbH Königsberger Straße 40 56269 Dierdorf, Germany</p>
--	--	---

INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

			General requirements.	
	Manufacturer	Indicates the medical device manufacturer	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.1
	Reorder Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.6
	Conformité Européene (European Conformity)	Signifies European technical conformity.	EU MDR 2017/745.	MDR 2017/745 (Annex XII, Article 20)
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.5
	Do Not Reuse	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.4.2
	Keep Dry	Indicates a medical device that needs to be protected from moisture.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.3.4
	Keep away from the sunlight	Indicates a medical device that needs protection from light sources	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.3.2
	Consult instructions for use	Indicates the need for the user to consult the instructions for use	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.2.3






INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

	Do not use if package is damaged.	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.2.8
	Do not re-sterilize	Indicates a medical device that has already subjected to a sterilization process, so do not re-sterilize.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.2.6
	Sterilized using EO.	Indicates a medical device that has been sterilized using ethylene oxide (EO).	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.2.4
	Double Sterile Barrier System	Indicates two sterile barrier system	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.2.12
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.3.7
	Quantity	Indicates quantity of medical devices contained within the packaging.	N/A	N/A
	Use by date	Indicates the date after which the medical device is not to be used.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.4
	Prescription only	The symbol for Prescription Device Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	N/A	21 CFR 801.15 ad 21 CFR 801.109 ((c) (1) (i) (F) (b) (1)).



KAULMED	INSTRUCTIONS FOR USE KNEE ARTHROSCOPY SYSTEM (EO STERILE)	KAUL-Medizintechnik GmbH Königsberger Straße 40 56269 Dierdorf, Germany
----------------	--	--

INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

	Medical device	Indicates the item is a medical device	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.7.7
	Unique Device Identifier	Indicates a carrier that contains unique device identifier information.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.7.10
	Caution	Indicates that caution is necessary when operating the device.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.4.4







Notified Body: DNV Product Assurance AS
Notified Body Number: 2460
Address Notified Body: Veritasveien 1, 1363 Høvik, Norway



Legal Manufactured by:
KAUL-Medizintechnik GmbH.
Address Manufacturing Unit:
 Königsberger Straße 40
 56269 Dierdorf, Germany
Website: <https://www.kaulmed.com/>
Single Registration Number: DE-MF-000009240



Revision History Table:

S. No.	Document No	Rev. No.	Description of Revision	Effective date	Prepared by	Approved by
1.	KAUL-IFU-KAS/S-04	00	Initially released.	29-09-2025		
2	KAUL-IFU-KAS/S-04	01	Product list is arranged and product life information is added as per LOF 1	16-12-2025		



KAULMED	INSTRUCTIONS FOR USE KNEE ARTHROSCOPY SYSTEM (EO STERILE)	KAUL-Medizintechnik GmbH Königsberger Straße 40 56269 Dierdorf, Germany
----------------	--	--

INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

3	KAUL-IFU-KAS/S-04	02	Indication is revised as per the LOF 2	05-02-2026		
---	-------------------	----	--	------------	---	---

