

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

DEVICE SYSTEM NAME

Shoulder Arthroscopy System

DEVICE DESCRIPTION

KAUL-Medizintechnik GmbH's Shoulder Arthroscopy System includes Suture Anchor devices. The suture anchors are recommended for use in both large and small joint soft tissue repairs in arthroscopic, mini open or open surgeries. The AC Button can be use in Acromioclavicular joint repair during arthroscopic or open surgeries. There are various types of devices included in the Shoulder Arthroscopy System which are as follows:

- 1. KR-1 Titanium Twist-Fit Suture Anchor with Needles**
- 2. KR-1 Titanium Twist-Fit Suture Anchor**

The self-tapping KR-1 Titanium Twist-Fit suture anchor is mostly used as a medial row anchor in rotator cuff repair, Bankart and SLAP surgery. It is recommended for use in small and large-joint repairs without the need for tapping or drilling. KR-1 Titanium Twist-Fit anchors are available in diameter of 2.0mm, 2.5mm, 2.8mm, 3.5mm, 5.0mm and 6.5mm with single, double and triple loaded options. The anchor design incorporates a cancellous thread with a very small core diameter to maximize pull-out strength in cancellous or osteoporotic bone. The anchor design also incorporates a cortical thread to maximize pull-out strength in a cortical or hard bone. The anchor is designed for ultimate mechanical properties (pull-out strength, tensile strength, etc.) and ease-of-use.

The anchors are also available with needles which are ideal for mini-open rotator cuff repair procedures. The anchors are also available with needles or without needles which are ideal for mini-open shoulder instability repair procedures.

- Ø2.0mm KR-3 Titanium Twist-Fit Suture Anchor With USP 0 K-Braid (1X), White/Blue, With Needles: MO-7, Sterile
 - Ø2.5mm KR-3 Titanium Twist-Fit Suture Anchor With USP 1 K-Braid (1X), White/Blue, With Needles: MO-7, Sterile
 - Ø2.8mm KR-1 Titanium Twist-Fit Suture Anchor With USP 2 K-Braid (1X): White/Blue, With Needles: MO-6, Sterile
 - Ø3.5mm KR-1 Titanium Twist-Fit Suture Anchor With USP 2 K-Braid (1X): White/Blue, With Needles: MO-6, Sterile
 - Ø3.5mm KR-1 Titanium Twist-Fit Suture Anchor With USP 2 K-Braid (2X): White & White/Blue, With Needles: MO-6, Sterile
 - Ø5.0mm KR-1 Titanium Twist-Fit Suture Anchor With USP 2 K-Braid (2X): White & White/Blue, With Needles: MO-6, Sterile
 - Ø6.5mm KR-1 Titanium Twist-Fit Suture Anchor With USP 2 K-Braid (2X): White & White/Blue, With Needles: MO-6, Sterile
 - Ø5.0mm KR-1 Titanium Twist-Fit Suture T-Anchor With USP 2 K-Braid (2X): White & White/Blue, With Needles: MO-6, Sterile
 - Ø6.5mm KR-1 Titanium Twist-Fit Suture T-Anchor With USP 2 K-Braid (2X): White & White/Blue, With Needles: MO-6, Sterile
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- Ø2.0mm KR-3 Titanium Twist-Fit Suture Anchor With USP 0 K-Braid (1X), White/Blue, Sterile



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

- Ø2.5mm KR-3 Titanium Twist-Fit Suture Anchor With USP 1 K-Braid (1X), White/Blue, Sterile
- Ø2.8mm KR-1 Titanium Twist-Fit Suture Anchor With USP 2 K-Braid (1X): White/Blue, Sterile
- Ø3.5mm KR-1 Titanium Twist-Fit Suture Anchor With USP 2 K-Braid (1X): White/Blue, Sterile
- Ø3.5mm KR-1 Titanium Twist-Fit Suture Anchor With USP 2 K-Braid (2X): White/Blue & White/Black, Sterile
- Ø5.0mm KR-1 Titanium Twist-Fit Suture Anchor With USP 2 K-Braid (2X): White/Blue & White/Black, Sterile
- Ø5.0mm KR-1 Titanium Twist-Fit Suture Anchor With USP 2 K-Braid (3X): White/Blue, White/Black & White, Sterile
- Ø6.5mm KR-1 Titanium Twist-Fit Suture Anchor With USP 2 K-Braid (2X): White/Blue & White/Black, Sterile

3. KR-1 PEEK OPTIMA Twist-Fit Suture Anchor with Needles**4. KR-1 PEEK OPTIMA Twist-Fit Suture Anchor**

KR-1 PEEK OPTIMA Twist-Fit Suture anchor is a fully threaded suture anchor featuring dual threads to maximize cortical and cancellous fixation. It is available in diameter of 4.5, 5.5 and 6.5mm with double and triple loaded options. It has a flat tip to protect the sutures and to facilitate the insertion. The anchor is particularly suitable for repairing rotator cuff and associated pathologies. The anchors are available with or without needles which are ideal for mini-open rotator cuff repair procedures.

- Ø4.5mm KR-1 PEEK OPTIMA Twist-Fit Suture Anchor With USP 2 K-Braid (2X): White & White/Blue, With Needles: MO-6, Sterile
- Ø5.5mm KR-1 PEEK OPTIMA Twist-Fit Suture Anchor With USP 2 K-Braid (2X): White & White/Blue, With Needles: MO-6, Sterile
- Ø6.5mm KR-1 PEEK OPTIMA Twist-Fit Suture Anchor With USP 2 K-Braid (2X): White & White/Blue, With Needles: MO-6, Sterile
- Ø4.5mm KR-1 PEEK OPTIMA Twist-Fit Suture Anchor With USP 2 K-Braid (2X): White/Blue & White/Black, Sterile
- Ø5.5mm KR-1 PEEK OPTIMA Twist-Fit Suture Anchor With USP 2 K-Braid (2X): White/Blue & White/Black, Sterile
- Ø6.5mm KR-1 PEEK OPTIMA Twist-Fit Suture Anchor With USP 2 K-Braid (2X): White/Blue & White/Black, Sterile
- Ø4.5mm KR-1 PEEK OPTIMA Twist-Fit Suture Anchor With USP 2 K-Braid (3X): White/Blue & White/Black & White, Sterile
- Ø5.5mm KR-1 PEEK OPTIMA Twist-Fit Suture Anchor With USP 2 K-Braid (3X): White/Blue & White/Black & White, Sterile
- Ø4.5mm KR-1 PEEK OPTIMA Twist-Fit Suture Anchor With USP 2 K-Braid (1X) 1.4mm Suture Tape (1X): White/Black & White/Blue, Sterile
- Ø5.5mm KR-1 PEEK OPTIMA Twist-Fit Suture Anchor With USP 2 K-Braid (1X) and 1.4mm Suture Tape (1X): White/Black & White/Blue, Sterile
- Ø6.5mm KR-1 PEEK OPTIMA Twist-Fit Suture Anchor With USP 2 K-Braid (1X) and 1.4mm Suture Tape (1X): White/Black & White/Blue, Sterile



KAULMED	INSTRUCTIONS FOR USE SHOULDER ARTHROSCOPY SYSTEM (EO STERILE)	KAUL-Medizintechnik GmbH Königsberger Straße 40 56269 Dierdorf, Germany
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INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

- Ø4.5mm KR-1 PEEK OPTIMA Twist-Fit Suture Anchor With 1.4mm Suture Tape (2X): White/Blue & White/Black, Sterile
- Ø5.5mm KR-1 PEEK OPTIMA Twist-Fit Suture Anchor With 1.4mm Suture Tape (2X): White/Blue & White/Black, Sterile
- Ø6.5mm KR-1 PEEK OPTIMA Twist-Fit Suture Anchor With 1.4mm Suture Tape (2X): White/Blue & White/Black, Sterile

5. KR-1 PEEK CF Twist-Fit Suture Anchor

KR-1 PEEK CF Twist-Fit Anchor is a fully threaded suture anchor featuring dual threads to maximize cortical and cancellous fixation. It is available in 4.5, 5.5 and 6.5mm with double and triple loaded options. It has a flat tip to protect the sutures and to facilitate the insertion. The anchor is particularly suitable for repairing the rotator cuff and associated pathologies.

- Ø4.5mm KR-1 PEEK CF Twist-Fit Suture Anchor With USP 2 K-Braid (3X): White/Blue & White/Black & White, Sterile
- Ø4.5mm KR-1 PEEK CF Twist-Fit Suture Anchor With USP 2 K-Braid (2X): White/Blue & White/Black, Sterile
- Ø5.5mm KR-1 PEEK CF Twist-Fit Suture Anchor With USP 2 K-Braid (3X): White/Blue & White/Black & White, Sterile
- Ø5.5mm KR-1 PEEK CF Twist-Fit Suture Anchor With USP 2 K-Braid (2X): White/Blue & White/Black, Sterile
- Ø6.5mm KR-1 PEEK CF Twist-Fit Suture Anchor With USP 2 K-Braid (2X): White/Blue & White/Black, Sterile
- Ø4.5mm KR-1 PEEK CF Twist-Fit Suture Anchor With USP 2 K-Braid (1X) and 1.4mm Suture Tape (1X): White/Black & White/Blue, Sterile
- Ø5.5mm KR-1 PEEK CF Twist-Fit Suture Anchor With USP 2 K-Braid (1X) and 1.4mm Suture Tape (1X): White/Black & White/Blue, Sterile
- Ø6.5mm KR-1 PEEK CF Twist-Fit Suture Anchor With USP 2 K-Braid (1X) and 1.4mm Suture Tape (1X): White/Black & White/Blue, Sterile
- Ø4.5mm KR-1 PEEK CF Twist-Fit Suture Anchor With 1.4mm Suture Tape (2X): White/Blue & White/Black, Sterile
- Ø5.5mm KR-1 PEEK CF Twist-Fit Suture Anchor With 1.4mm Suture Tape (2X): White/Blue & White/Black, Sterile
- Ø6.5mm KR-1 PEEK CF Twist-Fit Suture Anchor With 1.4mm Suture Tape (2X): White/Blue & White/Black, Sterile

6. KR-1 Labrumriss Suture Anchor, PEEK OPTIMA Eyelet

KR-1 Labrumriss Suture anchor is made with UHMWPE suture anchor body and PEEK OPTIMA eyelet tip. The anchor is designed to deliver efficiency and promote ease of use. The Labrumriss suture anchor is available in 1.8mm and 3.2mm diameter with various combination of K-Braid and suture tapes. It can be used for Bankart, SLAP, rotator cuff repair surgeries. The KR-1 Labrumriss Suture anchor provides a small footprint and also asserts subcortical fixation for anchor insertion. The drill guide and anchor driver combination is well-designed to improve the performance and reliability.

- Ø1.8mm KR-1 Labrumriss Suture Anchor, PEEK OPTIMA Eyelet With USP 2 K-Braid (1X): White/Blue, Sterile



KAULMED	INSTRUCTIONS FOR USE SHOULDER ARTHROSCOPY SYSTEM (EO STERILE)	KAUL-Medizintechnik GmbH Königsberger Straße 40 56269 Dierdorf, Germany
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INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

- Ø3.2mm KR-1 Labrumriss Suture Anchor, PEEK OPTIMA Eyelet With USP 2 K-Braid (2X): White/Blue & White/Black, Sterile
- Ø1.8mm KR-1 Labrumriss Suture Anchor, PEEK OPTIMA Eyelet With 1.4mm Suture Tape (1X): White/Blue, Sterile
- Ø3.2mm KR-1 Labrumriss Suture Anchor, PEEK OPTIMA Eyelet With USP 2 K-Braid (1X) And 1.4mm Suture Tape (1X): White/Black & White/Blue, Sterile

7. KR-1 Knotless PEEK CF Push-Fit Suture Anchor with Driver

8. KR-1 Knotless PEEK CF Push-Fit Suture Anchor

KR-1 knotless Push-Fit anchors provide a step-saving alternative to conventional knotted suture anchors. KR-1 knotless Push-Fit anchors are recommended for use in both large and small-joint soft tissue repairs (i.e. Bankart, SLAP Repair surgeries). PEEK CF Push-In Suture Anchors consists of carbon fibre reinforced PEEK OPTIMA and are available in a variety of diameters of 2.8mm, 3.5mm, 4.5mm and 5.5mm providing intraoperative flexibility. PEEK CF provides modulus of elasticity closely matching the cortical bone. It is non-absorbable, radiolucent, and MRI safe. The knotless technology of Push-Fit anchor also eliminates knot stacks associated with soft tissue irritation. The anchor is available with and without driver. The 4.5/5.5mm knotless anchor driver is provided separately in the instrument set. It is reusable driver that minimizes the cost of the surgery unlike the pre-loaded suture anchors.

- Ø2.8mm KR-1 Knotless PEEK CF Push-Fit Suture Anchor With Driver, With Suture Passer, Sterile
- Ø3.5mm KR-1 Knotless PEEK CF Push-Fit Suture Anchor With Driver, With Suture Passer, Sterile
- Ø4.5mm KR-1 Knotless PEEK CF Push-Fit Suture Anchor With Driver, With Suture Passer, Sterile
- Ø5.5mm KR-1 Knotless PEEK CF Push-Fit Suture Anchor With Driver, With Suture Passer, Sterile
- Ø2.8mm KR-4 Knotless PEEK CF Push-Fit Suture Anchor With Hip Length Driver, With Suture Passer, Sterile
- Ø4.5mm KR-1 Knotless PEEK CF Push-Fit Suture Anchor With Suture Passer, Sterile
- Ø5.5mm KR-1 Knotless PEEK CF Push-Fit Suture Anchor With Suture Passer, Sterile

9. KR-1 PEEK CF Push-Fit Suture Anchor

10. KR-1 PEEK CF Push-Fit Suture Anchor with needles

KR-1 PEEK CF Push-Fit Suture Anchor is a Push-Fit/ Bang-on anchor available in diameter of 2.8 and 3.5mm. It is available in double loaded sutures with and without needle options. The PEEK CF Push-Fit Suture Anchors are made of carbon fiber-reinforced PEEK-OPTIMA. The PEEK CF provides modulus of elasticity closely matching the cortical bone. It is non-absorbable, radiolucent, and MRI safe. The drill guide and drill bit are provided in the instrument set for the accurate placement of the anchor which minimizes the anchor slippage or breakage during the surgery. Anchor insertion and delivery are made simple by drilling a hole through a drill guide and inserting the anchor through the same drill guide into the drilled hole. The anchor is also available with needles which are ideal for mini-open Bankart or SLAP repair procedures.



KAULMED	INSTRUCTIONS FOR USE SHOULDER ARTHROSCOPY SYSTEM (EO STERILE)	KAUL-Medizintechnik GmbH Königsberger Straße 40 56269 Dierdorf, Germany
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INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

- Ø2.8mm KR-1 PEEK CF Push-Fit Suture Anchor With USP 2 K-Braid (1X): White/Blue, Sterile
- Ø3.5mm KR-1 PEEK CF Push-Fit Suture Anchor With USP 2 K-Braid (2X): White/Blue & White/Black, Sterile
- Ø2.8mm KR-1 PEEK CF Push-Fit Suture Anchor With USP 2 K-Braid (1X): White/Blue, With Needles: MO-6, Short Length, Sterile
- Ø3.5mm KR-1 PEEK CF Push-Fit Suture Anchor With USP 2 K-Braid (2X): White & White/Blue, With Needles: MO-6, Short Length, Sterile

11. KR-1 RCR PEEK OPTIMA Knotless Twist-Fit Anchor

KR-1 RCR PEEK OPTIMA Knotless Twist-Fit Anchors are fully threaded knotless anchors available in 4.75, 5.5 and 6.25mm diameters with PEEK OPTIMA anchor body and eyelet. These anchors are designed to be used with sutures or tapes for rotator cuff repair using the 'bridge' technique. Moreover, the 'knotless' technique consists of passing sutures or tapes of the medial row anchors through the tissue. They are finally inserted into the bone socket once they're loaded through the RCR anchor eyelet. This technique eliminates possible complications caused by knots compared to other conventional anchors. The eyelet of the anchor accommodates up to 6 sutures and 2 tapes at a time.

- Ø4.75mm x 15mm KR-1 RCR PEEK OPTIMA Knotless Twist-Fit Anchor, Sterile
- Ø5.5mm x 15mm KR-1 RCR PEEK OPTIMA Knotless Twist-Fit Anchor, Sterile
- Ø6.25mm x 15mm KR-1 RCR PEEK OPTIMA Knotless Twist-Fit Anchor, Sterile

12. KR-1 RCR PEEK CF Knotless Twist-Fit Anchor

KR-1 RCR PEEK CF Knotless Twist-Fit Anchors are fully threaded knotless anchors available in 4.75, 5.5 and 6.25mm diameters with PEEK CF anchor body and PEEK OPTIMA eyelet. These anchors are designed to be used with sutures or tapes for rotator cuff repair using the 'bridge' techniques. Moreover, the 'knotless' technique consists of passing sutures or tapes of the medial row anchors through the tissue. They are finally inserted into the bone socket once they're loaded through the RCR anchor eyelet. This technique eliminates possible complications caused by knots compared to other conventional anchors. The eyelet of the anchor accommodates up to 6 sutures and 2 tapes at a time.

- Ø4.75mm x 15mm KR-1 RCR PEEK CF Knotless Twist-Fit Anchor, Sterile
- Ø5.5mm x 15mm KR-1 RCR PEEK CF Knotless Twist-Fit Anchor, Sterile
- Ø6.25mm x 15mm KR-1 RCR PEEK CF Knotless Twist-Fit Anchor, Sterile

13. KR-1 Knotless PEEK OPTIMA Push-Fit Suture Anchor with Driver

KR-1 knotless Push-Fit Suture anchors are a step-saving alternative to conventional knotted suture anchors and are recommended for use in Bankart and SLAP repairs. The PEEK OPTIMA Push-Fit Suture Anchors are made of PEEK-OPTIMA (Poly-ether-ether-ketone). These Anchors are available in a variety of diameters of 2.8mm, 3.5mm, 4.5mm and 5.5mm providing



KAULMED	INSTRUCTIONS FOR USE SHOULDER ARTHROSCOPY SYSTEM (EO STERILE)	KAUL-Medizintechnik GmbH Königsberger Straße 40 56269 Dierdorf, Germany
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INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

intraoperative flexibility. The PEEK OPTIMA Push-Fit Suture Anchor is a one-piece body anchor with a material eyelet. It provides superior abrasion resistance due to PEEK's low coefficient friction. It is Biocompatible, radiolucent, and MRI safe. The knotless technology of Push-in anchor also eliminates knot stacks associated with soft tissue irritation.

- Ø2.8mm KR-1 Knotless PEEK OPTIMA Push-Fit Suture Anchor With Driver, With Suture Passer, Sterile
- Ø3.5mm KR-1 Knotless PEEK OPTIMA Push-Fit Suture Anchor With Driver, With Suture Passer, Sterile
- Ø4.5mm KR-1 Knotless PEEK OPTIMA Push-Fit Suture Anchor With Driver, With Suture Passer, Sterile
- Ø5.5mm KR-1 Knotless PEEK OPTIMA Push-Fit Suture Anchor With Driver, With Suture Passer, Sterile
- Ø2.8mm KR-4 Knotless PEEK OPTIMA Push-Fit Suture Anchor With Hip Length Driver, With Suture Passer, Sterile

14. KR-1 PEEK OPTIMA Push-Fit Suture Anchor

15. KR-1 PEEK OPTIMA Push-Fit Suture Anchor with Needles

KR-1 PEEK OPTIMA Push-Fit Suture Anchor is a Push-Fit/ Bang-on anchor available in diameter of 2.8 and 3.5mm. It is available in double loaded sutures with and without needle options. The PEEK OPTIMA Push-Fit Suture Anchors are made of PEEK-OPTIMA (Poly-ether-etherketone). The PEEK OPTIMA Push-Fit Suture Anchors are non-absorbable PEEK suture anchors with a material eyelet. It provides superior abrasion resistance due to PEEK's low coefficient friction. It is considered to be Biocompatible, radiolucent, and MRI safe. The drill guide and the drill bit are provided in the instrument set for an accurate placement of the anchor which minimizes the anchor slippage or breakage during the surgery. Anchor insertion and delivery are made simple by drilling a hole through a drill guide and inserting the anchor through the same drill guide into the drilled hole.

- Ø2.8mm KR-1 PEEK OPTIMA Push-Fit Suture Anchor With USP 2 K-Braid (1X): White/Blue, Sterile
- Ø3.5mm KR-1 PEEK OPTIMA Push-Fit Suture Anchor With USP 2 K-Braid (2X): White/Blue & White/Black, Sterile
- Ø2.8mm KR-1 PEEK OPTIMA Push-Fit Suture Anchor With USP 2 K-Braid (1X): White/Blue, With Needles: MO-6, Short Length, Sterile
- Ø3.5mm KR-1 PEEK OPTIMA Push-Fit Suture Anchor With USP 2 K-Braid (2X): White & White/Blue, With Needles: MO-6, Short Length, Sterile

16. KR-1 Knitted Suture Anchor

17. KR-1 Knitted Suture Anchor with Needles

KR-1 Knitted Suture Anchor Provides numerous advantages over traditional anchors for shoulder instability repair, rotator cuff repair procedures with its strong fixations, less bone removal and a push in techniques. Knitted anchor is available in diameter of 1.2mm, 1.5mm, 1.8mm and 2.9mm. It is available in single and double loaded options with various combination of K-Braid and suture tapes. The drill guide and 2.9mm Awl, 1.5mm drill bit are specially



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

designed for Knitted Suture Anchor while assuming an accurate hole placement for the anchor. The small 1.5mm footprint Knitted Suture anchor provides placement and fixation advantages when bone real estate is limited, especially during revision surgeries. The anchor is available with or without needles which are ideal for mini-open surgeries.

- Ø1.2mm KR-3 Knitted Suture Anchor With USP 0 K-Braid (1X): White/Blue, Sterile
 - Ø1.5mm KR-1 Knitted Suture Anchor With USP 2 K-Braid (1X): White/Blue, Sterile
 - Ø1.5mm KR-1 Knitted Suture Anchor With 1.4mm Suture Tape (1X): White/Blue, Sterile
 - Ø1.8mm KR-1 Knitted Suture Anchor With USP 2 K-Braid (2X): White/Blue & White/Green, Sterile
 - Ø1.8mm KR-1 Knitted Suture Anchor With USP 2 K-Braid (1X) and 1.4mm Suture Tape (1X): White/Black & White/Blue, Sterile
 - Ø2.9mm KR-1 Knitted Suture Anchor With USP 2 K-Braid (2X): White/Blue & White/Green, Sterile
 - Ø2.9mm KR-1 Knitted Suture Anchor With USP 2 K-Braid (3X): White, White/Blue & White/Green, Sterile
 - Ø2.9mm KR-1 Knitted Suture Anchor With USP 2 K-Braid (1X) and 1.4mm Suture Tape (1X): White/Black & White/Blue, Sterile
 - Ø2.9mm KR-1 Knitted Suture Anchor With 1.4mm Suture Tape (2X): White/Black & White/Blue, Sterile
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- Ø1.2mm KR-3 Knitted Suture Anchor With USP 0 K-Braid (1X): White/Blue, With Needles: MO-7, Sterile
 - Ø1.5mm KR-1 Knitted Suture Anchor With USP 2 K-Braid (1X): White/Blue, With Needles: MO-6, Sterile
 - Ø1.8mm KR-1 Knitted Suture Anchor With USP 2 K-Braid (2X): White/Blue & White/Green, With Needles: MO-6, Sterile
 - Ø1.8mm KR-1 Knitted Suture Anchor With USP 2 K-Braid (1X) and 1.4mm Suture Tape (1X): White/Black & White/Blue, With Needles: MO-6, Sterile
 - Ø2.9mm KR-1 Knitted Suture Anchor With USP 2 K-Braid (2X): White/Blue & White/Green, With Needles: MO-6, Sterile

18. KR-1 Sehno PEEK OPTIMA Twist-Fit Anchor

KR-1 Sehno PEEK OPTIMA Twist-Fit Anchor is ideal for proximal biceps tenodesis repair. It is available in 7.0, 8.0 and 9.0mm diameters with PEEK OPTIMA interference/tenodesis screw and PEEK OPTIMA Washer. The Eyelet is specifically designed to hold the biceps tendon at the bottom of the drill hole. After fixing up the tendon into the drill hole, it can be locked into the bone by advancing the tenodesis screw. The anchor is designed to save steps and minimize the length of the procedure.

- Ø7.0mm x 15mm KR-1 Sehno PEEK OPTIMA Twist-Fit Anchor, Sterile
- Ø8.0mm x 15mm KR-1 Sehno PEEK OPTIMA Twist-Fit Anchor, Sterile
- Ø9.0mm x 15mm KR-1 Sehno PEEK OPTIMA Twist-Fit Anchor, Sterile
- Ø7.0mm x 10mm KR-1 Sehno PEEK OPTIMA Twist-Fit Anchor, Sterile
- Ø8.0mm x 10mm KR-1 Sehno PEEK OPTIMA Twist-Fit Anchor, Sterile
- Ø9.0mm x 10mm KR-1 Sehno PEEK OPTIMA Twist-Fit Anchor, Sterile



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

19. KR-1 Sehno PEEK CF Twist-Fit Anchor

KR-1 Sehno PEEK CF Twist-Fit Anchor is ideal for proximal biceps tenodesis repair. It is available in 7.0, 8.0 and 9.0mm diameters with PEEK CF interference/tenodesis screw and PEEK OPTIMA washer. The Eyelet is specifically designed to hold the biceps tendon at the bottom of the drill hole. After fixing up the tendon into the drill hole, it can be locked into the bone by advancing the tenodesis screw. The anchor is designed to save steps and minimize the length of the procedure.

- Ø7.0mm x 15mm KR-1 Sehno PEEK CF Twist-Fit Anchor, Sterile
- Ø8.0mm x 15mm KR-1 Sehno PEEK CF Twist-Fit Anchor, Sterile
- Ø9.0mm x 15mm KR-1 Sehno PEEK CF Twist-Fit Anchor, Sterile
- Ø7.0mm x 10mm KR-1 Sehno PEEK CF Twist-Fit Anchor, Sterile
- Ø8.0mm x 10mm KR-1 Sehno PEEK CF Twist-Fit Anchor, Sterile
- Ø9.0mm x 10mm KR-1 Sehno PEEK CF Twist-Fit Anchor, Sterile

20. KR-1 AC Joint Button

KR-1 AC Joint Kit can be used for Acromioclavicular Joint (AC Joint) separation repair. The kit comprises of adjustable loop with round shaped button (Dia. 5.5mm) and oblong shaped button (L 12mm X W 3.2mm X H 1.5mm). A tunnel is made through the clavicle and coracoid using 1.5mm K-Wire and 3.5mm Cannulated Drill Bit. The kit is passed through 3.5mm drilling tunnel from clavicle to coracoid provides the fixation of round button on the clavicle and oblong shaped button on the coracoid. The AC Joint Kit provides a double locking mechanism which eliminates the need for knot tying and also provides very strong compression on the clavicles.

KR-1 AcroFix Button is a titanium button with holes that allow use of multiple suture tapes for AC joint reduction. It provides very strong compression on the clavicles. The button is laid on the outer surface of the clavicle or the underneath the coracoid. Only the suture material is passed through the clavicle and coracoid tunnel ensuring minimal bone loss during the procedures.

- KR-1 AcroFix Button (AC Joint), Sterile
- KR-1 AC Joint Kit, Titanium, Sterile

21. KR-1 K-Anchor Knotless PEEK OPTIMA Twist-Fit Anchor**22. KR-1 K-Anchor SP Knotless PEEK OPTIMA Twist-Fit Anchor, Self-Punching**

KR-1 K-Anchor Knotless PEEK OPTIMA Twist-Fit Anchors consists of PEEK-OPTIMA (Poly-ether-ether-ketone) material. The K-Anchor suture anchor comes with Dual start thread technology (fast inserting suture anchor) which allows anchor deployment in 3.5 rotation. Vented and cannulated K-Anchors are designed for repair and reconstruction with soft-tissue graft. K-Anchor is available with multiple K-Braid suture and suture tape configurations. K-Anchor eyelet can accommodate up to four 1.4mm tapes or four #2 sutures.

- KR-1 K-Anchor Ø3.5mm x 15.8mm Knotless PEEK OPTIMA Twist-Fit Anchor, Sterile
- KR-1 K-Anchor Ø4.75mm x 22.5mm Knotless PEEK OPTIMA Twist-Fit Anchor, Sterile
- KR-1 K-Anchor Ø5.5mm x 22.5mm Knotless PEEK OPTIMA Twist-Fit Anchor, Sterile



KAULMED	INSTRUCTIONS FOR USE SHOULDER ARTHROSCOPY SYSTEM (EO STERILE)	KAUL-Medizintechnik GmbH Königsberger Straße 40 56269 Dierdorf, Germany
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INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

- KR-1 K-Anchor SP Ø4.75mm x 24.5mm Knotless PEEK OPTIMA Twist-Fit Anchor, Self-Punching, Sterile
- KR-1 K-Anchor SP Ø5.5mm x 24.5mm Knotless PEEK OPTIMA Twist-Fit Anchor, Self-Punching, Sterile

23. KR-1 Knotless PEEK OPTIMA Push-Fit Suture Anchor

KR-1 knotless Push-Fit Suture anchors are a step-saving alternative to conventional knotted suture anchors and are recommended for use in Bankart and SLAP repairs. The PEEK OPTIMA Push-Fit Suture Anchors are made of PEEK-OPTIMA (Poly-ether-ether-ketone). These Anchors are available in a variety of diameters of 4.5mm and 5.5mm providing intraoperative flexibility. The PEEK OPTIMA Push-Fit Suture Anchor is a one-piece body anchor with a material eyelet. It provides superior abrasion resistance due to PEEK's low coefficient friction. It is Biocompatible, radiolucent, and MRI safe. The knotless technology of Push-Fit anchor also eliminates knot stacks associated with soft tissue irritation.

- Ø4.5mm KR-1 Knotless PEEK OPTIMA Push-Fit Suture Anchor With Suture Passer, Sterile
- Ø5.5mm KR-1 Knotless PEEK OPTIMA Push-Fit Suture Anchor With Suture Passer, Sterile

24. KR-1 PEEK CF Twist-Fit Suture Anchor with Needles

KR-1 PEEK CF Twist-Fit Anchor is a fully threaded suture anchor featuring dual threads to maximize cortical and cancellous fixation. It is available in 4.5, 5.5 and 6.5mm with double and triple loaded options. It has a flat tip to protect the sutures and to facilitate the insertion. The anchor is particularly suitable for repairing the rotator cuff and associated pathologies.

- Ø4.5mm KR-1 PEEK CF Twist-Fit Suture Anchor With USP 2 K-Braid (2X): White & White/Blue, With Needles: MO-6, Sterile
- Ø5.5mm KR-1 PEEK CF Twist-Fit Suture Anchor With USP 2 K-Braid (2X): White & White/Blue, With Needles: MO-6, Sterile
- Ø6.5mm KR-1 PEEK CF Twist-Fit Suture Anchor With USP 2 K-Braid (2X): White & White/Blue, With Needles: MO-6, Sterile

To achieve best results, do not use any of the KAUL-Medizintechnik GmbH's Shoulder 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 Shoulder Arthroscopy System components should ever be reused under any circumstances. Reuse may lead to infection and cross infection.

INTENDED USE/PURPOSE

The KAUL-Medizintechnik GmbH's Shoulder Arthroscopy System is indicated for use in the fixation of muscles, ligaments and tendon in patients requiring muscle, ligament or tendon repair.

MATERIALS

The KAUL-Medizintechnik's Shoulder Arthroscopy System implant components are fabricated from PEEK OPTIMA and PEEK CF described by such standards as ASTM F2026 and ASTM F3333



KAULMED	INSTRUCTIONS FOR USE SHOULDER ARTHROSCOPY SYSTEM (EO STERILE)	KAUL-Medizintechnik GmbH Königsberger Straße 40 56269 Dierdorf, Germany
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INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

respectively, UHMWPE Suture as per ASTM F2848-17, Titanium Alloy as per ISO 5832-3/ASTM F136 and Stainless Steel as per ISO 7153-1/ASTM F899 and Handle made up of Polycarbonate.

INDICATIONS OF USE

The KAUL-Medizintechnik GmbH's Shoulder Arthroscopy System is indicated for use in Bankart lesion repairs, SLAP lesion repairs, Acromioclavicular separation repairs, Rotator cuff tear repairs, Capsular shift or Capsulolabral reconstructions, Biceps tenodesis, and Deltoid Repairs.

CONTRAINDICATIONS

- Any case not described in the indications.
- In patients where there is a possibility for conservative treatment.
- Active, suspected or latent infection in the affected area.
- Sepsis
- Insufficient quantity or quality of bone, osteoporosis
- Blood supply limitations or other systemic conditions that may retard healing.
- Fever or leukocytosis.
- Foreign body sensitivity, if suspected.
- Female, who is pregnant or planning pregnancy (*If any case, the patients must need to implant, the patients should consult their gynecologist first.*)

WARNINGS & PRECAUTIONS

- The implants and instruments are intended only for professional use by a licensed surgeon.
- Do not re-use or re-sterilize an implant provided in sterile packaging if the package has been damaged. The sterility may be compromised and the cleanliness of the implant may be uncertain. Report damaged packaging to your distributor or KAULMED.
- Mixing implant components from different manufacturers is not recommended for metallurgical, mechanical and functional reasons.
- Do not use the sterile product past the use-by date. Refer to the device label.
- Implants should be stored in appropriate protective packages, in a clean, dry place with a moderate temperature and under conditions that provide protection from direct sunlight.
- The treatment or implant may fail, including sudden failure, because of Loose fixation and/or loosening, Stress, including stress from inappropriate bending of the implant during surgery, Stress concentrations
- Failure is more likely if the implant experiences increased loads due to delayed union, nonunion, or incomplete healing. Failure is more likely if the patient does not follow post-operative care instructions.
- Nerve or soft tissue damage may result from surgical trauma or the presence of an implant.
- Implants may cause distortion and/or block the view of anatomic structures on radiographic images.
- Female patient who is pregnant or planning pregnancy after the implantation of medical implant, Pregnancy alters the immune system and hormone levels, which could influence how the body reacts to an implanted device. This might increase the risk of inflammation, infection, or rejection of the device. Similarly, Sedatives, anesthesia, or other drugs used during the procedure could cross the placenta and affect fetal development. potentially affecting uterine blood flow and fetal well-being Surgical procedures can stress the body. Planning of pregnancy should avoid un-till, Intended use of achieved. Patients who are pregnant should be aware of the warning.

TARGET PATIENT GROUP

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



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

INTENDED USER GROUP

The KAULMED Shoulder Arthroscopy System is recommended to be used by only well-trained, certified and experienced surgeons.

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 Shoulder Arthroscopy System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of KAUL-Medizintechnik GmbH's Shoulder Arthroscopy System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

CLINICAL BENEFITS

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

PERFORMANCE CHARACTERISTICS

The KAUL-Medizintechnik GmbH's Shoulder 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

- Pain, discomfort, inflammation, scar, abnormal sensations, nerve or soft tissue damage, necrosis of bone or tissue, bone resorption, or inadequate healing from the presence of an implant or due to surgical trauma.
- Implant fracture due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion. Implant migration and/or loosening may occur.
- Metal sensitivity, histological, allergic or adverse foreign body reaction resulting from implantation of a foreign material.



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

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 muscle/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 Shoulder Arthroscopy System surgical technique. KAUL-Medizintechnik GmbH's Shoulder 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 Shoulder 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.
- To ensure proper protection of the fixation device until healing is complete, patient should be advised to follow the following:
 - Immobilization: Ensure the affected area is kept still using a splint, cast, or brace as recommended by a healthcare professional. This helps prevent movement that could disrupt healing.
 - Weight Bearing: Follow guidelines regarding weight-bearing activities. If advised, avoid putting weight on the affected limb to reduce stress on the fixation device.
 - Activity Modification: Limit activities that could strain the fixation site. Avoid high-impact sports or activities that risk falling or bumping the area.
 - Wound Care: Keep any surgical sites clean and dry. Follow specific wound care instructions provided by your healthcare provider.
 - Regular Check-ups: Attend follow-up appointments to monitor healing progress and ensure the device remains correctly positioned.



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

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

- Pain Management: Use prescribed medications as needed to manage pain, as discomfort can lead to unintended movements.

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.
- Patients should be advised to avoid smoking and consuming alcohol during the healing process for ligaments. Smoking can restrict blood flow and impair tissue healing, while alcohol can negatively affect the inflammatory response and overall recovery. By avoiding these substances, patients can enhance their healing potential and improve the success of their rehabilitation. Encouraging a healthy lifestyle during recovery is essential for optimal outcomes.
- If the healing of soft tissue or bone around an implant is not properly immobilized, it can lead to excessive stress on the implant. This can hinder healing and potentially result in complications such as implant failure, re-tear of repaired tissues, or chronic pain. Proper stabilization is crucial to ensure that the healing process proceeds effectively and that the implant maintains its position and function during recovery.

More of the following complications may occur:

- (1) Migration of implant position, possibly Resulting in injury; (2) Risk of additional injury from postoperative trauma; (3) Pain, discomfort, or abnormal sensations due to the presence of the device; (4) Possible increased risk of infection. In such complications re-surgery/removal of an Implant may be 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 Shoulder 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.



KAULMED	INSTRUCTIONS FOR USE SHOULDER ARTHROSCOPY SYSTEM (EO STERILE)	KAUL-Medizintechnik GmbH Königsberger Straße 40 56269 Dierdorf, Germany
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INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

STERILIZATION

Ethylene Oxide (EO) Sterilization-"KAUL-Medizintechnik GmbH's Shoulder 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 at a dry place. Care should be taken in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments. The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct and the temperature range shall be 10°C to 25°C.

Lifetime of the Product

Shoulder 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 explant 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 Shoulder Arthroscopy System component(s) 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 is 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 Manufacturer, 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.









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.











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

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—General requirements.	5.1.3
	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







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

	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
	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).	ISO & ANSI/AAMI/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



KAULMED	INSTRUCTIONS FOR USE SHOULDER ARTHROSCOPY SYSTEM (EO STERILE)	KAUL-Medizintechnik GmbH Königsberger Straße 40 56269 Dierdorf, Germany
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INSTRUCTION FOR USE, KAUL-REG-SOF-010-F9

	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)).
	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


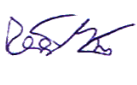




Legal Manufactured by:
KAUL-MEDIZINTECHNIK GMBH.
Address Manufacturing Unit:
Königsberger Straße 40
56269 Dierdorf, Germany
Website: <https://www.KAULMED.com/>
Single Registration Number: DE-MF-000009240



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

Revision History Table:

S. No.	Document No	Rev. No.	Description of Revision	Effective date	Prepared by	Approved by
1.	KAUL-IFU-SAS/S-05	00	Initially released	11-11-2025		
2.	KAUL-IFU-SAS/S-05	01	Information related to life and the removal of the product is added as per the LOF 1	22-12-2025		
3.	KAUL-IFU-SAS/S-05	02	Added description of the variant.	06-02-2026	