SUMMARY OF SAFETY AND CLINICAL PERFORMANCE FOR AUXILOCK KNEE ARTHROSCOPY SYSTEM

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1. The identification of the device and the manufacturer, including the Basic UDI-DI and, if already issued, the SRN.

Basic UDI-DI: 08903993KAS005LH and 08903993MRS005PW

SRN: IN-MF-000018837

The AUXILOCK Knee Arthroscopy System includes the following variants as listed below:

NAKED BUTTON

AUXILOCK® GFS Mini Naked Button L: 12mm, W: 3.9mm

AUXILOCK® GFS II Large Naked Button L: 16.5mm, W: 4.4mm

AUXILOCK® Ultimate Mini Naked Button L: 12mm, W: 3.9mm

AUXILOCK® Ultimate Large Naked Button L: 16.5mm, W: 3.9mm

ADJUSTABLE LOOP BUTTON

AUXILOCK® GFS Ultimate Mini Button, Button L: 12mm, W: 3.9mm (Adjustable Loop)

AUXILOCK® GFS Ultimate Large Button, Button L: 16.5mm, W: 3.9mm (Adjustable Loop)

MINI LOOP BUTTON

AUXILOCK® GFS Mini, Loop: 12mm to 55mm, Button L: 12mm, W: 3.9mm

LARGE LOOP BUTTON

AUXILOCK® GFS II Large, Loop: 12mm to 55mm, Button L: 16.5mm, W: 4.4mm

BUTTON EXTENDER

AUXILOCK® GFS Button Extender, L: 18mm, W: 5.0mm

AUXILOCK® GFS NO-BUTTON ADJUSTABLE LOOP

AUXILOCK® GFS No-Button Adjustable Loop

AUXILOCK® GFS CONCAVE BUTTON

AUXILOCK® GFS Concave Button 11mm with 4mm Collar
AUXILOCK® GFS Concave Button 14mm with 7mm Collar
AUXILOCK® GFS Concave Button 20mm with 9mm Collar
AUXILOCK® GFS Round Button without Collar, 14mm

PEEK CF INTERFERENCE SCREW

AUXILOCK® PEEK CF Interference Screw (Dia. 7mm to 12mm and Length 20mm to 35mm)

PEEK OPTIMA INTERFERENCE SCREW

AUXILOCK® PEEK OPTIMA Interference Screw (Dia. 7mm to 12mm and Length 20mm to 35mm)

TITANIUM INTERFERENCE SCREW

AUXILOCK® Titanium Interference Screw (Dia. 7mm to 12mm and Length 20mm to 35mm)

LIGAMENT STAPLE

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

MENISCO INSIDE-OUT MENISCAL REPAIR NEEDLE

AUXILOCK® MENISCO Inside-Out Meniscal Repair Needle with #2-0 BioBraid: White/Blue, Length 36In, Needle Length 25cm
AUXILOCK® MENISCO Inside-Out Meniscal Repair Needle with #0 BioBraid: White/Blue, Length 36In, Needle Length 25cm
AUXILOCK® MENISCO Inside-Out Meniscal Repair Needle with 1.0mm Suture Tape: White/Blue, Length 36In, Needle Length 25cm

MENI-FIX ALL-INSIDE MENISCAL REPAIR SYSTEM

AUXILOCK® MENI-FIX All-Inside Meniscal Repair System - Straight Needle
AUXILOCK® MENI-FIX All-Inside Meniscal Repair System - Curve Needle
AUXILOCK® MENI-FIX All-Inside Meniscal Repair System - Reverse Curve Needle

AUXILOCK BIOBRAID

AUXILOCK® Two #2 BioBraid: White/Blue & White/Black, 36in Total Length
AUXILOCK® #2 BioBraid: Blue, With Needles: MO-6 & CE, 36in Total Length
AUXILOCK® #2 BioBraid: White, With Needle: MO-6, 36in Total Length
AUXILOCK® #2 BioBraid: White/Black, With Needle: MO-6, 36in Total Length
AUXILOCK® #2 BioBraid: White/Blue, With Needle: MO-6, 36in Total Length
AUXILOCK® #2 BioBraid: White/Black, 36in Total Length
AUXILOCK® #2 BioBraid: White/Green, With Needle: MO-6, 36in Total Length
AUXILOCK® #2 BioBraid: White/Green, 36in Total Length
AUXILOCK® #2 BioBraid: Blue, 36in Total Length
AUXILOCK® #2 BioBraid: White, 36in Total Length
AUXILOCK® #2 BioBraid: White/Blue, 36in Total Length
AUXILOCK® #2-0 BioBraid: White/Blue, 36in Total Length
AUXILOCK® #0 BioBraid: White/Blue, With Needle: MO-6, 36 inch
AUXILOCK® #1 BioBraid: White/Blue, With Needle: MO-6, 36 inch

AUXILOCK® #0 BioBraid: White/Blue, 36 inch
AUXILOCK® #1 BioBraid: White/Blue, 36 inch
AUXILOCK® #2 BioBraid: White, With Needle: CCS, 36in Total Length
AUXILOCK® #5 BioBraid: White, With Needle: CCS, 36in Total Length
AUXILOCK® 1.8mm BioBraid Suture Tape: White/Blue, 39in Total length
AUXILOCK® 1.4mm BioBraid Suture Tape: White/Blue, 39in Total length
AUXILOCK® #2 BioBraid Infinity Loop: White, With Needle: Straight, 20in Loop Length, 24in Total Length
AUXILOCK® #2 BioBraid Infinity Loop: White/Blue, With Needle: Straight, 20in Loop Length, 24in Total Length
AUXILOCK® #5 BioBraid Infinity Loop: White/Blue, With Needle: Straight, 20in Loop Length, 24in Total Length
AUXILOCK® 1.4mm BioBraid Suture Tape: White/Black, 39in Total length
AUXILOCK® 2.0mm BioBraid Suture Tape: White/Blue, 39in Total length
AUXILOCK® 1.0mm BioBraid Suture Tape: White/Blue, 39in Total length
AUXILOCK® 1.4mm BioBraid Suture Tape: Solid Black, 39in Total length

Details Regarding the device are provided in below table:

Device Trade Name:	**AUXILOCK Knee Arthroscopy System**		
Manufacturer Details	**Name & Address of Manufacturer:** Auxein Medical Pvt. Ltd. **Manufacturing Unit:** Plot No. 168-169-170, Phase IV, Kundli Industrial Area, HSIIDC, Sector-57, Sonipat, Haryana– 131028, India **Phone:** +91-9910643638 **Email: info@auxeinmedical.com** **Website: www.auxein.com**		
Manufacturer's SRN	IN-MF-000018837		
Parameter	**Details**	**Certified By**	**Certificate Number**
Legacy Device	Yes, AUXILOCK Knee Arthroscopy System	DNV Product Assurance AS	10000434275-PA-NA-

	(Certified under MDD 93/42/EEC)		IND Rev. 0.0
Year when the first certificate (CE) was issued covering the device	2021		
Raw Materials of Implants	The Raw Materials used for manufacturing the Implants consists of Titanium Alloy (Ti-6Al-4V) as per EN ISO 5832-3:2021, PEEK OPTIMA as per ASTM F2026 and PEEK CF as per ASTM F3333, Stainless Steel as per EN ISO 5832-1:2024 and UHMWPE Yarn/Suture (BioBraid) as per ASTM F2848.		
USFDA Cleared	Yes (AUXILOCK Knee Arthroscopy System are approved by USFDA whose details are as follow:) **510(k) Number:** K213018, K203029		
Conformity Assessment Route	Conformity Assessment of Class IIb devices has been conducted as per Article 52 (4), Chapter I and III of Annex IX of EU MDR 2017/745.		
Risk Class	IIb {According to REGULATION (EU) 2017/745 (MDR) OF THE EUROPEAN PARLIAMENT, Annex VIII, Chapter-3, Rule 8 - Implantable devices and long-term surgically invasive devices (> 30 days)} are in Class IIb unless they are intended: 1. Are intended to be placed in the teeth, in which case they are classified as class IIa; **Applicable/ Not Applicable: Not Applicable** Justification: The AUXILOCK Knee Arthroscopy System intended to be placed in Knee joint to repair ligaments. 2. 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; **Applicable/ Not Applicable: Not Applicable** Justification: The AUXILOCK Knee Arthroscopy System comes in contact with the knee joint. Thus, it does not come in contact with the heart, the central circulatory system or the central nervous system. 3. Have a biological effect or are wholly or mainly absorbed, in which case they are classified as class III; **Applicable/ Not Applicable: Not Applicable**		

Justification: The AUXILOCK Knee Arthroscopy System is made up of medical grade metallic alloy and Polymer. Metallic alloy/Polymer does not achieve its intended use by biological effect or by absorption.

4. 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;

Applicable/ Not Applicable: Not Applicable

Justification: The Auxilock Knee Arthroscopy system is made up of medical grade metallic elements/polymers. These metallic element/polymer have high metallic bonds that do not undergo chemical change in the body.

5. Are intended to administer medicinal products, in which case they are classified as class III;

Applicable/ Not Applicable: Not Applicable

Justification: The AUXILOCK Knee Arthroscopy System implants made up of metal alloys/polymer to provide fixation for the repair of ligaments. The system is not intended to administer medicinal products.

6. Are active implantable devices or their accessories, in which cases they are classified as class III;

Applicable/ Not Applicable: Not Applicable

Justification: The AUXILOCK Knee Arthroscopy System does not depend on a source of energy. Thus it is not an active device.

7. Are breast implants or surgical meshes, in which cases they are classified as class III;

Applicable/ Not Applicable: Not Applicable

Justification: The AUXILOCK Knee Arthroscopy System fix the ligament rupture. Not intended as breast implants or surgical meshes.

8. Are total or partial joint replacements, in which case they are classified as class III, except ancillary components

	such as screws, wedges, plates and instruments; or; **Applicable/ Not Applicable: Not Applicable** Justification: The AUXILOCK Knee Arthroscopy System repair the ligaments. Not intended for Total or Partial Joint Replacements. 9. 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 except components such as screws, wedges, plates and instruments: **Applicable/ Not Applicable: Not Applicable** Justification: The AUXILOCK Knee Arthroscopy System is an implantable device to fix the ligaments. The AUXILOCK Knee Arthroscopy System is not recommended for the Spinal Disc Replacement Implants and do not come into contact with the spinal column.
Authorized Representative Name and Address	**Name:** CMC Medical Devices & Drug S.L **Address:** 29015 Málaga, Spain
Authorized Representative SRN	ES-AR-00000029
Notified Body Name and Single Identification Number	**Name:** DNV Product Assurance AS **Single Identification Number:** 2460

2. The intended purpose of the device and any indications, contraindications and target populations.

The Indications, Contraindication and Intended Patient Population related information is provided in below table:

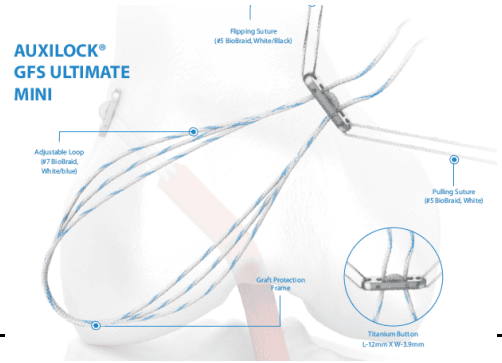
Indications of Use	The Auxilock Knee Arthroscopy System is indicated for used in reconstruction or repair of Knee ligaments (ACL, PCL). These devices are also used for treating meniscal tears in the anterior, middle and posterior horns of the meniscus.
Contraindications	Contraindications may be relative 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. ○ Active, suspected or latent infection in the affected area. ○ Blood supply limitations or other systemic conditions that may retard healing. ○ Fever or leukocytosis. ○ Foreign body sensitivity, if suspected.
Intended Patient Population	Male or Female, aged between 18 to 75 years and skeletally mature patient.
Intended Users	The AUXILOCK Knee Arthroscopy Systems are to be used by well experienced, qualified & specialized trained surgeons only.
Category	Non-Active, Implantable, Long term, Surgically Invasive Device.
Use	For Single Use only
Contact Duration	Long Term, intended for continuous use for more than 30 days (classified as per EU MDR 2017/745 as amended).
Biocompatibility	The devices covered in the AUXILOCK Knee Arthroscopy System are Bio-compatible. Biocompatibility of the devices is tested as per EN ISO 10993-1:2020 series of International Standard.

3. Description of the device

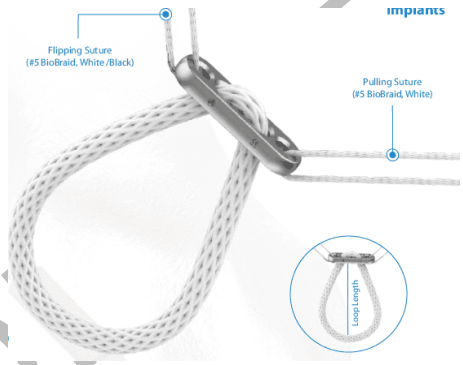
Naked Button		
S. No.	Device Name	AUXILOCK® NAKED BUTTON
1.	Picture	

	Description	GFS 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 GFS may eliminate the need for a stepped tunnel technique and are considered to be an excellent choice for revision surgeries.			
	Code	Product Description	Length	Width	Height
	6-007-11	AUXILOCK GFS Mini Naked Button L: 12mm, W: 3.9mm	12mm	3.9mm	1.5mm
	6-008-09	AUXILOCK GFS II Large Naked Button L: 16.5mm, W: 4.4mm	16.5mm	4.4mm	2.8mm
	6-006-03	AUXILOCK Ultimate Mini Naked Button L: 12mm, W: 3.9mm	12mm	3.9mm	1.5mm
	6-006-04	AUXILOCK Ultimate Large Naked Button L: 16.5mm, W: 3.9mm	16.5mm	3.9mm	1.5mm
	Raw Material	Titanium Alloy as per EN ISO 5832-3/ASTM F136.			

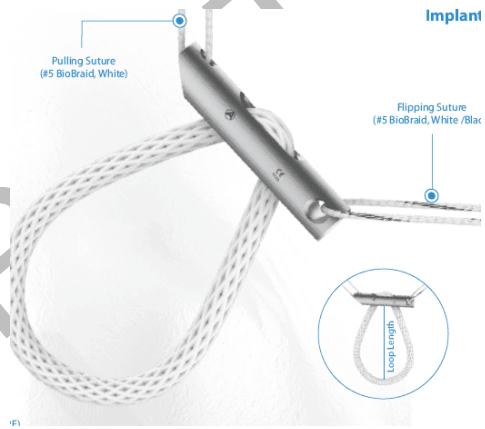
Adjustable Loop Button		
S. No.	Device Name	AUXILOCK® GFS ULTIMATE LARGE/AUXILOCK® GFS ULTIMATE MINI
2.	Picture	

	Description	GFS Ultimate Mini is an adjustable loop with an oblong shaped titanium button used for Cruciate Graft Reconstructions. GFS Ultimate provides a double locking mechanism which eliminates the need for knot tying. GFS Ultimate Mini provides three sutures (UHMWPE): Adjustable Suture (#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 (#5, White): It is available to pull the graft inside the tunnel. Flipping Suture (#5, White/Black): It ensures the flipping of the button. GFS Ultimate Large is an adjustable loop with an oblong shaped titanium button used for Cruciate Graft Reconstructions. GFS Ultimate provides a double locking mechanism which eliminates the need for knot tying. Hence, GFS Ultimate Large is considered as an excellent choice for revision surgeries. GFS Ultimate Large provides three sutures (UHMWPE): Adjustable Suture (#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 (#5, White): It is available to pull the graft inside the tunnel. Flipping Suture (#5, White/Black): It ensures the flipping of the button.	
	Code	Product Description	Length of Loop (mm)
	6-006-01	AUXILOCK® GFS Ultimate Mini Button, Button L: 12mm, W: 3.9mm (Adjustable Loop)	Max: 70, Min: 12
	6-006-02	AUXILOCK® GFS Ultimate Large Button, Button L: 16.5mm, W: 3.9mm	Max: 70, Min: 12

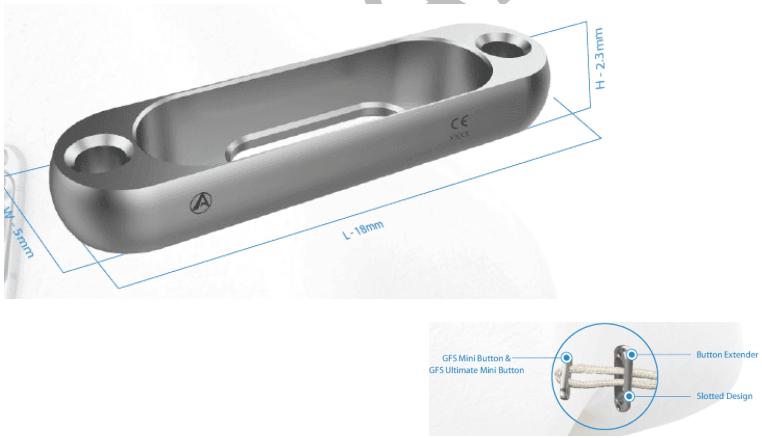
		(Adjustable Loop)	
	Raw Material	Titanium Alloy as per EN ISO 5832-3/ASTM F136 and UHMWPE Suture as per ASTM F2848.	

Mini Loop Button				
S. No.	Device Name	AUXILOCK® GFS Mini		
3.	Picture			
	Description	GFS Mini is a fixed loop with an oblong shaped button used for Graft Fixations in ACL/PCL Reconstruction. Being a continuous loop without any joint, GFS Mini provides a stronger fixation while eliminating the need for knot 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 GFS Mini button to pass easily into it. The fixed loop is made of UHMWPE (Ultra High Molecular Weight Polyethylene) and the oblong Button is made of titanium material. Pulling Suture (#5, White) : It is available to pull the graft inside the tunnel. Flipping Suture (#5, White/Black) : It ensures the flipping of the button.		
	Code	Product Description	Length	Width

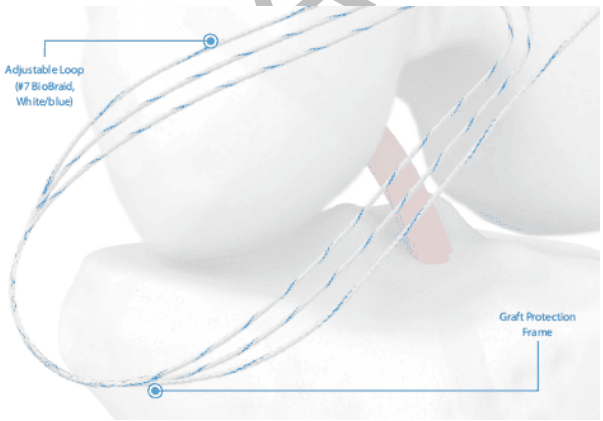
	6-007-01 to 6-007-10	AUXILOCK® GFS Mini, Loop: 12mm to 55mm, Button L: 12mm, W: 3.9mm	12mm	3.9mm
	Raw Material	Titanium Alloy as per EN ISO 5832-3/ASTM F136 and UHMWPE Suture as per ASTM F2848.		

Large Loop Button		
S. No.	Device Name	AUXILOCK® GFS Large
4.	Picture	
	Description	GFS II Large is a fixed loop with an oblong shaped button used for Graft Fixations in ACL/PCL Reconstruction. Being a continuous loop without any joint, GFS II Large provides a stronger fixation and also eliminates the need for knot tying. The GFS II Large includes a larger button compared to GFS Mini which eliminates the need for a stepped tunnel technique. Hence, GFS II 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 fiipping of the button in the transosseous tunnel. GFS II Large is available in various pre-measured loop sizes. The fixed loop is made up of

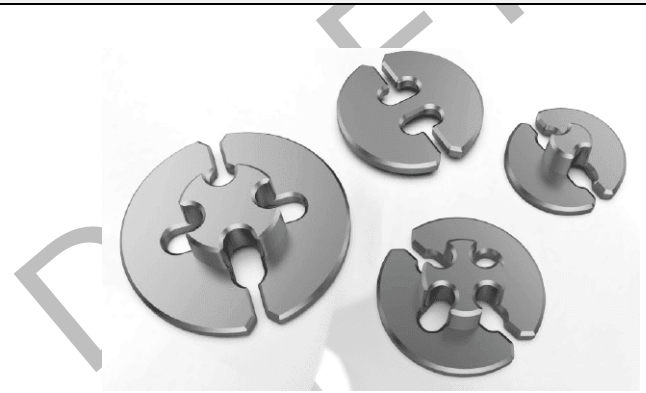
		UHMWPE (Ultra High Molecular Weight Polyethylene) while the oblong button is made up of titanium material. Pulling Suture (#5, White) : It is available to pull the graft inside the tunnel. Flipping Suture (#5, White/Black) : It ensures the flipping of the button.		
	Code	Product Description	Length	Width
	6-008-01 to 6-007-11	AUXILOCK® GFS II Large, Loop: 12mm to 55mm, Button L: 16.5mm, W: 4.4mm	16.5mm	4.4mm
	Raw Material	Titanium Alloy as per EN ISO 5832-3/ASTM F136 and UHMWPE Suture as per ASTM F2848.		

Button Extender		
S. No.	Device Name	AUXILOCK® GFS Button Extender
5.	Picture	
	Description	GFS Button Extender is an extension device designed to provide extended surface area during cruciate graft reconstructions.It can be used in conjunction with the GFS Mini and GFS Ultimate Mini button providing an

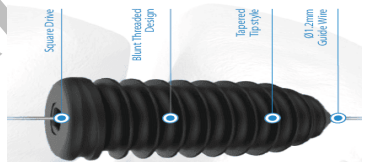
		effective solution for cortical blowouts. It also helps overcome intraoperative complications seen in revision surgeries.		
	Code	Product Description	Length	Width
	6-032-01	AUXILOCK® GFS Button Extender, L: 18mm, W: 5.0mm	18mm	5mm
	Height	2.3mm		
	Slot Depth	1.7mm		
	Raw Material	Titanium Alloy as per EN ISO 5832-3/ASTM F136.		

AUXILOCK® GFS No-Button Adjustable Loop		
S. No.	Device Name	AUXILOCK® GFS No-Button Adjustable Loop
6.	Picture	
	Description	GFS 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).

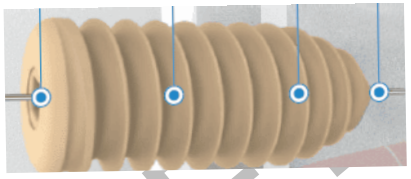
		Adjustable Suture (#7, White/Blue): It allows the surgeon to maximize the amount of graft inside the femoral tunnel, thereby optimizing the healing process. It also enables calibration of the loop to its optimum size.	
	Code	Product Description	Length of Loop (mm)
	6-049-01	AUXILOCK® GFS No-Button Adjustable Loop	Max: 70, Min: 12
	Raw Material	UHMWPE Suture as per ASTM F2848.	

AUXILOCK® GFS Button		
S. No.	Device Name	AUXILOCK® GFS Button
7.	Picture	
	Description	The GFS Concave Button is an attachable Button System that has revolutionized tibial fixation of ACL and PCL grafts. GFS 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 GFS Concave Button implant include: Maximum graft-to-bone contact improves incorporation and healing the ability to retension grafts after fixation and knee cycling several different button options for sockets and full tunnels

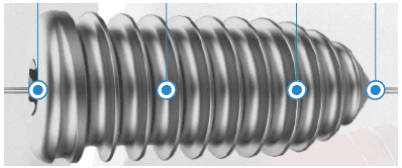
	Code	Product Description
	6-050-01	AUXILOCK® GFS Concave Button 11mm with 4mm Collar
	6-050-02	AUXILOCK® GFS Concave Button 14mm with 7mm Collar
	6-050-03	AUXILOCK® GFS Concave Button 20mm with 9mm Collar
	6-050-04	AUXILOCK® GFS Round Button without Collar, 14mm
	Raw Material	Titanium Alloy as per EN ISO 5832-3/ASTM F136.

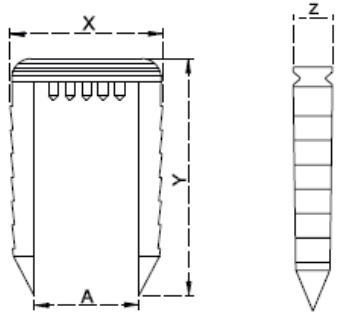
PEEK CF Interference Screw		
S.No.	Device Name	AUXILOCK® PEEK CF Interference Screw
8.	Picture	
	Description	The PEEK CF Interference Screw is made of A carbon fiber reinforced PEEK OPTIMA from Invibio, USA. The polymer in PEEK CF enhances the physical strength by nearly twice as much as natural PEEK. 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.
	Code	6-009-01 to 6-009-20
	Diameter (mm)	7 to 12
	Length (mm)	20 to 35

	Raw Material Specification	PEEK CF as per ASTM F3333.

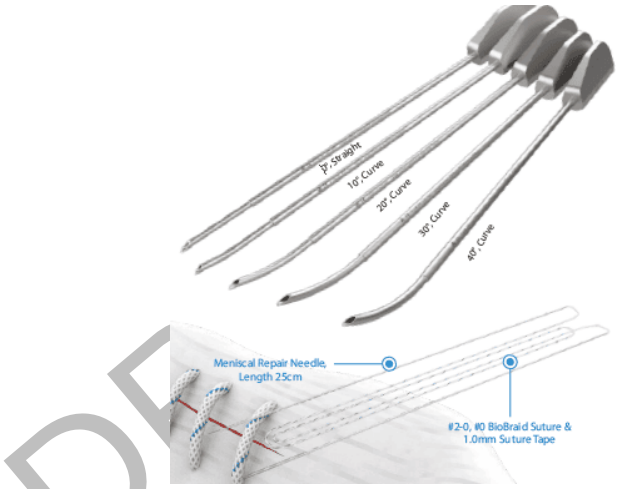
PEEK OPTIMA Interference Screw		
S.No.	Device Name	AUXILOCK® PEEK OPTIMA Interference Screw
9.	Picture	
	Description	The PEEK OPTIMA (From Invibio, USA) interference screw is made up of PEEK (Poly-Ether-Ether-Ketone). PEEK is a thermoplastic material and has radiolucent properties for easy artefact free 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 help minimize stress shielding and also stimulates bone healing.
	Code	6-014-01 to 6-014-20
	Diameter (mm)	7 to 12
	Length (mm)	20 to 35
	Raw Material Specification	PEEK OPTIMA as per ASTM F2026.

Titanium Interference Screw		
S.No.	Device Name	AUXILOCK® Titanium Interference Screw

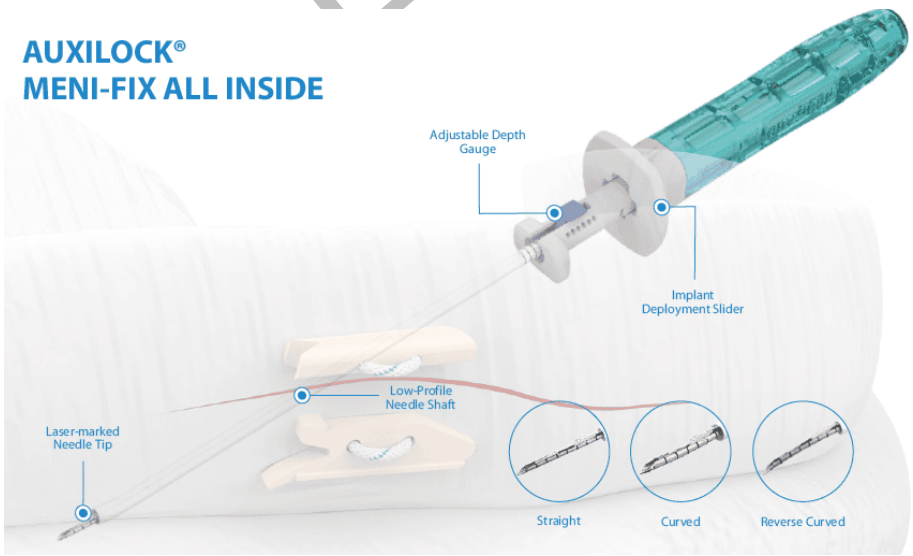
10.	Picture	
	Description	The Titanium interference screw is made up of Titanium alloy. The screw has a fully threaded design which provides strong mechanical fixation for both Bone-Tendon-Bone (BTB) and soft tissue grafts. The rounded edge of the threads protects tissue grafts. Titanium Interference Screw is a cannulated screw to be used with guide wire and cannulated screw driver.
	Code	6-010-01 to 6-010-21
	Diameter (mm)	7 to 12
	Length (mm)	20 to 35
	Raw Material Specification	Titanium as per EN ISO 5832-3/ASTM F136.

Ligament Staple		
S.No.	Device Name	Ligament Staple
11.	Picture	

	Description	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.		
	Code	Product Description		
	464-8-13-20	Ligament Staple, 8mm x 13mm x 20mm, Titanium		
	464-6-11-25	Ligament Staple, 6mm x 11mm x 25mm, Titanium		
	464-8-13-25	Ligament Staple, 8mm x 13mm x 25mm, Titanium		
	464-11-16-25	Ligament Staple, 11mm x 16mm x 25mm, Titanium		
	464-16-21-25	Ligament Staple, 16mm x 21mm x 25mm, Titanium		
	Dimension			
	A	X	Y	Z
	8mm	13mm	20mm	3.7mm
	6mm	11mm	25mm	3.7mm
	8mm	13mm	25mm	3.7mm
	11mm	16mm	25mm	3.7mm
	16mm	21mm	25mm	3.7mm
	Raw Material Specification	Titanium as per EN ISO 5832-3/ASTM F136.		

MENISCO Inside-Out Meniscal Repair Needle		
S. No.	Device Name	AUXILOCK® MENISCO Inside-Out Meniscal Repair Needle
12.	Picture	
	Description	Menisco 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 #2-0, #0 BioBraid 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.
	Code	Product Description
	6-047-01	AUXILOCK® MENISCO Inside-Out Meniscal Repair Needle with #2-0 BioBraid: White/Blue, Length 36in, Needle Length 25cm

	6-047-02	AUXILOCK® MENISCO Inside-Out Meniscal Repair Needle with #0 BioBraid: White/Blue, Length 36in, Needle Length 25cm
	6-047-03	AUXILOCK® MENISCO Inside-Out Meniscal Repair Needle with 1.0mm Suture Tape: White/Blue, Length 36in, Needle Length 25cm
	Raw Material	Stainless Steel needle as per EN ISO 5832-1/ASTM F138 and UHMWPE Suture as per ASTM F2848.

MENI-FIX All-Inside Meniscal Repair System		
S. No.	Device Name	AUXILOCK® MENI-FIX All-Inside Meniscal Repair System
13.	Picture	
	Description	MENI-FIX All-Inside Meniscal Repair System includes two 0.9mm PEEK anchors with a pretied, self-sliding knot

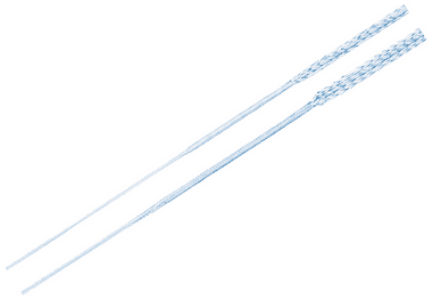
		comprised of #2-0, UHMWPE Biobraid Suture. The delivery needles are available in Curved, Straight, and Reverse Curved designs. The Curved and Reverse Curved designs allow the surgeon to rotate the needle tip away from the neurovascular structures when penetrating the meniscus, further reducing the risk 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.
	Code	Product Description
	6-048-01	AUXILOCK® MENI-FIX All-Inside Meniscal Repair System - Straight Needle
	6-048-02	AUXILOCK® MENI-FIX All-Inside Meniscal Repair System - Curve Needle
	6-048-03	AUXILOCK® MENI-FIX All-Inside Meniscal Repair System - Reverse Curve Needle
	Raw Material	PEEK OPTIMA as per ASTM F2026 and UHMWPE Suture as per ASTM F2848.

AUXILOCK BioBraid		
S.No.	Device Name	AUXILOCK BioBraid Suture
14 a.	Picture	
	Description	AUXILOCK® BioBraid 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. BioBraid sutures are non-absorbable and do not impose any significant changes in tensile strength retention known to occur in vivo. BioBraid sutures are available in a variety of colour combinations for easy suture management in complicated repairs.
	Code	Description
	6-011-03	AUXILOCK® Two #2 BioBraid: White/Blue & White/Black, 36in Total Length
	6-011-04	AUXILOCK® #2 BioBraid: Blue, With Needles: MO-6 & CE, 36in Total Length
	6-011-05	AUXILOCK® #2 BioBraid: White, With Needle: MO-6, 36in Total Length
	6-011-06	AUXILOCK® #2 BioBraid: White/Black, With Needle: MO-6, 36in Total Length
	6-011-08	AUXILOCK® #2 BioBraid: White/Blue, With Needle: MO-6, 36in Total Length
	6-011-09	AUXILOCK® #2 BioBraid: White/Black, 36in Total Length
	6-011-10	AUXILOCK® #2 BioBraid: White/Green, With Needle: MO-6, 36in Total Length

	6-011-11	AUXILOCK® #2 BioBraid: White/Green, 36in Total Length
	6-011-12	AUXILOCK® #2 BioBraid: Blue, 36in Total Length
	6-011-13	AUXILOCK® #2 BioBraid: White, 36in Total Length
	6-011-17	AUXILOCK® #2 BioBraid: White/Blue, 36in Total Length
	6-011-33	AUXILOCK® #2-0 BioBraid: White/Blue, 36in Total Length
	6-011-34	AUXILOCK® #0 BioBraid: White/Blue, With Needle: MO-6, 36 inch
	6-011-35	AUXILOCK® #1 BioBraid: White/Blue, With Needle: MO-6, 36 inch
	6-011-36	AUXILOCK® #0 BioBraid: White/Blue, 36 inch
	6-011-37	AUXILOCK® #1 BioBraid: White/Blue, 36 inch
	6-011-32	AUXILOCK® #2 BioBraid: White, With Needle: CCS, 36in Total Length
	6-011-07	AUXILOCK® #5 BioBraid: White, With Needle: CCS, 36in Total Length
	Raw Material	UHMWPE Suture as per ASTM F2848 and Stainless Steel Needle as per EN ISO 5832-1/ASTM F138.

AUXILOCK BioBraid		
S.No.	Device Name	AUXILOCK BioBraid Infinity Loop Needle
14 b.	Picture	

	Description	AUXILOCK® BioBraid Infinity Loop is a continuous loop of BioBraid with a straight needle. BioBraid Infinity Loop utilises the whipstitch technique for graft preparation and reduces the time spent. It also compresses the graft uniformly and improves strength.
	Code	Description
	6-012-01	AUXILOCK® #2 BioBraid Infinity Loop: White, With Needle: Straight, 20in Loop Length, 24in Total Length
	6-012-02	AUXILOCK® #2 BioBraid Infinity Loop: White/Blue, With Needle: Straight, 20in Loop Length, 24in Total Length
	6-012-03	AUXILOCK® #5 BioBraid Infinity Loop: White/Blue, With Needle: Straight, 20in Loop Length, 24in Total Length
	Raw Material	UHMWPE Suture as per ASTM F2848 and Stainless Steel Needle as per EN ISO 5832-1/ASTM F138.

AUXILOCK BioBraid		
S.No.	Device Name	AUXILOCK BioBraid Suture Tape
14 c.	Picture	

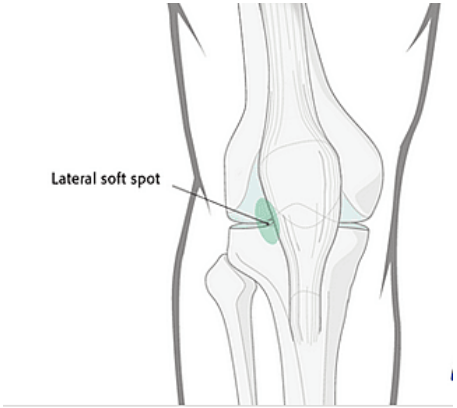
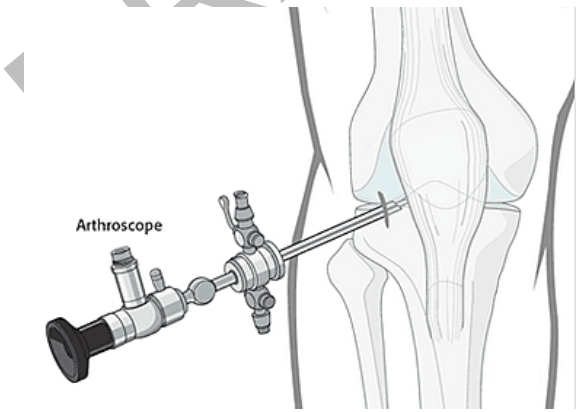
	Description	AUXILOCK® BioBraid Suture Tape made from UHMPWE has a width of 1.0mm to 2.0mm. The suture tape design accommodates the tape in the centre with a suture on the either sides of the tape. It can be used in Knee. The broad footprint of the BioBraid Suture Tape is appropriate for repairs in degenerative cuff tissue where tissue pull-through may be a concern.
	Code	Product Description
	6-013-01	AUXILOCK® 1.8mm BioBraid Suture Tape: White/Blue, 39in Total length
	6-013-02	AUXILOCK® 1.4mm BioBraid Suture Tape: White/Blue, 39in Total length
	6-013-03	AUXILOCK® 1.4mm BioBraid Suture Tape: White/Black, 39in Total length
	6-013-05	AUXILOCK® 2.0mm BioBraid Suture Tape: White/Blue, 39in Total length
	6-013-06	AUXILOCK® 1.0mm BioBraid Suture Tape: White/Blue, 39in Total length
	6-013-07	AUXILOCK® 1.4mm BioBraid Suture Tape: Solid Black, 39in Total length
	Raw Material	UHMWPE Suture as per ASTM F2848.

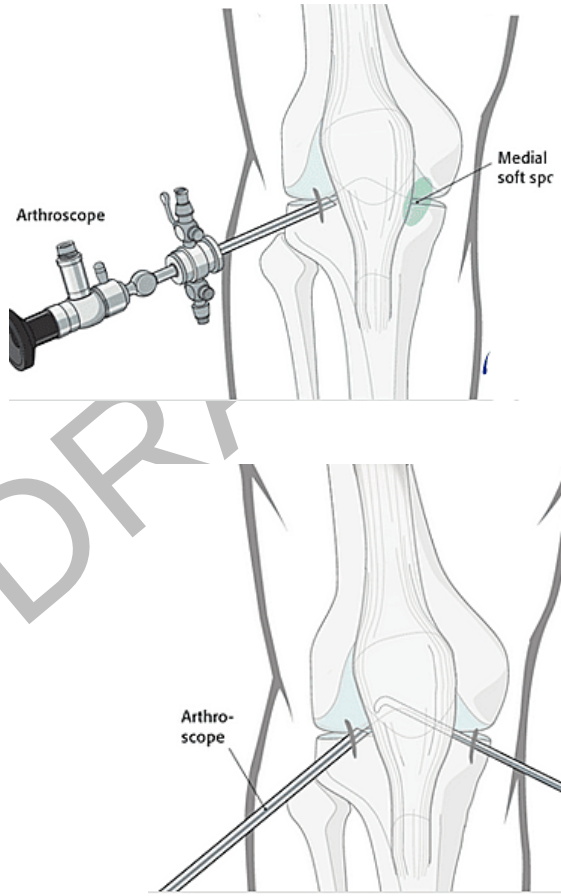
Other details of AUXILOCK Knee Arthroscopy System:

Device Compliance to regulation		We are proposing the AUXILOCK Knee Arthroscopy System as per the compliance to European Union Medical Device Regulation (EU MDR 2017/745).
1.	DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES	
1.1	Device Description and Specification	
a.	Product/Trade Name	Auxein AUXILOCK Knee Arthroscopy System
	General Description	AUXILOCK® Knee Arthroscopy system includes Graft Fixation System (GFS), Interference Screws, Meniscus Repair options and Ligament staples. The GFS are the suspensory devices indicated for fixation of ligament repair and reconstructions. The interference screws are cannulated indicated for ligaments repair in soft tissue or bone tendon bone application. The system provides an excellent combination of strength and stiffness required for successful cortical fixation. The large naked buttons of

		GFS may eliminate the need for a stepped tunnel technique. There are various types of devices included in the knee Arthroscopy system which are as follows: 1. Naked Button 2. Adjustable Loop Button 3. Mini Loop Button 4. Large Loop Button 5. Button Extender 6. AUXILOCK® GFS No-Button Adjustable Loop 7. AUXILOCK® GFS Concave Button 8. PEEK CF Interference Screw 9. PEEK OPTIMA Interference Screw 10. Titanium Interference Screw 11. Ligament Staple 12. MENISCO Inside-Out Meniscal Repair Needle 13. MENI-FIX All-Inside Meniscal Repair System 14. AUXILOCK BioBraid
	Intended Purpose	The AUXILOCK Knee Arthroscopy System is indicated for used in the surgical procedures related to the Knee Ligament (ACL, PCL) and meniscus repair.
	Intended Users	The AUXILOCK Knee Arthroscopy System is recommended to be used by only well-trained, certified and experienced surgeons.
b.	Intended Patient Population	Male or Female, aged between 18 to 75 years and skeletally mature patient.
	Medical Conditions to be diagnosed, treated and/or monitored	AUXILOCK Knee Arthroscopy System is used to reconstruct or repair the knee ligaments (ACL, PCL) and also these devices are used for treating meniscal tears in the anterior, middle and posterior horns of the meniscus.
	Patient Selection Criteria	**Inclusion criteria**

		Male or Female, aged between 18 to 75 years and skeletally mature patient. **Exclusion criteria** ○ Subjects with a disease entity or condition that could hindered healing and create unacceptable risk of fixation failure or complications such as known active cancer, neuromuscular disorder etc. ○ In case, subject has inadequate tissue coverage of the operative sight. ○ Subjects who are incarcerated or have pending incarceration. ○ Subjects with mental disorders
c.	Principles of Operation	The Auxilock Knee Arthroscopy System preserve the knee joint include joint alignment, meniscal status, and ligament stability. The stability of these factors provides knee joint functioning.
	Mode of Action	The Auxilock knee arthroscopy implants provides ligaments (ACL, PCL) repair and meniscal tear by fixing to the intra-articular structure that provides strong fixation to preserve knee physiology.

	Scientifically demonstration of Principle of Operation	Anterolateral port  

		Antero-medial port 
d.	Rationale for considering as a	As per Article 2 (1) of EU MDR 2017/745

	Medical device	'Medical Device' means any instruments, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: Thus, AUXILOCK Knee Arthroscopy System is an implant used in humans for medical purposes to treat the tear of ligaments. Applicable/Non-Applicable defines applicancy of the statement: a) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease- Not Applicable Rationale for Non Applicability The AUXILOCK Knee Arthroscopy System is an implant used for the treat the tear of ligaments. Thus, it is not used for diagnosis, prevention, monitoring, prediction, prognosis or alleviation of disease. b) diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or disability- Applicable Rationale for Applicability The AUXILOCK Knee Arthroscopy System is an implantable device used for the treat the tear of ligaments. c) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state- Not Applicable Rationale for Non Applicability The AUXILOCK Knee Arthroscopy System is intended to treat the tear of ligaments. The device is not meant for investigation, replacement or modification of the anatomy or of a physiological or pathological state purpose of use.

		d) providing information by means of in vitro examination of specimens derived from the human body, including organs, blood and tissue donations- Not Applicable Rationale for Non Applicability AUXILOCK Knee Arthroscopy System is made up of metal/Polymer and employed to fix the tear of ligaments. This system does not contain the In-vitro examination of specimens derived from the human body, including organ, blood and tissue donations. Moreover, the device does not achieve its principal intended action by any pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. Hence, the AUXILOCK Knee Arthroscopy System is considered to be a medical device. The following products shall also be deemed to be medical devices: e) Devices for the control or support of conception- Not Applicable Rationale for Non Applicability The AUXILOCK Knee Arthroscopy System used to treat the tear of ligaments. This device is not for the control or support of conception. f) Products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point- Not Applicable Rationale for Non Applicability The AUXILOCK Knee Arthroscopy System is intended for the fixation of ligaments. The system is not meant for cleaning, disinfection or sterilization of device.
e.	Novel Features	The AUXILOCK Knee Arthroscopy System comprises of already existing devices approved in EU market under the regulation MDD 93/42/EEC.

		Since the device was placed on the market, there are no changes or modifications in device related to raw material, design, manufacturing process (coolants, lubricants, chemicals), intended use, post processing, etc.
f.	Description of key functional elements	The Auxilock Knee Arthroscopy System comprises of : ● Button, Screws and staples in varying lengths and types ● Suture ● Needle Button and Screws are used with accessories for fixation of ligament and meniscus tear. The description of the components used with Button and Screws to preserve intra articular structure are enlisted below: *Suture* ● The suture helps in stitching and holding ligament, tendon together after a surgery. ● Helps in pulling and flipping of button *Needle* A needle is used for sewing the graft in combination with suture.
g.		
	Sterility	All Products covered in AUXILOCK Knee Arthroscopy System are supplied in Sterile state. The Sterile implants which are placed on the market are sterilized by using EO Sterilization (SAL 10-6).
	Radioactivity	Products covered in AUXILOCK Knee Arthroscopy System are metal products and does not emit any ionizing or non-ionizing radiation.
	Category	Non-Active, Implantable, Long term, Surgically Invasive Device.
	Use	For Single Use only
	Contact Duration	Long Term, intended for continuous use for more than 30 days (classified as per EU MDR 2017/745 as amended).

	MRI Compatibility	The AUXEIN MEDICAL AUXILOCK Knee Arthroscopy System have not been evaluated for safety and compatibility in the MR environment. The AUXEIN MEDICAL 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.
1.2	Reference to Previous and Similar Generations of the device	
a.	CE Mark (Legacy device)	CE Approved by DNV (2460) under MDD 93/42/EEC Certificate No. 10000434275-PA-NA-IND Rev. 0.0
	USFDA clearance	Yes (AUXILOCK Knee Arthroscopy System are cleared by USFDA whose details are as follow:) 510(k) Number: K213018, K203029
b.	Similar devices available in Union or international market.	The Similar devices available in the Union or International Market enlisted below: Smith & Nephew: Endobutton Arthrex Inc: TightRope Depuy Mitek: MILAGRO Advance Interference Screw Parcus (Anika): Interference Screw Arthrex Inc: Meniscal Repair

Measurable safety and performance parameters

- Measure the VAS Scores
- Measure the KOOS Score
- Record of any adverse event, serious adverse event and complication

4. Information on any residual risks and any undesirable effects, warnings and precautions.

Residual risks and undesirable effects

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

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

Warning & 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.

5. The summary of clinical evaluation and relevant information on post-market clinical follow-up.

Prospective Clinical Data (PMCF Study):

Prospective Study of the legacy device has been approved by the ethics committee.

Identity of the investigation/study: Post Market Clinical Follow-up (PMCF) study to evaluate the Safety and Performance of Knee Arthroscopy System.

Name or Code of Study	Completed (Yes/No)	Name of countries in study is conducted	No. of patients enrolled /and the target no.	No. of serious incidents	Serious incident rate (%)	No. of deaths
CR_PMCF/P_19	Ongoing	INDIA	35/60	0	0	0
Study Title	Post Market Clinical Follow-up (PMCF) study to evaluate the Safety and Performance of Knee Arthroscopy System.					

CTRI Number	CTRI/2023/12/060753			
CTRI Registration Date	26/12/2023			
Number of study sites	Two			
Name of Study Sites	Site 001 (24 Patients)	Dr. Saini Orthopedic Super Speciality Centre, Meerut, India	Site 002	All India Institute of Medical Science (AIIMS), Delhi, India (11 Patients)
No. of Patients enrolled	35			

Study design: The PMCF study have been designed according to the applicable rules and regulation to collect evidence based scientific data. The Sponsor in association with PI has designed the study and obtained the approval from the Institutional Ethics Committee and the same has also been registered on CTRI. The study aimed to recruit a total of 60 subjects, who meet Inclusion and Exclusion criteria as per the protocol. Subjects are followed at a stipulated time frame i.e. 6 weeks, 3 months, 6 months and 12 months after surgery.

Inclusion criteria

1. Subject is willing and able to give Written informed consent for participation in the study.
2. No history of surgery on affected knee.
3. Male or Female, aged between 18 to 75 years and skeletally mature patient.
4. Subject scheduled for Knee arthroscopic surgery for fixation of Knee related ligaments.

Exclusion criteria

1. Subjects with a disease entity or condition that could hindered healing and create unacceptable risk of fixation failure or complications such as known active cancer, neuromuscular disorder etc.
2. In case, subject has inadequate tissue coverage of the operative sight.
3. Subjects with substance abuse/alcohol issues.
4. Subjects who are incarcerated or have pending incarceration.

5. Subjects with mental disorders
6. Female participant who is pregnant or planning pregnancy during the course of the study.
7. Subject who has contraindication mentioned in the IFU.

Primary Objective

1. To assess the safety and performance of the Knee Arthroscopy System by radiological evaluation for the prospective results of surgical treatment of patients requiring ligament or tendon repair of knee.
2. Evaluation of functional performance from baseline to last follow up by recording the KOOS Score.

Secondary Objective

1. Pain evaluation through Visual Analogue Scale (VAS).
2. Adverse Event assessment.

Primary Endpoints

1. Radiologic evaluation by X-ray radiographs to observe the healing of tendon and ligament repair after knee arthroscopy . [Visit - Baseline, Follow-up at 6 Weeks, 3rd, 6th and 12th month]
2. Evaluation of functional performance from baseline to last follow up by recording the KOOS (Knee Injury and Osteoarthritis Outcome score). [Visit - Baseline, Follow-up at 6 Weeks, 3rd, 6th and 12th month].

Secondary Endpoints

1. Follow-up of the patient recovery by analysing visual analogue score (VAS score) for pain assessment [Visit - Baseline, Follow-up at 6 Weeks, 3rd, 6th and 12th month]
2. Evaluation of Safety of Device by record of any adverse event, serious adverse event and complication during follow up, especially the one mentioned in the Instruction of Use. (IFU) [Visit - Baseline, Follow-up at 6 Weeks, 3rd, 6th and 12th month]

Population Detail:

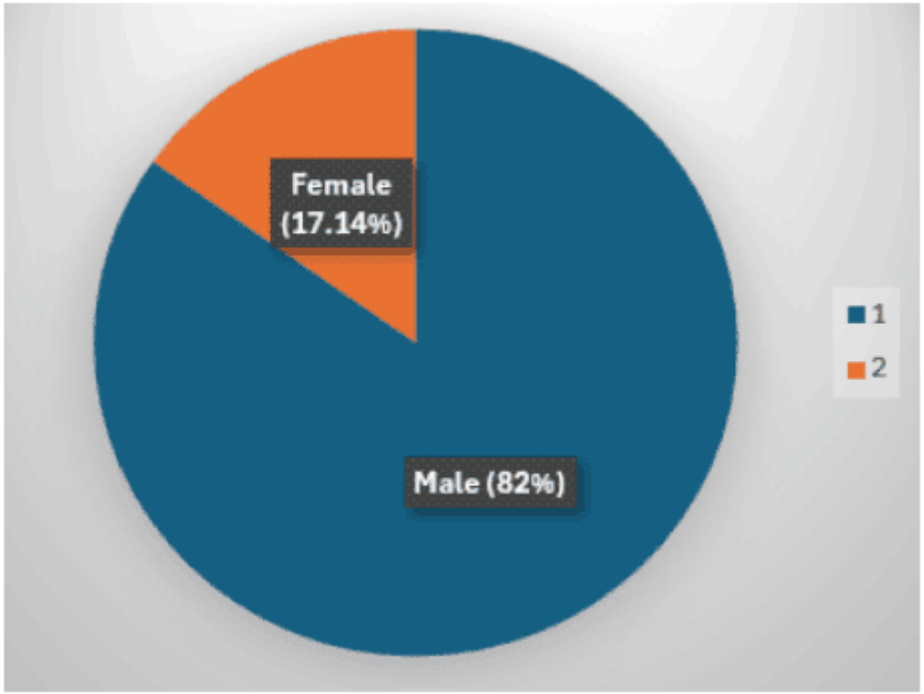
Summary of Demographics and Baseline Characteristics

Characteristic	Age (years)	Weight (kg)	Height (cm)	Body Mass Index (kg/m²)
Mean±SD	29.3±8.1	70.8±10.7	169.4±8.2	24.7±3.5
Range	19 - 47	50 - 92	152.4 -180.3	19.2 – 30.7
Median	30	70	170.6	24.8

Gender distribution of study subjects

Male	29/35 (82.8%)
Female	06/35 (17.14%)

The figures provide information of demographic and baseline characteristics.



	ACL	PCL	MENISCUS	ACL + MENISCUS	PCL + MENISCUS
n=35	20	1	3	8	3

Clinical Outcomes Measures

Pain and functional scores in study participants at baseline and follow up visits

Scoring	Baseline n=35 (a)	6 Week n=30 (b)	3 Month n=20 (c)	6 Month n=8 (d)	P value
VAS Score Mean± SD	8.1±1.6	5.3±1.5	3.6±1.5	1.6±1	a vs. b<0.001 a vs. c<0.001 a vs. d=NA
VAS Median	8	5	4	1	-
VAS Range	4-9	3-8	1-6	1-3	-
KOOS Mean± SD	24±19	44±16	60±18	43±26	a vs. b<0.001 a vs.c<0.001 a vs. d=NA
KOOS Median	15	43	60	32	-

KOOS Range	3-61	20-78	35-81	22-86	-

Vital signs of study participants

Vital Signs	Baseline [a] (n=35)	6 Week [b] (n=30)	3 Month [c] (n=20)	6 Month [c] (n=8)
Systolic Blood Pressure (mmHg)	125±14	125±7	124±5	126±10
Diastolic Blood Pressure (mmHg)	77±11	80±4	80±3	73±7
Respiratory Rate (breaths/minute)	18±2	19±2	18±2	17±2
Heart Rate (BPM)	78±8	80±8	82±6	80±5

RETROSPECTIVE DATA

We have also collected retrospective data from the hospital whose details are as follows:

Table 1: Baseline and follow up details of patients

Total patients	6 weeks follow up	3 months follow up	6 months follow up
29	23/26 (88%)	17/20 (85%)	12/15 (80%)

Table 2: Gender distribution among the patients

Male	11/29 (38%)
Female	18/29 (62%)

Table 3: Demographic characteristics of the patients

Characteristic	**Age (years)**	**Weight (kg)**	**Height (cm)**	**Body Mass Index (kg/m2)**
Mean (n=29)	38.1 ± 14.0	75.2 ± 6.6	166.7 ± 8.5	27.34 ± 4.1

Table 4: Pain and functional scores of patients at baseline and follow up visits

Scoring	**Baseline (n=29)**	**6 weeks follow up (n=23)**	**3 months follow up (n=17)**	**6 months follow up (n=12)**
VAS Score	8.7 ± 1.8	4.64 ± 1.0	2.9 ± 0.8	1.8 ± 0.6
KOOS	29.7 ± 21.31	42.6 ± 16.3	47 ± 12.6	59 ± 9.2

Study Method

The PMCF study have been designed according to the applicable rules and regulation to collect evidence based scientific data. The Sponsor in association with PI has designed the study and obtained the approval from the Institutional Ethics Committee and the same has also been registered on CTRI. The study aimed to recruit a total of 60 subjects, who meet Inclusion and Exclusion criteria as per the protocol. Subjects are followed at a stipulated time frame i.e. 6 weeks, 3 months, 6 months and 12 months after surgery.

PMCF: Knee Arthroscopy study is intended to answer specific questions relating to clinical performance, efficacy and safety (i.e. residual risks) of the device. It is a multicentric, single-arm and prospective study. The target population for this study is comprised of both males and females aged between 18 years to 75 years at the time of surgery. Study is designed to evaluate aspects related to issues with medium-term performance, the appearance of clinical events, events specific to defined subject populations, or the performance of the device in a more diverse population of the subjects with knee ligament and meniscus related problem.

As per statistical analysis plan (SAP), a comprehensive analysis will be carried out once the study is completed. According to study objectives, the data recorded over the one year follow up period will be analyzed. Time taken to regain the complete functionality of knee joint will be analyzed. KOOS that is being recorded in continuous data format, will be compared between different time points to assess the functional outcome. Similarly, VAS score will be analyzed for the improvement in pain. Safety related assessment will be done based on the number of adverse events and serious adverse event occurred during the study.

Study Result

The interim analysis of data of thirty five patients recruited in the study so far provides significant information with respect to implants safety and performance. Study key findings are; substantial improvement in pain score and function scores, and no occurrence of serious adverse events.

The substantial reduction in VAS score indicates that the intervention effectively alleviate pain in study population. This is particularly important as pain levels at baseline were found to be high, indicating that the intervention positively impacts the patients quality of life. Furthermore, the increase in functional score; KOOS highlights the effectiveness of the intervention. The progressive increase in KOOS over the follow-up done so far indicates a consistent and sustained improvement in Pain index, Symptoms, Activities of Daily Living, Sports and Recreation Functions and Knee Related Quality of Life. Findings of the interim report shows that knee arthroscopy system manufactured by Auxein Medical Private Limited is safe for the use in patient and perform the intended function.

Conclusion

The analysis of data from the thirty-five patients enrolled in the study so far provides valuable insights into the safety and performance of the implants. The key findings are as follows:

1. Significant improvement in pain and function scores: Patients experienced marked improvements, demonstrating the intervention's effectiveness.
2. No serious adverse events reported: The absence of major complications highlights the favorable safety profile of the implants.

3. Notable reduction in VAS scores: The considerable decrease in Visual Analog Scale (VAS) scores confirms the intervention's ability to effectively relieve pain in the study population.

These results suggest that the intervention is both safe and effective in reducing pain and enhancing functionality among the participants.

6. Possible diagnostic or therapeutic alternatives.

Diagnosing a knee injury or problem includes a medical examination and usually the use of a diagnostic procedure(s) such as an x-ray, MRI, CT scan or arthroscopy. Both non-operative and surgical treatment options are available to treat knee pain and problems depending on the type and severity of the condition.

Non-surgical Treatment

Bracing

A knee brace to provide external stability to the knee joint. Braces are designed to stabilize a joint, reduce pain and inflammation and strengthen the muscles of the knee. By putting pressure on the sides of the joint, the brace causes the joint to realign, which in turn decreases the contact between the two rough bone surfaces, reduces pain and increases mobility.

Injections and Infusions

Some medications can be injected directly into the knee to treat pain. These include corticosteroids to reduce inflammation. With infusion therapy, medications are delivered intravenously or directly into the muscles to reduce inflammation.

Lifestyle Modifications

Lifestyle modifications to daily routine, such as losing weight, avoiding activities such as running and performing low-impact exercise to reduce stress on knee.

Nutraceuticals

Nutraceuticals are herbal or dietary supplements that may have health benefits for knee joint. These supplements include glucosamine and chondroitin, which

may help with overall health of the bones and soft tissues.

Pain Medications

Over-the-counter pain relievers, such as acetaminophen (e.g., Tylenol) and ibuprofen (e.g., Advil and Motrin), are commonly used to ease knee pain. Topical analgesics such as muscle rubs can also be used for temporary pain relief. It is also recommend other prescription medications such as antirheumatic drugs and biological response modifiers.

Physical and Occupational Therapy

Rehabilitative medicine and exercise programs can stretch and strengthen the muscles and soft tissues of knee joint to improve flexibility and joint support. Changing the way of performing daily activities may also help in alleviating knee pain through limiting excessive strain on knee. This can be aided through the use of therapeutics and other apparel specially designed for knee pain.

Surgical Treatment

Available treatments based on the severity and type of injury diagnosed by the doctor:

Non-Surgical Treatment	Surgical Treatments
○ Bracing ○ Injections and Infusions ○ Lifestyle Modifications ○ Nutraceuticals ○ Pain Medications ○ Physical and Occupational Therapy	○ Interference Screw, Graft Fixation System, etc.

7. Suggested profile and training for users.

The intended user (surgeon) should be well-qualified and must have gained sufficient training regarding the use of the device and should have experience in

trauma surgery. The training materials i.e Surgical Technique, Instructions for Use, Catalog are already available on the manufacturer website (https://www.auxein.com/).

8. Reference to any harmonized standards and CS applied.

The following harmonized standards and guidance documents are applicable on AUXILOCK Knee Arthroscopy System:

Harmonized Standards		
S. No.	**Standard Designation**	**Title of Standard**
1.	EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)
2.	EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
3.	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021).
4.	EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
5.	EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
6.	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
7.	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
8.	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements.

Non Harmonized Standards	
Standard	**Description**
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices

ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good Clinical Practice.
ISO 14602:2011	Non-active surgical implants - Implants for osteosynthesis - Particular Requirements.
ISO 14630:2012	Non-active surgical implants - General Requirements
ISO 11737-1:2018/A1:2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
ISO 14644-1:2015	Clean-rooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration.
ISO 14644-2:2015	Clean-rooms and associated controlled environments - Part 2: Monitoring to provide evidence of clean-room performance related to air cleanliness by particle concentration.
ISO 14644-3:2019	Clean-rooms and associated controlled environments - Part 3: Test Methods.
ISO 14644-4:2022	Clean-rooms and associated controlled environments - Part 4: Design, construction and start-up.
ISO 14644-5:2004	Clean-rooms and associated controlled environments - Part 5: Operations
ISO 14644-7:2004	Clean-rooms and associated controlled environments - Part 7: Separative devices (clean air hoods, glove boxes, Isolators and mini).
ISO 14644-8 :2022	Clean-rooms and associated controlled environments - Part 8: Classification of air cleanliness by chemical concentration (ACC).
ISO 14644-9 :2022	Clean-rooms and associated controlled environments – Part 9: Classification of surface cleanliness by particle concentration.
ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020).
ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO 5832-1:2019	Implants for surgery - Metallic materials - Part 1: Wrought stainless steel (ISO 5832-1:2016)
ISO 5832-3:2021	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy (ISO 5832-3:2021)

ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-2: 2022	Biological evaluation of medical devices — Part 2: Animal welfare requirements
ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
ISO 11135:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)
ASTM F138-19	Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)
ASTM F136-13 (2021)e1	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
ASTM D4169-22	Standard Practice for Performance Testing of Shipping containers and System.
ASTM F2026-17	Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications
ASTM F3333-20	Standard Specification for Chopped Carbon Fiber Reinforced (CFR) Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications
ASTM F2848-17	Standard Specification for Medical-Grade Ultra-High Molecular Weight Polyethylene Yarns
ASTM 1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices.
ASTM F88/F88M-21	Standard Test Method for Seal Strength of Flexible Barrier Materials
ISO 19227:2018	Implants for surgery - Cleanliness of orthopedic implants - General requirements
ISO/TR 10993-33:2015	Biological evaluation of medical devices — Part 33: Guidance on tests to evaluate genotoxicity — Supplement to ISO 10993-3.

MDCG Guidelines	
Guidance Documents	**Description**
MDCG 2023-7	Practical Application of Article 61(4)
MDCG 2021-24	Guidance on classification of medical devices
MDCG 2020-13	Clinical Evaluation Assessment Report Template
MDCG 2020-8	Guidance on PMCF evaluation report template
MDCG 2020-7	Guidance on PMCF plan template
MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices
MDCG 2020-5	Guidance on clinical evaluation – Equivalence
MDCG 2019-9, Rev.01	Summary of safety and clinical performance
MDCG 2019-5	Registration of legacy devices in EUDAMED
MDCG 2021-12	FAQ on the European Medical Device Nomenclature (EMDN)
MDCG 2018-2	Future EU medical device nomenclature - Description of requirements
MDCG 2021-11	Guidance on Implant Card –'Device types'
MDCG 2022-16	Guidance on Authorized Representatives Regulation (EU) 2017/745 and Regulation (EU) 2017/746
MDCG 2022-9	Summary of safety and performance template
MDCG 2019-14	Explanatory note on MDR codes
MDCG 2021-19	Guidance note integration of the UDI within an organisation's quality management system
MDCG 2023-7	Guidance on exemptions from the requirement to perform clinical investigations pursuant to Article 61(4)-(6) MDR
MDCG 2018-1, Rev.04	Guidance on BASIC UDI-DI and changes to UDI-DI
MDCG 2021-25	Application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC
MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745 - December

	2022
MEDDEV 2.7/1 revision 4, 2016	Clinical Evaluation: A guide for manufacturers and notified bodies.

9. Revision history

SSCP Revision Number	Date Issued	Change Description	Revision Validated by the Notified Body
00	26-07-2024	Initial Release	☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
01	24-09-2024	Segregated the clinical data related to ACL, PC, Meniscus	☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
02	20-10-2024	Updated as per the finding receive in LOF 1	☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)

A summary of the safety and clinical performance of the device, intended for patients, is given below

Document revision: 00
Date issued: 24-09-2024

Device identification and general information

Device Trade Name: AUXILOCK Knee Arthroscopy System
Manufacturer Name: Auxein Medical Private Limited
Manufacturer Address: Plot No. 168-169-170, Phase-IV, Sector-57, Kundli, HSIIDC, Industrial Area, Sonipat, Haryana 131028, India
Basic UDI-DI: 08903993KAS005LH and 08903993MRS005PW
Year when the device was first CE-marked: 2021

Intended use of the device

Intended Purpose	The AUXILOCK Knee Arthroscopy System is indicated for used in the surgical procedures related to the Knee Ligament (ACL, PCL) and meniscus repair.
Indications of Use	The Auxilock Knee Arthroscopy System is indicated for used in reconstruction or repair of Knee ligaments (ACL, PCL). These devices are also used for treating meniscal tears in the anterior, middle and posterior horns 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. ○ Active, suspected or latent infection in the affected area. ○ Blood supply limitations or other systemic conditions that may retard healing. ○ Fever or leukocytosis. ○ Foreign body sensitivity, if suspected.

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

Device description

AUXILOCK® Knee Arthroscopy system includes Graft Fixation System (GFS), Interference Screws, Meniscus Repair options and Ligament staples. The GFS 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. The large naked buttons of GFS may eliminate the need for a stepped tunnel technique. The details regarding AUXILOCK Knee Arthroscopy System and screws can be found at **www.auxein.com**.

The more details regarding these AUXILOCK Knee Arthroscopy System are mentioned below:

Parameter	**Details**	**Certified By**	**Certificate Number**
Legacy Device	Yes, AUXILOCK Knee Arthroscopy System (Certified under MDD 93/42/EEC)	DNV Product Assurance AS	10000434275-PA-NA-IND Rev. 0.0
Material/substances in contact with patient tissues	The Raw Materials used for manufacturing the Implants consists of Titanium Alloy (Ti-6Al-4V) as per EN ISO 5832-3:2021, PEEK OPTIMA as per ASTM F2026 and PEEK CF as per ASTM F3333, Stainless Steel as per EN ISO 5832-1:2024 and UHMWPE Yarn/Suture (BioBraid) as per ASTM F2848.		
USFDA Cleared	Yes (AUXILOCK Knee Arthroscopy System are approved by USFDA whose details are as follow:) 510(k) Number: K213018, K203029		
Risk Class	IIb (According to the EU Regulation 2017/745 (MDR) Annex VIII Rule 8)		
Authorized Representative Name and Address	Name: CMC Medical Devices & Drug S.L Address: 29015 Málaga, Spain		
Notified Body Name and Single Identification Number	Name: DNV Product Assurance AS Single Identification Number: 2460		

Principle of operation

The Auxilock Knee Arthroscopy System preserve the knee joint include joint alignment, meniscal status, and ligament stability. The stability of these factors provides knee joint functioning. The Auxilock knee arthroscopy implants provides ligaments (ACL, PCL) repair and meniscal tear by fixing to the intra-articular structure that provides strong fixation to preserve knee physiology.

Description of Key functional elements:

The Auxilock Knee Arthroscopy System comprises of :

- Button, Screws and staples in varying lengths and types
- Suture
- Needle

Button and Screws are used with accessories for fixation of ligament and meniscus tear.

The description of the components used with Button and Screws to preserve intra articular structure are enlisted below:
Suture

- The suture helps in stitching and holding ligament, tendon together after a surgery.
- Helps in pulling and flipping of button

Needle
A needle is used for sewing the graft in combination with suture.

Risks and Warnings

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

The potential risks that arise regarding the device are controlled using risk mitigation method and conveying those risk to the patients from surgeon.

A listing of Remaining Risk and undesirable effects includes, but is not limited to:

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

- Risks due to anesthesia.
- Safety Parameter

Quantitative based risk is evident

Safety Parameters	Article No.	No. of Patients having Adverse Events	Percentage of Patients (%)
Implant Migration	3	35	35.1
Pain/Revision Surgery	5	3	4.9
Revision Surgery (ACL Instability and Re Tear)	9	3	3
Posterior Tibial Translation on the Femur	12	1	5.55

Warning & Precautions:

1. This product should only be used by or on the order of a surgeon.
2. 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.
3. 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.
4. The patient should be advised of the use and limitations of this device.
5. 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.
6. 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.
7. This device must never be re-sterilized.
8. Appropriate instrumentation should be used to implant this device.

Summary of any field safety corrective action, (FSCA including FSN) if applicable
Till now, regarding Auxein's AUXILOCK Knee Arthroscopy System there is no FSCA.

Summary of clinical evaluation and post-market clinical follow-up
Clinical background of the device

Description and consequences
The knee joint is a hinge type synovial joint, which mainly allows for flexion and extension (and a small degree of medial and lateral rotation). It is formed by articulations between the patella, femur and tibia. In this article, we shall examine the anatomy of the knee joint – its articulating surfaces, ligaments and neurovascular supply.

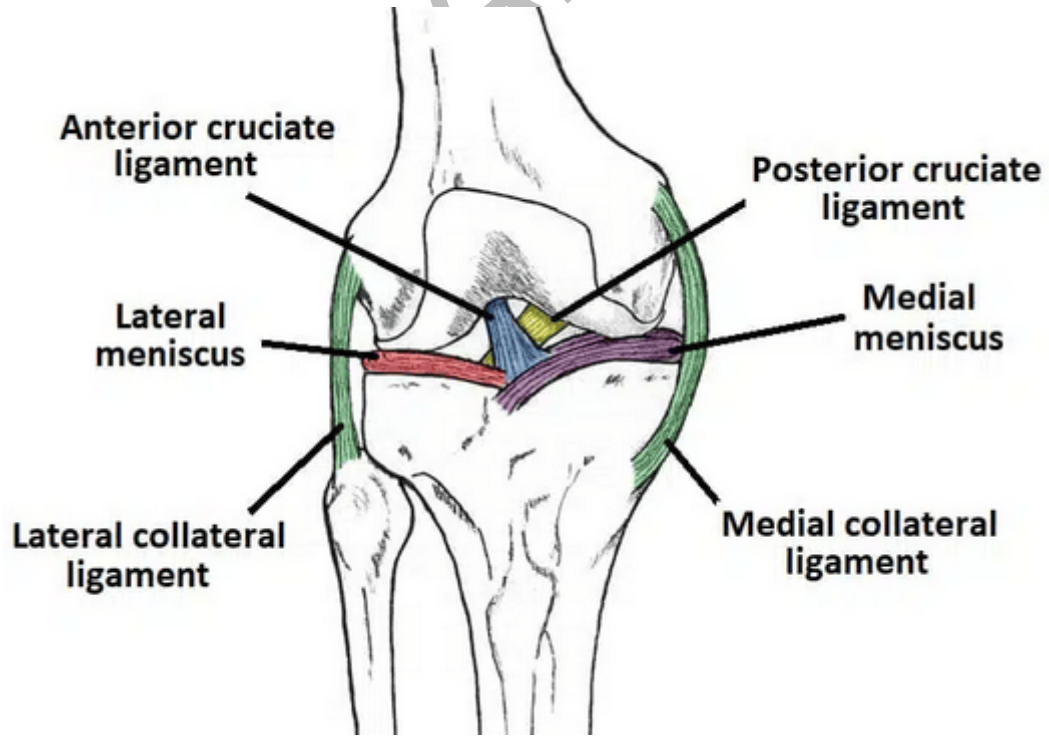


Figure: Knee Joint

Types of Knee Ligament Injuries

Knee ligaments are the short bands of tough, flexible connective tissue that hold the knee together. Knee ligament injuries can be caused by trauma, such as a car accident. Or they can be caused by sports injuries. An example is a twisting knee injury in basketball or skiing. The knee has 4 major ligaments. Ligaments connect bones to each other. They give the joint stability and strength. The 4 knee ligaments connect the thighbone (femur) to the shin-bone (tibia). They are:

- Anterior cruciate ligament (ACL). This ligament is in the center of the knee. It controls rotation and forward movement of the shin-bone.
- Posterior cruciate ligament (PCL). This ligament is in the back of the knee. It controls backward movement of the shin bone.
- Medial collateral ligament (MCL). This ligament gives stability to the inner knee.
- Lateral collateral ligament (LCL). This ligament gives stability to the outer knee.

Causes

Cruciate ligaments

The ACL is one of the most common ligaments to be injured. The ACL is often stretched or torn during a sudden twisting motion. This is when the feet stay planted one way, but the knees turn the other way. Slowing down while running or landing from a jump incorrectly can cause ACL injuries. Skiing, basketball, and football are sports that have a higher risk for ACL injuries. The PCL is also a common ligament to become injured in the knee. But a PCL injury usually occurs with sudden, direct hit, such as in a car accident or during a football tackle.

Collateral ligaments

The MCL is injured more often than the LCL. Stretch and tear injuries to the collateral ligaments are usually caused by a blow to the outer side of the knee. This can happen when playing hockey or football.

Symptoms:

Cruciate injury

A cruciate ligament injury often causes pain. Often you may hear a popping sound when the injury happens. Then your buckles when you try to stand on it. The knee also swells. You also are not able to move your knee as you normally would. You may also pain along the joint and pain when walking. The

symptoms of a cruciate ligament injury may seem like other health conditions. Always see your healthcare provider for a diagnosis.

Collateral ligament injury

An injury to the collateral ligament also causes the knee to pop and buckle. It also causes pain and swelling. Often you will have pain at the sides of the knee and swelling over the injury site. If it is an MCL injury, the pain is on the inside of the knee. An LCL injury may cause pain on the outside of the knee. The knee will also feel unstable, like it is going to give way.

Seek care immediately if:

- Unable to walk or move your leg.
- Obvious deformity of the knee or leg.

Call your doctor if:

- Knee locks or catches or makes a clicking, popping or grinding sound.
- Knee is painful and/or swollen.
- Knee feels weak or buckles.
- Unable to bend fully or straighten your knee.
- Have lost trust in your knee to perform activities without problems.

Diagnosis

The doctor will perform a series of tests that will check the muscle strength. Depending on the extent of your knee joint, you may need emergency surgery. The following tests will be performed to get a visual image of the fracture as follows:

- X-rays- To have an image of the knee
- MRI scan-For a detailed image of the muscles, ligaments around the Knee.

Pain Management

Most ligament rupture hurt moderately for a few days to a couple of weeks. RICE is an acronym for a type of treatment that involves rest, ice, compression, and elevation. Doctors may recommend this treatment when a person has injured ligament. These are soft tissue injuries. Doctor also may recommend pain killer medicines to relieve pain and inflammation. If the pain is severe, the doctor may suggest a prescription-strength medication for a few days. Patients should talk to their doctor if the pain has not begun to improve within a few days of surgery.

Rehabilitation and Return to Activity

Most people return to all their former activities after a injury. The nature of the injury, the treatment received, and the body's response to the treatment all have an impact, so the answer is different for individual. Most patients will have some stiffness. If the doctor thinks it is needed, the patient will start physical therapy within a few days to weeks after surgery, or right after the last cast is taken off.

Most patients will be able to resume light activities, such as walking, swimming or exercising the lower body in the gym, within 4 to 6 months after the surgery is done. Vigorous activities, such as skiing or football, may be resumed between 6 and 9 months after the surgery.

Clinical Evidence/Safety of the device

Prospective Clinical Evaluation

The summary of clinical evaluation and relevant information on post-market clinical follow-up.

Prospective Clinical Data (PMCF Study):
Prospective Study of the legacy device has been approved by the ethics committee.
Identity of the investigation/study: Post Market Clinical Follow-up (PMCF) study to evaluate the Safety and Performance of Knee Arthroscopy System.

Name or Code of Study	Completed (Yes/No)	Name of countries in study is conducted	No. of patients enrolled /and the target no.	No. of serious incidents	Serious incident rate (%)	No. of deaths
CR_PMCF/P_19	Ongoing	INDIA	35/60	0	0	0
Study Title	Post Market Clinical Follow-up (PMCF) study to evaluate the Safety and Performance of Knee Arthroscopy System.					
CTRI Number	CTRI/2023/12/060753					
CTRI Registration Date	26/12/2023					
Number of study sites	Two					
Name of Study Sites	Site 001 (24 Patients)	Dr. Saini Orthopedic Super Speciality Centre, Meerut, India	Site 002	All India Institute of Medical Science (AIIMS), Delhi, India (11 Patients)		
No. of Patients enrolled	35					

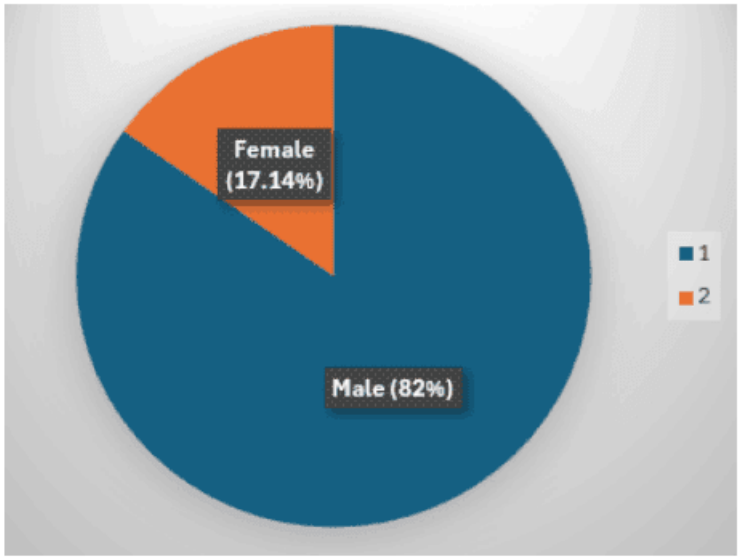
Population Detail:
Summary of Demographics and Baseline Characteristics

Characteristic	Age (years)	Weight (kg)	Height (cm)	Body Mass Index (kg/m²)
Mean±SD	29.3±8.1	70.8±10.7	169.4±8.2	24.7±3.5
Range	19 - 47	50 - 92	152.4 -180.3	19.2 – 30.7
Median	30	70	170.6	24.8

Gender distribution of study subjects

Male	29/35 (82.8%)
Female	06/35 (17.14%)

The figures provide information of demographic and baseline characteristics.



	ACL	PCL	MENISCUS	ACL + MENISCUS	PCL + MENISCUS
n=35	20	1	3	8	3

Clinical Outcomes Measures

Pain and functional scores in study participants at baseline and follow up visits

Scoring	Baseline n=35 (a)	6 Week n=30 (b)	3 Month n=20 (c)	6 Month n=8 (d)	P value

VAS Score Mean± SD	8.1±1.6	5.3±1.5	3.6±1.5	1.6±1	a vs. b<0.001 a vs. c<0.001 a vs. d=NA
VAS Median	8	5	4	1	-
VAS Range	4-9	3-8	1-6	1-3	-
KOOS Mean± SD	24±19	44±16	60±18	43±26	a vs. b<0.001 a vs.c<0.001 a vs. d=NA
KOOS Median	15	43	60	32	-
KOOS Range	3-61	20-78	35-81	22-86	-

Vital signs of study participants

Vital Signs	Baseline [a] (n=35)	6 Week [b] (n=30)	3 Month [c] (n=20)	6 Month [c] (n=8)
Systolic Blood Pressure (mmHg)	125±14	125±7	124±5	126±10
Diastolic Blood Pressure (mmHg)	77±11	80±4	80±3	73±7

Respiratory Rate (breaths/minute)	18±2	19±2	18±2	17±2
Heart Rate (BPM)	78±8	80±8	82±6	80±5

RETROSPECTIVE DATA

We have also collected retrospective data from the hospital whose details are as follows:

Table 1: Baseline and follow up details of patients

Total patients	**6 weeks follow up**	**3 months follow up**	**6 months follow up**
29	23/26 (88%)	17/20 (85%)	12/15 (80%)

Table 2: Gender distribution among the patients

Male	11/29 (38%)
Female	18/29 (62%)

Table 3: Demographic characteristics of the patients

Characteristic	**Age (years)**	**Weight (kg)**	**Height (cm)**	**Body Mass Index (kg/m2)**
Mean (n=29)	38.1 ± 14.0	75.2 ± 6.6	166.7 ± 8.5	27.34 ± 4.1

Table 4: Pain and functional scores of patients at baseline and follow up visits

Scoring	Baseline (n=29)	6 weeks follow up (n=23)	3 months follow up (n=17)	6 months follow up (n=12)
VAS Score	8.7 ± 1.8	4.64 ± 1.0	2.9 ± 0.8	1.8 ± 0.6
KOOS	29.7 ± 21.31	42.6 ± 16.3	47 ± 12.6	59 ± 9.2

Study Result

The interim analysis of data of twenty patients recruited in the study so far provides significant information with respect to implants safety and performance. Study key findings are; substantial improvement in pain score and function scores, and no occurrence of serious adverse events.

The substantial reduction in VAS score indicates that the intervention effectively alleviate pain in study population. This is particularly important as pain levels at baseline were found to be high, indicating that the intervention positively impacts the patients quality of life. Furthermore, the increase in functional score; KOOS highlights the effectiveness of the intervention. The progressive increase in KOOS over the follow-up done so far indicates a consistent and sustained improvement in Pain index, Symptoms, Activities of Daily Living, Sports and Recreation Functions and Knee Related Quality of Life. Findings of the interim report shows that knee arthroscopy system manufactured by Auxein Medical Private Limited is safe for the use in patient and perform the intended function.

6. **Possible diagnostic or therapeutic alternatives**

Diagnosing a knee injury or problem includes a medical examination and usually the use of a diagnostic procedure(s) such as an x-ray, MRI, CT scan or arthroscopy. Both non-operative and surgical treatment options are available to treat knee pain and problems depending on the type and severity of the condition.

Non-surgical Treatment

Bracing

A knee brace to provide external stability to the knee joint. Braces are designed to stabilize a joint, reduce pain and inflammation and strengthen the muscles of the knee. By putting pressure on the sides of the joint, the brace causes the joint to realign, which in turn decreases the contact between the two rough bone surfaces, reduces pain and increases mobility.

Injections and Infusions
Some medications can be injected directly into the knee to treat pain. These include corticosteroids to reduce inflammation. With infusion therapy, medications are delivered intravenously or directly into the muscles to reduce inflammation.

Lifestyle Modifications
Lifestyle modifications to daily routine, such as losing weight, avoiding activities such as running and performing low-impact exercise to reduce stress on knee.

Nutraceuticals
Nutraceuticals are herbal or dietary supplements that may have health benefits for knee joint. These supplements include glucosamine and chondroitin, which may help with overall health of the bones and soft tissues.

Pain Medications
Over-the-counter pain relievers, such as acetaminophen (e.g., Tylenol) and ibuprofen (e.g., Advil and Motrin), are commonly used to ease knee pain. Topical analgesics such as muscle rubs can also be used for temporary pain relief. It is also recommend other prescription medications such as antirheumatic drugs and biological response modifiers.

Physical and Occupational Therapy
Rehabilitative medicine and exercise programs can stretch and strengthen the muscles and soft tissues of knee joint to improve flexibility and joint support. Changing the way of performing daily activities may also help in alleviating knee pain through limiting excessive strain on knee. This can be aided through the use of therapeutics and other apparel specially designed for knee pain.

Surgical Treatment
Available treatments based on the severity and type of injury diagnosed by the doctor:

Non-Surgical Treatment	**Surgical Treatments**
○ Bracing ○ Injections and Infusions	○ Interference Screw, Graft Fixation System, etc.

○ Lifestyle Modifications ○ Nutraceuticals ○ Pain Medications ○ Physical and Occupational Therapy	

Suggested profile and training for users

The intended user (patient) should be have adequate knowledge regarding the device. The training materials i.e Surgical Technique, Instructions for Use, Catalog are already available on the manufacturer website (https://www.auxein.com/).