

SUTURE ANCHOR DELIVERY SYS



GALEN Medial Suture Anchor Small Joint Anchor

KOPIS Knotless Anchor

VIDA Interference Screws

ZENIVÄPEEK Ti6AI4V ELI

MADE IN AMERICA

Table of Contents

Galen Medial and XT Anchors	2
Kopís Knotless Anchor	3
Galen Medial with Needles	4
Galen Labral Anchor	5
Galen Small Joint Anchor	6
Vída Mini Interference Screw	7
Vida Interference Screw	8
Disposable Cannula System	9
Arthroscopic Instruments	10
Sutures	11
Performance Data	12
Product Warranty and Return Policy	13

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GALEN MEDIAL AND XT ANCHORS

The anchors are used for fixation of ligament, tendon, bone, or soft tissue to bone in knee, shoulder, foot/ankle, elbow, and hand/wrist procedures. These anchors consist of cannulated anchors with integrated suture attachment. The device is available in varying profile diameters. Each implant is manufactured from Titanium 6AL-4V ELI per ASTM F136 or ZENIVA[™] PEEK (polyetheretherketone) from Solvay Advanced Polymers per ASTM F2026.



GALEN MEDIAL SUTURE ANCHOR

Part#	Diameter (mm)	Length (mm)	Material	Description	
F-MSA-4515	4.5	15	PEEK	Screw-in, suture anchor, (2) #2 Sutures	
F-MSA-5515	5.5	15	PEEK	K Screw-in, suture anchor, (2) #2 Sutures	
F-MSA-6515	6.5	15	PEEK	Screw-in, suture anchor, (2) #2 Sutures	
F-MT-5515	5.5	15	PEEK	Screw-in, suture anchor, (2) 1.3mm round-flat-round tapes	
F-MSA-4515-TI	4.5	15	Titanium	Screw-in, suture anchor, (2) #2 Sutures	
F-MSA-5515-TI	5.5	15	Titanium	Screw-in, suture anchor, (2) #2 Sutures	
F-MSA-6515-TI	6.5	15	Titanium	Screw-in, suture anchor, (2) #2 Sutures	

GALEN XT SUTURE ANCHOR

Part#	Diameter (mm)	Length (mm)	Material Description		
F-XTS-5515	5.5	15	PEEK Screw-in, suture anchor, (3) #2 Sutures		
F-XTS-6515	6.5	15	PEEK	Screw-in, suture anchor, (3) #2 Sutures	
F-XTS-5515-TI	5.5	15	Titanium	Screw-in, suture anchor, (3) #2 Sutures	
F-XTS-6515-TI	6.5	15	Titanium	anium Screw-in, suture anchor, (3) #2 Sutures	

Part#	Diameter (mm)	Description	Disposable/Reusable
01-45P	4.5	Punch	Reusable
01-55P	5.5	Punch	Reusable
01-65P	6.5	Punch	Reusable
F-00-45P	4.5	Punch	Disposable
F-00-55P	5.5	Punch	Disposable
01-45T	4.5	Тар	Reusable
01-55T	5.5	Тар	Reusable
01-65T	6.5	Тар	Reusable



KOPIS KNOTLESS ANCHOR

The anchors are used for knotless fixation of ligament, tendon, bone, or soft tissue to bone in knee, shoulder, foot/ankle, elbow, and hand/wrist procedures. These anchors consist of cannulated anchors with integrated suture punch eyelet which leaves no metal in the body if desired. The device is available in varying profile diameters. Each implant is manufactured from Titanium 6AL-4V ELI per ASTM F136 or ZENIVA[™] PEEK (polyetheretherketone) from Solvay Advanced Polymers per ASTM F2026.



KOPIS KNOTLESS ANCHOR

Part#	Diameter (mm)	Length (mm)	Material (Screw)	Material (Eyelet)	Description
F-31-14520	4.5	20	PEEK	PEEK	Screw-in, suture anchor
F-31-15520	5.5	20	PEEK	PEEK Screw-in, suture anchor	
F-31-16520	6.5	20	PEEK	PEEK	Screw-in, suture anchor
F-31-14520-TI	4.5	20	PEEK	Titanium	Screw-in, suture anchor
F-31-15520-TI	5.5	20	PEEK	Titanium Screw-in, suture anchor	
F-31-16520-TI	6.5	20	PEEK	Titanium	Screw-in, suture anchor
F-31-14520S	4.5	20	PEEK	PEEK	Screw-in, suture anchor, (1) #2 Suture
F-31-15520S	5.5	20	PEEK	PEEK Screw-in, suture anchor, (1) #2 Suture	

Part#	Diameter (mm)	Description	Disposable/Reusable
01-45P	4.5	Punch	Reusable
01-55P	5.5	Punch	Reusable
01-65P	6.5	Punch	Reusable
F-00-45P	4.5	Punch	Disposable
F-00-55P	5.5	Punch	Disposable
01-45T	4.5	Тар	Reusable
01-55T	5.5	Тар	Reusable
01-65T	6.5	Тар	Reusable





GALEN MEDIAL WITH NEEDLES

The Galen Medial with Needles Delivery Systems are for use in fixation of ligament, tendon, bone, or soft tissue to bone in knee, shoulder, foot/ankle, elbow, and hand/wrist procedures. The Galen Small Joint Suture Anchor Delivery System consists of a single anchor with integrated multiple suture attachments. The anchors are provided loaded on individual inserters with integrated sutures with needles, sterile, for single use only. The device is available in varying profile diameters. Each implant is manufactured from ZENIVA[™] PEEK (polyetheretherketone) from Solvay Advanced Polymers per ASTM F2026.



GALEN MEDIAL WITH NEEDLES

Part#	Diameter (mm)	Length (mm)	Material	Description	
F-27-11145	4.5	15	PEEK Screw-in, suture anchor, (2) #2 Sutures, (4) MO-6 needles		
F-27-11155	5.5	15	PEEK Screw-in, suture anchor, (2) #2 Sutures, (4) MO-6 needles		
F-27-11165	6.5	15	PEEK	Screw-in, suture anchor, (2) #2 Sutures, (4) MO-6 needles	

Part#	Diameter (mm)	Description	Disposable/Reusable
01-45P	4.5	Punch	Reusable
01-55P	5.5	Punch	Reusable
01-65P	6.5	Punch	Reusable
F-00-45P	4.5	Punch	Disposable
F-00-55P	5.5	Punch	Disposable
01-45T	4.5	Тар	Reusable
01-55T	5.5	Тар	Reusable
01-65T	6.5	Тар	Reusable



GALEN LABRAL ANCHOR

The Galen Suture Anchor Delivery Systems are for use in fixation of ligament, tendon, bone, or soft tissue to bone in knee, shoulder, foot/ankle, elbow, and hand/wrist procedures. The Galen Suture Anchor Delivery System consists of a single anchor with integrated multiple suture attachments. The anchors are loaded on individual inserters with integrated sutures, sterile, for single use only. The device is available in varying profile diameters and lengths. Each implant is manufactured from Titanium 6AL-4V ELI per ASTM F136 or ZENIVA[™] PEEK (polyetheretherketone) from Solvay Advanced Polymers per ASTM F2026.



GALEN LABRAL ANCHOR

Part#	Diameter (mm)	Length (mm)	Material	Description
F-08-11101	2.9	6	PEEK	Press-in, suture anchor, (2) #2 sutures
F-08-11102	2.9	10	PEEK	Press-in, suture anchor, (2) #2 sutures
F-08-11104	3.3	10	PEEK	Press-in, suture anchor, (2) #2 sutures

Part#	Diameter (mm)	Description	Disposable/Reusable
08-02529	2.9	Drill with depth stop, long	Reusable
08-02533	3.3	Drill with depth stop, long	Reusable
08-20001		Drill and implant guide, sawtooth	Reusable
08-21125		Obturator, blunt	Reusable





GALEN SMALL JOINT ANCHOR

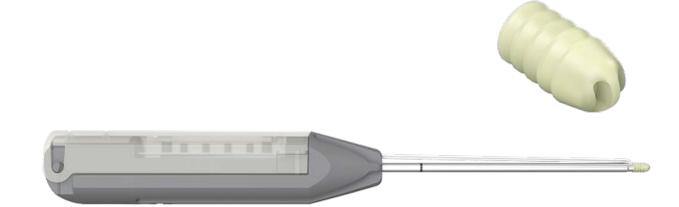


The Galen Suture Anchor Delivery Systems are for use in fixation of ligament, tendon, bone, or soft tissue to bone in knee, shoulder, foot/ankle, elbow, and hand/wrist procedures. The Galen Suture Anchor Delivery System consists of a single anchor with integrated multiple suture attachments. The anchors are provided loaded on individual inserters with integrated sutures with needles, sterile, for single use only. The device is available in varying profile diameters and lengths. Each implant is manufactured from Titanium 6AL-4V ELI per ASTM F136 or ZENIVA[™] PEEK (polyetheretherketone) from Solvay Advanced Polymers per ASTM F2026.

GALEN SMALL JOINT ANCHOR

Part#	Diameter (mm)	Length (mm)	Material	Description	
F-08-11105	2.9	6	PEEK Press-in, suture anchor, (2) #2 sutures, (4) MO-6 needles		
F-08-11107	3.3	6	PEEK	Press-in, suture anchor, (2) #2 sutures, (4) MO-6 needles	
F-08-11109	2.9	6	PEEK	Press-in, suture anchor, (2) #0 sutures, (4) CT-2 needles	
F-08-11111	3.3	6	PEEK	Press-in, suture anchor, (2) #0 sutures, (4) CT-2 needles	
F-08-11113	2.9	6	PEEK	Press-in, suture anchor, (2) #2-0 sutures, (4) CT-2 needles	
F-08-11115	3.3	6	PEEK	Press-in, suture anchor, (2) #2-0 sutures, (4) CT-2 needles	

Part#	Diameter (mm)	Description	Disposable/Reusable
08-32529	2.9	Drill with depth stop, small	Reusable
08-32533	3.3	Drill with depth stop, small	Reusable
08-20135		Drill and implant angled guide	Reusable



VDA mini interference screw



The Vida Mini Interference Screws are interference screws for use in fixation of ligament, tendon, bone, or soft tissue to bone in knee, shoulder, foot/ankle, elbow, and hand/wrist procedures. The device is available in varying profile diameters and lengths. Each implant is manufactured from ZENIVA[™] PEEK (polyetheretherketone) from Solvay Advanced Polymers per ASTM F2026.

VIDA MINI INTERFERENCE SCREW

Part#	Diameter (mm)	Length (mm)	Material	Description
F-TS-4515	4.5	15	PEEK	Interference Screw
F-TS-5015	5	15	PEEK	Interference Screw
F-TS-5515	5.5	15	PEEK	Interference Screw
F-TS-6015	6	15	PEEK	Interference Screw
F-TS-6515	6.5	15	PEEK	Interference Screw
F-TS-7012	7	12	PEEK	Interference Screw
F-TS-7015	7	15	PEEK	Interference Screw
F-TS-8012	8	12	PEEK	Interference Screw

Part#	Diameter (mm)	Description	Disposable/Reusable
10004-S		Mini screw driver, 1/4" quick connect, short	Reusable
0304-PH		1/4" quick connect palm handle	Reusable
0304-040	4	Bone tunnel reamer	Reusable
0304-045	4.5	Bone tunnel reamer	Reusable
0304-050	5	Bone tunnel reamer	Reusable
0304-055	5.5	Bone tunnel reamer	Reusable
0304-060	6	Bone tunnel reamer	Reusable
0304-065	6.5	Bone tunnel reamer	Reusable
0304-070	7	Bone tunnel reamer	Reusable
0304-080	8	Bone tunnel reamer	Reusable
0304-090	9	Bone tunnel reamer	Reusable
0304-100	10	Bone tunnel reamer	Reusable
0304-110	11	Bone tunnel reamer	Reusable
0304-120	12	Bone tunnel reamer	Reusable



VDA INTERFERENCE SCREW

The Vida Interference Screws are interference screws for use in fixation of ligament, tendon, bone, or soft tissue to bone in knee, shoulder, foot/ankle, elbow, and hand/wrist procedures. The device is available in varying profile diameters and lengths. Each implant is manufactured from ZENIVA[™] PEEK (polyetheretherketone) from Solvay Advanced Polymers per ASTM F2026.

VDA INTERFERENCE SCREW

Part#	Diameter (mm)	Length (mm)	Material	Description
F-IS-0723	7	23	PEEK	Interference Screw
F-IS-0730	7	30	PEEK	Interference Screw
F-IS-0823	8	23	PEEK	Interference Screw
F-IS-0830	8	30	PEEK	Interference Screw
F-IS-0923	9	23	PEEK	Interference Screw
F-IS-0930	9	30	PEEK	Interference Screw
F-IS-1023	10	23	PEEK	Interference Screw
F-IS-1030	10	30	PEEK	Interference Screw
F-IS-1123	11	23	PEEK	Interference Screw
F-IS-1130	11	30	PEEK	Interference Screw
F-IS-1223	12	23	PEEK	Interference Screw
F-IS-1230	12	30	PEEK	Interference Screw

INSTRUMENTATION

Part#	Diameter (mm)	Description	Disposable/Reusable
10003-S		Titan screw driver, 1/4" quick connect, short	Reusable
0304-PH		1/4" quick connect palm handle	Reusable
0304-040	4	Bone tunnel reamer	Reusable
0304-045	4.5	Bone tunnel reamer	Reusable
0304-050	5	Bone tunnel reamer	Reusable
0304-055	5.5	Bone tunnel reamer	Reusable
0304-060	6	Bone tunnel reamer	Reusable
0304-065	6.5	Bone tunnel reamer	Reusable
0304-070	7	Bone tunnel reamer	Reusable
0304-080	8	Bone tunnel reamer	Reusable
0304-090	9	Bone tunnel reamer	Reusable
0304-100	10	Bone tunnel reamer	Reusable
0304-110	11	Bone tunnel reamer Reusable	
0304-120	12	Bone tunnel reamer	Reusable





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DISPOSABLE CANNULA

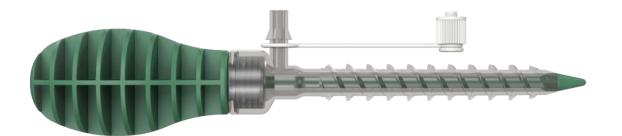
The Disposable Cannula System is a disposable cannula and obturator set for use in general arthroscopic surgical procedures to provide operating portals during the insertion and removal of instruments. The contents are provided sterile, for single use only.

DISPOSABLE CANNULA

Part#	Diameter (mm)	Length (mm)	Description
F-00-6570	6.5	70	Disposable Cannula
F-00-7570	7.5	70	Disposable Cannula
F-00-7590	7.5	90	Disposable Cannula
F-00-8570	8.5	70	Disposable Cannula
F-00-8590	8.5	90	Disposable Cannula

ACCESSORIES

Part#	Diameter (mm)	Length (mm)	Description
09-36570	6.5	70	Reusable cannulated obturator
09-37570	7.5	70	Reusable cannulated obturator
09-37590	7.5	90	Reusable cannulated obturator
09-38570	8.5	70	Reusable cannulated obturator
09-38590	8.5	90	Reusable cannulated obturator
09-40305	4	305	Switching stick



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ARTHROSCOPIC INSTRUMENTS



Arthroscopic instruments are used to manipulate tissue and suture to assist in arthroscopic procedures.

ARTHROSCOPIC INSTRUMENTS

Part#	Description	Disposable/Reusable
26-20001	Tissue grasper, straight 2.7mm	Reusable
26-20005	knot pusher	Reusable
26-20027	Suture retriever, straight	Reusable
26-20035	suture cutter, carbide cutting edge	Reusable
26-20033	Suture passer	Reusable
F-26-30001	Suture passer needle	Disposable



SUTURE / TAPE



High strength, non-absorbable suture and tape to be used in sport medicine procedures.

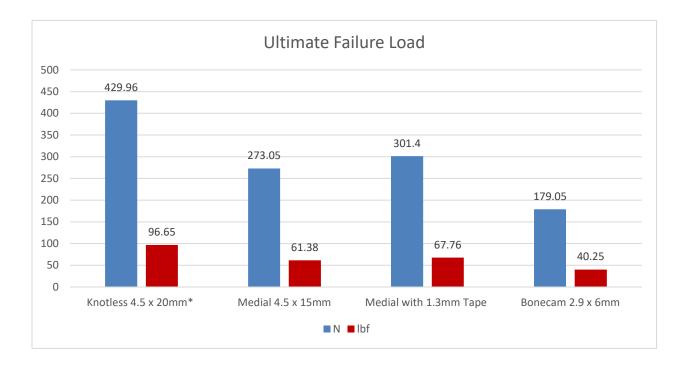
SUTURE AND TAPE

Part#	Size	Needle	Description
F-VAL4020WBN	4-0	C-1	UHMWPE, white/blue, 20"
F-VAL3020WBN	3-0	BB	UHMWPE, white/blue, 20"
F-VAL2020WBN	2-0	CT-2	UHMWPE, white/blue, 20"
F-VAL0030WBN	0	CT-2	UHMWPE, white/blue, 30"
F-VAL0239WBN	2	MO-6	UHMWPE, white/blue, 39"
F-VAL0239B	2	Non-Needled	UHMWPE, blue, 39"
F-VAL0539WBN	5	MO-6	UHMWPE, white/blue, 39"
F-VAL0236GL	2	Non-Needled	Suture loop, 36"
F-VAL0220SS	2	Non-Needled	Split stitch, 20" loop
F-VAL1340BT	2	Non-Needled	Round-flat-round tape, blue, 40"
F-VAL1340WBT	2	Non-Needled	Round-flat-round tape, white/blue, 40"



ANCHOR PERFORMANCE





Materials & Methods

- Using the appropriate punch, tap, and drill for each anchor, pilot holes were created in polyurethane foam blocks. The blocks used were Sawbones 40 pcf with a nominal density of .64g/cc.
- Knotless anchors were loaded with (2) #2 suture and inserted into the pilot holes per the surgical technique guide.
- Medial and Press-In anchors were used as packaged and inserted into the pilot holes per their respective surgical technique guides.
- The suture was tied into a loop and then hooked onto a tensile tester. The tensile tester will be initiated, and the sutures were pulled until failure.
- 5 samples of each anchor were tested in this repeatable manner to determine the ultimate failure load

*Failure mode for knotless anchor was the suture. Anchor remained intact and flush with sawbone.

FOR INFORMATIONAL PURPOSES ONLY

Product Warranty and Return Policy



Product Warranty

Fuse Medical, Inc warrants that all products will be free from defects in material and workmanship, will be fit and sufficient for the purpose intended and will conform to the performance specifications issued by Fuse Medical, Inc. This is provided that the products are handled, stored and implanted by end-users, according to reasonable instructions from Fuse Medical, Inc. The length of the warranty for each of the products is 90 days after delivery to distributor, or its end-user where the products is ship directly to end-user. THE WARRANTIES MADE HEREIN ARE MADE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF THE MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT AND ANY WARRANTY ARISING OUT OF A COURSE OF DEALING, A CUSTOMER OR USAGE OF TRADE, EXCEPT AS EXPRESSLY PROVIDED IN THIS WARRANTY. To make a warranty claim, the purchaser must comply with the procedure set forth in the return policy below. Purchases sole remedy for breach of warranty is limited to replacement of the product or credit for the price of the product.

Return Policy

All orders should be checked on receipt and inspected for correct catalog numbers, correct quantities, expiration dates, damage product and package integrity. Only products in their original, unopened packaging will be accepted for return. All Fuse Medical, Inc branded inventory can be returned within 10 days of receipt without penalty. After 10 days, a 30% restocking fee will apply. All products returned to Fuse Medical, Inc must have a Return Materials Authorization ("RMA") number in order for customer service to process the return. To obtain an RMA number, contact Fuse Medical, Inc Customer Service and provide the following information: Catalog Number, Lot Number, Quantity and Reason for return.

ABOUT FUSE MEDICAL :

Fuse is an emerging manufacturer and distributor of innovative medical devices for the orthopedic and spine marketplace. We provide a comprehensive portfolio of products in the orthopedic total joints, sports medicine, trauma, foot and ankle, as well as, degenerative and deformity spine, orthobiologics and regenerative medicine products.

