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Bezirksregierung Düsseldorf

<p style="text-align: center;"><b>Freiverkaufszertifikat nach § 10</b></p> <p style="text-align: center;">des Medizinprodukte- Durchführungsgesetzes (MPDG) und Artikel 60 Absatz 1 auch i.V.m. Artikel 120 Abs. 3 und Abs. 4</p> <p>der Verordnung (EU) 2017/745 des Europäischen Parlaments und des Rats vom 05. April 2017 in der jeweils gültigen Fassung</p> <p style="text-align: center;">zur Vorlage bei den zuständigen Behörden/Stellen von</p> <p style="text-align: center;"><b>Vietnam</b></p> <p>Es wird bescheinigt, dass</p> <ul style="list-style-type: none"> <li>• die eingetragene Niederlassung des Europäischen Bevollmächtigten ihren Sitz in Deutschland hat,</li> <li>• dass das Medizinprodukt gemäß der oben genannten Verordnung die CE-Kennzeichnung trägt</li> </ul> <p>und in den Mitgliedsstaaten der Europäischen Union gehandelt werden darf.</p> <p><b>Produkte:</b></p> <p>- siehe Anlage (30 Seiten) -</p> <p><b>Europäischer Bevollmächtigter:</b></p> <p>Caretechion GmbH Niederrheinstr. 71 40474 Düsseldorf Deutschland</p> <p><b>Hersteller:</b></p> <p>Star Sports Medicine Co., Ltd. Room A018, Floor 1, Building 1, NO.25, JingHai 2 Road, Beijing Economic and Technological Development Zone, 100176 Beijing, China</p>	<p style="text-align: center;"><b>Free Sales Certificate according to § 10</b></p> <p style="text-align: center;">of the Medical Devices Law Implementing Act (MPDG) and Article 60 Chapter 1 also in conjunction with Article 120 para. 3 and para. 4</p> <p>of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 in the current valid version</p> <p style="text-align: center;">for presentation to the competent authorities/bodies of</p> <p style="text-align: center;"><b>Viet Nam</b></p> <p>It is certified that</p> <ul style="list-style-type: none"> <li>• the European Representative has its registered place of business in Germany,</li> <li>• the device in question bearing the CE marking in accordance with the aforementioned Regulation</li> </ul> <p>and may be marketed in the European Union.</p> <p><b>Products:</b></p> <p>- see attachment (30 pages) -</p> <p><b>European Representative:</b></p> <p>Caretechion GmbH Niederrheinstr. 71 40474 Düsseldorf Germany</p> <p><b>Manufacturer:</b></p> <p>Star Sports Medicine Co., Ltd. Room A018, Floor 1, Building 1, NO.25, JingHai 2 Road, Beijing Economic and Technological Development Zone, 100176 Beijing, China</p>
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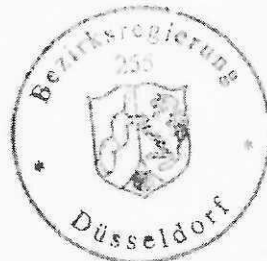


<p>Mit dem CE-Kennzeichen bringt der Hersteller zum Ausdruck, dass die Medizinprodukte die Grundlegenden Sicherheits- und Leistungsanforderungen</p> <p>der Verordnung (EU) 2017/745 des Europäischen Parlaments und des Rats vom 05. April 2017 über Medizinprodukte in der jeweils gültigen Fassung</p> <p>erfüllen und das vorgeschriebene Konformitätsbewertungsverfahren durchgeführt wurde.</p> <p>Düsseldorf, den 01.10.2024          Bezirksregierung Düsseldorf          Im Auftrag</p> <p><i>Carolyn Jansch</i>          Carolyn Jansch</p>	<p>With the CE-mark the manufacturer confirms that the medical devices comply with the general safety and performance requirements of</p> <p>the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices in the current valid version</p> <p>and that the required conformity assessment procedure has been completed.</p>
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Die Echtheit der **vorstehenden** Unterschrift der **Frau Jansch** Angehörige der **Bezirksregierung Düsseldorf** und die Echtheit des Dienstsiegels werden hiermit beglaubigt. Gleichzeitig wird bescheinigt, dass die Vorgenannte zur Ausstellung dieser Urkunde berechtigt war.

Düsseldorf, 17. Okt. 2024



Bezirksregierung Düsseldorf  
 Im Auftrag  
*Hermen*  
 Hermen  
 Regierungsamtsinspektorin

Nr.	Produktbezeichnung	Klassifikation I, Is, Im, IIa, IIb, III	Models	UMDNS, EMDA	Registriernummer
1.	Metal Suture Anchors	IIb	See Attachment below	17-782	DE/CA20/00189523
2.	Non-absorbable Surgical Sutures	IIb		13-896	DE/CA20/00189524
3.	Suture Buttons	IIb		13-891	DE/CA20/00186530
4.	Shaver Blades	IIa		10-456	DE/CA20/00189504
5.	Peek Suture Anchors	IIb		17-782	DE/CA20/00184664
6.	Peek Interference Screw Systems	IIb		16-101	DE/CA20/00189512
7.	Arthroscopic Shaver Systems	IIa		17-918	DE/CA20/00189528
8.	Arthroscopic Surgical Instruments	I		13-180	DE/CA20/00190048
9.	All-Suture Anchors	IIb		17-782	DE/CA20/00188901
10.	Meniscal Repair Devices	IIb		17-993	DE/CA20/00187361
11.	Arthroscopic Access Cannulas	IIa		15-260	DE/CA20/00188899
12.	Spiked Ligament Staples	IIb		16-103	DE/CA20/00186532
13.	Endoscopic Video Image Systems	I		18-037	DE/CA20/00189530
14.	Arthroscopic Surgical Instruments	IIa		13-180	DE/CA20/00201558



## Annex 1



### Attachment: Model list per product

#### 1. Metal Suture Anchors

Model list							
TA1A1	TA2A1	TA3A1	TA4A1	/			
TA1A2	TA2A2	TA3A2	TA4A2	/			
TA1A3	TA2A3	TA3A3	TA4A3	/			
TA1B1	TA2B1	TA3B1	TA4B1	/			
TA1B2	TA2B2	TA3B2	TA4B2	/			
TA1B3	TA2B3	TA3B3	TA4B3	/			
TA1C1	TA2C1	TA3C1	TA4C1	/			
TA1C2	TA2C2	TA3C2	TA4C2	/			
TA1C3	TA2C3	TA3C3	TA4C3	/			
TA1HA1	TA2HA1	TA3HA1	TA4HA1	TA5HA1	TA6HA1	TA5A1	TA6A1
TA1HA2	TA2HA2	TA3HA2	TA4HA2	TA5HA2	TA6HA2	TA5A2	TA6A2
TA1HA3	TA2HA3	TA3HA3	TA4HA3	TA5HA3	TA6HA3	TA5A3	TA6A3
TA1HB1	TA2HB1	TA3HB1	TA4HB1	TA5HB1	TA6HB1	TA5B1	TA6B1
TA1HB2	TA2HB2	TA3HB2	TA4HB2	TA5HB2	TA6HB2	TA5B2	TA6B2
TA1HB3	TA2HB3	TA3HB3	TA4HB3	TA5HB3	TA6HB3	TA5B3	TA6B3
TA1HC1	TA2HC1	TA3HC1	TA4HC1	TA5HC1	TA6HC1	TA5C1	TA6C1
TA1HC2	TA2HC2	TA3HC2	TA4HC2	TA5HC2	TA6HC2	TA5C2	TA6C2
TA1HC3	TA2HC3	TA3HC3	TA4HC3	TA5HC3	TA6HC3	TA5C3	TA6C3
TA1ZA1	TA2ZA1	TA3ZA1	TA4ZA1	TA5ZA1	TA6ZA1		
TA1ZA2	TA2ZA2	TA3ZA2	TA4ZA2	TA5ZA2	TA6ZA2		
TA1ZA3	TA2ZA3	TA3ZA3	TA4ZA3	TA5ZA3	TA6ZA3		
TA1ZB1	TA2ZB1	TA3ZB1	TA4ZB1	TA5ZB1	TA6ZB1		
TA1ZB2	TA2ZB2	TA3ZB2	TA4ZB2	TA5ZB2	TA6ZB2		
TA1ZB3	TA2ZB3	TA3ZB3	TA4ZB3	TA5ZB3	TA6ZB3		
TA1ZC1	TA2ZC1	TA3ZC1	TA4ZC1	TA5ZC1	TA6ZC1		
TA1ZC2	TA2ZC2	TA3ZC2	TA4ZC2	TA5ZC2	TA6ZC2		
TA1ZC3	TA2ZC3	TA3ZC3	TA4ZC3	TA5ZC3	TA6ZC3		



## 2. Non-absorbable Surgical Sutures

Model
UHS,UHT,UHSN

## 3. Suture Buttons

Product model				
EB1F,EB1FI,EB1FII,EBIJ,EB1JI,EB1JII	EB0F, EB0FI, EB0FII	EB2F, EB2FI, EB2FII	EB3F, EB3FI, EB3FII	EB4F, EB4FI, EB4FII
EB1A,EB1AI,EB1AII,EBIK,EBIKI,EB1KII, EB2A,EB2AI,EB2AII,EB3A,EB3AI,EB3AII,EB4A,EB4AI,EB4AII				

Suture Buttons specification table

Suture Button specification/size			
Loop diameter φ(mm)	Titanium plate Type (1,2,3 Type)		
	Length Lx Width W x Thickness D(mm)		
10,12 or 15-60(each size interval 5mm)  (Only 1 Types)	10-30(each size interval 2mm), 30-50(each size interval 5mm)	3.5-15(each size interval 0.5mm),	1.2-5.1(each size interval 0.3mm),
	4 Types: Diameterφ6-30(each size interval 1mm) Thickness D1.2-5.1(each size interval 0.3mm)		

Combined set code			
Single model	Number of Button	Number of Suture with needle	Number of Suture
EB1F(A),EB1FI(B),EB1FII(C),EB1J(D),EB1JI(E),EB1JII(F),EB1A(G),EB1AI(H),EB1AII(T),EB1K(J),EB1KI(K),EB1KII(L),EB0F(M),EB0FI(N),EB0FII(O),EB2F(P),EB2FI(Q),EB2FII(R),EB3F(S),EB3FI(T),EB3FII(U),EB4F(V),EB4FI(W),EB4FII(X),UHS(a),UHSN(b),UHT1(c),UHT2(d)	1;2;3;4	0;1;2;3;4;5;6	0;1;2;3;4



Combined set code	
Combined Type	Model
2 pcs 0 Type Button+1 pcs UHS	M1M1b0a1,M1N1b0a1,M1O1b0a1, N1N1b0a1,O1O1b0a1
2 pcs 0 Type Button+2 pcs UHS	M1M1b0a2,M1N1b0a2,M1O1b0a2, N1N1b0a2,O1O1b0a2
2 pcs 0 Type Button+3 pcs UHS	M1M1b0a3,M1N1b0a3,M1O1b0a3, N1N1b0a3,O1O1b0a3
1 pcs 0 Type Button +1 pcs 3 Type Button +3pcs UHS	M1S1b0a3,N1S1b0a3,O1S1b0a3,M1T1b0a3, M1U1b0a3,N1T1b0a3,N1U1b0a3,O1T1b0a3, O1U1b0a3
1pcs 1 Type Button with adjustable loop+1pcs 2 Type Buttons +2pcs UHSN+2 pcs pulling Suture	G1P1b2a2,G1Q1b2a2,G1R1b2a2,H1P1b2a2 ,H1Q1b2a2,H1R1b2a2,I1P1b2a2,I1Q1b2a2, I1R1b2a2
1pcs 1 Type Button with adjustable loop+1pcs 4 Type Buttons +2pcs UHSN+2 pcs pulling Suture	G1V1b2a2,G1W1b2a2,G1X1b2a2,H1V1b2a2, H1W1b2a2,H1X1b2a2,I1V1b2a2,I1W1b2a2, I1X1b2a2
1pcs 1 Type Button with adjustable loop and tail Suture+1 pcs 2 Type Button +2pcs pulling Suture	J1P1b0a2,J1Q1b0a2,J1R1b0a2,K1P1b0a2, K1Q1b0a2,K1R1b0a2,L1P1b0a2,L1Q1b0a2, L1R1b0a2
1pcs 1 Type Button with adjustable loop and tail Suture+1 pcs 4 Type Button+2pcs pulling Suture	J1V1b0a2,J1W1b0a2,J1X1b0a2,K1V1b0a2, K1W1b0a2,K1X1b0a2,L1V1b0a2,L1W1b0a2, L1X1b0a2
3pcs 0 Type Button +2 pcs UHS;	M1M2b0a2,M1N2b0a2,M2N1b0a2 ,M2O1b0a2,M1O2b0a2,N2N1b0a2, O1O2b0a2
3pcs 0 Type Button +3 pcs UHS;	M1M2b0a3,M1N2b0a3,M2N1b0a3 ,M2O1b0a3,M1O2b0a3,N2N1b0a3,O1O2b0a3
3pcs 0 Type Button +4 pcs UHS;	M1M2b0a4,M1N2b0a4,M2N1b0a4, M2O1b0a4,M1O2b0a4,N2N1b0a4,O1O2b0a4
2pcs 3 Type Button +2 pcs flat Suture	S1S1b0c2,S1T1b0c2,S1U1b0c2, T1T1b0c2,U1U1b0c2,S1S1b0d2, S1T1b0d2,S1U1b0d2,T1T1b0d2,U1U1b0d2

#### 4. Shaver Blades

Product code	Outer tube	Inner tube	Cutter bar	Handle
B	A-O	01-20	S、C、T	F、S、T

Note: Models of the product are arbitrary combination of Product code, Outer tube, Inner tube, Cutter bar and Handle.

#### 5. Peek Suture Anchors

Molded anchors model specification list

Model			Specification	
Anchors model	Type of inserters	Number of sutures(pcs)	Anchors size	
			φ(mm)	L (mm)
AK1,AK2,AK3,AK9,AK10	A,B	1,2,3	3.0~6.5(space 0.25)	10~19(space 0.5)
AK2,AK3	/	/	3.0~9.0(space 0.25)	7~25(space 0.5)
AK2,AK3	D	1,2,3	3.0~9.0(space 0.25)	7~25(space 0.5)
AK4	A,B	1,2,3	2.0~4.0(space 0.25)	10~15(space 0.2)
AK5	A,B,C	/	2.0~5.0(space 0.25)	8~28(space 0.5)
AK6,AK7	D	1,2,3	4.0~9.0(space 0.25)	18~21(space 0.5)
AK8	D	/	3.0~6.0(space 0.25)	14~25(space 0.5)



Machined anchors model specification list

Model			Specification	
Anchors model	Type of inserters	Anchors model	Anchors model	
			φ(mm)	L (mm)
AKM1,AKM2, AKM3,AKM7,AKM8	A,B,D,E	1,2,3	3.0~6.5(space 0.25)	10~19(space 0.5)
AKM2, AKM3	/	/	3.0~9.0(space 0.25)	7~25(space 0.5)
AKM2, AKM3	A,B,D,E	1,2,3	3.0~9.0(space 0.25)	7~25(space 0.5)
AKM4, AKM5,AKM6	A,B,E	1,2,3	2.0~4.0(space 0.25)	10~15(space 0.2)
AKM9M3,AKM9P4	A,B,C,E	/	2.0~5.0(space 0.25)	8~28(space 0.5)
AKM10P1,AKM10P2, AKM10P5	A,B,D,E	1,2,3	3.0~9.0(space 0.25)	
AKM10M3, AKM10P4	A,B,D,E	/		

Machined eyelets model specification list

φD (mm)	L (mm)
2.0~9.0(space 0.2)	3.0~12.0(space 0.2)

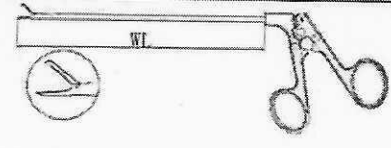
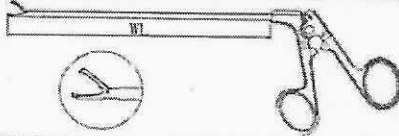
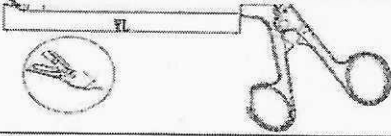
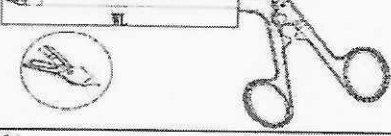
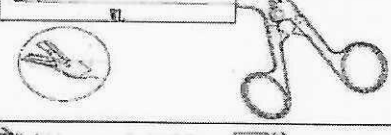
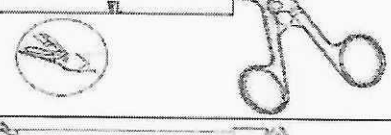


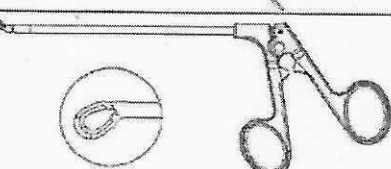
6. Peek Interference Screw Systems

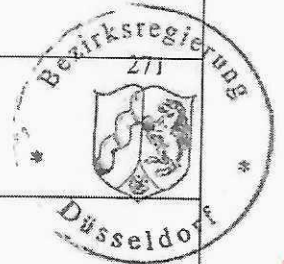
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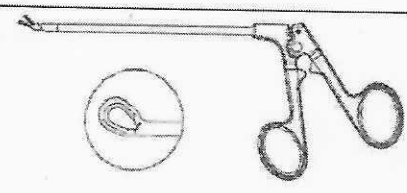
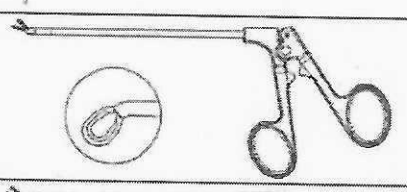
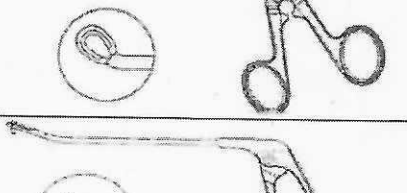
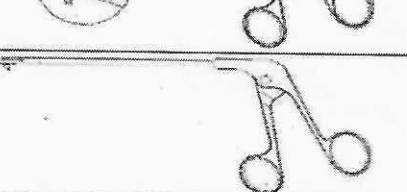
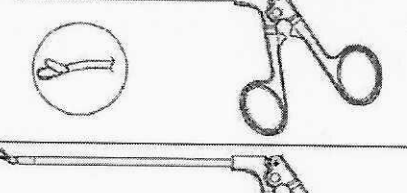
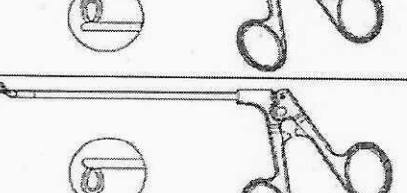
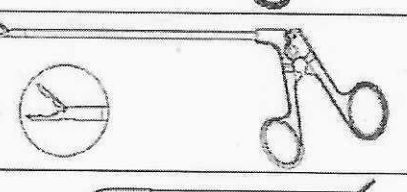
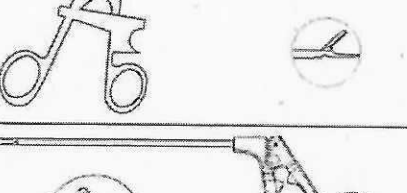
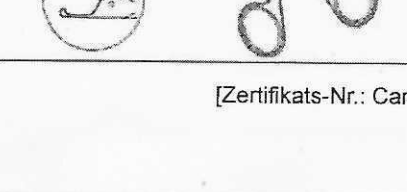

7. Arthroscopic Shaver Systems

Model
SV-100

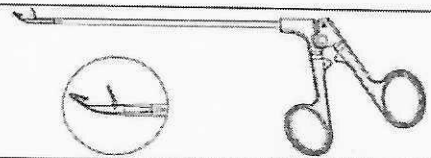
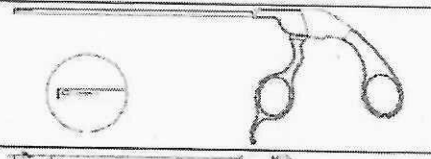

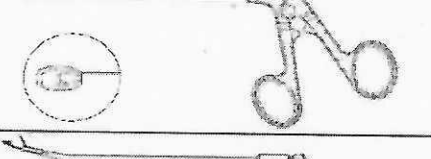
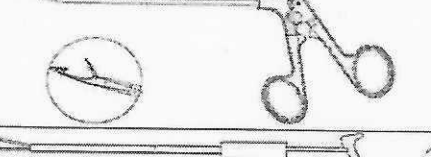
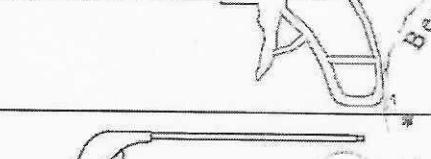
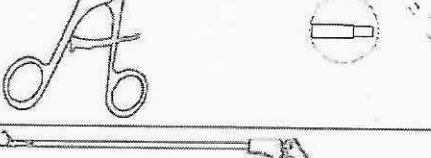
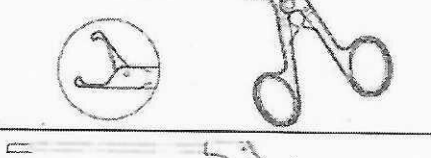

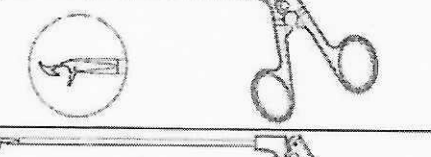


## 8. Arthroscopic Surgical Instruments

Classification code	Category Name	Product specification	
100	Pliers	Working length 125mm-400mm (1mm per interval); insert part maximum width 4mm-8mm (0.5mm per interval); maximum opening length 4-10mm (0.5mm per interval); maximum opening angle 30°- 45° (5° per interval).	
Model	Product Name	Product Description	Product Icon
ST1001	Grasper	Straight	
ST1002	Loosebody Forceps	Pointed	
ST1003	Basket Punches	Duckbill Upbiter	
ST10031	Basket Punches	Narrow rectangle	
S10032	Basket Punches	Duckbill Upbiter, 30°Left	
ST10033	Basket Punches	Duckbill Upbiter, 30°Right	
ST1004	Basket Punches	Oval Upbiter	
ST10041	Basket Punches	Pole, 15°up, Backbiter	
ST10042	Basket Punches	Pole, 30°Left	



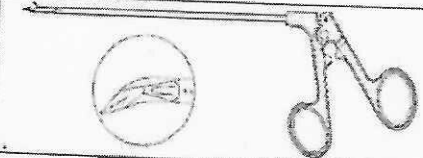
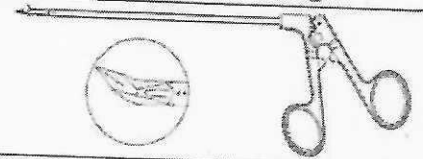
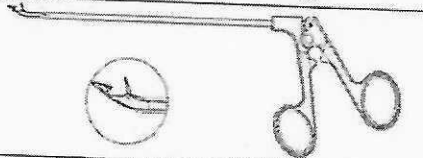
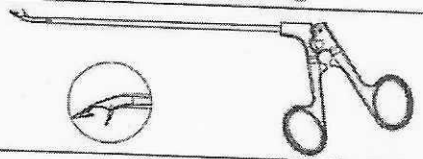
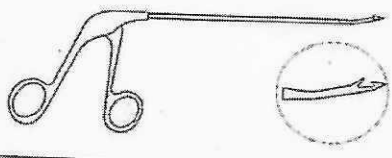
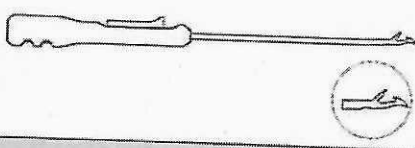
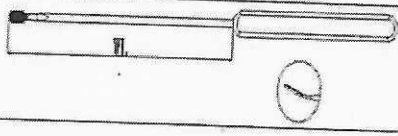
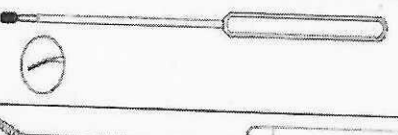

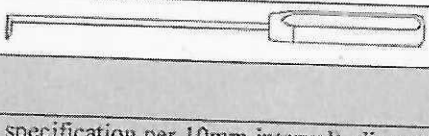
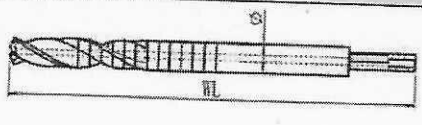
ST10043	Basket Punches	Pole, 30° Right	
ST10044	Basket Punches	Side Cut, 45° Left	
ST10045	Basket Punches	Side Cut, 45° Right	
ST10046	Basket Punches	Backbiter, 15° up	
ST100461	Basket Punches	Head straight	
ST10047	Half-moon Grasper	Leftbiter	
ST10048	Basket Punches	Straight, 90° Right	
ST10049	Basket Punches	Straight, 90° Left	
ST1005	Tissue Grasper	Straight	
ST10051	Tissue Grasper	Straight, "M" shape	
ST1006	Suture Manipulator	Straight, Universal	



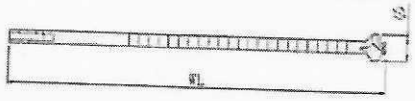

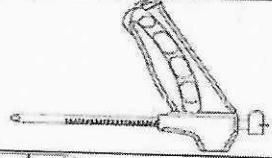



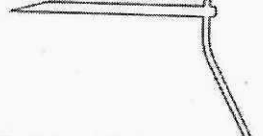
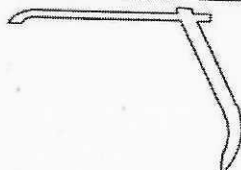
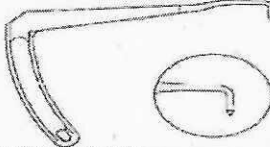
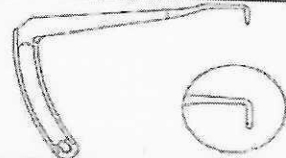
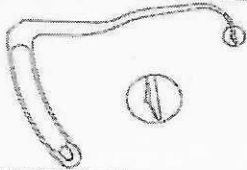
ST10061	Suture Manipulator	22°upbiter, Crane	
ST10062	Suture Cutter	Straight (No opening Angle)	
ST10063	Suture Cutter	Closed	
ST10064	Suture Cutter	Opening	
ST10065	Suture Grasper	20°upbiter	
ST10066	Multifire Suture Passer	Straight	
ST10067	Suture Cutter	Straight (Closed)	
ST10068	Suture Grasper	Pole, Straight	
ST10069	Flat strip wire cutting pliers	Clamp head square mouth	
ST1007	Smart Hook	Right, upper opening or lower opening	
ST10071	Smart Hook	Left, upper opening or lower opening	
ST10072	Penetrating Grasper	Straight	



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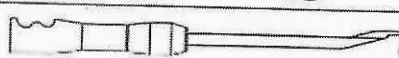
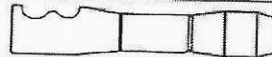



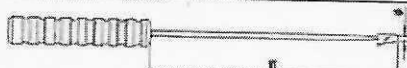






ST10073	Penetrating Grasper	Left 45°	
ST10074	Penetrating Grasper	Right 45°	
ST10075	Penetrating Grasper	Up 35°	
ST10076	Penetrating Grasper	Down 35°	
ST10077	Smart Hook	Straight, Up	
ST10078	Smart Hook	Right opening 30°, Left opening	
ST100781	Smart Hook	Left opening 30°, Right opening	
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>	
200	Rasp	Working length 125mm-400mm (1mm per interval)	
<b>Model</b>	<b>Product Name</b>	<b>Product Description</b>	<b>Product Icon</b>
ST2000	Rasp	Upswept	
ST2001	Rasp	Downswept	
ST2002	Rasp	Spiralswept	
ST2003	Rasp	Verticalswept	
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>	
300	Cannulated Drill Bits	Length 160-200mm (one specification per 10mm interval) diameter φ4-14mm (one specification per 0.5mm interval)	
ST3000	Cannulated Drill Bits	Tibial, Threaded, reusable	
ST300A	Cannulated Drill Bits	Tibial, Threaded, Disposable	

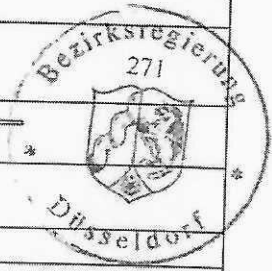


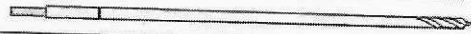








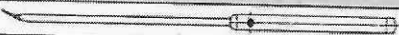
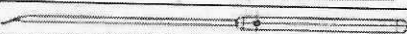
ST3001	Cannulated Drill Bits	Femoral, mushroom-shaped, reusable	
ST300B	Cannulated Drill Bits	Femoral, mushroom-shaped, Disposable	
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>	
400	Director Drill Guide	Diameter $\varnothing$ 0-10mm (0.5mm per interval)	
<b>Model</b>	<b>Product Name</b>	<b>Product Description</b>	<b>Product Icon</b>
ST4000	Femoral Drill Guide	diameter $\varnothing$ 0-10mm (one specification per 0.5mm interval)	
ST4001	Director Drill Guide		
ST40011	Director Drill Guide Handle		
ST40012	Director Drill Guide Handle (arc)		
ST400111	Director		
ST40013	Director		
ST40014	Needle Catcher		
ST4002	Director ACL Tip Aimer		
ST4003	Director ACL Elbow Aimer		
ST4004	Director PCL Tibial Aimer		



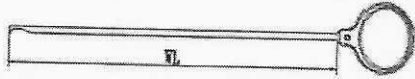
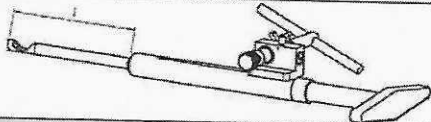
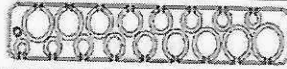
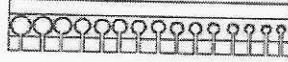

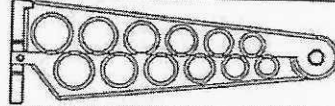
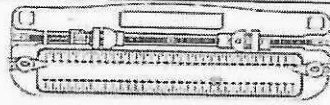

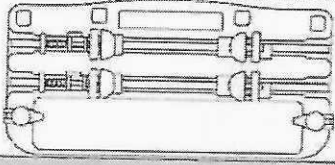


ST400E	Director Drill Aimer (Footprint Femoral ACL Guide, Right)		
ST400F	Aiming hook, Right		
ST400G	Aiming hook, Left		
ST400H	Director Drill Guide (AC Guide)		
ST400I	PCL Elevater		
ST400J	Transportal Guide		
ST400J1	Transportal Guide Handle		
ST400J2	Transportal Guide		
Model			Product Icon
ST400k	Meniscal Dart Gun Sheath	30°Left/Right	
ST400k1	Meniscal Dart Gun Sheath	15°Left/Right	
ST400k2	Meniscal Dart Gun Sheath	Straight	
S400K3	Sight handle	Cooperate with flexible needle sights	
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>	
500	Tendon Strippers	Working length 300mm; diameter $\phi$ 5-10mm (1mm per interval)	
<b>Model</b>	<b>Product Name</b>	<b>Product Description</b>	<b>Product Icon</b>
ST5000	Tendon Strippers	Slotted	
ST5001	Tendon Strippers	Closed	
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>	
600	Threading Device	Working length 150-300mm, (one interval per 0.5mm)	
<b>Model</b>	<b>Product Name</b>	<b>Product Description</b>	<b>Product Icon</b>
ST6000	Threading Device	Left 45°	
ST6001	Threading Device	Right 45°	
ST6002	Threading Device	Left 25°	
ST6003	Threading Device	Right 25°	
ST6004	Threading Device	Straight	



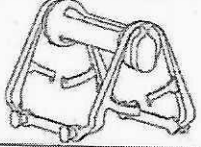
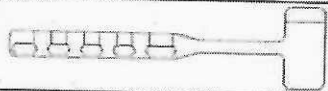
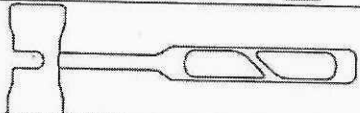



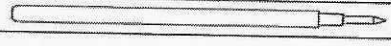



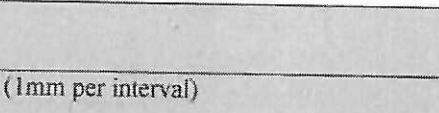



ST7007	Cannula pin		
S70071	Drill		
ST7009	Stitching Device	Left 15°/45°/75°, Right 15°/45°/75°	
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>	
700	Passing Pin	Diameter ( φ ) : 0.6-5 (with an interval of 0.2); Length (L): 50-300 (interval 5)	
<b>Model</b>	<b>Product Name</b>	<b>Product Description</b>	<b>Product Icon</b>
ST70091	Suture lasso Device		
ST70092	Straight needle		
ST70093	Curved needle		
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>	
700	Passing Pin	Diameter φ: 1mm-3mm, one gauge per 0.5mm interval, working length 120-400mm (one gauge per 5mm interval)	
<b>Model</b>	<b>Product Name</b>	<b>Product Description</b>	<b>Product Icon</b>
ST7008	Pin for Multifire Suture Passer		
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>	
800	Calibrated Probe	Working length 100mm-300mm (one specification per 50mm interval)	
<b>Model</b>	<b>Product Name</b>	<b>Product Icon</b>	
ST8000	Calibrated Probe		
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>	
900	Depth Probe	Working length 100mm-300mm (10mm per interval)	
<b>Model</b>	<b>Product Name</b>	<b>Product Icon</b>	
ST9000	Depth Probe		
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>	
110	Detacher	Working length 100mm-300mm (5mm per interval)	
<b>Model</b>	<b>Product Name</b>	<b>Product Description</b>	<b>Product Icon</b>
ST1100	Detacher	Upbiter	
ST1101	Detacher	Downbiter	
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>	









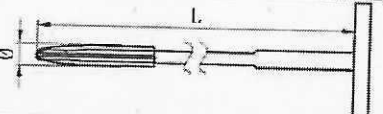



111	Knot Manipulator	Working length 100mm-300mm (5mm per interval)	
Model	Product Name	Product Icon	
ST1110	Knot Manipulator		
ST1111	Knot Manipulator		
Classification code	Category Name		
112	Graft Sizing Tubes		
Model	Product Name	Product Icon	
ST1120	Graft Sizing Tubes		
ST1121	Graft Sizing Block		
ST1122	Graft Sizing Block (Closed)	Diameter $\phi$ 2-14mm (0.5mm interval) per	
ST1123	Opening and closing tenometer	/	
Classification code	Category Name		
113	Graft Preparation Working Station		
Model	Product Name	Product Icon	
ST1130	Graft Preparation Working Station		
S1131	Graft preparation station, Starter		
S1133	Graft preparation station, Double track		
Classification code	Category Name		
114	Tension separator		
Model	Product Name	Product Icon	







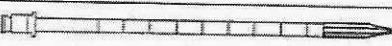
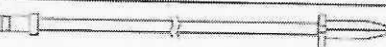



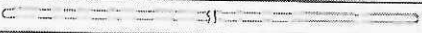
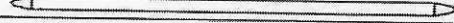



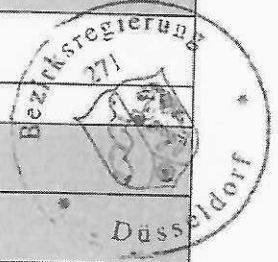
ST1140	Tie Tensioner		
ST1141	Graft Spreader		
ST1142	Tendon dilator		
<b>Classification code</b>	<b>Category Name</b>		
115	Bone Hammer		
<b>Model</b>	<b>Product Name</b>	<b>Product Icon</b>	
ST1150	Bone Hammer		
ST1151	Extractor		
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>	
116	Bone Cone	Working length 120-300mm, diameter $\phi$ 1-5mm (0.1mm per interval)	
<b>Model</b>	<b>Product Name</b>	<b>Product Icon</b>	
ST1160	Bone Cone		
ST1161	Punch/Tap		
ST11611	Punch		
ST1162	Punch		
ST11621	Punch	Knife type	
ST1163	Punch/Tap		
ST11631	Guide handle		
ST1164	Punch	Cone	
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>	
117	Trial	Working length 5-14mm (1mm per interval)	
<b>Model</b>	<b>Product Name</b>	<b>Product Description</b>	<b>Product Icon</b>
ST1170	Trial	Trocar-Tip	


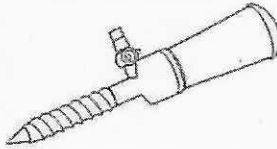
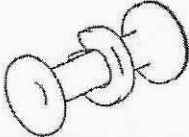
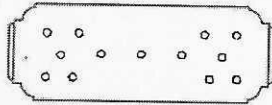







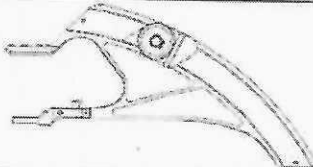




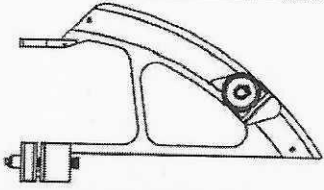
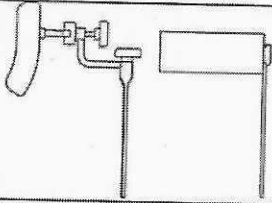
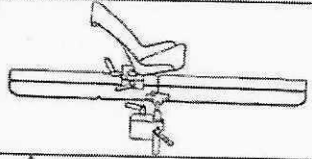
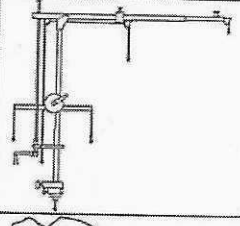
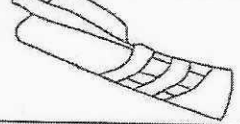

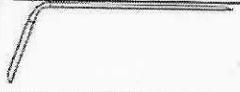
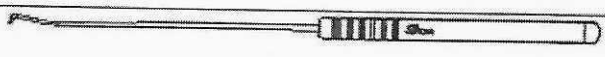
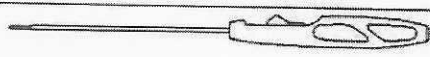
ST1171	Trial	Drill-Tip	
Classification code	Category Name	Product specification	
118	Punch	Diameter $\phi$ 2-14mm (0.1mm per interval)	
Model	Product Name	Product Icon	
ST1180	Punch		
ST1181	Punch		
ST1182	Punch	 	
Classification code	Category Name	Product specification	
119	Graft Dilator	Diameter $\phi$ 2mm-15mm, one specification per interval 0.5mm	
Model	Product Name	Product Icon	
ST1190	Graft Dilator		
ST1191	Graft Dilator		
Classification code	Category Name	Product specification	
120	Hook	Working length 160-400 (1mm per interval)	
Model	Product Name	Product Description	Product Icon
ST1200	Suture Hook	Curved hook at the head end	
ST1201	Suture Hook	H-type	
Classification code	Category Name	Product specification	
121	Sheath Inserter	Diameter $\phi$ 6mm-13mm, one specification per interval 1mm	
Model	Product Name	Product Icon	
ST1210	Sheath Inserter		
Classification code	Category Name	Product specification	

122	Sheath Removal Tool	Diameter $\phi$ 6mm-13mm, one specification per interval 1mm	
Model	Product Name	Product Icon	
ST1220	Sheath Removal Tool		
Classification code	Category Name	Product specification	
123	Screwdriver Handle		
Model	Product Name	Product Description	Product Icon
ST1230	Screwdriver Handle	Head end "⬡" type	
ST1231	Screwdriver	Plum blossom	
ST1232	Screw Sheath driver	Cone	
ST1233	Ratcheting Screwdriver Handle	Used in conjunction with quick coupler	
ST1234	Screwdriver Pole	Hexagonal	
ST1235	Screwdriver Pole	Plum blossom	
ST1236	Screw Sheath driver Pole	Cone	
ST1237	Quick Connect T-Handle	Collaborate with ligament dilators, sheath inserters, and sheath extractors	
Classification code	Category Name	Product specification	
124	Tissue Screwdriver	Working length 125mm-400mm (1mm per interval)	
Model	Product Name	Product Description	Product Icon
ST1240	Tissue Screwdriver	15°Up	
ST1241	Tissue Screwdriver	30°Up	
Classification code	Category Name	Product specification	
125	Guide Pin	Diameter $\phi$ 0.1-10.0mm, 0.2mm per interval	
Model	Product Name	Product Description	Product Icon
ST1250	Guide Pin		
ST1251	Exchange bar		
ST1252	Lasso	Single ring	




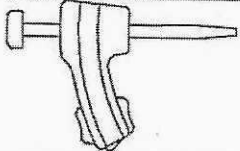
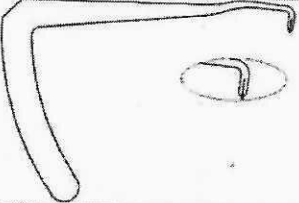

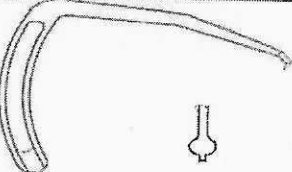
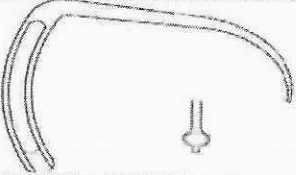
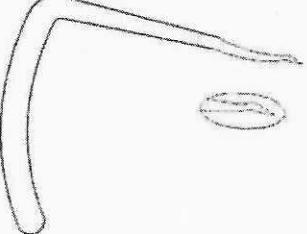
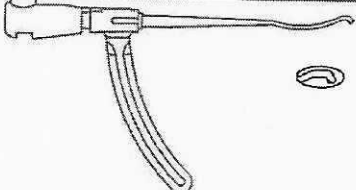


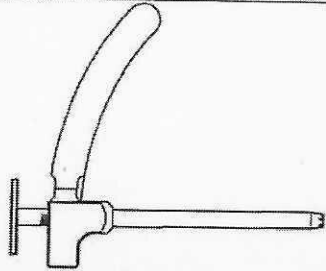
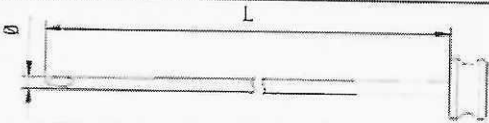
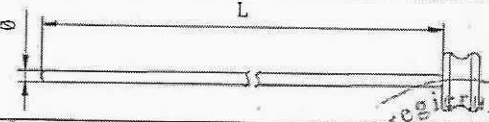
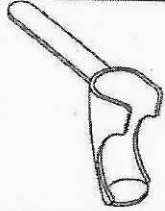

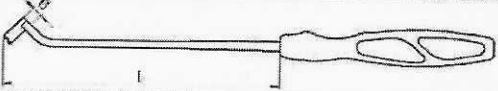
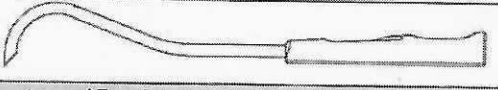
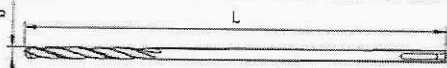
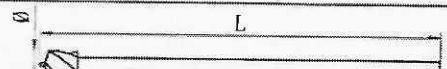
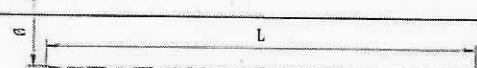

ST12521	Lasso	Double ring	
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>	
126	Cannulas	Diameter $\phi$ 3-15mm Working length 15mm-120mm	
<b>Model</b>	<b>Product Name</b>	<b>Product Icon</b>	
ST1260	Cannulas		
ST1261	Cannulas		
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>	
127	Instrument Box	ngth (L): 100-800 (interval 10), width (w): 50-400 (interval 10)	
<b>Model</b>		<b>Product Icon</b>	
ST1270	Instrument Box		
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>	
/	Orthopedic locator	Length: 80-300(interval 10), tolerance $\pm 4$ :	
<b>Model</b>	<b>Product Name</b>	<b>Product Icon</b>	
HT10	Cannulated Obturator		
HT20	Hip cannula		
HT21	Hip cannula		
HT30	Switching stick		
HT40	Hip Guide Bullet		
HT50	Slotted cannula		
HT60	Hip guide pin		
HT70	Hip guide		



HT71	Hip guide		
<b>Classification code</b>	<b>Category Name</b>		<b>Product specification</b>
/	Position retainer		/
<b>Model</b>	<b>Product Name</b>		<b>Product Icon</b>
SK1000	Knee position system		
SK2000	Knee position system		
S300101	Shoulder traction system		
S300102	Cuff		
<b>Classification code</b>	<b>Category Name</b>		<b>Product specification</b>
/	Knee surgery kit		
<b>Model</b>	<b>Product Name</b>	<b>Product specification</b>	<b>Product Icon</b>
MX011	Cannula	Width: 3.5-10.5 (spaced at 1mm intervals), Length: 110-150 (spaced at 10mm intervals)	
MX012	Cannula		
MX03	Depth probe hook	Diameter: 1.0-2.6 (spacing 0.4mm), length: 116-156 (spacing 10mm)	
MX04	Knot pusher and wire cutter	Diameter: 2.0-5.0 (interval 0.5mm), length: 115-155 (interval 10mm)	
<b>Classification code</b>	<b>Category Name</b>		<b>Product specification</b>
/	Knot pusher and wire cutter		Diameter : 2.0-5.0 (interval 0.5mm); Working length: 110-150 (with an interval of 10 mm); Width: 3.5-10.5 (spaced 1 mm apart)
<b>Model</b>	<b>Product Name</b>		<b>Product Icon</b>



SCLS	Cannula	
SC1S	Knot pusher and wire cutter	
SC1LS	Knot pusher and wire cutter	
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>
400	Drilling sight	/
<b>Model</b>	<b>Product Name</b>	<b>Product Icon</b>
S40015	Director Drill Guide	
S4002	Sight - tibial ACL point-to-point	 
S40041	Sight - tibial ACL	
S40051	Sight - tibial ACL	
S40091	Sight - Multifunctional Sight	
S400F	Sight - Root of meniscus	

S400G	Sight - Transosseous	
Classification code	Category Name	Product specification
700	Director	Diameter ( $\varphi$ ) : 2-10 (interval 0.3), tolerance: $\pm 0.14$ Length (L): 50-300 (interval 5), tolerance: $\pm 2.5$
Model	Product Name	Product Icon
S70031	Blocker - pointed type	
S70032	Blocker - blunt head type	
S70077	Popliteal fossa guide	 
S70078	Director	
S70079	Director	
Classification code	Category Name	Product specification
700	Drill	Diameter ( $\varphi$ ) : 0.5-15 (interval 0.5), tolerance: $\pm 0.24$ Length (L): 50-300 (interval 10), tolerance: $\pm 4.5$
Model	Product Name	Product Icon
S7001	Passing Pin	
S70072	Position Drill	
S70073	Medical drill	
S70076	Flexible bone drill	
Classification code	Category Name	Product specification
700	Drill	Diameter ( $\varphi=2R$ ) : 5-15 (interval 0.5), tolerance: $+1.1/+0.61$ Length (L): 50-300 (interval 10), tolerance: $\pm 4.5$


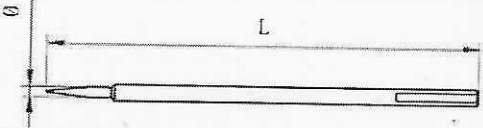
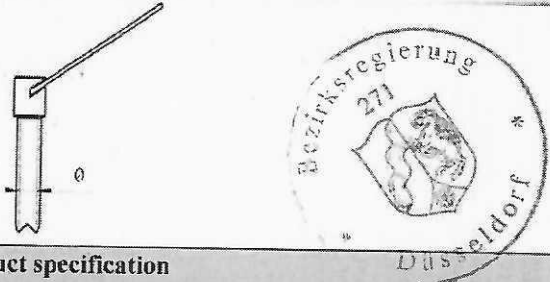
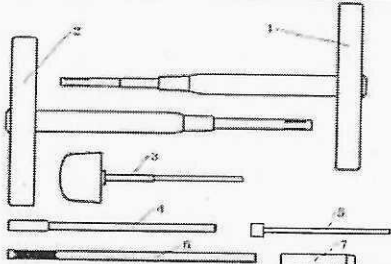
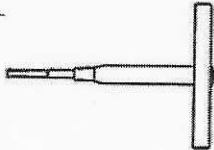
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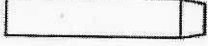
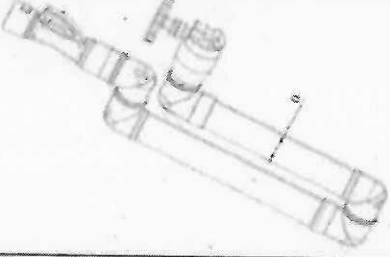
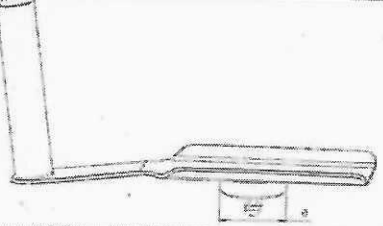
Model	Product Name	Product Icon
S70074	Retrograde reamer	
S70075	Retrograde reamer	
Classification code	Category Name	Product specification
123	Nail sheath implant inserter	Length (L): 20-400 (interval 10), tolerance: $\pm 4.5$ Width (W): 1-10 (interval 0.5), tolerance: $\pm 0.24$
Model	Product Name	Product Icon
S12311	Screwdriver	
S12312	Sheath Inserter	
S12351	植入器 Implant	
Classification code	Category Name	Product specification
1001	Orthopedic gripper	/
Model	Product Name	Product Icon
S100101	Needle pusher	
Classification code	Category Name	Product specification
1011	Knee joint gap assessment block	/
Model	Product Name	Product Icon
S101101	Knee measuring instrument	
Classification code	Category Name	Product specification
/	Spiked Ligament staples- Tool	/
Model	Product Name	Product Icon
U1	Staple punch-in device	
U2	Staple puller	
U3	Staple seating punch	
U4	Extractor	



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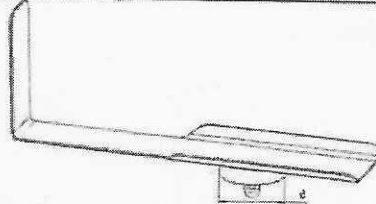
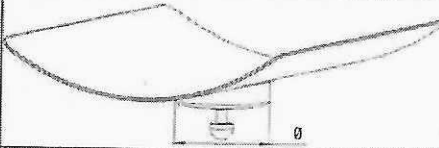
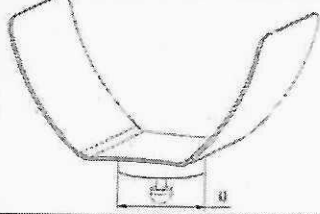
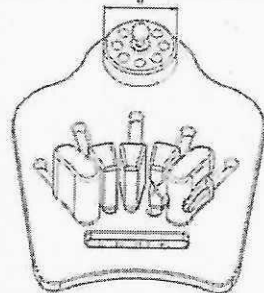

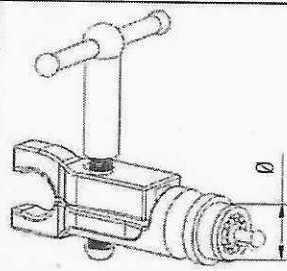
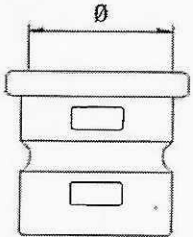
U5	Staple removal	
Classification code	Category Name	Product specification
/	Drill	Diameter ( $\varphi$ ) : 1.3, 1.8, 2.4, 2.8, tolerance: $\pm 0.24$ Length (L): 70-200 (interval 5), tolerance: $\pm 2.4$
Model	Product Name	Product Icon
TAX10	Drill	
Classification code	Category Name	Product specification
/	Director	Diameter ( $\varphi$ ) : 5.0, tolerance: $\pm 0.2$
Model	Product Name	Product Icon
TAX20	Guide Cannula	
Classification code	Category Name	Product specification
/	bone grafting instrument	Diameter ( $\varphi$ ) : 5-12, (Interval 1) Tolerance: $\pm 0.45$
Model	Product Name	Product Icon
R05	1) Graft Delivery; 2) Delivery Tamp; 3) Control handle; 4) Osteoclast; 5) Harvesting Tamp; 6) Depth guard; 7) Delivery Tube ;	
R06		
R07		
R08		
R09		
R10		
R11		
R12		
Classification code	Category Name	Product specification
/	Graft Delivery	Diameter ( $\varphi$ ) : 5-12, (Interval 1) Tolerance: $\pm 0.45$
Model	Product Name	Product Icon
R051		
R061		
R071		
R081		
R091		
R101		
R111		



R085		
R095		
R105		
R115		
R125		
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>
/	Depth guard	Diameter ( $\varphi$ ) : 5-12, (Interval 1) Tolerance: $\pm 0.45$
<b>Model</b>	<b>Product Name</b>	<b>Product Icon</b>
R056	/	
R066		
R076		
R086		
R096		
R106		
R116		
R126		
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>
/	Delivery Tube	Diameter ( $\varphi$ ) : 5-12, (Interval 1) Tolerance: $\pm 0.45$
<b>Model</b>	<b>Product Name</b>	<b>Product Icon</b>
R057	/	
R067		
R077		
R087		
R097		
R107		
R117		
R127		
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>
4001	holder	Diameter ( $\varphi$ ) : 10-70 (interval 5), tolerance: $\pm 2.4$
<b>Model</b>	<b>Product Name</b>	<b>Product Icon</b>
S400101	holder	
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>
4002	Bracket	Diameter ( $\varphi$ ) : 10-70 (interval 5), tolerance: $\pm 2.4$
<b>Model</b>	<b>Product Name</b>	<b>Product Icon</b>
S400201	Vertical bracket	



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S400202	Horizontal bracket	
S400203	Foot bracket	
S400204	Leg bracket	
S400205	Elbow bracket	
S400206	Hand bracket	 
S400207	Holding fixture	
<b>Classification code</b>	<b>Category Name</b>	<b>Product specification</b>
4003	Accessory adapter	Diameter ( $\varnothing$ ) : 10-70 (interval 5), tolerance: $\pm 2.4$
<b>Model</b>	<b>Product Name</b>	<b>Product Icon</b>
S400301	Accessory adapter	

## 9. All-Suture Anchors

Model								
AS1A1	AS1A2	AS1A3	AS1B1	AS1B2	AS1B3	AS1C1	AS1C2	AS1C3
AS2A1	AS2A2	AS2A3	AS2B1	AS2B2	AS2B3	AS2C1	AS2C2	AS2C3
AS3A1	AS3A2	AS3A3	AS3B1	AS3B2	AS3B3	AS3C1	AS3C2	AS3C3
AS4A1	AS4A2	AS4A3	AS4B1	AS4B2	AS4B3	AS4C1	AS4C2	AS4C3
AS5A1	AS5A2	AS5A3	AS5B1	AS5B2	AS5B3	AS5C1	AS5C2	AS5C3

## 10. Meniscal Repair Devices

Product Model					
M01AR	M01BR	M01CR	M02AR	M02BR	M02CR
M01AS	M01BS	M01CS	M02AS	M02BS	M02CS
M01AT	M01BT	M01CT	M02AT	M02BT	M02CT

## 11. Arthroscopic Access Cannulas

Model
C11,C12,C13,C14,C15,C16,C17,C18,C19,C110,C111; C21,C22,C23,C24,C25,C26,C27,C28,C29,C210,C211; C31,C32,C33,C34,C35,C36,C37,C38,C39,C310,C311; C41,C42,C43,C44,C45,C46,C47,C48,C49,C410,C411; C51,C52,C53,C54,C55,C56,C57,C58,C59,C510,C511; C61,C62,C63,C64,C65,C66,C67,C68,C69,C610,C611; C71,C72,C73,C74,C75,C76,C77,C78,C79,C710,C711; C0



## 12. Spiked Ligament Staples

Product model (sterile)	
UN I	UN V
UN II	UN VII
UN III	UN VIII
UN IV	UN IX
UN V	UN X

Product model (non-sterile)	
UN IR	UN VR
UN IIR	UN VIIr
UN IIIr	UN VIIIr
UN IVr	UN IXr
UN VR	UN Xr

## 13. Endoscopic Video Image Systems

Model
IS10,IS20,IS30,IS40,4K-A1-101(A),4K-A1-101(B),4K-A1-101(C),4K-A1-102(A),4K-A1-102(B), 4K-A1-102(C), 4K01-101(A), 4K01-101(B), 4K01-101(C), 4K01-101(D),4K01-102(A), 4K01-102(B), 4K01-102(C), 4K01-102(D), HD-01-101(A),HD-01-101(B),HD-01-102(A), HD-01-102(B), IS20000

## 14. Arthroscopic Surgical Instruments

Product Name	Code / Cat. No.	Model	Description
Arthroscopic Surgical Instruments	F14600001	ST70081	Φ 1.5×L240 Disposable suture passer
Arthroscopic Surgical Instruments	F14600003		Φ 1.0×L200 Disposable suture passer
Arthroscopic Surgical Instruments	F14600027		Φ 1.5×L205 Disposable suture passer
Arthroscopic Surgical Instruments	F14600002	ST12522	Φ 0.5×L560 Disposable suture lasso, single ring
Arthroscopic Surgical Instruments	F14600004		Φ 0.2×L560 Disposable suture lasso, single ring
Arthroscopic Surgical Instruments	F14600006		Φ 0.2×L500 Disposable suture lasso, single ring
Arthroscopic Surgical Instruments	F14600014	ST12523	Φ 0.5×L560 Disposable suture lasso, double ring





**TỔNG LÃNH SỰ QUÁN NƯỚC CHXHCN VIỆT NAM**  
tại Frankfurt am Main, CHLB Đức

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Lãnh sự / Consul  
Hermen Khuê

VIỆT  
PHÁP  
6 CN



**Chính quyền cấp vùng TP. Düsseldorf**

**Giấy chứng nhận lưu hành tự do theo § 10**

của Luật Thi hành các Quy định về Thiết bị Y tế (MPDG)

và Điều 60 Chương 1, đồng thời kết hợp với Điều 120 khoản 3 và khoản 4  
của Quy định (EU) 2017/745 của Nghị viện và Hội đồng Châu Âu ngày 5 tháng 4 năm 2017  
để trình lên các cơ quan/tổ chức thẩm quyền của

**Việt Nam**

Chứng nhận rằng

- Đại diện Châu Âu có địa điểm kinh doanh đã đăng ký tại Đức,
- thiết bị đang được đề cập có dấu CE theo Quy định đã nêu ở trên

và có thể được lưu hành trong Liên minh Châu Âu.

**Sản phẩm:**

- xem tài liệu đính kèm (30 trang) -

**Đại diện Châu Âu**

**Caretechion GmbH  
Niederrheinstr. 71  
40474 Düsseldorf  
Đức**

**Nhà sản xuất:**

**Star Sports Medicine Co., Ltd.  
Phòng A018, Tầng 1, Tòa nhà 1, SỐ 25, Đường JingHai 2, Khu phát triển kinh tế và  
công nghệ Bắc Kinh, 100176 Bắc Kinh, Trung Quốc**

Với dấu CE, nhà sản xuất xác nhận rằng các thiết bị y tế tuân thủ các yêu cầu chung về an toàn và hiệu suất theo

Quy định (EU) 2017/745 của Nghị viện và Hội đồng Châu Âu ngày 5 tháng 4 năm 2017 về các thiết bị y tế theo phiên bản hiện hành

và quy trình đánh giá sự phù hợp bắt buộc đã được hoàn tất.

Düsseldorf, ngày 01/10/2024

Thay mặt Chính quyền cấp vùng TP. Düsseldorf

*(Đã ký và đóng dấu)*

Carolyn Jänsch

Tính xác thực của chữ ký ở trên của

**bà Jänsch**

**nhân viên của Chính quyền cấp vùng TP. Düsseldorf**

và tính xác thực của con dấu công vụ được chứng nhận tại đây.

Đồng thời xác nhận rằng người nêu trên có thẩm quyền cấp văn bản này.

Düsseldorf, ngày 17/10/2024

Thay mặt

Chính quyền cấp vùng TP. Düsseldorf

*(Đã ký và đóng dấu)*

Hermen

Thanh tra Văn phòng Chính phủ

Số	Tên sản phẩm	Phân loại I, Is, Im, IIa, IIb, III	Mẫu	UMDNS, EMDA	Số đăng ký
1.	Neo chỉ kim loại	IIb	Xem phần đính kèm bên dưới	17-782	DE/CA20/00189523
2.	Chỉ phẫu thuật không tiêu	IIb		13-896	DE/CA20/00189524
3.	Nút chỉ	IIb		13-891	DE/CA20/00186530
4.	Lưỡi dao cạo	IIa		10-456	DE/CA20/00189504
5.	Neo chỉ Peek	IIb		17-782	DE/CA20/00184664
6.	Hệ thống ốc xuyên Peek	IIb		16-101	DE/CA20/00189512
7.	Hệ thống máy cạo nội soi khớp	IIa		17-918	DE/CA20/00189528
8.	Dụng cụ phẫu thuật nội soi khớp	I		13-180	DE/CA20/00190048
9.	Neo chỉ toàn sợi	IIb		17-782	DE/CA20/00188901
10.	Thiết bị sửa chữa sụn chêm	IIb		17-993	DE/CA20/00187361
11.	Ống thông xâm nhập nội soi	IIa		15-260	DE/CA20/00188899
12.	Dập kim dây chằng	IIb		16-103	DE/CA20/00186532
13.	Hệ thống hình ảnh video nội soi	I		18-037	DE/CA20/00189530
14.	Dụng cụ phẫu thuật nội soi khớp	IIa		13-180	DE/CA20/00201558



**TỔNG LÃNH SỰ QUÁN NƯỚC CHXHCN VIỆT NAM**

tại Frankfurt am Main, CHLB Đức

1. Quốc gia: **Việt Nam**

**Giấy tờ, tài liệu này**

2. do ông/bà **Hermen** ký

3. với chức danh **Cán bộ phụ trách**

4. và con dấu của: **Chính quyền cấp vùng TP. Düsseldorf**

**Được chứng nhận/hợp pháp hóa lãnh sự**

5. tại: **Frankfurt**

6. Ngày: **22/11/2024**

7. Cơ quan cấp: **Tổng lãnh sự quán Việt Nam tại**

**Frankfurt/Main**

8. Số: **2913/2024/CN-HPHLS**

**Lãnh sự**

*(Đã ký và đóng dấu)*

**Lưu Minh Khuê**

Ich NGUYEN THI THU  
Bürgerausweis Nr.: 033190012786  
Ausstellungsdatum: 17/03/2023,  
Ausstellungsstelle: Polizeiabteilung für  
administrative Verwaltung der sozialen  
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Căn cước công dân số: 033190012786  
Cấp ngày: 17/03/2023 tại Cục cảnh sát quản  
lý hành chính về trật tự xã hội, tôi cam đoan  
đã dịch chính xác nội dung của giấy tờ/ văn  
bản này từ tiếng Đức sang tiếng Việt.

Ngày 22 tháng 04 năm 2025  
Der 22/ 04/ 2025

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Stadt

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Ngày 22 tháng 04 năm 2025  
Der 22/ 04/ 2025



*Dinh Hoàng Việt*