



Surgical Motor Systems
Battery Operated

**OPERATION
UNDER CONTROL**



Battery Operated Surgical Motor Systems

Light weight provides efficient and reliable performance with new generation powerful motor

sharpline.de

SHARPLINE®





We Believe

Developing a creative mindset leads to innovative technologies that can change the World. Our passion is to bring products to markets that can enhance lives. One of the key ingredients to our success is having 25 years of producing and marketing experience.

What We Do

We are interested in connecting with individuals who are trying to innovate the World into a better place and willing to share creativity. If we can help in any way please feel free to e-mail us at info@sharpline.de



Sagittal Saw System



Reciprocating Saw System



Sternum Saw System



Hexa - Function System

- Drill SKode (F&R)
- Drill Oscillation SKode
- Screwing SKode (F&R)
- Tapping SKode
- Reamer SKode (F&R)
- Reamer Oscillation SKode



- Light weight provides efficient and reliable cutting performance with new generation powerful motor.
- One hand piece solution for reaming, high speed drilling, screw driving and tapping functions with high torque performance.
- Lithium-ion battery technology provides consistent power during the operation.
- Easy handling and ergonomic design of SharpX ensures reliable and better controlled operation results.
- Efficient torque for acetabular reaming.
- SharpX is an innovative new generation power tool with high quality engineering materials.
- Providing efficiency with Engineering Solutions
- Extended battery life.
- Comfortable ergonomic design.
- Easy attachment assembly.
- High speed drilling and oscillating.

- Less Weight, High Power
- Next Generation Cutting Technology
- New Generation Surgical Motor Technology
- Li-ion Technology



SharpX power box records all data about usage for technical service information.

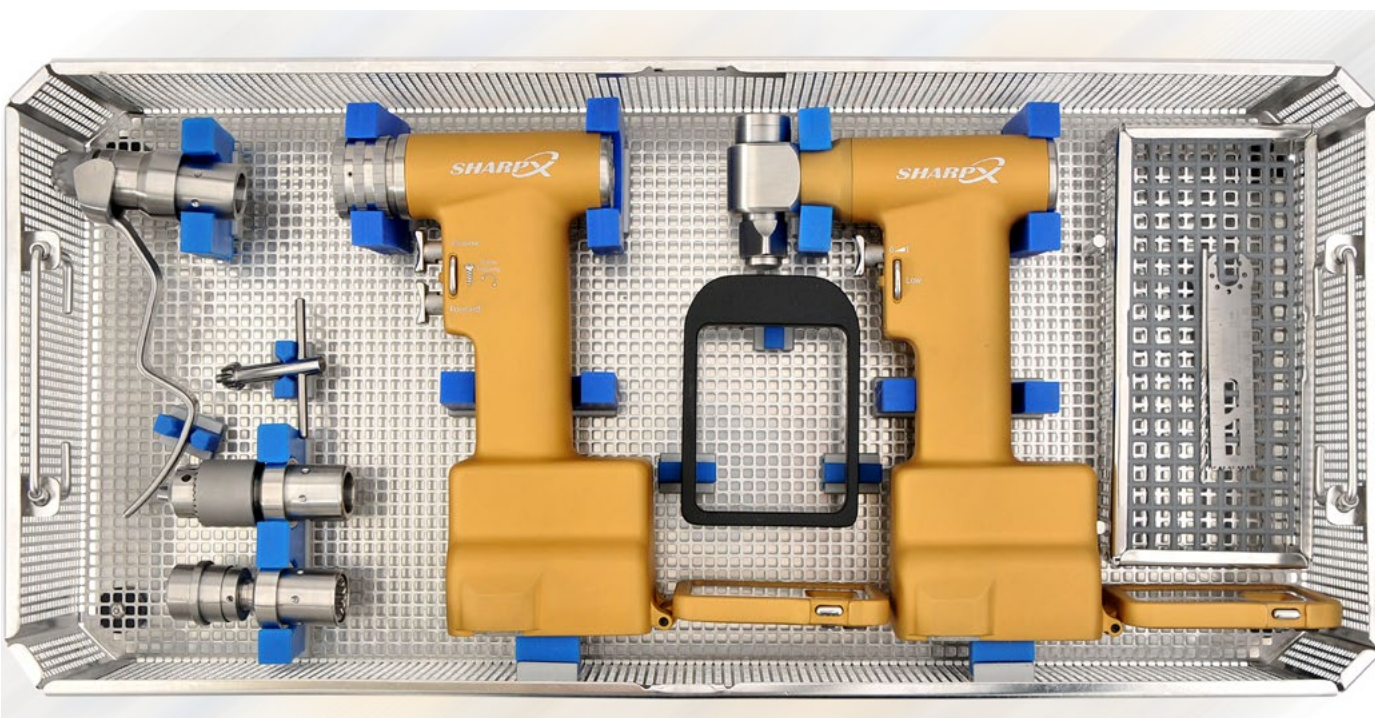


Power box oled screen enables users to indicate battery capacity by pressing the test button.



Sterile funnel

“Technical structure of SharpX HandPieces provides users non-restrictive washing and disfection.”



- Less Weight, High Power
- Next Generation Cutting Technology
- New Generation Surgical SKotor Technology
- Li-ion Technology



SharpX provides users to observe battery level without removing the power box.

Hexa - Function System

Six Different Trigger Functions

Weight: 1440g (Including Power Box)

Sagittal Saw System

High-Low speed options

Weight: 1290g (Including Power Box)





Reciprocating Saw System

High-Low speed options

Weight: 1250g (Including Power Box)

Sternum Saw System

High-Low speed options

Weight: 1430g (Including Power Box)



Battery Charging Units



SharpX can also provide information about battery process cycles like how many times, minutes, seconds the battery is charged, half charged or fully charged.



Power box oled screen enables users to indicate battery capacity by pressing the test button.



Battery, motor and all electrical components are combined together and exempt from sterilization by aim of increasing life time of the device



S-210

Power box

- Swiss made powerful DC motor technology
- Battery capacity: 2.5 Ah
- Voltage: 14.8 Volts
- Integrated oled screen audible alert motification
- Not autoclaveable
- 75 x 61 x 160 mm / 465 g



S-212

Autoclaveable sterile funnel for aseptic battery loading

- Steam sterilisable
- 30 x 74 x 104 mm / 55 g



Sterile funnel

**S-226**

Charger unit for 1 battery

- Main voltage 100-240 Volts, 50-60 Hz
- Charging current 2 A
- Charging voltage 16.8 Volts
- Protections: Short circuit / Overload / Over voltage
- Charging indicator led
- Battery not included
- 130 x 250 x 130 mm / 900 g

**S-227**

Charger unit for 2 batteries

- Main voltage 100-240 Volts, 50-60 Hz
- Charging current 2 A (x2)
- Charging voltage 16.8 Volts
- Protections: Short circuit / Overload / Over voltage
- Charging indicator led
- Battery not included
- 230 x 250 x 130 mm / 2000 g

**S-229**

Charger unit for 4 batteries

- Main voltage 100-240 Volts, 50-60 Hz
- Charging current 2 A (x4)
- Charging voltage 16.8 Volts
- Protections: Short circuit / Overload / Over voltage
- Charging indicator led
- Battery not included
- 430 x 250 x 130 mm / 3500 g

Drill-Reamer Handpiece

Six
Different
Trigger
Functions



S-200

Hexa - Function System

Dual trigger system for speed control and direction control

Steam sterilisable

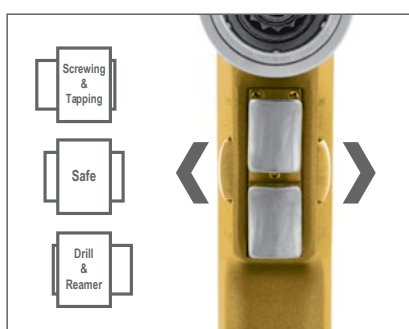
Cannulated Ø 4 mm

77 x 140 x 210 mm / 785 g

- Drill SKode F&R (1200 rpm)
- Drill Oscillation SKode (1200 cpm)
- Screwing SKode F&R (50 rpm)
- Tapping SKode (50 rpm)
- Reamer SKode F&R (300 rpm)
- Reamer Oscillation SKode (300 cpm)



Screwing and tapping options enable smooth control with one-handpiece solution.



Drilling, Reaming, Screwing and Tapping options in one-handpiece



Forward, reverse and oscillation mode options provide versatile alternatives to the users.

Drill Attachments


S-308

Drill attachment with keyed chuck
 Ø4 mm Cannulated
 Ø 1.0 mm - 4.0 mm
 1200 rpm / 5 Nm
 29 x 70 mm / 140 g


S8-473

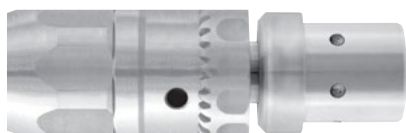
Chuck key
 for S-308


S-309

Drill attachment with keyed chuck
 Ø4 mm Cannulated
 Ø 1.0 mm - 6.35 mm
 1200 rpm / 5 Nm
 29 x 87 mm / 205 g


S7-250

Chuck key
 for S-309


S-311

Drill attachment with hybrid chuck
 Both keyed and keyless operation
 Ø4 mm Cannulated
 Ø 0.3 mm - 3 mm
 1200 rpm / 5 Nm
 29 x 87 mm / 225 g

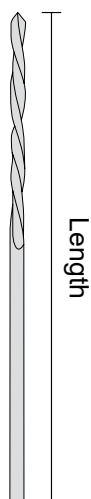

S7-252

Chuck key
 for S-310, S-311


S-310

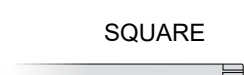
Drill attachment with hybrid chuck
 Both keyed and keyless operation
 Ø4 mm Cannulated
 Ø 1.0 mm - 7.4 mm
 1200 rpm / 5 Nm
 34 x 100 mm / 320 g

Drills



Code	(Ø) Diameter mm	Length mm
S7-500	1.5	60
S7-501	2.0	100
S7-502	2.5	100
S7-503	2.7	100
S7-504	3.0	100
S7-505	3.2	100
S7-506	3.5	100
S7-507	4.0	110
S7-508	4.5	130
S7-509	5.0	160
S7-510	6.0	160

Shank Drill Bit Attachments



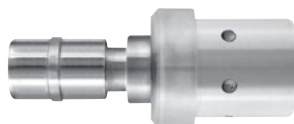
SQUARE

**S-360**

Attachment for SQUARE shank

1200 rpm / 5 Nm
29 x 75 mm / 115 g

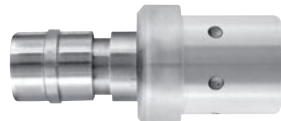
AO

**S-361**

Attachment for AO shank

1200 rpm / 5 Nm
29 x 73 mm / 125 g

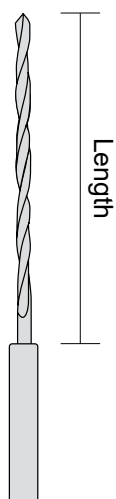
TRINKE

**S-362**

Attachment for TRINKE shank

1200 rpm / 5 Nm
29 x 70 mm / 130 g

Drills



L Length mm	Ø Diameter mm	SQUARE	AO	TRINKE
38	1.5	S7-520	S7-540	S7-560
45	2.0	S7-521	S7-541	S7-561
53	2.5	S7-522	S7-542	S7-562
57	2.7	S7-523	S7-543	S7-563
57	3.0	S7-524	S7-544	S7-564
57	3.2	S7-525	S7-545	S7-565
65	3.5	S7-526	S7-546	S7-566
70	4.0	S7-527	S7-547	S7-567
70	4.5	S7-528	S7-548	S7-568
95	5.0	S7-529	S7-549	S7-569
120	6.0	S7-530	S7-550	S7-570

OSTEO



S-375

Attachment for OSTEO shank

Ø4 mm Cannulated
300 rpm / 22 Nm
29 x 78 mm / 160 g

DHS

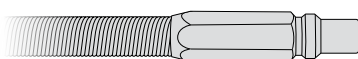


S-376

Attachment for DHS shank

Ø4 mm Cannulated
300 rpm / 22 Nm
29 x 100 mm / 170 g

AO-PROTEK

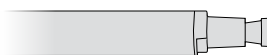


S-377

Attachment for AO-PROTEK shank

Ø4 mm Cannulated
300 rpm / 22 Nm
29 x 82 mm / 210 g

HUDSON

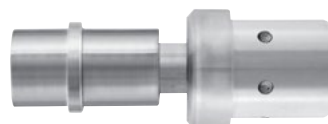


S-378

Attachment for HUDSON shank

Ø4 mm Cannulated
300 rpm / 22 Nm
29 x 68 mm / 145 g

HARRIS

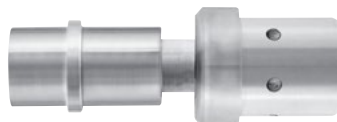
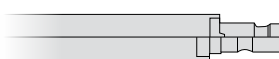


S206-379

Attachment for HARRIS shank

Ø4 mm Cannulated
300 rpm / 22 Nm
29 x 102 mm / 145 g

ZISKSKER-HUDSON



S-380

Attachment for ZISKSKER-HUDSON shank

Ø4 mm Cannulated
300 rpm / 22 Nm
29 x 115 mm / 155 g

ZISKSKER



S-381

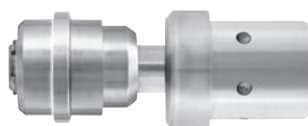
Attachment for ZISKSKER shank

Ø4 mm Cannulated
300 rpm / 22 Nm
29 x 115 mm / 155 g

Reamer Attachment



DIN 58809



S-330

Reamer attachment for wire and pin

Cannulated Ø 4 mm
300 rpm / 22 Nm
29 x 80 mm / 185 g

AO PROTEK



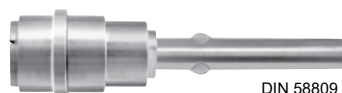
DIN 58809

S7-905

Adaptor for AO-Protek shank

Cannulated Ø 4 mm

HUDSON



DIN 58809

S7-908

Adaptor for Hudson

Cannulated Ø 4 mm

HARRIS



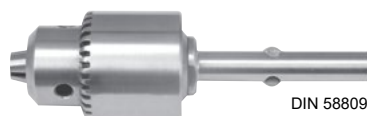
DIN 58809

S7-907

Adaptor for Harris

Cannulated Ø 4 mm

DRILL



DIN 58809

S7-906




Universal three-jaw chuck

with key S7-250
SKax Ø 6.35 mm
Cannulated Ø 4 mm



S7-250

Chuck key
for S7-906

	Intramedullary reamers, flexible, with drilling heads		 Guides, blunt			 Guides, with drill tip		
	Ø mm	Length 430 mm	Ø mm	Length 600 mm	Length 990 mm	Ø mm	Length 600 mm	Length 990 mm
	5.5	S7-920						
	6.0	S7-921						
	6.5	S7-922	1.9	S7-960	S7-961	1.9	S7-962	
	7.0	S7-923						
	7.5	S7-924						
	8.0	S7-925						
	8.5	S7-926						
	9.0	S7-927						
	9.5	S7-928						
	10.0	S7-929						
	10.5	S7-930						
	11.0	S7-931						
	11.5	S7-932						
	12.0	S7-933	3.4	S7-963	S7-964	3.4		S7-965
	12.5	S7-934						
	13.0	S7-935						
	13.5	S7-936						
	14.0	S7-937						
	14.5	S7-938						
	15.0	S7-939						
	15.5	S7-940						
	16.0	S7-941						
	16.5	S7-942						
	17.0	S7-943						
	17.5	S7-944						
	18.0	S7-945						
	18.5	S7-946						
	19.0	S7-947						

DIN 58809

Acetabular Reamer Attachment



HARRIS

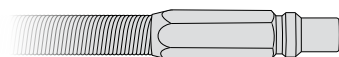


S-320

Acetabular reamer attachment

150 rpm / 35 Nm
29 x 80 mm / 175 g

AO-PROTEK

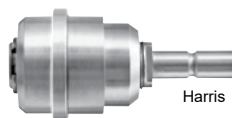


Harris

S7-705

Adaptor for AO-Protek shaft

DIN 58809

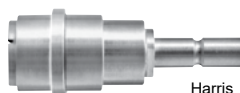
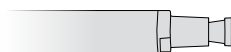


Harris

S7-706

Adaptor for DIN 58809 shaft

HUDSON



Harris

S7-707

Adaptor for Hudson shaft

DRILL



Harris

S7-708

Universal three-jaw chuck
with key S7-250



S7-250

Chuck key
for SK7-708



S7-709
Shaft only,
With Harris Connection
for S7-750, S7-757



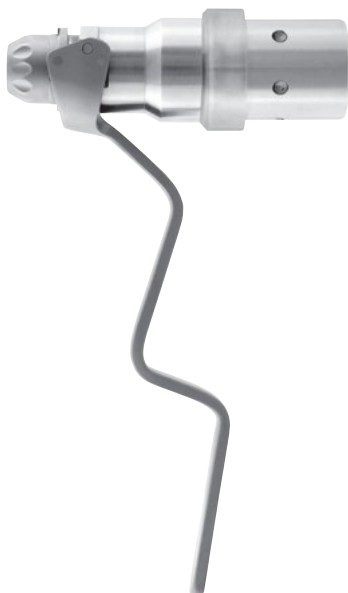
S7-789
SKovable protector case,
Fits with all reamer shafts

Only Acetabular
Reamer



S7-750	Ø 46 mm
S7-751	Ø 48 mm
S7-752	Ø 50 mm
S7-753	Ø 52 mm
S7-754	Ø 56 mm
S7-755	Ø 60 mm
S7-756	Ø 64 mm
S7-757	Ø 68 mm

Quick - action chuck (K-wire Driver)



S-352

Quick - action chuck (K-wire Driver)

Cannulated Ø 0.7 mm - 2.5 mm

1200 rpm / 5 Nm

29 X 77 mm / 300 g

S-353

Quick - action chuck (K-wire Driver)

Cannulated Ø 1.5 mm - 4.0 mm

1200 rpm / 5 Nm

29 X 77 mm / 300 g

Reciprocating Saw System

**S-235**

Reciprocating saw system

(Without saw blades and power box)

- High-Low speed options
- Steam sterilisable
- 11.000 - 14.000 cpm / \longleftrightarrow 4 mm
- 77 X 180 x 210 mm / 860 g

**S103-236**Usable length: 62 mm
Width: 8 mm**S103-237**Usable length: 75 mm
Width: 13 mm**S103-238**Usable length: 60 mm
Width: 13 mm**S103-239**Usable length: 75 mm
Width: 13 mm

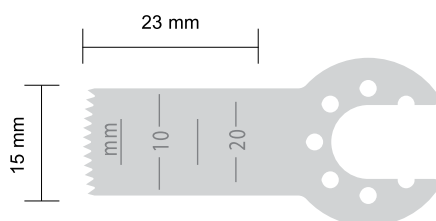
Sagittal Saw System


S-300

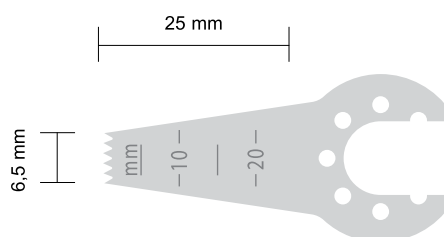
Sagittal saw system

(Without saw blades and power box)

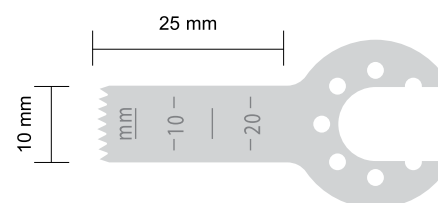
- High-Low speed options
- Steam sterilisable
- 10.000 - 12.000 cpm / \angle 4° 50'
- 77 x 153 x 218 mm / 850 g


S103-1110

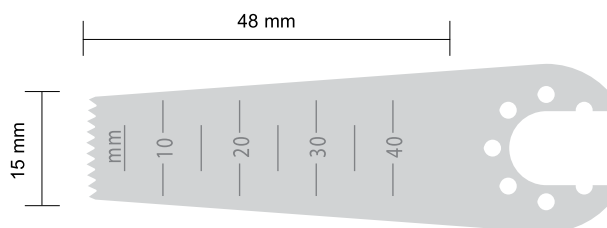
SKaterial Thickness: 0.4 mm
 Cutting Thickness: 0.6 mm


S103-1111

SKaterial Thickness: 0.4 mm
 Cutting Thickness: 0.6 mm

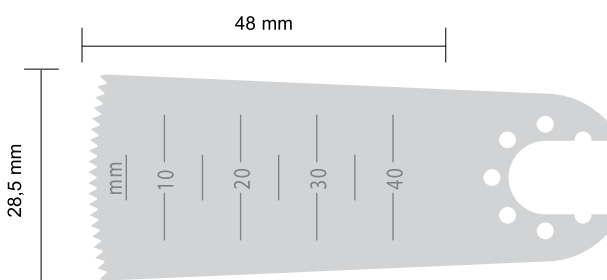

S103-1112

SKaterial Thickness: 0.4 mm
 Cutting Thickness: 0.6 mm



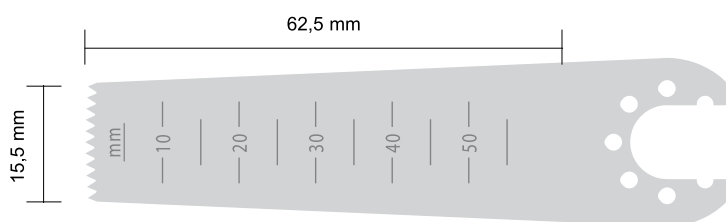
S103-1113

SKaterial Thickness: 0.4 mm
Cutting Thickness: 0.6 mm



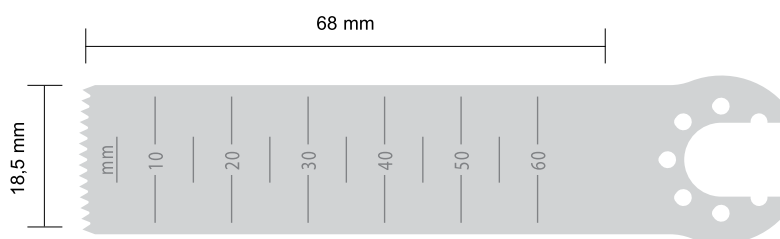
S103-1114

SKaterial Thickness: 0.4 mm
Cutting Thickness: 0.6 mm



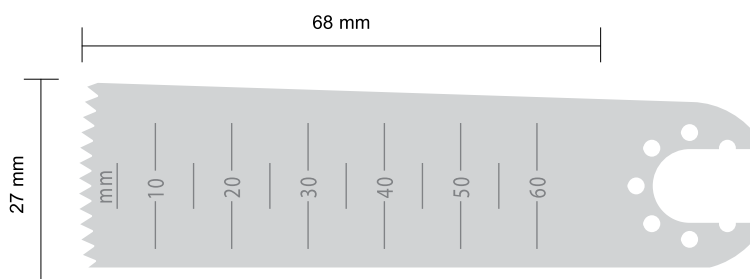
S103-1115

SKaterial Thickness: 0.6 mm
Cutting Thickness: 0.8 mm



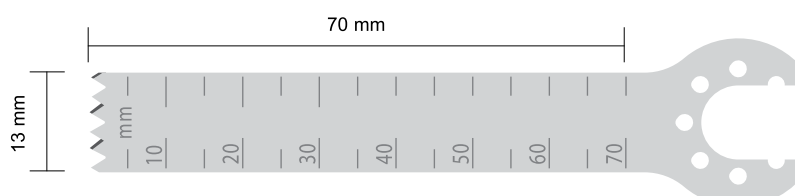
S103-1116

SKaterial Thickness: 0.6 mm
Cutting Thickness: 0.8 mm



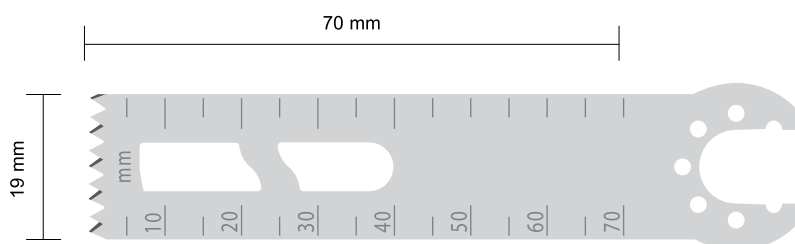
S103-1117

SKaterial Thickness: 0.6 mm
Cutting Thickness: 0.8 mm

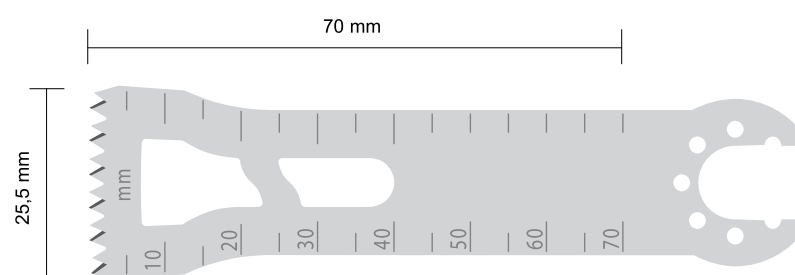


S103-1118

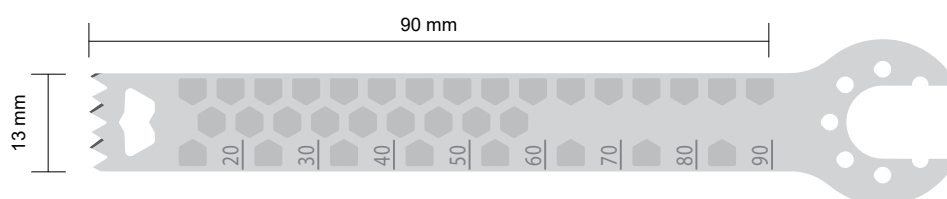
SKaterial Thickness: 1.19 mm



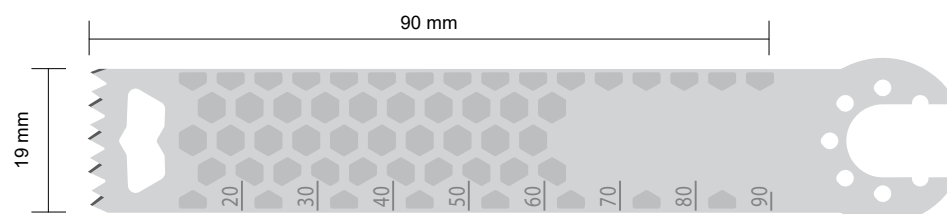
S103-1119
SKaterial Thickness: 1 mm



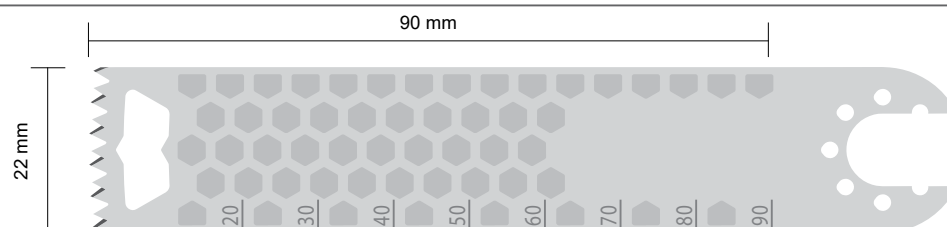
S103-1120
SKaterial Thickness: 1 mm



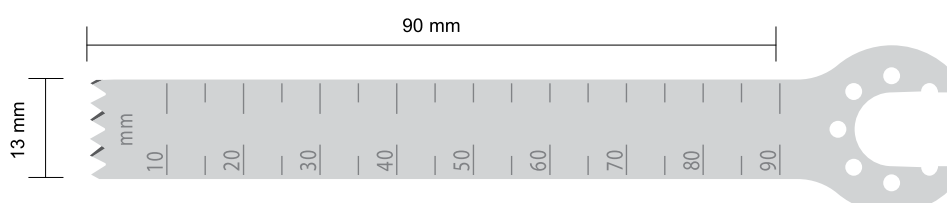
	SKaterial Thickness
S103-1121	1 mm
S103-1122	1.19 mm
S103-1123	1.27 mm
S103-1124	1.37 mm



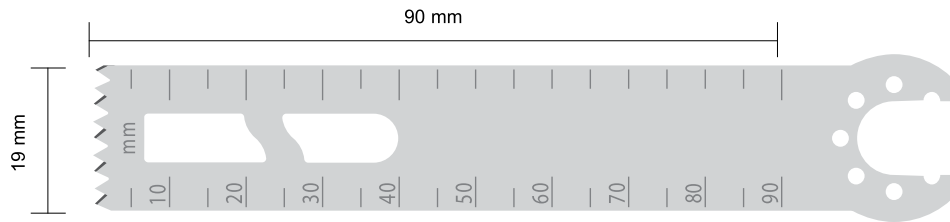
	SKaterial Thickness
S103-1125	1.19 mm
S103-1126	1.27 mm
S103-1127	1.37 mm



	SKaterial Thickness
S103-1128	1 mm
S103-1129	1.19 mm
S103-1130	1.27 mm
S103-1131	1.37 mm
S103-1132	1.47 mm



	SKaterial Thickness
S103-1133	1 mm
S103-1134	1.19 mm
S103-1135	1.27 mm



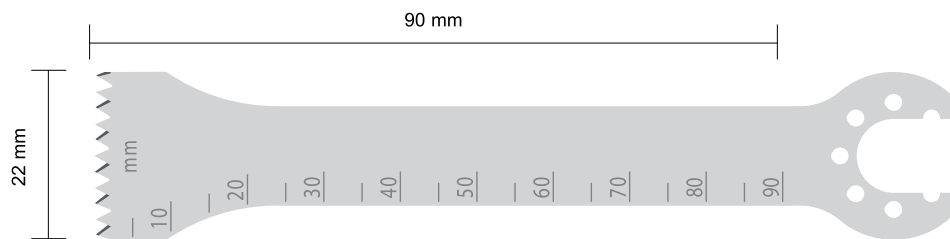
SKaterial
Thickness

S103-1136

1.27 mm

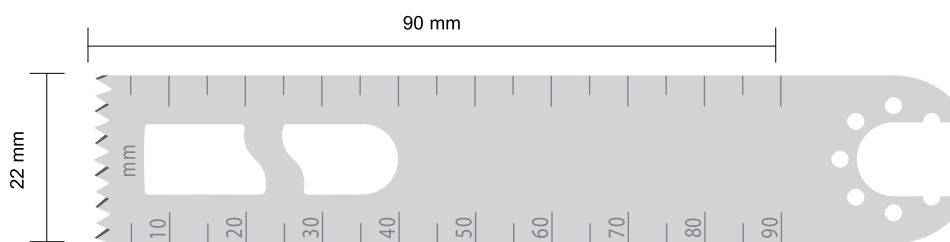
S103-1137

1.37 mm



S103-1138

SKaterial Thickness: 1.27 mm



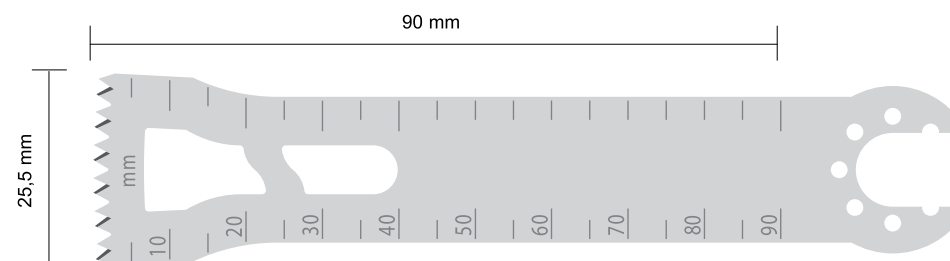
SKaterial
Thickness

S103-1139

1 mm

S103-1140

1.27 mm



SKaterial
Thickness

S103-1141

1 mm

S103-1142

1.19 mm

S103-1143

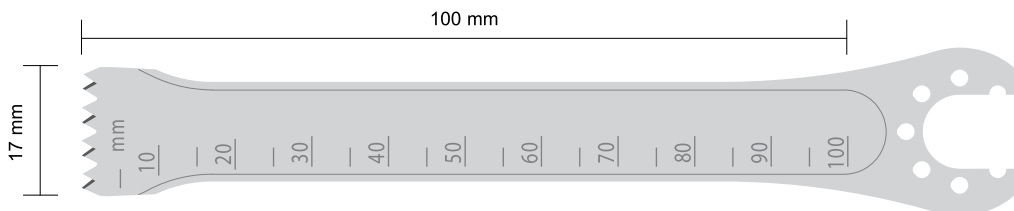
1.27 mm

S103-1144

1.37 mm

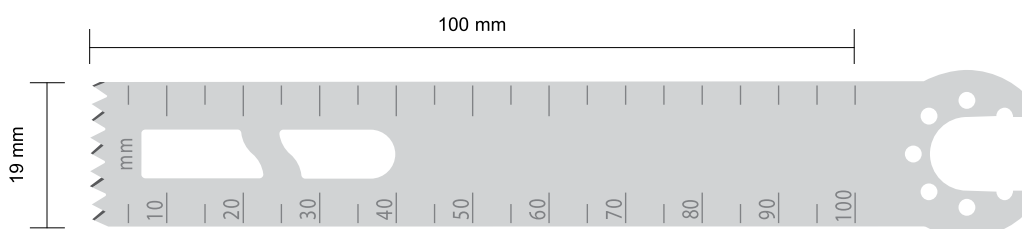
S103-1145

1.47 mm



S103-1146

SKaterial Thickness: 1.27 mm



S103-1147

SKaterial Thickness: 1.19 mm

Sternum Saw System


S-240


Sternum saw system

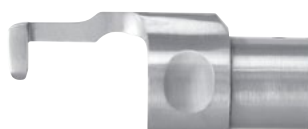
(Without saw blades, guide and power box)

- High-Low speed options
- Steam sterilisable
- 11.000 x 14.000 cpm / \longleftrightarrow 4 mm
- 77 x 180 x 210 mm / 930 g


S103-715

Adult saw guide

Adult saw blade	Code	Length	Usable Length	Blade Thickness	Cutting Thickness
	S103-709	58 mm	35 mm	0,6 mm	1 mm
	S103-710	58 mm	35 mm	0,8 mm	1,2 mm


S103-716

Pediatric saw guide

Pediatric saw blade	Code	Length	Usable Length	Blade Thickness	Cutting Thickness
	S103-711	40 mm	18 mm	0.6 mm	0.6 mm
	S103-712	40 mm	18 mm	0.6 mm	0,8 mm

Re-Operation Oscillating Saw System

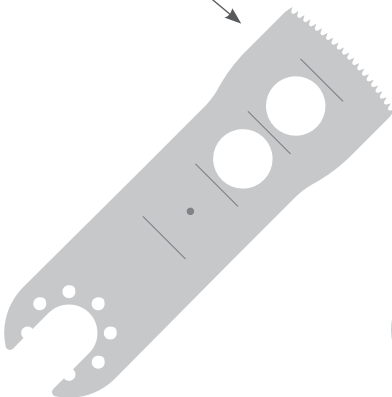

S-300

Oscillating saw system

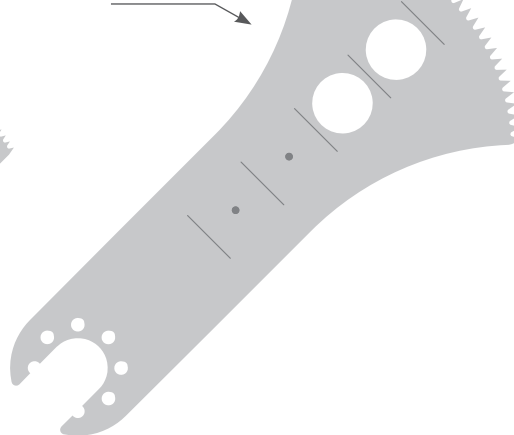
(Without saw blades and power box)

- High-Low speed options
- Steam sterilisable
- 10.000 x 12.000 cpm / \angle 4° 50'
- 77 x 180 x 210 mm / 850 g

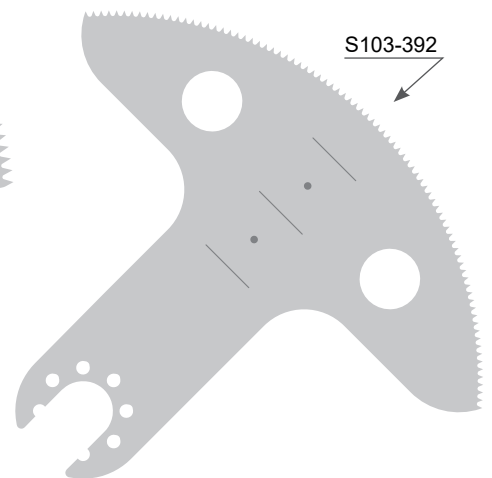
S103-390



S103-391

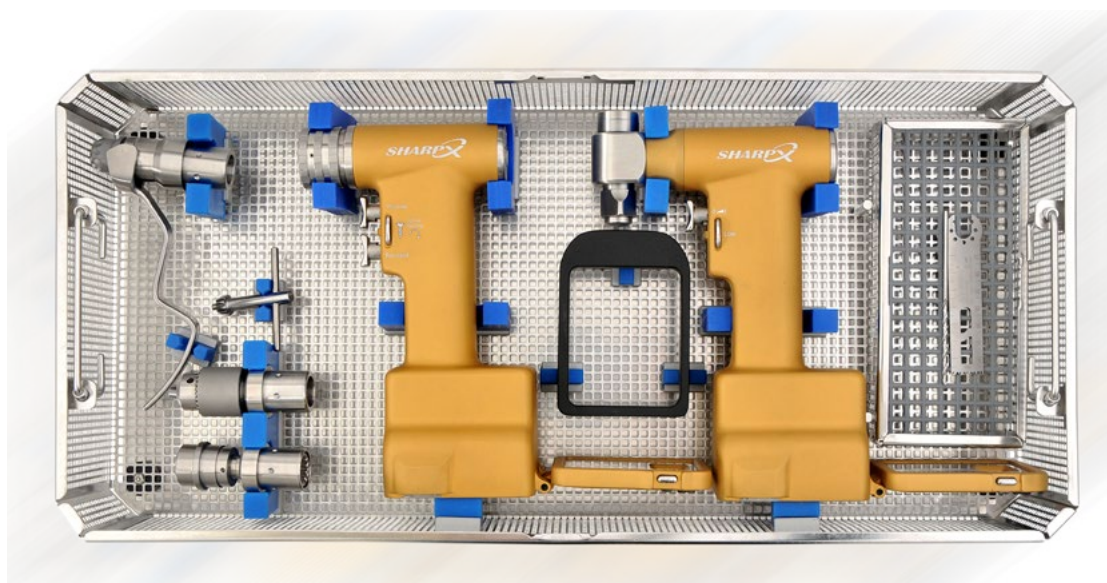


S103-392



Code	Length	Width	Thickness
S103-390	35 mm	25 mm	0.8 mm
S103-391	50 mm	40 mm	0.8 mm
S103-392	35 mm	75 mm	0.8 mm

Orthopedic Set



S-1001 Orthopedic Set

Set Content

S-200	SharpX Drill-Reamer Handpiece
S-210	Power box (2 pcs)
S-212	Autoclaveable sterile funnel for aseptic battery loading
S-227	Charger unit for 2 battery
S-309	Drill attachment with keyed chuck
S7-502	Drill bit
S7-504	Drill bit
S7-250	Chuck key for S-309
S-300	SharpX Sagittal saw Handpiece
S103-1117	Sagittal saw blade
S103-1146	Sagittal saw blade
S-320	Acetabular reamer attachment
S-330	Reamer attachment for wire and pin
S-352	Quick - action chuck (K-wire Driver)
S8-510	Sprey oil
S3-2723	Basket with silicone fixations 540 x 253 x 113 mm



S-210
Power box
(2 pcs)



S-227
Charger unit for 2 batteries



S8-510
Sprey oil, for motor and additional pcs.
After cleaning of every use. Oil inside of all moving pcs of device by spraying method and run the device for 2-3 seconds.



S3-2723
Basket with silicone fixations
540 x 253 x 113 mm



Drill Set

S-1005 Drill Set

Set Content

S-200	Sharpx Drill-Reamer Handpiece
S-210	Power box
S-212	Autoclaveable sterile funnel for aseptic battery loading
S-226	Charger unit for 1 battery
S-309	Drill attachment with keyed chuck
S7-502	Drill bit
S7-504	Drill bit
S7-250	Chuck key for S-309
S8-510	Sprey oil
S3-2731	Basket with silicone fixations 405 x 253 x 113 mm



S-210
Power box



S-226
Charger unit for 1 battery



S8-510

Sprey oil, for motor and additional pcs.
After cleaning of every use. Oil inside of all moving pcs of device by spraying method and run the device for 2-3 seconds.



S3-2731

Basket with silicone fixations
405 x 253 x 113 mm



Sagittal Saw Set

S-1007 Sagittal Saw Set

Set Content

S-300	Sharpx Sagittal saw Handpiece
S-210	Power box
S-212	Autoclaveable sterile funnel for aseptic battery loading
S-226	Charger unit for 1 battery
S103-1117	Sagittal saw blade
S103-1146	Sagittal saw blade
S8-510	Sprey oil
S3-2731-S2	Basket with silicone fixations 405 x 253 x 113 mm



S-210
Power box



S-226
Charger unit for 1 battery



S8-510

Sprey oil, for motor and additional pcs.
After cleaning of every use. Oil inside of all moving pcs of device by spraying method and run the device for 2-3 seconds.



S3-2731-S2

Basket with silicone fixations
405 x 253 x 113 mm



Reciprocating Saw Set

S-1013 Reciprocating Saw Set

Set Content

S-235	Sharpx Reciprocating saw Handpiece
S-210	Power box
S-212	Autoclaveable sterile funnel for aseptic battery loading
S-226	Charger unit for 1 battery
S103-239	Reciprocating saw blade
S8-510	Sprey oil
S3-2731-S3	Basket with silicone fixations 405 x 253 x 113 mm



S-210
Power box



S-226
Charger unit for 1 battery



S8-510

Sprey oil, for motor and additional pcs.
After cleaning of every use. Oil inside of all moving pcs of device by spraying method and run the device for 2-3 seconds.



S3-2731-S3

Basket with silicone fixations
405 x 253 x 113 mm



Sternal Saw Set



S-210
Power box



S-226
Charger unit for 1 battery

S-1009	Sternal Saw Set
Set Content	
S-240	Sharpx Sternum saw Handpiece
S-210	Power box
S-212	Autoclaveable sterile funnel for aseptic battery loading
S-226	Charger unit for 1 battery
S103-715	Adult saw guide
S103-710	Adult saw blade
S8-510	Sprey oil
S3-2731-S4	Basket with silicone fixations 405 x 253 x 113 mm



S8-510
Sprey oil, for motor and additional pcs.
After cleaning of every use. Oil inside of all moving pcs of device by spraying method and run the device for 2-3 seconds.



S3-2731-S4
Basket with silicone fixations
405 x 253 x 113 mm



Cardio Vascular Set



S-210
Power box
(2 pcs)



S-227
Charger unit for 2 batteries

S-1011 Cardio Vascular Set	
Set Content	
S-240	Sharpx Sternum saw Handpiece
S-210	Power box (2 pcs)
S-212	Autoclaveable sterile funnel for aseptic battery loading
S-227	Charger unit for 2 battery
S-300	Sharpx Re-Operation saw Handpiece
S103-715	Adult saw guide
S103-710	Adult saw blade
S103-392	Re-Operation saw blade
S8-510	Sprey oil
S3-2723-S2	Basket with silicone fixations 540 x 253 x 113 mm



S8-510
Sprey oil, for motor and additional pcs.
After cleaning of every use. Oil inside of all moving pcs of device by spraying method and run the device for 2-3 seconds.



S3-2723-S2
Basket with silicone fixations
540 x 253 x 113 mm

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EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-11-102

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

SHARPLINE MEDIKAL IC VE DIS TICARET LIMITED SIRKETI

Hancerli Mah. Derviszade Sk. No: 6/4 Ilkadim SAMSUN-TURKEY

Product: Electrical and battery operated surgical motor system

Model Name: Sharp X

Product: High speed surgical motor system

Model Name: HSM, HSM Micro

Product: Electrical and pneumatical surgical motor systems

Model Name: Electrical Control Unit (M6-034), Pneumatic Surgical Motor

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa Certification Services for details.

Report Number: M.3608.09

Date of first issue: 05 July 2011

Date of last issue: 28 May 2019

Revision Number: 07

Expiry Date: 27 May 2024

Kiwa Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

28 May 2019, Istanbul, Turkey

Head of Notified Body

Kiwa Certification Services Inc.
ITOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

EC DECLARATION OF CONFORMITY
Full quality assurance procedureNo:TD05-02-009 / 20190206-002
Samsun 02.2019

Manufacturer: Sharpline Medical İç ve Dış Ticaret Ltd.
Manufacturer's Address: Hancıerli Mah. Dervişzade Sk. No:6/4
55020 İlkadım, SAMSUN, TURKEY
Medical Device Product Name: Surgical Motor Systems Electrical and Battery Operated
Model Name: Sharp X
Classification: Enclosure IX rule 2 and rule 9, class IIA
Notified Body
Name: Kiwa Certification Services Inc.
Address: ITOSB 9. Cadde No:15 Tepeören Tuzla, İstanbul, TÜRKİYE
No: 1984

GMDN Code and Term: [58187] Surgical Drill System multifunctional rechargeable battery/electrical
[58188] Surgical Saw System rechargeable battery/electrical

We declare under our sole responsibility, that the medical device of class IIA, to which this declaration relates are in conformity with the provisions of the Council Directive 93/42/EEC (2007/47/EC). Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules, at each stage, from the design of the device until its final inspection before being supplied. The medical devices are in conformity with the essential requirements of Annex I of the EEC directive. The conformity assessment procedure was performed according to Annex II (class IIA) of the EEC directive.

Standards and Directives Applied:	93/42/EC	EN 60601-1:2006	EN 60601-1-2:2015
	EN 60601-1-6:2010/	EN ISO 15223-1:2016	EN ISO 14971:2012
	EN 62366-1:2015	EN 1041:2008	

Notes: These standards do not necessarily apply to all parts of the product Sharp X and its accessories.

Authorides Signatory:

Murat BAHADIR , Founder - CEO

Date: 29.02.2019



DD-01R(01) 06.06.2016



CERTIFICATE

SHARPLINE®

**SHARPLINE MEDİKAL
İÇ VE DIŞ TİCARET LTD. ŞTİ.**

HANÇERLİ MAH. DERVİŞZADE SOK. NO: 6/4
İLKADIM - SAMSUN - TURKEY

with a scope of

**DESIGN, DEVELOPMENT, MANUFACTURING AND DISTRIBUTION
OF ELECTRICAL, PNEUMATIC AND BATTERY OPERATED
SURGICAL MOTOR SYSTEMS, SURGICAL ILLUMINATION
SYSTEMS AND STERILISATION CONTAINERS**

Medical devices - Quality management systems - Requirements for
regulatory purposes

"Following elements of the standard are excluded"

"7.5.5" "7.5.7" "7.5.9.2"

EN ISO 13485:2016

Certificate No	: M 8693
Initial Certification Date	: 05 July 2011
Certification Date	: 01 June 2020
Expiration Date	: 31 May 2023

General Manager

Kiwa Certification Services Inc.

İTOSB 9. Cadde No. 15 Tepeören Tuzla - İstanbul - Turkey

Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74

Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.

Please contact above numbers for detailed information.

Last Modified: 01 June 2020 - R 05



Medical Device Q.M.S.
TS EN ISO/IEC 17021-1
AB-0006-YS



TÜRKAK BDS NO
YS-C267-70CD