CANNULATED SCREWS Ø 1,8/2,3/2,7/3,0/3,5/4,0/4,5MM

Risk class	IIb Invasive medical devices
Manufacturer	Episcan Srl Via Custoza, 10 20811 Cesano Maderno (MB) Italy info@episcan.it www.episcan.it
Certification	Dir.93/42/CEE 2007/47/CE All. II Italcert Srl Viale Sarca, 336 20126 Milano (MI) Italy
Sterilization	Gamma Ray 25 kGy Gammatom Srl Via XXIV Maggio, 14 22070 Guanzate CO Italy

STERILE R

CE 0426

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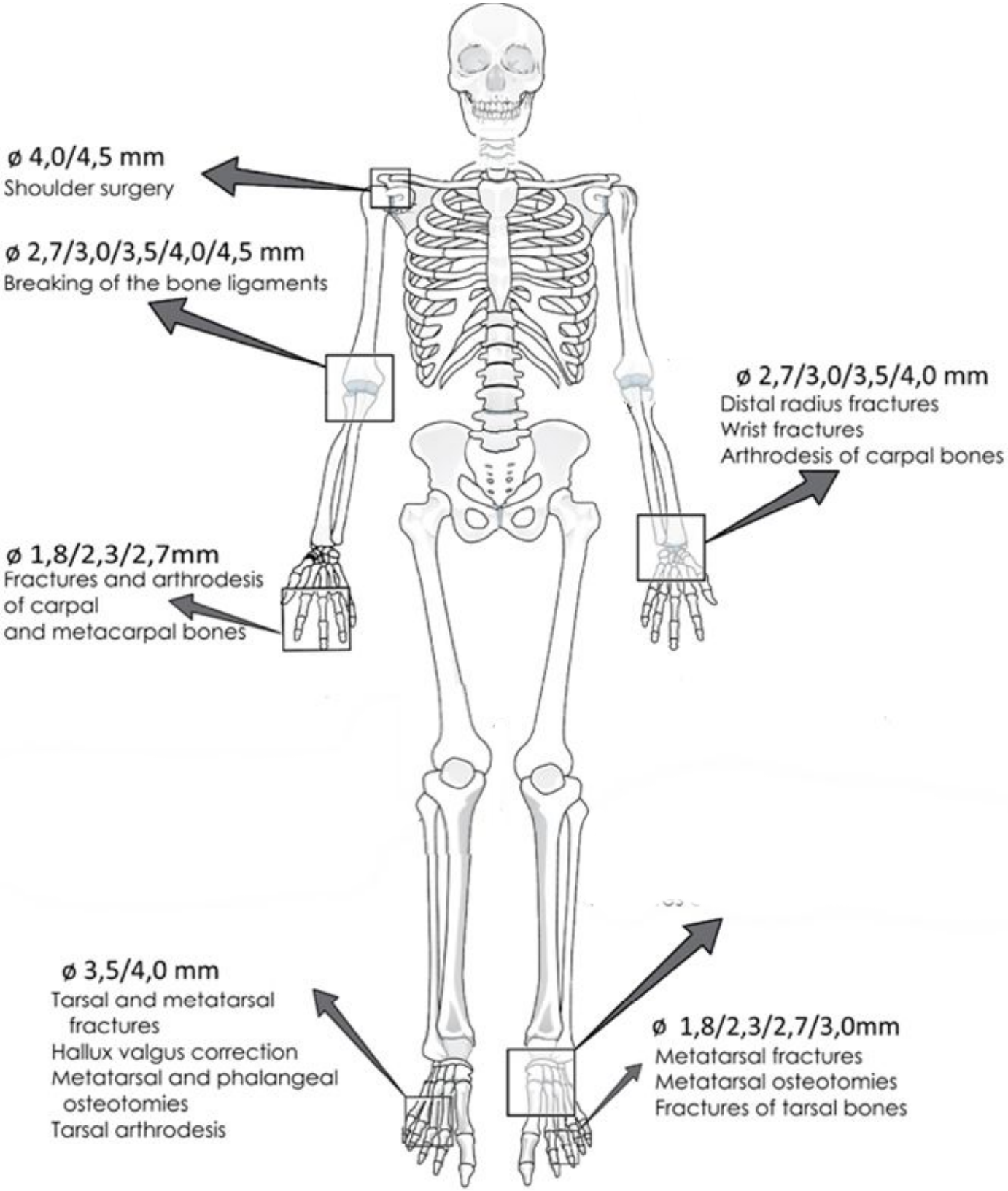

ø 4,0/4,5 mm
Shoulder surgery
ø 2,7/3,0/3,5/4,0/4,5 mm
Breaking of the bone ligaments
ø 2,7/3,0/3,5/4,0 mm
Distal radius fractures
Wrist fractures
Arthrodesis of carpal bones
ø 1,8/2,3/2,7mm
Fractures and arthrodesis
of carpal
and metacarpal bones
ø 3,5/4,0 mm
Tarsal and metatarsal
fractures
Hallux valgus correction
Metatarsal and phalangeal
osteotomies
Tarsal arthrodesis
ø 1,8/2,3/2,7/3,0mm
Metatarsal fractures
Metatarsal osteotomies
Fractures of tarsal bones

CORTICAL CANNULATED SCREWS Ø 1,8/2,3MM

L.	Ø 1,8mm	Ø 2,3mm
6 mm	TT.C18.33.006	TT.C23.33.006
8 mm	TT.C18.33.008	TT.C23.33.008
10 mm	TT.C18.33.010	TT.C23.33.010
12 mm	TT.C18.33.012	TT.C23.33.012
14 mm	TT.C18.33.014	TT.C23.33.014
16 mm	TT.C18.33.016	TT.C23.33.016
18 mm	TT.C18.33.018	TT.C23.33.018
20 mm	TT.C18.33.020	TT.C23.33.020
22 mm	TT.C18.33.022	TT.C23.33.022
24 mm	TT.C18.33.024	TT.C23.33.024
26 mm	TT.C18.33.026	TT.C23.33.026
28 mm	TT.C18.33.028	TT.C23.33.028
30 mm	TT.C18.33.030	TT.C23.33.030

TECHNICAL DATA SHEET

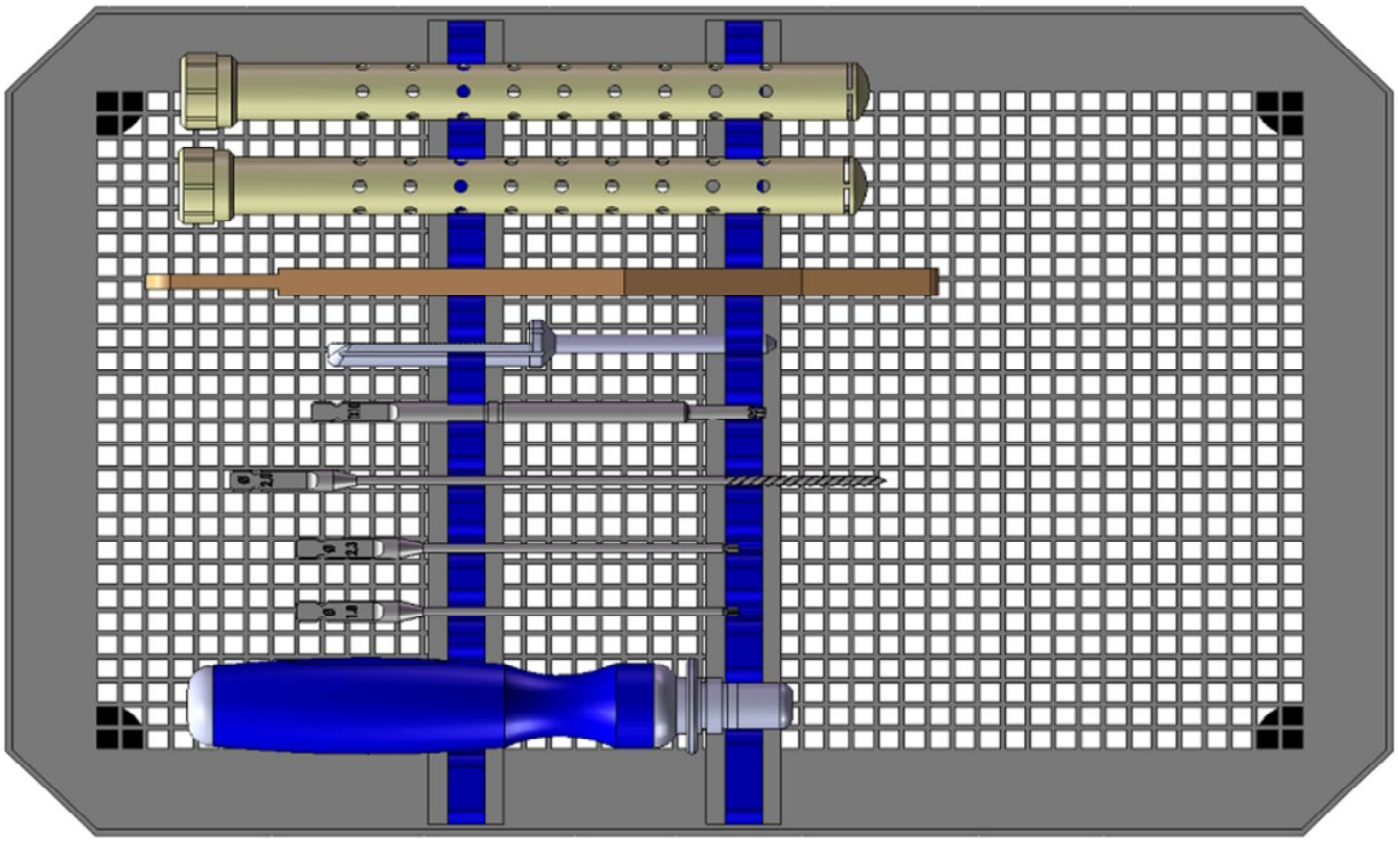
Cannulation: ø 1,0mm
K-Wire Guide: ø 0,7mm for ø 1,8mm screw
K-Wire Guide: ø 0,9mm for ø 2,3mm screw
Head: Torx TX6
Raw material: Titanium 5 (TI6AL4V ELI - ISO 5832.3)

SURGICAL INDICATIONS

Revision, fixation and treatment of human bones

CORTICAL CANNULATED SCREWS Ø 1,8/2,3MM INSTRUMENTS

Code	Description	Q.TY
1307S	K-Wire single trocar 0,7mm L.100mm (pack 20 pcs not sterile)	1
1309S	K-Wire single trocar 0,9mm L.100mm (pack 20 pcs not sterile)	1
IS.DG.323940	Depth gauge for cannulated screws L. 45/100mm	1
IS.FC.020105	Cannulated drill bit Ø 2,0mm L. 105mm for k-wires Ø 1,0mm	1
IS.MA.004355	Countersink for screws Ø1.8mm short	1
IS.MA.004356	Countersink for screws Ø2.3mm short	1
IS.PI.11110.13	Forceps	1
IS.SD.4TX06090	Screwdriver Cannulated insert TX6 L. 90mm	1
IS.SH.004632B	Screwdriver silicone handle AO small	1
SB.KD.019100	K-wire dispenser L. 100mm	2
TA.605.070100	K-wre guide trocar single tip Ø 0,7 L.100mm	1
TA.605.090100	K-Wire guide trocar single tip Ø 0,9 L.100mm	1
SB.S271705.0	Instrument tray with lid stainless steel size 2S	1



CORTICAL CANNULATED SCREWS Ø 2,7MM

L.	Ø 2,7mm
20 mm	TT.C27.33.020
22 mm	TT.C27.33.022
24 mm	TT.C27.33.024
26 mm	TT.C27.33.026
28 mm	TT.C27.33.028
30 mm	TT.C27.33.030
32 mm	TT.C27.33.032
34 mm	TT.C27.33.034
36 mm	TT.C27.33.036
38 mm	TT.C27.33.038
40 mm	TT.C27.33.040
45 mm	TT.C27.33.045
50 mm	TT.C27.33.050
55 mm	TT.C27.33.055
60 mm	TT.C27.33.060

TI-WASHER FOR CANNULATED SCREW 2,7 mm
TM.528.023027

TECHNICAL DATA SHEET

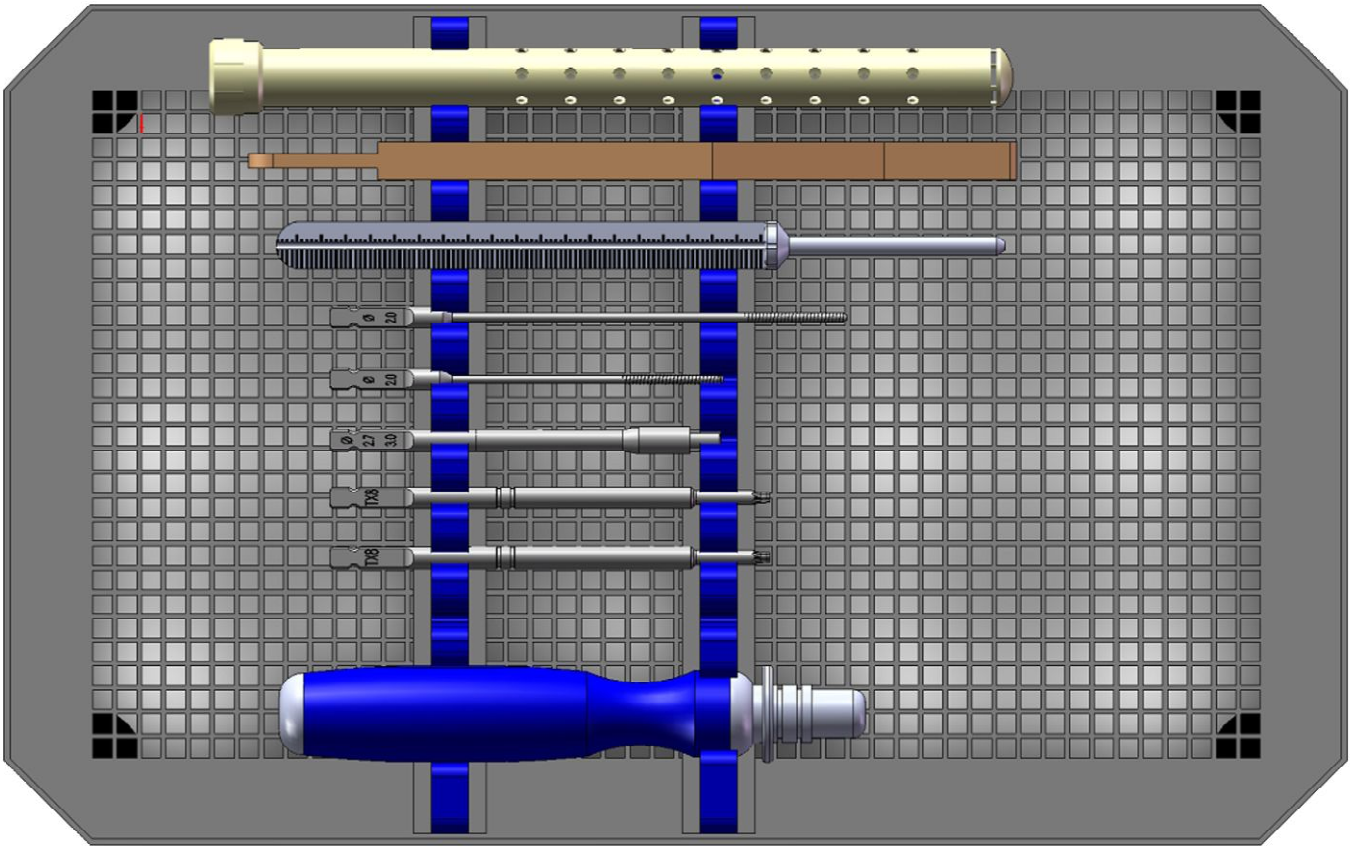
Cannulation: ø 1,1mm
K-Wire Guide: ø 1,0mm
Head: Torx TX8
Raw material: Titanium 5 (TI6AL4V ELI - ISO 5832.3)

SURGICAL INDICATIONS

Revision, fixation and treatment of human bones

CORTICAL CANNULATED SCREWS Ø 2,7MM INSTRUMENTS

CODE	DESCRIPTION	Q.TY
1310S	K-Wire single trocar 1,0mm L.150mm (pack 20 pcs not sterile)	1
IS.DG.450095	Depth gauge for cannulated screws Ø 2,7/3,5/4,5mm L. 95/150mm	1
IS.FC.020105	Cannulated drill bit Ø 2,0mm L. 105mm for k-wires Ø 1,0mm	1
IS.MA.004119	Tap for screws Ø 2,7/3,0mm	1
IS.MA.004121	Countersink for screws Ø 2,7/3,0mm short	1
IS.PI.11110.13	Forceps	1
IS.SD.3TX08090	Screwdriver insert TX8 L. 90mm	1
IS.SD.4TX08090	Screwdriver Cannulated insert TX8 L. 90mm	1
IS.SH.004632B	Screwdriver silicone handle AO small	1
SB.KD.019160	K-wire dispenser L. 160mm	1
TA.605.100150	K-Wire guide trocar single tip Ø 1,0 L.150mm	1
SB.S271705.0	Instrument tray with lid stainless steel size 2S	1



CORTICAL CANNULATED SCREWS Ø 3,0MM

L.	Ø 3,0 mm Full Thread	Ø 3,0 mm Short Thread
12 mm	TT.C30.31.012	TT.C30.33.012
14 mm	TT.C30.31.014	TT.C30.33.014
16 mm	TT.C30.31.016	TT.C30.33.016
18 mm	TT.C30.31.018	TT.C30.33.018
20 mm	TT.C30.31.020	TT.C30.33.020
22 mm	TT.C30.31.022	TT.C30.33.022
24 mm	TT.C30.31.024	TT.C30.33.024
26 mm	TT.C30.31.026	TT.C30.33.026
28 mm	TT.C30.31.028	TT.C30.33.028
30 mm	TT.C30.31.030	TT.C30.33.030
32 mm	TT.C30.31.032	TT.C30.33.032
35 mm	TT.C30.31.035	TT.C30.33.035
38 mm	TT.C30.31.038	TT.C30.33.038
40 mm	TT.C30.31.040	TT.C30.33.040
42 mm	TT.C30.31.042	TT.C30.33.042
45 mm	TT.C30.31.045	TT.C30.33.045
50 mm	TT.C30.31.050	TT.C30.33.050
55 mm	TT.C30.31.055	TT.C30.33.055
60 mm	TT.C30.31.060	TT.C30.33.060

TECHNICAL DATA SHEET

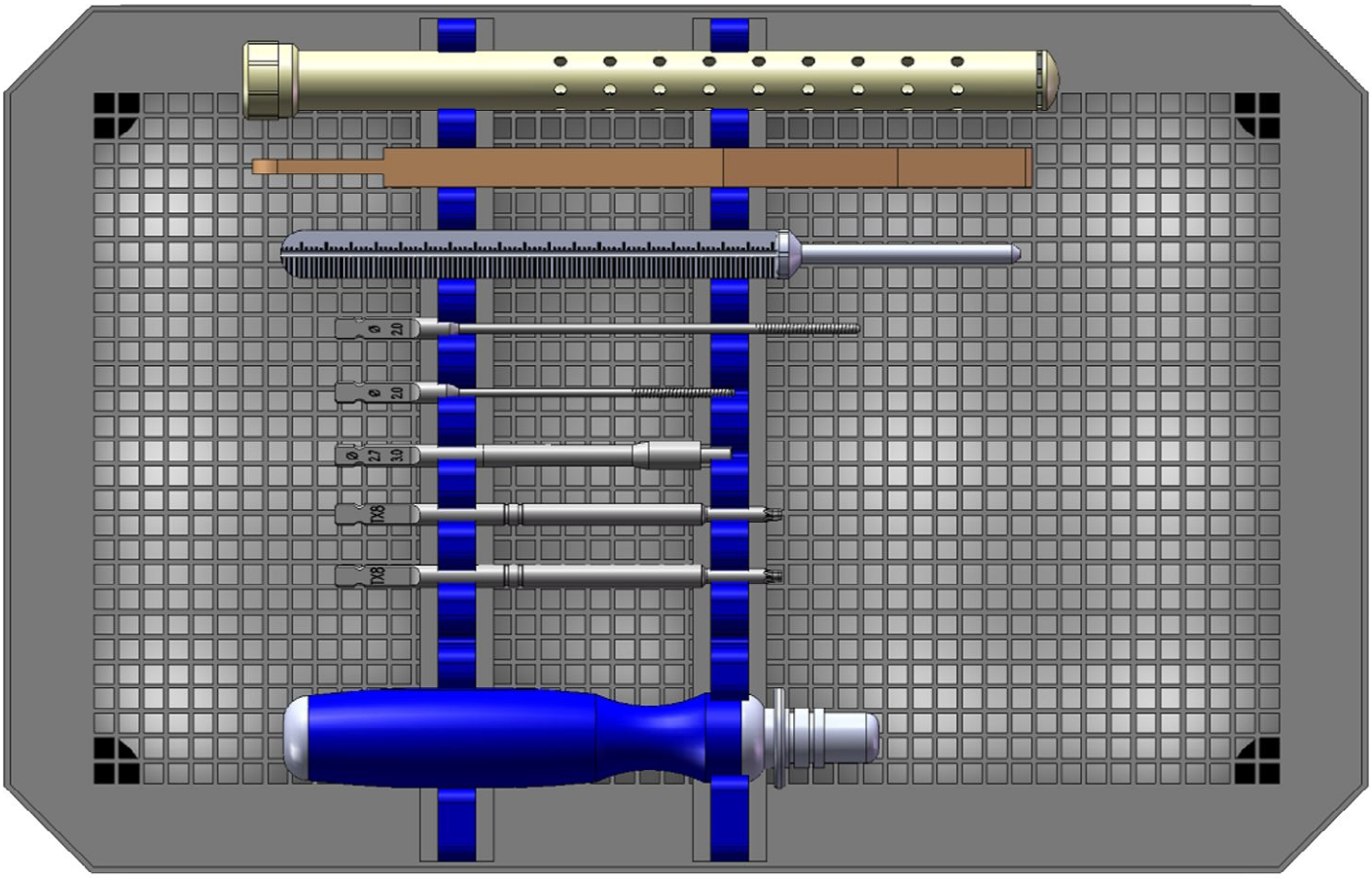
Cannulation: ø 1,1mm
K-Wire Guide: ø 1,0mm
Head: Torx TX8
Raw material: Titanium 5 (TI6AL4V ELI - ISO 5832.3)

SURGICAL INDICATIONS

Revision, fixation and treatment of human bones

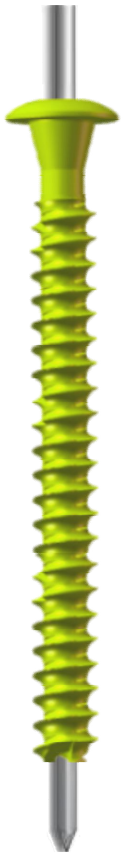
CORTICAL CANNULATED SCREWS Ø 3,0MM
INSTRUMENTS

CODE	DESCRIPTION	Q.TY
1310S	K-Wire single trocar 1,0mm L.150mm (pack 20 pcs not sterile)	1
IS.DG.450095	Depth gauge for cannulated screws Ø 2,7/3,5/4,5mm L. 95/150mm	1
IS.FC.020105	Cannulated drill bit Ø 2,0mm L. 105mm for k-wires Ø 1,0mm	1
IS.MA.004119	Tap for screws Ø 2,7/3,0mm	1
IS.MA.004121	Countersink for screws Ø 2,7/3,0mm short	1
IS.PI.11110.13	Forceps	1
IS.SD.3TX08090	Screwdriver insert TX8 L. 90mm	1
IS.SD.4TX08090	Screwdriver Cannulated insert TX8 L. 90mm	1
IS.SH.004632B	Screwdriver silicone handle AO small	1
SB.KD.019160	K-wire dispenser L. 160mm	1
TA.605.100150	K-Wire guide trocar single tip Ø 1,0 L.150mm	1
SB.S271705.0	Instrument tray with lid stainless steel size 2S	1



CORTICAL CANNULATED SCREWS Ø 3,5MM

L.	Ø 3,5 mm Full Thread	Ø 3,5mm Short Thread
12 mm	TT.C35.31.012	TT.C35.33.012
14 mm	TT.C35.31.014	TT.C35.33.014
16 mm	TT.C35.31.016	TT.C35.33.016
18 mm	TT.C35.31.018	TT.C35.33.018
20 mm	TT.C35.31.020	TT.C35.33.020
22 mm	TT.C35.31.022	TT.C35.33.022
24 mm	TT.C35.31.024	TT.C35.33.024
26 mm	TT.C35.31.026	TT.C35.33.026
28 mm	TT.C35.31.028	TT.C35.33.028
30 mm	TT.C35.31.030	TT.C35.33.030
32 mm	TT.C35.31.032	TT.C35.33.032
34 mm	TT.C35.31.034	TT.C35.33.034
36 mm	TT.C35.31.036	TT.C35.33.036
38 mm	TT.C35.31.038	TT.C35.33.038
40 mm	TT.C35.31.040	TT.C35.33.040
45 mm	TT.C35.31.045	TT.C35.33.045
50 mm	TT.C35.31.050	TT.C35.33.050
55 mm	TT.C35.31.055	TT.C35.33.055
60 mm	TT.C35.31.060	TT.C35.33.060



TI-WASHER FOR CANNULATED SCREW 3,5 mm
TM.528.023035

TECHNICAL DATA SHEET

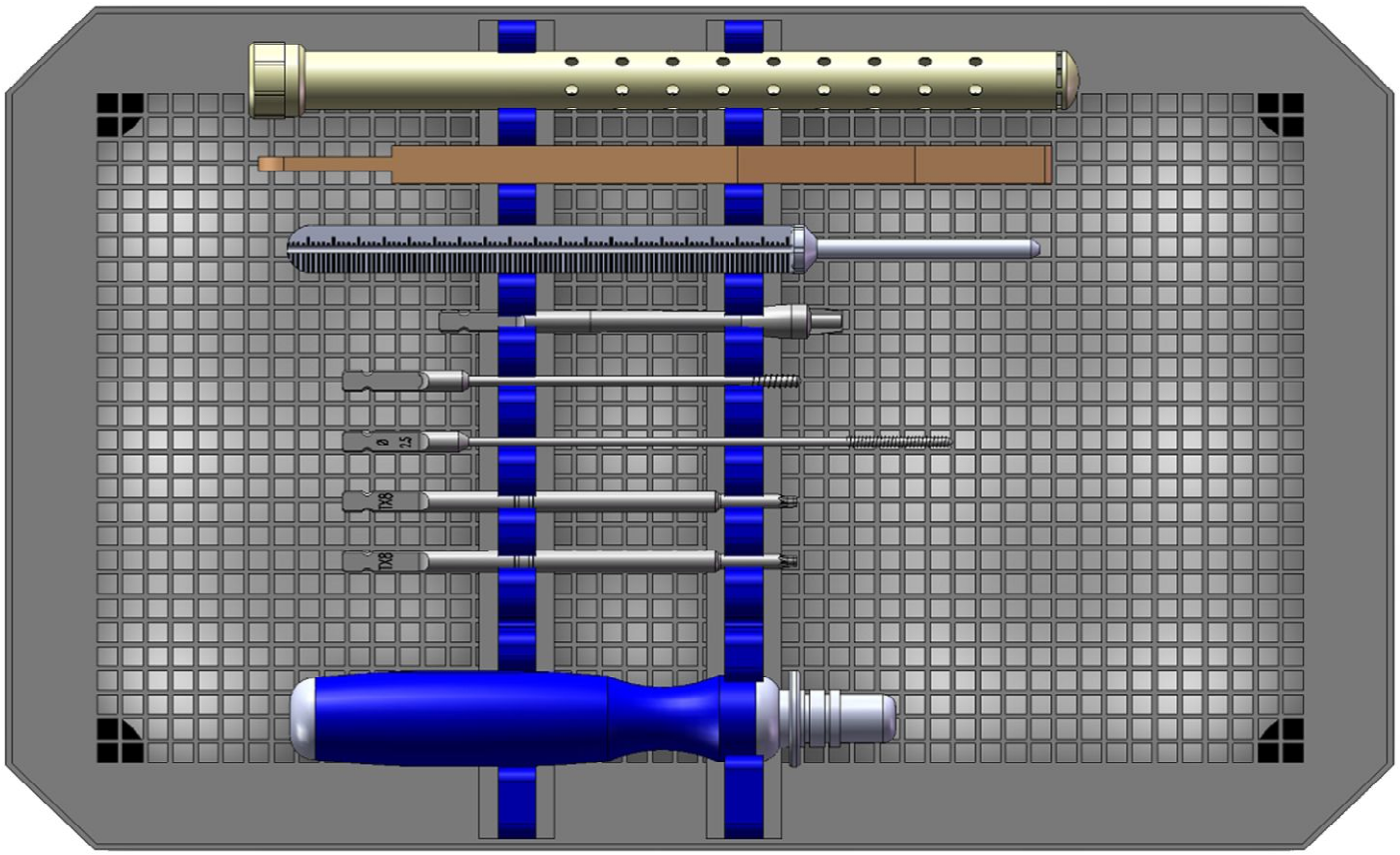
Cannulation: ø 1,3mm
K-Wire Guide: ø 1,1mm
Head: Torx TX8
Raw material: Titanium 5 (TI6AL4V ELI - ISO 5832.3)

SURGICAL INDICATIONS

Revision, fixation and treatment of human bones

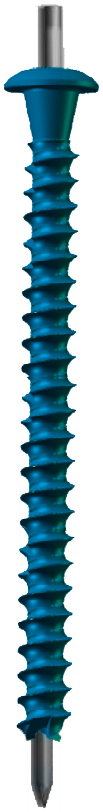
CORTICAL CANNULATED SCREWS Ø 3,5MM
INSTRUMENTS

CODE	DESCRIPTION	Q.TY
IS.DG.450095	Depth gauge for cannulated screws Ø 2,7/3,5/4,5mm L. 95/150mm	1
IS.PI.11110.13	Forceps	1
IS.SD.3TX08090	Screwdriver insert TX8 L. 90mm	1
IS.SD.4TX08090	Screwdriver Cannulated insert TX8 L. 90mm	1
IS.SH.004632B	Screwdriver silicone handle AO small	1
SB.KD.019160	K-wire dispenser L. 160mm	1
IS.FC.025120	Cannulated drill bit Ø 2,5mm L. 120mm for k-wires Ø 1,2mm	1
IS.MA.004175	Tap for screws Ø 3,5/4,0mm	1
IS.MA.004280	Countersink for screws Ø 3,5mm short	1
TA.605.110150	K-Wire guide trocar single tip Ø 1,1 L.150mm	1
1311S	K-Wire single trocar 1,1mm L.150mm (pack 20 pcs not sterile)	1
SB.S271705.0	Instrument tray with lid stainless steel size 2S	1



CANCELLOUS CANNULATED SCREWS Ø 4,0MM

L.	Ø 4,0 mm Full Thread	Ø 4,0mm Short Thread
12 mm	TT.S40.31.012	TT.S40.33.012
14 mm	TT.S40.31.014	TT.S40.33.014
16 mm	TT.S40.31.016	TT.S40.33.016
18 mm	TT.S40.31.018	TT.S40.33.018
20 mm	TT.S40.31.020	TT.S40.33.020
22 mm	TT.S40.31.022	TT.S40.33.022
24 mm	TT.S40.31.024	TT.S40.33.024
26 mm	TT.S40.31.026	TT.S40.33.026
28 mm	TT.S40.31.028	TT.S40.33.028
30 mm	TT.S40.31.030	TT.S40.33.030
32 mm	TT.S40.31.032	TT.S40.33.032
35 mm	TT.S40.31.035	TT.S40.33.035
40 mm	TT.S40.31.040	TT.S40.33.040
45 mm	TT.S40.31.045	TT.S40.33.045
50 mm	TT.S40.31.050	TT.S40.33.050
55 mm	TT.S40.31.055	TT.S40.33.055
60 mm	TT.S40.31.060	TT.S40.33.060



TECHNICAL DATA SHEET

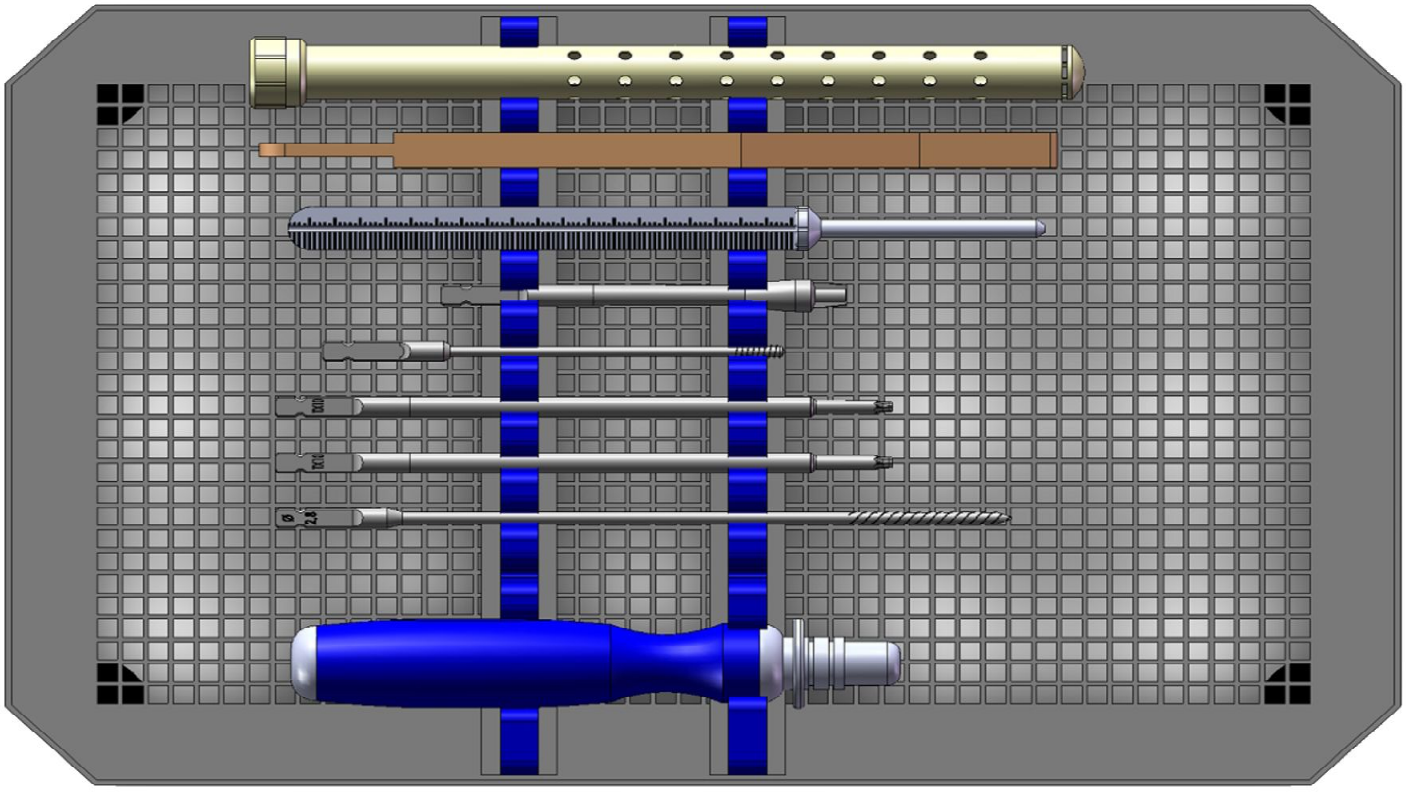
Cannulation: ø 1,5mm
K-Wire Guide: ø 1,2mm
Head: Torx TX10
Raw material: Titanium 5 (TI6AL4V ELI - ISO 5832.3)

SURGICAL INDICATIONS

Revision, fixation and treatment of human bones

CANCELLOUS CANNULATED SCREWS Ø 4,0MM
INSTRUMENTS

CODE	DESCRIPTION	Q.TY
IS.DG.450095	Depth gauge for cannulated screws Ø 2,7/3,5/4,5mm L. 95/150mm	1
IS.PI.11110.13	Forceps	1
IS.SH.004632B	Screwdriver silicone handle AO small	1
SB.KD.019160	K-wires dispenser L. 160mm	1
IS.MA.004175	Tap for screws Ø 3,5/4,0mm	1
IS.MA.004280	Countersink for screws Ø 3,5mm short	1
IS.FC.028150	Cannulated drill bit Ø 2,8mm L. 150mm for k-wires Ø 1,4mm	1
IS.SD.3TX10120	Screwdriver insert TX10 L. 120mm	1
IS.SD.4TX10090	Screwdriver Cannulated insert TX10 L. 90mm	1
TA.605.120150	K-wire guide trocar single tip Ø 1,2 L.150mm	1
1312S	K-Wire single trocar 1,2mm L.150mm (pack 20 pcs not sterile)	1
SB.S271705.0	Instrument tray with lid stainless steel size 2S	1



CORTICAL CANNULATED SCREWS Ø 4,5MM

L.	Ø 4,5 mm Full Thread	Ø 4,5mm Short Thread
18 mm	TT.C45.31.018	TT.C45.33.018
20 mm	TT.C45.31.020	TT.C45.33.020
22 mm	TT.C45.31.022	TT.C45.33.022
24 mm	TT.C45.31.024	TT.C45.33.024
26 mm	TT.C45.31.026	TT.C45.33.026
28 mm	TT.C45.31.028	TT.C45.33.028
30 mm	TT.C45.31.030	TT.C45.33.030
32 mm	TT.C45.31.032	TT.C45.33.032
34 mm	TT.C45.31.034	TT.C45.33.034
36 mm	TT.C45.31.036	TT.C45.33.036
38 mm	TT.C45.31.038	TT.C45.33.038
40 mm	TT.C45.31.040	TT.C45.33.040
45 mm	TT.C45.31.045	TT.C45.33.045
50 mm	TT.C45.31.050	TT.C45.33.050
55 mm	TT.C45.31.055	TT.C45.33.055
60 mm	TT.C45.31.060	TT.C45.33.060
65 mm	TT.C45.31.065	TT.C45.33.065
70 mm	TT.C45.31.070	TT.C45.33.070
75 mm	TT.C45.31.075	TT.C45.33.075
80 mm	TT.C45.31.080	TT.C45.33.080
85 mm	TT.C45.31.085	TT.C45.33.085
90 mm	TT.C45.31.090	TT.C45.33.090

TI-WASHER FOR CANNULATED SCREW 4,5 mm
TM.528.023045

TECHNICAL DATA SHEET

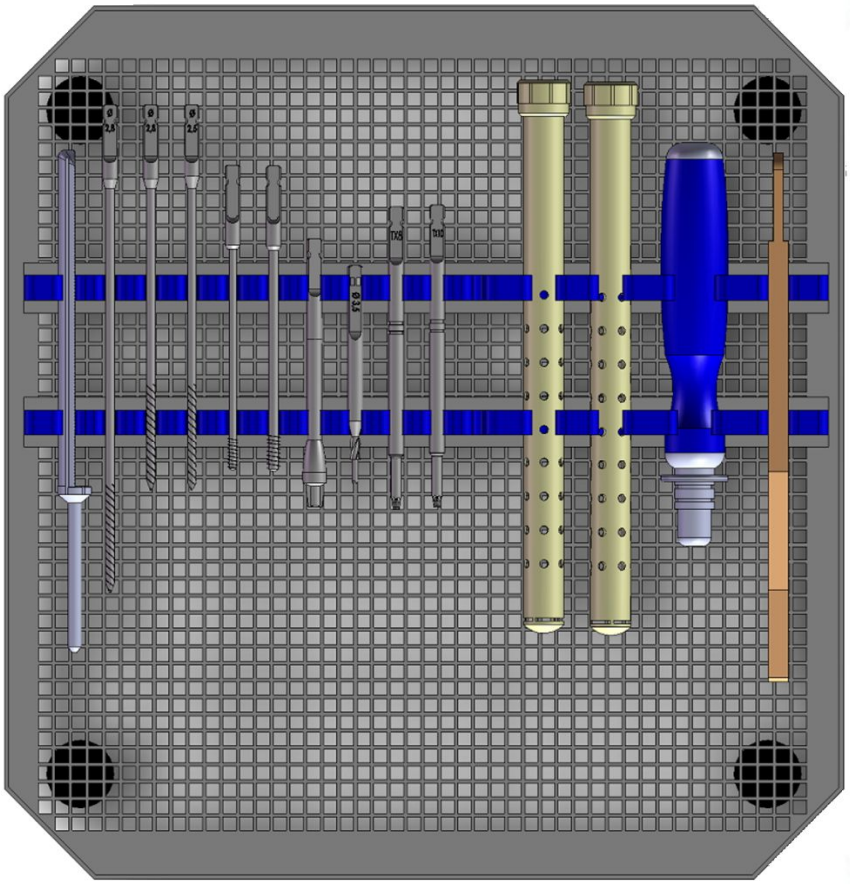
Cannulation: ø 1,5mm
K-Wire Guide: ø 1,4mm
Head: Torx TX10
Raw material: Titanium 5 (TI6AL4V ELI - ISO 5832.3)

SURGICAL INDICATIONS

Revision, fixation and treatment of human bones

INSTRUMENTS

CODE	DESCRIPTION	Q.TY
1314S	K-Wire single trocar 1,4mm L.150mm (pack 20pcs not sterile)	1
IS.DG.450095	Depth gauge for cannulated screws Ø 2,7/3,5/4,5mm L. 95/150mm	1
IS.FC.028120	Cannulated drill bit Ø 2,8mm L. 120mm for k-wires Ø 1,4mm	1
IS.FC.028150	Cannulated drill bit Ø 2,8mm L. 150mm for k-wires Ø 1,4mm	1
IS.MA.004185	Tap for screws Ø 3,5/4,5mm	1
IS.MA.004351	Countersink for screws Ø 3,5/4,5mm short	1
IS.PI.11110.13	Forceps	1
IS.SD.4TX08090	Screwdriver Cannulated insert TX8 L. 90mm	1
IS.SD.4TX10090	Screwdriver Cannulated insert TX10 L. 90mm	1
IS.SH.004634B	Screwdriver silicone handle AO medium	1
SB.KD.019160	K-wires dispenser L. 160mm	2
SB.S252506.0	Instrument tray with lid stainless steel size MQ	1



1. After having made a deep incision
2. Insert the single guide through the soft tissues until the bone is reached.
3. Insert the guide wire through the guide until the desired position is reached.
4. Remove the guide and assess the position of the wire
5. Drill the area using the appropriate bur provided in the instrument set. If a second guide wire is required, use the double guide
6. Detect the depth
7. If the cortical bone is particularly hard, use the appropriate bone tap.
8. Insert the selected screw onto the guide wire and tighten with the cannulated insert.
9. Remove the screwdriver and the guide wire
10. Tighten with the solid screwdriver as far as it will go.

CLINICAL CONTRAINDICATIONS

- Patients with suspected infection, active infection, or with immune deficiencies.
- Patients with metabolic, degenerative, cardio-circulatory or systemic disease.
- Patients with tumours in the treatment area or with degenerative bone disease.
- Patients with drug, alcohol or medical addiction, or who are mentally instable.
- Patients who perform activities that require walking, running, or other excessive muscular strain, as the resulting forces may cause malfunction of the implant.

POTENTIAL RISKS AND POSSIBLE SECONDARY EFFECTS

- Infections, pain, and allergic reactions to implant materials.
- Damage to nerves, vascular lesions, and wound healing disorders.
- Damage to soft tissue including swelling and functional lesions of the musculoskeletal system.
- Limited motion.
- Insufficient, abnormal and/or delayed scarring.
- Breakage, bending, loosening, or migration of the implant in the event of excessive loads or weights.
- Osteonecrosis, due to overheating after exceeding 42 °C for more than 1 minute during drilling or boring.
- Anaesthesiological issues and problems with the patient's position (vomiting, dental lesions, or neurological disturbances).
- Thrombosis, embolism, excessive bleeding, neural damage, and iatrogenic vascular trauma.
- Sudeck's atrophy.

RECOMMENDATIONS AND INSTRUCTION

- Before surgery, the patient must be informed of all collateral effects and risks of the product used and the expected result from surgery (for example, temporary motion restriction). Doctors must instruct their patients to immediately inform them of any changes in the operated area, so as to take suitable action for continuing treatment.
- Product choice and surgical technique must be based on the type of bone deficiency, anatomical position, surgical indications, accepted medical standards, patient's weight, physical condition and activity level.
- Carefully check the implants and instruments prior to use.
- Before implanting the medical devices, the orthopaedic surgeon must ascertain whether the patient is allergic to any of the components of the medical device.
- Titanium implants are coloured to help identify the medical devices; any slight variations in colour have no effect on the quality of the implant.
- The device is sold in sterile packaging as it has been subject to gamma irradiation at 25 kGy.
- Keep the device in its original protective packaging and remove it from the packaging only immediately before use.
- Check the expiry date of the device before use and verify package seal integrity. Do not use the product if the packaging is damaged.
- The medical device can be used only once; consequently the civil and criminal responsibilities of the manufacturer are limited to its first use.
- Disposable medical devices cannot be reused. Re-sterilisation can compromise the structural integrity of the device and/or cause it to malfunction with consequent possible lesions, illnesses, or death of the patient. Civil and criminal liability in the event of re-sterilisation and/or re-use shall be borne entirely by the health care operator/facility, as this is an illegal act.
- Furthermore, re-use and reconditioning can cause contamination due to the transmission of infectious material from one patient to another, which can cause injury or death to the patient or the user. Therefore, re-sterilisation of the medical device and re-use of the implant are prohibited and relieve the manufacturer from any and all civil and criminal liability for the damage that this may cause to third parties. In this case, the civil and criminal responsibilities are entirely borne by the facility, hospital or other organisation that performs such a service.

- The device cannot be used after the expiry date shown on the packaging or if the pH colour change indicator is not red. The use of the device beyond the period of validity indicated by the manufacturer, or in a non-sterile condition because opened before the surgery can cause serious or lethal damage to the patient
- The medical device may only be implanted by orthopaedic surgeons.
- CAT/NMR treatments are allowed for titanium implants and are prohibited for steel implants.

WARNINGS AND PRECAUTIONS

- The professional responsible for the surgical procedure is also responsible for proper patient assessment, for adequate training and information, for experience in the choice and location of the implants, and the decision to remove implants in the post-operative phase. If possible, implants should be removed after complete bone consolidation.
- The surgeon must have dedicated training, experience and complete familiarity with the use of rigid devices for internal fixing, surgical techniques and post-operative care. Patients must scrupulously follow the post-operative instructions provided by their surgeon. The patient must be informed of the type of load that can be exerted until the fracture has consolidated fully.
- For implants, it is essential to use the dedicated Episcan instruments. Not using the instruments specially designed to facilitate each step of the operative technique can compromise the integrity of the implanted device, leading to its premature failure and consequent injury of the patient.
- Episcan has not tested compatibility with devices supplied by other manufactures and does not take any responsibility in these cases; it is therefore not recommended to use implants from different manufacturers, due to possible incompatibility of the metals, mechanisms and concept of the implant.
- It is prohibited to couple this medical device with other implants from other manufacturers.
- Using implants from different manufacturers is not recommended due to possible incompatibility of the metals, mechanisms and concept of the implant.
- Osteosynthesis devices are recommended for use in patients with bone quality sufficient to sustain the effectiveness and benefits of the rigid fixing.
- Implants are intended for temporary fixing, until osteogenesis has taken place.
- Implants must be applied in a sterile operating environment.
- The probability of success of the operation increases with the correct choice of medical device, its shape, size and design.
- The surgeon must inform the patient about the recovery times also in relation to the load exerted on the affected area.

DISCLAIMER OF LIABILITY

- Episcan Srl declines any responsibility for damages to the patient due to:
- Improper use of the products.
- Use of the same medical device in different patients.
- Reuse and/or re-sterilisation and/or reconditioning of the sterile medical device.
- Use of incompatible materials or instruments.
- Use of the medical devices by surgeons other than orthopaedic surgeons.

DISPOSAL OF THE PRODUCTS

For disposal, it is recommend to follow a procedure appropriate to the indicated class of risk, and in any case to proceed according to hospital protocols and/or the reference standards and as established for hazardous healthcare waste with blood contamination.

SYMBOLS LEGEND

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CE	CE Mark
	Do not re-use
	Date of manufacture
	Expiry date
	Manufacturer
STERILE R	Gamma Ray sterilised
LOT	Lot number
REF	Item number
DIST	Exclusive Distributor
	Consult instructions for use
	Consult instructions for use
	Consult electronic instrusction for use
	Keep dry
	Do not use if package is opened or damaged

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