Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System

No. 11 0673 QS/NB

The quality system of manufacturer

Samay Surgical

Survey No. 212, Plot No. 6, Nr. Patidar Plastic, NH-8B, Veraval (Shapar) – 360 024, Dist. Rajkot, Gujarat, India

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):

Orthopaedic Implants, Spinal Implants

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2016-08-09
Valid until: 2021-08-08
First Issued: 2011-08-09
Revision: b

Date: 2016-08-09

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

| evaluate | assess | certify |

assessors of quality

Management System Certificate

Certificate No. **MD-QMS/91/R/1933**

This is to certify that

Samay Surgicals

**Survey No. 212, Plot No. 6, Nr. Patidar Plastic, Nh-8b,
Veraval (Shapar) – 360 024, Dist. Rajkot, Gujarat, India**

has been found to conform to the requirements of
Medical Devices - Quality Management System Standard :

ISO 13485:2016

This certificate is valid for the following scope :

**Design, Manufacture & Supply of Orthopedic Implants,
Spinal Implant & related Instruments.**

Initial Certification	:	20th August, 2011
Re-certification	:	20th August, 2017
Valid until	:	19th August, 2020

Authorised Signatory

This Certificate is valid when confirmed by data listed in the International Register of Quality Assessed Organisations <www.irqao.org>.
Further clarification regarding the scope of this certificate and the applicability of ISO 13485:2016 requirements may be obtained by consulting the certified organization.
Lack of fulfillment of conditions as set out in the Certification Agreement may render this certificate invalid.

Zenith Quality Assessors Pvt. Ltd.
(Management System Certification Division, MSCD002)
306, 4th Floor, Sai Apex, Near Datta Mandir, Viman Nagar, Pune - 411 014, Maharashtra, India.
www.zenith-worldwide.com

Accreditation Body : ACCREDITATION SERVICE FOR CERTIFYING BODIES (EUROPE) Ltd.
6, Ferris Place, Bournemouth, Dorset, BH8 0AU, United Kingdom.
www.ascb.co.uk

C/ASCB/MDQMS16/00/121216 (Cl.8.2)

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60125623 0001

Report No.: 15096224 001

Manufacturer:
CANWELL MEDICAL CO., LTD.
No. 466 South Xianhua Street
High-Tech Industrial Zone
Jinhua
321016 Zhejiang
China

Products:
- Metal Bone Plates
- Metal Bone Screws
- Intramedullary Nail Systems
- Spinal Fixation Systems
- Interbody Fusion Cages
- Vertebral Body Replacements

Expiry Date: 2023-01-09

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Notified Body

Effective Date: 2018-01-10

Date: 2018-01-10

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

CANWELL MEDICAL CO., LTD.
No. 466 South Xianhua Street
High-Tech Industrial Zone
Jinhua
321016 Zhejiang
China

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of Medical Devices
(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-01-10
Certificate Registration No.:	SX 60125624 0001
An audit was performed. Report No.:	15096224 001
This Certificate is valid until:	2021-01-09

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2018-01-10

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60125624 0001
Report No.: 15096224 001

Organization:
CANWELL MEDICAL CO., LTD.
No. 466 South Xianhua Street
High-Tech Industrial Zone
Jinhua
321016 Zhejiang
China

Scope:

Products:

- Metal Bone Plates
- Metal Bone Screws
- Intramedullary Nail Systems
- Spinal Fixation Systems
- Interbody Fusion Cages
- Vertebral Body Replacements
- External Fixation Systems
- Orthopedic Instruments

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2018-01-10

X. Ren

CanPCC

Pelvic C-Clamp

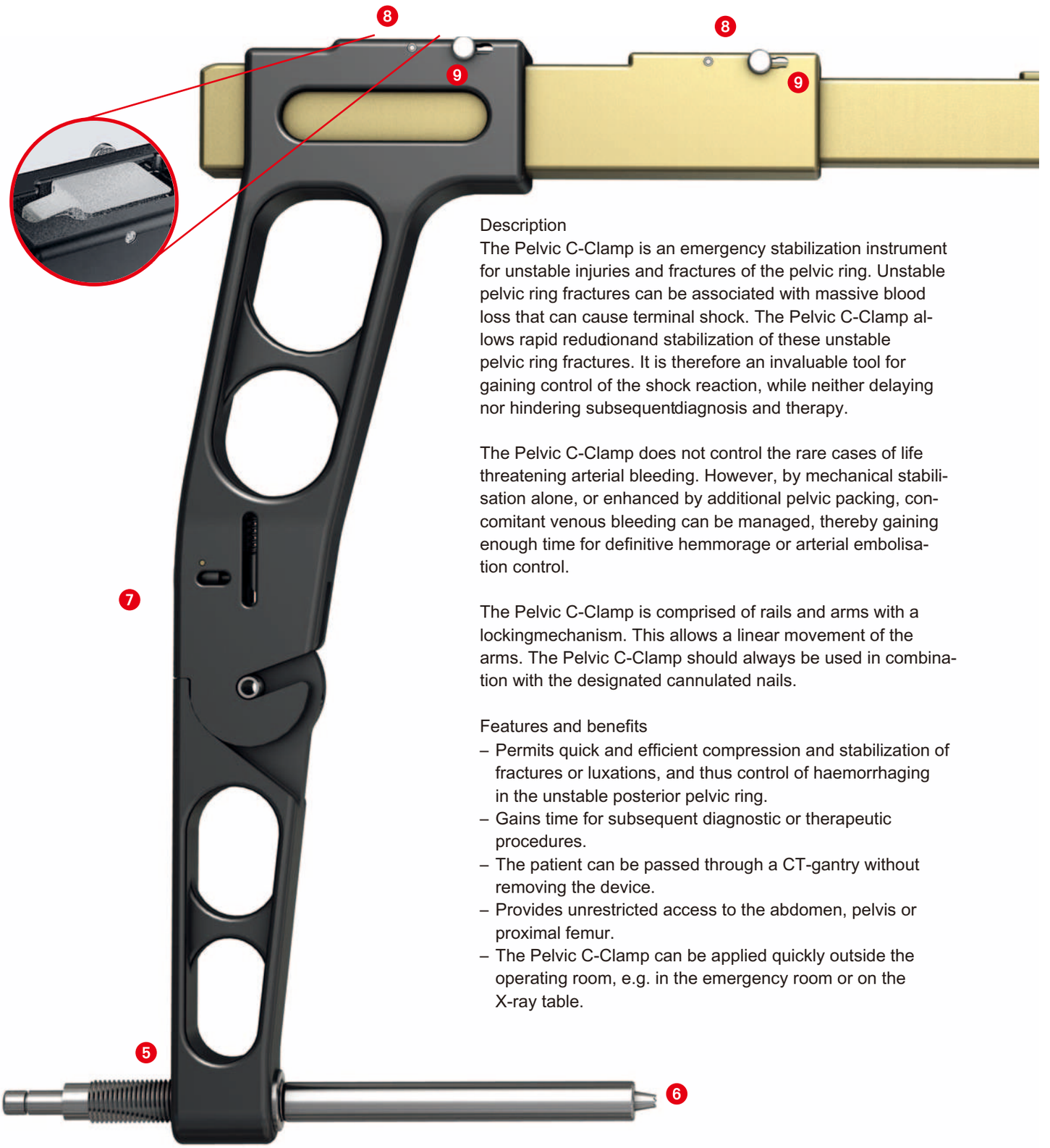
CANWELL
MEDICAL CO., LTD

Table of Contents

Image intensifier control

Warning
This guide is not sufficient for an immediate application of the Pelvic C-Clamp. Instruction by an experienced surgeon in hand-ling the Pelvic C-Clamp is highly recommended.

Pelvic C-Clamp. Permits rapid reduction and stabilization of the posterior pelvic ring.



Description

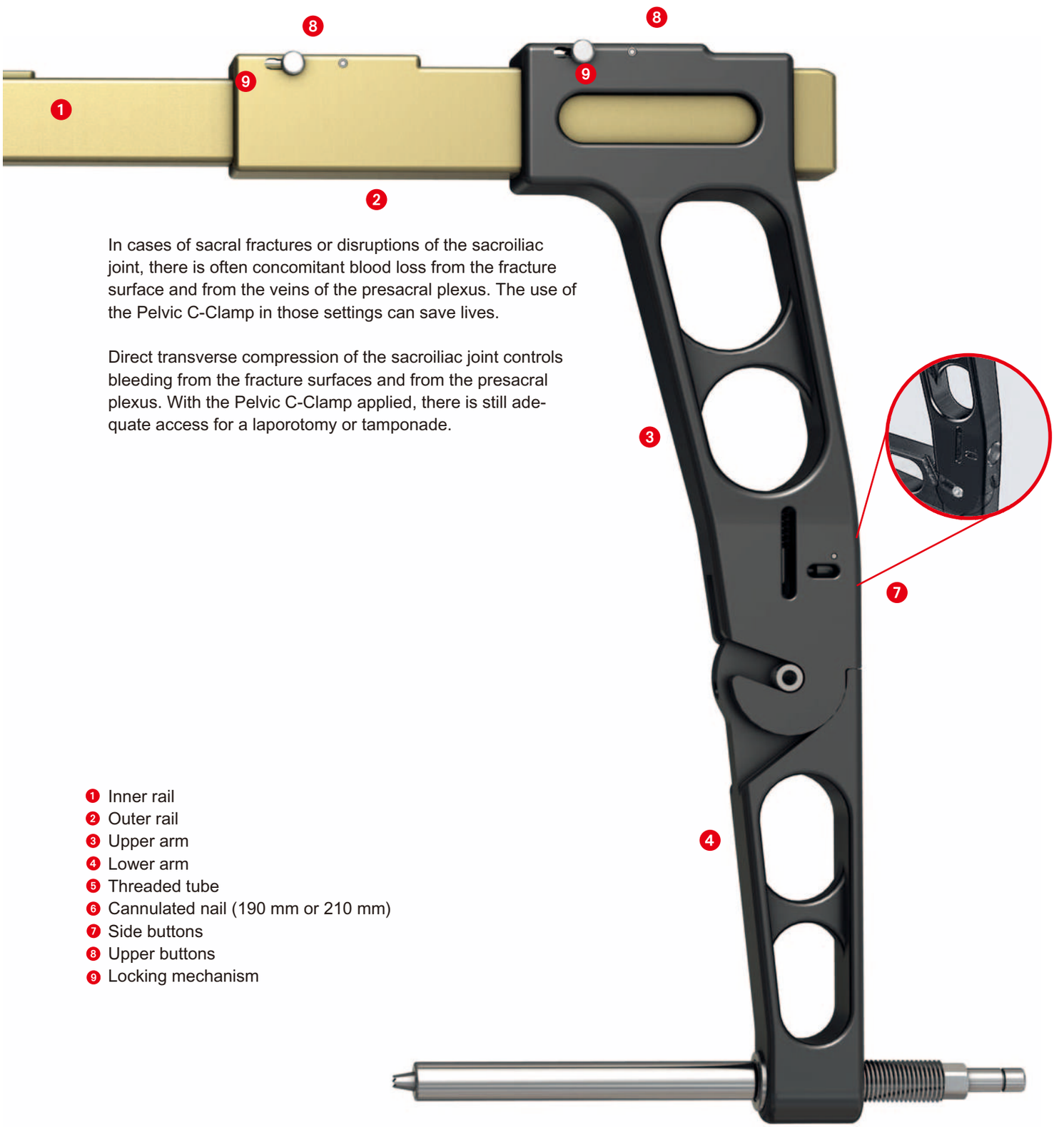
The Pelvic C-Clamp is an emergency stabilization instrument for unstable injuries and fractures of the pelvic ring. Unstable pelvic ring fractures can be associated with massive blood loss that can cause terminal shock. The Pelvic C-Clamp allows rapid reductionand stabilization of these unstable pelvic ring fractures. It is therefore an invaluable tool for gaining control of the shock reaction, while neither delaying nor hindering subsequentdiagnosis and therapy.

The Pelvic C-Clamp does not control the rare cases of life threatening arterial bleeding. However, by mechanical stabilisation alone, or enhanced by additional pelvic packing, concomitant venous bleeding can be managed, thereby gaining enough time for definitive hemmorage or arterial embolisation control.

The Pelvic C-Clamp is comprised of rails and arms with a lockingmechanism. This allows a linear movement of the arms. The Pelvic C-Clamp should always be used in combination with the designated cannulated nails.

Features and benefits

- Permits quick and efficient compression and stabilization of fractures or luxations, and thus control of haemorrhaging in the unstable posterior pelvic ring.
- Gains time for subsequent diagnostic or therapeutic procedures.
- The patient can be passed through a CT-gantry without removing the device.
- Provides unrestricted access to the abdomen, pelvis or proximal femur.
- The Pelvic C-Clamp can be applied quickly outside the operating room, e.g. in the emergency room or on the X-ray table.



In cases of sacral fractures or disruptions of the sacroiliac joint, there is often concomitant blood loss from the fracture surface and from the veins of the presacral plexus. The use of the Pelvic C-Clamp in those settings can save lives.

Direct transverse compression of the sacroiliac joint controls bleeding from the fracture surfaces and from the presacral plexus. With the Pelvic C-Clamp applied, there is still adequate access for a laporotomy or tamponade.

1. Inner rail
2. Outer rail
3. Upper arm
4. Lower arm
5. Threaded tube
6. Cannulated nail (190 mm or 210 mm)
7. Side buttons
8. Upper buttons
9. Locking mechanism

Indications

The Pelvic C-Clamp is intended for emergency stabilization of sacrum fractures or disruptions of the sacroiliac joint with associated circulatory instability.

Caution:
Avoid use where:
- Fractures of the ilium are present as there is risk of pin perforation through the fracture line
- There are comminuted sacral fractures with the risk of compression of the sacral nerve plexus

Note: In life threatening situations hemorrhage control takes priority over the potential risk of nerve root compression.

1

Pre-operative preparation

Instrument	
116069000	Pelvic C-Clamp complete system

The Pelvic C-Clamp set consists of the instruments and implants for the emergency treatment of the indicated fracture types. The bottom layer of the Vario Case houses the Pelvic C-Clamp and the optional pliers. The upper layer houses the cannulated nails in two lengths and the remaining instruments.

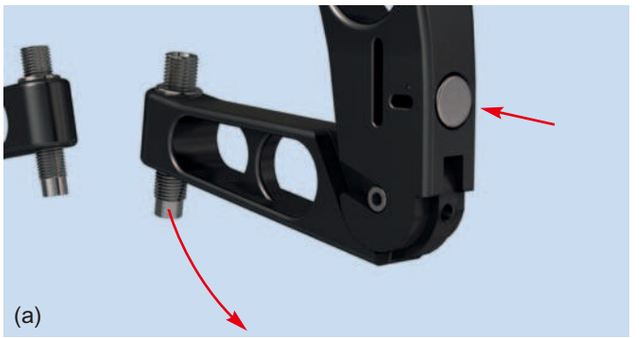
The complete sterile Pelvic C-Clamp set should be kept ready for use in the resuscitation room. Depending on the type of injury, the orientation points in the pelvic region of the injured person may be unclear. Should there be doubts about the anatomic references, use an image intensifier during application of the Pelvic-C-Clamp.

Pre-operative preparation
- Anteroposterior (AP) plain pelvic radiograph if necessary, oblique views (Inlet and Outlet) or CT.
- Patient positioning must allow for intraoperative fluoroscopic controls in AP, Inlet and Outlet Projections.
- Have an image intensifier available.

Positioning
- Place the patient in a supine position.
- To facilitate reduction, ensure free draping of the leg on the injured side. Strive for good draping coverage of the genital region.
- To prepare the patient, disinfect the proximal femur and the buttocks and cover with sterile sheets.

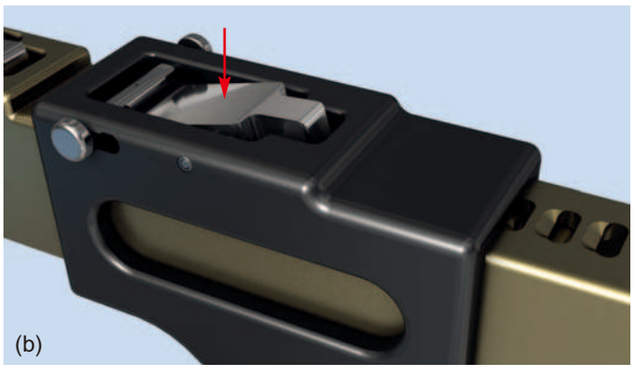
Preparation of the Pelvic C-Clamp
Open the lower side arms by depressing the buttons on the arms to prepare the Pelvic C-Clamp for use. (a)

Note: Hold upper and lower arms with both hands and ensure that the lower arm is locked when fully extended.

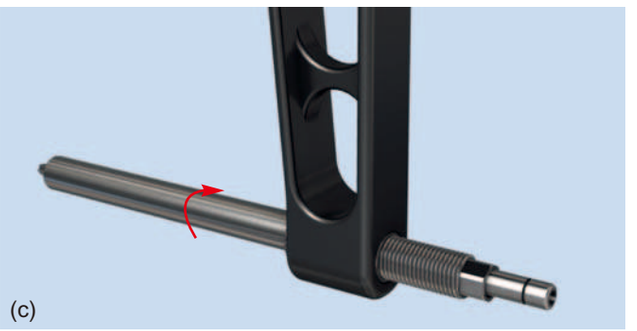


Extend the upper bars by depressing the buttons on the upper rails while simultaneously pulling on the side arms. (b)

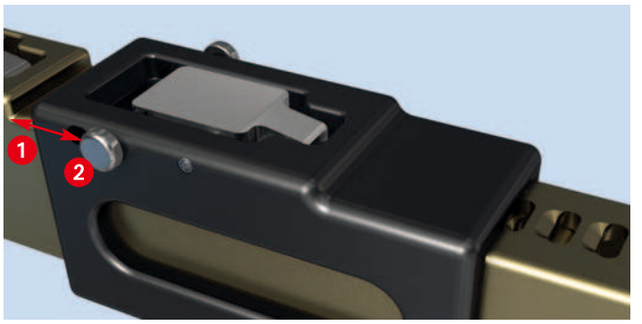
Note: Maximal extension of the Pelvic C-Clamp is advantageous for easy and safe positioning.



With a light twist, place the cannulated nails of preferred length into the threaded tubes. (c)
The little teeth on the tip of the nail allow a better grip onto the bone.



The buttons on the top of the Pelvic C-Clamp can be locked. Ensure the buttons are not locked when applying the Pelvic C-Clamp to the patient, otherwise no or insufficient compression can be achieved.

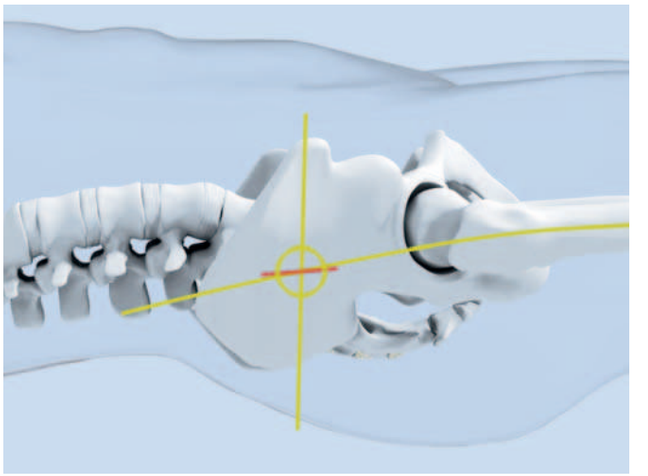


1 Unlock
2 Lock

2

Identifying nail insertion point

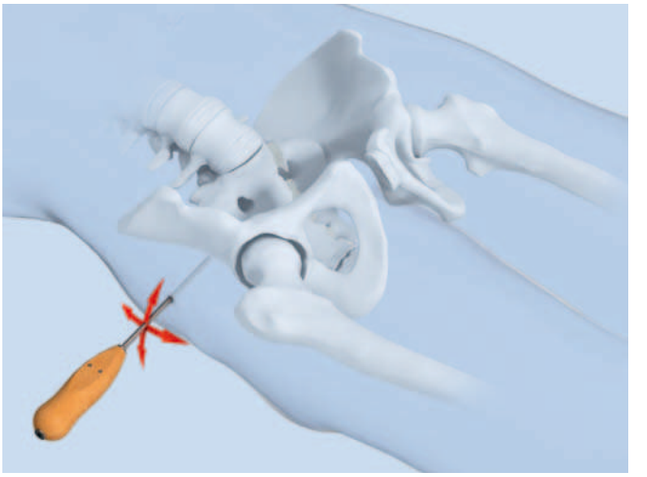
Instrument	
116060002	Guide Handle, for Kirschner Wire



Make an incision at the intersection between the extension of the line of the femoral axis over the tip of the greater trochanter, and a vertical line from the anterior superior iliac spine in the dorsal direction (see illustration).

If orientation is difficult, use an image intensifier.

The surface reference point of the outer side of the ilium changes at the level of the sacroiliac joints. In emergency situations, the resulting “fossa” can be used as a relatively secure point of reference aid. For secure anchoring, the Pelvic C-Clamp must be placed at the level of the sacroiliac joints. Palpation with a blunt instrument, such as the Guide Handle for Kirschner Wire, allows for easy identification of this site, even with severe soft-tissue swelling.



Note

- If the nails are placed too ventrally to the correct insertion point, there is a risk of perforation of the ilium, which can result in organ injury.
- Placement of the pins in an excessively dorsal position may result in injury to gluteal nerves and vessels.
- Inserting the nail too distally endangers the sciatic nerve and the gluteal vessels in the sciatic notch. Malpositioning of the nail in osteoporotic bone, combined with excessive compression, can result in unwanted nail penetration.

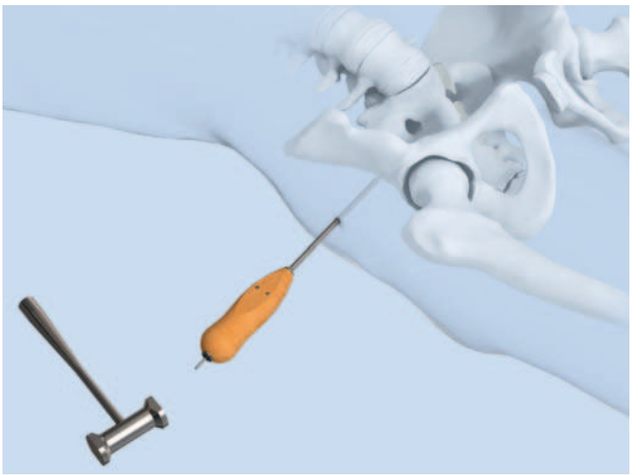
3

Kirschner Wire placement

Instruments	
116060002	Guide Handle, for Kirschner Wire
116060005	Kirschner Wire with trocar tip, length
116060001	Socket Wrench with Hammer

After having identified the insertion point, a Kirschner Wire can be placed through the Guide Handle (only on the uninjured side). Gently hammer the Kirschner Wire into the bone with the Socket Wrench with Hammer. This Kirschner Wire will ensure an exact placement of the cannulated nail and prevents the nail from slipping.

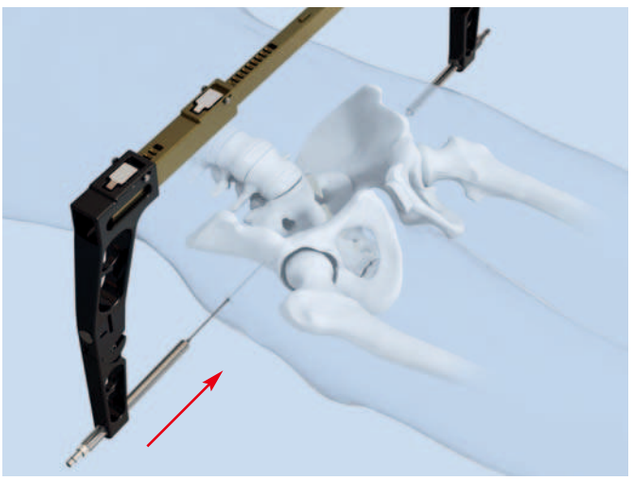
Note: Malpositioned Kirschner wires can be removed with the optional pliers or the wire cutter.



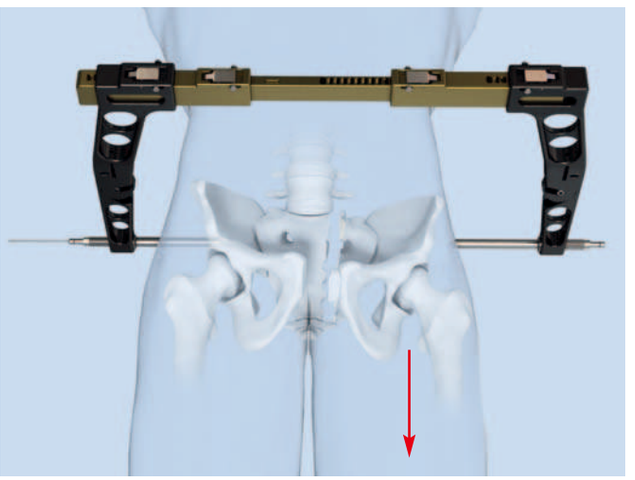
4

Placement of the Pelvic C-Clamp

Instruments	
116063000	Pelvic C-Clamp Instrument Tray
116060003	Nail for Pelvic C-Clamp, cannulated, short
116060004	Nail for Pelvic C-Clamp, cannulated, long
115400031	Ratchet Wrench for Nut, hexagonal



Optional instruments	
212040008	Screw Clamp
116060010	Threaded Tube



Be sure the fracture is correctly reduced before placement of the Pelvic C-Clamp.

After inserting the Kirschner Wire on the uninjured side, slide the clamp with cannulated nails over the wire and ensure that the tip of the nail grips the bone securely. Then place the second nail on the injured side (no Kirschner wire is necessary on this side).

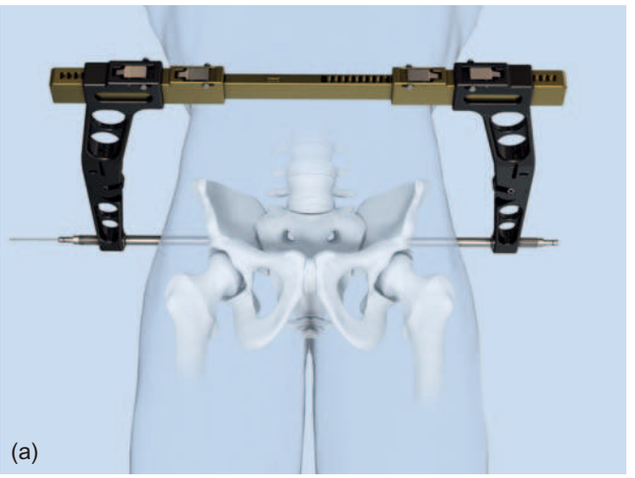
Note: In cases of severe dislocations of the pelvis, pulling on the leg, internal rotation and even lateral compression may improve reduction and facilitate application of the Pelvic C-Clamp.

Alternative: Both nails can be placed at the same time. To do this take off one side arm. After both nails have been seated properly the arm can be placed over the rail again and compression can be achieved as described below.

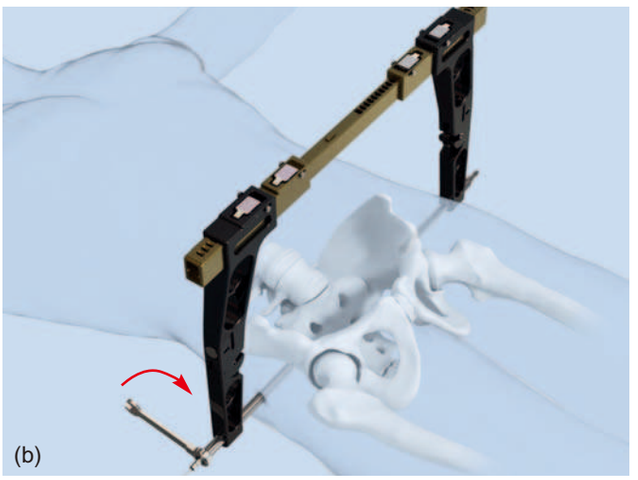
When both nails are correctly seated, manually compress the upper side arms (a) and ensure final fixation by tightening the threaded tubes with the Ratchet Wrench (b).

The Kirschner wire must be cut off with the wire cutter or removed. If desired, place a protective cap on each end of the two cannulated nails.

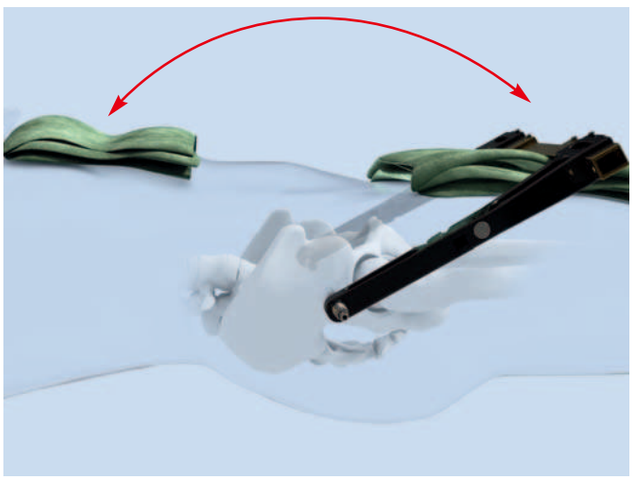
After complete application of the Pelvic C-Clamp, verify fixation with an image intensifier or X-ray (pelvic AP view) and pad the nails.


(a)

Note: The locking mechanism locks the upper buttons, thus preventing unintended loss of compression during movement of the Pelvic C-Clamp.


(b)

Once mounted, the Pelvic C-Clamp can be swung caudally and cranially, e.g. for a laparotomy or an angiography.



Notes
- It is recommended to place a drape cloth or lap sponges as a cushion between the Pelvic C-Clamp and the patient.
- Do not use the Pelvic C-Clamp to lift the patient.

5

Postoperative management

- AP plain radiograph, CT if required, rarely oblique view films after application of Pelvic C-Clamp and during follow-up.
- Do not use the Pelvic C-Clamp to lift the patient.
- Wound closure; extended incisions may require a coapting skin suture.
- Continuing injury management according to polytrauma protocols.
- The nail insertion sites must be meticulously disinfected and dressed.
- Should the patient need to be moved, he/she should on no account be placed on his/her side as this could cause one of the nails to penetrate the bone excessively.

6

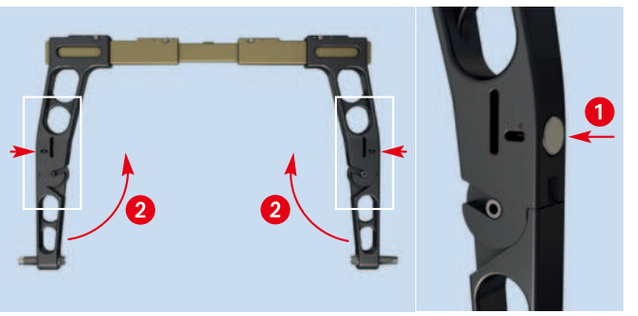
Removal

The Pelvic C-Clamp is removed prior to definitive treatment of the posterior pelvic ring injury. Be sure to remove protective caps from cannulated nails and Kirschner wire from uninjured side.

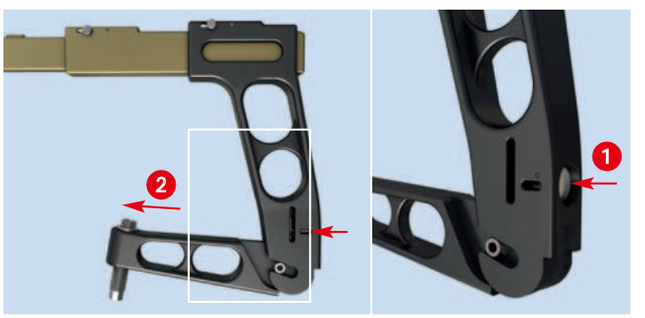
Disassembly of the Pelvic C-Clamp

Note: Before cleaning, the Pelvic C-clamp should be disassembled.

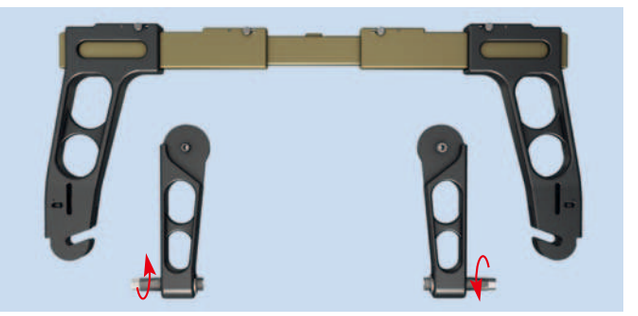
The lower arms can be raised (2) by pressing the side buttons (1) as depicted by the red arrows.



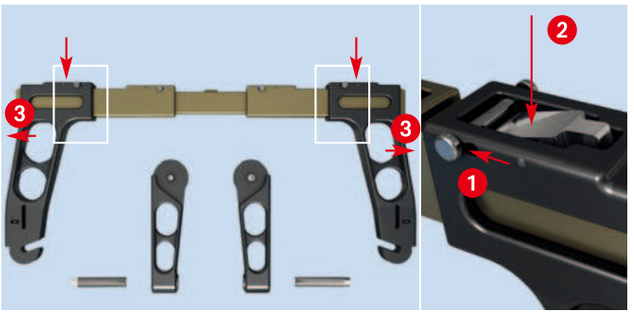
To remove the lower arms completely, keep pushing the buttons (1) and slide the arms out (2).



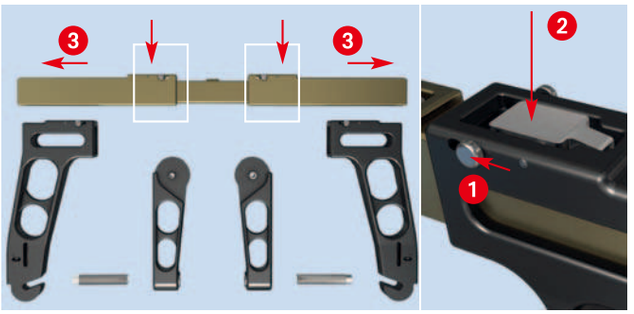
Unscrew the threaded tubes from the lower arms.



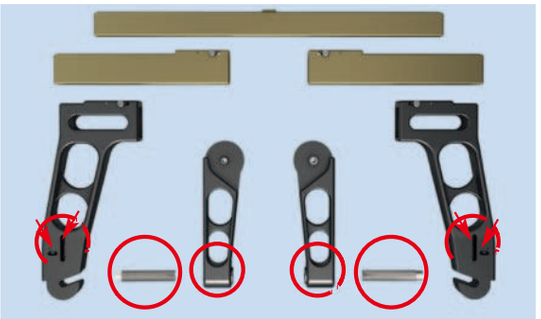
Before removing the upper arms from the upper rails, make sure the locking mechanism is unlocked (1). The upper arms can then be removed by pressing the top buttons (2) while simultaneously pulling on the arms (3). Be sure to hold the rails during this procedure to prevent the rails from falling.



The outer rails can be separated from the inner rail by pressing the buttons on the outer rails and pulling the two rails apart (3).



After disassembly, clean the rails, arms and threaded tubes manually, e.g. by using a brush. The springs in the upper arm at button should be cleaned too. If necessary, broken or damaged parts should be exchanged.



After cleaning, oil the thread of the threaded tube as well as the two holes next to the side buttons with special oil (see red circles) and reassemble the device.
The Pelvic C-Clamp should be checked after every use/cleaning/sterilization to confirm correct function, i.e. that all parts move freely as intended.
The complete sterile Pelvic C-Clamp should be kept ready for use in the resuscitation room.
Due to the fact that the Pelvic C-Clamp consists of stainless steel, aluminum and a few pieces of polymer, it should only be cleaned at temperatures below 140°C and at a pH level between 7 and 9.5 (detergents).

Note: The cannulated nails are only for single use.

CANWELL
MEDICAL CO.,LTD

Canwell Medical Co.,Ltd.

Marketing headquarters

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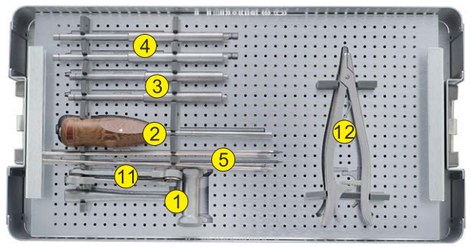
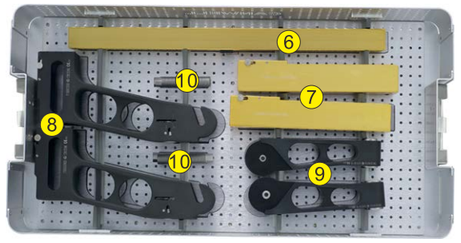
Fax:+86-579-89108791
Email:export@canwell.com.cn
Web:http://www.canwell.com.cn

Production headquarters

Add:No.466 South Xinahua Street,Jinhua, Zhejiang,China
Tel: +86-579-82239656
Fax:+86-579-89102927

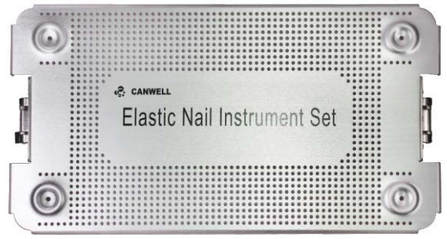
Pelvic C-Clamp Instrument Set CanPCC

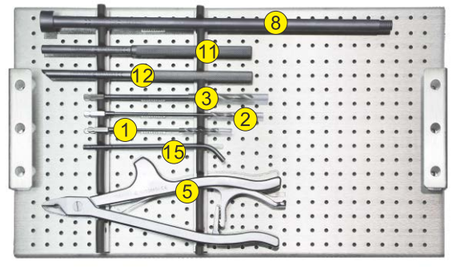


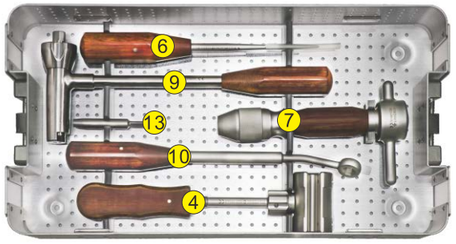


NO.	P.N	Description	Qty.
1	116060001	Socket Wrench with Hammer	1
2	116060002	Guide Handle, for Kirschner Wire	1
3	116060003	Cannulated Nail for Pelvic C-Clamp, short	2
4	116060004	Cannulated Nail for Pelvic C-Clamp, long	2
5	116060005	Kirschner Wire with trocar tip	10
6	116060006	Inner Rail	1
7	116060007	Outer Rail	2
8	116060008	Upper Arm	2
9	116060009	Lower Arm	2
10	116060010	Threaded Tube	2
11	115400031	Ratchet Wrench for Nut, hexagonal	2
12	212040008	Screw Clamp	1
13	116063000	Instrument tray	1

Elastic Nail Instruments set







NO.	P.N	Description	Qty.
1	112100016	Drill Bit, Φ2.5mm Length 112mm Thread Length 30mm	1
2	113100002	Drill Bit, Φ3.2mm Length 147mm Thread Length 40mm	1
3	113100003	Drill Bit, Φ4.5mm Length 145mm Thread Length 48mm	1
4	115410032	Slotted Hammer	1
5	115820001	Holder	1
6	115820002	Awl	1
7	115820003	Holder	1
8	115820004	extractor	1
9	115820005	Cutter	1
10	115820006	Wrench	1
11	115820007	Impactor	1
12	115820008	Impactor	1
13	115820009	Screwdriver	1
14	115823000	Instrument tray	1
15	113400008	Wrench	1

SS242 AO TYPE CLAMP
4.5MM TO 11MM

SS242 ROD TO ROD CLAMP
11MM TO 11MM

SS242 CONNECTING ROD
100-500MM

SS296 SCHANZ SCREW
DIAMETER 4.5MM
LENGTH 100-250mm
16 or 32MM THREAD