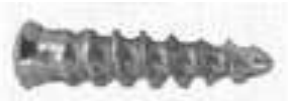
SURGICAL TECHNIQUE

Cervical LCP Plate

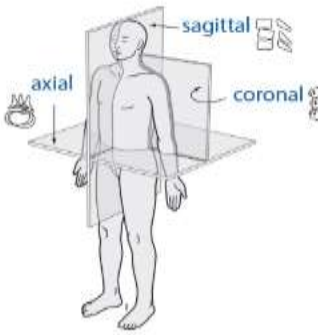
PLATES	
Cervical LCP Plate • Catalogue Number: Stainless Steel: SS 452 Titanium: TT 452 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 22cm to 100cm • Width: 16mm • Thickness: 2.5mm	
SCREWS	
4.0mm SCREW FOR CERVICAL PLATE • Catalogue Number: Stainless Steel: SS 453 Titanium: TT 453 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 10mm to 20mm • Diameter: 4 mm	

INSTRUMENT SET DETAILS	
SIS 124	Cervical Plate Instruments Set
SIS 124-001	Cervical Pin Retractor
SIS 124-002	Bone Curette
SIS 124-003	Plate holding Forcep
SIS 124-004	Drill & Tap Sleeve Adjustable
SIS 124-005	Plate Holding Pin
SIS 124-006	A.C.P. Plate Bender
SIS 124-007	Pin Holder
SIS 124-008	Q.C. T-Handle
SIS 124-009	Self Holding Screw Driver For 4.0mm Locking Screw
SIS 124-010	Q.C.Drill
SIS 124-011	Q.C.Bone Tap
SIS 124-012	Lock Screw Driver
SIS 124-013	Box

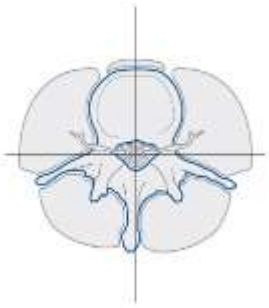
AO SPINE PRINCIPLES

The four AO Spine Principles that create the foundation for proper spinal patient management lie at the core of the design and delivery of the curriculum: Safety, Alignment, Biology, Function

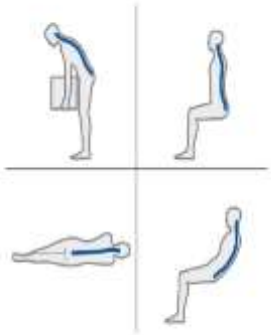
Stability: Stabilization to achieve a therapeutic outcome.



Alignment: Balancing the spine in three dimensions.



Biology: Etiology, pathogenesis, neural protection and tissue healing.



Function: Preservation and restoration of function to prevent disability.

INDICATIONS AND CONTRAINDICATIONS

INDICATIONS:

This system is intended for anterior interbody screw/plate fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis, or scoliosis), 5) pseudarthrosis, and/or 6) failed previous fusions.

CONTRAINDICATION:

Contraindications include, but are not limited to:

- Infection, local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
- Suspected or documented metal allergy or intolerance.
- Any case not needing a bone graft and fusion or where fracture healing is not required.
- Any case requiring the mixing of metals from different components.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any case not described in the Indications.
- Any patient unwilling to cooperate with the post-operative instructions.
- Any time implant utilization would interfere with anatomical structures or expected physiological performance.

PRECAUTIONS –

- Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese,

malnourished, and/or alcohol and/or other drug abuse patients are also not good candidates for spine fusion.

- Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion.
- Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the Cervical Plate by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results.

WARNINGS:

- Potential risk associated with use of this system may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of vertebrae, neurological injury, vascular or visceral injury.
- Under no circumstances may the implants be re-used.
- Although the device may appear intact on removal, internal modification due to the stress and strains placed on it, or small defects may exist which may lead to fracture of the implant.
- Implants removed from a patient that contact bodily tissues or fluids should never be reused at risk of contamination of the patient.
- The device can break if subjected to increased load associated with delayed union or non-union. If healing is delayed or does not occur, the implant could eventually break due to material fatigue. Factors such as the patient weight, activity level, and compliance to weight bearing or load bearing instructions, have an effect in the stresses to which the implant may be subjected, and may affect the longevity of the implant.
- Use of this product without a bone graft or in cases that develop into a non-union will not be successful.
- This spinal implant cannot withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur.

ADVERSE EVENT:

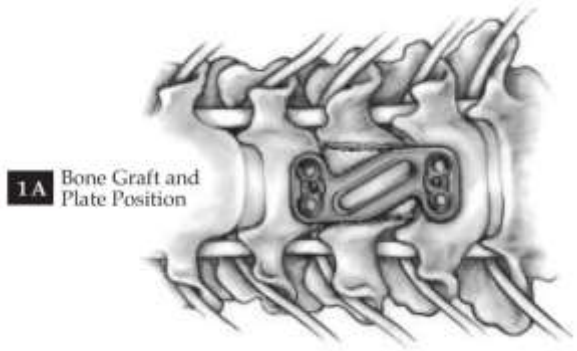
- Early or late loosening of any or all of the components.
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Bursitis. Tissue damage caused by improper positioning and placement of implants or instruments.

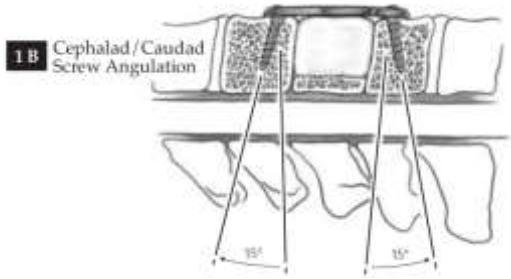
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection**.**
- Dural tears.
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
- Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
- Loss of bowel and/or bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants.
- Non-union (or pseudarthrosis). Delayed union. Mal-union.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of spinal mobility or function.
- Inability to perform the activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stress shielding**.**
- Graft donor site complications including pain, fracture, or wound healing problems.
- Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
- Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound
- dehiscence, or damage to blood vessels.
- Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
- Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
- Change in mental status
- Death.

TLIF CAGE SURGICAL TECHNIQUE

1. DETERMINE APPROPRIATE PLATE LENGTH

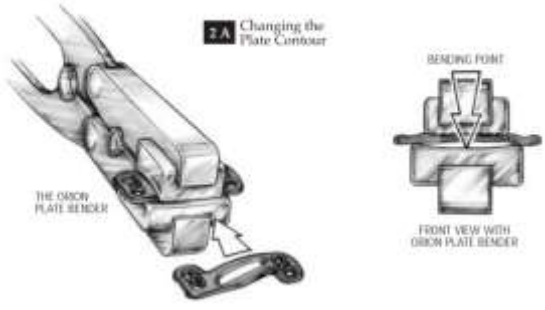
Position the plate screw holes close to the graft receptor site at both cranial and caudal ends (figure 1A). This allows for the 15° cephalad and caudal screw angulation (figure 1B) and helps ensure that the plate does not extend over the adjacent disc spaces.





2. Adjust lordotic curvature of plate if necessary:

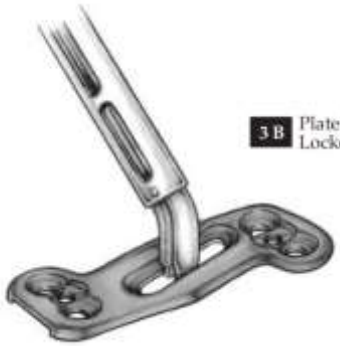
The amount of lordosis designed into the Cervical Plate is acceptable in a majority of cases. If required, changes can be made to the standard machined lordotic curve by using the Plate Bender (figure 2A). A gentle bend should be made over the entire length of the plate and sharp angulations must be avoided. It is important to note that plate contouring will alter the standard cranial and caudal angulation of the end screws (figure 2B).



3. Secure the Cervical Plate to the Plate Holder:

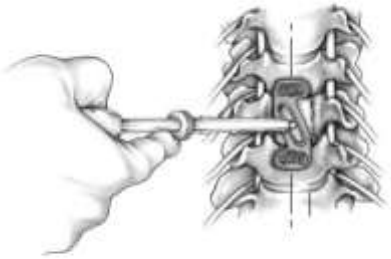
The Plate Holder (figure 3A) will lock within any of the central slots on the various plates. The smallest plates do not have diagonal central slots. A kocher, bayonet, sucker tip, etc. will suffice for holding these smaller size plates.

To attach the Plate Holder to the plate, slide the sleeve toward the handle and engage the feet into the plate's diagonal slot. Slide the sleeve down toward the plate to lock the holder to the plate (figure 3B)

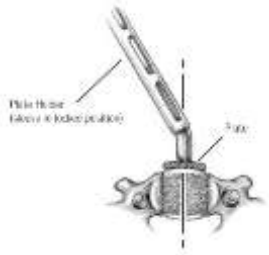


4. Position the Plate on the anterior surface of the spine:

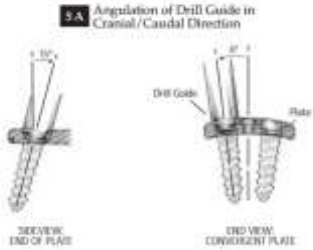
Review landmarks to ensure the plate is centered medially/laterally on the spine (figure 4A). The uncinate processes serve as excellent reference points.



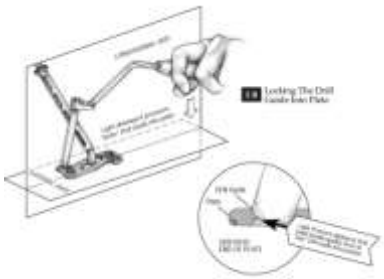
4A Positioning the Plate Medially/Laterally



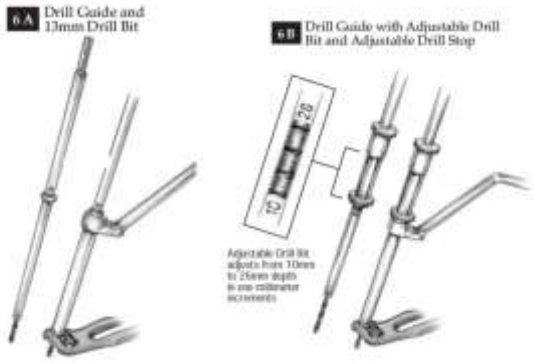
5. Insert the Drill Guide



Seat the Drill Guide into the plate at the correct cranial/caudal and convergent angle (figure 5A). For Convergent Plate constructs, the Drill Guide angles 6° toward the midline of the plate.
Once the Drill Guide is correctly seated into the plate, the Drill Guide can then be securely locked into the plate by applying light downward pressure on the Drill Guide handle, making sure to align the handle along the longitudinal axis of the plate (figure 5B).



6. Drill holes for taps/screws:



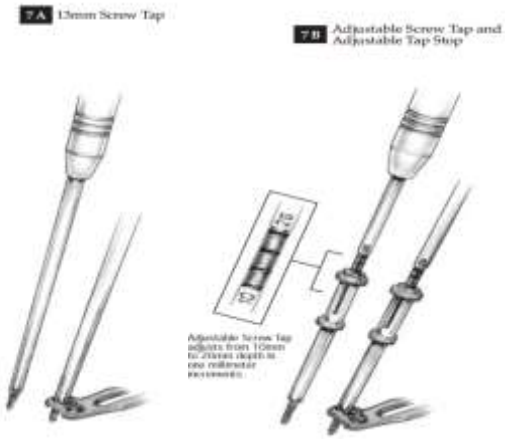
Insert the appropriate Drill Bit into the Drill Guide. Drill the screw holes using either the 13 mm Drill Bit (figure 6A) or the Adjustable Drill Bit and Adjustable Drill Stop (figure 6B). Screw length is determined by the depth of bone purchase required (figure 6C).

For standard unicortical screw purchase, the 13 mm Drill Bit is used. For screws other than 13 mm in length, the Adjustable Drill Bit (10- 26 mm depth) and Adjustable Drill Stop are used (figure 6B). If required, controlled penetration of the posterior cortex may be achieved by setting the Adjustable Drill Stop at the appropriate depth. The Adjustable Drill Stop provides for 1 mm increments and an additional safety

factor during the drilling procedure, in addition to fluoroscopic visualization.

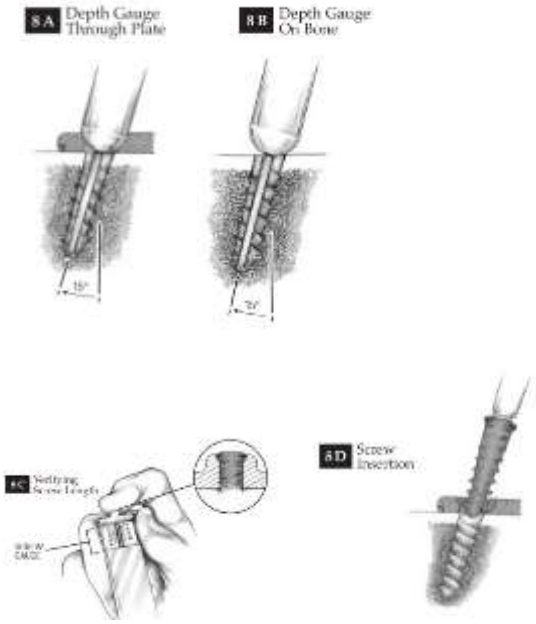
7. Tap the vertebral bodies

Remove the Drill Guide, insert the appropriate Tap into the predrilled hole at the same angulation, and tap the vertebral bodies using the Tap which corresponds to the Drill Bit length determined in Step 6. Taps are available in the same configuration as the Drill Bits, i.e. 13 mm Screw Tap (figure 7A) and
Adjustable Screw Tap and Adjustable Tap Stop for 10-26 mm (figure 7B).



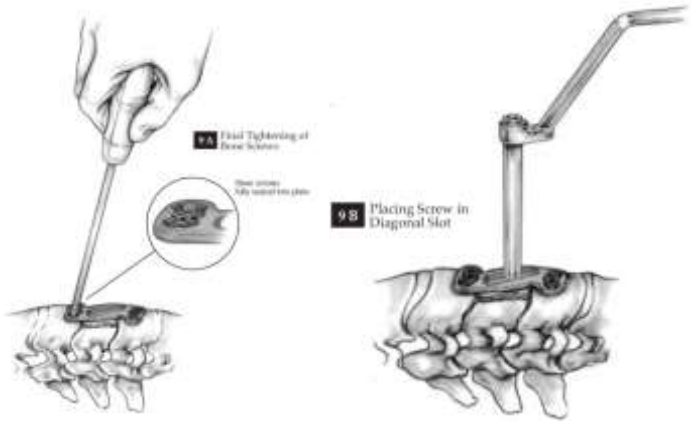
8. Implant screws

If required, a Depth Gauge may be used to confirm depth of hole for proper screw length. The Depth Gauge works either through the plate (figure 8A) or against the bone (figure 8B) and is accurate for both unicortical and bicortical techniques.
The appropriate length screw can be verified using the Screw/Plate Gauge (figure 8C).
Insert the appropriate length screw through the plate, using the Screwdriver with tapered, self-holding tip and tighten screw securely (not final tightening) (figure 8D).



9. FIXATION

Tighten the screws to ensure they are seated below the surface of the plate (figure 9A). Obtain radiographs to ensure that screw length and screw position are appropriate. Although plate malposition may be determined from a lateral radiograph (i.e. screws not aligned in the same plane,) an AP radiograph provides additional information regarding verification of implant position.
Screws can now be placed in the diagonal slot (figure 9B) if deemed necessary (i.e. multi-level interbody fusions or long strut graft reconstructions).

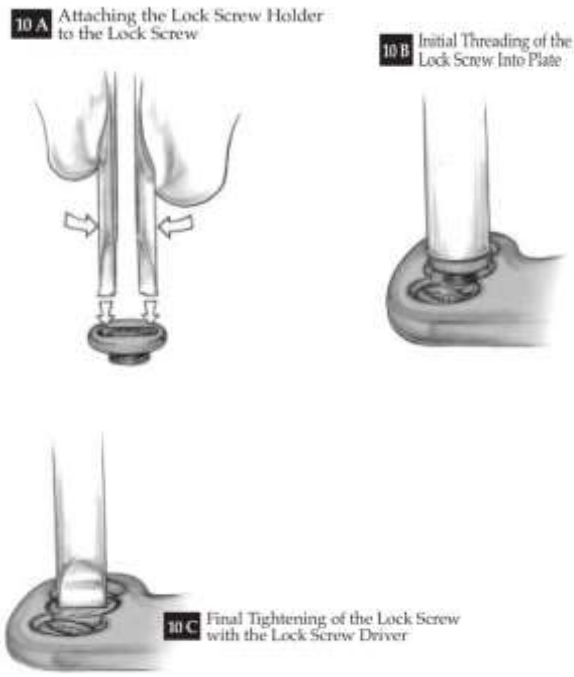


10. INSERT THE LOCKING SCREWS:

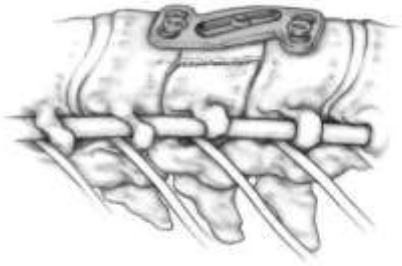
Attach the Lock Screw Holder to the Lock Screw by gently squeezing the prongs, then engage the Holder into the Lock Screw (figure 10A).

Slide the sleeve down toward the end of the holder. After the Lock Screw is initially threaded into the plate (figure 10B), detach the Lock Screw Holder by pulling the sleeve up and tilting the holder to release from the Lock Screw.

Final tightening of the Lock Screw is accomplished through the use of the Lock Screw Driver (figure 10C). One the Lock Screw Driver is firmly placed into the slot, turn the Lock Screw clockwise until the Screw Driver slips out of the slot (this is a self-limiting device). The Lock Screw is now firmly secured.



The completed cervical LCP plate construct.



IMPLANT REMOVAL

- First remove locking screw using screw driver shaft.
- Then remove screw using screw driver shaft.
- Repeat this for all screw.
- Remove the plate.

CAUTION

Used Implants:

Used implants which appear un-damaged may have internal and/or external defects. It is possible that individual stress analysis of each part fails to reveal the accumulated stress on the metals as a result of use within the body. This may lead ultimately to implant failure after certain point of time due to metal fatigue. **Therefore, reuse of implants is strictly not recommended.**

Disposal of Used Implants:

Every used or removed implant must be discarded after use and must never be re- used. It should be bent or scratched & then disposed of properly so that it becomes unfit for reuse. While disposing it off, it should be ensured that the discarded implant does not pose any threat to children, stray animals and environment. Dispose of the implants as per applicable medical practices and local, state and country specific regulatory requirement of Bio Medical Waste rules.

Packaging Materials Disposal:

The packaging material of this device is made of LDPE and therefore if swallowed, may cause choking Hazards. Therefore, it should be disposed of in such a way that keep out of reach of children and stray animals.

Single Brand Usage:

Implant components from one manufacture should not be used with those of another. Implants from each manufacture may have metal, dimensions and design differences so that the use in conjunction with different brands of devices may lead to inadequate fixation or adverse performances of the devices.

MRI SAFETY INFORMATION

- Samay Surgical implants are manufactured from Titanium Gr.5, SS316L material are non-magnetic material, hence it does not pose any safety risk.
- Patients should be directed to seek a medical opinion before entering potentially adverse environments that could affect the performance of the implants, such as electromagnetic or magnetic field or including a magnetic resonance environment.
- Doctor shall conduct a Risk Benefit Analysis before directing the patient to enter electromagnetic or magnetic fields or including a magnetic resonance environment.
- The Samay Surgical implants has not been evaluated for safety and compatibility in the MR environment but on the basis of literature study below mentioned points can be taken care during MRI
  - The minimum recommended time after the implantation that allows patients to safely undergo MRI examination or allowing the patient or an individual to enter the MRI environment is 6 (six) weeks.
  - The maximum recommended time limit for MRI examination in patients implanted with the evaluated device is 30 min with a scanner operating at 1.5T (Tesla) or less.

PRODUCT NAME	SS316L CATALOG NO.	TITANIUM GRADE 5 CATALOG NO,	LENGTH
4.0mm Screw For Cervical Plate 	SS 453-001	TT 453-001	10 mm
	SS 453-002	TT 453-002	12 mm
	SS 453-003	TT 453-003	14 mm
	SS 453-004	TT 453-004	16 mm
	SS 453-005	TT 453-005	18 mm
	SS 453-006	TT 453-006	20 mm

PRODUCT NAME	SS316L CATALOG NO.	TITANIUM GRADE 5 CATALOG NO,	LENGTH	WDTH	DIAMETER
Cervical LCP Plate 	SS 452-001	TT 452-001	22 mm	16.0mm	2.5mm
	SS 452-002	TT 452-002	24 mm	16.0mm	2.5mm
	SS 452-003	TT 452-003	26 mm	16.0mm	2.5mm
	SS 452-004	TT 452-004	28 mm	16.0mm	2.5mm
	SS 452-005	TT 452-005	30 mm	16.0mm	2.5mm
	SS 452-006	TT 452-006	32 mm	16.0mm	2.5mm
	SS 452-007	TT 452-007	35 mm	16.0mm	2.5mm
	SS 452-008	TT 452-008	37 mm	16.0mm	2.5mm
	SS 452-009	TT 452-009	40 mm	16.0mm	2.5mm
	SS 452-010	TT 452-010	42 mm	16.0mm	2.5mm
	SS 452-011	TT 452-011	45 mm	16.0mm	2.5mm
	SS 452-012	TT 452-012	47 mm	16.0mm	2.5mm
	SS 452-013	TT 452-013	50 mm	16.0mm	2.5mm
	SS 452-014	TT 452-014	52 mm	16.0mm	2.5mm
	SS 452-015	TT 452-015	55 mm	16.0mm	2.5mm
	SS 452-016	TT 452-016	57 mm	16.0mm	2.5mm
	SS 452-017	TT 452-017	60 mm	16.0mm	2.5mm
	SS 452-018	TT 452-018	65 mm	16.0mm	2.5mm
	SS 452-019	TT 452-019	70 mm	16.0mm	2.5mm
	SS 452-020	TT 452-020	75 mm	16.0mm	2.5mm
	SS 452-021	TT 452-021	80 mm	16.0mm	2.5mm
	SS 452-022	TT 452-022	85 mm	16.0mm	2.5mm
	SS 452-023	TT 452-023	90 mm	16.0mm	2.5mm
	SS 452-024	TT 452-024	95 mm	16.0mm	2.5mm
	SS 452-025	TT 452-025	100 mm	16.0mm	2.5mm

Implants Certified by : CE XXXX

Instruments Certified by Self Declaration : CE

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