



SURGICAL TECHNIQUE

CANNULATED CANCELLOUS SCREW SYSTEM

(4.0mm, 6.5mm, 7.0mm)








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SYSTEM OVERVIEW

SCREWS

| | |
|---|---|
| <p>4.0 mm CANNULATED CANCELLOUS SCREW SHORT THREADED</p> <ul style="list-style-type: none"> • Catalogue Number: Stainless Steel: SS 116 Titanium: TT 116 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 10mm to 80mm • Diameter: ϕ 4.0 |  |
| <p>4.0 mm CANNULATED CANCELLOUS SCREW FULLY THREADED</p> <ul style="list-style-type: none"> • Catalogue Number: Stainless Steel: SS 117 Titanium: TT 117 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 10mm to 80mm • Diameter: ϕ 4.0 |  |
| <p>6.5 mm CANNULATED CANCELLOUS SCREW 16.0 MM THREADED</p> <ul style="list-style-type: none"> • Catalogue Number: Stainless Steel: SS 118 Titanium: TT 118 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 20mm to 120mm • Diameter: ϕ 6.5 |  |
| <p>6.5 mm CANNULATED CANCELLOUS SCREW 32.0 mm THREADED</p> <ul style="list-style-type: none"> • Catalogue Number: Stainless Steel: SS 119 Titanium: TT 119 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 35mm to 120mm • Diameter: ϕ 6.5 |  |
| <p>6.5 mm CANNULATED CANCELLOUS SCREW FULLY THREADED</p> <ul style="list-style-type: none"> • Catalogue Number: Stainless Steel: SS 120 Titanium: TT 120 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 20mm to 120mm • Diameter: ϕ 6.5 |  |

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| | |
|---|---|
| <p>7.0 mm CANNULATED CANCELLOUS SCREW 16.0 mm THREADED</p> <ul style="list-style-type: none"> • Catalogue Number: Stainless Steel: SS 121 Titanium: TT 121 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 20mm to 120mm • Diameter: ϕ 6.5 |  |
| <p>7.0 mm CANNULATED CANCELLOUS SCREW 32.0 mm THREADED</p> <ul style="list-style-type: none"> • Catalogue Number: Stainless Steel: SS 122 Titanium: TT 122 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 35mm to 120mm • Diameter: ϕ 6.5 |  |
| <p>7.0 mm CANNULATED CANCELLOUS SCREW FULLY THREADED</p> <ul style="list-style-type: none"> • Catalogue Number: Stainless Steel: SS 123 Titanium: TT 123 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 20mm to 120mm • Diameter: ϕ 6.5 |  |
| <p>GUIDE WIRES</p> | |
| <p>Guide wire (simple)</p> <ul style="list-style-type: none"> • Catalogue Number: Stainless Steel: SS 291-010 • Available in Stainless Steel 316L • Length: 225 mm • Diameter: ϕ 1.0 mm |  |
| <p>Guide wire (Threaded)</p> <ul style="list-style-type: none"> • Catalogue Number: Stainless Steel: SS 291-110 • Available in Stainless Steel 316L • Length: 225 mm • Diameter: ϕ 1.0 mm |  |
| <p>INSTRUMENT SET DETAILS</p> | |
| <p>SIS 101 4.0mm C.C. Screw Instruments Set</p> <p>SIS 101-001 Stylet 1.2mm SIS 101-002 Cannulated Drill Bit 2.7mm X 5" SIS 101-003 Cannulated Drill Bit 3.5mm X 5"</p> | |



SIS 101-004Cannulated Tap with T Handle 4.0mm
SIS 101-005Double Drill Sleeve 2.7/1.25
SIS 101-006Drill Sleeve with Stop 3.5mm/2.7mm with Two Insert
SIS 101-007Cannulated Screw Driver (2.5 TIP)
SIS 101-008Direct Measuring Device
SIS 101-009Stylet 1.2MM
SIS 101-010Holding Sleeve
SIS 101-011Box

SIS 102 6.5mm C.C. Screw Instruments Set

SIS 102-001 Cannulated Tap with T Handle 7mm
SIS 102-002Parallel Stylet
SIS 102-003Direct Measuring Device
SIS 102-004Stylet 2mm
SIS 102-005Drill Bit 4.5mm X 8"
SIS 102-006Cannulated Screw Driver (3.5 TIP)
SIS 102-007Cannulated Countersink 230mm
SIS 102-008Drill Sleeve for 7MM Cannulated Screw (Triple Sleeve)
SIS 102-009Drill Sleeve 4.5mm/7mm
SIS 102-010Box

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1) Introduction-

Cannulated screw system is intended for fixation of fractures, fusions, osteotomies of large and small bones appropriate for the size of device. All screws are Cannulated in order to be used over a guide wire, and each screw is either partially or fully threaded using a Cancellous thread form.

Partially threaded screw may be used to lag one bone fragment to another, where bone fragment is captured by the threads of screw and pulled toward near cortex fragment on the head side of screw. Fully threaded screws are intended to be used to stabilize fractures with little to no compression across the fracture.

Bone Screw is intended for internal fixation of fractures and reconstruction of bones including the Humerus, Tibia, Fibula, Hand and Foot in adults and for long bones in adolescents. Bone Screws fasten plates to bone, maintain bone fragments in their relative position, or hold together fragments of bone (in the case of lag screws). They vary according to the manner in which they are inserted into bone, their function, size, the type of bone they are intended for, and the manner in which they couple with the screw driver (i.e. slot, cruciate, square, hexagon).

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INDICATIONS-

4.5mm screw

- Fixation of fractures of medium fragments, e.g.:
- Tarsal and metatarsal fractures and fixation in metatarsal and phalangeal osteotomies
- Tarsometatarsal and metatarsophalangeal arthrodeses
- Ligament fixations
- Hallux valgus corrections

7mm screw

- Femoral neck fractures
- Slipped Capital Femoral Epiphysis (SCFE)
- As an adjunct to DHS in basilar neck fractures
- Tibial plateau fractures
- Ankle arthrodeses
- Pediatric femoral neck fractures
- Intercondylar femur fractures
- Sacroiliac joint disruptions
- Subtalar arthrodeses

CONTRAINDICATIONS-

- Inadequate bone quantity and/or bone quality.
- Hypersensitivity to metal or allergic reaction.
- Early or Late Inspection, both deep and / or superficial.
- Patients with limited blood supply.
- Patient within whom co-operation or mental competence is lacking, thereby reducing patient compliance.

ADVERSE REACTION-

Adverse reactions may include but are not limited to:

- Clinical failure (i.e. pain or injury) due to bending, loosening, breakage of implant, loose fixation, dislocation and/or migration
- Pain, discomfort, and/or abnormal sensations due to the presence of the implant.
- Primary and/or secondary infections.
- Allergic reactions to implant material.
- Necrosis of bone or decrease of bone density.
- Injury to vessels, nerves and organs.
- Elevated fibrotic tissue reaction around the surgical area.

SAFETY PRECAUTIONS

- The Product should only be used by the medical personnel who hold relevant qualification.

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- Never use the product that has been damaged by Improper handling in the hospital or in any other way.
- Never reuse an implant. Although the implant appears to be undamaged, previous stresses may have created non-visible damage that could result in implant failure.

- Safety Precaution for Special Cases

Pregnant Women

- Ensure that there should be less blood loss during the surgery.
- Anaesthesia should not be used in such case.
- Operational environment must be free from radiation.

Infant / Children

- Ensure that there should be less blood loss during the surgery.
- Operational environment must be free from radiation.
- Epiphysis should not be damaged

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Technique can be explained by using ankle fracture.

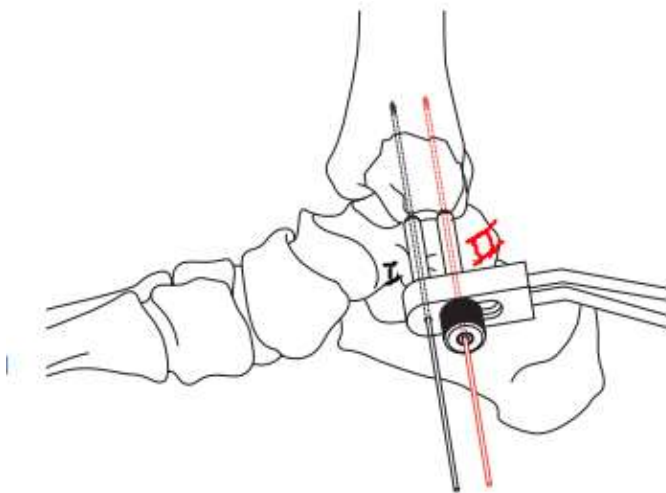
STEP I

Reduce fracture and insert guide wire –

After a stab incision, advance the drill sleeve or drill sleeve assembly through the soft tissues to the bone. Insert the guide wire through the drill sleeve to the desired depth and position.

Remove the drill sleeve and check the position of the guide wire under the image intensifier

STEP II



Option: Insert guide wires in parallel

Slide the non-adjustable guide sleeve (I) of the parallel guide over the already inserted guide wire. Move the guide sleeve (II) to the desired position and tighten the nut. Insert the second guide wire. Insert the desired number of parallel guide wires as described and remove the parallel guide.

Note: The placement of three guide wires is recommended to achieve adequate rotational stability

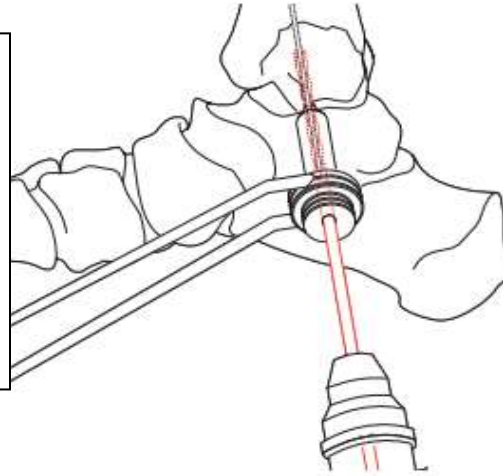
STEP III

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Drilling-

Even though the screws are self-tapping, the desired length must be predrilled with the cannulated drill bit. The drill bit is having a calibration showing drill depth which can be considered as measure earlier.



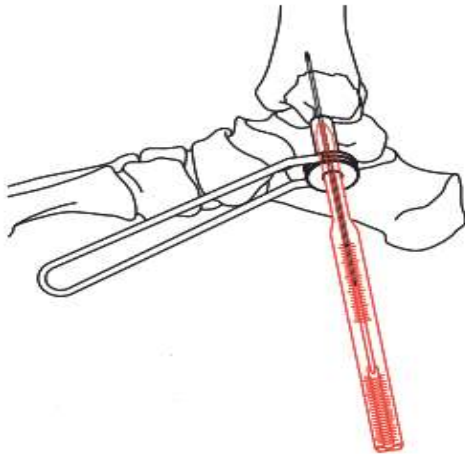
STEP IV-

Tapping- Where necessary tap near cortex with cannulated tap.

STEP V-

Determine screw length-

Insert the measuring device to determine the screw length.



STEP-VI

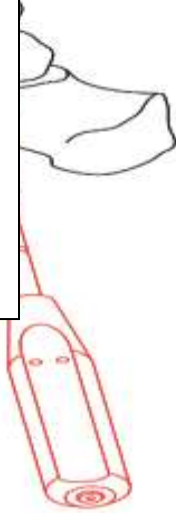
Insert screw

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Insert the appropriate cannulated screw through the protection sleeve using the hexagonal cannulated screwdriver. Next, remove the protection sleeve.

Remove and dispose of the guide wire. Check the final position of the screw under the image intensifier.



➤ **Procedure for osteoporotic bones:**

In osteoporotic bone, the screw head can be prevented from sinking into the bone by using a washer. Avoid tightening the screw very firmly, because otherwise the thread may strip and the screw's grip in the bone could be compromised.

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IMPLANT REMOVAL

The Plate should first be removed by following screw removal technique of cortical screws with the help of Hexagonal Screw Driver. The following should be noted in order to avoid damage to the instrument or implants: Always engage the screw driver tip firmly into the head of screw to remove. Don't give extra quick torque to damage screw head. If screw head gets damaged during removal, use the screw removal instruments to remove damage head screws.

Note: The final decision of removing the implants shall be taken by the operating surgeon only. It is recommended that the implant used as an aid for healing should be removed once its service is over after proper consultation and examination by the operating surgeon in final follow up, particularly in younger and more active patients.

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 fail to reveal the accumulated stress on the metals as a result of use within the body. This may lead ultimately to implants failure after certain point of time due to metal fatigue. Therefore reuses of implants are 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 MATERIAL 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 ways 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

Implants are manufactured from Titanium Gr.5, SS316L material for Bone Screw & Titanium Gr.5, SS316L material for Bone Screw. Both 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.

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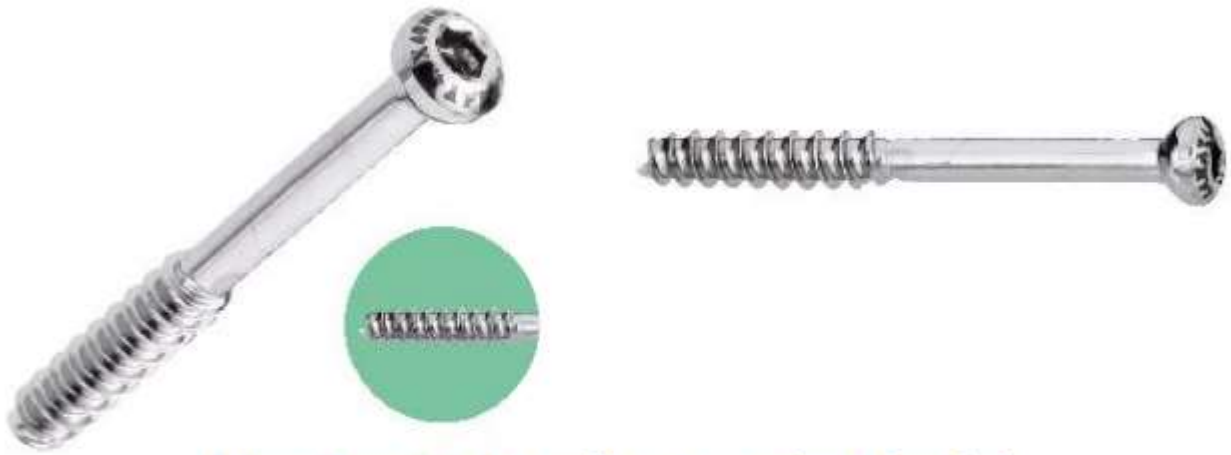
- Doctor shall conduct a Risk Benefit Analysis before directing the patient to enter electromagnetic or magnetic fields or including a magnetic resonance environment.

- 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.

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4.0mm Cannulated Cancellous Screw Short Threaded

| Code No. S.S. 316L | Code No. Titanium | Length |
|-----------------------|----------------------|--------|
| SS 116-012 | TT 116-012 | 12mm |
| SS 116-014 | TT 116-014 | 14mm |
| SS 116-016 | TT 116-016 | 16mm |
| SS 116-018 | TT 116-018 | 18mm |
| SS 116-020 | TT 116-020 | 20mm |
| SS 116-022 | TT 116-022 | 22mm |
| SS 116-024 | TT 116-024 | 24mm |
| SS 116-026 | TT 116-026 | 26mm |
| SS 116-028 | TT 116-028 | 28mm |
| SS 116-030 | TT 116-030 | 30mm |
| SS 116-035 | TT 116-035 | 35mm |
| SS 116-040 | TT 116-040 | 40mm |
| SS 116-045 | TT 116-045 | 45mm |
| SS 116-050 | TT 116-050 | 50mm |
| SS 116-055 | TT 116-055 | 55mm |
| SS 116-060 | TT 116-060 | 60mm |
| SS 116-065 | TT 116-065 | 65mm |
| SS 116-070 | TT 116-070 | 70mm |
| SS 116-075 | TT 116-075 | 75mm |
| SS 116-080 | TT 116-080 | 80mm |



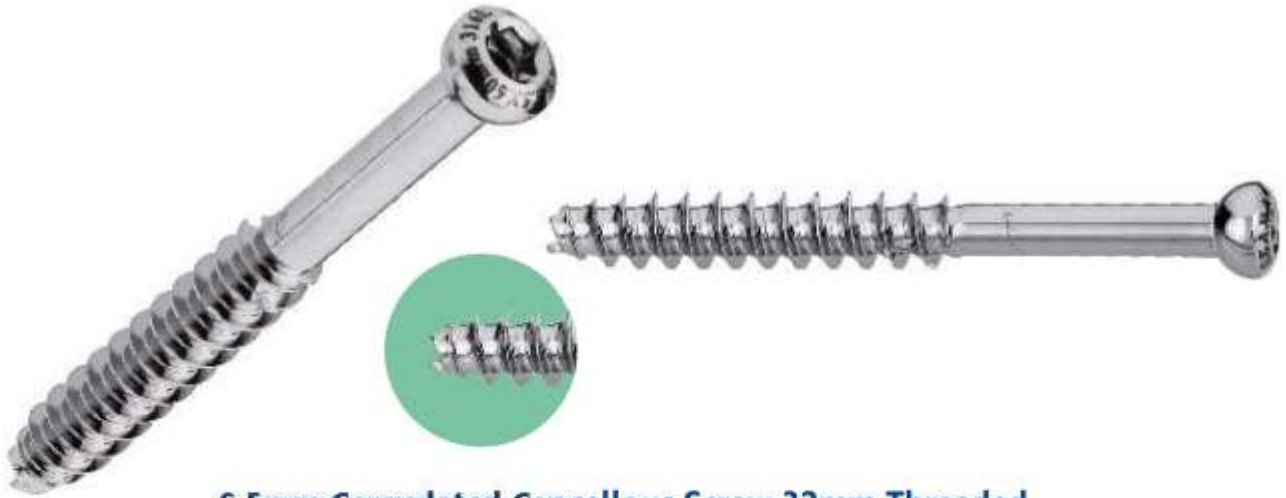
4.0mm Cannulated Cancellous Screw Fully Threaded

| Code No. S.S. 316L | Code No. Titanium | Length |
|-----------------------|----------------------|--------|
| SS 117-012 | TT 117-012 | 12mm |
| SS 117-014 | TT 117-014 | 14mm |
| SS 117-016 | TT 117-016 | 16mm |
| SS 117-018 | TT 117-018 | 18mm |
| SS 117-020 | TT 117-020 | 20mm |
| SS 117-022 | TT 117-022 | 22mm |
| SS 117-024 | TT 117-024 | 24mm |
| SS 117-026 | TT 117-026 | 26mm |
| SS 117-028 | TT 117-028 | 28mm |
| SS 117-030 | TT 117-030 | 30mm |
| SS 117-035 | TT 117-035 | 35mm |
| SS 117-040 | TT 117-040 | 40mm |
| SS 117-045 | TT 117-045 | 45mm |
| SS 117-050 | TT 117-050 | 50mm |
| SS 117-055 | TT 117-055 | 55mm |
| SS 117-060 | TT 117-060 | 60mm |
| SS 117-065 | TT 117-065 | 65mm |
| SS 117-070 | TT 117-070 | 70mm |



6.5mm Cannulated Cancellous Screw 16mm Threaded

| Code No. S.S. 316L | Code No. Titanium | Length |
|-----------------------|----------------------|--------|
| SS 118-025 | TT 118-025 | 25mm |
| SS 118-030 | TT 118-030 | 30mm |
| SS 118-035 | TT 118-035 | 35mm |
| SS 118-040 | TT 118-040 | 40mm |
| SS 118-045 | TT 118-045 | 45mm |
| SS 118-050 | TT 118-050 | 50mm |
| SS 118-055 | TT 118-055 | 55mm |
| SS 118-060 | TT 118-060 | 60mm |
| SS 118-065 | TT 118-065 | 65mm |
| SS 118-070 | TT 118-070 | 70mm |
| SS 118-075 | TT 118-075 | 75mm |
| SS 118-080 | TT 118-080 | 80mm |
| SS 118-085 | TT 118-085 | 85mm |
| SS 118-090 | TT 118-090 | 90mm |
| SS 118-095 | TT 118-095 | 95mm |
| SS 118-100 | TT 118-100 | 100mm |
| SS 118-105 | TT 118-105 | 105mm |
| SS 118-110 | TT 118-110 | 110mm |
| SS 118-115 | TT 118-115 | 115mm |
| SS 118-120 | TT 118-120 | 120mm |



6.5mm Cannulated Cancellous Screw 32mm Threaded

| Code No. S.S. 316L | Code No. Titanium | Length |
|-----------------------|----------------------|--------|
| SS 119-040 | TT 119-040 | 40mm |
| SS 119-045 | TT 119-045 | 45mm |
| SS 119-050 | TT 119-050 | 50mm |
| SS 119-055 | TT 119-055 | 55mm |
| SS 119-060 | TT 119-060 | 60mm |
| SS 119-065 | TT 119-065 | 65mm |
| SS 119-070 | TT 119-070 | 70mm |
| SS 119-075 | TT 119-075 | 75mm |
| SS 119-080 | TT 119-080 | 80mm |
| SS 119-085 | TT 119-085 | 85mm |
| SS 119-090 | TT 119-090 | 90mm |
| SS 119-095 | TT 119-095 | 95mm |
| SS 119-100 | TT 119-100 | 100mm |
| SS 119-105 | TT 119-105 | 105mm |
| SS 119-110 | TT 119-110 | 110mm |
| SS 119-115 | TT 119-115 | 115mm |
| SS 119-120 | TT 119-120 | 120mm |



6.5mm Cannulated Cancellous Screw Fully Threaded

| Code No. S.S. 316L | Code No. Titanium | Length |
|-----------------------|----------------------|--------|
| SS 120-020 | TT 120-020 | 20mm |
| SS 120-025 | TT 120-025 | 25mm |
| SS 120-030 | TT 120-030 | 30mm |
| SS 120-035 | TT 120-035 | 35mm |
| SS 120-040 | TT 120-040 | 40mm |
| SS 120-045 | TT 120-045 | 45mm |
| SS 120-050 | TT 120-050 | 50mm |
| SS 120-055 | TT 120-055 | 55mm |
| SS 120-060 | TT 120-060 | 60mm |
| SS 120-065 | TT 120-065 | 65mm |
| SS 120-070 | TT 120-070 | 70mm |
| SS 120-075 | TT 120-075 | 75mm |
| SS 120-080 | TT 120-080 | 80mm |
| SS 120-085 | TT 120-085 | 85mm |
| SS 120-090 | TT 120-090 | 90mm |
| SS 120-095 | TT 120-095 | 95mm |
| SS 120-100 | TT 120-100 | 100mm |
| SS 120-105 | TT 120-105 | 105mm |
| SS 120-110 | TT 120-110 | 110mm |



Implants Certified : XXXX



Instruments Certified by Self Declaration :



SAMAY[®]
Surgical

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