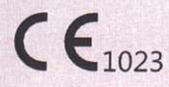


3 PIRKIMO DALIS

Mfg. : Orthopedic Implants & Instruments

An ISO 13485:2003
Certified Company



Locking Plates

Reconstruction Locking Plate Straight 3.5 mm

(Stainless Steel & Titanium)

Code No. SS	Code No. TT	Holes
SS 315-004	TT 315-004	4
SS 315-005	TT 315-005	5
SS 315-006	TT 315-006	6
SS 315-007	TT 315-007	7
SS 315-008	TT 315-008	8
SS 315-009	TT 315-009	9
SS 315-010	TT 315-010	10
SS 315-011	TT 315-011	11
SS 315-012	TT 315-012	12
SS 315-014	TT 315-014	14
SS 315-016	TT 315-016	16
SS 315-018	TT 315-018	18
SS 315-020	TT 315-020	20
SS 315-022	TT 315-022	22
SS 315-024	TT 315-024	24
SS 315-025	TT 315-025	25

Screw Places :
3.5 mm Locking Screw



Reconstruction Locking Plate Straight D.C Holes 3.5 mm

(Stainless Steel & Titanium)

Code No. SS	Code No. TT	Holes
SS 315-104	TT 315-104	4
SS 315-105	TT 315-105	5
SS 315-106	TT 315-106	6
SS 315-107	TT 315-107	7
SS 315-108	TT 315-108	8
SS 315-109	TT 315-109	9
SS 315-110	TT 315-110	10
SS 315-111	TT 315-111	11
SS 315-112	TT 315-112	12
SS 315-114	TT 315-114	14
SS 315-116	TT 315-116	16
SS 315-118	TT 315-118	18
SS 315-120	TT 315-120	20
SS 315-122	TT 315-122	22
SS 315-124	TT 315-124	24
SS 315-125	TT 315-125	25

3.1.1.
3.1.2.
3.1.3.
3.1.4.
3.1.5.
3.1.6.
3.1.7.
3.1.8.
3.1.9.
3.1.10.
3.1.11.



Screw Places :
3.5 mm Locking Screw 3.1.12
3.5 mm Cortical Screw 3.1.13



SAMAY
Surgical

www.samaysurgical.com

Locking Screws



2.7 mm Locking Screw

(Stainless Steel & Titanium)

Code No. SS	Code No. TT	Size mm
SS 303-012	TT 303-012	12
SS 303-014	TT 303-014	14
SS 303-016	TT 303-016	16
SS 303-018	TT 303-018	18
SS 303-020	TT 303-020	20
SS 303-022	TT 303-022	22
SS 303-024	TT 303-024	24
SS 303-026	TT 303-026	26
SS 303-028	TT 303-028	28
SS 303-030	TT 303-030	30
SS 303-032	TT 303-032	32
SS 303-034	TT 303-034	34
SS 303-036	TT 303-036	36
SS 303-038	TT 303-038	38
SS 303 040	TT 303 040	40
SS 303-042	TT 303-042	42
SS 303-044	TT 303-044	44
SS 303-046	TT 303-046	46
SS 303-048	TT 303-048	48
SS 303-050	TT 303-050	50
SS 303-052	TT 303-052	52
SS 303-054	TT 303-054	54
SS 303-056	TT 303-056	56
SS 303-058	TT 303-058	58
SS 303-060	TT 303-060	60

3. 1. 12.



3.5 mm Locking Screw Self Taping

(Stainless Steel & Titanium)

Code No. SS	Code No. TT	Size mm
SS 304-012	TT 304-012	12
SS 304-014	TT 304-014	14
SS 304-016	TT 304-016	16
SS 304-018	TT 304-018	18
SS 304-020	TT 304-020	20
SS 304-022	TT 304-022	22
SS 304-024	TT 304-024	24
SS 304-026	TT 304-026	26
SS 304-028	TT 304-028	28
SS 304-030	TT 304-030	30
SS 304-032	TT 304-032	32
SS 304-034	TT 304-034	34
SS 304-036	TT 304-036	36
SS 304-038	TT 304-038	38
SS 304 040	TT 304 040	40
SS 304-042	TT 304-042	42
SS 304-044	TT 304-044	44
SS 304-046	TT 304-046	46
SS 304-048	TT 304-048	48
SS 304-050	TT 304-050	50
SS 304-052	TT 304-052	52
SS 304-054	TT 304-054	54
SS 304-056	TT 304-056	56
SS 304-058	TT 304-058	58
SS 304-060	TT 304-060	60
SS 304-065	TT 304-065	65
SS 304-070	TT 304-070	70
SS 304-075	TT 304-075	75
SS 304-080	TT 304-080	80

3. 1. 12.

3 PIRATMO DALIS



SAMAY
Surgical

www.samaysurgical.com

Locking Screws



3.1.13

3.5 mm Cortical Screw Self Tapping

(Stainless Steel & Titanium)

Code No. SS	Code No. TT	Size mm
SS 107-012	TT 107-012	12
SS 107-014	TT 107-014	14
SS 107-016	TT 107-016	16
SS 107-018	TT 107-018	18
SS 107-020	TT 107-020	20
SS 107-022	TT 107-022	22
SS 107-024	TT 107-024	24
SS 107-026	TT 107-026	26
SS 107-028	TT 107-028	28
SS 107-030	TT 107-030	30
SS 107-032	TT 107-032	32
SS 107-034	TT 107-034	34
SS 107-036	TT 107-036	36
SS 107-038	TT 107-038	38
SS 107-040	TT 107-040	40
SS 107-042	TT 107-042	42
SS 107-044	TT 107-044	44
SS 107-046	TT 107-046	46
SS 107-048	TT 107-048	48
SS 107-050	TT 107-050	50
SS 107-052	TT 107-052	52
SS 107-054	TT 107-054	54
SS 107-056	TT 107-056	56
SS 107-058	TT 107-058	58
SS 107-060	TT 107-060	60

3.1.13



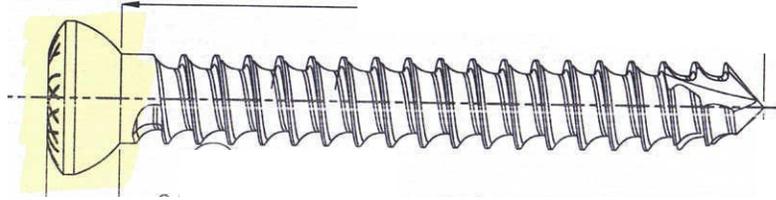
4.5 mm Cortical Screw Self Tapping

(Stainless Steel & Titanium)

Code No. SS	Code No. TT	Size mm
SS 109-016	TT 109-016	16
SS 109-018	TT 109-018	18
SS 109-020	TT 109-020	20
SS 109-022	TT 109-022	22
SS 109-024	TT 109-024	24
SS 109-026	TT 109-026	26
SS 109-028	TT 109-028	28
SS 109-030	TT 109-030	30
SS 109-032	TT 109-032	32
SS 109-034	TT 109-034	34
SS 109-036	TT 109-036	36
SS 109-038	TT 109-038	38
SS 109-040	TT 109-040	40
SS 109-042	TT 109-042	42
SS 109-044	TT 109-044	44
SS 109-046	TT 109-046	46
SS 109-048	TT 109-048	48
SS 109-050	TT 109-050	50
SS 109-052	TT 109-052	52
SS 109-054	TT 109-054	54
SS 109-056	TT 109-056	56
SS 109-058	TT 109-058	58
SS 109-060	TT 109-060	60
SS 109-065	TT 109-065	65
SS 109-070	TT 109-070	70
SS 109-075	TT 109-075	75
SS 109-080	TT 109-080	80

3 PIRKIMO DALIS. KONTIDENCIALU

Nerodkinami



Material: SS316L / TITANIUM GR. 5		Description: 3.5 mm Cortex Screw Low Profile Self Tapping (Pitch 1.25) <i>3.1.13</i>	
Remark:		Signature:	
		Signature:	
Company Confidential		Part Number: 107-110 TO 107-180	
Legal Owner:		Drawing Number: S 107-1	
			

IFU– Plates, Screws, Wires & Pins	Document No:	SS/IFU/002
	Revision	02
	Dated	26/09/2019
	Page	Page 5 of 7

- Reiterate preoperative instructions to the patient.
- During the post-operative phase, in addition to mobility it is of vital importance that the physician keeps the patient well informed about post-surgical behavioral requirements.
- Ensure that the patient is aware of physical activity restrictions and possible adverse reactions.

IMPLANT REMOVAL

- The surgeon must make the final decision on implant removal if either of these occurs;
 - ✓ Choice of Patient
 - ✓ Doctor’s Advice based on the clinical condition of the patient
 - ✓ Deep Wound Infection/Bone Atrophy
 - ✓ Growing Skeleton
 - ✓ Tenosynovitis
 - ✓ Intra-Articular Material
 - ✓ Post – traumatic Arthritis
 - ✓ Avascular Necrosis
 - ✓ Intractable Pain
 - ✓ Perforating Material
 - ✓ Infection
 - ✓ Paresthesia
- Time of removal of implant shall be suggested by the doctor depending upon the clinical condition of the patient either after the surgery or during the follow ups.
- Removal of Implant may cause the risk of re-fracture, neurovascular injury & infection.
- Bone in-growth and wear of the implant can make the removal difficult.

Note: Detailed Removal Procedure is provided in respective Surgical Techniques, which are available on our website. (<http://www.samaysurgical.com/download.php>)

MRI SAFETY INFORMATION

- Samay Surgical implantai yra gaminami iš SS316L ir Titano (5 kl.), abi medžiagos yra nemagnetiškos, todėl nepažeidžia saugumo reikalavimų. Pacientams rekomenduojama pasikonsultuoti su gydytoju, prieš patenkant į potencialiai nepalankią aplinką, galinčią turėti įtakos implantų funkcijai, pavyzdžiui elektromagnetinius arba magnetinius laukus, įskaitant magnetinius laukus, kuriems priskiriama ir magnetinio rezonanso aplinka, įskaitant magnetinius laukus, įskaitant magnetinio rezonanso aplinką.
- Samay Surgical implants are manufactured from SS 316L & Titanium Grade 5 material, both are non-magnetic material, hence it do 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 fields, including a magnetic fields, including a magnetic resonance environment.
 - 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.
- Minimalus rekomenduojamas laikas po implantacijos, po kurio pacientams galima saugiai atlikti MRI tyrimą arba leisti pacientui patekti į MRI aplinką yra 6 savaites. Maksimalus rekomenduojamas MRI tyrimo laikas pacientams su implantais yra įvertintas 30 min kai skaitytuvai veikia 1.5T ar mažiau.

CLINICAL EVALUATION OF PLATES, SCREWS, WIRES & PINS

- The Samay Surgical Plates, Screws, Wires & Pins is clinically safe, and effective in use as discussed and proved up to the mark in the clinical evaluation of the device.

DISPOSAL OF PLATES, SCREWS, WIRES & PINS

