



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



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



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



UK

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

Proximal Femoral Locking Plate

(Stainless Steel & Titanium)

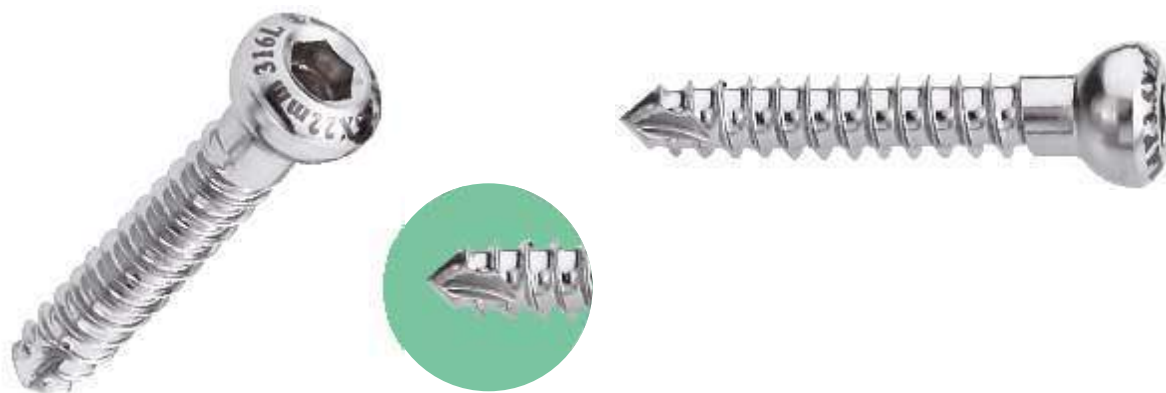
Code No. SS	Code No. TT	Holes	
SS 333-002	TT 333-002	2	Right
SS 333-003	TT 333-003	3	Right
SS 333-004	TT 333-004	4	Right
SS 333-005	TT 333-005	5	Right
SS 333-006	TT 333-006	6	Right
SS 333-007	TT 333-007	7	Right
SS 333-008	TT 333-008	8	Right
SS 333-009	TT 333-009	9	Right
SS 333-010	TT 333-010	10	Right
SS 333-011	TT 333-011	11	Right
SS 333-012	TT 333-012	12	Right
SS 333-013	TT 333-013	13	Right
SS 333-014	TT 333-014	14	Right
SS 333-015	TT 333-015	15	Right
SS 333-016	TT 333-016	16	Right

Code No. SS	Code No. TT	Holes	
SS 333-102	TT 333-102	2	Left
SS 333-103	TT 333-103	3	Left
SS 333-104	TT 333-104	4	Left
SS 333-105	TT 333-105	5	Left
SS 333-106	TT 333-106	6	Left
SS 333-107	TT 333-107	7	Left
SS 333-108	TT 333-108	8	Left
SS 333-109	TT 333-109	9	Left
SS 333-110	TT 333-110	10	Left
SS 333-111	TT 333-111	11	Left
SS 333-112	TT 333-112	12	Left
SS 333-113	TT 333-113	13	Left
SS 333-114	TT 333-114	14	Left
SS 333-115	TT 333-115	15	Left
SS 333-116	TT 333-116	16	Left

Screw Places :

5.0 mm Locking Screw
7.3 mm C.C. Locking Screw
4.5 mm Cortical Screw





3.5mm Cortex Screw (Pitch 1.25) Self Tapping

Code No. S.S. 316L	Code No. Titanium	Code No. S.S. 316LVM	Length
SS 107-010	TT 107-010	LM 107-010	10mm
SS 107-012	TT 107-012	LM 107-012	12mm
SS 107-014	TT 107-014	LM 107-014	14mm
SS 107-016	TT 107-016	LM 107-016	16mm
SS 107-018	TT 107-018	LM 107-018	18mm
SS 107-020	TT 107-020	LM 107-020	20mm
SS 107-022	TT 107-022	LM 107-022	22mm
SS 107-024	TT 107-024	LM 107-024	24mm
SS 107-026	TT 107-026	LM 107-026	26mm
SS 107-028	TT 107-028	LM 107-028	28mm
SS 107-030	TT 107-030	LM 107-030	30mm
SS 107-032	TT 107-032	LM 107-032	32mm
SS 107-034	TT 107-034	LM 107-034	34mm
SS 107-036	TT 107-036	LM 107-036	36mm
SS 107-038	TT 107-038	LM 107-038	38mm
SS 107-040	TT 107-040	LM 107-040	40mm
SS 107-042	TT 107-042	LM 107-042	42mm
SS 107-044	TT 107-044	LM 107-044	44mm
SS 107-046	TT 107-046	LM 107-046	46mm
SS 107-048	TT 107-048	LM 107-048	48mm
SS 107-050	TT 107-050	LM 107-050	50mm
SS 107-052	TT 107-052	LM 107-052	52mm
SS 107-054	TT 107-054	LM 107-054	54mm
SS 107-056	TT 107-056	LM 107-056	56mm
SS 107-058	TT 107-058	LM 107-058	58mm
SS 107-060	TT 107-060	LM 107-060	60mm
SS 107-065	TT 107-065	LM 107-065	65mm
SS 107-070	TT 107-070	LM 107-070	70mm
SS 107-075	TT 107-075	LM 107-075	75mm
SS 107-080	TT 107-080	LM 107-080	80mm

Mfg. : Orthopedic Implants & Instruments

Bone Screw

An ISO 13485
Certified Company

CE 1023



4.5mm Cortex Screw (Pitch 1.75) Self Tapping

Code No. S.S. 316L	Code No. Titanium	Code No. S.S. 316LVM	Length
SS 109-012	TT 109-012	LM 109-012	12mm
SS 109-014	TT 109-014	LM 109-014	14mm
SS 109-016	TT 109-016	LM 109-016	16mm
SS 109-018	TT 109-018	LM 109-018	18mm
SS 109-020	TT 109-020	LM 109-020	20mm
SS 109-022	TT 109-022	LM 109-022	22mm
SS 109-024	TT 109-024	LM 109-024	24mm
SS 109-026	TT 109-026	LM 109-026	26mm
SS 109-028	TT 109-028	LM 109-028	28mm
SS 109-030	TT 109-030	LM 109-030	30mm
SS 109-032	TT 109-032	LM 109-032	32mm
SS 109-034	TT 109-034	LM 109-034	34mm
SS 109-036	TT 109-036	LM 109-036	36mm
SS 109-038	TT 109-038	LM 109-038	38mm
SS 109-040	TT 109-040	LM 109-040	40mm
SS 109-042	TT 109-042	LM 109-042	42mm
SS 109-044	TT 109-044	LM 109-044	44mm
SS 109-046	TT 109-046	LM 109-046	46mm
SS 109-048	TT 109-048	LM 109-048	48mm
SS 109-050	TT 109-050	LM 109-050	50mm
SS 109-052	TT 109-052	LM 109-052	52mm
SS 109-054	TT 109-054	LM 109-054	54mm
SS 109-056	TT 109-056	LM 109-056	56mm
SS 109-058	TT 109-058	LM 109-058	58mm
SS 109-060	TT 109-060	LM 109-060	60mm
SS 109-062	TT 109-062	LM 109-062	62mm
SS 109-064	TT 109-064	LM 109-064	64mm
SS 109-066	TT 109-066	LM 109-066	66mm
SS 109-068	TT 109-068	LM 109-068	68mm
SS 109-070	TT 109-070	LM 109-070	70mm
SS 109-075	TT 109-075	LM 109-075	75mm
SS 109-080	TT 109-080	LM 109-080	80mm

Mfg. : Orthopedic Implants & Instruments

Bone Screw

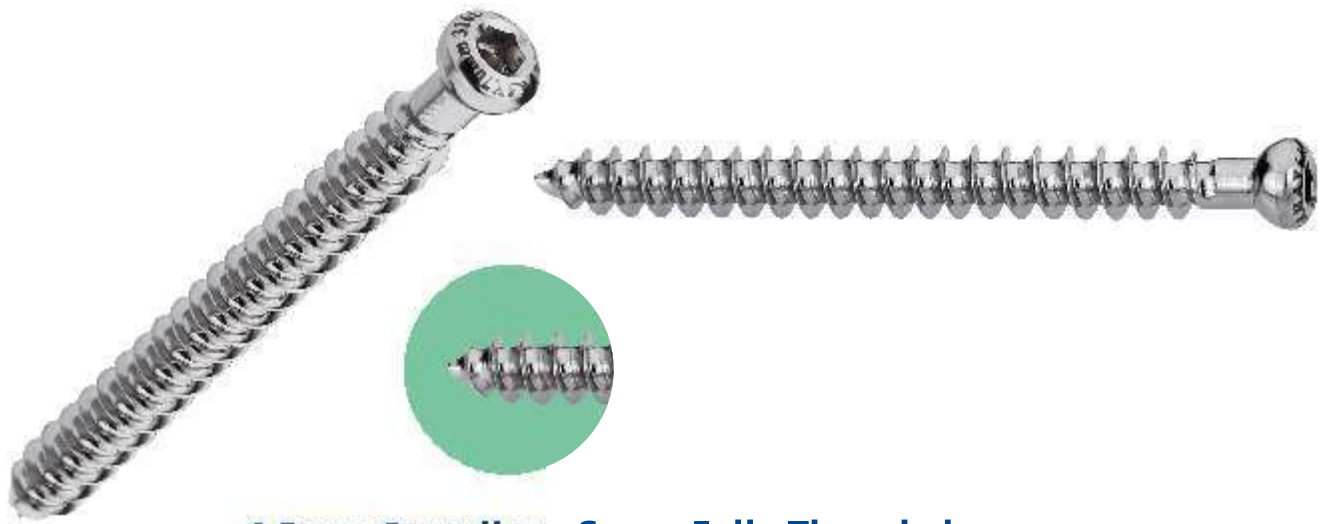
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6.5mm Cancellous Screw 32mm Threaded

Code No. S.S. 316L	Code No. Titanium	Code No. S.S. 316LVM	Length
SS 114-040	TT 114-040	LM 114-040	40mm
SS 114-045	TT 114-045	LM 114-045	45mm
SS 114-050	TT 114-050	LM 114-050	50mm
SS 114-055	TT 114-055	LM 114-055	55mm
SS 114-060	TT 114-060	LM 114-060	60mm
SS 114-065	TT 114-065	LM 114-065	65mm
SS 114-070	TT 114-070	LM 114-070	70mm
SS 114-075	TT 114-075	LM 114-075	75mm
SS 114-080	TT 114-080	LM 114-080	80mm
SS 114-085	TT 114-085	LM 114-085	85mm
SS 114-090	TT 114-090	LM 114-090	90mm
SS 114-095	TT 114-095	LM 114-095	95mm
SS 114-100	TT 114-100	LM 114-100	100mm
SS 114-105	TT 114-105	LM 114-105	105mm
SS 114-110	TT 114-110	LM 114-110	110mm
SS 114-115	TT 114-115	LM 114-115	115mm
SS 114-120	TT 114-120	LM 114-120	120mm



6.5mm Cancellous Screw Fully Threaded

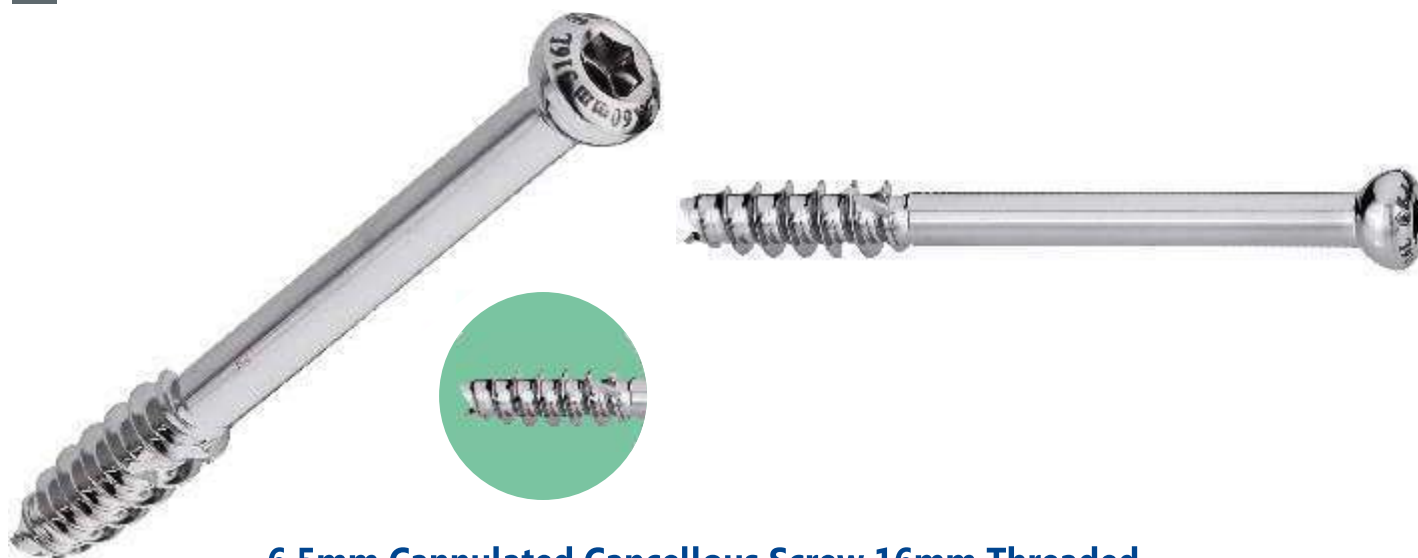
Code No. S.S. 316L	Code No. Titanium	Code No. S.S. 316LVM	Length
SS 115-020	TT 115-020	LM 115-020	20mm
SS 115-025	TT 115-025	LM 115-025	25mm
SS 115-030	TT 115-030	LM 115-030	30mm
SS 115-035	TT 115-035	LM 115-035	35mm
SS 115-040	TT 115-040	LM 115-040	40mm
SS 115-045	TT 115-045	LM 115-045	45mm
SS 115-050	TT 115-050	LM 115-050	50mm
SS 115-055	TT 115-055	LM 115-055	55mm
SS 115-060	TT 115-060	LM 115-060	60mm
SS 115-065	TT 115-065	LM 115-065	65mm
SS 115-070	TT 115-070	LM 115-070	70mm
SS 115-075	TT 115-075	LM 115-075	75mm
SS 115-080	TT 115-080	LM 115-080	80mm
SS 115-085	TT 115-085	LM 115-085	85mm
SS 115-090	TT 115-090	LM 115-090	90mm
SS 115-095	TT 115-095	LM 115-095	95mm
SS 115-100	TT 115-100	LM 115-100	100mm
SS 115-105	TT 115-105	LM 115-105	105mm
SS 115-110	TT 115-110	LM 115-110	110mm

Mfg. : Orthopedic Implants & Instruments

Bone Screw

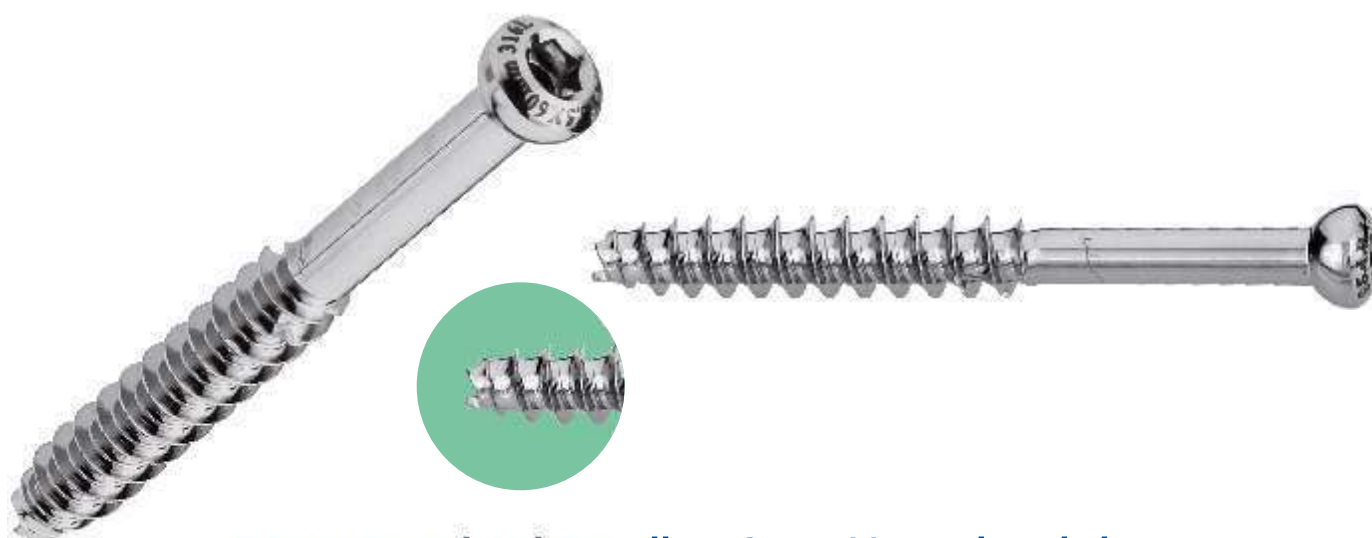
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6.5mm Cannulated Cancellous Screw 16mm Threaded

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



6.5mm Cannulated Cancellous Screw 32mm Threaded

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

Mfg. : Orthopedic Implants & Instruments

Bone Screw

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6.5mm Cannulated Cancellous Screw Fully Threaded

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

95° Condylar Angled Blade Plate DCP Hole

(Also available in 55mm,60mm,65mm,70mm,75mm,80mm Blade Length)

Code No. S.S. 316L	Code No. Titanium	Code No. S.S. 316LVM	Blade Length	Hole
SS 159-004	TT 159-004	LM 159-004	50mm	4
SS 159-005	TT 159-005	LM 159-005	50mm	5
SS 159-006	TT 159-006	LM 159-006	50mm	6
SS 159-007	TT 159-007	LM 159-007	50mm	7
SS 159-008	TT 159-008	LM 159-008	50mm	8
SS 159-009	TT 159-009	LM 159-009	50mm	9
SS 159-010	TT 159-010	LM 159-010	50mm	10
SS 159-011	TT 159-011	LM 159-011	50mm	11
SS 159-012	TT 159-012	LM 159-012	50mm	12



130° Condylar Angled Blade plate DCP Hole

(Also available in 55mm,60mm,65mm,70mm,75mm,80mm Blade Length)

Code No. S.S. 316L	Code No. Titanium	Code No. S.S. 316LVM	Blade Length	Hole
SS 160-004	TT 160-004	LM 160-004	50mm	4
SS 160-005	TT 160-005	LM 160-005	50mm	5
SS 160-006	TT 160-006	LM 160-006	50mm	6
SS 160-007	TT 160-007	LM 160-007	50mm	7
SS 160-008	TT 160-008	LM 160-008	50mm	8
SS 160-009	TT 160-009	LM 160-009	50mm	9
SS 160-010	TT 160-010	LM 160-010	50mm	10
SS 160-011	TT 160-011	LM 160-011	50mm	11
SS 160-012	TT 160-012	LM 160-012	50mm	12

Mfg. : Orthopedic Implants & Instruments

Bone Plate

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