

FORM 26

(See Rules 73 and 83)

Certificate of Renewal of licence to manufacture for sale of Drugs Other than those specified in Schedule X

Certified that Licence in Form 28 No: G/28/1356 Granted on the Date: 30/10/2010

To M/s. HARDIK INTERNATIONAL

For the manufacture of the drugs Specified in Schedule C and C (1) excluding those specified in Schedule "X" to the Drugs and Cosmetics Rules, 1945, at the premises situated at,

PLOT NO. G-2041-42/A, LODHIKA G.I.D.C. KISHAN GATE, KALAWAD ROAD, METODA, DIST - RAJKOT.

has been renewed from : 30/10/2015 To 29/10/2020

Name(s) of drugs (each item to be separately specified) : As per list Approved & Annexed.

Names of approved competent technical staff : As per list Approved & Annexed.



Signature :

Designation :

Commissioner
Food & Drugs Control Administration
Gujarat State.

Date:- 31/03/2016

Dr. G. N. SINGH

Central Licencing Approving Authority
Drugs Controller General (India)
Ministry of Health & Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi - 110002



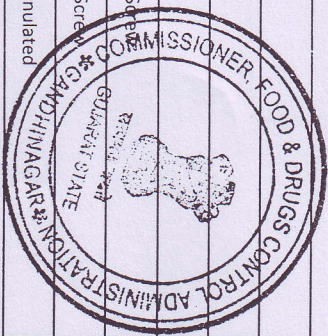
HARDIK
INTERNATIONAL

House of Ortho Tools

Orthopedic Implants

PLOT NO. G-2041-42/A, LODHIKA G.I.D.C., KISHAN GATE,
KALAWAD ROAD, METODA, DIST- RAJKOT
LIC. NO. G/28/1356 VALIDITY PERIOD FROM 30/10/2010 TO 29/10/2015

S.no	Model Name	Generic name	Length in mm	Diameter in mm	Other Information Like Hole	Material of Construction	Intended Use	sterile /Non Sterile	Self-life	Export/Domestic
1		BONE SCREW								
	HARDIK	Cortex Screw	10mm to 60mm	3.5mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Cortex Screw	12mm to 80mm	4.5mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Cancellous Screw	10mm to 70mm	4mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Cancellous Screw	25mm to 110mm	6.5mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Cannulated Cancellous Screw	25mm to 120mm	6.5mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Cannulated Cancellous Screw	25mm to 120mm	7mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Malleolar Screw	25mm to 100mm	4.5mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	DHS/DCS Lag Screw	50mm to 120mm	N.A.	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Interlocking Screw	20mm to 80mm	4.9mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Interlocking Screw	16mm to 60mm	3.9mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Interlocking Screw	16mm to 60mm	3.4mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Interlocking Screw	14mm to 50mm	2.9mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Locking Compression Screw	12mm to 70mm	3.5mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Locking Compression Screw	14mm to 80mm	5mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Hip Locking Screw Cannulated	50mm to 120mm	6.2mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Proximal Femoral Screw	50mm to 120mm	8mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Cortex Screw with Locking Head	10mm to 50mm	3.5mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Cortex Screw with Locking Head	14mm to 60mm	5mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH

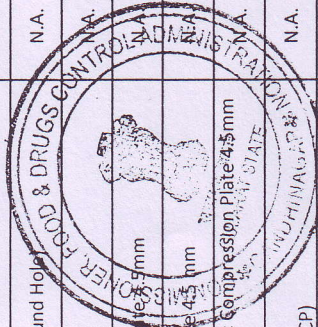


Dr. C. SINGH
Dte. General (India)
Ministry of Health & Family Welfare
FDA Bhawan, Kolia Road, I.T.O.
New Delhi-110002

For, Commissioner
Food & Drugs Control Administration
Gujarat State
30 OCT 2015
29 OCT 2020

Orthopedic Implants

S.no	Model Name	Generic name	Length in mm	Diameter in mm	Other Information Like Hole	Material of Construction	Intended Use	sterile /Non Sterile	Self-life	Export/Domestic
	HARDIK	Locking Cancellous Screw	25mm to 110mm	6.5mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Locking Cancellous Screw	14mm to 80mm	4mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Herbert Screw Cannulated	14mm to 34mm	3.5mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	ACL Screw	20mm to 40mm	6mm to 10mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Schanz Screw	100mm to 250mm	2mm to 6.5mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
2		BONE PLATES								
	HARDIK	One Third Tubular Plate 3.5mm	N.A.	N.A.	2hole to 14hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Small Dynamic Compression Plate 3.5mm	N.A.	N.A.	2hole to 14hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Small Limited Contact Dynamic Compression Plate 3.5mm (LC-DCP)	N.A.	N.A.	4hole to 14hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Small T-Plate 3.5 mm	N.A.	N.A.	3hole to 8hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Small Oblique T-Plate 3.5mm	N.A.	N.A.	3hole to 8hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Reconstruction Plate 3.5mm (DC Hole)	N.A.	N.A.	4hole to 28hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Reconstruction Plate 3.5mm (Round Hole)	N.A.	N.A.	4hole to 28hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Semi Tubular Plate 4.5mm	N.A.	N.A.	2hole to 18hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Narrow Dynamic Compression Plate 4.5mm	N.A.	N.A.	2hole to 18hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Broad Dynamic Compression Plate 4.5mm	N.A.	N.A.	4hole to 18hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Narrow Limited Contact Dynamic Compression Plate 4.5mm (LC-DCP)	N.A.	N.A.	2hole to 16hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Broad Limited Contact Dynamic Compression Plate 4.5mm (LC-DCP)	N.A.	N.A.	4hole to 18hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	T-Plate 4.5 mm	N.A.	N.A.	3hole to 14hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH



Dr. G. N. SINGH
General (India)
Drugs Control Services
Ministry of Health & Family Welfare
F.D.A. Bhawan, Kotla Road, I.T.O.
New Delhi-110002

For, Commissioner
Food & Drugs Control Administration
Gujarat State

30 OCT 2015
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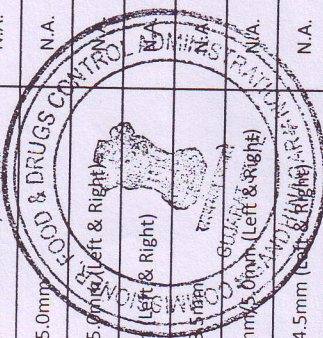
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Orthopedic Implants

S.no	Model Name	Generic name	Length in mm	Diameter in mm	Other Information Like Hole	Material of Construction	Intended Use	Sterile /Non Sterile	Self-life	Export/Domestic
	HARDIK	T-Butress Plate 4.5mm	N.A.	N.A.	3hole to 14hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not	BOTH
	HARDIK	L-Butress Plate 4.5mm (Left & Right)	N.A.	N.A.	3hole to 14hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not	BOTH
	HARDIK	Condylar Butress Plate 4.5mm (Left & Right)	N.A.	N.A.	4hole to 16hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not	BOTH
	HARDIK	DHS Plate (DC Hole) 125°/130°/135°/140°	N.A.	N.A.	2hole to 20hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not	BOTH
	HARDIK	Barrel Length 25mm, 32mm & 38mm	N.A.	N.A.	2hole to 20hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not	BOTH
	HARDIK	DHS Plate (Round Hole) 125°/130°/135°/140°	N.A.	N.A.	2hole to 20hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not	BOTH
	HARDIK	Barrel Length 25mm, 32mm & 38mm	N.A.	N.A.	2hole to 20hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not	BOTH
	HARDIK	95° DCS Plate (DC Hole)	N.A.	N.A.	4hole to 22hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not	BOTH
	HARDIK	95° DCS Plate (Round Hole)	N.A.	N.A.	4hole to 22hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not	BOTH
	HARDIK	Small Locking Compression Plate 3.5mm	N.A.	N.A.	4hole to 14hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not	BOTH
	HARDIK	Narrow Locking Compression Plate 4.5mm/5.0mm	N.A.	N.A.	4hole to 18hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not	BOTH
	HARDIK	Broad Locking Compression Plate 4.5mm/5.0mm	N.A.	N.A.	4hole to 20hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not	BOTH
	HARDIK	Locking Small T Plate 3.5mm	N.A.	N.A.	3hole to 8hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not	BOTH
	HARDIK	Locking Small Oblique T Plate 3.5mm (Left & Right)	N.A.	N.A.	3hole to 8hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not	BOTH
	HARDIK	Locking Reconstruction Plate 3.5mm & 4.5mm/5.0mm	N.A.	N.A.	4hole to 28hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not	BOTH
	HARDIK	Locking T Butress Plate 4.5mm/5.0mm	N.A.	N.A.	4hole to 14hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not	BOTH
	HARDIK	Locking L-Butress Plate 4.5mm/5.0mm (Left & Right)	N.A.	N.A.	3hole to 14hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not	BOTH
	HARDIK	Locking Lateral Tibia Plate 4.5mm (Left & Right)	N.A.	N.A.	4hole to 16hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not	BOTH
	HARDIK	Locking Proximal Humeral Plate 3.5mm	N.A.	N.A.	3hole to 16hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not	BOTH
	HARDIK	Locking Distal Femoral Plate 4.5mm (Left & Right)	N.A.	N.A.	4hole to 16hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not	BOTH
	HARDIK	Locking Condylar Butress Plate 4.5mm (Left & Right)	N.A.	N.A.	4hole to 16hole	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not	BOTH



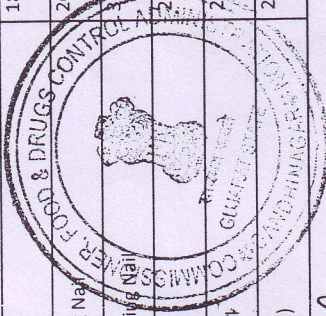
Dr. G. N. SINGH
Drugs Controller General (India)
Director of Health Services
Ministry of Health & Family Welfare
FDA Bhawan, Kolia Road, I.T.O.
New Delhi-110002

For, Commissioner
Food & Drugs Control Administration
Gujarat State

130 OCT 2015 29 OCT 2020

Orthopedic Implants

S.no	Model Name	Generic name	Length in mm	Diameter in mm	Other Information Like Hole	Material of Construction	Intended Use	Sterile /Non Sterile	Self-life	Export/Domestic
	HARDIK	Staffe Plate	1 slot to 5 slot	N.A.	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Anterior Cervical Plate	21.5 mm to 110 mm	N.A.	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Bone Screw for Anterior Cervical Plate	10mm to 24mm	4mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Lock Screw for Anterior Cervical Plate	N.A.	N.A.	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
3		BONE WIRES, PINS AND STAPLES								
	HARDIK	Kirchner Wire (K-Wire)	100mm to 300mm	0.8mm to 3mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Stainmann Pin	125mm to 300mm	3.5mm to 5mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	SS Wire Reel 16SWG to 34SWG	N.A.	N.A.	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Staple	N.A.	N.A.	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
4		ENDOPROSTHESIS								
	HARDIK	Bipolar Prosthesis (Non-Fen. & Fen.)	N.A.	37mm to 55mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Austin Moore Prosthesis	N.A.	37mm to 55mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Thompson Prosthesis	N.A.	37mm to 55mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
5		BONE NAILS								
	HARDIK	Humeral Interlocking Nail	180mm to 320mm	6mm to 8mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Universal Tibial Interlocking Nail	260mm to 380mm	8mm to 12mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Universal Femoral Interlocking Nail	300mm to 400mm	8mm to 14mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	XL Tibial Interlocking Nail	255mm to 420mm	8mm to 12mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	XL Femoral Interlocking Nail	285mm to 460mm	8mm to 12mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Proximal Femoral Nail (PFN)	220mm to 250mm	9mm to 12mm	N.A.	SS 316L /SS 316LVM /TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH



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[Signature]
 For, Commissioner
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 Gujarat State
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Orthopedic Implants

S.no	Model Name	Generic name	Length in mm	Diameter in mm	Other Information Like Hole	Material of Construction	Intended Use	Sterile / Non Sterile	Self-life	Export/Domestic
	HARDIK	Antegrade Femoral Nail (AFN Nail)	340mm to 440mm	9mm to 14mm	N.A.	SS 316L / SS 316LVM / TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Sirustype Femur Nail	340mm to 440mm	9mm to 12mm	N.A.	SS 316L / SS 316LVM / TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Multifunctional Femoral Nail	340mm to 460mm	9mm to 14mm	N.A.	SS 316L / SS 316LVM / TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Enders Nail	150mm to 300mm	2.5mm to 4.5mm	N.A.	SS 316L / SS 316LVM / TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Reconstruction Femoral Nail (Recon Nail) (Left & Right)	340mm to 460mm	9mm to 12mm	N.A.	SS 316L / SS 316LVM / TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Elastic Nail	440mm	4mm	N.A.	SS 316L / SS 316LVM / TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
6		SPINE IMPLANTS								
	HARDIK	Monoaxial Screw	30mm to 60mm	4mm to 7mm	N.A.	SS 316L / SS 316LVM / TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Polyaxial Screw	30mm to 60mm	4mm to 7mm	N.A.	SS 316L / SS 316LVM / TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Reduction Screw	30mm to 60mm	4mm to 7mm	N.A.	SS 316L / SS 316LVM / TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Monoaxial Screw Single Lock	30mm to 60mm	5mm to 7mm	N.A.	SS 316L / SS 316LVM / TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Polyaxial Screw Single Lock	30mm to 60mm	5mm to 7mm	N.A.	SS 316L / SS 316LVM / TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Staffe Screw	26mm to 42mm	4.5mm to 5.5mm	N.A.	SS 316L / SS 316LVM / TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Hooks	N.A.	N.A.	N.A.	SS 316L / SS 316LVM / TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Transversers Connector	N.A.	N.A.	N.A.	SS 316L / SS 316LVM / TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Rod	50mm to 150mm	3mm	N.A.	SS 316L / SS 316LVM / TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Rod	50mm to 480mm	5.5mm	N.A.	SS 316L / SS 316LVM / TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH
	HARDIK	Cage Eco	20mm to 50mm	10mm to 24mm	N.A.	SS 316L / SS 316LVM / TITANIUM	BONE FRACTURE	NON STERILE	Not Applicable	BOTH

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