



सत्यमेव जयते

FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/MD/2021/000156

1. M/s ORTHOFLEX MEDISYS INDIA PVT LTD, REG OFFICE 2ND FLOOR SHIV MARKET OPP BUS STATION VISNAGARVISNAGAR, --, Gujarat (India) - 384315 Telephone No.: 09727973005 FAX: 02765225295 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Orthoflex Medisys India Pvt Ltd, survey no 1591,shed no 7,ramdevchikori industrialestate,vijapur road,at visnagar,dist mehsana gujrat 284315 india, Mehsana, Gujarat (India) - 384315 Telephone No.: 9727973005 FAX: 2765 225295

2. Details of medical device(s) [Annexed]

3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer

4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
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सत्यमेव जयते

CDSCO
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1

Generic Name: BONE SCREW

Model No.: Washer - Length- 4 mm to 15 mm ,LHS cancellous bone screws (16 mm thread) - Dia 5.0 mm length 30 mm to 120 mm ,LHS cancellous bone screws (32 mm thread) - Dia 5.0 mm length 30 mm to 120 mm ,Mini Screws (Single Slot Head) - Dia- 2.7mm Length- 06mm to 30mm ,Cancellous BoneScrews (32 mm Thread) - Dia- 6.5mm Length- 40mm to 120mm , Cancellous Bone Screws (Fully Threaded) - Dia- 6.5mm Length- 20mm to 120mm ,ACL Screw - Dia- 06mm to 10mm Length- 20mm to 40mm ,Cortex Screws 20 TPI (self-tapping) - Dia- 3.5 mm Length- 10mm to 60mm ,LHS Cancellous Bone Screws (Partially Threaded) - Dia- 4.0 mm Length- 14mm to 80mm ,LHS Cannulated Screws (32 mm Thread) - Dia- 6.5mm Length- 20mm to 130mm ,DHS/DCS Lag Screws - Length- 50mm to 120mm ,Cannulated Screws (Short Thread) - Dia- 3.5mm Length- 14mm to 70mm ,Cannulated Screws (Full Thread) - Dia- 3.5mm Length- 14mm to 70mm ,Mini Screws (Single Slot Head - Dia- 1.5mm Length- 04mm to 20mm , Mini Screws (Cross Head) - Dia- 1.5mm Length- 04mm to 20mm ,Mini Screws (Single Slot Head) - Dia- 2.0mm Length- 04mm to 20mm ,Mini Screws (Cross Head) - Dia- 2.0mm Length- 04mm to 20mm ,Mini Screws (Single Slot Head) - Dia- 2.5mm Length- 04mm to 20mm ,Mini Screws (Cross Head) - Dia- 2.5mm Length- 04mm to 20mm ,Cannulated Screws (Fully Threaded) - Dia- 7.3mm Length- 25mm to 130mm ,LHS Cannulated Screws (16 mm Thread) - Dia- 5.5mm Length- 20mm to 130mm ,LHS Cannulated Screws (32 mm Thread) - Dia- 5.5mm Length- 20mm to 130mm ,LHS Cannulated Screws (Fully Threaded) - Dia- 5.5mm Length- 20mm to 130mm ,LHS Cannulated Screws (16 mm Thread) - Dia- 6.5mm Length- 20mm to 130mm ,PFN-2 Blade Screw - Dia- NA Length- 60mm to 120mm ,Spacer - -Length- 3.5 mm & 5.0 mm ,Wire Mount - Length- 3.5 mm & 5.0 mm ,LHS cancellous bone screws (Fully thread) - Dia 5.0 mm length 30 mm to 120 mm ,Mini Screws (Cross Head) - Dia- 2.7mm Length-06mm to 30mm ,Cortex Screws - Dia- 1.5mm Length- 06mm to 30mm ,Cortex Screws - Dia- 2.0mm Length- 06mm to 20mm ,Cortex Screws - Dia- 2.4mm Length- 06mm to 30mm ,Cortex Screws (Without Self - tapping) - Dia- 2.7mm Length- 06mm to 40mm ,Cortex Screws (self-tapping) - Dia- 2.7mm Length- 06mm to 40mm ,Cortex Screws 20 TPI (Without Self - tapping) - Dia- 3.5mm Length- 10mm to 60mm ,Cortex Screws 14 TPI (Without Self - tapping) - Dia- 3.5 mm Length- 10mm to 60mm ,Cortex Screws 14 TPI (self-tapping) - Dia- 3.5mm Length- 10mm to 60mm ,Cortex Screws (Without Self - tapping) - Dia- 4.5mm Length- 10mm to 80mm , Cortex Screws (self-tapping) - Dia- 4.5mm Length- 10mm to 80mm ,Malleolar Screws - Dia- 4.5mm Length- 20mm to 100mm ,LHS Screws (self-tapping) - Dia- 2.4mm Length- 10mm to 60mm ,LHS Screws (self-tapping) - Dia- 2.7mm Length- 10mm to 60mm ,LHS Screws (self-tapping) - Dia- 3.5mm Length- 10mm to 70mm ,LHS Screws (self-tapping) - Dia-5.0mm Length- 10mm to 120mm ,LHS Screws (self-tapping) Star Head - Dia- 2.4mm Length- 06mm to 30mm ,LHS Screws (self-tapping) Star Head - Dia- 2.7mm Length- 10mm to 40mm ,LHS Screws (self-tapping) Star Head - Dia- 3.5mm Length- 10mm to 60mm ,LHS Screws (self-tapping) Star Head - Dia- 5.0mm Length- 10mm to 90mm ,LCDCP Shaft Screws - Dia- 3.5mm Length- 12mm to 50mm ,LC- DCP Shaft Screws - Dia- 4.5mm Length- 28mm to 80mm , Cancellous Bone Screws (Partially Threaded) - Dia- 3.5mm Length- 12mm to 70mm , Cancellous Bone Screws (Fully Threaded) - Dia- 3.5mm Length- 12mm to 70mm ,Cancellous Bone Screws (Partially Threaded) - Dia- 4.0mm Length-10mm to 70mm ,Cancellous Bone Screws (Fully Threaded) - Dia- 4.0mm Length- 10mm to 70mm ,Cancellous Bone Screws (16 mm Thread) - Dia- 6.5mm Length- 20mm to 120mm ,LHS Cancellous Bone Screws (Partially Threaded) - Dia- 3.5mm Length- 10mm to 80mm ,LHS Cancellous Bone Screws (Fully Threaded) - Dia- 3.5mm Length- 10mm to 80mm ,LHS Cancellous Bone Screws (Fully Threaded) - Dia- 4.0mm Length-14mm to 80mm ,LHS Cancellous Bone Screws (16 mm Thread) - Dia- 5.5mm Length- 30mm to 110mm ,LHS Cancellous Bone Screws (32 mm Thread) - Dia- 5.5 mm Length- 45mm to 110mm ,LHS Cancellous Bone Screws (Fully Threaded) - Dia- 5.5mm Length- 30mm to 110mm ,LHS Cancellous Bone Screws (16 mm Thread) - Dia- 6.5mm Length-

30mm to 120mm ,LHS Cancellous Bone Screws (32 mm Thread) - Dia- 6.5mm Length- 40mm to 120mm ,LHS Cancellous Bone Screws (Fully Threaded) - Dia- 6.5mm Length- 30mm to 120mm ,Cannulated Screws (Short Thread) - Dia- 4.0mm Length- 14mm to 70mm ,Cannulated Screws Full Thread) - Dia- 4.0mm Length- 14mm to 70mm ,Cannulated Screws (Short Thread) - Dia- 3.5mm Length- 14mm to 70mm ,Cannulated Screws Full Thread) - Dia- 3.5mm Length- 14mm to 70mm ,Cannulated Screws (16 mm Thread) - Dia- 6.5mm Length- 25mm to 120mm ,Cannulated Screws (32 mm Thread) - Dia- 6.5mm Length- 40mm to 120mm ,Cannulated Screws (Fully Threaded) - Dia- 6.5mm Length- 25mm to 120mm ,Cannulated Screws (16 mm Thread) - Dia- 7.0mm Length-30mm to 130mm ,Cannulated Screws (32 mm Thread) - Dia- 7.0 mm Length- 40mm to 130mm ,Cannulated Screws (Fully Threaded) - Dia- 7.0mm Length- 25mm to 130mm ,Cannulated Screws (16 mm Thread) - Dia- 7.3mm Length- 30mm to 130mm ,Cannulated Screws (32 mm Thread) - Dia- 7.3mm Length- 40mm to 130mm ,LHS Cannulated Screws (Fully Threaded) - Dia- 6.5mm Length- 20mm to 130mm ,LHS Cannulated Screws (16 mm Thread) - Dia- 7.0mm Length- 20mm to 130mm ,LHS Cannulated Screws (32 mm Thread) - Dia- 7.0 mm Length- 20mm to 130mm ,LHS Cannulated Screws (Fully Threaded) - Dia- 7.0mm Length- 20mm to 130mm ,Compression Screw For DHS/DCS Lag Screws - Length- 20mm to 50mm ,Pediatric DHS/DCS Lag Screws - Dia- 9.5mm Length- 40mm to 100mm ,Compression Screw For Pediatric DHS/DCS Lag Screws - Length- 10mm to 50mm ,Interlocking Screw - Dia- 2.9mm Length- 14mm to 50mm ,Interlocking Screw - Dia- 3.4 mm Length- 16mm to 60mm , Interlocking Screw - Dia- 3.9mm Length- 16mm to 60mm ,Interlocking Screw - Dia- 4.9mm Length- 20mm to 80mm ,Lag Screw For PFN - Dia- 6.2mm Length- 50mm to 120mm ,Lag Screw For PFN - Dia- 8.0mm Length- 50mm to 120mm ,Herbert Screw Cannulated - Dia- 3.5 mm Length- 14 mm to 50 mm ,Schanz Screw - Dia- 2.0mm to 6.5mm Length- 100mm to 250mm ,Suture Anchor Screw - Dia- 3.0mm & 5.0mm Length- N.A.

Intended Use:Bone Screws intended for use in internal fixation of bones affected by trauma or for reconstruction or arthrodesis. Screws along with plates, nails, pins and wires are indicated for pelvic,small and long bone fracture fixation. Screws are of so many different types e.g. (Locked Screws,Locking bolts etc.).

Class of medical device:Class C

Material of construction:SS 316L

Dimension(if any):Different Dimension for different model, dimension with model as mentioned below.

Shelflife:NIL

Sterile or Non sterile:Non-Sterilized

Brand Name(if registered under the Trade Marks Act, 1999):ORTHOFLEX MEDISYS (I) PVT LTD

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Generic Name: BONE SCREW

Model No.: Mini Screws (Single Slot Head) - Dia- 2.5mm Length- 04mm to 20mm ,Mini Screws (Cross Head) - Dia- 2.5mm Length- 04mm to 20mm ,Mini Screws (Single Slot Head) - Dia- 2.7 mm Length- 06mm to 30mm ,Mini Screws (Cross Head) - Dia- 2.7mm Length- 06mm to 30mm ,Cortex Screws - Dia- 1.5mm Length- 06mm to 30mm ,Cortex Screws - Dia- 2.0mm Length- 06mm to 20mm ,Cortex Screws - Dia- 2.4mm Length- 06mm to 30mm ,Cortex Screws (Without Self - tapping) - Dia- 2.7mm Length- 06mm to 40mm ,Cortex Screws (self-tapping) - Dia- 2.7mm Length- 06mm to 40mm ,Cortex Screws 20 TPI (Without Self - tapping) - Dia- 3.5 mm Length- 10mm to 60mm ,Cortex Screws 20 TPI (self-tapping) - Dia- 3.5mm Length- 10mm to 60mm ,Cortex Screws 14 TPI (Without Self - tapping) - Dia- 3.5mm Length- 10mm to 60mm ,Cortex Screws 14 TPI (self-tapping) - Dia- 3.5mm Length- 10mm to 60mm ,Cortex Screws (Without Self - tapping) - Dia- 4.5mm Length- 10mm to 80mm ,Cortex Screws (self-tapping) - Dia- 4.5mm Length- 10mm to 80mm ,Malleolar Screws - Dia- 4.5mm Length- 20mm to 100mm ,LHS Cancellous Bone Screws (Fully Threaded) - Dia- 5.5mm Length- 30mm to 110mm ,Cannulated Screws (32 mm Thread) - Dia- 7.0mm Length- 40mm to 130mm ,Cannulated Screws (Fully Threaded) - Dia- 7.0mm Length- 25mm to 130mm ,Cannulated Screws (16 mm Thread) - Dia- 7.3mm Length- 30mm to 130mm ,Cannulated Screws (32 mm Thread) - Dia- 7.3 mm Length- 40mm to 130mm ,Cannulated Screws (Fully Threaded) - Dia- 7.3mm Length- 25mm to 130mm ,LHS Cannulated Screws (16 mm Thread) - Dia- 5.5mm Length- 20mm to 130mm ,Washer - Length- 4 mm to 15 mm ,Spacer - Length- 3.5 mm & 5.0 mm ,Wire Mount - Length- Spacer - Length- 3.5 mm & 5.0 mm ,Wire Mount - Length- 3.5 mm & 5.0 mm ,Mini Screws (Single Slot Head - Dia- 1.5mm Length- 04mm to 20mm ,Mini Screws (Cross Head) - Dia- 1.5mm Length- 04mm to 20mm ,Mini Screws (Single Slot Head) - Dia- 2.0mm Length- 04mm to 20mm ,Mini Screws (Cross Head) - Dia- 2.0mm Length- 04mm to 20mm ,Lag Screw For PFN - Dia- 8.0mm Length- 50mm to 120mm ,LHS cancellous bone screws (16 mm thread) - Dia 5.0 mm length 30 mm to 120 mm ,LHS cancellous bone screws (32 mm thread) - Dia 5.0 mm length 30 mm to 120 mm ,LHS cancellous bone screws (Fully thread) - Dia 5.0 mm length 30 mm to 120 mm ,LHS Screws (self-tapping) - Dia- 2.7mm Length- 10mm to 60mm ,LHS Cancellous Bone Screws (16 mm Thread) - Dia- 6.5mm Length- 30mm to 120mm ,LHS Cancellous Bone Screws (Fully Threaded) - Dia- 6.5mm Length- 30mm to 120mm ,Cannulated Screws (Short Thread) - Dia- 4.0mm Length- 14mm to 70mm ,Cannulated Screws Full Thread) - Dia- 4.0mm Length- 14mm to 70mm ,PFN-2 Blade Screw - Dia- NA Length- 60mm to 120mm ,Pediatric DHS/DCS Lag Screws - Dia- 9.5mm Length- 40mm to 100mm ,LHS Cancellous Bone Screws (32 mm Thread) - Dia- 6.5mm Length- 40mm to 120mm ,Cannulated Screws (Short Thread) - Dia- 3.5mm Length- 14mm to 70mm ,Cannulated Screws Full Thread) - Dia- 3.5mm Length- 14mm to 70mm ,Herbert Screw Cannulated - Dia- 3.5 mm Length- 14 mm to 50 mm ,ACL Screw - Dia- 06mm to 10mm Length- 20mm to 40mm ,Schanz Screw - Dia- 2.0mm to 6.5 mm Length- 100mm to 250mm ,Suture Anchor Screw - Dia- 3.0mm & 5.0mm ,Cannulated Screws (Short Thread) - Dia- 3.5 mm Length- 14mm to 70mm ,Cannulated Screws (Full Thread) - Dia- 3.5mm Length- 14mm to 70mm ,LHS Cannulated Screws (16 mm Thread) - Dia- 7.0mm Length- 20mm to 130mm ,Compression Screw For Pediatric DHS/DCS Lag Screws - Length- 10mm to 50mm ,Interlocking Screw - Dia- 2.9 mm Length- 14mm to 50mm ,Interlocking Screw - Dia- 3.4mm Length- 16mm to 60mm ,Interlocking Screw - Dia- 3.9mm Length- 16mm to 60mm ,Interlocking Screw - Dia- 4.9mm Length- 20mm to 80mm ,Lag Screw For PFN - Dia- 6.2mm Length- 50mm to 120mm ,Cannulated Screws (16 mm Thread) - Dia- 7.0mm Length- 30mm to 130mm ,LHS Cannulated Screws (32 mm Thread) - Dia- 7.0mm Length- 20mm to 130mm ,LHS Cannulated Screws (Fully Threaded) - Dia- 7.0 mm Length- 20mm to 130mm , DHS/DCS Lag Screws - Length - 50mm to 120mm ,Compression Screw For DHS/DCS Lag Screws - Length- 20mm to 50mm ,LHS Screws (self-tapping) - Dia- 2.4mm Length- 10mm to 60mm ,LHS Screws (self-tapping) Star Head - Dia- 2.4mm Length- 06mm to 30mm ,LHS

Screws (self-tapping) Star Head - Dia- 2.7mm Length- 10mm to 40mm ,LHS Screws (self-tapping) Star Head - Dia- 3.5mm Length- 10mm to 60mm ,LHS Screws (self-tapping) Star Head - Dia- 5.0mm Length- 10mm to 90mm , - ,LCDCP Shaft Screws - Dia- 3.5mm Length- 12mm to 50mm ,LC- DCP Shaft Screws - Dia- 4.5mm Length- 28mm to 80mm ,Cancellous Bone Screws (Partially Threaded) - Dia- 3.5mm Length- 12mm to 70mm ,Cancellous Bone Screws (Fully Threaded) - Dia- 3.5mm Length- 12mm to 70mm ,LHS Screws (self-tapping) - Dia- 3.5mm Length- 10mm to 70mm ,LHS Screws (self-tapping) - Dia- 5.0mm Length- 10mm to 120mm , Cancellous Bone Screws (Partially Threaded) - Dia- 4.0mm Length- 10mm to 70mm , Cancellous Bone Screws (Fully Threaded) - Dia- 4.0mm Length- 10mm to 70mm ,Cancellous Bone Screws (16 mm Thread) - Dia- 6.5mm Length- 20mm to 120mm ,Cancellous Bone Screws (32 mm Thread) - Dia- 6.5mm Length- 40mm to 120mm ,Cancellous Bone Screws (Fully Threaded) - Dia- 6.5 mm Length- 20mm to 120mm ,LHS Cancellous Bone Screws (Partially Threaded) - Dia- 3.5mm Length- 10mm to 80mm ,LHS Cancellous Bone Screws (Fully Threaded) - Dia- 3.5mm Length- 10mm to 80mm ,LHS Cancellous Bone Screws (Partially Threaded) - Dia- 4.0mm Length- 14mm to 80mm ,LHS Cancellous Bone Screws (Fully Threaded) - Dia- 4.0mm Length- 14mm to 80mm ,LHS Cancellous Bone Screws (16 mm Thread) - Dia- 5.5mm Length- 30mm to 110mm ,LHS Cancellous Bone Screws (32 mm Thread) - Dia- 5.5mm Length- 45mm to 110mm ,LHS Cannulated Screws (32 mm Thread) - Dia- 5.5mm Length- 20mm to 130mm ,LHS Cannulated Screws (Fully Threaded) - Dia- 5.5mm Length- 20mm to 130mm ,LHS Cannulated Screws (16 mm Thread) - Dia- 6.5mm Length- 20mm to 130mm ,LHS Cannulated Screws (32 mm Thread) - Dia- 6.5mm Length- 20mm to 130mm ,LHS Cannulated Screws (Fully Threaded) - Dia- 6.5mm Length- 20mm to 130mm ,Cannulated Screws (16 mm Thread) - Dia- 6.5mm Length- 25mm to 120mm ,Cannulated Screws (32 mm Thread) - Dia- 6.5mm Length- 40mm to 120mm ,Cannulated Screws (Fully Threaded) - Dia- 6.5 mm Length- 25mm to 120mm

Intended Use:ORTHOFLEX MEDISYS (INDIA) PVT. LTD.'s Bone Screws when used in combination with plates are intended for fixation of various fractures, osteotomies, malunions, replacement, reconstruction, correction, stabilization of various bones [clavicle, pelvis, scapula, long bone (humerus, ulna, radius, femur, tibia and fibula), and small bone (metacarpals, metatarsals, phalanges)] in general. The ORTHOFLEX MEDISYS (INDIA) PVT. LTD.'s Bone washer are intended to prevent a screw head from breaking through the cortex of the bone by distributing the forces/load over a large area when used for fracture fixation of large bone and bone fragments.

Class of medical device:Class C

Material of construction:TITANIUM GRADE 5

Dimension(if any):Different Dimension for different model, dimension with model as mentioned below.

Shelflife:NIL

Sterile or Non sterile:Non-Sterilized

Brand Name(if registered under the Trade Marks Act, 1999):ORTHOFLEX MEDISYS INDIA PVT LTD

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Generic Name: BONE PLATES

Model No.: LCP Distal Humerus Plate (Left & Right) - Size- 3.5 mm Hole- 03 to 12 ,LCP Posterior Medial Proximal Tibia Plate - Size- 3.5 mm Hole- 01 to 10 ,Mini Straight Plate - Size- 2.0 mm Hole- 3 to 12 ,Mini DCP Plate - Size-2.0 mm Hole- 4 to 8 ,Mini L Plate (Left & Right) - Size-2.0 mm Hole- 2 ,Mini T Plate - Size- 2.0 mm Hole- 2 ,Mini DCP Plate - Size-2.7 mm Hole- 2 to 07 ,Mini LC-DCP Plate - Size-2.7 mm Hole- 4 to 12 ,LCP Distal Radius Plate (Straight) - Size- 2.4/2.7 mm Hole- 5 to 6 ,LCP Hook Plate - Size - 3.5 mm Hole- 03 to 06 ,Mini L/T Plate - Size- 2.7 mm Hole- 3 ,LCP Reconstruction Plate - Size- 3.5 mm Hole- 4 to 28 ,LCP Clavicle Hook Plate 3.5 mm Hook Depth (Left & Right) - Size- 12mm/15mm/18mm Hole- 4 to 08 ,LCP Superior Anterior Clavicle Plate (Left & Right) - Size- 3.5 mm Hole- 6 to 10 ,LCP Superior Anterior Clavicle Plate With Lateral Extension (Left & Right) - Size- 3.5 mm Hole- 03 to 10 ,LCP Proximal Humerus Plate - Size- 3.5 mm Hole- 03 to 16 ,LCP Proximal Humerus (Philos) Plate - Size-3.5 mm Hole- 03 to 18 ,LCP Distal Humerus Plate With Support (Left & Right) - Size- 3.5 mm Hole- 03 to 12 ,LCP Medial Distal Humerus Plate (Left & Right) - Size- 3.5 mm Hole- 3.5 mm ,LCP Distal Medial Humerus (Metaphyseal) Plate - Size- 3.5 mm Hole- 06 to 16 ,LCP Extra Articular Distal Humerus Plate - Size- 3.5 mm Hole- 04 to 14 ,LCP Olecranon Plate (Left & Right) - Size- 3.5 mm Hole- 02 to 12 ,Duraline Distal Kopis Plate - Size- 2.7/3.5 mm Hole- 03 to 08 ,LCP Distal Radius Plate (Head 5) - Size- 2.4/2. 7 mm Hole- 03 to 05 ,LCP Distal Radius L Plate (Oblique Angle Head 2) (Left & Right) - Size- 2.4/2. 7 mm Hole - 03 to 06 Hole ,LCP Distal Radius T Plate (Head 3) - Size- 2.4/2.7 mm Hole- 03 to 06 ,LCP Distal Radius Plate (Extraarticular Head 4/5) - Size- 2.4/2.7 mm Hole- 03 to 06 ,LCP Distal Radius Plate (Extra Long Head 4) - Size- 2.4/2.7 mm Hole- 08 to 12 ,LCP T Plate Right Angled - - Size- 3.5mm Hole- 03 to 08 ,LCP T Plate Oblique Angled (Left & Right) - Size- 3.5 mm Hole- 03 to 08 ,LCP Calcaneal Plate - Size - 3.5 mm Hole Small/ Medium/ Large ,LCP Cloverleaf Plate - Size- 3.5 mm Hole- 03 to 12 ,LCP Reconstruction Plate (Thin) - Size- 4.5 mm Hole- 04 to 22 ,LCP Narrow Plate - Size- 4.5/5.0 mm Hole- 02 to 20 ,LCP Broad Plate - Size- 4.5/5.0 mm Hole- 04 to 20 , - ,LCP Reconstruction Plate 8 - Size- 4.5/5.0 mm Hole- 04 to 2 ,LCP Distal Radius L Plate Head 2/3 (Left & Right) - Size- 2.4/2.7 mm Hole- 03 to 06 ,Spoon Plate - Size- - 4.5 mm Hole-5 to 6 ,Lateral Tibia Head Buttress Plate (Left & Right) - Size- 4.5 mm Hole- 3 to 18 , Trochanter Stabilization Plate - - Size- 138/148 ,LCP Ulna Osteotomy Plate - Size- 2.7 mm Hole- 4 to 8 ,Universal LCP Trochanter Stabilization Plate - Length- 131 mm ,LCP Meta Volar Distal Radius Plate - Size- 2.4mm/2.7mm Hole- 5 to 15 ,LCP One Third Tubular Plate - Size- 3.5 mm Hole- 3 to 14 ,Small LCP Plate - Size- 3.5 mm Hole- 4 to 15 ,LCP T Buttress Plate - Size- 4.5/5.0 mm Hole- 03 to 14 , - ,LCP Tomo Fix Plate - Size- 4.5/5.0 mm Hole- 02 to 04 , Semi Tubular plate - Size- 4.5 mm Hole- 2 to 18 ,LCP Distal Radius Buttress Plate (Head 5) (Left & Right) - Size- 2.4/2.7 mm Hole- 03 ,LCP Distal Radius L Plate (Oblique Angle Head 3) (Left & Right) - Size- 2.4/2.7 mm Hole- 03 to 06 ,LCP Volar Distal Radius Plate (Left & Right) - Size- 2.4/2.7 mm Hole- 02 to 08 ,LCP XVA Volar Distal Radius Plate (Head 6/7) (Left & Right) - Size- 2.4/2.7 mm Hole- 02 to 06 ,LCP Proximal Radius Neck/ Rim Plate - Size- 2.4 /2.7 mm Hole- 02 to 06 ,LCP Distal Febula Plate - Size- 3.5 mm Hole- 03 to 12 ,LCP Anterolateral Distal Tibia Plate (Left & Right) - Size- 3.5 mm Hole- 03 to 17 ,LCP Medial Distal Tibia Plate With Tab (Left & Right) - Size- 3.5 mm Hole- 04 to 18 ,LCP Medial Distal Tibia Plate Without Tab (Left & Right-) - Size- 3.5 mm Hole- 03 to 17 ,LCP Anatomical Proximal Tibia Plate - Size- 3.5 mm Hole- 04 to 14 , - ,LCP Reconstruction Plate (Thin) - Size- 3.5 mm Hole- 04 to 22 ,LCP Proximal Tibia Plate (Left & Right) - Size- 3.5 mm Hole- 03 to 16 ,LCP Proximal Medial Tibia Plate - - Size 3.5 mm Hole- 04 to 14 ,LCP PILON Tibia Plate - Size- 3.5 mm Hole- 07 to 09 ,LCP Curved Narrow Plate - Size- 3.5 mm Hole- 10 to 22 ,LCP Curved Broad Plate - Size- 3.5 mm Hole- 10 to 30 ,LCP L Buttress Plate (Left & Right) - Size- 4.5/5.0 mm Hole 03 to 14 ,LCP T Plate - Size- 4.5/5.0 mm Hole- 03 to 14 ,LCP Proximal Lateral Tibia Plate (Left & Right) - Size- 3.5 mm & 4.5/5.0 mm Hole- 04 to 18 ,LCP Proximal Tibia Plate (Left & Right) - Size- 4.5/5.0

mm Hole- 03 to 16 ,LCP Distal Femur Plate (Left & Right) - Size- 4.5/5.0 mm Hole- 05 to 18 , LCP Condylar Buttress Plate (Left & Right) - Size- 4.5/5.0 mm Hole- 04 to 16 ,LCP Proximal Femur Plate (Left & Right) - - Size- 4.5/5.0 mm Hole- 03 to 18 ,LCP Metaphyseal Plate - Size- 4.5/5.0 mm Hole- 03 to 14 ,LCP Proximal Femur Hook Plate - Size- 4.5/5.0 mm Hole- 06 to 12 ,LCP Pediatric Hip Plate - Hole- 03 & 04 ,Infinity Plate - Hole- Small/ Medium/ Large ,DHS Plate (DC) 125/130/135/140/145/150 Barrel - Length 25 mm ,32 mm & 38 mm Hole- 02 to 20 - ,DHS Plate (Round) 125/130/135/140/145/150 Barrel - Length 25 mm ,32 mm & 38 mm Hole- 02 to 20 - ,LCP DHS Plate 125/130/135/140/145/150 Barrel - Length 25 mm ,32 mm & 38 mm Hole- 02 to 20 - ,DCS 95 Plate (DC) - Hole- 04 to 22 ,DCS 95 Plate (Round) - ,LCP DCS 95 Plate (DC) - Hole- 04 to 22 ,Pediatric DHS Plate (DC) - Hole- 02 to 22 , - ,95 Degree Condylar Plate (DC) Blade - Size- 50mm/60mm/70mm/80mm Hole- 05 to 20 ,130 Degree Angle Blade Plate (D.C.) Blade - Size- 50mm/60mm/70mm/80mm ,95 Degree Angle Blade Plate (Round) Blade - Size- 50mm/60mm/70mm/80mm Hole- 05 to 20 , - ,Mandible Plate - Dia- 1.5 mm to 2.5 mm Hole- 2 to 20 ,Mandible Plate with Center Space - Dia- 1.5 mm to 2.5 mm Hole- 2 to 10 ,Orbital Plate - Dia- 1.5 mm to 2.5 mm Hole- 2 to 10 ,Orbital Plate with Center Space - Dia- 1.5 mm to 2.5 mm Hole- 2 to 10 ,L Shape Plate 2/3 (Left & Right) - Dia- 1.5 mm to 2.5 mm Hole- 2 to 6 ,T Shape Plate Head 2/3 - Dia- 1.5 mm to 2.5 mm Hole- 2 to 6 ,X shape plate - Dia- 1.5 mm to 2.5 mm 05 ,Y shape plate - Dia- 1.5 mm to 2.5 mm Hole- 3 to 8 ,Double Y Shape Plate - Dia- 1.5 mm to 2.5 mm 06 ,Z Shape plate - Dia 1.5 mm to 2.5 mm 04 ,Curved Plate (Left & Right) - Dia- 1.5 mm to 2.5 mm Hole- 2 x 2 3 x 3 ,L Shape Plate 2/3 Without Bar (Left & Right) - Dia- 1.5 mm to 2.5 mm Hole- 2 to 6 ,Angular Plate 150 (Left & Right) - Dia- 1.5 mm to 2.5 mm Hole- 04 to 06 ,L Shape 120 Oblique Angle Plate (Left & Right) - Dia- 1.5 mm to 2.5 mm Hole- 04 to 06 ,Nose Y/H Shape Plate - Dia- 1.5 mm to 2.5 mm ,Chin Plate - Dia- 1.5 mm to 2.5 mm ,I shape plate - Dia- 1.5 mm to 2.5 mm Hole- 04 to 06 ,3D Plate - Dia- 1.5 mm to 2.5 mm Hole- 2+2/ 2+3/ 2+4 ,TMJ Plate - Dia- 1.5 mm to 2.5 mm Hole- 4 to 22 ,Mini Reconstruction Plate 2.4 mm - Hole- 2 to 30 ,Reconstruction Plate Angled (Left & Right) - Hole- 4 to 22 ,Reconstruction Plate (Full Mandible Shape) - - Hole- 22 to 40 ,Mesh - Dia- 1.5 mm to 2.5 mm Hole- 22 to 40 ,Mini LCDCP Plate - Size- 2.0 mm Hole- 4 to 8 ,Mini Quarter Tubular Plate with Collar - Size-2.7 mm Hole- 3 to 08 ,Mini Reconstruction Straight Plate - Size-2.7 mm Hole- 6 to 24 ,One Third Tubular Plate - Size-3.5 mm Hole- 2 to 18 ,Semi Tubular Plate - Size-3.5 mm Hole- 4 to 1 8 ,Small Dynamic Compression(DCP) Plate - Size-3.5 mm Hole- 4 to 16 ,Small LC-DCP Plate - Size-3.5 mm Hole- 4 to 16 ,Reconstruction Plate Straight (DC) - Size-3.5 mm Hole- 4 to 28 ,Reconstruction Plate Thin (Round) - Size-3.5 mm Hole- 4 to 28 , Small T-Plate Right Angled - Size-3.5 mm Hole- 3 to 12 , - ,Small T-Plate Oblique Angled - Size- 3.5 mm Hole- 3 to 12 ,Small T-Plate Right Angled (Head 4) - - Size-3.5 mm Hole- 2 to 12 ,Hook Plate - Size-3.5 mm Hole- 3 to 6 ,Cloverleaf Plate - Size- 3.5 mm Hole- 3 to 14 ,Distal Fibula Plate VT - - Size- 3.5 mm Hole- 5 to 10 ,Reconstruction Y-Plate - Size- 3.5 mm Hole- 3 to 08 , Pelvic Reconstruction J Plate - Size- 3.5 mm Hole- 10 to 16 ,LCP Periarticular Proximal Humerus Plate - Size- 3.5 mm hole 02 to 14 ,Hole- 04 to 22 - ,Pelvic Reconstruction Curved Plate - Size- 3.5 mm Hole- 06 to 16 ,Pelvic Reconstruction Straight Plate - - Size- 3.5 mm Hole- 5 to 20 ,Symphyseal plate (Coaxial Combi & 2 DCP) - Size-3.5 mm Hole- 4 to 6 , Symphyseal plate (Coaxial Combi) - Size- 3.5 mm Hole- 4 to 6 ,Reconstruction Plate (DC) - Size- 4.5 mm Hole- 3 to 30 ,Narrow DCP Plate - Size- 4.5 mm Hole- 4 to 20 ,Broad DCP Plate - Size- 4.5 mm Hole- 4 to 20 ,Narrow/ Broad LC-DCP Plate - Size- 4.5 mm Hole- 4 to 20 ,T - Plate - Size- 4.5 mm - Hole- 3 to 14 ,T Buttress Plate - Size- 4.5 mm Hole- 3 to 14 ,L - Buttress Plate (Left & Right) - Size- 4.5 mm Hole- 3 to 14 ,Condylar Buttress Plate (Left & Right) - Size- 4.5 mm Hole- 4 to 16 ,LCP Proximal Humerus (Long Philos) Plate - Size- 3.5 mm Hole- 03 to 18

Intended Use: Bone Plates intended to be attached to fractured long bone fragment with screw to bridge and stabilize the fracture gap, and shield the site from stress as the bone heals. it may also be used to temporarily augment bone following a lengthening procedure, or for

	<p>arthrodesis.</p> <p>Class of medical device:Class C</p> <p>Material of construction:SS 316L</p> <p>Dimension(if any):Different Dimension for different model, dimension with model as mentioned below.</p> <p>Shelflife:NIL</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):ORTHOFLEX MEDISYS (I) PVT LTD</p>
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Generic Name: BONE PLATE

Model No.: LCP Condylar Buttress Plate (Left & Right) - Size- 4.5/5.0 mm Hole- 04 to 16 ,LCP Proximal Femur Plate (Left & Right) - Size- 4.5/5.0 mm Hole- 03 to 18 ,LCP Metaphyseal Plate - Size- 4.5/5.0 mm Hole- 03 to 14 ,LCP Tomo Fix Plate - Size- 4.5/5.0 mm Hole- 02 to 04 ,LCP Proximal Femur Hook Plate - Size- 4.5/5.0 mm Hole- 06 to 12 ,LCP Pediatric Hip Plate - Hole- 03 & 04 ,Infinity Plate - Hole- Small/ Medium/ Large ,DHS Plate (DC) 125/130/135/140/145/150 Barrel - Length 25 mm ,32 mm & 38 mm Hole- 02 to 20 - ,DHS Plate (Round) 125/130/135/140/145/150 Barrel - Length 25 mm ,32 mm & 38 mm Hole- 02 to 20 - ,LCP DHS Plate 125/130/135/140/145/150 Barrel - Length 25 mm ,32 mm & 38 mm Hole- 02 to 20 - ,Pediatric DHS Plate (DC) - Hole- 02 to 22 ,130 Degree Angle Blade Plate (D. C.) Blade - Size 50mm/60mm/70mm/80mm Hole-05 to 20 ,Semi Tubular plate - Size- 4.5 mm Hole- 2 to 18 ,Reconstruction Plate (DC) - Size- 4.5 mm Hole- 3 to 30 ,Narrow DCP Plate - Size- 4.5 mm Hole- 4 to 20 ,Lateral Tibia Head Buttress Plate (Left & Right) - Size-4.5 mm Hole- 3 to 18 ,Trochanter Stabilization Plate - Size- 138/148 ,LCP Ulna Osteotomy Plate - Size- 2.7 mm Hole- 4 to 8 ,Universal LCP Trochanter Stabilization Plate - Length- 131 mm ,LCP Meta Volar Distal Radius Plate - Size- 2.4mm/2.7mm Hole- 5 to 15 ,LCP One Third Tubular Plate - Size-3.5 mm Hole- 3 to 14 ,Small LCP Plate - Size- 3.5 mm Hole- 4 to 15 ,LCP Reconstruction Plate - Size- 3.5 mm Hole- 4 to 28 ,LCP Clavicle Hook Plate 3.5 mm Hook Depth (Left & Right) - Size 12mm/15mm/18mm Hole- 4 to 08 ,LCP Posterior Medial Proximal Tibia Plate - Size- 3.5 mm Hole- 01 to 10 ,LCP Medial Distal Tibia Plate With Tab (Left & Right) - Size- 3.5 mm Hole- 04 to 18 ,LCP XVA Volar Distal Radius Plate (Head 6/7) (Left & Right) - Size- 2.4/2.7 mm Hole- 02 to 06 ,LCP Proximal Radius Neck/ Rim Plate - Size- 2.4/2.7 mm Hole- 02 to 06 ,LCP Distal Fibula Plate - Size- 3.5 mm Hole- 03 to 12 ,DCS 95 Plate (DC) - Hole- 04 to 22 ,LCP DCS 95 Plate (DC) - Hole- 04 to 22 ,DCS 95 Plate (Round) - Hole- 04 to 22 ,LCP Cloverleaf Plate - Size- 3.5 mm Hole- 03 to 12 ,LCP Hook Plate - Size- 3.5 mm Hole- 03 to 06 ,Mandible Plate - Dia- 1.5 mm to 2.5 mm Hole- 2 to 20 ,LCP Proximal Medial Tibia Plate - Size- 3.5 mm Hole- 04 to 14 ,LCP PILON Tibia Plate - Size- 3.5 mm Hole- 07 to 09 ,LCP Broad Plate - Size- 4.5/5.0 mm Hole- 04 to 20 ,LCP Reconstruction Plate - Size- 4.5/5.0 mm Hole- 04 to 28 ,LCP L Buttress Plate (Left & Right) - Size- 4.5/5.0 mm Hole- 03 to 14 ,LCP Reconstruction Plate (Thin) - Size- 3.5 mm Hole- 04 to 22 ,LCP Proximal Tibia Plate (Left & Right) - Size- 3.5 mm Hole- 03 to 16 ,LCP Calcaneal Plate - Size-3.5 mm Hole- Small/ Medium/ Large/ Extra Small , LCP Anatomical Proximal Tibia Plate - Size- 3.5 mm Hole- 04 to 14 ,LCP Curved Narrow Plate - Size- 3.5 mm Hole- 10 to 22 ,LCP Curved Broad Plate - Size- 3.5 mm Hole- 10 to 30 ,LCP Reconstruction Plate (Thin) - Size- 4.5 mm Hole- 04 to 22 ,LCP Narrow Plate - Size- 4.5/5.0 mm Hole- 02 to 20 ,Z Shape plate - Dia 1.5 mm to 2.5 mm 04 ,Curved Plate (Left & Right) Dia - 1.5 mm to 2.5 mm Hole- 2 x 2 3 x 3 ,L Shape Plate 2/3 Without Bar (Left & Right) - Dia- 1.5 mm to 2.5 mm Hole- 2 to 6 ,Small Dynamic Compression(DCP) Plate - Size-3.5 mm Hole- 4 to 16 , Pelvic Reconstruction J Plate - Size- 3.5 mm Hole- 10 to 16 ,Broad DCP Plate - Size- 4.5 mm Hole- 4 to 20 ,Narrow/ Broad LC-DCP Plate - Size- 4.5 mm Hole- 4 to 20 ,T - Plate - Size- 4.5 mm Hole- 3 to 14 ,T - Buttress Plate - Size- 4.5 mm Hole- 3 to 14 ,L - Buttress Plate (Left & Right) - Size- 4.5 mm Hole- 3 to 14 ,Condylar Buttress Plate (Left & Right) - Size- 4.5 mm Hole- 4 to 16 ,Spoon Plate - Size- 4.5 mm Hole-5 to 6 ,95 Degree Condylar Plate (DC) Blade - Size 50mm/60mm/70mm/80mm Hole- 05 to 20 ,95 Degree Angle Blade Plate (Round) Blade - Size- 50mm/60mm/70mm/80mm Hole- 05 to 20 ,Mandible Plate with Center Space - Dia- 1.5 mm to 2.5 mm Hole- 2 to 10 ,Orbital Plate - Dia- 1.5 mm to 2.5 mm Hole- 2 to 10 ,Orbital Plate with Center Space - Dia- 1.5 mm to 2.5 mm Hole- 2 to 10 ,Angular Plate 150 (Left & Right) - Dia- 1.5 mm to 2.5 mm Hole- 04 to 06 ,L Shape 120 Oblique Angle Plate (Left & Right) - Dia- 1.5 mm to 2.5 mm Hole- 04 to 06 ,Nose Y/Shape Plate - Dia- 1.5 mm to 2.5 mm ,Chin Plate - Dia- 1.5 mm to 2.5 mm ,I shape plate - Dia- 1.5 mm to 2.5 mm Hole- 04 to 06 ,3D Plate - Dia- 1.5 mm to 2.5 mm Hole- 2+2/ 2+3/ 2+4 ,TMJ Plate - Dia- 1.5 mm to 2.5 mm Hole- 4 to 22 ,Mini

Reconstruction Plate 2.4 mm - Hole- 2 to 30 ,Reconstruction Plate Angled (Left & Right) - Hole- 4 to 22 ,Reconstruction Plate (Full Mandible Shape) - Hole- 22 to 40 ,Mesh - Dia- 1.5 mm to 2.5 mm Hole- 22 to 40 ,Mini Straight Plate - Size-2.0 mm Hole- 3 to 12 ,Mini LC-DCP Plate - Size- 2.0 mm Hole- 4 to 8 ,Mini DCP Plate - Size-2.0 mm Hole- 4 to 8 ,Mini L Plate (Left & Right) - Size-2.0 mm Hole- 2 ,Mini T Plate - Size- 2.0 mm Hole- 2 ,Mini DCP Plate - Size-2.7 mm Hole- 2 to 07 ,Mini LC-DCP Plate - Size-2.7 mm Hole- 4 to 12 ,Mini Quarter Tubular Plate with Collar - Size-2.7 mm Hole- 3 to 08 ,Mini L/T Plate - Size-2.7 mm Hole- 3 ,Mini Reconstruction Straight Plate - Size-2.7 mm Hole- 6 to 24 ,One Third Tubular Plate - Size-3.5 mm Hole- 2 to 14 ,Semi Tubular Plate - Size-3.5 mm Hole- 4 to 8 ,Small LC-DCP Plate - Size-3.5 mm Hole- 4 to 16 ,Reconstruction Plate Straight (DC) - Size-3.5 mm Hole- 4 to 28 ,Reconstruction Plate Thin (Round) - Size-3.5 mm Hole- 4 to 28 ,Small T-Plate Right Angled - Size-3.5 mm Hole- 3 to 10 ,Small T-Plate Oblique Angled - Size-3.5 mm Hole- 3 to 10 ,Small T-Plate Right Angled (Head 4) - Size-3.5 mm Hole- 2 to 10 ,Hook Plate - Size-3.5 mm Hole- 3 to 6 ,Cloverleaf Plate - Size- 3.5 mm Hole- 3 to 14 ,Distal Fibula Plate VT - Size- 3.5 mm Hole- 5 to 10 ,Reconstruction Y-Plate - Size- 3.5 mm Hole- 3 to 08 ,Pelvic Reconstruction Curved Plate - Size- 3.5 mm Hole- 06 to 16 ,Pelvic Reconstruction Straight Plate - Size- 3.5 mm Hole- 5 to 20 ,Symphyseal plate (Coaxial Combi & 2 DCP) - Size-3.5 mm Hole- 4 to 6 ,Symphyseal plate (Coaxial Combi) - Size 3.5 mm Hole- 4 to 6 ,LCP Superior Anterior Clavicle Plate (Left & Right) - Size- 3.5 mm Hole- 6 to 10 ,LCP Superior Anterior Clavicle Plate With Lateral Extention (Left & Right) - Size- 3.5 mm Hole- 03 to 10 ,LCP Proximal Humerus Plate - Size- 3.5 mm Hole- 03 to 16 ,LCP Proximal Humerus (Philos) Plate - Size-3.5 mm Hole- 03 to 18 ,LCP Proximal Humerus (Long Philos) Plate - Size- 3.5 mm Hole- 03 to 18 ,LCP Periarticular Proximal Humerus Plate - Size- 3.5 mm 02 to 14 ,LCP Distal Humerus Plate (Left & Right) - Size- 3.5 mm Hole- 03 to 12 ,LCP Distal Humerus Plate With Support (Left & Right) - Size- 3.5 mm Hole- 03 to 12 ,LCP Medial Distal Humerus Plate (Left & Right) - Size- 3.5 mm Hole- 3.5 mm ,LCP Distal Medial Humerus (Metaphyseal) Plate - Size- 3.5 mm Hole- 06 to 16 ,LCP Extra Articular Distal Humerus Plate - Size- 3.5 mm Hole- 04 to 14 ,LCP Olecranon Plate (Left & Right) - Size- 3.5 mm Hole- 02 to 12 , Duraline Distal Kopis Plate - Size- 2.7/3.5 mm Hole- 03 to 08 ,LCP Distal Radius L Plate Head 2/3 (Left & Right) - Size- 2.4/2.7 mm Hole- 03 to 06 ,LCP Distal Radius Plate (Head 5) - Size- 2.4/2.7 mm Hole- 03 to 05 ,LCP Distal Radius Buttress Plate (Head 5) (Left & Right) - Size- 2.4/2.7 mm Hole- 03 ,LCP Distal Radius Plate (Straight) - Size- 2.4/2.7 mm Hole- 5 to 6 ,LCP Distal Radius L Plate (Oblique Angle Head 3) (Left & Right) - Size- 2.4/2.7 mm Hole- 03 to 06 , LCP Distal Radius L Plate (Oblique Angle Head 2) (Left & Right) - Size- 2.4/2.7 mm Hole- 03 to 06 ,LCP Distal Radius T Plate (Head 3) - Size- 2.4/2.7 mm Hole- 03 to 06 ,LCP Distal Radius Plate (Extraarticular Head 4/5) - Size- 2.4/2.7 mm Hole- 03 to 06 ,LCP Distal Radius Plate (Extra Long Head 4) - Size- 2.4/2.7 mm Hole- 08 to 12 ,LCP Anterolateral Distal Tibia Plate (Left & Right) - Size- 3.5 mm Hole- 03 to 15 ,LCP Medial Distal Tibia Plate Without Tab (Left & Right) - Size- 3.5 mm Hole- 04 to 18 ,LCP T Plate Right Angled - Size- 3.5 mm Hole- 03 to 12 , LCP T Plate Oblique Angled (Left & Right) - Size- 3.5 mm Hole- 03 to 12 ,LCP Volar Distal Radius Plate (Left & Right) - Size- 2.4/2.7 mm Hole- 02 to 08 ,LCP T Buttress Plate - Size- 4.5 /5.0 mm Hole- 03 to 14 ,LCP T Plate - Size- 4.5/5.0 mm Hole- 03 to 14 ,LCP Proximal Lateral Tibia Plate (Left & Right) - Size- 3.5 mm & 4.5/5.0 mm Hole- 04 to 18 ,LCP Proximal Tibia Plate (Left & Right) - Size- 4.5/5.0 mm Hole- 03 to 16 ,LCP Distal Femur Plate (Left & Right) - Size- 4.5/5.0 mm Hole- 05 to 18 ,T Shape Plate Head 2/3 - Dia- 1.5 mm to 2.5 mm Hole- 2 to 6 , L Shape Plate 2/3 (Left & Right) - Dia- 1.5 mm to 2.5 mm Hole- 2 to 6 ,X shape plate - Dia- 1.5 mm to 2.5 mm 05 ,Y shape plate - Dia- 1.5 mm to 2.5 mm Hole- 3 to 8 ,Double Y Shape Plate - Dia- 1.5 mm to 2.5 mm 06

Intended Use: Bone Plates intended to be attached to fractured long bone fragment with screw to bridge and stabilize the fracture gap, and shield the site from stress as the bone heals. it may also be used to temporarily augment bone following a lengthening procedure, or for

arthrodesis. Class of medical device:Class C Material of construction:TITANIUM Dimension(if any):Different Dimension for different model, dimension with model as mentioned below. Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):ORTHOFLEX MEDISYS INDIA PVT. LTD.
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Supracondylar Fracture. Interlocking Nail Cap, Nail Plug Safety Star drive (Gam Nail Cap), Interlocking Guide Wire-Simple and Interlocking Guide Wire-Olive Tip (Ball Tip) are indicated for Nail and Bone Fixation.

Class of medical device:Class C

Material of construction:SS 316L

Dimension(if any):Different Dimension for different model, dimension with model as mentioned below

Shelflife:NIL

Sterile or Non sterile:Non-Sterilized

Brand Name(if registered under the Trade Marks Act, 1999):ORTHOFLEX MEDISYS INDIA PVT LTD



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Generic Name: BONE NAILS (INTRAMEDULLARY NAILS)

Model No.: Trochanteric Femoral Nail (TFN Nail) - Dia- 9 mm to 14 mm Length- 150 mm to 170 mm , Unreamed Femoral Interlocking Nail - Dia- 9 mm to 14 mm Length- 285 mm to 420 mm , Expert Tibial Nail - Dia- 8 mm to 14 mm Length- 280 mm to 420 mm , PFN-2 Nail - Dia- 9 mm to 12 mm Length- 170 mm & 200 mm & 240 mm , PFN-2 Nail (Long) - Dia- 9 mm to 14 mm Length- 300 mm to 420 mm , End Cap For Nails - NA , Unreamed Tibia Interlocking Nail - Dia- 8 mm to 14 mm Length- 285 mm to 420 mm , Antegrade Femoral Nail (AFN Nail) - Dia- 9 mm to 14 mm Length- 340 mm to 440 mm , Tibia Interlocking Nail (Distal Tip) - Dia- 8 mm to 12 mm Length- 285 mm to 440 mm , Universal Tibia Nail - Dia- 8 mm to 13 mm Length- 280 mm to 400 mm , Humeral Nail (Cannulated) - Dia- 6 mm to 8 mm Length- 180 mm to 320 mm , Square Nail For Radius - Dia- 1.5 mm to 5 mm Length- 160 mm to 420 mm , Long Proximal Femoral Nail (Left & Right) - Dia- 9 mm to 14 mm Length- 320 mm to 460 mm , K Nail - Dia- 6 mm to 16 mm Length- 260 mm to 500 mm , Universal Femoral Nail - Dia- 8 mm to 14 mm Length 320 mm to 440 mm , Tibia Interlocking Nail - Dia- 8 mm to 12 mm Length- 260 mm to 420 mm , Femoral Interlocking Nail - Dia- 9 mm to 13 mm Length- 340 mm to 460 mm , Humeral Nail (Solid) - Dia- 6 mm to 8 mm Length- 180 mm to 320 mm , Rush Nail - Dia- 1.5 mm to 7 mm Length- 160 mm to 420 mm , Reconstruction Femoral Nail (Left & Right) - Dia- 9 mm to 12 mm Length- 340 mm to 420 mm , Square Nail For Ulna - Dia- 1.5 mm to 5 mm Length- 160 mm to 420 mm , Elastic Nail - Dia- 1.5 mm to 4.5 mm Length- 400 mm & 440 mm , Sirius Femoral Nail - Dia- 9 mm to 12 mm Length- 340 mm to 440 mm , Supra Condylar Nail - Dia- 9 mm to 14 mm Length- 100 mm to 350 mm , Enders Nail - Dia- 2.5 mm to 4.5 mm Length- 200 mm to 500 mm , Proximal Femoral Nail (PFN Nail) - Dia- 9 mm to 12 mm Length- 180 mm to 250 mm

Intended Use: Interlocking nails include severely comminuted, spiral, large oblique and segmental fractures; nonunion and mal-unions; and bone lengthening/shortening. Femoral interlocking nails include the indication for proximal, middle and distal third femoral shaft fractures. Tibial interlocking nails also include the same indications for tibial shaft fractures. Humeral interlocking nails are indicated for humeral shaft fractures, including severely comminuted, spiral, large oblique and segmental fractures; nonunion and mal-unions, proximal, middle and distal third shaft fractures; polytrauma and/or multiple fractures; humerus reconstruction, following tumor resection and grafting; and prophylactic nailing of impending pathologic fractures. R/U Interlocking nails are indicated for radial and ulnar shaft fractures, including severely comminuted, spiral, large oblique and segmental fractures; nonunion and malunion; proximal middle and distal third shaft fractures; polytrauma and/or multiple fractures. Interlocking reconstruction nails are indicated for the following: Subtrochanteric fractures with lesser Trochanteric involvement; ipsilateral femoral shaft/neck fractures; severely comminuted shaft fractures; femur reconstruction following tumor resection and grafting; bone shortening/lengthening; and prophylactic nailing of impending pathologic fractures. Retrograde nails are indicated for shaft fractures including severely comminuted, spiral, large oblique and segmental fractures; nonunion and malunion; bone lengthening/shortening; femur reconstruction Following tumor resection and grafting; fractures in osteoporotic bone; severely comminuted shaft fractures; pathologic fractures, pseudoarthrosis, failed osteosynthesis; closed Supracondylar fractures; and prophylactic nailing of impending pathologic fractures. Additional indications for retrograde nails include: severely comminuted Supracondylar fractures with or without difficult intra-articular extension, fractures that require opening the knee joint to stabilize the femoral condylar segment. K-Nail is indicated for Tibia, Femur and Humerus shaft fracture. Gam Nail is indicated for Subtrochanteric Fracture. Elastic Nail (Flexible Nail) is indicated for Humerus and Tibia and Femur Fracture. Ender's Nail is indicated for Humerus and Tibia and Femur Fracture. Ankle Arthodesis Nail is indicated for Foot and ankle Fracture. DIMSC Locked Nail is indicated for Supracondylar Fracture. Interlocking Nail Cap, Nail Plug Safety Star drive (Gam Nail Cap),

Interlocking Guide Wire-Simple and Interlocking Guide Wire-Olive Tip (Ball Tip) are indicated for Nail and Bone Fixation. Class of medical device:Class C Material of construction:TITANIUM Dimension(if any):Different Dimension for different model, dimension with model as mentioned below. Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):ORTHOFLEX MEDISYS INDIA PVT LTD



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Generic Name:: SPINAL IMPLANTS

Model No.:Occipital T Plate - Length- 34 mm to 50 mm ,Cervicle Self Drilling Bone Screw 4.0 mm - Dia- 4.0 mm Length- 12 mm to 22 mm ,Cervicle Revision Bone Screw 4.3 mm - Dia- 4.3 mm Length- 12 mm to 22 mm ,Cervicle Cage - Dia- 12mm to16 mm Length- 5 mm to 9 mm , Anterior Cervical Fusion Cage - Dia- 12mm to16 mm Length- 5 mm to 9 mm ,Plate With Cage - Dia- 14mm to16 mm Length- 5 mm to 9 mm ,Occipital Cervical Screw Connector - Length- 15 mm to 20 mm ,Cervical Plate - Length- 21.5 mm to 77 mm ,Cervicle Bone Screw 4.0 mm - Length- 12 mm to 22 mm ,Monoaxial Screw - - Dia- 4 mm to 7 mm Length- 25 mm to 60 mm , Reduction Mono Screw - Dia- 4 mm to 7 mm Length- 25 mm to 60 mm ,Cervicle Cage DIO II - Dia- 12mm to16 mm Length- 5 mm to 9 mm ,Staple - Length- Small/ Large Rod - Dia- 3.0 mm 6.0 mm Length- 30 mm to 500 mm ,Crosslink Connector - Length- 30 mm to 70 mm , Transverse Connector - Length- Small/ Large ,Eco Cage - Dia- 10 mm to 20 mm Length- 20 mm to 100 mm ,Expandable Eco Cage - Dia- 12 mm to 18 mm Length- 20 mm to 75 mm , Parallel Connector - Length- 3.5 mm to 5.5 mm ,Pedicle Hook - Length- Small/ Large ,Lamina Hook Reduced Distance - Length- Small/ Large ,Lamina Hook Angle Blade - Length- Small/ Large ,Lamina Hook Narrow Blade - Length- Small/ Large ,Lamina Hook Wide Blade - Length- Small/ Large ,Bullet Cage - Dia- 20mm and 25 mm Length- 7 mm to 12 mm ,Kidney Cage - Dia- 25mm and 30 mm Length- 7 mm to 12 mm ,Kidney Cage II - - Dia- 25mm and 30 mm Length- 7 mm to 12 mm ,Polyaxial Occipital Screw - Dia- 3.5 mm & 4.0 mm Length- 10 mm to 30 mm , Occipital Plate - Length- 150 mm to 200 mm ,Polyaxial Screw - Dia- 4 mm to 7 mm Length- 25 mm to 60 mm ,Reduction Polyaxial Screw - Dia- 4 mm to 7 mm Length- 25 mm to 60 mm

Intended Use:Spinal Implants are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: fracture, dislocation, failed previous fusion (pseudoarthrosis), spinal stenosis, degenerative spondylolisthesis with objective evidence of neurological impairment, spinal deformations such as scoliosis or kyphosis and loss of stability due to tumors. Spinal implants are intended to be used as a temporary construct that assists normal healing and are not intended to replace normal body structures. They are intended to stabilize the spinal operative site during fusion procedures and should be removed after fusion. The IMPLANET Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion of the thoracic, lumbar and/or sacral spine. The IMPLANET Spine System is intended for posterior, non-cervical pedicle and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, spinal deformities (i.e., scoliosis, kyphosis and/or lordosis), tumor, pseudarthrosis, or revision of a failed fusion attempt.

Class of medical device:Class C

Material of construction:TITANIUM

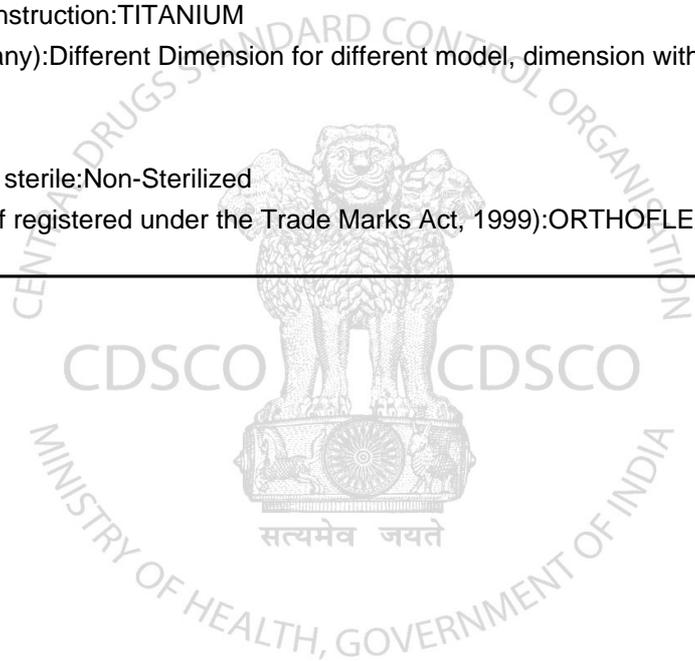
Dimension(if any):Different Dimension for different model, dimension with model as mentioned below.

Shelflife:NIL

Sterile or Non sterile:Non-Sterilized

Brand Name(if registered under the Trade Marks Act, 1999):ORTHOFLEX MEDISYS INDIA PVT LTD

8	<p>Generic Name:ARTHROSCOPY IMPLANTS</p> <p>Model No.:ACL screws - Dia 6 to 12 and length 10 to 60 ,Herbert screws - Dia 2.0 mm to 4.0 mm length 10 mm to 60 mm ,Endobutton With Loop - Length- 15 mm to 50 mm ,Suture Disk Washer - 15 mm and 17 mm ,Suture Disk Regular & Conical with 2 Holes - 15 mm and 17 mm , Spiked Washer - 17 mm and 21 mm ,Spiked Ligament Staple - - size -6 mm to 16 mm length -20 mm ,Endobutton - 10 mm to 60 mm , - , - , - , - , - , - , - , - , - , - , - , - , - , - , -</p> <p>Intended Use:Arthroscopy Implants are intended for use in fixation of semitendinous and/or gracile tendon grafts. ACL/PCL Screw is intended for use in anterior/posterior cruciate ligament (ACL/PCL) reconstruction procedures. ACL/PCL Screw is indicated for fixation of bone-patellar tendon- bone graft to the femoral/tibial bone drill hole in the anterior cruciate ligament reconstruction, fixation of the soft tissue graft to the femoral/tibial bone drill hole in the anterior cruciate ligament (ACL) reconstruction and reconstruction of posterior cruciate ligament (PCL). The Arthroscope is intended to be used as an endoscope in arthroscopic procedures performed on the knee, shoulder, hip, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release) to view the surgical site.</p> <p>Class of medical device:Class C</p> <p>Material of construction:TITANIUM</p> <p>Dimension(if any):Different Dimension for different model, dimension with model as mentioned</p> <p>Shelflife:NIL</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):ORTHOFLEX MEDISYS INDIA PVT. LTD.</p>
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9	<p>Generic Name: BONE WIRES, PINS & STAPLES</p> <p>Model No.: K Wire (Single Side Threaded & Double Side Threaded) - Dia- 0.8 mm to 5 mm Length- 100 mm to 500 mm , Schanz Screw (16mm Thread/25mm Thread/32mm Thread/40 mm Thread/50 mm Thread/Tapper Thread) - Dia- 2.0 mm to 6 mm Length- 100 mm to 300 mm , Kirschner wires (Kwires) - Dia- 0.8 mm to 3 mm Length- 100 mm to 300 mm , Steinmann Pin - Dia- 2 mm to 6 mm Length- 100 mm to 300 mm , SS Wire Reel - 16 SWG to 34 SWG , Endobutton - 10 mm to 60 mm , - , - , - , - , - , - , Staple - dia 1.5 mm to 3.0 mm length 15 mm to 25 mm , K Wire (Single Side Trocar Tip) - Dia- 0.8 mm to 5 mm Length- 100 mm to 500 mm</p> <p>Intended Use: Indications for Pins and Wires include Fixation of Bone Fractures, Bone Reconstructions, as guide pins for insertion of other implants and Implanted through the skin for traction applied to the skeletal system. Wires are used in the fixation of fractures in which loading is minimal. Wires are easier to bend, so, are supplemented with other immobilization devices where necessary. Pin or wire fixation is mostly used for fractures of the Phalanges, Metacarpals, Metatarsals, Proximal Humerus and Distal Humerus. Pins are used in fixation of fractures where minimal bone and soft tissue damage are involved. Pins provide provisional fixation leaving room for additional hardware placement. The provisional fixation is planned to avoid faulty permanent Fix tion. Depending on the diameter, pins may also be used as guidewires for cannulated screw fixation. Staples are used for fragment fixation, where inter-fragmental screw fixation is difficult. These are an effective internal fixation method and are widely used in foot and ankle surgery. The staples are also used in fixation of soft tissues to bone</p> <p>Class of medical device: Class C</p> <p>Material of construction: SS 316L</p> <p>Dimension(if any): Different Dimension for different model, dimension with model as mentioned below.</p> <p>Shelflife: NIL</p> <p>Sterile or Non sterile: Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): ORTHOFLEX MEDISYS INDIA PVT. LTD.</p>
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Place:

Date 07-Jun-21

Central Licensing Authority