F NO: **HQ/NCC/MD/2024/000813**

Government of India Directorate General of Health Services Central Drugs Standard Control Organisation Ministry of Health and Family welfare (Medical Device and Diagnostic Division) NON CONVICTION CERTIFICATE

Certificate Number: NCC/MD/2024/001058 Dated: 20-Sep-2024

This is to certify that M/s. Splint Meditec Private Limited situated at address Plot No 1/2,2,3 Survey No 605, JD Industrial Area-1, At Ravki Road ,Rajkot Gujarat ,360035,9099969869, India Rajkot Gujarat 360035 9099969869 India is holding Manufacturing/Import License no. MFG/MD/2024/000617 dated 29-AUG-2024

Based on the undertaking submitted by the firm, firm has not been convicted under Drugs and Cosmetics Act 1940 and rules thereunder.

Name of the products with their product name and dimensions if any mentioned below:

S.NO	Medical Device Details
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1. Generic Name: BONE PLATE

2. Brand Name: SPLINT

3. Notified Category: Orthopaedic Implants

4. Class of Medical Device : Class C

5. Shelf life: NIL

6. Sterile/Non-Sterile: Non-Sterilized

7. Intended Use: These implants are used in human body to unite bones of different parts of the body. Bone plates are generally for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

8. Material of Construction: Stainless Steel 316L, Titanium

9. Dimension: Various Dimensions

10. Model/Catalogue No./Name: Straight Plate 2.0mm - Size (2 Hole to 8Hole), Micro T Plate 2.0mm - Size (2 Hole) - "Micro L Plate 2.0mm - Size (2 Hole) - "Micro Reconstruction Plate 2.0mm - Size (4 Hole to 12 Hole) - LCP Micro Straight Plate 2.0mm - Size (4 Hole to 8 Hole), LCP Micro Reconstruction Plate 2.0mm - Size (4 Hole to 12 Hole) - "LCP Micro Condylar Plate 2.0mm - Size (2 Hole to 10 Hole) - "LCP Micro Rotation Correction Plate 2.0mm - Size (2 Hole to 10 Hole) - "LCP Micro Y Plate 2.0mm - Size (2 Hole to 10 Hole) - "LCP Micro T Plate (Short Head) 2.0mm - Size (2 Hole to 10 Hole) - LCP Micro T Plate (Long Head) 2.0mm - Size (2 Hole to 10 Hole), Dynamic Compression plate 2.7mm - Size (2 Hole to 10 Hole) - "Quarter Tubular Plate 2.7mm -Size (2 Hole to 10 Hole) - ,, Reconstruction Plate 2.7mm - Size (2 Hole to 24 Hole) - ,, Micro T Plate 2.7mm - Size (3 Hole) - ,,Micro L Plate 2.7mm - Size (3 Hole) - ,,LCP Cloverleaf Fusion Plate 2.7mm - Size (Small - ,,Large) - ,,LCP First MTP Fusion Plate 2. mm (Left & Right) - Size (Small - ,,Large) - ,,LCP First TMT Fusion Plate 2.7mm - Size (Small Large) - LCP Second TMT Fusion Plate 2.7mm - Size (Small, Large) - ,,LCP T Fusion Plate 2.7mm - Size (Small - ,,Large) - ,,LCP L Fusion Plate 2.7mm (Left & Right) - Size (Small - ,,Large) - ,,LCP X Fusion Plate 2.7mm - Size (Extra Small - ,,Small - ,,Medium -Large) - ,,LCP Straight Fusion Plate 2.7mm - Size (4Hole) - ,,LCP Foot Calcaneal Plate 2.7 mm (Left & Right) - Size (Small - "Large) - "One Third Tubular Plate 3.5mm - Size (4 Hole to 12 Hole) - "Small DCP Plate 3.5mm - Size (4 Hole to 16 Hole) - Small LC-DCP Plate 3.5mm - Size (4 Hole to 16 Hole), Reconstruction Plate Straight (DC Hole) 3.5mm Size (4 Hole to 24 Hole) - ,,Reconstruction Plate Thin (Round Hole) 3.5mm - Size (4 Hole to 24 Hole) - ,,Small T-Plate Right Angled 3.5mm - Size (3 Hole to 10 Hole) - ,,Small T-Plate Oblique Angled 3.5mm - Size (3 Hole to 10 Hole) - "Small T-Plate Right Angled (Head 4Hole) 3.5mm - Size (3 Hole to 10 Hole) - ,, Clavicle S Plate 3.5mm - Size (6 hole to 9 hole) - Cloverleaf Plate 3.5mm - Size (3 Hole to 10 Hole), Clavicle Hook Plate 3.5mm -Size (4 Hole to 8 Hole) - "Distal Humerus Plate With Support 3.5mm - Size (3 Hole to 12 Hole) - "Medial Distal Humerus Plate 3.5mm - Size (3 Hole to 12 Hole) - "Pelvic Reconstruction Plate Straight (Thin) 3.5mm - Size (4 Hole to 20 Hole) - "Pelvic Reconstruction Plate Curved (Thin) 3.5mm - Size (4 Hole to 16 Hole) - ,,Pelvic Reconstruction Plate Angled (Thin) 3.5mm - Size (4 Hole to 16 Hole) - "Pelvic Reconstruction Plate Straight (DC Hole) 3.5mm - Size (4 Hole to 20 Hole) - Pelvic Reconstruction Plate Curved (DC Hole) 3.5mm - Size (4 Hole to 16 Hole), Pelvic Symphyseal Plate 3.5mm - Size (4 Hole to 6 Hole) - ,,Pelvic Symphyseal Plate (2 DC Hole) 3.5mm - Size (4 Hole to 6 Hole) - ,,Pelvic Spring Plate 3.5mm - Size (1 Hole to 3 Hole) - ,,Reconstruction Y Plate 3.5mm - Size (4 Hole to 10 Hole) - ,,Eight Plate 3.5mm Size (20mm - ,,25mm - ,,30mm) - ,,Semi Tubular Plate 4.5mm - Size (4 Hole to 12 Hole) "Narrow DCP Plate 4.5mm - Size (5 Hole to 16 Hole) - Narrow LC-DCP Plate 4.5mm -Size (5 Hole to 16 Hole), Broad DCP Plate 4.5mm - Size (5 Hole to 16 Hole) - ,, Broad LC DCP Plate 4.5mm - Size (5 Hole to 16 Hole) - "Reconstruction Plate straight (DC Hole) 4.5mm - Size (5 Hole to 16 Hole) - ,,Reconstruction Plate straight (Thin) 4.5mm - Size (5 Hole to 16 Hole) - "T - Plate 4.5mm - Size (3 Hole to 12 Hole) - "T - Buttress Plate 4.5 mm - Size (3 Hole to 12 Hole) - .,L - Buttress Plate 4.5mm (Left & Right) - Size (3 Hole to 12 Hole) - "Proximal Lateral Tibia Plate 4.5/6.5mm - Size (5 Hole to 15 Hole) - Condylar Buttress Plate 4.5mm (Right / Left) - Size (5 Hole to 15 Hole), Cobra Plate 4.5mm - Size (5 Hole to 14 Hole) - ,,Distal Tibia Plate 4.5mm - Size (3 Hole to 13 Hole) - ,,Proximal Tibia Plate 4.5mm - Size (3 Hole to 13 Hole) - "Proximal Femoral Plate 4.5mm - Size (3 Hole to 13 Hole) - ,,Distal Femoral Plate 4.5mm - Size (3 Hole to 13 Hole) - ,,Spoon Plate 4.5mm - Size (5 Hole - ,,6 Hole) - ,,LCP One Third Tubular Plate (Combi- Hole) 3.5mm Size (4 Hole to 12 Hole) - ,,Eight Plate 4.5mm - Size (12mm - ,,16mm - ,,20mm - ,,25mm - "30mm) - "LCP One Third Tubular Plate 3.5mm - Size (4 Hole to 12 Hole) - LCP Smal Compression Plate 3.5mm - Size (4 Hole to 16 Hole), LCP Reconstruction Plate 3.5mm Size (4 Hole to 16 Hole) - ,,LCP Reconstruction Plate (Thin) 3.5mm - Size (4 Hole to 16 Hole) - ,,LCP T Plate Right Angled 3.5mm - Size (3 Hole to 10 Hole) - ,,LCP T Plate Oblique Angled 3.5mm (Left & Right) - Size (3 Hole to 10 Hole) - ,,LCP Superior Anterior Clavicle Plate 3.5mm (Left & Right) - Size (6 hole to 9 hole) - ..LCP Superior Anterior Clavicle Plate With Lateral Extension 3.5mm (Left & Right) - Size (3 hole to 9 hole) - LCP

Clavicle Hook Plate 3.5mm Hook Depth 12mm (Left & Right) - Size (4 Hole to 8 Hole), LCP Clavicle Hook Plate 3.5mm Hook Depth 15mm (Left & Right) - Size (4 Hole to 8 Hole) - ,,LCP Clavicle Hook Plate 3.5mm Hook Depth 18mm (Left & Right) - Size (4 Hole to 8 Hole) - ,,LCP Proximal Humerus Plate (Long Head Philos) 3.5mm - Size (2 Hole to 14 Hole) - "LCP Peri-Articular Proximal Humerus Plate 3.5mm (Left & Right) - Size (2 Hole to 12 Hole) - .,LCP Distal Humerus Plate 3.5mm (Left & Right) - Size (3 Hole to 12 Hole) - ,,LCP Distal Humerus Plate With Support 3.5mm (Left & Right) - Size (3 Hole to 12 Hole) - LCP Medial Distal Humerus Plate 3.5mm (Left & Right) - Size (3 Hole to 12 Hole), LCP Metaphyseal Distal Humerus Plate 3.5mm - Size (5 Hole to 15 Hole) - ,,LCP Extra-Articular Distal Humerus Plate 3.5mm (Left & Right) - Size (4 Hole to 14 Hole) - ,, LCP Proximal Tibia Plate 3.5mm (Left & Right) - Size (5 Hole to 14 Hole) - ,,LCP Anatomical Proximal Tibia Plate (Raft) 3.5mm - Size (5 Hole to 15 Hole) - ,,LCP Proximal Medial Tibia Plate 3.5mm - Size (4 Hole to 14 Hole) - "LCP Posterior Medial Proximal Tibia Plate 3.5mm - Size (3 Hole to 12 Hole) - ,,LCP Anterolateral Distal Tibia Plate 3.5 mm (Left & Right) - Size (5 Hole to 15 Hole) - LCP Medial Distal Tibia Plate With Tab 3.5 mm (Left & Right) - Size (4 Hole to 14 Hole), LCP Medial Distal Tibia Plate (Low Band) 3.5 mm (Left & Right) - Size (4 Hole to 14 Hole) - ,,LCP Olecranon Plate 3.5mm (Left & Right) - Size (4 Hole to 12 Hole) - "LCP Distal Febula Plate 3.5mm - Size (3 Hole to 10 Hole) - ,,LCP Distal Febula Plate 2.7/3.5mm (Left & Right) - Size (3 Hole to 10 Hole) - , LCP Proximal Radius Neck Plate 2.4/2.7mm - Size (2 Hole to 4 Hole) - "LCP Proximal Radius Rim Plate 2.4/2.7mm (Left & Right) - Size (2 Hole to 4 Hole) - LCP Calcaneal Plate 3.5mm (Left & Right) - Size (64mm,69mm - ,,76mm - ,,81mm) - ,,LCP VA Distal Febula Plate with Support 2.7/3.5mm (Left & Right) - Size (4 Hole to 10 Hole) - ,,LCP Hook Plate 3.5mm - Size (3 Hole to 10 Hole) - "LCP Volar Distal Radius Plate - "Column 2.4/2.7mm (Left & Right) - Size (3 Hole to 6 Hole) - , LCP Volar Distal Radius Plate 2.4/2.7mm (Left & Right) - Size (3 Hole to 6 Hole) - , LCP Duraline Distal Kopis Plate 2.7/3.5mm (Left & Right) - Size (2 Hole to 6 Hole) - "LCP Distal Radius Plate - "Juxta articular 2.4/2.7mm (Left & Right) - Size (3 Hole to 6 Hole) - ,,LCP Distal Radius Buttress Plate 2.4/2.7mm (Left & Right) - Size (3 Hole to 5 Hole) - LCP Distal Radius Plate, Extra articular (Head 4 Hole) 2.4/2.7mm (Left & Right) - Size (3 Hole to 5 Hole) - ,,LCP Distal Radius Plate - ,, Extra articular (Head 5 Hole) 2.4/2.7mm (Left & Right) - Size (3 Hole to 5 Hole) - ,,LCP Distal Radius Plate - "Straight 2.4/2.7mm - Size (3 Hole to 5 Hole) - "LCP Distal Radius L Plate (Head 2 Hole) 2.4/2.7mm (Left & Right) - Size (3 Hole to 5 Hole) - ,,LCP Distal Radius L Plate (Head 3 Hole) 2.4/2.7mm (Left & Right) - Size (3 Hole to 5 Hole) - ,,LCP Distal Radius L Plate - ,,Oblique Angle (Head 3 Hole) 2.4/2.7mm (Left & Right) - Size (3 Hole to 5 Hole) - LCP Distal Radius T Plate 2.4/2.7mm - Size (3 Hole to 5 Hole), LCP Volar Distal Radius Plate - "Variable Angle (Head 6 Hole) 2.4/2.7mm (Left & Right) - Size (2 Hole to 6 Hole) - ,,LCP Volar Distal Radius Plate - ,,Variable Angle (Head 7 Hole) 2.4/2. 7mm (Left & Right) - Size (2 Hole to 6 Hole) - ,,LCP Volar Distal Radius Rim Plate 2.4/2. 7mm (Left & Right) - Size (2 Hole to 6 Hole) - "LCP Pelvic Reconstruction Plate Straight (Thin) 3.5mm - Size (4 Hole to 20 Hole) - ,,LCP Pelvic Reconstruction Plate Curved (Thin) 3.5mm - Size (4 Hole to 16 Hole) - "LCP Pelvic Symphyseal Plate 3.5mm - Size (4 Hole to 6 Hole) - LCP Pelvic Reconstruction Plate Angled (Thin) 3.5mm - Size (4 Hole to 16 Hole), LCP Pelvic Symphyseal Plate (2 DC Hole) 3.5mm - Size (4 Hole to 6 Hole) - ,,LCP T-Plate Right Angle (Head 4 Hole) 3.5mm - Size (3 Hole to 10 Hole) - ,,LCP Pilon Plate 3. mm - Size (7 Hole to 9 Hole) - "LCP Wrist Fusion Plate 3.5mm - Size (8 Hole to 9 Hole) "LCP Cloverleaf Plate 3.5mm - Size (3 Hole to 6 Hole) - "LCP Pediatric Hip Plate 3.5mm - Size (100° - ,,110° - ,,120° - ,,150°) - ,,LCP Narrow Plate 4.5/5.0mm - Size (5 Hole to 16 Hole) - ,,LCP Broad Plate 4.5/5.0mm - Size (5 Hole to 16 Hole) - ,,LCP Reconstruction Plate 4.5/5.0mm - Size (5 Hole to 16 Hole) - "LCP Reconstruction Plate (Thin) 5.0mm -Size (5 Hole to 16 Hole) - LCP T Plate 4.5/5.0mm - Size (3 Hole to 12 Hole), LCP T Buttress Plate 4.5/5.0mm - Size (3 Hole to 12 Hole) - ,,LCP L Buttress Plate 4.5/5.0mm (Left & Right) - Size (3 Hole to 12 Hole) - "LCP Proximal Lateral Tibia Plate 4.5/5.0mm (Left & Right) - Size (3 Hole to 15 Hole) - ,,LCP Proximal Femur Plate 4.5/5.0mm (Left & Right) - Size (3 Hole to 15 Hole) - "LCP Distal Femur Plate 4.5/5.0mm (Left & Right) -Size (3 Hole to 15 Hole) - ,,LCP Tomofix Proximal Medial Tibia Plate 4.5/5.0mm - Size (4 Hole) - "LCP Tomofix Medial Distal Femoral Plate 4.5/5.0mm - Size (4 Hole) - "LCP Trochanteric Buttress Plate Combined with PFN 4.5/5.0mm X 2 Hole - Size (2 Hole) - ,, LCP Medial Distal Femoral Plate 4.5/5.0mm (Left & Right) - Size (2 Hole to 12 Hole) -LCP Proximal Femur Plate 4.5/5.0/6.0mm (Left & Right) - Size (4 Hole to 14 Hole),LCP Metaphyseal Plate 3.5/4.5/5.0mm - Size (5 Hole to 12 Hole) - ,,LCP Proximal Femur Plate Hook 4.5/5.0mm (Left & Right) - Size (2 Hole to 14 Hole) - ,,LCP Proximal Femur Multiaxail compression Plate 4.5/5.0mm - Size (5 Hole) - ,,LCP Broad Curved Plate 4.5 /5.0mm - Size (12 Hole to 18 Hole) - ,,LCP Condylar Femoral Plate 4.5/5.0mm (Left & Right) - Size (3 Hole to 15 Hole) - ,,LCP Cable Plate 4.5/5.0mm - Size (6 Hole to 10 hole) -"LCP Cable Plate Hook 4.5/5.0mm - Size (2 Hole to 14 hole) - "LCP Pediatric Hip Plate 4.5/5.0mm - Size (100° - ,,110° - ,,120° - ,,150°) - ,,LCP Tomofix Lateral Tibia Plate 4.5/5 0mm - Size (3 Hole) - LCP Tomofix Distal Femoral Plate 4.5/5.0mm - Size (4 Hole),

Pediatric DHS Plate (DC Hole) 125°/ 130°/ 135°/ 140° - Size (2 Hole to 8 hole) - "DHS Plate (DC Hole) 38mm/32mm/25mm Barrel 125°/ 130°/ 135°/ 140°/ 145° - Size (2 Hole to 16 hole) - "DHS Plate (Round Hole) 38mm/32mm/25mm Barrel 125°/ 130°/ 135°/ 140°/ 145° - Size (2 Hole to 16 hole) - "LCP DHS Plate 38mm/32mm/25mm Barrel 125°/ 130°/ 135°/ 140°/ 145° - Size (2 Hole to 16 hole) - "DCS 95° Plate (DC Hole) - Size (4 Hole to 16 hole) - "LCP DCS 95° Plate - Size (4 Hole to 12 hole) - "Blade Plate 90°/ 95°/ 125°/ 130°/ 135°/ - Size (4 Hole to 12 hole) - "Trochanter Stabilizing Plate - Size (3 Hole) - "LCP Trochanter Stabilizing Plate - Size (3 Hole) - "



1. Generic Name :BONE SCREW

2. Brand Name: SPLINT

3. Notified Category: Orthopaedic Implants

4. Class of Medical Device : Class C

5. Shelf life: NIL

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6. Sterile/Non-Sterile: Non-Sterilized

7. Intended Use: Bone Screws are intended to treat fractures and osteotomies of various bones, including the clavicle, acetabulum, pelvis, scapula, humerus, radius, ulna, femur, tibia, phalanges, carpals, metacarpals, tarsals, metatarsals and fibula.

8. Material of Construction: Stainless Steel 316L, Titanium

9. Dimension: Various Dimensions 10. Model/Catalogue No./Name: Micro Cortex Screw (Star Head) 2.0mm - Size (6mm to 12mm) - Micro LHS Screw (Star Head) 2.0mm - Size (6mm to 12mm), Cortex Screw (Low Profile Star Head) 2.7mm - Size (10mm to 30mm) - ,,LHS Screw (Low Profile Star Head) 2.7mm - Size (10mm to 30mm) - Washer - Size (7mm,10mm - ,,13mm) - ,,Cortex Screws (self-tapping) 2.7mm - Size (10mm to 30mm) - ,,Cortex Screws 20 TPI (selftapping) 3.5mm - Size (12mm to 60mm) - ,,Cortex Screws 14 TPI (self-tapping) 3.5mm Size (12mm to 60mm) - ,,Cortex Screws (self-tapping) 4.5mm - Size (14mm to 90mm) "Malleolar Screws 4.5mm - Size (25mm to 100mm) - "LHS Screws (self-tapping) 2.7mm Size (10mm to 50mm) - ,LHS Screws (self-tapping) 3.5mm - Size (12mm to 90mm) -LHS Screws (self-tapping) 5.0mm - Size (14mm to 100mm), Cancellous Screws (Short Thread) 4.0mm - Size (14mm to 80mm) - ,,Cancellous Screws (Full Thread) 4.0mm -Size (14mm to 80mm) - ,,Cancellous Screws (16mm Thread) 6.5mm - Size (25mm to 120mm) - ,,Cancellous Screws (32mm Thread) 6.5mm - Size (45mm to 120mm) - ,, Cancellous Screws (Full Thread) 6.5mm - Size (25mm to 120mm) - "LHS Cancellous Screws (Short Thread) 3.5mm - Size (14mm to 90mm) - "LHS Cancellous Screws (Full Thread) 3.5mm - Size (14mm to 90mm) - "LHS Cancellous Screws (16mm Thread) 5.0 mm - Size (25mm to 100mm) - LHS Cancellous Screws (32mm Thread) 5.0mm - Size (25mm to 100mm), LHS Cancellous Screws (Full Thread) 5.0mm - Size (25mm to 100mm) - ,,Cannulated Screw (Short Thread) Tapper Head 6.0mm - Size (25mm to 120mm) - ,,LHS Cannulated Screw (Full Thread) 6.0mm - Size (25mm to 120mm) - ,, Cannulated Cancellous Screws (Short Thread) 4.0mm - Size (14mm to 80mm) - ,, Cannulated Cancellous Screws (Full Thread) 4.0mm - Size (14mm to 80mm) - ,, Cannulated Cancellous Screws (16mm Thread) 6.5mm - Size (25mm to 120mm) - ,, Cannulated Cancellous Screws (32mm Thread) 6.5mm - Size (45mm to 120mm) -Cannulated Cancellous Screws (Full Thread) 6.5mm - Size (25mm to 120mm), Cancellous Screws (16mm Thread) 5.0mm - Size (25mm to 100mm) - ,,Cancellous Screws (32mm Thread) 5.0mm - Size (25mm to 100mm) - ,,Cannulated Cancellous Screws (16mm Thread) 7.0mm - Size (25mm to 120mm) - ,,Cannulated Cancellous Screws (32mm Thread) 7.0mm - Size (25mm to 120mm) - ,,Cannulated Cancellous Screws (Full Thread) 7.0mm - Size (25mm to 120mm) - ,,LHS Screws (Star Head) 2.4mm - Size (10mm to 30mm) - ,,LHS Screws (Star Head) 2.7mm - Size (10mm to 50mm) - LHS Screws (Star Head) 3.5mm - Size (12mm to 90mm), LHS Screws (Star Head) 5.0mm -Size (14mm to 100mm) - ,,LHS Cancellous Screws (Star Head) 3.5mm - Size (14mm to 90mm) - ,,Cancellous Screws (16mm Thread) 6.0mm - Size (25mm to 120mm) - ,,LHS Cancellous Screws (Star Head) 5.0mm - Size (25mm to 100mm) - ,,Cancellous Screws (32mm Thread) 6.0mm - Size (25mm to 120mm) - "Cancellous Screws (Full Thread) 6.0 mm - Size (25mm to 120mm) - ,,Cortex Screws (Low Profile) 3.5mm - Size (12mm to 60mm) - "Cortex Screws (Low Profile) 4.5mm - Size (14mm to 80mm) - "Herbert Screw Cannulated 2.0mm - Size (12mm to 40mm) - Herbert Screw Cannulated 2.5mm - Size (12mm to 40mm), Herbert Screw Cannulated 3.5mm - Size (12mm to 60mm) - ,, Headless Compression Screw 2.5mm - Size (08mm to 30mm) - ,,Headless Compression Screw 3.5mm - Size (16mm to 50mm) - "Headless Compression Screw 4.0mm - Size (16mm to 50mm) - ... Headless Compression Screw 4.7mm - Size (20mm to 50mm) - ... Headless Compression Screw 5.5mm - Size (25mm to 60mm) - ,,Headless Compression Screw 6.5mm - Size (25mm to 100mm) - ,, Headless Compression Screw 7.5mm - Size (25mm to 100mm) - ,,DHS/DCS Lag Screw - Size (50mm to 120mm) - ,,Pediatric DHS Lag Screw - Size (50mm to 100mm) - FNS Bolt - Size (75mm to 115mm),FNS Antirotation Screw - Size (75mm to 115mm) - ,,Hip Screw 6.5mm - Size (20mm to 50mm) - "End Cap For Elastic Nail 2.5mm - Size (2.5mm - "4.0mm) - "End Cap For Humeral Nail - Size (0mm - ,,5mm - ,,10mm) - ,,End Cap For Tibia & Femoral Nail - Size (0mm) - "PFNA-2 Nail Cap - Size (0mm - "5mm - "10mm) - "End Cap For Proximal Femoral Nail - Size (0mm) - ,,End Cap For Distal Femoral Nail - Size (0mm) - ,, Interlocking Screws 2.9mm - Size (18mm to 40mm) - ,,Interlocking Screws 3.4mm - Size (18mm to 50mm) - Interlocking Screws 3.9mm - Size (18mm to 50mm), Interlocking Screws 4.9mm - Size (18mm to 80mm) - "Lag Screw For PFN 6.4mm - Size (50mm to 120mm) - ,,Lag Screw For PFN 8.0mm - Size (50mm to 120mm) - ,,PFNA-2 Blade - Size (70mm to 120mm) - "Lag Screw For PFNA-2 - Size (70mm to 120mm) - "Humerus Blade

- Size (30mm to 60mm) -,

1. Generic Name :INTERLOCKING INTRAMEDULLARY NAILS
2. Brand Name :SPLINT

- 3. Notified Category: Orthopaedic Implants
- Notified Category : Orthopaedic Impial
 Class of Medical Device : Class C
- 5. Shelf life: NIL

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- 6. Sterile/Non-Sterile: Non-Sterilized
- 7. Intended Use: Interlocking Intramedullary Nails are intended to use for simple and complex long bone fractures which is severely comminuted, spiral, large oblique and segmental fractures; non-unions and mal-unions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures and grafting supra condylar fractures for bone lengthening and shortening. Interlocking Nails are indicated for fixation of fractures that occur in between the proximal and distal third of the long bones being treated.
- 8. Material of Construction: Stainless Steel 316L, Titanium
- 9. Dimension: Various Dimensions
- 10. Model/Catalogue No./Name: Elastic Nail 440mm Size (Ø 1.5mm to Ø 4.5mm), Square Nail For Radius Ø 2.0mm - ,,2.5mm - ,,3.0mm - ,,3.5mm - Size (180mm to 300mm) - ,,Square Nail For Ulna - Ø 2.0mm,2.5mm - ,,3.0mm - ,,3.5mm - Size (180mm to 300mm) - ,,Rush Nail Ø 2.0mm - ,,2.5mm - ,,3.0mm - ,,3.5mm - ,,4.0mm - ,,4.5mm -5.0mm - Size (180mm to 300mm) - "Enders Nail 2.5mm - "3.5mm - "4.5mm - "- Size (180mm to 400mm) - ,,Screw Nail Ø 2.0mm - ,,2.5mm - ,,3.0mm - ,,3.5mm - ,,4.0mm -Size (120mm to 300mm) - "Humeral Nail Ø 6mm - ",7mm - ",8mm - Size (180mm to 300mm) - "Tibia Interlocking Nail Ø 8mm - "9mm - "10mm - "11mm - Size (280mm to 400mm) - ,,Tibia Interlocking Nail (Tip Locking) - Ø 8mm,9mm - ,,10mm - ,,11mm - Size (280mm to 400mm) - "Femoral Interlocking Nail Ø 9mm - "10mm - "11mm - "12mm -Size (320mm to 460mm) - ,, Proximal Femoral Nail 130° Ø 9mm - ,, 10mm - ,, 11mm - ,, 12mm - Size (180mm to 460mm) - ,,Proximal Femoral Nail 135° Ø 9mm - ,,10mm - ,, 11mm - ,,12mm - Size (180mm to 460mm) - ,,PFNA-2 125°/130°/135° Ø 9mm - ,,10mm - ,,11mm - ,,12mm - Size (170mm to 460mm) - ,,Distal Femoral Nail Ø 9mm - ,,10mm -"11mm - "12mm - Size (150mm to 350mm) - "Smart Tibia Nail Ø 8mm - "9mm - " 10mm - ,,11mm - Size (280mm to 400mm) - ,,Supracondylar Nail (IMSC) - Ø 9mm, 10mm - ,,11mm - ,,12mm - Size (150mm to 350mm) - ,,Syrus Femoral Nail Ø 9mm - ,, 10mm - ,,11mm - ,,12mm - Size (320mm to 460mm) - ,,Gamma Femoral Nail Ø 9mm -10mm - ,,11mm - ,,12mm - Size (320mm to 460mm) - ,,Antegrade Femoral Nail (AFN) Ø 9mm - ,,10mm - ,,11mm - ,,12mm - Size (320mm to 460mm) - ,,Tibia Interlocking Nail (High Bend) Ø 8mm - ,,9mm - ,,10mm - ,,11mm - Size (280mm to 400mm) - ,,Ankle Nail Ø 8mm - "9mm - "10mm - Size (180mm to 270mm) - "Humeral Nail with Multilock - Ø 6mm,7mm - ,,8mm - Size (180mm to 300mm) - ,,Humeral Nail with Blade Ø 6mm - ,, 7mm - ,,8mm - ,,9mm - Size (180mm to 300mm) - ,,Universal Interlocking Tibia Nail Size - 8.0mm to 14mm Length, Universal Interlocking Femoral Nail Size - 8.0mm to 14mm Length, Unreamed Tibia Nail Size - 8.0mm to 14mm Length

- 1. Generic Name: SPINAL IMPLANT
 - 2. Brand Name: SPLINT
 - 3. Notified Category: Orthopaedic Implants
 - 4. Class of Medical Device : Class C
 - 5. Shelf life: NIL
 - 6. Sterile/Non-Sterile: Non-Sterilized
 - 7. Intended Use: Spinal implants are used to stabilize the unstable spine caused by trauma or by slipped vertebrae (spondylolisthesis) originating from degenerative intervertebral disks. Surgical stabilization can be achieved from either the anterior or posterior approach.
 - 8. Material of Construction: Stainless Steel 316L, Titanium
 - **9. Dimension:** Various Dimensions
 - 10. Model/Catalogue No./Name: PEDICAL SCREW Monoaxial Screw (Regular) Ø 4.5 mm, 5.5mm, 6.5mm - Size (25mm to 50mm), Polyaxial Screw (Regular) Ø 4.5mm, 5.5 mm, 6.5mm - Size (25mm to 50mm), Monoaxial Reduction Screw (Regular) - Ø 4.5mm, 5.5mm, 6.5mm - Size (25mm to 50mm), Polyaxial Reduction Screw (Regular) Ø 4.5mm, 5.5mm, 6.5mm - Size (25mm to 50mm), Monoaxial Screw (Premium) Ø 4.5mm, 5.5mm, 6.5mm - Size (25mm to 50mm), Polyaxial Screw (Premium) Ø 4.5mm, 5.5mm, 6.5mm Size (25mm to 50mm), Monoaxial Reduction Screw (Premium) Ø 4.5mm, 5.5mm, 6.5 mm - Size (25mm to 50mm), Polyaxial Reduction Screw (Premium) Ø 4.5mm, 5.5mm, 6.5mm - Size (25mm to 50mm), Polyaxial Screw (Dual Thread) Ø 4.5mm, 5.5mm, 6.5 mm - Size (25mm to 50mm), Monoaxial Screw (Dual Thread) - Ø 4.5mm, 5.5mm, 6.5 mm - Size (25mm to 50mm), Monoaxial Reduction Screw (Dual Thread) Ø 4.5mm, 5.5 mm, 6.5mm - Size (25mm to 50mm), Polyaxial Reduction Screw (Dual Thread) Ø 4.5 mm, 5.5mm, 6.5mm - Size (25mm to 50mm), Connecting Rod 5.5mm - Size (50mm to 400mm), Connecting Rod (Hexagonal End) 5.5mm - Size (50mm to 200mm), Connecting Rod 3.0mm - Size (40mm to 100mm), Transverse Connector, Crosslink Connector - Size (Small, Medium, Large), Spinal Hook Staple - Size (Small, Large), Minimal Invensive Spinal (MIS) Polyaxial Screw Ø 5.5mm, 6.5mm, 7.5mm - Size (30mm to 50mm), Pre Bend Connecting Rod (MIS) 5.5mm - Size (35mm to 150mm) - CAGE / SPACERTLIF (Transformational Lumbar Interbody Fusion) Bullet Cage 25mm, 30mm -Size (7mm to 12mm), TLIF (Transformational Lumbar Interbody Fusion) Kidney Cage 04°, 08°, 11° - Size (7mm to 12mm), PLIF (Posterior Lumbar Interbody Fusion) Cage 20mm, 25mm - Size (7mm to 12mm), Mesh Cage Ø 10mm, 12mm, 14mm, 16mm, 18mm, 20mm - Size (50mm, 100mm), Expandable Cage Ø 12mm, 14mm, 16mm, 18mm, 20mm - Size (20mm to 75mm), CERVICLE PLATE & SCREW Cervical Plate - Size (22mm to 60mm), Cervical Bone Screw - Size (10mm to 18mm), Cervical Revision Bone Screw - Size (10mm to 18mm), Self-Drilling Cervical Bone Screw - Size (10mm to 18mm) - Anterior Cervical Interbody Fusion Cage 12mm, 14mm, 16mm - Size (4mm to 7mm), Cervical Impacted Fusion Cage 14mm, 16mm - Size (mm to 8mm), Posterior Multiaxial Cancellous Screw (Lateral Mass) 3.5mm, 4.0mm - Size (14mm to 32mm), Connecting Rod (PMCS) Ø 3.2mm - Size (25mm to 200mm), Posterior Hook Ø 3.2mm - Size (4.5 mm, 6.0mm), Posterior Connector 3.2mm, 5.0mm - Size (9mm to 15mm), Posterior Occipital T Plate - Size (32mm to 44mm), Posterior Occipital Y Plate (With Connector Set) - Size (32mm to 44mm) - Posterior Occipital Cancellous Screw - Size (12mm), Posterior Occipital Connecting Rod (Bend) 3.2mm - Size (65mm to 85mm), Posterior Occipital Combi. Connecting Rod (Step Rod) 3.2 mm (150 mm) x 5.5 mm (270 mm) -Size (), Posterior Occipital Plate with Rod 3.2 mm x 250 mm - Size (4 Hole)

- 2. Brand Name: SPLINT
- 3. Notified Category: Orthopaedic Implants
- 4. Class of Medical Device : Class C
- 5. Shelf life: NIL
- 6. Sterile/Non-Sterile: Non-Sterilized
- 7. Intended Use: Pins and Wires is intended for use in fixation of bone fractures. fusion of joints or bone reconstruction, for osteotomies in the presence of adequate immobilization and as guide pins for insertion of other implants.
- 8. Material of Construction: Stainless Steel 316L, Titanium
- 9. Dimension: Various Dimensions

10. Model/Catalogue No./Name: Wire Spool - Size (16 swg to 26 swg) - Cerclage Wire With Eye - Size (0.8mm to 1.5mm), Kirschner wires (K-wire) 150mm - Size (0.8mm to 3.5 mm) - "Kirschner wires (K-wire) 225mm - Size (0.8mm to 3.5mm) - "Kirschner wires (Kwire) 300mm - Size (0.8mm to 3.5mm) - Kirschner wires (K-wire) 150mm (Sterile) - Size (0.8mm to 3.5mm), Kirschner wires (K-wire) 225mm (Sterile) - Size (0.8mm to 3.5mm) -"Kirschner wires (K-wire) 300mm (Sterile) - Size (0.8mm to 3.5mm) - "Kirschner wires (K-wire) Single Side Treaded 150mm - Size (0.8mm to 3.5mm) - ,, Kirschner wires (Kwire) Single Side Treaded 225mm - Size (0.8mm to 3.5mm) - "Kirschner wires (K-wire) Single Side Treaded 300mm - Size (0.8mm to 3.5mm) - ,,Kirschner wires (K-wire) Double Side Treaded 150mm - Size (0.8mm to 3.5mm) - ,,Kirschner wires (K-wire) Single Side Treaded 225mm - Size (0.8mm to 3.5mm) - Kirschner wires (K-wire) Double Side Treaded 300mm - Size (0.8mm to 3.5mm), Steinman Pin 2.5mm - Size (100mm to 250mm) - "Steinman Pin 3.0mm - Size (100mm to 250mm) - "Steinman Pin 3.5mm -Size (100mm to 250mm) - ,, Steinman Pin 4.0mm - Size (100mm to 250mm) - ,, Steinman Pin 4.5mm - Size (100mm to 250mm) - "Steinman Pin 5.0mm - Size (100mm to 250mm) - "Steinman Pin 5.5mm - Size (100mm to 250mm) - "Steinman Pin 6.0mm Size (100mm to 250mm) - ,,Steinman Pin (Central Threaded) Ø 3.5/4.0mm - ,,Ø 4.5/5. 0mm - Size (225mm) - ,,Schanz Screw (16mm Thread) Ø 2.0mm - Size (100mm to 250mm) - Schanz Screw (16mm Thread) Ø 2.5mm - Size (100mm to 250mm), Schanz Screw (16mm Thread) Ø 3.5mm - Size (100mm to 250mm) - ,,Schanz Screw (16mm Thread) Ø 4.5mm - Size (100mm to 250mm) - ,,Schanz Screw (16mm Thread) Ø 5.0mm - Size (100mm to 250mm) - ,,Schanz Screw (16mm Thread) Ø 3.0mm - Size (100mm to 250mm) - ,,Schanz Screw (16mm Thread) Ø 4.0mm - Size (100mm to 250mm) - ,,Scharz Screw (32mm Thread) Ø 2.0mm - Size (100mm to 250mm) - ,,Schanz Screw (32mm Thread) Ø 2.5mm - Size (100mm to 250mm) - ,,Schanz Screw (32mm Thread) Ø 4.5mm - Size (100mm to 250mm) - "Schanz Screw (32mm Thread) Ø 3.5mm - Size (100mm to 250mm) - Schanz Screw (32mm Thread) Ø 5.0mm - Size (100mm to 250mm), Schanz Screw (32mm Thread) Ø 3.0mm - Size (100mm to 250mm) - ,,Schanz Screw (32mm Thread) Ø 4.0mm - Size (100mm to 250mm) - ,,Schanz Screw (50mm Thread) Ø 3.5mm Size (100mm to 250mm) - "Schanz Screw (50mm Thread) Ø 4.5mm - Size (100mm to 250mm) - ,,Schanz Screw (50mm Thread) Ø 5.0mm - Size (100mm to 250mm) - ,,Scharz Screw (50mm Thread) Ø 3.0mm - Size (100mm to 250mm) - ,,Schanz Screw (50mm Thread) Ø 4.0mm - Size (100mm to 250mm) - ,,Schanz Screw (16mm Cancellous Threaded) - Ø 3.5/4.5,6.5/4.5 - Size (100mm to 250mm) - ,,Schanz Screw (32mm Cancellous Threaded) Ø 3.5/4.5 - ,,6.5/4.5 - Size (100mm to 250mm) - ,,Schanz Screw (50mm Cancellous Threaded) Ø 3.5/4.5 - ,,6.5/4.5 - Size (100mm to 250mm) - ,,Schanz Screw (32mm Tapper Threaded) Ø 6.0mm - Size (100mm to 250mm) - ,,Schanz Screw (50mm Tapper Threaded) Ø 6.0mm - Size (100mm to 250mm) - ,,6.5mm - ,,7.5mm -Size (30mm to 50mm) - "Pre Bend Connecting Rod (MIS) 5.5mm - Size (35mm to 150mm) - CAGE / SPACERTLIF (Transformational Lumbar Interbody Fusion) Bullet Cade 25mm,30mm - Size (7mm to 12mm) - ,,TLIF (Transformational Lumbar Interbody Fusion) Kidney Cage 04° - "08° - "11° - Size (7mm to 12mm) - "PLIF (Posterior Lumbar Interbody Fusion) Cage 20mm - ,,25mm - Size (7mm to 12mm) - ,,Mesh Cage Ø 10mm "12mm - "14mm - "16mm - "18mm - "20mm - Size (50mm - "100mm) - "Expandable Cage Ø 12mm - ,,14mm - ,,16mm - ,,18mm - ,,20mm - Size (20mm to 75mm) - ,, CERVICLE PLATE & SCREW Cervical Plate - Size (22mm to 60mm) - ,,Cervical Bone Screw - Size (10mm to 18mm) - ,,Cervical Revision Bone Screw - Size (10mm to 18mm) - ,,Self-Drilling Cervical Bone Screw - Size (10mm to 18mm) - Anterior Cervical Interbody Fusion Cage 12mm,14mm - ,,16mm - Size (4mm to 7mm) - ,,Cervical Impacted Fusion Cage 14mm - ,,16mm - Size (mm to 8mm) - ,,Posterior Multiaxial Cancellous Screw (Lateral Mass) 3.5mm - ,,4.0mm - Size (14mm to 32mm) - ,,Connecting Rod (PMCS) Ø 3.2mm - Size (25mm to 200mm) - ,,Posterior Hook Ø 3.2mm - Size (4.5mm - ,,6.0mm) -"Posterior Connector 3.2mm - "5.0mm - Size (9mm to 15mm) - "Posterior Occipital T Plate - Size (32mm to 44mm) - ,,Posterior Occipital Y Plate (With Connector Set) - Size (32mm to 44mm) - Posterior Occipital Cancellous Screw - Size (12mm), Posterior Occipital Connecting Rod (Bend) 3.2mm - Size (65mm to 85mm) - ,.Posterior Occipital Combi. Connecting Rod (Step Rod) 3.2 mm (150 mm) x 5.5 mm (270 mm) - Size () - ,,

	Posterior Occipital Plate with Rod 3.2 mm x 250 mm - Size (4 Hole) - ,
6	1. Generic Name :ARTHROSCOPY IMPLANTS 2. Brand Name :SPLINT 3. Notified Category :Orthopaedic Implants 4. Class of Medical Device :Class C 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :The Arthroscopy Implants are intended to used especially for attaching the damaged / strained soft tissues and bone fragments in repair treatment of cruciate ligament (anterior or posterior) of the knee joint and the rotator cuff of the shoulder joints. They are intended to be used for arthroscopic and less invasive approach.
	8. Material of Construction: Stainless Steel 316L, Titanium 9. Dimension: Various Dimensions 10. Model/Catalogue No./Name: ACL Screw (Cannulated Interference Screw) - Ø 7mm, 8mm, 9mm, 10mm, 11mm - Size (20mm to 35mm), Endobutton With Loop - Size (10mm to 35mm), Endobutton, Suture Disc, Suture Anchor Screw Loaded - Size (Ø 3.0 mm, 5.0mm), Suture Anchor Screw Loaded with Needle - Size (Ø 3.0mm, 5.0mm), U Staple, Suture Anchor Screw - Size (Ø 3.0mm, 5.0mm), Fier Wire with Needle, Knotless Suture Anchor Screw Loaded, Spiked Washer, Tibial Post Fixation Screw, 6.5mm, Ligament Spiked Staple, Tibial Attachable Disk, Endobutton With Adjustable Loop, Cancellous Screw Low Profile 4.0mm, Cancellous Screw Low Profile 6.5mm, Healfix PEEK Anchor, PEEK Anchor Loop, WasherLoop, Washer with Button, ABS Button, Tighrope Button Extender

THEALTH, GOVERNMENT OF

1. Generic Name: CRANIO-MAXILLOFACIAL IMPLANT

- 2. Brand Name: SPLINT
- 3. Notified Category: Orthopaedic Implants
- 4. Class of Medical Device : Class C
- 5. Shelf life: NIL

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- 6. Sterile/Non-Sterile: Non-Sterilized
- **7. Intended Use**: Maxillofacial Implant is indicated for the augmentation and/or restoration of bony and/or soft tissue deformities in the cranial and craniofacial skeleton comprised of the mouth, jaws, face, neck, and skull.
- 8. Material of Construction: Stainless Steel 316L, Titanium

9. Dimension: Various Dimensions 10. Model/Catalogue No./Name: Mini Screws (Single Slot Head) 1.5 mm - Size (4mm to 16mm) - Mini Screws (Single Slot Head) 2.5 mm - Size (4mm to 18mm), Mini Screws (Single Slot Head) 2.0 mm - Size (4mm to 16mm), Mini Screws (Cross Slot Head) 1.5 mm - Size (4mm to 16mm), Mini Screws (Cross Slot Head) 2.0 mm - Size (4mm to 16mm) - Mini Screws (Cross Slot Head) 2.5 mm - Size (4mm to 18mm), Mandible Plate 1.5mm - Size (4 Hole to 30 Hole), Mandible Plate 2.0mm - Size (4 Hole to 30 Hole), Mandible Plate 2.5mm - Size (4 Hole to 30 Hole), Mandible Plate with Center Space 1.5 mm - Size (2 Hole to 6 Hole), Mandible Plate with Center Space 2.0mm - Size (2 Hole to 6 Hole), Mandible Plate with Center Space 2.5mm - Size (2 Hole to 6 Hole), Orbital Plate 1.5mm - Size (4 Hole to 10 Hole), Orbital Plate 2.0mm - Size (4 Hole to 10 Hole), Orbital Plate 2.5mm - Size (4 Hole to 10 Hole) - Orbital Plate with Center Space 1.5mm - Size (4 Hole to 8 Hole), Orbital Plate with Center Space 2.0mm - Size (4 Hole to 8 Hole), Orbital Plate with Center Space 2.5mm - Size (4 Hole to 8 Hole), L Shape Plate 1.5mm x 02 Hole (Left & Right) - Size (2 Hole, 3 Hole), L Shape Plate 2.0mm x 02 Hole (Left & Right) -Size (2 Hole, 3 Hole), L Shape Plate 2.5mm x 02 Hole (Left & Right) - Size (2 Hole, 3 Hole), L Shape Plate 1.5mm x 03 Hole (Left & Right) - Size (3 Hole), L Shape Plate 2.0mm x 03 Hole (Left & Right) - Size (3 Hole) - L Shape Plate 2.5mm x 03 Hole (Left & Right) Size (3 Hole), L Shape Plate 1.5mm With Space 02 Hole (Left & Right) - Size (2 Hole, 3 Hole), L Shape Plate 2.0mm With Space 02 Hole (Left & Right) - Size (2 Hole, 3 Hole), I Shape Plate 2.5mm With Space 02 Hole (Left & Right) - Size (2 Hole, 3 Hole), L Shape Plate 1.5mm With Space 03 Hole (Left & Right) - Size (3 Hole), L Shape Plate 2.0mm With Space 03 Hole (Left & Right) - Size (3 Hole), L Shape Plate 2.5mm With Space 03 Hole (Left & Right) - Size (3 Hole), L Shape 120° Oblique Angle Plate 1.5mm x 02 Hole (Left & Right) - Size (2 Hole, 3 Hole), L Shape 120° Oblique Angle Plate 2.0mm x 02 Hole (Left & Right) - Size (2 Hole, 3 Hole) - L Shape 120° Oblique Angle Plate 2.5mm x 02 Hole (Left & Right) - Size (2 Hole, 3 Hole), L Shape 120° Oblique Angle Plate 1.5mm x 03 Hole (Left & Right) - Size (3 Hole), L Shape 120° Oblique Angle Plate 2.0mm x 03 Hole (Left & Right) - Size (3 Hole), L Shape 120° Oblique Angle Plate 2.5mm x 03 Hole (Left \$ Right) - Size (3 Hole), L Shape 150° Oblique Angle Plate 1.5mm x 02 Hole (Left & Right) -Size (2 Hole, 3 Hole), L Shape 150° Oblique Angle Plate 2.0mm x 02 Hole (Left & Right) Size (2 Hole, 3 Hole), L Shape 150° Oblique Angle Plate 2.5mm x 02 Hole (Left & Right) Size (2 Hole, 3 Hole), L Shape 150° Oblique Angle Plate 1.5mm x 03 Hole (Left & Right) Size (3 Hole), L Shape 150° Oblique Angle Plate 2.0mm x 03 Hole (Left & Right) - Size (Hole) - L Shape 150° Oblique Angle Plate 2.5mm x 03 Hole (Left & Right) - Size (3 Hole T Shape Plate Head 2 Hole x 1.5mm - Size (2 Hole, 3 Hole), T Shape Plate Head 2 Hole x 2.0mm - Size (2 Hole, 3 Hole), T Shape Plate Head 2 Hole x 2.5mm - Size (2 Hole, 3 Hole), T Shape Plate Head 3 Hole x 1.5mm - Size (3 Hole), T Shape Plate Head 3 Hole 2.0mm - Size (3 Hole), T Shape Plate Head 3 Hole x 2.5mm - Size (3 Hole), T Shape Plate Head 2 Hole With Space 1.5mm - Size (2 Hole, 3 Hole), T Shape Plate Head 2 Hole With Space 2.0mm - Size (2 Hole, 3 Hole), T Shape Plate Head 2 Hole With Space 2.5mm -Size (2 Hole, 3 Hole), T Shape Plate Head 3 Hole With Space 1.5mm - Size (3 Hole), T Shape Plate Head 3 Hole With Space 2.0mm - Size (3 Hole), T Shape Plate Head 3 Hole With Space 2.5mm - Size (3 Hole) - X Shape Plate 1.5mm - Size (5 Hole), X Shape Plate 2.0mm - Size (5 Hole), X Shape Plate 2.5mm - Size (5 Hole), Y Shape Plate 1.5mm - Size (4 Hole, 5 Hole), Y Shape Plate 2.0mm - Size (4 Hole, 5 Hole), Y Shape Plate 2.5mm -Size (4 Hole, 5 Hole), Y Shape Plate With Space 1.5mm - Size (4 Hole, 5 Hole), Y Shape Plate With Space 2.0mm - Size (4 Hole, 5 Hole), Y Shape Plate With Space 2.5mm - Size (4 Hole, 5 Hole), Double Y Shape Plate 1.5mm - Size (6 Hole), Double Y Shape Plate 2. mm - Size (6 Hole), Double Y Shape Plate 2.5mm - Size (6 Hole), Z Shape Plate 1.5mm (Left & Right) - Size (4 Hole) - Z Shape Plate 2.0mm (Left & Right) - Size (4 Hole), Z Shape Plate 2.5mm (Left & Right) - Size (4 Hole), Curved Plate 1.5mm (Left & Right) - Size (6 Hole), Curved Plate 2.0mm (Left & Right) - Size (6 Hole), Curved Plate 2.5mm (Left & Right) - Size (6 Hole), Nose H Shape Plate 1.5mmNose H Shape Plate 2.0mmNose H Shape Plate 2.5mmNose Y Shape Plate 1.5mmNose Y Shape Plate 2.0mmNose Y Shape Plate 2.5mmChin Plate 2.0mml Shape Plate 1.5mml Shape Plate 2.0mml Shape Plate 2.5mm3D Plate 2.0mm - Size (4 Hole, 6Hole, 8 Hole, 16 Hole), TMJ Plate 2.5mm (Left & Right) - Size (20 Hole to 28 Hole) - Reconstruction Plate Angled 2.5mm (Left & Right) -

Size (20 Hole to 28 Hole), Reconstruction Plate Angled 2.7mm (Left & Right) - Size (20 Hole to 28 Hole), Reconstruction Plate For Mandible Straight 2.7mm - Size (8 Hole to 30 Hole), Reconstruction Plate For Mandible Double Angled 2.7mm - Size (16 Hole to 24 Hole), Reconstruction Plate For Mandible U Shape 2.7mm - Size (14 Hole, 16 Hole), Easy Mesh 1.5 mm - Size (50mm x 50mm to 15mm x 150mm), Easy Mesh 2.0 mm - Size (50mm x 50mm to 15mm x 150mm), Easy Mesh 1.5 mm (PRE-BEND) - Size (50mm x 50mm to 15mm x 150mm), Easy Mesh 2.0 mm (PRE-BEND) - Size (50mm x 50mm to 15mm x 150mm), Wire Mesh 1.5 mm - Size (50mm x 50mm to 15mm x 150mm) - Wire Mesh 2.0 mm - Size (50mm x 50mm to 15mm x 150mm), Emergency Screws (Single Slot Head) 1.7 mm - Size (6mm to 14mm), Emergency Screws (Single Slot Head) 2.3 mm - Size (6mm to 14mm), Emergency Screws (Single Slot Head) 2.7 mm - Size (6mm to 14mm), Emergency Screws (Cross Slot Head) 1.7 mm - Size (6mm to 14mm), Emergency Screws (Cross Slot Head) 2.3 mm - Size (6mm to 14mm), Emergency Screws (Cross Slot Head) 2.7 mm - Size (6mm to 14mm), Self-Drilling Screws (Cross Slot Head 1.5 mm - Size (3mm to 14mm), Self-Drilling Screws (Cross Slot Head) 2.0 mm - Size (3mm to 14mm) - Self-Drilling Screws (Cross Slot Head) 2.5 mm - Size (3mm to 14mm), Burr Hole Plate 1.5 mm - Size (22.5mm, 28mm), Orbital Floor Plate 1.5 mm - Size (Small, Medium, Large), Burr Hole Plate 2.0 mm - Size (22.5mm, 28mm), Orbital Floor Plate 2.0 mm - Size (Small, Medium, Large), Mastoid Mesh Plate 1.5 mm - Size (Small, Medium, Large), Mastoid Mesh Plate 2.0 mm - Size (Small, Medium, Large)

1. Generic Name :HIP REPLACEMENT SYSTEM

- 2. Brand Name : SPLINT
- 3. Notified Category: Orthopaedic Implants
- 4. Class of Medical Device : Class D
- 5. Shelf life :NIL
- 6. Sterile/Non-Sterile: Non-Sterilized
- **7. Intended Use**: Total Hip Replacement System is intended for use in total hip arthroplasty. Total hip arthroplasty is intended to provide patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is an evidence of sufficient sound bone to fix and support the components.
- 8. Material of Construction: Stainless Steel 316L, Titanium
- 9. Dimension: Various Dimensions
- 10. Model/Catalogue No./Name: Hip Cement Restrictor Thompson Prosthesis Size (Ø 37mm to 55mm), Austin Moore Prosthesis - Size (Ø 37mm to 55mm) - "Austin Moore Prosthesis (Narrow Stem) - Size (Ø 37mm to 55mm) - "Bipolar Prosthesis (FENESTRATED) - Size (Ø 37mm to 55mm), Bipolar Prosthesis (NON-FENESTRATED) Size (Ø 37mm to 55mm) - "Modular Bipolar Head (-6mm - "-3mm - "0mm - "+3mm - " +6mm) - Size (Ø 37mm to 55mm) - ,,Muller Stem - Size (130mm to 160mm) - ,,Muller Uncoated Stem - Size (130mm to 160mm) - ,,Standard Stem - Size (130mm to 160mm) "Quixotic Uncemented Stem - Size (120mm to 150mm) - "Quixotic Uncemented (HA Coated) Stem - Size (120mm to 150mm) - ,,Ring Lock Modular Head - Size (Ø 41mm to 55mm), Modular Internal Head (External Tapper) Ø 28mm - Size ((-6mm - ,,-3mm - ,, 0mm - ,,+3mm - ,,+6mm)) - ,,Modular Internal Head (Internal Tapper) Ø 22mm - ,, 28mm - ,,32mm - ,,36mm - Size ((-5mm - ,,-3mm - ,,0mm - ,,+3mm - ,,+5mm)) - , Standard Long Stem Ø 9mm - ,,10mm - ,,11mm - ,,12mm - ,,- Size (225mm to 300mm) .,-, standard Long Stem Uncemented Ø 9mm - ,,10mm - ,,11mm - ,,12mm - ,,13mm -Size (225mm to 300mm) - ,,Acetabular Cup - Ø 28mm,32mm - Size (Ø 40mm to 56mm) - "Uncemented Cup Shell (40 to 60) - Size (Ø 40mm to 60mm) - "Liner Cup Ø 22 - "28 ,,32 - ,,36 - Size (Ø 40mm to 60mm) - ,,Hip Screw 6.5mm - Size (20mm to 50mm) - ,, Centraliser - Size (Ø 9 - ,,10 - ,,11) - ,,Redial Head Prosthesis Ø 16mm - ,,18mm - ,, 20mm - ,,22mm - ,,24mm - Size (6mm to 8mm) - ,

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9 1. Generic Name :SHOULDER PROSTHESIS

2. Brand Name: SPLINT

3. Notified Category: Orthopaedic Implants

4. Class of Medical Device : Class C

5. Shelf life: NIL

6. Sterile/Non-Sterile: Non-Sterilized

7. Intended Use: Shoulder System is intended for use as an orthopedic implant for partial or total shoulder arthroplasty to treat the following: significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint, united humeral head fractures of long duration, irreducible 3- and 4-part proximal humeral fractures, avascular necrosis of the humeral head.

8. Material of Construction: Stainless Steel 316L, Titanium

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9. Dimension: Various Dimensions

10. Model/Catalogue No./Name: Shoulder Prosthesis - Size (Ø 35mm to 43mm), Shoulder Cup - Size (Ø 35mm to 43mm) - "Shoulder Neck ShaftShoulder Stem Ø 6mm - "7mm - "8mm - Size (100mm - "120mm) - "Shoulder Prosthesis - Dia. (Ø) 37.0 mm to 41.0 mm,Radial Head Prosthesis (Radial Head) - Dia. (Ø) 14.0 mm to 30.0 mm - Sizes (+4 - "+2 - "0 - ") - "Radial Head Prosthesis (Radial Stem) - Dia. (Ø) 3.5 mm to 13.5 mm - Sizes (+4 - "+2 - "0 - ") - "Radial Head Prosthesis (Radial Stem HA Coated) - Dia. (Ø) 3.5 mm to 13.5 mm Sizes (+4 - "+2 - "0 - ") - "Radial Head Prosthesis (Radial Head) - Dia. (Ø) 14.0 mm to 30.0 mm - "

Competent Authority