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Indications and Contraindications

Wires Indication:

Wire implants are indicated for a wide range of orthopedic trauma applications including:

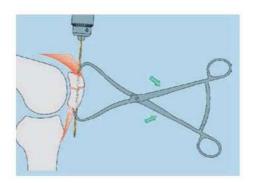
- Stand-alone device for fracture fixation
- Fracture fixation in conjunction use with other fixation systems
- For temporary holding bony fragements

S.S. Wire Reels Indications:

- Orthopedic trauma surgery (incl. periprosthetic fractures, femur fractures, olecranon fractures, patella fractures, humerus and ankle fractures)
- Acromio clavicular dislocation
- Hip and acetabular fractures
- Prophylactic banding in total joint replacements
- Temporary fixation during open reductions
- Reattachment of the greater trochanter following osteotomy in total hip arthroplasty or fractures

Steps for S.S. Wiring Technique



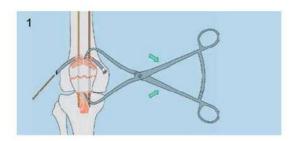


Note: The wire implants are multifunctional devices. The following techniques describe two possible applications of the wire implants.

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1. Reduce fracture



Reduce fracture with large reduction forceps with points. Preliminary fix it with two parallel 1.5 to 2mm K wires.

2. Insert S.S. wires:



Pass the S.S. wires through the ligamentous structures and around the K wires close to the bone. To do so, it may be helpful to use a curved large bore needle, cannula or wire passer.

(1)The S.S. wire should lie anteriorly to the patella so as to act as a tension band.



(2) A circular wire is preferable to a figure-of-eight. The lateral view demonstrates the tension band principle, where by flexing the knee, tensile forces are converted into compressive ones (arrows).

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3. Implant removal

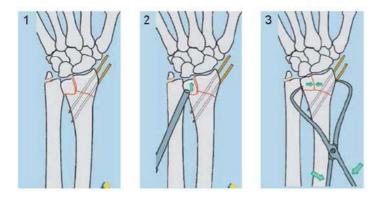
In case the physician decides to remove the implants, implants can be removed by using general surgical instruments like Plier, Wire Cutter/Bender/Plier etc.

Note: The final decision of removing the Pins or wires shall be taken by the operating surgeon only. It is recommended that the implant used as an aid for healing should be removed once its service is over after proper consultation and examination by the operating surgeon in final follow up, particularly in younger and more active patients.

Steps for Percutaneous Pinning:

If closed or percutaneous reduction is possible and low forces exist like in upper extremity, the fracture may be stabilized with percutaneous pinning. The following section describes step by step the percutaneous reduction and K wire fixation for the treatment of a C1 distal radius fracture.

1. Reduce fracture



Fragments that can be easily reduced can be fixed by percutaneous pinning. Certain fragments need to be reduced with the help of an awl or a periosteal elevator through a small skin incision with a minimum of soft-tissue dissection.

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2. Perform percutaneous pinning

If the fragment is correctly reduced, perform percutaneous pinning.



3. Implant removal

In case the physician decides to remove the implant, it can be removed by using general surgical instruments like pliers and K wire Bender/Cutter/Plier.

Note: The final decision of removing the Pins or wires shall be taken by the operating surgeon only. It is recommended that the implant used as an aid for healing should be removed once its service is over after proper consultation and examination by the operating surgeon in final follow up, particularly in younger and more active patients.

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CAUTION:

Used Implants:

Used implants which appear un-damaged may have internal and/or external defects. It is possible that individual stress analysis of each part fail to reveal the accumulated stress on the metals as a result of use within the body. This may lead ultimately to implant failure after certain point of time due to metal fatigue. Therefore reuses of implants are strictly not recommended.

Disposal of Used Implants:

Every used or removed implant must be discarded after use and must never be re- used. It should be bent or scratched & then disposed of properly so that it becomes unfit for reuse. While disposing it off, it should be ensured that the discarded implant does not pose any threat to children, stray animals and environment. Dispose of the implants as per applicable medical practices and local, state and country specific regulatory requirement of Bio Medical Waste rules.

PACKAGING MATERIAL DISPOSAL:

The packaging material of this device is made of LDPE and therefore if swallowed, may cause choking Hazards. Therefore, it should be disposed of in such ways that keep out of reach of children and stray animals.

SINGLE BRAND USAGE:

Implant components from one manufacture should not be used with those of another. Implants from each manufacture may have metal, dimensions and design differences so that the use in conjunction with different brands of devices may lead to inadequate fixation or adverse performances of the devices.

MRI SAFETY INFORMATION

- Ortho Max Mfg. Co Pvt. Ltd. implants are manufactured from Titanium Gr.2, SS316L, SS316LVM material for Bone Plate & Titanium Gr.5, SS316L, SS316LVM material for Bone Screw, Pins & Wires, both are non-magnetic material, hence it do not pose any safety risk.

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- Patients should be directed to seek a medical opinion before entering potentially adverse environments that could affect the performance of the implants, such as electromagnetic or magnetic field or including a magnetic resonance environment.
- Doctor shall conduct a Risk Benefit Analysis before directing the patient to enter electromagnetic or magnetic fields or including a magnetic resonance environment.
- The Ortho Max Mfg. Co Pvt. Ltd. implants has not been evaluated for safety and compatibility in the MR environment but on the basis of literature study below mentioned points can be taken care during MRI

The minimum recommended time after the implantation that allows patients to safely undergo MRI examination or allowing the patient or an individual to enter the MRI environment is 6 (six) weeks.

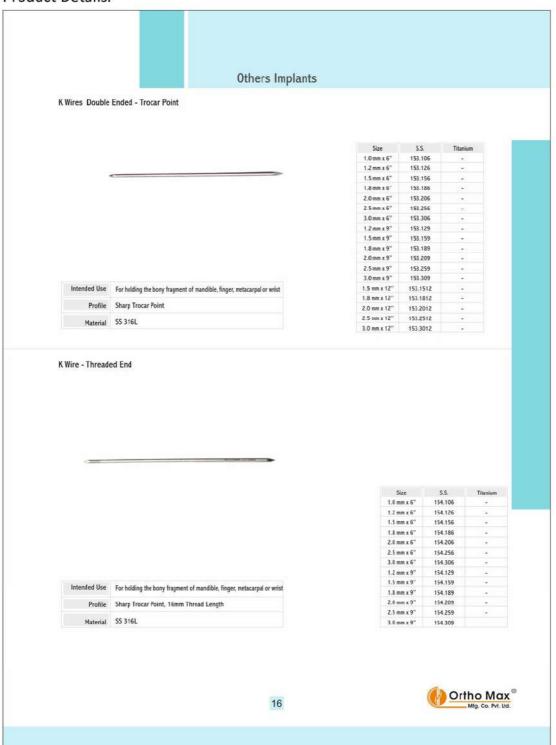
The maximum recommended time limit for MRI examination in patients implanted with the evaluated device is 30 min with a scanner operating at 1.5T (Tesla) or less.

END OF SURGICAL TECHNIQUE

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Product Details:



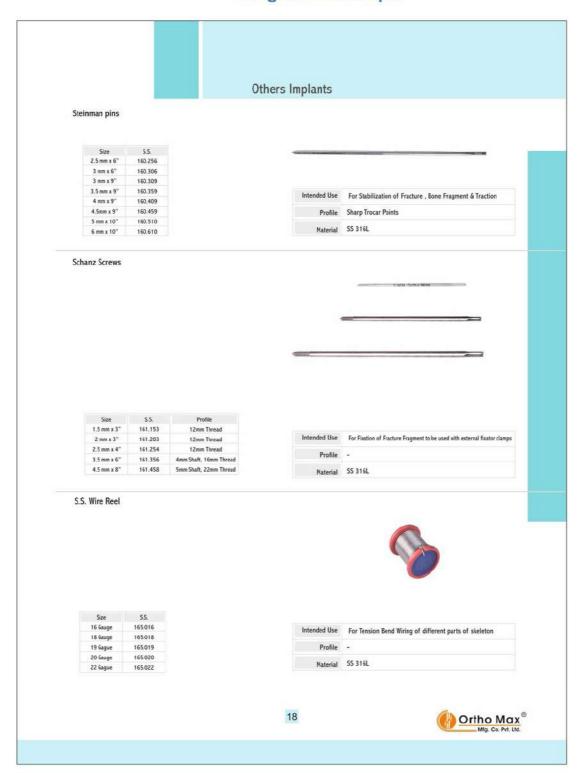
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	Others Implants			
	Others implants			
Square Nails For Radius				
			4 mm X 24cm To 30cm 4.5 mm X 24cm To 30cm	155.2518R To 155.25 155.320R To 155.33 155.3520R To 155.35 155.4524R To 155.43 155.4524R To 155.45
Source Maile For Illea			5mm X 24cm To 30cm	155.524R To 155.53
Square Nails For Ulna				
			3mm X 20cm To 30cm 3.5mm X 20cm To 30cm 4 mm X 24cm To 30cm	155.2518U To 155.25 155.320U To 155.33 155.3520U To 155.35
Rush Nails			Shim X 24cm to Soon	155,5240 10 155,55
			2 mm X 15cm To 30cm 2.5mm X 15cm To 30cm 3mm X 18cm To 30cm 3.5mm X 18cm To 30cm 4.5mm X 24cm To 30cm 4.5 mm X 24cm To 30cm 5 mm X 26cm To 30cm 6 mm x 26cm To 30cm	1 156.2515 To 156.25 156.318 To 156.33 1 156.3518 To 156.35 156.424 To 156.43 1 156.4524 To 156.45 156.526 To 156.53
Lambrinudi Wires				
			2 mm	ize 5.5. x 30cm 158.230 x x 30cm 158.2530
			3 mm 3.5mm 4 mm	x 30cm 158.330 x 30cm 158.3530 x 30cm 158.430 x 30cm 158.4530
Denham Pins				
		Intended Use	For Stabilization of Fracture	
		Profile	Centre Thread 4mm x 38mm,	5.5mm x 38mm , 9" L
Size S.S. 3.5 mm Shaft 159.350 4.5 mm Shaft 159.450		Material	SS 316L	

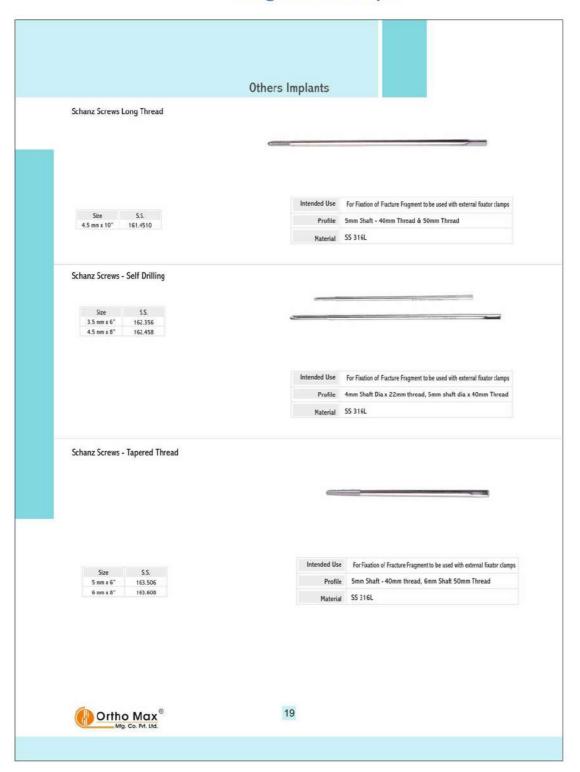
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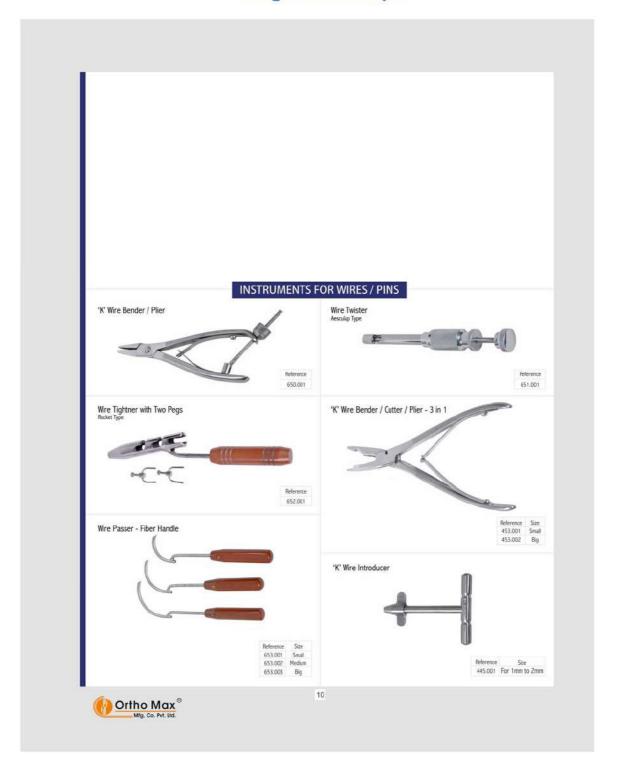
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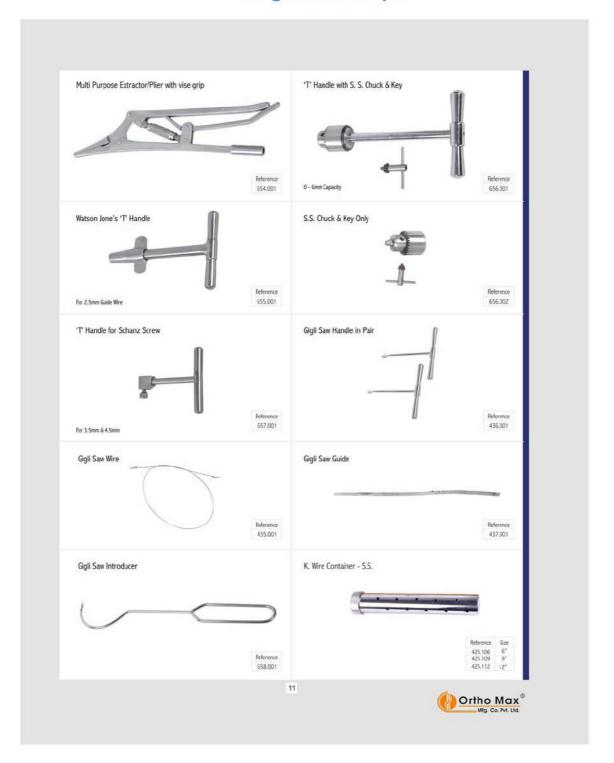
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Instruments Certified : (€



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