



SURGICAL TECHNIQUE






ENDERS NAIL



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SYSTEM OVERVIEW

NAILS	
<p>Enders Nail (3.0 mm)</p> <ul style="list-style-type: none">• Catalogue Number: Stainless Steel: SS 208 Titanium: TT 208• Available in Stainless Steel 316L and Titanium Grade 5• Length: 16cm to 48cm• Diameter: 3mm	
<p>Enders Nail (3.5 mm)</p> <ul style="list-style-type: none">• Catalogue Number: Stainless Steel: SS 208 Titanium: TT 208• Available in Stainless Steel 316L and Titanium Grade 5• Length: 16cm to 48cm• Diameter: 3.5mm	
<p>Enders Nail (4.0 mm)</p> <ul style="list-style-type: none">• Catalogue Number: Stainless Steel: SS 208 Titanium: TT 208• Available in Stainless Steel 316L and Titanium Grade 5• Length: 16cm to 48cm• Diameter: 4.0mm	
<p>Enders Nail (4.5 mm)</p> <ul style="list-style-type: none">• Catalogue Number: Stainless Steel: SS 208 Titanium: TT 208• Available in Stainless Steel 316L and Titanium Grade 5• Length: 16cm to 48cm• Diameter: 4.5mm	
<p>GUIDE WIRE LONG SIMPLE</p> <ul style="list-style-type: none">• Catalogue number- Stainless Steel 316L: SS 292-020 & 025• Available in Stainless Steel 316L• Diameter: 2.0mm, 2.5mm• Length: 40"	

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GUIDE WIRE LONG BDED

- Catalogue number-
Stainless Steel 316L: SS 292-120 & 125
- Available in Stainless Steel 316L
- Diameter: 2.0mm, 2.5mm
- Length: 40"



INSTRUMENT SET DETAILS

SIS 120	Enders Nail
SIS 120-001	AWL Curved
SIS 120-002	AWL Strangth
SIS 120-003	Round Bander
SIS 120-004	Impactor 3.5mm
SIS 120-005	Impactor 4.5mm
SIS 120-006	Final Punch
SIS 120-007	Square Handle Extrector
SIS 120-008	Sloted Hammer
SIS 120-009	Extractor Set
SIS 120-010	PattaBander



INDICATIONS:

- Fracture of the neck
- Trochanteric, and subtrochanteric region of the femur;
- Distal femoral fractures with a distal fragment 10cm or longer;
- Tibial shaft fractures
- Proximal humeral fractures

CONTRAINDICATIONS:

1. These systems should not be used in crossing open epiphyseal plates.
2. Insufficient quantity or quality of bone, obliterated medullary canal or conditions which tend to retard healing, blood supply limitations, previous infections, etc.
3. Active infection.
4. Any hardware that would preclude use of nails.
5. Congenital or acquired bony deformity.
6. Hypovolemia, hypothermia and coagulopathy.
7. Mental conditions that preclude cooperation with the rehabilitation regimen.
8. The ENDER Nail is contraindicated for the younger and/or more active patient, where open reduction techniques provide firm fixation without a substantially increased risk of mortality or morbidity.

PRECAUTIONS:

An implant shall never be reused. Previous stresses may have created imperfections which can lead to device failure. Instruments shall be inspected for wear or damage prior to usage. Protect implant appliances against scratching and nicking. Such stress concentrations can lead to failure.

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.

ADVERSE EFFECTS:

1. Loosening, bending, cracking or fracture of the implant components.
2. Limb shortening or loss of anatomic position with non-union or mal-union with rotation or angulation.
3. Infections, both deep and superficial.
4. Irritational injury of soft tissues, including impingement syndrome.
5. Supracondylar fractures from retrograde nailing.
6. Tissue reactions which include macrophage and foreign body reactions adjacent to implants.
7. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients.

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8. Restricted range of motion of the joint adjacent to the insertion point of the ENDER Nail, usually transitory due to protruding nails.

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PREOPERATIVE PLANNING

1. Correct surgical technique is essential to a successful outcome. Proper reduction of fractures and proper placement of implants are necessary to effectively treat patients using metallic surgical implants. Please review the surgical technique for effective surgical procedures.

2. Implant Selection. A proper type and size of implant must be selected to insure effective treatment of patients. The following factors should be considered:

- Patient's size, strength, skeletal characteristics, skeletal health, and general health. Overweight or musculoskeletally deficient or unhealthy patients may create greater loads on implants that may lead to breakage or other failure of the implants.
- A patient's activity level during the time the implant is in the patient's body, including such factors as whether the patient's occupation or typical activities include running, heavy lifting, impact loading, or the like.
- Whether a patient has a degenerative or progressive disease that delays or prevents healing, and consequently decreases the effective life of the implant.
- If a patient is suspected of having material or foreign body sensitivities, appropriate testing should be accomplished prior to implantation.
- Mental conditions or substance abuse problems that may prevent a patient from understanding or following directions or observing precautions.

3. Implant Alterations. Unless an implant is designed to be physically altered, it should not be altered in any way. If the implant is designed to be altered, it should only be altered in accordance with manufacturer's instructions. In no case should an implant be sharply or reverse bent, notched, gouged, reamed, scratched or cut.

4. Component Compatibility. Components such as intramedullary nails, screws, wires, pins, and the like are available in many styles and sizes and are manufactured from various types of metals. The component material is provided on the outside carton label. Use only components made from the same material together unless specifically approved by the manufacturer. Do not mix dissimilar metals or components from different manufacturers unless specifically approved by a manufacturer of the components. Refer to manufacturers' literature for specific product information.

5. Implant Removal. The patient should be advised that a second procedure for the removal of implants may be necessary.

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POSTOPERATIVE CARE:

- 1. Care Prior to Bony Union.** Immobilize and/or externally support skeletal structures that have been implanted with surgical metallic implants until skeletal union is observed. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending or breaking the device. Early weight bearing should only be considered where there are stable fractures with good bone-to-bone contact. Patients who are obese and/or noncompliant, as well as patients who could be pre-disposed to delayed or non-union, should have auxiliary support. The implant may be exchanged for a larger, stronger nail subsequent to the management of soft tissue injuries. **PATIENTS AND NURSING CARE PROVIDERS SHOULD BE ADVISED OF THESE RISKS.**
- 2. Care Subsequent to Bony Union.** Even after bony union, the patient should be cautioned that a fracture is more likely with the implant in place and soon after its removal, rather than later, when voids in the bone left by implant removal have been filled in completely. Patients should be cautioned against unassisted activity that requires walking or lifting. Postoperative care and physical therapy should be structured to prevent loading of the operative extremity until stability is evident. Additional postoperative precautions should be taken when the fracture line occurs within 5 cm of the nail's screw hole, as this places greater stress on the nail at the location of the transverse screw hole.
- 3. Implant Removal.** The operating surgeon will make final recommendations regarding removal of implants, considering all facts and circumstances. Samay Surgical suggests that whenever possible, and after bony union is observed, that implants be removed. Removal is particularly advisable for younger and more active patients. In the absence of a bursa or pain, removal of the implant in elderly or debilitated patients is not suggested.
- 4.** Patients should be directed to seek medical opinion before entering potentially adverse environments that could affect the performance of the implant, such as electromagnetic or magnetic fields, including a magnetic resonance environment.

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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.

MRI SAFETY INFORMATION:

Samay Surgical implants are manufactured from Titanium Gr.5 and SS316L materials and are non-magnetic material, hence it do not pose any safety risk.

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.

Samay Surgical 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.

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Note : Define Code for S.S. 316L/SS 208, Titanium/TT 208, S.S. 316LVM/LM 208

Code No. S.S. 316L	Code No. S.S. 316L	Code No. S.S. 316L	Code No. S.S. 316L	Code No. S.S. 316L	Length
Dia. (2.0mm)	Dia. (3.0mm)	Dia. (3.5mm)	Dia. (4.0mm)	Dia. (4.5mm)	
SS 208-517	SS 208-017	SS 208-117	SS 208-217	SS 208-317	17cm
SS 208-518	SS 208-018	SS 208-118	SS 208-218	SS 208-318	18cm
SS 208-519	SS 208-019	SS 208-119	SS 208-219	SS 208-319	19cm
SS 208-520	SS 208-020	SS 208-120	SS 208-220	SS 208-320	20cm
SS 208-521	SS 208-021	SS 208-121	SS 208-221	SS 208-321	21cm
SS 208-522	SS 208-022	SS 208-122	SS 208-222	SS 208-322	22cm
SS 208-523	SS 208-023	SS 208-123	SS 208-223	SS 208-323	23cm
SS 208-524	SS 208-024	SS 208-124	SS 208-224	SS 208-324	24cm
SS 208-525	SS 208-025	SS 208-125	SS 208-225	SS 208-325	25cm
SS 208-526	SS 208-026	SS 208-126	SS 208-226	SS 208-326	26cm
SS 208-527	SS 208-027	SS 208-127	SS 208-227	SS 208-327	27cm
SS 208-528	SS 208-028	SS 208-128	SS 208-228	SS 208-328	28cm
SS 208-529	SS 208-029	SS 208-129	SS 208-229	SS 208-329	29cm
SS 208-530	SS 208-030	SS 208-130	SS 208-230	SS 208-330	30cm
Dia. (2.5mm)	SS 208-031	SS 208-131	SS 208-231	SS 208-331	31cm
	SS 208-032	SS 208-132	SS 208-232	SS 208-332	32cm
SS 208-617	SS 208-033	SS 208-133	SS 208-233	SS 208-333	33cm
SS 208-618	SS 208-034	SS 208-134	SS 208-234	SS 208-334	34cm
SS 208-619	SS 208-035	SS 208-135	SS 208-235	SS 208-335	35cm
SS 208-620	SS 208-036	SS 208-136	SS 208-236	SS 208-336	36cm
SS 208-621	SS 208-037	SS 208-137	SS 208-237	SS 208-337	37cm
SS 208-622	SS 208-038	SS 208-138	SS 208-238	SS 208-338	38cm
SS 208-623	SS 208-039	SS 208-139	SS 208-239	SS 208-339	39cm
SS 208-624	SS 208-040	SS 208-140	SS 208-240	SS 208-340	40cm
SS 208-625	SS 208-041	SS 208-141	SS 208-241	SS 208-341	41cm
SS 208-626	SS 208-042	SS 208-142	SS 208-242	SS 208-342	42cm
SS 208-627	SS 208-043	SS 208-143	SS 208-243	SS 208-343	43cm
SS 208-628	SS 208-044	SS 208-144	SS 208-244	SS 208-344	44cm
SS 208-629	SS 208-045	SS 208-145	SS 208-245	SS 208-345	45cm
SS 208-630	SS 208-046	SS 208-146	SS 208-246	SS 208-346	46cm



Implants Certified by : 
XXXX

Instruments Certified by Self Declaration : 



SAMAY®
Surgical

Samay Surgical

Survey no- 212, plot no.-06 NH 08B,

Veravel- Shapar 360024

Diat- Rajkot, Gujrat, India.

Email- info@samaysurgical.com

- Samaysurgical@yahoo.com

Mobile no:- 9978104395(for international market)

:- 9429115008(for Domestic Market)

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