FIXION® INTRAMEDULLARY NAILING SYSTEM

Instructions for Use

INTENDED USE

The Fixion Intramedullary Nail (Fixion IM Nail) is intended for use in the fixation of long bone fractures, including diaphyseal fractures in the humerus, tibia and femur. It is indicated for shaft fractures 5cm below the surgical neck, and 5cm proximal to the distal end of the medullary canal.

SYSTEM DESCRIPTION

NAIL

- The Nail Implant (Fig. 1a)
  An expandable, stainless steel, cylindrical, ribbed rod without interlocking holes. It is supplied in a reduced diameter.

ACCESSORIES

Note: The Instrumentation Set may include components intended for use with other products of the Fixion Intramedullary Nailing Systems. Make sure to use only components relevant to the procedure you are performing.

- The Insertion Handle (Fig. 1b)
  A multi-use device, designed to be connected to the nail proximal end, and used for the nail insertion.

- The Pump – 2 Optional Designs (Fig. 1c)
  A pump, which clockwise rotation of its handle delivers saline into the nail. The Pump is available in two designs – a single use, plastic Pump and a multi use Pump. The Pump pressure gauge indicates the saline pressure during nail expansion.

- The Nail’s Sealing Cap (Fig. 1d)
  The cap prevents bony ingrowth to the proximal end of the nail.

- The Slide Hammer (Fig. 1e)
  A device which is used to insert and/or remove the nail. During insertion, it may be connected to the insertion handle using the slide hammer adapter (Fig. 1g). During removal, it is connected to the nail’s proximal end using the removal adapter (Fig. 1f).

- The Removal Adapter (Fig. 1f)
  A device which connects the nail proximal end to the slide hammer during extraction.
  Note: for nails that were inserted with a “small” insertion kit a “small” removal adapter shall be used. The “small” removal adapter is not provided with the Fixion and Fixion IM Instrumentation Sets.

- The Slide Hammer Adapter (Fig. 1g)
  A device which connects the insertion handle to the slide hammer when use of the slide hammer is required during the insertion procedure.

- The Screwdriver (Fig. 1d)
  A device which is used to insert and/or remove the cap from the nail proximal end.

PRINCIPLE OF OPERATION

The Fixion IM Nail is supplied in its reduced diameter. It is inserted into the intramedullary canal, utilizing the insertion handle. Once in position, the nail is expanded under controlled pressure, utilizing the pump. Fixation is achieved by the abutment of the nail longitudinal bars against the inner surface of the intramedullary canal.
### Table 1: Fixion Intramedullary Nail - Available Sizes Selection Chart

<table>
<thead>
<tr>
<th>Bone</th>
<th>Reduced Diameter (mm)</th>
<th>Maximal Expanded Diameter (mm)</th>
<th>Length **</th>
<th>Recommended For Isthmus Diameter (mm)</th>
<th>Proximal End Diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humerus</td>
<td>6.7</td>
<td>10.0</td>
<td>180, 200, 220, 240, 260, 280, 300</td>
<td>7.0-8.0</td>
<td>7.8</td>
</tr>
<tr>
<td></td>
<td>7.4</td>
<td>11.0</td>
<td></td>
<td>8.0-9.0</td>
<td>8.0</td>
</tr>
<tr>
<td></td>
<td>8.0</td>
<td>12.7</td>
<td></td>
<td>9.0-10.5</td>
<td>9.0</td>
</tr>
<tr>
<td></td>
<td>8.5</td>
<td>13.5</td>
<td></td>
<td>10.5-12.0</td>
<td>10.7</td>
</tr>
<tr>
<td>Tibia</td>
<td>8.5</td>
<td>13.5</td>
<td>260, 280, 300, 320, 340, 360, 380, 400, 420</td>
<td>10.5-12.0</td>
<td>10.7</td>
</tr>
<tr>
<td></td>
<td>10.0</td>
<td>16.0</td>
<td></td>
<td>12.0-14.0</td>
<td>12.4</td>
</tr>
<tr>
<td>Femur</td>
<td>8.5*</td>
<td>13.5*</td>
<td></td>
<td>10.5-12.0</td>
<td>10.7</td>
</tr>
<tr>
<td></td>
<td>10.0</td>
<td>16.0</td>
<td>300, 320, 340, 360, 380, 400, 420, 440, 460, 480</td>
<td>12.0-14.0</td>
<td>12.4</td>
</tr>
<tr>
<td></td>
<td>12.0</td>
<td>19.0</td>
<td></td>
<td>14.0-17.0</td>
<td>14.5</td>
</tr>
</tbody>
</table>

* Use of the Femoral 8.5/13.5 is recommended only in patients where the nail is expected to experience relatively small loads or in cases where the medullary canal is too small to inhibit a bigger nail.

** Within ± 2 mm

### INDICATIONS

1. Acute fractures which are 5cm below the surgical neck, and 5cm proximal to the distal end of the medullary canal.
2. Osteotomy.
3. Nonunions and malunions.
4. Long bone reconstruction following tumor resection, grafting and prophylactic nailing of impending pathological fractures.
5. Revision procedures where other treatments and devices have failed.

### CONTRAINDICATIONS

1. Very proximal or distal fractures.
2. Highly comminuted fractures.
3. Longitudinal splits or longitudinal fractures.
4. Active and/or latent infection.
5. Insufficient quantity or quality of bone, conditions that retard healing (not including pathological fractures) and conditions causing poor blood supply or obliteration of the medullary canal.
6. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.

### ADVERSE EFFECTS

1. Loosening, bending cracking or fracture of the nail with subsequent loss of fixation in bone attributable to nonunion, osteoporosis, markedly unstable comminuted fractures, or one or more of the factors listed in contraindications above and/or warnings and precautions below.
2. Loss of anatomic position with nonunion or malunion with rotation or angulation.
3. Infections.
4. Supracondylar fractures from retrograde nailing.
5. Nail migration.

### WARNINGS AND PRECAUTIONS

**Preoperative:**

1. The surgeon should be familiar with the general principles and techniques of intramedullary nailing of long bone fractures and should be familiar with the Fixion IM Nail.
2. Proper handling and storage of the nail is mandatory. Damage or alterations to the nail may produce stresses and cause defects, which could become the focal point for nail failure.
3. Selection of the correct nail length and diameter according to the nail size selection table is most important. Determination of the medullary canal diameter should be performed by fluoroscopy and/or x-ray, designated gauges and/or radiographic ruler/nail template.
4. The sterile packaging of the Fixion IM implant system and accessories should be inspected for visible damage prior to use. Do not use if damage is suspected.
5. Do not re-sterilize sterile-supplied, single use items. Prior to use, the non-sterile items shall be cleaned and sterilized as detailed in the Packaging and Sterilization Section.
6. Do not re-use the system components which are intended for single use. Re-use of items indicated for single use may result in mechanical failure. In the case of implants, re-use may result also in biological implications (e.g., contamination).
7. The integrity of all multi use instruments, including functionality, where applicable, shall be verified prior to use.

**Operative:**

1. When priming the pump with saline verify that there are no air bubbles in the system.
2) The Nail is to be expanded to 50 bar, or until it expands, and is attached to the intramedullary wall. Maximal pressure should not exceed 70 bar. **In any case, do not over expand the nail beyond 70 bar.**

3) The surgeon should be cautious with limb position changing and/or excessive force exertion while accessories are still connected to the nail, in order to avoid tissue and/or device damage.

**Postoperative:**

1) Patients should be cautioned against significant load bearing prior to good callus formation. Patients who are either non-compliant or predisposed to delayed union or non-union, must have auxiliary support.

2) Periodic x-rays are recommended for at least six months to detect any changes in position, nonunion, loosening, bending or cracking of components.

3) Metallic implants can loosen, fracture, corrode, migrate, cause pain or stress shield bone even after a fracture has healed. When considering removal of the nail, the surgeon must weigh the risks versus benefits of removal surgery.

4) Patients should be cautioned that even after complete healing there is a relative higher risk for re-fracture while the nail is in position, and soon after removal.

5) Post-operative care and physical therapy should be structured to prevent excessive loading of the operated extremity.

**PACKAGING AND STERILIZATION**

The Fixion IM nail, its cap and the single use pump are supplied sterile.

The instrumentation set is for multiple use and is supplied non-sterile. Before each procedure, these parts should be cleaned carefully, and sterilized by standard steam at 122°C, at Prevac cycle of 20 minutes, or at 134°C, at Prevac cycle of 3-4 minutes, as applicable. Prion cycle (134°C, at Prevac cycle of 18 minutes) is also possible. Further instructions are provided in the Instrumentation Handling Instructions by the company (Ref. 4698).

**Note:**

a. The sterilization tray can withstand up to 125 steaming cycles at 122°C for 20 min. or 134°C for 3-4 min. (Prevac cycle).

b. The instrumentation set can withstand up to 110 Prion steaming cycles (134°C, at Prevac cycle of 18 min.).

2) Verify that a representative of the manufacturer replaces the multi use Pump O-Rings every 100 steaming cycles.

**PROCEDURE**

1) Determine the bone medulla narrowest point by x-ray, and select the required nail diameter according to table 1.

2) Perforate an entry hole and dilate it according to the proximal end diameter indicated in table 1.

3) If desired, verify again the bone medulla narrowest point by insertion of a diameter gauge and/or radiographic ruler and/or nail template.

4) If required, reaming may be performed. In general, nail diameter should be smaller compared to the medullary isthmus by about 1-2 mm.

5) Fill the pump with sterile saline solution, by immersing its tube outlet in the saline and rotating the pump handle counter-clockwise until saline fills the pump.

6) Verify lack of air in the pump cylinder and in the tube. Hold the device vertically (pressure gauge up) and rotate the handle clockwise until saline comes out of the tube and air bubbles are completely removed. **Verify that there are no air bubbles within the pump.**

7) Connect the tube outlet of the pump to the insertion handle connector.

8) In order to remove the air from the insertion handle, fill it with saline solution by rotating the pump handle clockwise until the solution emerges from the insertion handle distal end.

9) Disconnect the pump tube from the insertion handle connector.

10) Hold the nail, and fasten the insertion handle into the nail proximal end. Verify that the teeth at the distal end of the handle are aligned with the grooves at the nail proximal end.

11) Lock the insertion handle to the nail by rotating the proximal part of the handle’ inner tube in a clockwise direction, until the teeth of the handle (at its distal end) engage the grooves in the nail proximal end. This mechanism prevents relative rotation between the nail and the insertion handle.

12) Insert the nail into the bone and perform reduction of the fracture under fluoroscopy. During this action, verify anatomic position of the fracture.

Note: The slide hammer could be used, connected to the insertion handle via the slide hammer adapter, in order to facilitate nail insertion. Following positioning of the nail remove the slide hammer and its adapter.

13) Once the nail is in position, and the fracture is adequately reduced, connect the pump tube outlet to the insertion handle connector again.

14) Under fluoroscopy, expand the nail by rotating the pump handle clockwise to 50 bar. At this stage if abutment of the nail bars to the medullary canal walls is not evident radiographically, or manual rotation indicates instability, continue to expand the nail up to 70 bar. **In any case, do not over-expand the nail beyond 70 bar.**

15) When nail expansion is completed and the fracture is stabilized, rotate the pump handle counter-clockwise to decrease pressure to zero (as indicated in the gauge), and allow the pump easy detachment.

16) Disconnect the pump tube from the insertion handle connector.

17) Unlock the insertion handle by rotating the locking ring counter-clockwise.

18) Disconnect the insertion handle from the nail by rotating it counter-clockwise.

19) Seal the nail proximal end with the cap, utilizing the screwdriver.

20) Close the bone penetration point according to the surgical procedure for intramedullary nailing.

**REMOVAL PROCEDURE**

If nail removal is required:

1) Expose and expand a bone entry hole according to the proximal end diameter indicated in table 1.

2) Connect the screwdriver to the cap at the nail proximal end, and remove the nail cap by counter-clockwise rotation.

3) Fasten the removal adapter’s narrow end to the nail proximal end. **The removal adapter must be completely screwed into the nail.**

4) Connect the slide hammer to the removal adapter.

5) Using the slide-hammer, strike gently to extract the nail from the bone.

6) Close the bone penetration point according to the surgical procedure for intramedullary nailing.

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### ORDERING INFORMATION

**Fixion IM Nails – Catalogue No.**

<table>
<thead>
<tr>
<th>Bone</th>
<th>Reduced Diameter (mm)</th>
<th>Maximal Expanded Diameter (mm)</th>
<th>Length ** (mm)</th>
<th>Part No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humerus</td>
<td>6.7</td>
<td>10.0</td>
<td>180, 200, 220, 240, 260, 280*, 300*</td>
<td>11100xx</td>
</tr>
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<td></td>
<td>8.0</td>
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<td></td>
<td>11127xx</td>
</tr>
<tr>
<td></td>
<td>8.5</td>
<td>13.5</td>
<td></td>
<td>11135xx</td>
</tr>
<tr>
<td>Tibia</td>
<td>8.5</td>
<td>13.5</td>
<td>260*, 280, 300, 320, 340, 360, 380, 400*, 420*</td>
<td>12135xx</td>
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<tr>
<td></td>
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<td>12160xx</td>
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<tr>
<td>Femur</td>
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<td></td>
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</tr>
<tr>
<td></td>
<td>10.0</td>
<td>16.0</td>
<td>300, 320, 340, 360, 380, 400, 420, 440, 460*, 480*</td>
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<td>19.0</td>
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<td>13190xx</td>
</tr>
</tbody>
</table>

- xx - Specify nail length in cm.
- * - Special order
- ** - Within ± 2 mm

**Accessories – Catalogue No.**

<table>
<thead>
<tr>
<th>Accessories</th>
<th>Catalogue No.</th>
</tr>
</thead>
<tbody>
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<td>Nail Cap</td>
<td>9103350</td>
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<tr>
<td>Fixion IM Instrumentation Set</td>
<td>9130011</td>
</tr>
<tr>
<td>Fixion IM/IL Instrumentation Set</td>
<td>9133010</td>
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<tr>
<td>Pump (Single/Multi)</td>
<td>9101000/9101100</td>
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</tbody>
</table>

**Explanation of symbols on product labels:**

- Do not use if pack or seal is damaged

**Caution:** In the U.S.A., federal law restricts this device to sale by or on the order of a physician

**Manufactured By**

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Patented, U.S.A. Patents No. 6,025,537, 6,127,597; Australian Patent No. 745916. Other patents are pending