INDICATIONS FOR USE

**NexFix™ Compression Pin**
Implant is a one-piece device made of Stainless Steel, intended for fixation of bone fractures, bone reconstruction, osteotomy or arthrodesis. The implant is designed in 3 sizes, 2.0mm, 2.7mm, and 3.5mm. The device is tapered and threaded on the leading end and smooth on the trailing end.

The NexFix™ Compression Pin is intended to be implanted for the fixation of bone fractures, bone reconstruction, osteotomy or arthrodesis of the foot, ankle, hand and wrist.

**NexFix™ Snap-off Screw**
The Snap-off screws are made of Titanium Alloy intended to be implanted into the bones of the foot, and hand. The screws are provided in 6 sizes, 2 diameters and 5 lengths.

The NexFix™ Snap-off Screw System provides fixation of fractures, fusions, or osteotomies of bones of the hand and foot.

**NexFix™ MTP Fusion Plate System**
The Tornier, Inc. bone plate and screw system is a system of plates and screws made of Stainless Steel and are intended to be implanted into the bones of the forefoot. The plates are provided in 3 sizes, right and left configuration. The screws are provided in 2 diameters 2.7 mm, 3.2 mm and in lengths ranging from 12 to 28 mm.

The NexFix™ MTP Fusion Plate System is intended for use in providing fixation during fractures, fusions and osteotomies. The system consists of plates and screws for treatment of the phalanges, and metatarsals bones.

**NexFix™ Compression Screw**
The Nexa Compression Screw is made of Stainless Steel, and is intended to be implanted into the bones of the foot and hand, and bones appropriate for the size of the device. The screws are provided in three diameters (3.0, 4.5, 6.5) of various lengths ranging from 10 mm to 120 mm.

The NexFix™ Compression Screw is indicated for bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device.

CONTRAINDICATIONS
General contraindications for the use of these implants for joint reconstruction, osteotomy or fusion include:

- Significant bone demineralization.
- Inadequate neurovascular status.
- Inadequate skin or musculotendinous system.
- Inadequate bone stock.
- Psychologically unsuitable patient.
- Active sepsis.
- Possibility for conservative treatment.
- Patients with high levels of activity.

WARNINGS
(See also the Patient Counseling Information Section)
Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device. If excessive loading cannot be prevented, an implant should not be used. Abnormal or excessive forces could lead to delayed union, non-union, or failure of the implant.

Patients should be made aware of the increased potential for device failure if excessive demands are made upon it. Implants are mechanical devices that can be worn away, fatigued or broken. An implant site may become infected, painful, swollen, or inflamed. The status of the adjacent bone and soft tissue may be inadequate to support the implant, or may deteriorate in time resulting in instability, deformity, or both. The benefits from implant surgery may not meet the patient’s expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are not uncommon.

This product has not been evaluated for safety and compatibility or tested for heating or migration in the MR environment.

Although published studies indicate, patients should be informed that there are several different manufacturers and
generations of MRI equipment, and Tornier Inc. cannot make claims regarding the compatibility of this product with any specific MRI unit. It is recommended that patients and physicians consult with the MRI equipment manufacturers to discuss the compatibility of this product with the MRI equipment before undergoing any MRI procedure.

**PRECAUTIONS**

Implants should only be handled with blunt instruments to avoid scratching, cutting or nicking the device.

Meticulous preparation of the implant site and selection of the proper size implant increase the potential for successful outcome.

The NexFix™ System implants are for single use only and should never be resterilized after contact with body tissues or fluids in order to prevent any risks of cross-contamination.

**ADVERSE EVENTS**

Potential adverse events reported include pain, loosening, fracture, dislocation, or infection. There have been some reports of patients with metal sensitivity reactions following implantation. Implantation of implant materials may result in foreign body reaction adjacent to the implant site. Injury to the surrounding bone, nerves, blood vessels, tendons, or soft tissues can occur as a consequence of implanting this device.

**SURGICAL PROCEDURES**

A surgical procedure for use of this implant device is available. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the procedure before use.

**PATIENT COUNSELING INFORMATION** (See also Warnings)

Providing each patient scheduled for surgery with documented counseling of potential complications and alternatives, which may include non-implant procedures such as soft tissue reconstruction or arthrodesis, prior to surgery is necessary. In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be conveyed to the patient:

1) Adverse effects may necessitate reoperation, revision, or fusion of the involved joint.
2) While the expected life of a device is difficult to estimate, it is finite. These components are made of foreign materials, which are placed within the body. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.

**CLEANING AND STERILIZATION INFORMATION**

**WARNINGS**

Clean, not sterile, implants, instruments and sizers must be sterilized prior to each use. Sizers are designed to aid in implant site preparation only. They must never be used as implants.

The most common cause of instrument breakage is misuse. Specialty instrumentation should never be used for tasks it was not specifically designed to perform. Misuse of an instrument may result not only in damage to the instrument, but also trauma to the patient and operating room personnel.

If not handled properly, instruments with cutting edges or sharp corners may compromise sterility by tearing surgical gloves. If an instrument tip becomes bent, chipped, or otherwise damaged the instrument should be replaced or repaired before further use. Attempts to straighten bends are not advised as the metallurgical integrity of the metal may be compromised in the process, and the instrument may subsequently break during use.

**CLEANING INSTRUCTIONS**

New instruments are packaged clean, not sterile and should be assumed to be contaminated. Instruments must be cleaned and sterilized before each use.

For your safety, be familiar with the procedures for handling contaminated materials at your facility before following these instructions. A cleaning process done out of qualification ranges can lead to sterility or toxicity issues.

Clean instruments as soon as possible after use and avoid allowing soiled instruments to dry. Immerse, use damp towels or sponges with deionized or distilled water to keep soiled instruments moist prior to cleaning.

Manually scrub with a clean, soft-bristled brush or soft cloth in mild detergent following the detergent manufacturers instructions for use. Avoid using extreme detergent concentration levels. Detergents with enzyme cleaners or separate enzyme solutions may be used, but their effectivity has not been evaluated. Warm or hot water (300°F/149°C maximum) should be used to aid in cleaning. Ultrasonic cleaning is recommended for instruments with internal surfaces or crevices which may be hard to clean manually.

pH neutral cleaners (pH 6.0-8.0) are recommended for longer life of the instruments. If acidic or alkaline solutions are used follow the manufacturers recommendations for neutralizing the pH by rinsing with water or neutralizing agent. Highly alkaline or acidic cleaners (used in some mechanical washers) are not recommended as they will reduce the life of the instruments and may effect instrument performance. Avoid prolonged exposure to acidic or alkaline solutions and solutions containing chlorides, bromides or iodine.

Use of water soluble lubricants is recommended for instruments with moving parts or those intended to be assembled intraoperatively to another instrument. Rinse thoroughly with deionized water or distilled water. Dry completely before sterilizing. Inspect each instrument and implant thoroughly for cleanliness, especially in broach teeth, internal surfaces and crevices. Instruments should be re-washed if there are any signs of foreign matter or residue. Check instruments thoroughly for damage. Do not use damaged instruments as they may compromise the surgical outcome, replace damaged instruments before next use.

Use of mechanical washers have not been evaluated by the manufacturer. Qualification of specific wash cycles and equipment should be completed by the user.
STERILIZATION

The recommended sterilization method is steam sterilization. The following sterilization cycles have been shown to produce a sterility assurance level of 10^-6 when parts have been cleaned to the instructions above. Other similar steam cycles and cleaning procedures may be used but have not been evaluated. Sterilization qualification was performed using specific equipment and procedures. Use of cycles, equipment and procedures other than those listed should be qualified by the user. Do not exceed 300°F/149°C.

Wrapped Gravity Steam Sterilization 25 minutes minimum @ 270-275°F (132-135°C), dry time 20 minutes minimum. The following cycle has been validated, but it is not recommended as a sterilization method for implants:

Unwrapped Pre-vacuum Steam Sterilization 4 minutes minimum @ 270-275°F (132-135°C)

After sterilization, remove the materials from their packaging or the sterilization tray using accepted sterile technique. Ensure that implants are at room temperature prior to implantation.

LIMITED WARRANTY

Tornier, Inc. warrants that this product meets the manufacturer’s specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse or improper handling of the product subsequent to receipt by the purchaser. Tornier, Inc. does not warrant the outcome of the surgical procedure.

INFORMATION

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