A GLOBAL EXTREMITY COMPANY

# NEOSPAN® COMPRESSION STAPLE IMPLANT WITH INSTRUMENTS

## PRODUCT INSERT

## STERILE IMPLANTS & INSTRUMENTS

**CAUTION**: Federal Law (USA) restricts this device to sale by or on the order of a physician.

The In2Bones **NeoSpan™ Compression Staple Implant w/instruments** is a compression staple made of superelastic NITINOL (ASTM F 2063). The devices are available in multiple sizes. The implant is designed to hold bones together until healing occurs.

The associated sterile instruments are made of medical grades of stainless steel and polymer materials. The implant and associated instruments are provided in a single sterile individual package. The individual package contents are listed below:

1. Implant with inserter
2. Drill
3. Drill guide
4. Tamp
5. Locator Pin

• *Implant Material: Superelastic Nitinol*

A sizing instrument is also available separately in its own package.

## INDICATIONS

The In2Bones NeoSpan Compression Staple Implant w/instruments is indicated for hand and foot bone fragments, osteotomy fixation and joint arthrodesis.

## PATIENT SELECTION

The following general indications should be considered:

- Good condition of the patient
- Adequate skin coverage
- Good neurovascular status
- Possibility of an adequate musculotendinous system
- Cooperative patient
- Availability of post-operative therapy

## CONTRAINDICATIONS

General contraindications for the use of these implants for fusion, osteotomy and arthrodesis include:

- Significant bone demineralization
- Inadequate neurovascular status
- Inadequate skin or musculotendinous system
- Inadequate bone stock
- Physiologically or Psychologically unsuitable patient
- Possibility for conservative treatment
- Bone, musculature, tendons, or adjacent soft tissue compromised by disease, infection, or prior implantation, which cannot provide adequate support or fixation for the prosthesis
- Known metal allergy
- Diabetes
- Active infection
- Possibility of conservative treatment
- Growing patients with open epiphyses
- Patients with high level of activity

## WARNINGS: *(See also the Patient Counseling Information Section)*

- Patients should be made aware of the increased potential for device failure when excessive demands are made upon it. Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device.
- Correct selection and sizing of the implant is extremely important.
- Modification or reshaping of the implant must be avoided.
- If excessive loading cannot be prevented, an implant should not be used.
- Abnormal or excessive forces could lead to failure of the implant.
- This device has not been evaluated for safety and compatibility in the MR environment.
- This device has not been tested for heating or migration in the MR environment.

## PRECAUTIONS

- If either the implant or the package appears damaged the implant should not be used.
- Meticulous preparation of the implant site and selection of the proper size implant increase the potential for a successful outcome.
- Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device.
- This implantable product is for single use only. An implant should never be re-sterilized after contact with body tissues or fluids.

## POTENTIAL ADVERSE EFFECTS

General Surgery Related Risks

- Bleeding
- Infection
- Pain, discomfort, inflammation, swelling or abnormal sensation due to the presence of the implant
- Metal sensitivity or allergic reaction to a foreign body
- Migration of particle wear debris possibly resulting in a physiological response
- Fracture of the implant
- Loosening or dislocation of the implant requiring revision surgery
- Delayed correction in alignment
- Decrease in bone density due to stress shielding
- Bone over-production
- Bursitis
- Loss of use of the foot
- Permanent disability
- Embolism
- Death

## SURGICAL PROCEDURES

A manual is available describing detailed surgical procedures for use of these implant devices. 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 implant procedures before use.

## POST-OPERATIVE PROTOCOL

A gradual return to limited activity in 4 to 6 weeks is allowed as tolerated. Patient specific post- operative care is the responsibility of the surgeon.

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

In addition to the patient related information contained in the Warnings, Adverse Effects and Post-Operative Protocol sections, the following information should be conveyed to the patient:

While the expected life of an implant is difficult to estimate it is finite. These components are made of foreign materials, which are placed within the body for the potential fusion. 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.

- Adverse effects of this device may necessitate reoperation, revision, or fusion of the involved bone or joint.

## STERILIZATION

- This implant component and the accompanying instruments packaged with it have been sterilized by gamma irradiation.
- Do not re-sterilize if the implant comes in direct contact with human tissue. Dispose of implants that come in contact with human tissue and are not used in the surgery. If either the implant or the package appears damaged the implant should not be used.
- If packaging or seal is damaged, sterility cannot be assured and the implant and instruments should not be used
- The implant is non-pyrogenic. Surgical instruments are not evaluated for pyrogens.

## LIMITED WARRANTY

In2Bones 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. In2Bones does not warrant the outcome of the surgical procedure.

## SYMBOL GLOSSARY DEFINITIONS

Symbols and abbreviations may be used on the package label. The following tables provide the definitions of these symbols and abbreviations. Symbols are referenced in ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements or other references.

| SYMBOL | STANDARD REFERENCE | STANDARD TITLE | SYMBOL TITLE | EXPLANATORY TEXT |
|---|---|---|---|---|
|  | EN 980, Clause 5.12<br><br>ISO 15223-1, Clause 5.1.1 | Symbols for use in the labelling of medical devices.<br><br>Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Manufacturer | Indicates the medical device manufacturer. |
|  | EN 980, Clause 5.6<br><br>ISO 15223-1, Clause 5.1.3 | Symbols for use in the labelling of medical devices.<br><br>Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Date of manufacture | Indicates the date when the medical device was manufactured. |
|  | EN 980, Clause 5.13<br><br>ISO 15223-1, Clause 5.1.2 | Symbols for use in the labelling of medical devices.<br><br>Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Authorized European representative | Indicates the Authorized representative in the European Community. |
|  | EN 980, Clause 5.10<br><br>ISO 15223-1, Clause 5.1.6 | Symbols for use in the labelling of medical devices.<br><br>Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Catalogue or model number | Indicates the manufacturer's catalogue number so that the medical device can be identified. |
|  | EN 980, Clause 5.5<br><br>ISO 15223-1, Clause 5.1.7 | Symbols for use in the labelling of medical devices.<br><br>Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Serial number | Indicates the manufacturer's serial number so that a specific medical device can be identified. |

## SYMBOL GLOSSARY DEFINITIONS CONTINUED

| SYMBOL | STANDARD REFERENCE | STANDARD TITLE | SYMBOL TITLE | EXPLANATORY TEXT |
|---|---|---|---|---|
|  | EN 980, Clause 5.4<br><br>ISO 15223-1, Clause 5.1.5 | Symbols for use in the labelling of medical devices.<br><br>Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Batch code | Indicates the manufacturer's batch code so that the batch or lot can be identified. |
|  | EN 980, Clause 5.3<br><br>ISO 15223-1, Clause 5.1.4 | Symbols for use in the labelling of medical devices.<br><br>Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Use by | Indicates the date after which the medical device is not to be used. |
|  | EN 980, Clause 5.18<br><br>ISO 15223-1, Clause 5.4.3 | Symbols for use in the labelling of medical devices.<br><br>Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Consult instructions for use | Indicates the need for the user to consult the instructions for use. |
|  | EN 980, Clause 5.11<br><br>ISO 15223-1, Clause 5.4.4 | Symbols for use in the labelling of medical devices.<br><br>Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Attention: Read all warnings and precautions in instructions for use | Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. |
|  | ASTM F2503 | Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. | Magnetic Resonance (MR) unsafe<br>**SYMBOL** | Keep away from magnetic resonance imaging (MRI) equipment. |
|  | EN 980, Clause 5.21<br><br>ISO 15223-1, Clause 5.3.4 | Symbols for use in the labelling of medical devices.<br><br>Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Keep dry | Indicates a medical device that needs to be protected from moisture. |
|  | EN 980, Clause 5.2<br><br>ISO 15223-1, Clause 5.4.2 | Symbols for use in the labelling of medical devices.<br><br>Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Do not reuse | Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure. |
|  | EN 980, Clause 5.22<br><br>ISO 15223-1, Clause 5.2.6 | Symbols for use in the labelling of medical devices.<br><br>Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Do not resterilize | Indicates a medical device that is not to be resterilized. |
|  | ISO 7000-3079 | Graphical symbols for use on equipment. | Open here | To identify the location where the package can be opened and to indicate the method of opening it. |
|  | EN 980, Clause 5.23<br><br>ISO 15223-1, Clause 5.2.7<br>EN 980, Clause 5.7 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.<br><br>Symbols for use in the labelling of medical devices. | Non sterile | Indicates a medical device that has not been subjected to a sterilization process. |
|  | ISO 15223-1, Clause 5.2.1<br><br>EN 980, Clause 5.8.2 | Medical devices — Symbols to be used with medical device labels, labelling and information.<br><br>Symbols for use in the labelling of medical devices. | Product subjected to a sterilization process | Indicates a medical device that has been subjected to a sterilization process. |
|  | ISO 15223-1, Clause 5.2.3<br><br>EN 980, Clause 5.8.3 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.<br><br>Symbols for use in the labelling of medical devices. | Sterilized by ethylene oxide treatment | Indicates a medical device that has been sterilized using ethylene oxide. |
|  | ISO 15223-1, Clause 5.2.4 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Sterilized using irradiation | Indicates a medical device that has been sterilized using irradiation. |
|  | EN 980, Clause 5.8.4<br><br>ISO 15223-1, Clause 5.2.5 | Symbols for use in the labelling of medical devices.<br><br>Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Sterilized using steam or dry heat | Indicates a medical device that has been sterilized using steam or dry heat. |
|  | ISO 15223-1, Clause 5.6.3 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Non-pyrogenic | Indicates a medical device that is non-pyrogenic. |
|  | ISO 15223-1, Clause 5.2.8 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Do not use if package is damaged | Indicates a medical device that should not be used if the package has been damaged or opened. |

## SYMBOLS NOT FROM STANDARDS

| | REFERENCE | TITLE | SYMBOL TITLE | EXPLANATORY TEXT |
|---|---|---|---|---|
|  | 21 CFR 801.15(c)(1)(i)F<br><br>21 CFR 801.109 | Labeling-Medical devices; prominence of required label statements.<br><br>Labeling-Prescription devices. | Prescription only | Requires prescription in the United States. |
|  | 765/2008/EC 768/2008/EC MDD 93/42/EEC Articles 4,11,12,17, Annex II ) | The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive. | CE marking | Signifies European technical conformity. |
|  | N/A | N/A | Non-pyrogenic | Indicates a medical device that is non-pyrogenic. |

## MATERIAL REFERENCE NOT FROM STANDARDS

| ABBREVIATION | MATERIAL |
|---|---|
| CoCr Cobalt Chrome Alloy | Cobalt Chrome Alloy |
| Nickel-Titanium | Nickel-Titanium Alloy (Nitinol). |
| PEEK | Poly Ether Ether Ketone |
| SS | Stainless Steel |
| Silicone | Polydimethylsiloxane Elastomer |
| Ti | Titanium |
| Ti6Al4V | Titanium Alloy |
| UHMWPE | Ultra High Molecular Weight Polyethylene |