# Nextra® CH

## Cannulated Hammertoe System

**SYMBOL LEGEND LOCATED AT END OF DOCUMENT**

**Instructions for Use**

Please read this information carefully before using the Nextra CH Cannulated Hammertoe System

## DESCRIPTION

The Nextra CH Cannulated Hammertoe System consists of a two-part cannulated screw implant construct. The implants are offered in two designs; one set of implants to accept 0.9mm diameter Kirschner wires and the other set to accept 1.1mm diameter Kirschner wires. Implant screws are provided sterile. The system is provided with sterile packaged accessory instruments designed for preparation of the implant site and inserting the implant into bone.

## SYSTEM COMPONENTS

**Nextra CH Screw Implant**

Implantable Ti-6Al-4V ELI

**Nextra CH Kirschner Wire (K-Wire) 1.1mm x 127mm**

Implantable 316 Stainless Steel

**Nextra CH Instrument Kit**

Implantable Ti-6Al-4V ELI, Stainless Steel (SS), Polycarbonate, K-Resin

**Nextra CH Retriever**

Stainless Steel (SS)

**Nextra CH Sterile Driver Set**

Stainless Steel (SS), Polycarbonate

## INDICATIONS

The Nextra CH Cannulated Hammertoe System is indicated for small bone reconstruction limited to interphalangeal repair and fusion of the lesser toes.

## CONTRAINDICATIONS

The Nextra CH Cannulated Hammertoe System is **NOT** intended for use in procedures involving the great toe. In addition, the device is contraindicated in the following:

- Patient conditions including insufficient quantity or quality of bone.
- Blood supply limitations and previous or active infections that may inhibit healing.

- Surgical procedures other than for the indications listed.
- Patients with conditions that limit their ability or willingness to follow postoperative care instructions.
- The device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature.
- Where material sensitivity is suspected, appropriate testing should be performed, and sensitivity ruled out prior to implantation.

**POTENTIAL ADVERSE EFFECTS**

- Infection, deep and superficial with possible sepsis
- Nerve damage due to surgical trauma
- Loosening or migration of the implant
- Bending or fracture of implant
- Pain, soft tissue discomfort, or abnormal sensation due to the presence of the device
- Foreign body reactions, allergies, or other reactions to implant materials
- Nonunion or delayed union which may lead to breakage of the implant
- Inadequate healing
- Thrombosis and embolism
- Difficulty of removal due to bone in-growth and overgrowth.

**PRECAUTIONS**

- It is mandatory that the user, surgeon, and surgery personnel are acquainted with the respective surgical technique and implants used. A detailed surgical technique in print and/or electronic formats can be obtained by contacting Medartis Inc. or found online at nsinc-ifu.com.
- Surgical instruments and implants may only be used for surgeries for which the designated application of the instrument and implant is explicitly necessary and defined.
- The trained expert staff is obligated to examine the surgical implant(s), sterile instrument(s), and its sterile packaging for damage prior to use. In case of the implant, sterile instrument, or its packaging being damaged or deformed, it is not to be used.
- Only Medartis Inc. specially manufactured instruments and implants (contained in the respective set) are to be used. If using other instruments and implants, function, warranty, and liability are omitted.
- The device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature.
- Where material sensitivity is suspected, appropriate testing should be performed and sensitivity ruled out prior to implantation.
- The Nextra CH Cannulated Hammertoe System must be used only with the provided insertion instrumentation.
- Cutting edges, blades, tips etc. can be very sensitive to mishandling. Thus, these instruments must be handled with care.
- Implant materials are subject to corrosion. Implanting metals and alloys subjects them to

constant changing environments of salts, acids, and alkalis that can cause corrosion. Putting dissimilar metals and alloys in contact with each other can accelerate the corrosion process that may enhance fracture of implants. Every effort should be made to use compatible metals and alloys.

- This system should only be used by physicians with training in and a thorough understanding of orthopedic surgery.
- The Nextra CH Cannulated Hammertoe System is for SINGLE USE ONLY. DO NOT RE-STERILIZE OR REUSE IMPLANTS OR INSTRUMENTS THAT ARE PROVIDED STERILE.
- The Nextra CH Cannulated Hammertoe System has not been tested to withstand the forces needed for partial or full weight bearing or excessive activity until healing has occurred. The post-op regimen prescribed by the physician should be strictly followed to avoid stresses applied to the implant. Weight-bearing post operatively should be at the discretion of the surgeon.
- The optional implantable K-Wire is a temporary implant to be used ONLY in conjunction with the appropriate size screw implant construct. The K-Wire should be removed upon the physician's discretion.

**WARNINGS**

Although the surgeon is the learning intermediary between the company and the patient, the important information conveyed in this document should be conveyed to the patient. The patient must be cautioned about the use, limitations and possible adverse effects of these implants including the potential for these devices failing as a result of loosening, stress, excessive activity, and/or load bearing particularly when the implants experience increased loads due to a delayed union, non-union, or incomplete healing. The patient must be warned that failure to follow postoperative care instructions may cause the implant or treatment to fail.

**MRI SAFETY INFORMATION**

- The Nextra CH Cannulated Hammertoe System has not-been evaluated for safety and compatibility in the MRI environment. It has not been tested for heating, migration, or image artifact in the MRI environment. The safety of the Nextra CH Cannulated Hammertoe System in the MRI environment is unknown. Scanning a patient who has this device may result in patient injury.

**DIRECTIONS FOR USE**

Warning: The Nextra CH Cannulated Hammertoe System should only be used with the supplied, dedicated instruments. See the Nextra CH Cannulated Hammertoe System surgical technique for an illustrated description of the technique.

**HOW SUPPLIED**

The Nextra CH Cannulated Hammertoe System sterile screw implants are individually packaged. Dedicated Nextra CH Cannulated Hammertoe System Kits including an implant and instruments are also sterile packaged. A driver set including standard and mini drivers with a handle are sterile packaged. A dedicated retriever instrument, if applicable, is individually sterile packaged. The

components of the Nextra CH Cannulated Hammertoe System are for single use only. DO NOT RE-STERILIZE IMPLANTS OR INSTRUMENTS THAT ARE PROVIDED STERILE. DO NOT REUSE.
Re-use or reprocessing (cleaning and re-sterilization) of a device labeled for single use only may result in the transmission of infectious material from one patient to another or to the user. This could result in serious injury or death. In addition, re-use or reprocessing may weaken or damage the implants and/or instruments, leading to mechanical failure and/or devices not functioning as intended. This could also result in death or serious injury to the patient or user.

**STORAGE AND HANDLING**
Store in a cool, dry place and in a manner that protects the integrity of the packaging of all implants and instruments. Keep away from direct sunlight. Prior to use, inspect product packaging for sign of tampering and/or damage.

**PACKAGING AND LABELING**

1. Medartis Inc. devices should be accepted only if the factory packaging and labeling arrive intact.
2. Contact Customer Service if the package has been opened or altered.

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


**SYMBOL LEGEND**

| **Standard: ISO 15223-1, Medical Devices - Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements** | | | |
|---|---|---|---|
| **Symbol** | **Symbol Reference No** | **Title of Symbol** | **Description of Symbol** |
|  | 5.1.1 | Manufacturer | Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC. |
|   | 5.1.2 | Authorized representative in the European Community | Indicates the authorized representative in the European Community. |
|  | 5.1.3 | Date of Manufacture | Indicates the date when the medical device was manufactured. |
|  | 5.1.4 | Use by date | Indicates the date after which the medical device is not to be used. |

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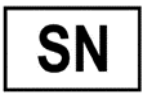
| **Symbol** | **Symbol Reference No** | **Title of Symbol** | **Description of Symbol** |
|  | 5.1.5 | Batch code | Indicates the manufacturer's batch code so that the batch or lot can be identified. |
|  | 5.1.7 | Serial Number | Indicates the manufacturer's serial number so that a specific medical device can be identified. |
|  | 5.1.6 | Catalog number | Indicates the manufacturer's catalog number so that the medical device can be identified. |
|  | 5.2.4 | Sterilized using irradiation | Indicates a medical device that has been sterilized using irradiation. |
|  | 5.2.6 | Do not re-sterilize | Indicates a medical device that is not to be re-sterilized. |
|  | 5.2.7 | Non-sterile | Indicates a medical device that has not been subjected to a sterilization process. |
|  | 5.2.8 | Do not use if package is damaged. | Indicates a medical device that should not be used if the package has been damage or opened. |
|  | 5.4.2 | Do not re-use | Indicates a medical device that is intended for one use or for use on a single patient during a single procedure. |
|  | 5.4.3 | Consult instructions for use | Indicates the need for the user to consult the instruction for use. |
|  | 5.4.4 | Caution | Indicates that the instructions for use contain important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. |

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| **Symbol** | **Symbol Reference No** | **Title of Symbol** | **Description of Symbol** |
|  | 21 CFR 801.109 | The symbol statement for Prescription Device | Indicates that the product is a medical device as defined in 21 CFR 820.3(l) and Federal Law (USA) restricts this device to sale by or on the order of a physician (21 CFR 801.109) |
|  | European Medical Devices Directive 93/42/EEC of 14 June 1993 (as amended by Directive 2007/47/EC) as described in Article 17 of the Directive | Conformité Européene or European Conformity | Indicates manufacturer declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation. |

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