Instructions for Use
HAMMERLOCK™ 2 Intramedullary Nitinol Implant System

This instruction for use is not intended for distribution in the USA.

Not all products are currently available in all markets.

Manuals are subject to change;
the most current version of each manual is always available online.
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Instructions for Use

The HAMMERLOCK™ 2 Intramedullary Nitinol Implant System gives the surgeon a means of intramedullary bone fixation and helps in the management of reconstructive surgery.

Devices in scope:
HL2L
HL2LA
HL2M
HL2MA
HL2S
HL2SA

Basic Structure
The devices of the HAMMERLOCK 2 Intramedullary Nitinol Implant System are made of biocompatible Nitinol and possess shape memory and superelastic properties. The HAMMERLOCK 2 Implant is a one-piece Nitinol device with legs that deflect outward in the medullary cavity and towards each other resulting in implant stabilization and compression.

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Material
Nitinol

Intended Use
The HAMMERLOCK 2 is intended as a means of bone fixation and helps in the management of fracture and reconstructive surgery.

Indications for Use
Small bone reconstruction and fusion such as in the phalanges of the fingers and toes.

Contraindications
- Pathologic conditions of bone such as osteopenia that would impair the ability to securely fix the implant.
- Foreign body sensitivity to metals including nickel. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

Intended User
This IFU alone does not provide sufficient background for direct use of the Device or System. Instruction by a surgeon experienced in handling these devices is highly recommended.

This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the IFU, the surgical procedures, if applicable, and/or the Synthes "Important Information" brochure as appropriate.
Implantation is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the device is suitable for the pathology/condition indicated and that the operation is carried out properly.

Expected Clinical Benefits
Expected clinical benefits of internal fixation devices such as HAMMERLOCK 2 Intramedullary Nitinol Implant System when used according to instructions for use and recommended technique are,
- Stabilize bone segment and facilitate healing
- Restore anatomical relationship and function

Potential Adverse Events, Undesirable Side Effects and Residual Risks
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:
Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, malunion, non-union, bone damage and damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck's disease, allergy/hypersensitivity reactions, and side effects associated with implant failure and hardware prominence.

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Sterile Device

STERILE R Sterilized using irradiation

Do not resterilize

Single-Use Device

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.

Re-use or clinical reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.
Furthermore, re-use or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Warnings and Precautions

Warnings
- The HAMMERLOCK 2 Implant cannot be expected to replace normal healthy bone or withstand the stress placed upon the device by full or partial weight bearing or load bearing in the presence of nonunion, delayed union or incomplete healing. Therefore, it is important that immobilization of the treatment site using routine methods (casting, splints, etc.) be maintained until bone healing has occurred (4–6 weeks).
- Reduction of the site should be achieved and maintained after implanting the device. The compressive force of the HAMMERLOCK 2 Implant should not be relied upon to achieve closure or reduction of a fracture line.
- Prior to use, check the product expiration date and verify the packaging integrity. Product with damaged packaging should be discarded and must not be used, as sterility cannot be assured.
- If sterilization is compromised prior to insertion, a different sterile implant or associated instrument(s) will need to be used. Product cannot be re-sterilized due to the heat lability of the polycarbonate materials.
- Reprocessing of any instrument may affect its compatibility with other instruments and the usability of the reprocessed instrument.
- Any additional processing or reprocessing of the implant may affect the shape memory properties of the nitinol, changing or otherwise reducing the effectiveness of the implant.

Combination of Medical Devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Magnetic Resonance Environment

MR Compatibility Section
- The HAMMERLOCK 2 Intramedullary Nitinol Implant System has been evaluated for safety and compatibility in the MR environment. The device was tested under nonclinical conditions.
- Testing has demonstrated the HAMMERLOCK 2 Implant is MR Conditional.
- A patient with this device can be scanned safely under the following conditions:
  - Static magnetic field of 1.5 Tesla (1.5 T) or 3.0 Tesla (3.0 T), only;
  - Maximum spatial gradient magnetic field 4,000 G/cm (40 T/m);
  - Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of scanning (i.e. per pulse sequence) in the Normal Operating Mode.

Heating:
After 15 minutes of scanning (i.e. per pulse sequence), HAMMERLOCK 2 Implant is expected to produce a maximum temperature rise of 2 °C.

Artifact:
In non-clinical testing, the image artifact caused by HAMMERLOCK 2 Implant extends approximately 15 mm from the device when imaged with gradient echo pulse sequence in a 3.0 T MR system.

Implant Removal
Expose the joint 1–2 mm and secure the HAMMERLOCK 2 Implant with forceps. With the forceps, pinch the distal arms of the implant together and distract the middle phalanx. To remove the proximal end, lock forceps onto the distal arms of the implant and gently rotate and distract the implant from the proximal phalange. If the implant is solidly connected, create a dorsal window to expose and remove the distal and/or proximal portion of the implant.

Disposal
Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol.

Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

Special Operating Instructions
1. Perform incisions and bone resections and address soft tissue contractures as necessary. Note: Resections should be perpendicular to the long axis of the bones in the transverse plane. In the sagittal plane, resections should be perpendicular to the long axis if using a straight implant. If using an angled implant, a 10-degree proximal-dorsal to distal-plantar bias on the middle phalange should be considered.
2. Open the HAMMERLOCK 2 Implant Drill Kit (DK-H2) and, using the 2.1 mm Drill Bit supplied, drill into the medullary canal of the middle phalange until the attached plastic drill stop is reached or resistance from subchondral bone is met.
3. Remove the drill stop and drill into the medullary canal of proximal phalange until the shoulder of the Drill Bit is reached or resistance from subchondral bone is met.
4. Slide the pin of the HAMMERLOCK 2 Implant Sizing Guide supplied in the Drill Kit into each of the drilled canals of the phalanges and read the markings on the Sizing Guide to determine the size of the distal and proximal segments of the implant.
5. Using the #1 Starter Broach supplied in HAMMERLOCK 2 Drill Kit, broach into the distal and proximal canals, using an in-and-out motion without rotating. Make sure wide aspect of the Broach is parallel to the medial plane of the bone. Repeat the broaching process into both canals using the #2 Broach.
6. Open the appropriate Implant Kit containing the HAMMERLOCK 2 Implant preloaded on the Implant Inserter. Do not remove the Retaining Tab. Insert the exposed proximal end of the Implant into the proximal phalange until the Retaining Tab makes contact with the bone.
7. Pull back on Slider Button on Inserter to release Implant from the Inserter.
8. Without removing the Retaining Tab, reduce the joint by pulling the middle phalange over exposed distal legs of the Implant. The tab should be in contact with both phalanges.
9. Squeeze the top of the Retaining Tab to release it from Implant and then fully reduce the joint.

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Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
www.jnjmedicaldevices.com